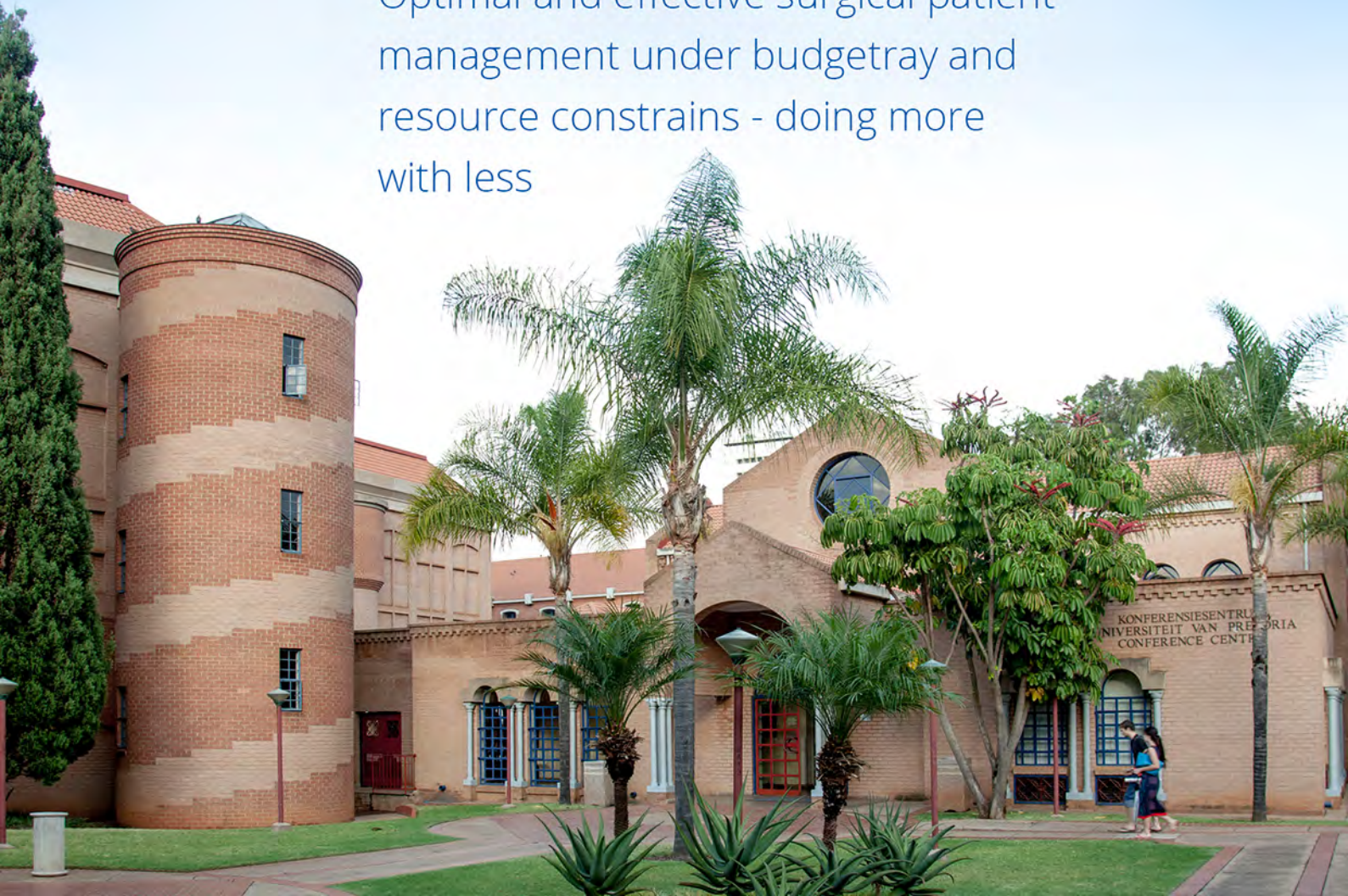
UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of
Health Sciences
Fakulteit Gesondheidswetenskappe
Lefapha la Disaense tša Maphelo

# 22nd Annual Controversies and Problems in Surgery Symposium 2018

Optimal and effective surgical patient management under budgetray and resource constrains - doing more with less



# Contents

# Welcome Note

## Prof OD Montwedi

It is with great pleasure that I welcome you to the 22nd Annual Controversies and Problems in Surgery Symposium in 2018.

We feel very honoured to present what has now become a feature of continued educational development in South Africa. We are leaving in difficult economic times that need us to adjust our practices without necessarily compromising standard of patient care. Our theme for this year sought to explore various options in light of these constrains.

Our theme for this year is "Optimal and effective surgical patient management under budgetary and resource constraints- Doing more with less." I urge you to debate and engage robustly but with respect to each other as you do so.

We would like to thank the speakers who accepted to give up their precious time to grace this occasion. Without you, these proceedings would not be possible. We welcome the delegates and thank you for your continued support. We are aware of a number of competing interests and thank you for choosing us. I hope this conference will meet your expectations of high-level academic discourse.

Welcome and big thank you to the trade colleagues. Your loyalty even during these times of austerity is acknowledged and appreciated.

A special thanks to members of staff of the Department of Surgery, especially the secretarial staff, for their outstanding work during the preparations for this conference. The success of this conference is the fruit of your collective efforts; its failure will simply be a reflection of my own indisposition.

I hope you all enjoy the conference.

Professor OD Montwedi

# **Opening address** by Deanery Faculty of Health Sciences

Prof Robin J Green

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My Dear Colleagues

It gives me great pleasure, on behalf of the Dean of the Faculty of Health Sciences at the University of Pretoria, to welcome you to this symposium.

The title of this meeting is a fascinating one for an non-surgeon. As a Paediatrician I always thought that only non-surgeons disagreed with one another on the best way to treat a patient. Nice to know that surgeons do too!

But on a serious note may I wish you well in your deliberations. I trust the meeting will be fruitful and advances your science.

Whilst you spend your days listening to these exciting and important lecturers and their messages may I ask you to consider something that has struck me this year.

That is the issue of our own welfare and the welfare of our families and medical colleagues. A number of high profile doctors have taken their own lives this year. And it seems that at the heart of the problem is the pressure of having to maintain a facade of coping in a highly pressurised environment.

As doctors, we sometimes ignore our own wellbeing and the wellbeing, and care, of our colleagues as we rush from patient to patient.

Take a few minutes in your day, today, to be a little kinder and a little more generous to a colleague, or co-worker, or even stranger.

Each of us can make the world a little better, in what we do to be better professionals, and what we do to be better human beings.

May I wish you a wonderful meeting and a wonderful weekend.

Best regards

Robin J Green

# Should we still offer **surgical intervention for varicose veins?**

Dr Cloete (NO)

Varicose veins is a common condition that affects more than 25 million people in the United States with about 6 million people having more advanced venous disease . ( 1) Unfortunately no accurate data is available for the South African context . The Vein Consult Programme study found the global prevalence to be 63.9 % . (2) ,with a higher prevalence amongst women . The recommended indications for surgical intervention C2 varicose veins have been for symptomatic and complicated varicose veins.
Compression therapy can provide significant improvement for symptomatic varicose veins when high compliance is maintained (3) .Lurie and Kistner compared the surgical outcomes of cohorts of patients who had favourable and unfavourable responses to initial compression therapy respectively using Specific Quality of Life and Outcomes – Response Venous Questionnaire .(4) The study concluded that the cohort with favourable response to compression therapy were 21 times more likely to have significant improvement from surgical intervention at 1 year follow – up compared to the other group . This data suggests that unfavourable outcome to initial conservative treatment predicts modest response to surgery that may not be cost effective strategy in a resource constraint enviroment .

**Symptomatic C2 varicose in patients with a good response to initial compression appear to be the subgroup that derive benefit from surgical intervention – I would argue that this is the very group who have already derived benefit from non surgical treatment , provided the necessary compliance is achieved .**

Compicated varicose veins are defined by variceal bleeding , superficial venous thrombosis ( SVT ) or progression to advanced manifestations . Historically the preferred surgical option for the SVT complicating varicose veins have been sapheno-femoral junction ligation and stripping , especially where the thrombus was in proximity of the junction with the deep venous system . A recent systemic review of 6 studies comparing surgical treatment to medical treatment with low molecular weight heparin showed no difference in SVT progression , DVT or PE incidence . ( 5 ) The overall surgical complication rate , including seroma , haematoma and sepsis was noted to be 7,7 % . The presentation of a variceal bleed is usually treated with compression with susequent foam sclerotherapy of the involved tributary . Formal surgical treatment is often not required .
The more advanced venous disease ( C3 – C6 ) manifestations associated with clinically significant varicose veins have been evaluated by the ESCHAR study and concluded that

compression therapy alone resulted in similar healing rates of leg ulcers as compared with a combination of compression and open surgical treatment of superficial reflux when deemed appropriate . ( 6) The recurrence rates were in favour of surgery and compression .The recent publication of the results of the EVRA trial – comparing early endovenous intervention to ablate superficial reflux to standard compression up to 6 months - revealed that early endovenous intervention resulted in faster healing rates , but the healing rates at 1 year showed no significant difference and the quality of life assessments were similar( 7)

**The dogma of mandatory surgical treatment of complicated varicose veins should be challenged given the lack of convincing evidence to support this practice .**

The high prevalence and significant morbidity of chronic venous disease have a significant socio-economic impact on healthcare services , making the judicious and pragmatic approach to choice of cost-effective treatment very important . In France the total,healthcare expenditure for patients with chronic venous disease in 1991 amounted to 2,24 billion euro ,which represented 2,6% of the total budget .( 8) The financial impact of the more advanced stages of venous disease is even more substantial . Data from the Cleveland Clinic Foundation in 1999 reported that the average annual cost per patient with active leg ulcers amounted to $ 9685 which inflated to $ 16 524 in 2011 . ( 9)

**Healthcare expenditure for venous disease is substantial given the technological advances that come with a significant price tag for most instances limited or questionable benefit . In a resource constrained country like South Africa , I would argue that routine surgical treatment of varicose veins in whichever way it may manifest cannot be justified .**

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# **Cost and efficacy of EVAR** compared to open repair of AAA.

Prof Abdool Carrim (EVAR)

Patients with larger than 5,5cm abdominal aortic aneurysms are presently offered intervention as the risk of rupture is high. They are offered OSR (Open Surgical Repair) or Endovascular(EVAR) treatment. Several trials such as DREAM 1,EVAR 1 2,OVER 3 and ACE 4 trials have compared the effectiveness of EVAR versus Open repair and have concluded that EVAR leads to decrease mortality in the short term . A systematic review 5 also confirmed a decrease in 30 day as well as 6 month all cause mortality .EVAR is associated with increased risk of AAA related re-interventions 9%(EVAR) vs 1.7%(OSR) and Randomized studies have also shown the gain in allcause mortality disappears after 2 years. 6,7,8,9 EVAR repair is a very dynamic field and the devices in the earlier studies were not as good as those being used today hence cost effectiveness should be evaluated using recent data which should include cost data, technological improvements in devices and technical skills of vascular surgeons.

The OVER trial in 20123 reported lower cost and better survival than open repair after initial hospitalization for repair , but at 2 years, survival , quality of life and costs were not significantly different between the two treatment groups. The same group looked 11 looked at the cost effectiveness of EVAR versus OPEN repair and found at 2 years the total health care costs remained lower in the EVAR group. This study also showed a high number of aorto-iliac related abnormalities detected after open surgery detected by CT scan detected at 1 year indicating that OPEN surgery also needs post-op surveillance.13

A more recent study 10 estimated the life time cost-effectiveness of elective EVAR vs OPEN repair in the Netherlands based on recently published literature have shown that EVAR and OPEN are equally effective in treating AAA , EVAR was found to be a cost-effective solution for patients with AAA in that the EVAR was slightly more effective in QALY and less expensive (E24,483 vs E25,595). Clearly, the costs of post op surveillance are also being curtailed by more circumspect assessment of EVAR with Duplex ultrasound and the costs of EVAR devices have also decreased furthermore the re intervention rates have also decreased to less than 8% 12 as the experience of the surgeon with EVAR has increased and better selection of patients and more newer devices in the industry have been introduced the outcomes will improve. Although EVAR 2 trial showed no benefit in high risk patients EVAR is still widely undertaken in these patients a recent retrospective study 14 confirmed a better peri-operative and long term outcome of 4 years at 65% compared with lower risk patient and even better

in comparison to EVAR 2 (36%), therefore EVAR is also effective in these high risk patients where OPEN surgery not feasible.

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# **Cost and efficacy of EVAR** compared to open repair of AAA.

Prof Mulaudzi (OPEN)

Since the first report of EVAR in 1986, the procedure has been met with great enthusiasm with performance of the procedure on constant rise. The indications for EVAR have been expanded from the procedure being performed for patients unfit for open repair to the procedure being mainly performed for any AAA anatomically suitable for EVAR.

The presenter questions the latter trend and agues for comparable/ better efficacy and cheaper cost with open repair of abdominal aortic aneurysms.

**Efficacy: EVAR vs Open repair AAA:**

Large randomized trials have been published comparing EVAR vs Open repair for AAA. In all but one, short term data suggested lower 30 day morbidity and mortality with EVAR as compared to open repair. The findings have however been offset by long term findings suggesting that the early advantage is lost at 2 to 3years with comparable survival observed at those respective time points. Furthermore, a higher rate of re-interventions has been reported with EVAR, with a higher mortality reported in one study after 8 years of follow up.

The following is a summary of the literature comparing clinical efficacy of EVAR vs Open repair for AAA:

***EVAR 1 TRIAL***

In the EVAR 1 trial 1082 patients were randomized to either EVAR of Open repair for AAA (EVAR = 543 and Open repair = 539). 30 day mortality in the EVAR group was 1.7% vs 4.7% in the open group (p= 0.009). Secondary interventions were more common in the EVAR group vs open group (p=0.02). The researchers concluded that EVAR reduced the 30 day operative mortality by two- thirds compared with open repair.

With an estimated 25% re- intervention risk post EVAR and a 1% risk of rupture following EVAR, the study did not answer the question of long term durability. The results were mainly a license to continue scientific evaluation of EVAR but not to change clinical practice.

| | EVAR | Open repair | Odds ratio (95% CI) | | | | p |
|---|---|---|---|---|---|---|---|
| | | | Crude | p | Adjusted* | p | |
| **Outcome by intention to treat (number of patients)** | 531 | 516 | | | | | |
| 30-day mortality (number of deaths) | 1·7% (9) | 4·7% (24) | 0·35 (0·16–0·77) | 0·009 | 0·37 (0·17–0·83) | 0·016 | |
| In-hospital mortality (number of deaths) | 2·1% (11) | 6·2% (32) | 0·32 (0·16–0·64) | 0·001 | 0·30 (0·14–0·62) | 0·001 | |
| Median (IQR) length of hospital stay (days)† | 7 (5–10) | 12 (9–16) | | | | | <0·0001‡ |
| Median (IQR) length of operation (min)† | 180 (140–215) | 200 (155–240) | | | | | <0·0001‡ |
| Secondary interventions either during 30 days or during the primary admission | | | | | | | |
| Conversion to open repair | 10 | 0 | | | | | |
| Correction of endoleak | 18 | 1 | | | | | |
| Re-exploration of open repair | 1 | 15 | | | | | |
| Other surgery | 21 | 14 | | | | | |
| Unknown | 2 | 0 | | | | | |
| Total | 52 (9·8%) | 30 (5·8%) | | | | | 0·025 |
| **Outcome by per protocol (number of patients)** | 512 | 496 | | | | | |
| 30-day mortality (number of deaths) | 1·6% (8) | 4·6% (23) | 0·33 (0·15–0·74) | 0·007 | 0·34 (0·15–0·78) | 0·011 | |
| In-hospital mortality (number of deaths) | 1·6% (8) | 6·0% (30) | 0·25 (0·11–0·54) | 0·001 | 0·24 (0·11–0·54) | 0·001 | |

*Adjusted for age, sex, $FEV_1$, AAA diameter, log[creatinine], statin use, and time from randomisation to surgery. †For primary procedure only. ‡Mann-Whitney test. §$\chi^2$ test.

### *EVAR 1 15 year follow up results*

Long term follow up results of the EVAR 1 trial were published in 2016 by Patel et al. Data from the EVAR 1 trial was used which included a total of 1252 patients from 37 centers from September 1999 to August 2004. Over a mean of 12.7 years a total of 9.3 deaths per 100 person years in the EVAR were recorded vs 8.9 deaths per 100 person years in the open repair group (p=0.14). At 6 months of follow up the EVAR group had a lower mortality but a significantly lower mortality was recorded in the open repair group at 8 years of follow up (p= 0.048 for total mortality and p = 0.0064 for aneurysm related mortality). The higher mortality in the EVAR was mainly attributed to higher incidence of secondary aneurysm rupture.

It is however important to note that the weakness in the trial was that EVAR technique and equipment have improved since then. Patients in the EVAR group were more diligently followed up than those in the open group which may have resulted in an under- estimation of aneurysm related mortality in the open repair group.

The investigators of the study concluded that EVAR is associated with early survival benefit but an inferior late survival compared to open repair.

| | Endovascular repair (N=626) | | Open repair (N=626) | | Hazard ratio (95% CI) | | p value† |
|---|---|---|---|---|---|---|---|
| | n/N (%) | Rate per 100 person-years | n/N (%) | Rate per 100 person-years | Unadjusted | Adjusted* | |
| **Total mortality** | | | | | | | |
| All patients | 466/626 (74%) | 9·3 | 444/626 (71%) | 8·9 | 1·05 (0·92–1·19) | 1·11 (0·97–1·27) | 0·14 |
| 0–6 months | 26/626 (4%) | 8·5 | 45/626 (7%) | 15·0 | 0·57 (0·35–0·92) | 0·61 (0·37–1·02) | 0·06 |
| >6 months to 4 years | 126/600 (21%) | 6·7 | 116/581 (20%) | 6·3 | 1·07 (0·83–1·38) | 1·13 (0·87–1·47) | 0·35 |
| >4–8 years | 135/474 (28%) | 8·3 | 129/464 (28%) | 8·0 | 1·03 (0·81–1·31) | 1·07 (0·83–1·37) | 0·62 |
| >8 years | 179/339 (53%) | 14·9 | 154/333 (46%) | 12·7 | 1·18 (0·95–1·47) | 1·25 (1·00–1·56) | 0·048 |
| **Aneurysm-related mortality** | | | | | | | |
| All patients | 56/626 (9%) | 1·1 | 45/626 (7%) | 0·9 | 1·24 (0·84–1·83) | 1·31 (0·86–1·99) | 0·21 |
| 0–6 months | 14/626 (2%) | 4·6 | 30/626 (5%) | 10·0 | 0·46 (0·24–0·87) | 0·47 (0·23–0·93) | 0·031 |
| >6 months to 4 years | 12/599 (2%) | 0·6 | 8/581(1%) | 0·4 | 1·48 (0·60–3·62) | 1·46 (0·56–3·83) | 0·44 |
| >4–8 years | 14/474 (3%) | 0·9 | 4/464 (1%) | 0·2 | 3·46 (1·14–10·52) | 3·11 (0·99–9·72) | 0·05 |
| >8 years | 16/339 (5%) | 1·3 | 3/333 (1%) | 0·2 | 5·50 (1·60–18·89) | 5·82 (1·64–20·65) | 0·0064 |

*Hazard ratios adjusted for age, sex, maximum aneurysm diameter, forced expiratory volume in 1 s, log creatinine, statin use, body-mass index, smoking status, systolic blood pressure and total cholesterol; 77 individuals excluded due to missing data. †p value adjusted for covariates.

***Table 1:*** **Deaths from any cause and aneurysm-related causes, according to time since randomisation in the intention-to-treat population**

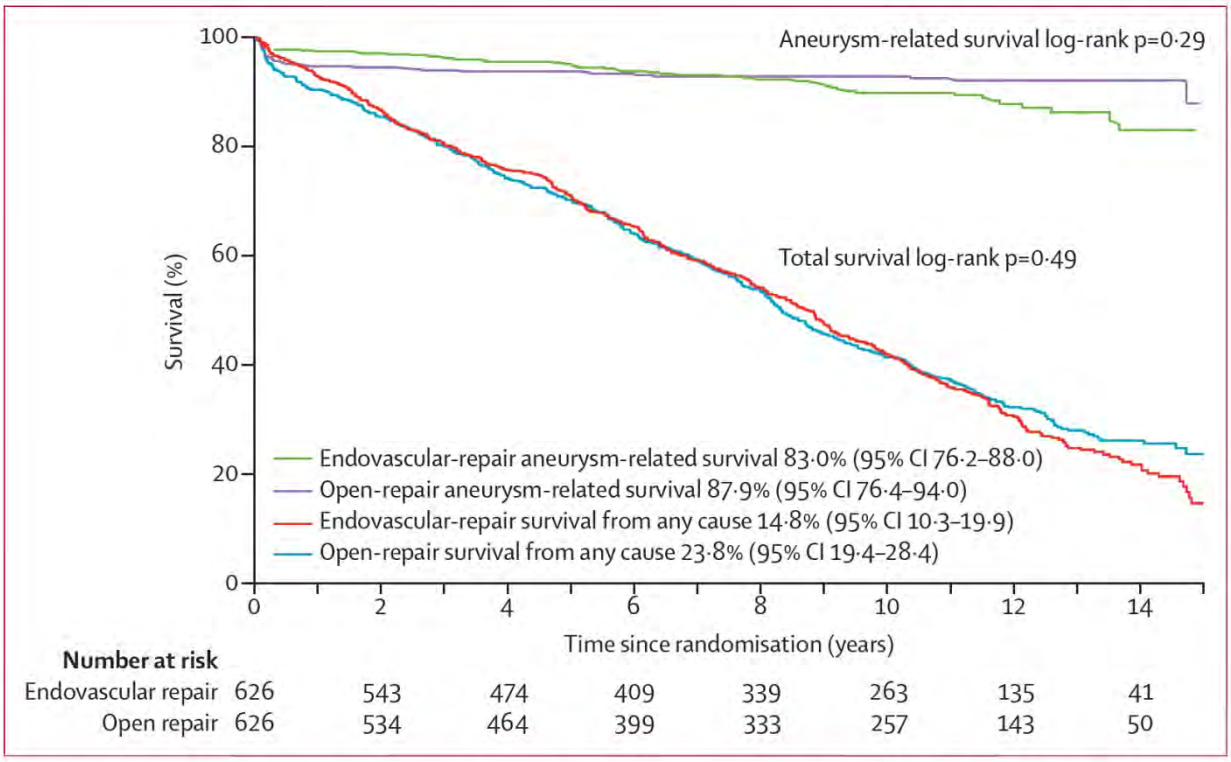



***Figure 2:*** **Kaplan-Meier estimates for total survival and aneurysm-related survival up to 15 years of follow-up**
The hazard ratio is 1·05 (95% CI 0·92–1·19) for total mortality, and is 1·24 (0·84–1·83) for aneurysm-related mortality.

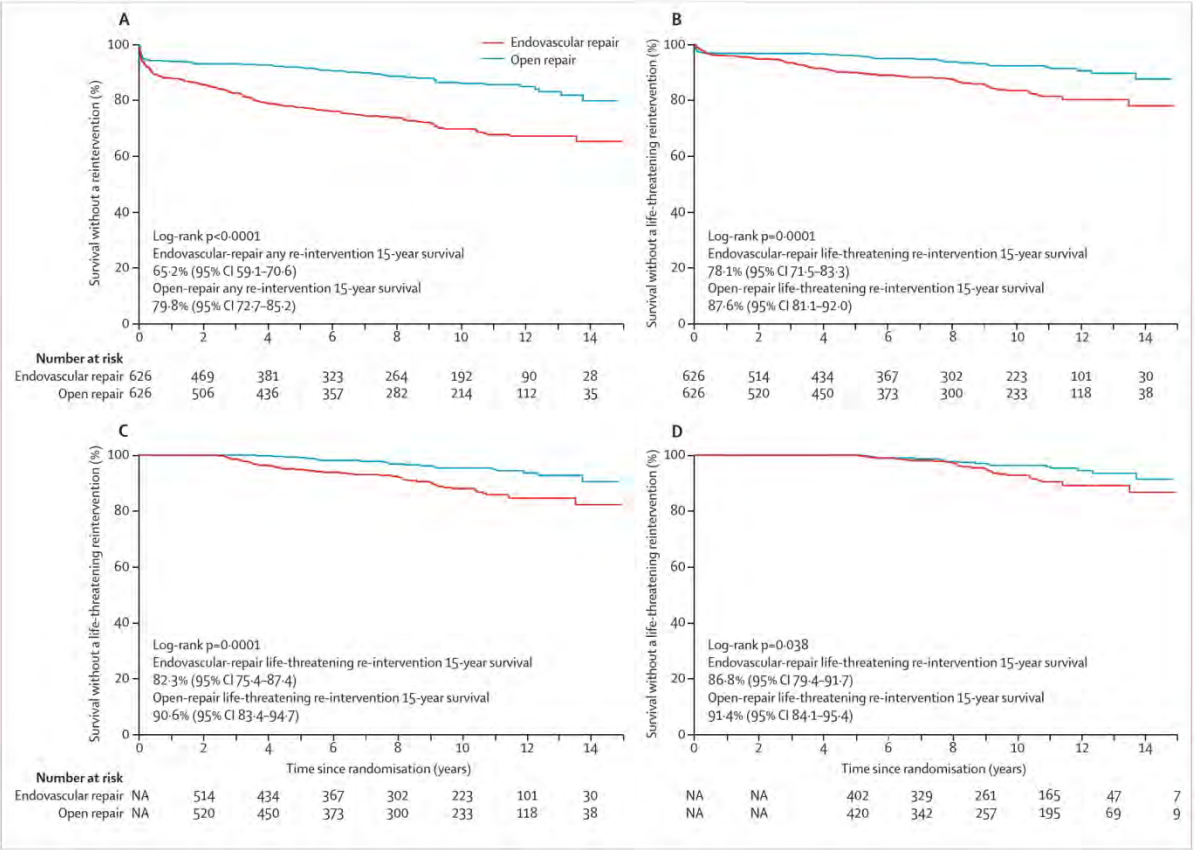



***Figure 3:*** **Kaplan-Meier estimates of time to first re-intervention in the EVAR and open repair groups during 15 years of follow-up**
The time to first re-intervention (A), to first life-threatening re-intervention (B), to first life-threatening re-intervention for individuals who have survived 2 years free of a life-threatening re-intervention (C), and the time to first life-threatening re-intervention for individuals who have survived 5 years free of a life-threatening re-intervention (D). EVAR=endovascular aneurysm repair. NA=not applicable.

## *Dream Trial*

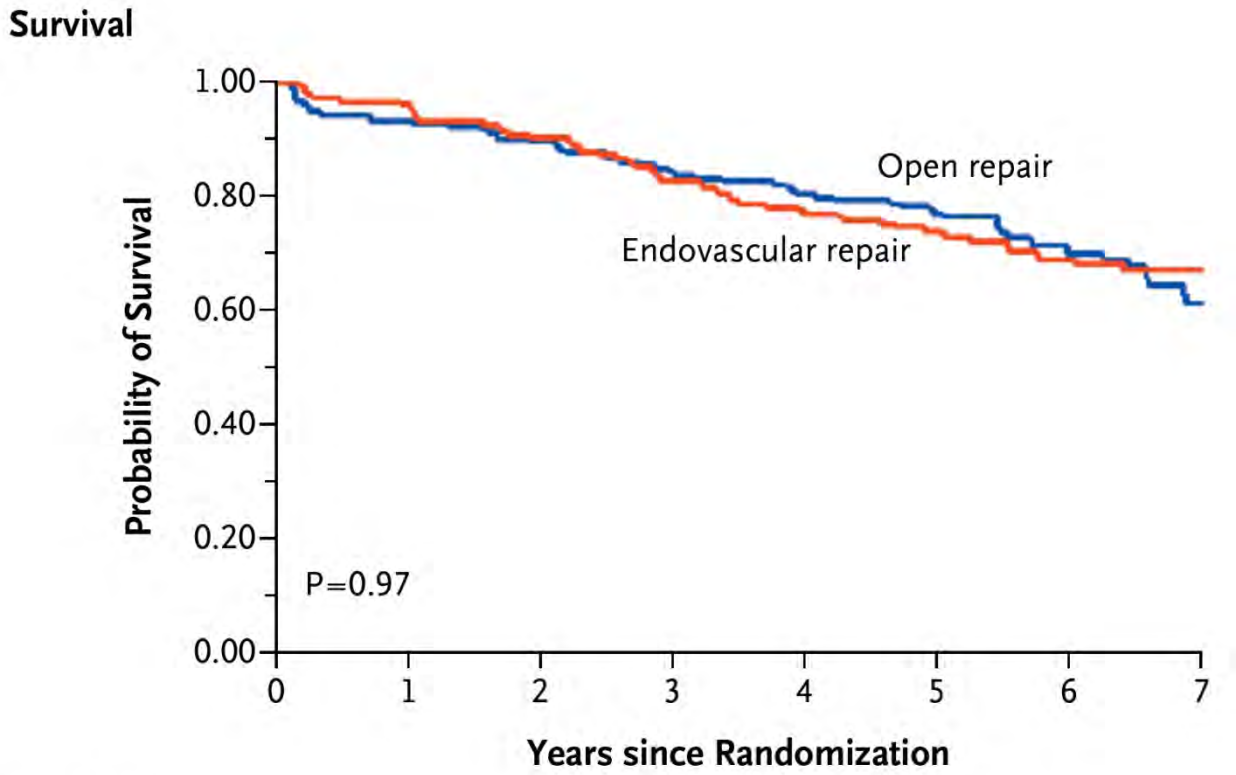
Three hundred and forty four patients were collected in the DREAM trial and randomized to EVAR vs open repair. The operative mortality rate was 4.6% in the open group vs 1.2% in the EVAR group (p= 0.10). The researchers concluded that EVAR was preferable to open repair with longer term follow up needed to assess sustainability of this effect.

| Variable | Open Repair (N=174) | Endovascular Repair (N=171) | Risk Ratio (95% CI) | P Value |
|---|---|---|---|---|
| | *no. of patients (%)* | | | |
| **End point†** | | | | |
| Operative mortality | 8 (4.6) | 2 (1.2) | 3.9 (0.9–32.9) | 0.10 |
| Operative mortality and severe complications | 17 (9.8) | 8 (4.7) | 2.1 (0.9–5.4) | 0.10 |
| Operative mortality and moderate or severe complications | 41 (23.6) | 31 (18.1) | 1.3 (0.9–2.0) | 0.23 |

***Dream Long Term follow up results***

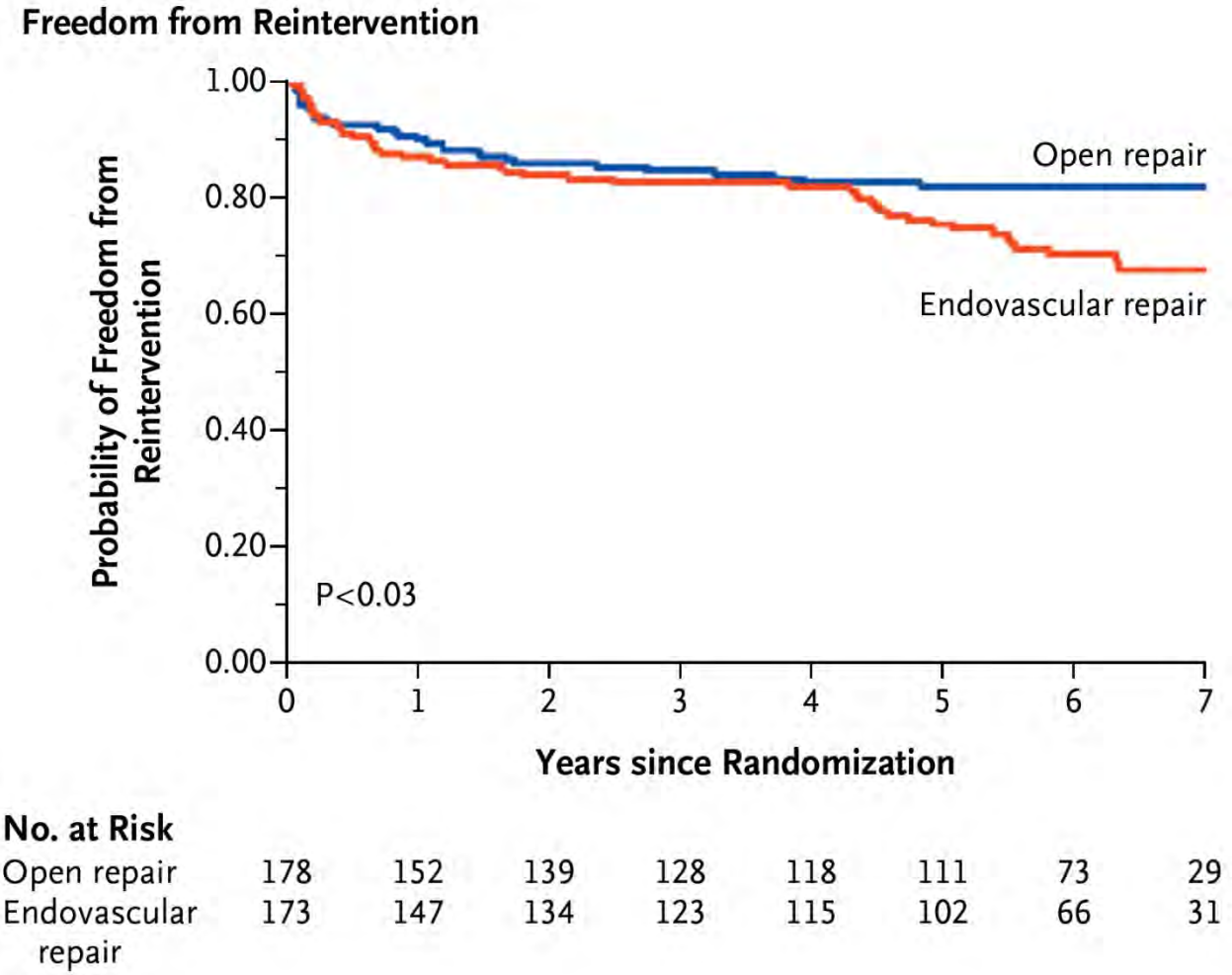
After 6 years of randomization, the cumulative survival rates were 69.9% and 68.9% for open re pair and EVAR respectively (p=0.97). The rates of freedom from secondary intervention were 81.9% for open repair and 70.4 % for endovascular repair (p=0.03).

There was clearly no difference in overall survival between open repair and endovascular repair. An important additional finding was that endovascular repair was associated with a significantly higher rate of re- intervention than open repair.




**No. at Risk**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Open repair | 178 | 166 | 159 | 150 | 143 | 137 | 88 | 36 |
| Endovascular repair | 173 | 166 | 156 | 143 | 133 | 128 | 83 | 39 |




### *The OVER trial*

The OVER trial was a randomized controlled trial that included 42 VA Medical centers in the United States. Eight hundred and eighty one patients with AAA were collected and randomized to either EVAR or Open repair. The endovascular group had significantly shorter average procedure time, duration of mechanical ventilation, ICU stay. Average blood loss and need for blood transfusion was also less in the endovascular group. The 30 day operative mortality was 0.5% in the endovascular group and 3.0% in the open repair group (p= 0.004). All-cause mortality was not significantly different. Furthermore the secondary intervention rate was similar in both groups.

The conclusion of the study was that EVAR was associated with significantly lower postoperative mortality than the open repair group. The finding was sustained to 2 years post follow-up.

### *Long Term Outcomes of Abdominal Aortic Aneurysm in the Medicare Population*

An article assessing the long term outcomes of Medicare patients undergoing EVAR and open repair through the periods 2001 to 2008 was published in 2015. A total of 39966 matched pairs of patients that had undergone either open or endovascular repair were identified. The perioperative mortality was 1.6% in the EVAR group and 5.2% in the open repair group (p=0.001). Early survival advantage was sustained for the first three years only, in favor of EVAR after which time the rates of survival were similar. Aneurysm related complications were more common after EVAR, whereas laparotomy related complications were more common after open repair. Late aneurysm rupture occurred in 5.4% of patients after endovascular repair vs 1.4% in the open repair group through 8 years of follow up (p<0.001).

## Concluding Remarks

Three large randomized trials including a cohort of patients from medicare data confirmed lower 30 day post- operative mortality in EVAR vs open repair. Apart from the OVER trial, long term follow up revealed loss of this early advantage of EVAR with higher re- intervention rates and even higher mortality recorded in the EVAR1 trial. Researchers postulate that the sustained advantage of EVAR over Open repair in the OVER is due to better technique and equipment in the OVER trial. Furthermore, the rate of incisional hernias was not reported in the EVAR1 and DREAM trials which may have accounted for lower re- intervention rates.

## Cost Effectiveness: EVAR vs Open Repair AAA

In the current economic climate, discussions around cost effectiveness of EVAR vs open repair are necessary.

### *Cost- effectiveness of open aneurysm repair vs EVAR in the OVER trial*

The study was conducted to compare the costs and comparative cost effectiveness of EVAR vs Open AAA repair in the OVER trial, a randomized controlled trial of 881 patients as stated above.

The primary outcomes were mean total health care cost per life- year and per quality adjusted life year (QALY) from time of randomization to 2 years after.

Table: Outcomes after 2 years

| Outcomes | EVAR | Open repair | P value |
|---|---|---|---|
| Mean life years | 1.78 | 1.74 | 0.29 |
| Mean QALY's | 1.462 | 1.461 | 0.78 |
| Mean graft cost | $14.052 | $1363 | <0.001 |
| Mean hospital admission costs | $37068 | $42970 | 0.04 |

| | | | |
|---|---|---|---|
| Total health care costs | | | 0.35 |

The study concluded that EVAR resulted in lower costs and hospital survival after initial hospitalization, but after 2 years, survival, quality of life and costs were not significantly different between the 2 treatment groups.

The above findings are not in keeping with Cost analyses in both the EVAR1 and DREAM trials. In the EVAR 1 trial there was a trend toward higher EVAR related costs ($19.698 vs $ 17, 917) that became statistically significant when late AAA related costs were added ($23153 vs $18586). In the DREAM trial, EVAR related costs were significantly higher (€18,179 vs €13,886).

The following are possible reasons for discrepancies in findings between the OVER vs EVAR1 and DREAM trials:

1. Inpatient costs increased > 50% between 1999 and 2007 in the USA, whilst stent graft costs remained relatively unchanged
2. Cost of hospital stay in the US is much higher than in Europe

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# **Does use of algorithms and trauma scores for management of trauma at different levels of trauma care** results in better and or cost effective outcomes?

Prof Moeng

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**Overview**

Trauma remains pandemic in RSA, a country with associated burden of poverty, chronic health and HIV infection. Trauma affects the young, potentially employable, members of the society. Despite the prevalence of trauma in the country, we still have significant room of improvement in offering trauma care to the community. The disparity between urban and rural health care expertise remains a challenge to provision of care in prehospital, hospital and rehabilitation facilities. The state facilities remain chronically overwhelmed by the number of trauma cases seen, especially over the weekends and the holidays. There are more casualties seen in our country than in most of the war-torn countries. We still have a long way to go, in achieving sustainable preventative measures.

The growing inequality in wealth further adds on to the problem. Only 15% of the population have access to Private Health Care, which unfortunately still remains costly. About 4,5% of the GDP is spend in the care of these 15 percent that can access the private facilities. This implies that the reset of the 85% of the population has to survive on the remaining similar amount for their health care needs. This has further added burden on the budgets available to offer basic needs in state facilities. When you add up other factors like maladministration at state health care facilities, mismanagements of cases, chronic fatigue, fraud, porous borders, increased state litigation, then you realize that the health care system is under an incredible amount of pressure.

Health care is a very costly business. A unit of blood from South African National Blood Services will cost between R1868-R3052 (normal to leucocyte depleted blood), and R1494.00 for a unit of FFP. Pooled platelets cost at least R7870.00 for normal and R9909.00 for leucocyte depleted units. All these prices are state patient prices as in 1$^{st}$ April 2018. ICU cost for major Trauma, estimated form Private practice, can cost anything between R10,000.00 and R20,000.00. The pharmacy bill, including the broad spectrum antibiotics, is high. Laboratory costs are always underestimated, and yet they remain amongst the high drivers of health care expenditure. Length of hospital stay, is

grossly under evaluated, in a system that does not have proper functional itemised billing systems. We should not remain ignorant of the cost of Trauma to the health care of our country. Keep in mind that the above costs do not include the overall cost to the economy, including loss of earning and loss of productive days.

Compared to international communities, we see more penetrating trauma. There is still a high association between alcohol intake and the trauma we see in our emergency departments. The warm wonderful all year weather seem to encourage night life that has its own implications to trauma. The urban and lower socioeconomic groups remain more vulnerable to injuries patterns noted in our institutions. There is a significant number of people that are assaulted by those known to them. Women and children are of particular concern due to the abuse nature of some of the patterns of injury.

The opportunity of improving Trauma care, lies in attempts to improve the Trauma care system as a whole. Implementing effective strategies can optimize quality and quantity of health care we are able to provide to our trauma patients. It simply requires a major paradigm shift in realigning the already stretched Health care system.

**What kind of algorithms may be helpful**

Trauma by nature is seen and managed by different specialities. There is also a high turnover of the junior members of the health team. It is therefore critical to designs protocols that will aid in the maintenance of trauma health care standards. These protocols should be based on sound scientific evidence that has been shown to be effective. They should be easily understood and aimed at covering frequently occurring conditions, and those conditions commonly leading to mismanagement and, or delayed care. The protocol recommendations should at least follow Advanced Trauma Life Support (ATLS®) principles of trauma care; a system that has been shown to reduce mortality rates and improve outcomes if applied properly.

More than a million health care providers globally have been trained on ATLS®, most of whom have adopted these principles as part of their trauma care provision. ATLS® offers a common language that reduces misunderstanding during hand overs and transfers between different health care providers. It is based on a concept of prioritising the greatest threats to life first, and treating them accordingly. It promotes early recognition of the threats and applies simple teachable manoeuvres that may save a life: establishing that threatened airway, decompressing the tension pneumothorax, inserting an intercostal drain, calling and organizing surgery early for a bleeding patient.

There are two major causes of early death in trauma: head injuries and uncontrollable haemorrhage. Construction of algorithm pathways that helps the healthcare provider to recognize head injury, and refer head injuries early with appropriate interventions, will impact on better survival. Emphasising early detection and prompt management of bleeding will also have a great impact on reducing preventable mortality outcomes. The emphasis should be on stopping the bleeding, while resuscitating with appropriate fluid products. The earlier the bleeding is stopped, the better the outcome, and the less the blood products required.

Attention should also be given to reduction of missed injuries. The algorithm should cater for increased awareness of potential missed injuries. This includes encouragement of appropriate radiological investigations, such as Focused Assessment with Sonography in Trauma (FAST) or even e-FAST, which expands basic FAST into looking for pneumothoraces and haemothoraces in emergency department using the same ultrasound machine. This may save a life and allow for earlier intervention way before a standard X-ray is available. Proper staff training and accreditation is essential in appropriate interpretation and application of these findings on the ultrasound machine.

Early referral to appropriate facility should also be incorporated as part of the protocol. This will reduce unnecessary delay, but also encourage minimal standard of care to maintain safety during the transfer period. Early identification of complex injuries, vascular injuries as well as unstable patient can make a huge difference in outcomes. This will be beneficial at a primary facility, to assist in early activation of the emergency transport system. Emergency department is not a safe place for an ongoing bleeding patients, they need surgery and, or early transfer to another facility.

When protocols are written properly, they complement activation of treatment pathways, thus avoiding delays. They further enhance communication between different healthcare providers to streamline involvement with other disciplines: orthopaedic team knows when and what they should offer as an intervention, the surgical team will know when and how soon they should respond to an emergency physician request for help on an unstable patient. Overall, this leads to less confusion in a usually busy environment. A protocol that recognises that a vascular injury requires early intervention, will make it easier for the facility to sort their prioritization of care to reduce an unnecessary need for amputation.

Prioritization of care is therefore essential in trauma. Being able to rapidly assess and classify patient into different groups helps with triaging of casualties. Universally, the Priority One (P1) patient has life threatening injuries that requires immediate attention;

usually designated Red colour. Priority Two patient (P2) has potential life threatening injuries but can be seen within 1-2 hours (usually designated yellow colour). Priority Three (P3) patient can been seen within a reasonable time (at most 4 hours) once other cases have been stabilized (designated green colour). The Cape Town triage score, adds a fourth classification: Orange. This identifies P2 patient that should be seen within 10 min. The whole idea is that this creates a culture of treating the more injured patient first (not necessarily the patient who arrived first). A principle we may reverse in Mass Casualty (MCI) situations depending on resource availability.

Protocols can further be utilized to drive current teaching and research based recommendations. The Massive transfusion protocol is one example. This will allow for activation of transfusion according to the 1:1:1 ratio as part of resuscitation for major bleeding patients. The earlier the appropriate transfusion strategy, the better the chances of survival. This will obviously be part of Damage Control Resuscitation in the unit. This blood ordering initiative, can further be extended to general hospital haemovigilance protocols that are aimed at reducing blood wastage within facilities.

**Common Trauma Scores and their relevance to Trauma care**

Scores offer a practical common language that allows for activation of treatment pathways, comparison for research purposes, and can be beneficial for quality control purposes. Not all proposed scores over the years have been effective enough to be universally adopted by all.

Revised Trauma Score is mathematically weighted combination of respiratory rate, Glasgow coma scale (GCS) and blood pressure to assess the physiological state of the patient. It has a total mark of 7.84. The lower the score, the worse the prognosis. Another physiological score is GCS, which is calculated out of 15. The GCS of equal of less than 8 is associated with threatened airway and requires prompt maintenance of the airway. Both these scores assist with the triaging in the emergency department to prioritize care. Recently some centres have added the Shock index score to assist with complimenting assessment of perfusion and also to trigger ordering of blood products in bleeding trauma patients. Shock index simply divides the heart rate by systolic blood pressure and should be 0.5-0.7 in normal subjects.

Anatomical scores include AIS organ score, which will allocate each organ and grades the injuries from I-VI, and allocates a number to the grade of injury. Grade I-II are mild injuries and can be managed conservatively in some instances. Grade VI organ injuries are usually fatal e.g. decapitation. Grade IV-V require intervention in most of the organs involved; this may mean interventional radiology in solid organ injuries. Final decision on surgery for these Grading system depend on whether we are dealing with a solid or

hollow viscus. It also depends on the haemodynamic status of the patient. Unfortunately, the grading is usually done after radiological investigation or surgical involvement. It is usually added on later to complement the overall management. The accurate evaluation of organ injury is important for quality control measures as well.

Injury Severity Score (ISS) is based on the Grading of organ injury. This mathematically derived score will sum the square of three greatest organ injuries in three different regions. These regions in general include, Head and neck, chest cavity, abdominal cavity, pelvis, longs bones etc. The highest ISS score is 75. ISS of 16 and above is considered major trauma. The higher the score the greater the mortality. This differs from the New Injury Severity Score(NISS), which allows for the sum of the three largest Grades of injury, even if they occur in the same region. NISS is therefore more accurate for penetrating trauma than blunt trauma. An isolated gunshot abdomen with a Grade V liver, Grade IV Stomach and Grade III spleen will have an ISS of 25 (liver was the largest organ Grade in abdomen) versus NISS of 50 (25+16+9), which is a more accurate calculation for this scenario.

TRISS methodology is the combination of ISS and RTS and can be used to estimate the probability of survival. These calculations are based on American data. The same can be achieved with the combination of NISS and RTS. We consider death of anyone with a probability of survival equal or greater than 50% to be an unanticipated mortality (Preventable death). We then look at the associated factors and see if this preventable death had a room for improvement. Room for improvement is further classified into system issues, errors etc. etc. This assist us in maintaining quality during the morbidity and Mortality meetings by identify areas of improvement.

Consider the following illustration; A 24-year old man with a stabbed right ventricle presents at Hospital A with normal blood pressure and pulse rate. They decide to transfer him to Hospital B, where he ultimately arrives at Hospital B on a basic ambulance four (4) hours later in extremis, and dies despite CPR and Emergency room thoracotomy etc. at Hospital B. This case will be deemed Unanticipated mortality (potentially preventable), with room for improvement: system issues. This implies that, had the deceased arrived at the correct facility the first time, or had he been transferred earlier, he would have had a chance of survival. This decision allows for further evaluation into the factors that led to the delay of this case. An in-depth assessment allows for an opportunity to improve overall trauma care.

Penetrating Abdominal Trauma Index (PATI) score is usually used in research and can correlated to the outcomes of surgical interventions in the abdominal trauma. A PATI score greater than 15 is associated with high septic complication rate. The Acute

Physiology Assessment and Chronic Health Evaluation (APACHE II) score and Sequential Organ Function Assessment Score (SOFA) scores are usually used in ICU care with their own short comings in correlation with outcomes of trauma patients.

**Implementation at different levels of care and impact on cost effectiveness**

Despite the evidence and impact seen in other places, we need to find a solution that will best describe and apply to our circumstances. South Africa's solution will have to take into consideration the reality that we are middle to a low income country that is always judged on the standards that are of a high income country. We hold ourselves to high constitutional rights, even if the circumstances do not allow us to practice to that level. With our country's past history, we have tried hard to place patients' autonomy first even with limited resources.

Litigation and legal expectation are measured and judged as though the ideal situation exists throughout the day. Mitigating circumstances and fatigue that may contribute to errors in judgment pay less impact on the final decision. We therefore need to create a safe enabling environment if trauma care has to survive. Whatever the circumstances, we should be driven by the zeal to offer optimal care. If we succeed in offering this care, then we can reduce litigation and further have more finances available for health care provision.

i) The Primary health care facilities will benefit from a structured training as well as protocols than enhance care. At this level we need to strengthen Triage criteria, with an intent to identify and transfer the P1 and P2 cases as soon as possible. Emphasis being on avoiding unnecessary delays. The protocols should aim at easy access to emergency transport facilities and ability to offer basic treatment to optimize outcome; this will include identifying bleeding and stopping compressible bleeding, recognizing concealed bleeding and referring them early.

It must further reduce failure to recognize potential internal injuries. Discourage suturing chest and abdominal injuries without further referral. Discourage suturing of hand injuries without examining tendon function. Discourage suturing of wounds near vascular structures without further referral. Give clear pathways for patients to return for further care should complications arise, or failure to improve.

ii) The Community Health care facility should have similar protocols as the Primary Health care facility. They should be able to offer care over 24hrs to the community.

iii) District and Regional Hospitals should be able to offer some surgical expertise. Protocols at this level should also add response times by the surgical team for unstable and vascular injuries. Some of these emergency department are run by emergency physicians, who do not have surgical capabilities. The protocols should also specify time frames for surgical interventions. Complex injuries must have clear pathways and referral guidelines. These complex cases should be referred out as soon as the condition is stable enough for transfer; even if the institution must perform Damage Control Surgery first before transfer. This should include training and ability to perform shunts in vascular trauma cases to salvage limbs before transfer. Damage Control Surgical Training should be standard for all with surgical expertise at this level of care.

iv) Tertiary and Central hospitals should hold themselves to a higher academic standard. They need full Trauma protocols, and even dedicated Trauma Units with a strong teaching responsibilities. These protocols should be equivalent to level 1 Trauma centre protocols with minimal changes to the international standard of care. The protocols should be all inclusive and allow for easy orientation and training of all health care professionals. Their protocols should also ease the transfer logistics from lower level institutions and also allow for down-referral to optimize bed availability for complex demanding cases.

New trauma patient send in for special investigations like CT scan at Central and Tertiary hospitals, should be assessed and seen by the Trauma team before returning to referring institution. Constant feedback to all stake holder should be encouraged to maintain the standards, and close the loop in quality control matters.

v) All institutions should have regular mortality and morbidity meetings that seek to maintain acceptable standards, and to improve overall trauma care. These meetings should be open to all health care workers and should allow for teaching moments to improve conditions of service. Strict confidentiality at these forums is not negotiable. The TRISS methodology should be included as a gauge of whether the outcomes were anticipated of unanticipated. Feedback and corrective action should be encouraged to improve conditions for service delivery.

## Conclusion

Trauma care can be standardized and optimized at each Level of Health Care. This can be consolidated by tailoring the Protocols to each level of care while maintaining the core trauma treatment principles and values. This will require training of all health care workers to facilitate implementation and compliance with protocols. ATLS® should be the minimal trauma standard offered at all levels of care.

By focusing on quality trauma care and monitoring it regularly, we can reduce the overall exposure and actually minimize mismanagement of cases. The overall cost of care can be greatly impacted by focusing on optimal care. This implementation need not be expensive, as most of it will require just the reorganization of thought processes, and maintaining relevant trauma standards at each level.

Teaching should be aimed at making the protocols know to all healthcare workers in each institution. The template for each level should be made available and adopted aggressively. Outreach to each facility should be done regularly to maintain competence and ensure application of these protocol.

We desperately need proper compulsory National Trauma Data to have a meaningful assessment of the cost of Trauma to our country. Properly structured protocols and the use of scores can enhance Trauma care and most probably lead to improved cost-effective outcomes.

Table 1

| **Mortality Decisions Trauma Terminology** | | |
|---|---|---|
| **Old Terminology** | **Current Terminology** | (further description) |
| NOT Preventable | Anticipated | (N/A) |
| Preventable | Unanticipated | No Room for improvement |
| Preventable | Unanticipated | Room for improvement |

Table 2

| **Trauma Care System** | (Still very fragmented in RSA) |
|---|---|
| Prehospital | Scene<br>Modes of transport<br>Primary health facility |
| Acute care | Emergency department<br>Theatre<br>ICU<br>Ward |
| Post Hospital Care | Rehabilitation centre<br>Home care |

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3) Hardcastle TC, Steyn E, Boffard KD, Goosen J et al. Guideline for the assessment of trauma centres for South Africa. S Afr Med J 2011 Mar 1;101(3):189-194
4) Bowley DM, Cherry R, Snyman T, Vellema J, Rein P, Moeng S, Boffard KD. Seroprevalence of the human immunodeficiency virus in major trauma patients in Johannesburg. S Afr Med J 2002 Oct;92(10);792–3
5) Goosen J, Bowley M, Degiannis E, Plani F. Trauma care systems in South Africa. Injury 2003;34:704-708
6) D Demetriades , M Martin, A Salim et al. The effect of trauma center designation and trauma volume on outcome in specific severe injuries. Ann Surg 2005;242(4);512-517
7) Schaffer N, Driessen A, Frohlith M et al, Diversity in Clinical management for the treatment of major bleeding Trauma Patient across European Level 1 trauma Centres. Sca J of Trauma 2015;23:74-85

**General surveillance/ screening for colon cancer** in a resource constrain environment is imperative.

Prof Ally (For)

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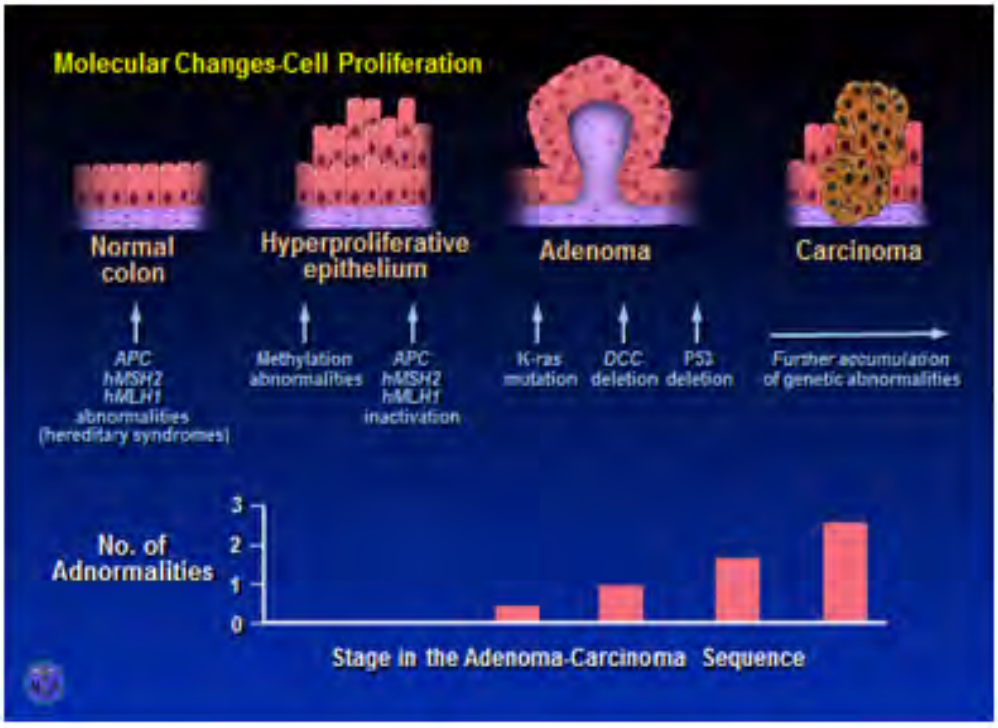
**TABLE 2: Summary of selected risk factors for colorectal cancer**

| Factor | | Relative risk |
|---|---|---|
| ***Heredity and medical history*** | | |
| Family history | | |
| 1 first-degree relative | | 2.2 |
| > 1 first-degree relative | | 4 |
| Relative with diagnosis before age 45 | | 3.9 |
| Inflammatory bowel disease | | |
| Crohn's disease | colon | 2.6 |
| Ulcerative colitis | colon | 2.8 |
| Ulcerative colitis | rectum | 1.9 |
| ***Others*** | | |
| Obesity (per 5-unit increase in BMI) | | |
| Men | colon | 1.3 |
| | rectum | 1.1 |
| Women | colon | 1.1 |
| Alcohol consumption | | 1.1 |
| Red meat consumption | | 1.3 |
| Diabetes | | 1.3 |
| Processed meat consumption | | 1.2 |

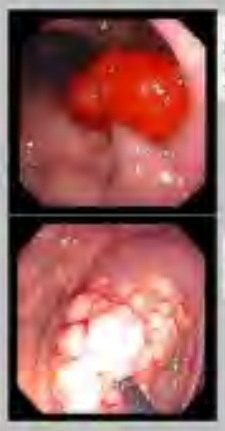
Source: Colorectal Cancer Facts and Figures, 2008-2010. Atlanta, American Cancer Society, 2010.
BMI = body mass index



# Colorectal Cancer - Screening

**Prevention and Screening Methods**

- **Between 70 and 90 percent of colorectal cancers arise from adenomatous polyps, and 10 to 30 percent arise from sessile adenomas.**
- The larger the polyp, the greater the potential for malignancy.
- Diminutive polyps (5 mm or less in diameter) have a negligible malignant potential.
- Polyps with a diameter of 5 to 10 mm are considered small, whereas polyps greater than 10 mm in diameter are considered large.
- **Polyps larger than 2 cm in diameter have a 50 percent chance of becoming malignant over time.**

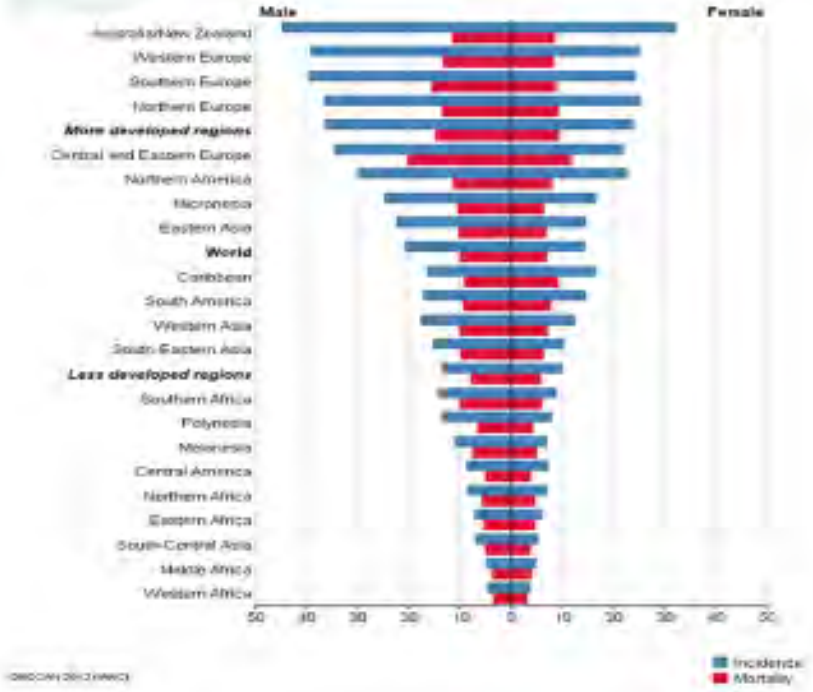


1.5 cm bi-lobed benign tubular adenoma on a stalk.

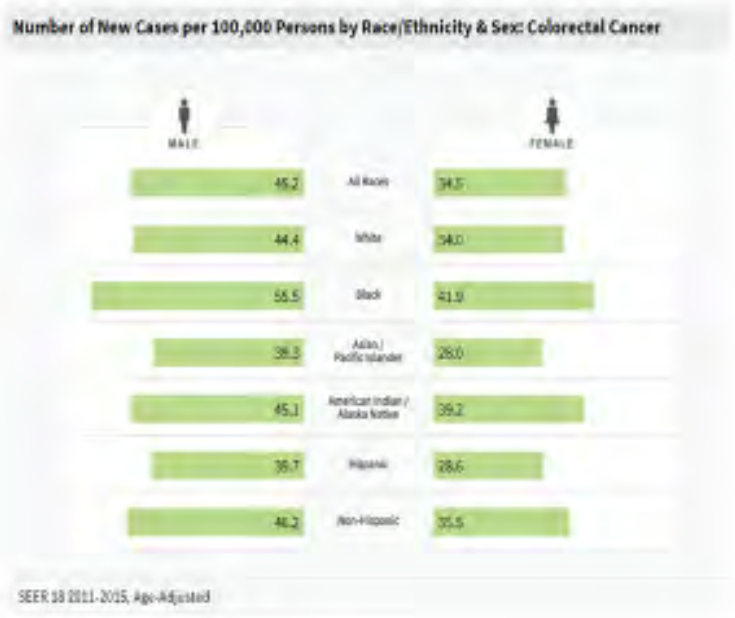
Sessile villous adenoma

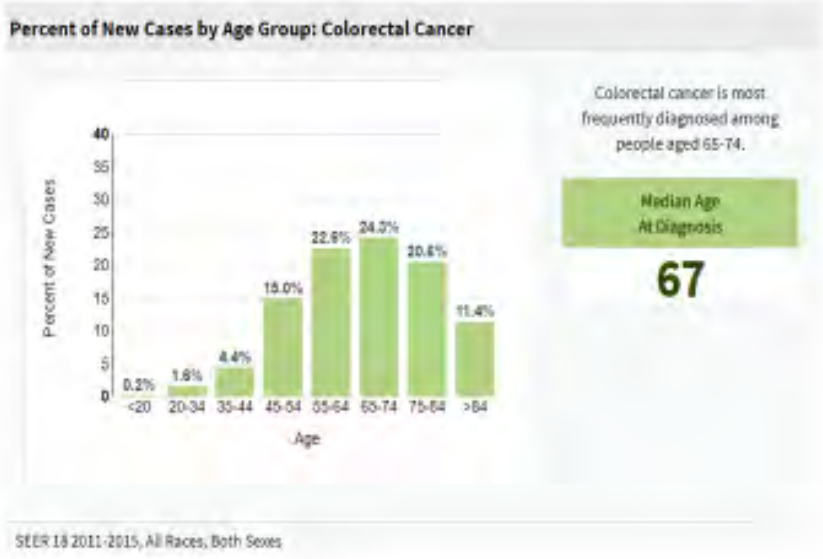
**Globocan 2012**

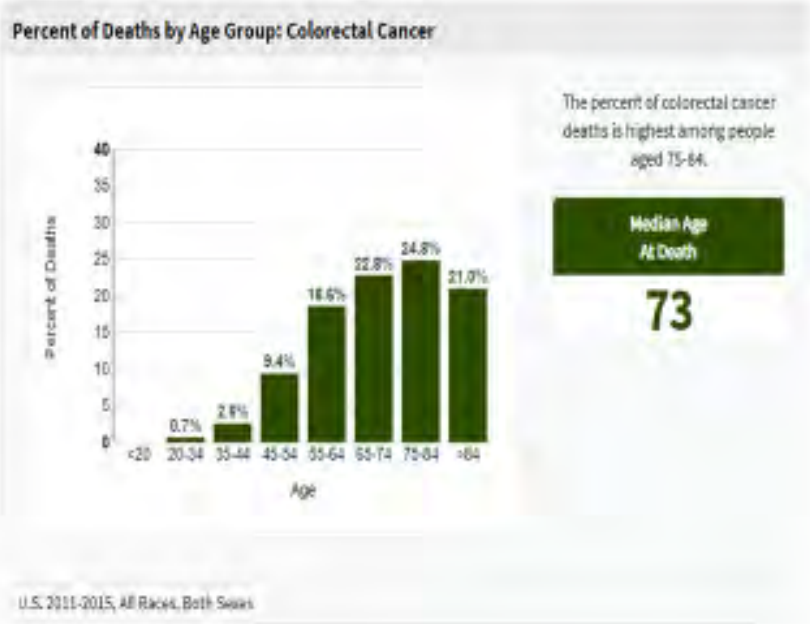
| per 100,1000 | ETHIOPIA | SOUTH AFRICA | HIGHEST |
|---|---|---|---|
| Oesophageal | 7,1 - 11,2 | >12,9 | >12,9 |
| Stomach | 2,4 - 5,2 | 7,2 - 12,7 | >23,8 |
| Colorectal | 2,6 - 7,1 | 13,0 - 10,5 | >31 |
| Liver | 4,5 – 8,5 | 4,2 - 8,5 | >25,9 |

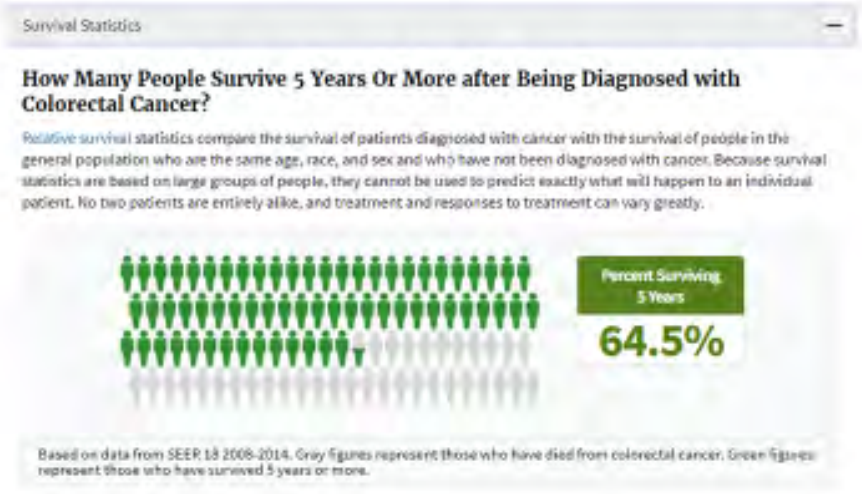

Male
Female
Australia/New Zealand
Western Europe
Southern Europe
Northern Europe
More developed regions
Central and Eastern Europe
Northern America
Micronesia
Eastern Asia
World
Caribbean
South America
Western Asia
South-Eastern Asia
Less developed regions
Southern Africa
Polynesia
Melanesia
Central America
Northern Africa
Eastern Africa
South-Central Asia
Middle Africa
Western Africa
50 40 30 20 10 0 10 20 30 40 50
Incidence
Mortality

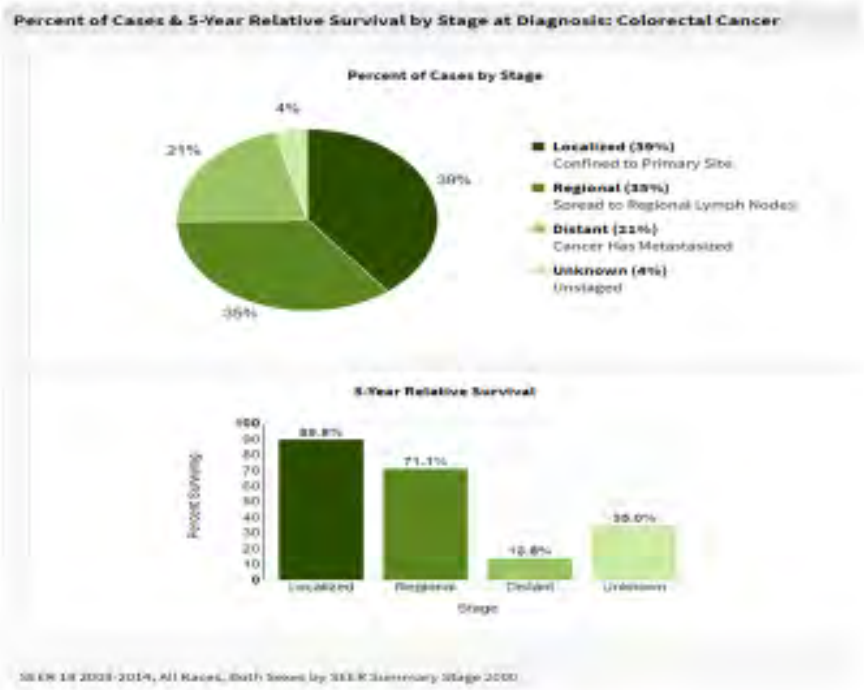

Statistics at a Glance
At a Glance
Estimated New Cases in 2018
140,250
% of All New Cancer Cases
8.1%
Estimated Deaths in 2018
50,630
% of All Cancer Deaths
8.3%
Percent Surviving 5 Years
64.5%
2008-2014
Number Per 100,000 Persons
Year
New Cases - SEER 13
Deaths - U.S.
Modeled trend lines were calculated from the underlying rates using the Joinpoint Trend Analysis Software.


Number of New Cases per 100,000 Persons by Race/Ethnicity & Sex: Colorectal Cancer
MALE
FEMALE
46.2
All Races
34.5
44.4
White
34.0
55.5
Black
41.9
38.3
Asian / Pacific Islander
26.0
45.1
American Indian / Alaska Native
39.2
36.7
Hispanic
28.6
46.2
Non-Hispanic
35.5
SEER 18 2011-2015, Age-Adjusted

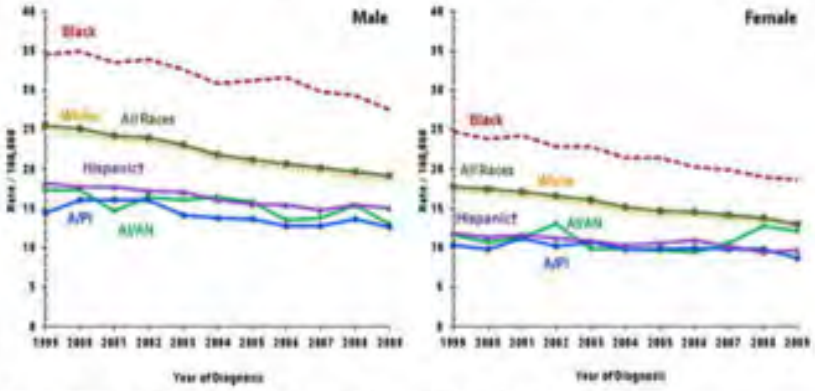

Percent of New Cases by Age Group: Colorectal Cancer
Percent of New Cases
40
35
30
25
20
15
10
5
0
0.2%
1.8%
4.4%
15.0%
22.6%
24.3%
20.6%
11.4%
<20
20-34
35-44
45-54
55-64
65-74
75-84
>84
Age
Colorectal cancer is most frequently diagnosed among people aged 65-74.
Median Age At Diagnosis
67
SEER 18 2011-2015, All Races, Both Sexes


Percent of Deaths by Age Group: Colorectal Cancer
The percent of colorectal cancer deaths is highest among people aged 75-84.
Median Age At Death
73
Percent of Deaths
40
35
30
25
20
15
10
5
0
0.7%
2.8%
9.4%
18.6%
22.8%
24.8%
21.0%
<20
20-34
35-44
45-54
55-64
65-74
75-84
>84
Age
U.S. 2011-2015, All Races, Both Sexes

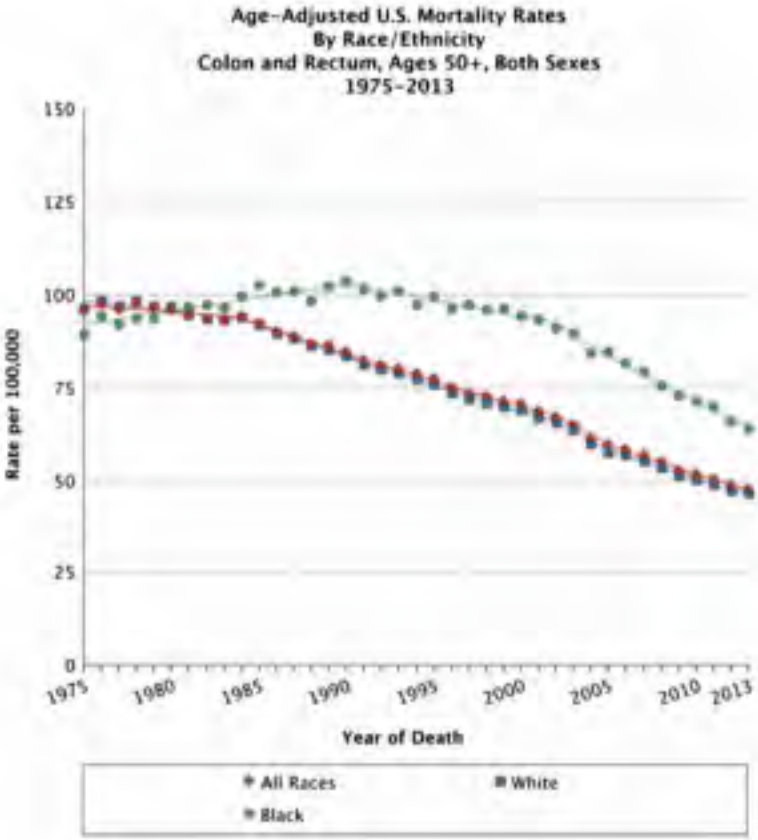

Survival Statistics
How Many People Survive 5 Years Or More after Being Diagnosed with Colorectal Cancer?
Relative survival statistics compare the survival of patients diagnosed with cancer with the survival of people in the general population who are the same age, race, and sex and who have not been diagnosed with cancer. Because survival statistics are based on large groups of people, they cannot be used to predict exactly what will happen to an individual patient. No two patients are entirely alike, and treatment and responses to treatment can vary greatly.
Percent Surviving 5 Years
64.5%
Based on data from SEER 18 2008-2014. Gray figures represent those who have died from colorectal cancer. Green figures represent those who have survived 5 years or more.

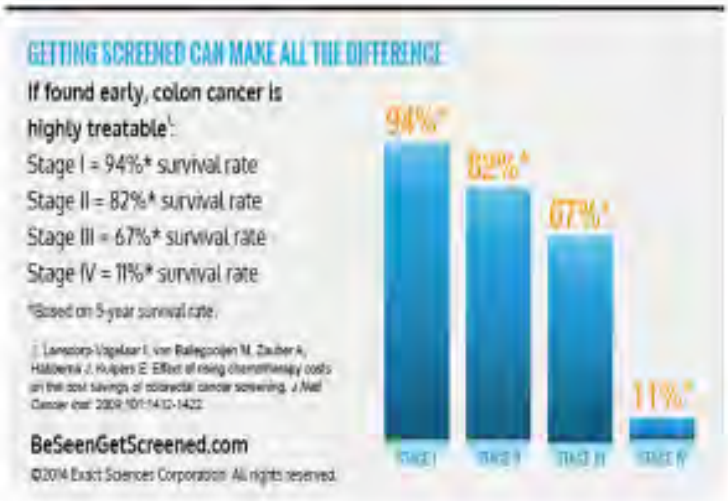



**Colorectal Cancer**
**Death Rates* by Race/Ethnicity and Sex, U.S., 1999–2009**




**Mortality source:** U.S. Mortality Files, National Center for Health Statistics, CDC.
*Rates are per 100,000 persons and are age-adjusted to the 2000 U.S. standard population (19 age groups – Census P25-1130). Death rates cover 100% of the U.S. population.
†Hispanic origin is not mutually exclusive from race categories (white, black, Asian/Pacific Islander, American Indian/Alaska Native).


Age-Adjusted U.S. Mortality Rates
By Race/Ethnicity
Colon and Rectum, Ages 50+, Both Sexes
1975-2013
Rate per 100,000
150
125
100
75
50
25
0
1975
1980
1985
1990
1995
2000
2005
2010
2013
Year of Death
All Races
White
Black


GETTING SCREENED CAN MAKE ALL THE DIFFERENCE
If found early, colon cancer is highly treatable[1]:
Stage I = 94%* survival rate
Stage II = 82%* survival rate
Stage III = 67%* survival rate
Stage IV = 11%* survival rate
*Based on 5-year survival rate.
1. Lansdorp-Vogelaar I, van Ballegooijen M, Zauber A, Habbema J, Kuipers E. Effect of rising chemotherapy costs on the cost savings of colorectal cancer screening. J Natl Cancer Inst. 2009;101:1412-1422.
BeSeenGetScreened.com
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94%*
82%*
67%*
11%*

Gastroenterology

Volume 100, Issue 4, April 1991, Pages 1033-1040

Adenocarcinomas of the colon and rectum in persons under 40 years old: A population-based study

Patricia M. Griffin, Jonathan M. Lilly, Raymond S. Greenberg, W. Scott Clark

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https://doi.org/10.1016/0016-5085(91)90275-T

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## Increasing Rates of Young Rectal Cancer

- Colorectal cancer rates have declined overall in the past few decades, 30% of cases are now diagnosed in people younger than 55 years, according to 2017 data from the American Cancer Society
- Updated its guidelines and now recommends that colorectal cancer screening begin at age 45, rather than age 50

## Increasing Rates of Young Rectal Cancer

- Analyzed data on 68,699 patients with rectal cancer from the 2010 to 2012 National Inpatient Sample database.
- During that 3-year period, 2748 (4%) of the cases diagnosed were in people younger than 50 years.
- But in that younger age group, the incidence rose over each of the 3 years, by 2.8%, 3.0%, and 3.4%.
- Notably, the younger people diagnosed with rectal cancer were more likely to be women than men (62% vs 39%).
- More research is needed to discern the reason for this, authors pointed out.

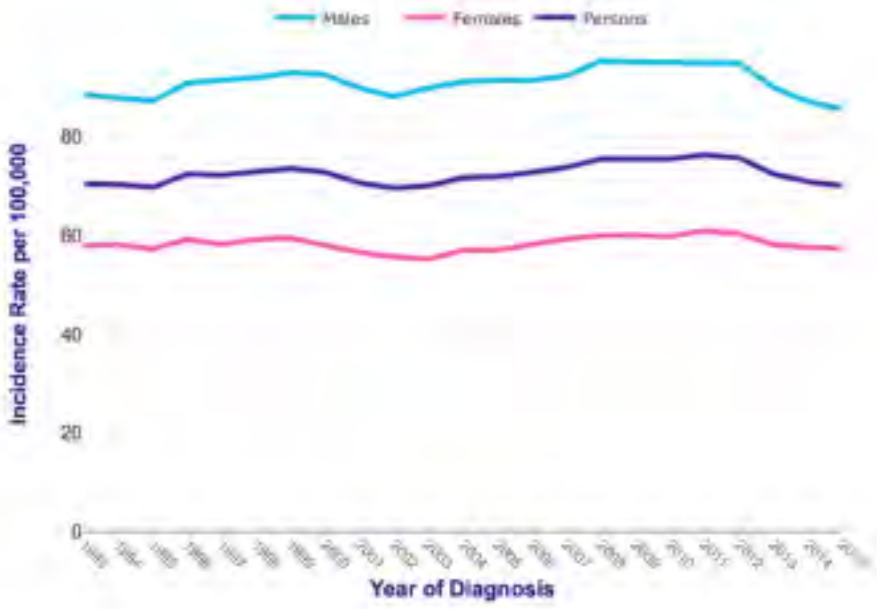
DDW

## Increasing Rates of Young Rectal Cancer

- Rates of rectal cancer are increasing in young people, and those affected are overwhelmingly female and white
- The work shows an annual increase in rates of the malignancy in people younger than 50 years of about 3%.

DDW

# Colorectal Cancer UK




Cancerresearchuk.org

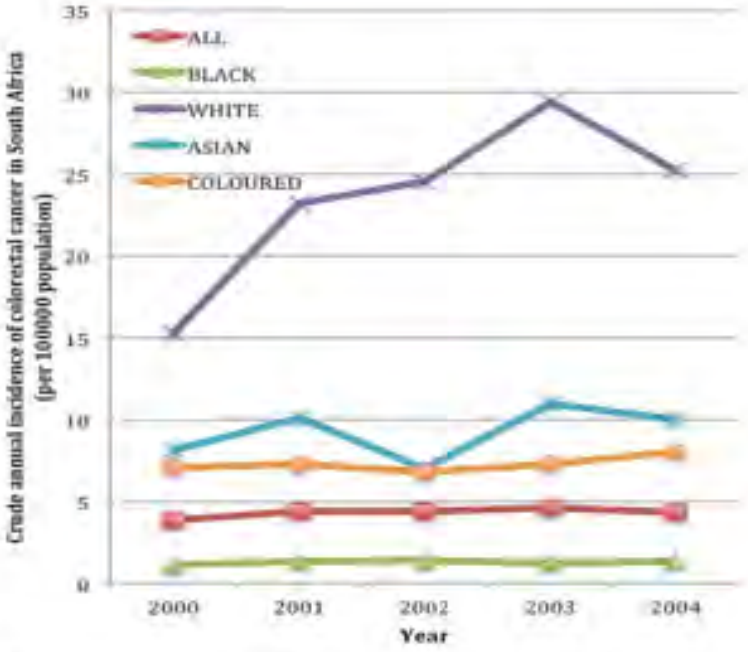
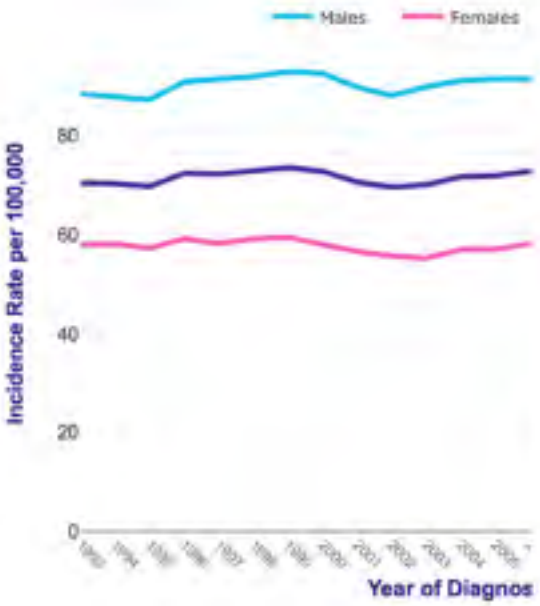
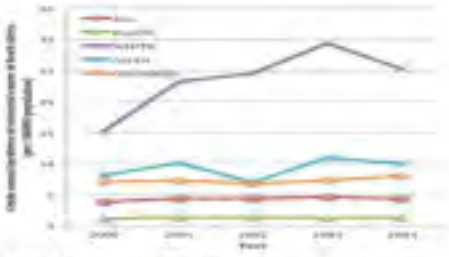


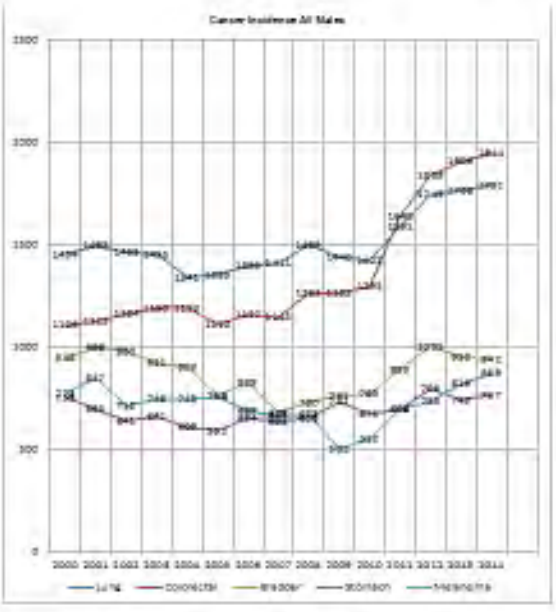

**Figure 9** Crude incidence of colorectal cancer in South Africa (per 100 000 population) by ethnicity for 2000–2004.

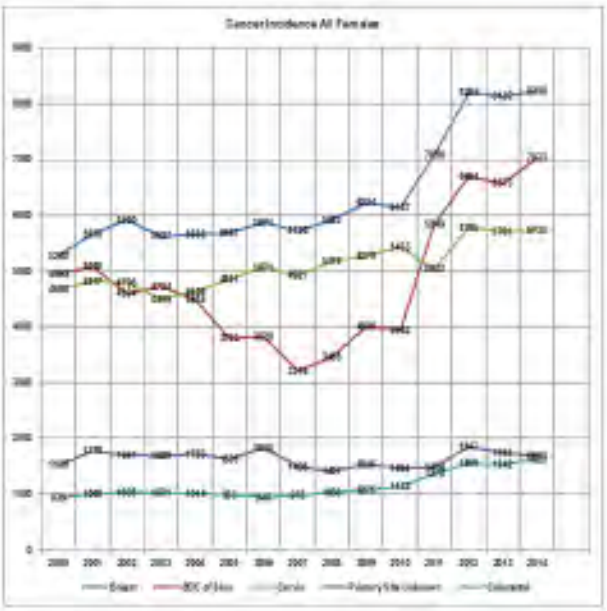
*Graham et al JOGH December 2012 • Vol. 2 No. 2 • 020404*



# 2014 Cancer Registry





Herbst et al CANSA fact sheet

Cancer Epidemiology 44 (2016) 96–100

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The International Journal of Cancer Epidemiology, Detection, and Prevention

journal homepage: www.cancerepidemiology.net

Short communication

# The incidence and histo-pathological characteristics of colorectal cancer in a population based cancer registry in Zimbabwe

Leolin Katsidzira[a,b,*], Eric Chokunonga[c], Innocent T. Gangaidzo[d], Simbarashe Rusakaniko[d], Margaret Borok[a,c], Zvifadzo Matsena-Zingoni[e], Sandie Thomson[b], Raj Ramesar[f], Jonathan A. Matenga[g]

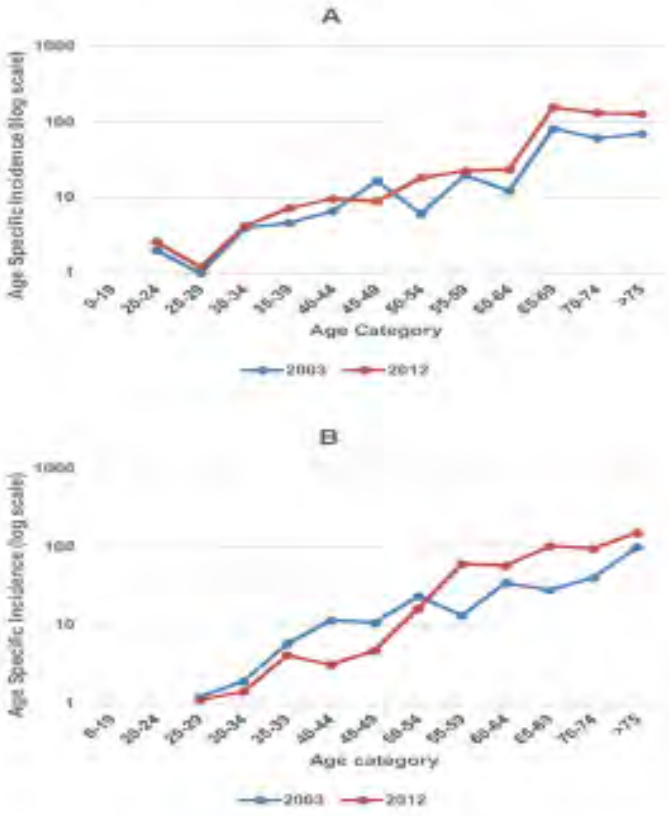


**Table 1**
Comparison of demographic and pathological characteristics between different population groups.

| Variable | Black Africans n = 886 | Caucasians n = 216 | P value |
|---|---|---|---|
| Gender | | | |
| Males | 471 (53%) | 136 (63%) | 0.009 |
| Mean age (SD)[a] | 52.9 (16.6) | 69.5 (10.8) | <0.001 |
| Site | | | |
| Colon | 487 (55%) | 135 (62%) | |
| Rectum | 399 (45%) | 81 (38%) | 0.133 |
| Histology[b] | | | |
| Adenocarcinoma | 768 (87%) | 202(94%) | |
| Mucinous adenocarcinoma | 59 (7%) | 10(4%) | |
| Signet ring cell carcinoma | 37 (4%) | 3(1%) | |
| Other | 22 (2%) | 1(1%) | 0.024 |

[a] 39 black Africans and 4 Caucasians had missing ages.
[b] Fisher's exact test.

**Table 2**
Differences in demographic and pathologic characteristics between young adults and older individuals among black Africans with colorectal cancer.

| Variable | Age < 40 n = 223 | Age > 40 n = 624 | P value |
|---|---|---|---|
| Sex | | | |
| Male | 119 (53%) | 332 (53%) | |
| Female | 104 (47%) | 292 (47%) | 0.970 |
| Site | | | |
| Colon | 111 (50%) | 347 (55%) | |
| Rectum | 112 (50%) | 277 (45%) | 0.305 |
| Histology | | | |
| Adenocarcinoma | 172 (77%) | 565 (90%) | |
| Mucinous adenocarcinoma | 20 (9%) | 36 (6%) | |
| Signet ring cell carcinoma | 22 (10%) | 12 (2%) | |
| Others | 9 (4%) | 11 (2%) | <0.001 |

NB: Age was unavailable in 39 cases and they are not included in this table.

*Int. J. Cancer:* **112**, 860–864 (2004)

UICC Publication of the International Union Against Cancer

# CANCER SURVIVAL IN A SOUTHERN AFRICAN URBAN POPULATION

Adam GONDOS[1*], Eric CHIKUNDUNGA[2], Hermann BRENNER[3], Donald Maxwell PARKIN[3], Risto SANKILA[4], Margaret Z. BORUK[2], Z. Michael CHIRENJE[5], Anna M. NYAKABAU[6] and Mary Travis BASSETT[2]

TABLE II – COMPARISON OF PATIENTS' MEDIAN AGE AT DIAGNOSIS, ZIMBABWEAN CANCER PATIENT POPULATIONS AND SEER CANCER PATIENT POPULATIONS, 1993–1997

| Cancer site | Zimbabwe (Harare) | | USA (SEER) | |
|---|---|---|---|---|
| | Black patients | White patients | Black Americans | White Americans |
| Oesophagus | 58 | — | 63 | 69 |
| Stomach | 62 | — | 68 | 72 |
| Colorectal | 54 | 67.5 | 68 | 72 |
| Liver | 56 | — | 62 | 69 |
| Larynx | 59 | 71 | 62 | 66 |
| Lung | 59 | 67.5 | 65 | 70 |
| Skin melanoma | 56 | 50 | 64 | 57 |
| Breast | 46 | 63 | 57 | 64 |
| Cervix | 46.5 | — | 50 | 47 |
| Ovary | 45 | — | 62 | 64 |
| Prostate | 68 | 70 | 68 | 70 |
| Bladder | 58 | 73 | 71 | 73 |
| Eye | 30 | — | 3.5 | 63 |
| Lymphomas | 36 | — | 47 | 64 |
| Kaposi sarcoma | 26 | — | 37 | 39 |

TABLE V – COMPARISON OF CANCER SURVIVAL (IN %) BETWEEN ZIMBABWE AND OTHER DEVELOPING COUNTRIES

| Cancer site | 5-year relative survival, Zimbabwe | | Other developing countries[1] range |
|---|---|---|---|
| | Black patients | White patients | |
| Oesophagus | 7.6 | — | 3.3–26.5 |
| Stomach | 13.2 | — | 7.5–28.2 |
| Colorectal | 17.4 | 19.4 | 29.2–45.5 |
| Liver | 1.4 | — | 0.6–12.9 |
| Larynx | 2.4 | 55.3 | 25.8–60.9 |
| Lung | 5.7 | 10.2 | 3.2–13.8 |
| Skin melanoma | 49.9 | 97.7 | 39.2–47.0 |
| Breast | 37.9 | 74.4 | 44.1–72.7 |
| Cervix | 30.5 | — | 28.0–64.9 |
| Ovary | 38.0 | — | 33.6–45.0 |
| Prostate[2] | 27.1 | 83.7 | 34.5–45.9 |
| Bladder | 16.8 | 72.8 | 34.5–45.9 |
| Lymphomas | 23.1 | — | 17.7–59.0 |

# DGC-Data

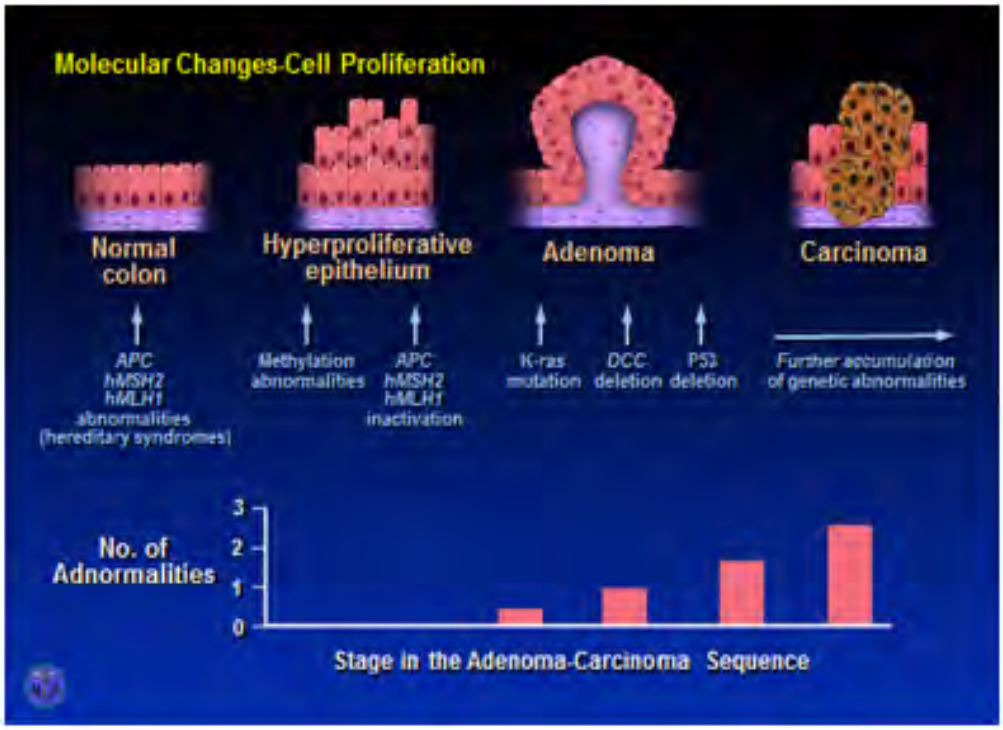
**Table 1: Characteristics of colorectal cancer patients**

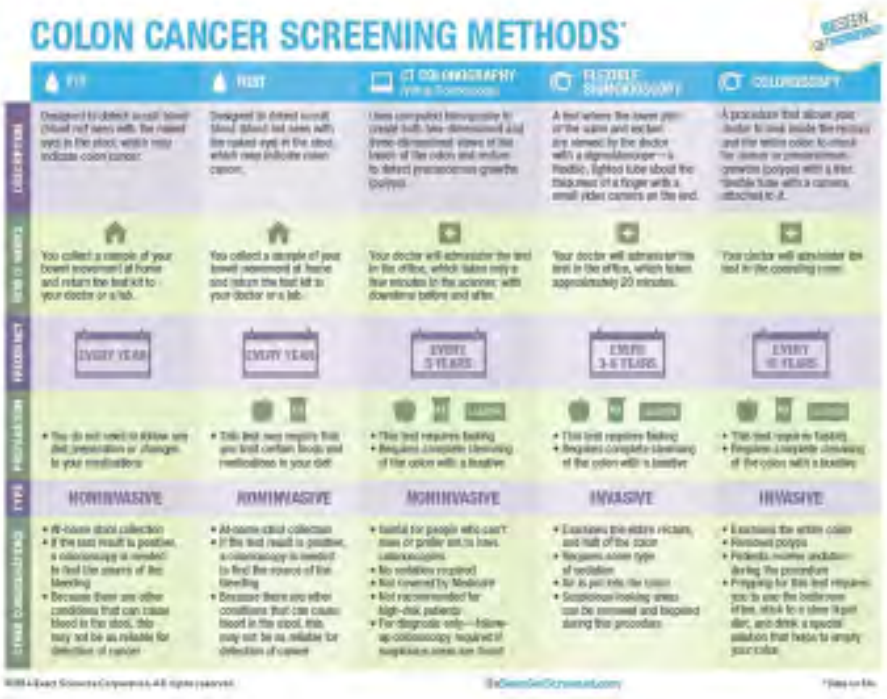
| Patient Characteristics | | N | % |
|---|---|---|---|
| Demographic characteristics | | | |
| Age | | | |
| Overall age (median & IQR) | 59 (49 - 67) | | |
| Age group | | | |
| <=50 years | | 104 | 28.97 |
| Over 50 | | 255 | 71.03 |
| Self-reported race | | | |
| Black | | 189 | 52.65 |
| White | | 119 | 33.15 |
| Indian/Asian | | 27 | 7.52 |
| Coloured/ Mixed race | | 24 | 6.69 |
| Gender | | | |
| Male | | 182 | 50.7 |
| Female | | 177 | 49.3 |

| Clinical features | | | |
|---|---|---|---|
| Family history of CRC | | | |
| Yes | | 15 | 4.18 |
| No | | 344 | 95.82 |
| Site of malignancy | | | |
| Right | | 64 | 17.83 |
| Left | | 100 | 27.86 |
| Rectal | | 187 | 52.09 |
| Missing | | 8 | 2.23 |
| AJCC Stage | | | |
| Stage 1/2 | | 73 | 20.33 |
| Stage 3/4 | | 193 | 54.32 |
| Not staged | | 91 | 25.35 |
| Elective vs Emergency | | | |
| Elective | | 162 | 45.4 |
| Urgent/Emergency | | 30 | 10.03 |
| Missing | | 160 | 44.57 |

**Risk factors for mortality among colorectal cancer patients**

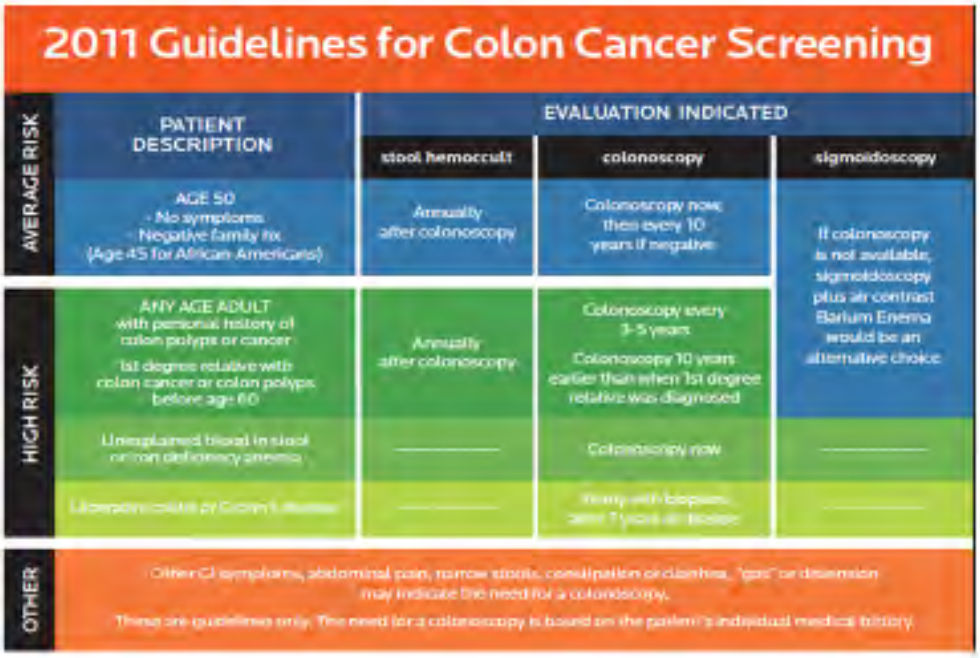
| | Univariate Models | | Multivariate Model | |
|---|---|---|---|---|
| | | | | |
| Age group | | P value | | P value |
| Over 50 | Reference | | | |
| <=50 | 1.18 (0.71 - 1.94) | 0.525 | 1.25 (0.07 - 2.31) | 0.475 |
| Self-reported race (Black vs other) | | | | |
| Other | Reference | | Reference | |
| Black | 2.19 (1.30 - 3.68)** | 0.003 | 1.59 (0.83 - 3.05) | 0.161 |
| AJCC Stage | | | | |
| Stage 1/2 | Reference | | | |
| Stage 3/4 | 4.33 (1.72 - 10.86)** | 0.002 | 3.32 (1.31 - 8.41)** | 0.012 |
| Education | | | | |
| Less than matric | Reference | | Reference | |
| Matric or better | 0.32 (0.18 - 0.55)** | <0.001 | 0.31 (0.16 - 0.59)** | <0.001 |






# New Colorectal Cancer Screening Guidelines

| | |
|---|---|
| ***Adults age 50 and older*** | |
| ***Tests That Detect Adenomatous Polyps and Cancer*** | |
| | Flexible sigmoidoscopy (FSIG) every 5 years, or |
| | Colonoscopy every 10 years, or |
| | Double contrast barium enema (DCBE) every 5 years, or |
| | **CT colonography (CTC) every 5 years** |
| ***Tests That Primarily Detect Cancer*** | |
| | Annual guaiac-based fecal occult blood test (gFOBT) with high test sensitivity for cancer, or |
| | Annual fecal immunochemical test (FIT) with high test sensitivity for cancer, or |
| | **Stool DNA test** (sDNA), with high sensitivity for cancer, interval uncertain |

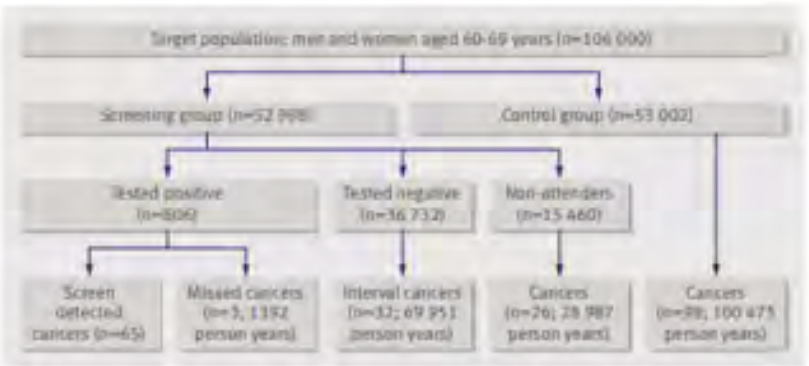



BMJ

RESEARCH

## Test, episode, and programme sensitivities of screening for colorectal cancer as a public health policy in Finland: experimental design

Nea Malila, director of Mass Screening Registry,[1] Tiina Ovaines, chief medical officer,[2] Outi Malminiemi, hospital chemist,[3] Matti Hakama, professor[1 4]




**Flow chart of Finnish colorectal cancer screening programme. Screen detected cancers provide no follow-up time in current analysis**

**DISCUSSION**

We found high attendance in the screening programme for colorectal cancer that was run as a public health policy in Finland. The faecal occult blood test was able to detect a major proportion (55%) of cancers in the detectable preclinical phase and more than one third (38%) in the total target population.

Only the faecal occult blood test has been evaluated for effect on mortality when screening for colorectal cancer.[8,9] With screening every two years the reduction in mortality from colorectal cancer varies between 25% at 18 years of follow-up[10] and 12% at eight years of follow-up.[4] In one trial with a follow-up of 18 years, a 20% reduction in incidence of colorectal cancer was also seen.[11] In light of these results several organisa-

# Our Reality

- We have a young population
- At the moment we have less colorectal cancer than Europe
- We probably have significant differences of colorectal cancer in different groups of patients
- We can probably expect a significant increase in colorectal cancer (aging population & urbanization)

# The Private Sector

- Currently serves about 15% of the population
- Likely that the incidence of CRC is higher in this group
- Resource rich

# The Discovery Bowel Cancer Screening Project

- Mandated by SAGES
- Preliminary talks
  - Dion Levin
  - Adam Boutall
  - Hannah Aldean (Discovery)

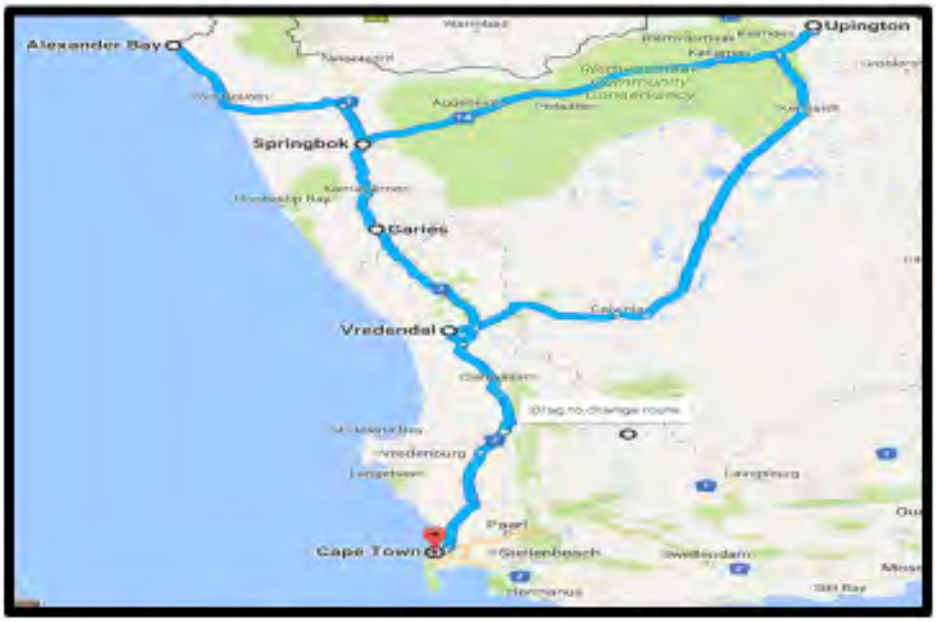
# The State Sector

- Can we afford a population based bowel cancer screening program ( FOB )
- With the current prevalence of colorectal cancer do we need a bowel cancer screening program . HOWEVER , because of the aggressive nature and early onset ????
- We definitely need more research to evaluate emerging trends – small population based studies ( 100,000 – Finland )

# But

- In a low incidence area do inherited cancer syndromes play a proportionally larger role
- What about targeted surveillance for high risk groups.

# HNPCC and the Northern Cape




- 1985 HNPCC diagnosed in a Northern Cape Community
- 1996 R Ramasar identified the first mutation

# What is the incidence of CRC in the Northern Cape?

SAJS

General Surgery

## Incidence and histological features of colorectal cancer in the Northern Cape province, South Africa

M. Q. WENTINK
M. RÄKERS

Colorectal Surgery Unit, Department of Surgery, University of Cape Town and Groote Schuur Hospital and the Vrije Universiteit, Amsterdam

D. A. STUPART, F.C.S. (S.A.)
U. ALGAR, M.SC. (NURSING)

Colorectal Surgery Unit, Department of Surgery, University of Cape Town and Groote Schuur Hospital

R. RAMESAR, PH.D.

MRC/UCT Human Genetics Research Unit, Division of Human Genetics, Institute for Infectious Diseases and Molecular Medicine, University of Cape Town and Groote Schuur Hospital

P. A. GOLDBERG, M.MED.

Colorectal Surgery Unit, Department of Surgery, University of Cape Town and Groote Schuur Hospital

**3.7/100 000** and histological features suggestive of increased HNPCC

# How do we survey this group?

Original article

doi:10.1111/j.1463-1318.2006.01172.x

## Mobile colonoscopic surveillance provides quality care for hereditary nonpolyposis colorectal carcinoma families in South Africa

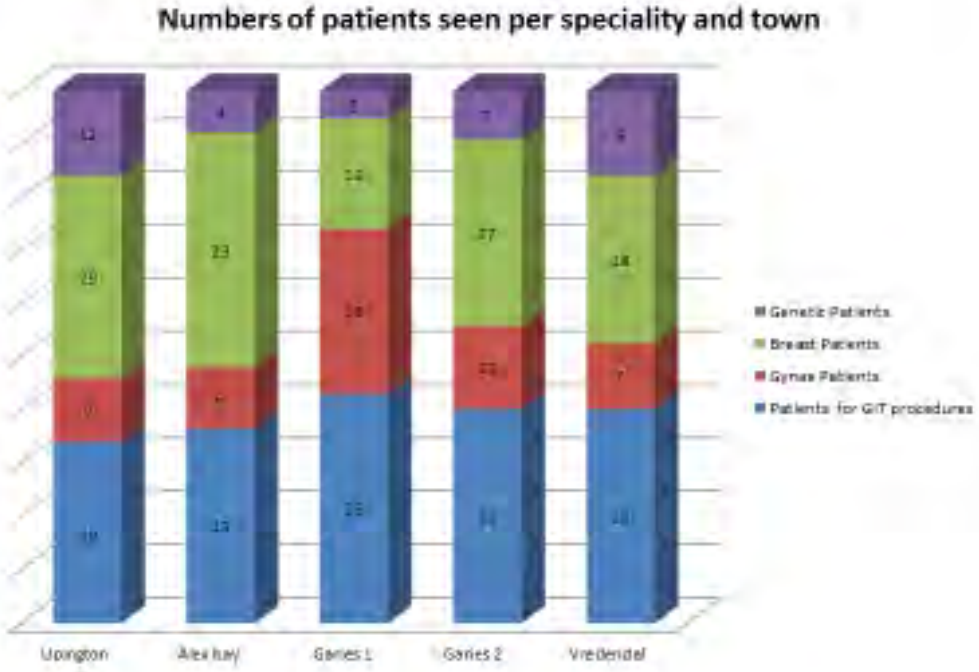
**D. W. Anderson*, P. A. Goldberg*, U. Algar*, R. Felix† and R. S. Ramesar†**

*Colorectal Unit, Department of Surgery and †MRC/UCT Human Genetics Research Unit, Division of Human Genetics, Institute for Infectious Diseases and Molecular Medicine, University of Cape Town and Groote Schuur Hospital, Cape Town, South Africa

Received 17 November 2005; accepted 28 July 2006

Northern Cape Lynch Syndrome Surveillance
trip
2016 Report
'Splash of Red'
Sunday 27th August - Friday 2nd September

| | | | |
|---|---|---|---|
| 1 | Paul Goldberg | GSH Colorectal Surgery | Endoscopist |
| 2 | Adam Boutall | GSH Colorectal Surgery | Endoscopist |
| 3 | Reid Ally | Baragwanath Hosp. GIT | Endoscopist |
| 4 | Faizel Kimmie | KHC Surgery | Endoscopist |
| 5 | Klaus Matzel | Coloproctology, University Erlangen, Germany | Endoscopist |




# Does targeted surveillance work?

Original article

Surveillance colonoscopy improves survival in a cohort of subjects with a single mismatch repair gene mutation

D. A. Stupart*, P. A. Goldberg*, U. Algar* and R. Ramesar†

- 129 patients colonoscopic surveillance 49 refused
- Cancers diagnosed 14/129 and 13/49
- Death from colorectal cancer 3/129 (2%) and 6/49 (12%) (P=0.021)

# In a low incidence areas does HNPCC play a bigger role?


**Mismatch repair deficiency in colorectal cancer patients in a low-incidence area**

F Vergouwe, A Boutall, D Stupart, U Algar, D Govender, G D van der Linde, A Mall, R Ramesar, P A Goldberg

- 21.8% of cases deficient for hMLH1 or hMSH2
- It would appear that more cancers follow a MMR gene pathway but we have yet to demonstrate that this is due to HNPCC

# Surveilance/Screening

- Managed to serve a remote high risk community in a low incidence area by
  - Performing targeted outreach colonoscopy
  - With a confirmed survival benefit
  - By offering sub-total colectomy we simplified surveillance and reduced metachronous cancers

## Personal History: Surveillance after Initial Colonoscopy

| Colonoscopy Findings: | Recommended Interval: |
|---|---|
| Colon cancer | 1 year after cancer resection |
| No polyp | 10 years |
| Hyperplastic, left- sided | 10 years |
| 1-2 Tubular Adenomas < 1 cm | 5 – 10 years |
| Adenoma with low grade dysplasia | 5 – 10 years |
| 3-10 Tubular adenomas > 1 cm | 3 years |
| Villous adenoma > 25% villous | 3 years |
| Adenoma with high grade dysplasia | 3 years |
| > 10 adenomas | 3 years (genetic testing should be considered- FAP/HNPCC) |
| Sessile adenomas with piecemeal resection | 2-6 months after resection |

# Conclusion

- Active research into colorectal cancer incidence in South Africa is desperately needed.
- Research into cost effectiveness of screening
- Targeted screening in low incidence, higher risk areas
- Safe and effective colonoscopy is crucial

# **Laparoscopic v/s open surgery** for appendicitis

Prof Molaoa (OPEN)

---

**Introduction**

Open appendicectomy for acute uncomplicated appendicitis through McBurney's point or Lanz incision has been proven safe; and has been used since its introduction by McBurney in 1894. The procedure has remained unchanged, efficacious, with low morbidity and mortality (Sauerland 2010, Ali 2010, Kahagias 2008). Ever since Semm (1983) performed the first laparoscopic appendicectomy, the efficiency and superiority of laparoscopic versus open approach has been the subject of much debate (Kahagias 2008).

Numerous prospective randomized studies, meta-analyses, and systematic reviews have been published on the topic of LA, with a general consensus that the heterogeneity of the measured variables and other weaknesses in the methodology have not allowed to draw definitive conclusions and generalizations (Katkhouda n.d.)

However, advocates for laparoscopic appendicectomy contend that the procedure is associated with shorter hospital stay, reduced analgesic requirement, early return to normal daily activities, early feeding, reduced incidence of SSI and intra-abdominal abscesses, and besides, operation time and costs are not different between the two approaches (Manjunath 2016, Southgate 2012).

The purpose of this presentation/ review is to explore whether there is any evidence to support these claims; if any, whether the evidence in favour of laparoscopy is strong enough to change the Gold standard – open appendicectomy.

**The objective** of this presentation /review is to compare these two procedures in terms of the following outcome measures:

1. Mean procedure time
2. Length of hospital stay (LOS)
3. incidence of Surgical site infection (SSI)
4. Incidence of Intra-abdominal abscesses
5. Parenteral analgesia requirement
6. Procedure costs

**Methods**

We conducted a literature review of both systematic review and original articles comparing LA and OA with regard to the outcomes listed above.

## Results

### 1. Mean Operation Time

**Table 1: Mean operation time: LA vs. OA**

| Study A | Study period | Type of study | LA | OA | p-value | 95% CI | Comment |
|---|---|---|---|---|---|---|---|
| Kehagias, I et. al (2008) | 2006-2008 | | 44.3±24 | 47±19.7 | 0.31 | | No signif. difference |
| Ali, R et al(2010) | 2002-2006 | | 82 (40-180) | 70(30-120) | <0.001 | | Signif -OA |
| Minutolo et al (2014) | 2008-2012 | Retro-spective | 52.2 (20-155) | 49.3 (20-110) | 0.476 | | Not sign |
| Manjnath A et al (2016) | | RCT | 73.36 | 63.67 | 0.8293 | | Not sig |
| Suerland S et al (2010) | | Review | 10 min longer | | | 6-15 | Not sig |
| Southgate et al (2012) | | Review | 0.06 | | 0.58 | -0.16-0.29 | Not sig |

Though LA is marginally longer than OA (about 10 minutes), for individual operations, the mean difference is not statistically significant. However, cumulatively, LA is costly in terms of both anaesthesia and operation time, especially in centres with high volume.

### 2. Requirement for injectable analgesia

**Table 2: Requirements for parenteral analgesia**

| Study | | | LA | OA | p-value | 95%CI | Comment |
|---|---|---|---|---|---|---|---|
| Ali R et al (2010) | | | | | <0.001 | | Sig.-LA |
| Karatparambil et al (2016) | | | 6.5±0.6 doses | 6.5±0.8 | 0.781 | | Not sign |
| Manjnath A et al (2016) | | | 1.81 days | 4.79 | 0.0014 | | Sign-LA |
| Tsai et al (2012) | | | | | >0.05 | | Not sign |
| | | | | | | | |

Requirement for parenteral analgesia varied among different studies. Others showed no difference in the requirements for analgesia between the two groups; while others showed reduction in favour of LA group.

### 3. Wound sepsis

**Table 3: Incidence of SSI: LA vs OA**

| | | | | LA | OA | p-value | 95%CI | Comment |
|---|---|---|---|---|---|---|---|---|
| Kehagias, I et. al (2008) | | | | 5.3%(c)<br>0% (uc) | 12.8%(c)<br>0.8% (uc) | 0.03<br>0.01 | | sign |
| Karatparambil et al (2016) | | | | 2.3 | 6 | 0.212 | | Not sign |
| Suerland S et al (2010) | | | | OR:0.43 | | | 0.34-0.54 | Sign-LA |
| Tan et al (2014) | | | | 3.7 | 6 | 0.528 | | Not sign |
| Southgate et al (2012) | | | | OR:0.53 | | 0.44 | 0.11-2.63 | Not sig |
| Beg et al (2016) | | | | 12.2% | 15.1% | 0.48 | | Not sign |

With regard to SSI there is no consistency in the incidence of this complication in LA versus OA. The data is not conclusive in favour of any particular approach.

### 4. Intra-abdominal abscesses

**Table 4: Intra-abdominal sepsis: LA vs OA**

| | | | LA | OA | p-value | 95%CI | Comment |
|---|---|---|---|---|---|---|---|
| Kehagias, I et. al (2008) | | | 5.3% (c) | 2.1% (c) | 0.002 | | Sign-OA |
| Suerland S et al (2010) | | | OR:1.87 | | | 1.14-2.76 | sign |
| Southgate et al (2012) | | | OR:1.19 | | 0.62 | 0.61-2.31 | Not sign |
| Beg et al (2016) | | | 2.2% | 0 | | | Not sig |

Similarly, there is variability in the studies with regard to intra-abdominal abscess formation following either approach.

### 5. Average length of stay

**Table 5: Average length of hospital stay: LA vs OA**

| | | | LA | OA | p-value | 95%Ci | Comment |
|---|---|---|---|---|---|---|---|
| Kehagias, I et. al (2008) | | | 2.2 | 3.1 | 0.04 | | ?? |
| Ali, R et al(2010) | | | | | 0.672 | | Not sig |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Minutolo et al (2014) | | | 2.75 | 3.87 | 0.011 | -1.25-0.33 | Not sign |
| Karatparambil et al (2016) | | | 3.4± 0.7 | 3.5±0. 8 | | | Not sign |
| Suerland S et al (2010) | | | 1-7 | 1-7 | | | No diff |
| Southgate et al (2012) | | | -0.51 | | <0.05 | -0.64to-0.37 | Sign-LA |
| Manjnath A et al (2016) | | | 3.65( 2-7) | 6.87 (3-12) | 0.0010 | | |

In terms of the average length of stay, though numerically LA demonstrate reduced LOS, this was not statistically significant in most studies; and therefore is of no clinical or economic significance.

6. **Average costs**

**Table 6: Average procedure cost: LA vs OA**

| | | | | LA | OA | p-value | 95%CI | Comment |
|---|---|---|---|---|---|---|---|---|
| Kehagias, I et. al (2008) | | | | **€ 370 higher** | | | | |
| Ali R et al (2010) | | | | PR 7803 higher | | <0.001 | | |
| Minutolo et al (2014) | | | | €55 Higher | | 0.812 | | |
| Karatparambil et al (2016) | | | | Rs4569.5 higher | | | | |
| Manjnath A et al (2016) | | | | Rs5313 higher | | 0.0001 | | |
| Tan et al (2014) | | | | 4794 | 4725 | 0.721 | | |

Cost of LA in comparison to that of OA are individually and cumulatively high for LA without variability demonstrated by other outcome measures.

**Discussion**

This review has demonstrated the following:

1. Average operating time is variable. In most studies there is about 10 minutes mean difference which has been shown be not statistically significant. The reported studies do not specify when counting procedure time commenced. It is not known whether it start with setting up of laparoscopic instrument, or port insertion. Though the difference for individual procedures has been shown to be not statistically significant, cumulatively LA is more costly than OA in terms of theatre time.

2. The studies demonstrate variability in terms of other outcome measures, such as SSI, intra-abdominal collections, need for analgesia and length of stay. None of these has shown superiority of one approach to the other.
3. In contrast to low incidence of SSI and intra-abdominal collection reported in some studies, when comparing patients with similar disease severity, there is no difference in SSI between LA and OA (Beg 2017, Kahagias 2008).
4. All the studies reviewed have demonstrated that cost of LA are individually and cumulatively higher than those of OA.

## Conclusion

In the absence of evidence demonstrating superiority of one procedure over the other in terms of length of hospital stay, requirement for analgesia, SSI and intra-abdominal abscesses on one hand, and the exorbitant costs and long cumulative operating time for LA, OA should remain a "Gold standard" and a standard of care for acute appendicitis, unless there is diagnostic uncertainty where laparoscopy may be used as a therapeutic and diagnostic modality; and in the obese patients where who would require a bigger incision with associated pain and increased risk of wound infection.

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# **Laparoscopic v/s open surgery** for appendicitis

Dr Sardiwalla (Laparoscopy)

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The overarching theme for the program is: Optimal and effective surgical management under budgetary and resource constraints – doing more with less. I have been tasked to debate in favor of laparoscopic appendectomy with the above in mind. I am quite certain by the end of my talk you will be absolutely convinced that laparoscopic appendectomy fulfills the above criteria.

Acute appendicitis is a common cause of acute abdominal pain. Appendectomy is one of the most frequently performed surgical procedures internationally and in South Africa the situation is no different. However, in South Africa due to socioeconomic factors we see a plethora of delayed appendicitis with up to 40% of all appendicitis being complicated.

The open appendectomy was first described by McBurney almost a 100 years ago. Laparoscopic appendectomy was described by Semm in 1983[1] and is certainly the new kid on the block. So does the old adage 'if it ain't broke don't fix it' apply or should we shift completely toward the laparoscopic approach. My talk will show you that open appendectomy is certainly not the procedure of choice for patient with acute appendictis and the minimally invasive approach certainly has a lot of advantages to offer.

So this debate has raged on in the surgical literature for the last few years, and as the data has accumulated, the answers have become clearer.

**The proponents for the laparoscopic approach argue that laparoscopy offers:**

1. Shorter hospital stay
2. Less wound sepsis
3. Less pain
4. Better cosmesis
5. Earlier return to work
6. Improved diagnostic accuracy

I will irrevocably prove that all the above is true

**The opponents to laparoscopy cite:**

1. Cost
2. Concerns around increased collection or intrabdominal abscess

**My talk will lay these concerns to rest.**

The Oxford Centre for Evidence Based Medicine states the highest category of evidence for Therapeutic procedure is a Systematic review with homogeneity of randomized control trials. There are two such systematic reviews for laparoscopic versus open appendectomy, which showed strikingly similar results. This is high level evidence and is very difficult to argue against. One meta-analysis included adults and children, the other was adults only.

**The results of these systematic reviews are summarized below:**

1. Wound Infection

51 in 1696 patients (3,01%) in Laparoscopic group

130 in 1727 patients (7,53%) in Open group

The rate of wound infection is significantly reduced in laparoscopic appendectomy versus open surgery. Odds ratio 0,38, 95% CI 0,28-0,53; p<0,00001

In the subset of children analyzed there was however no difference.

Concerning intra-abdominal abscess rate which it must be noted has been raised by opponents to laparoscopy. Neither systematic review found an increased rate of intrabdominal abscess with laparoscopy. This certainly lays to rest the argument that laparoscopic surgery increases intrabdominal collection.

The rate of intraabdominal abscess in laparoscopic appendectomy was 3,17% and in open surgery 3,7%. Not statistically significant.

Laparoscopic surgery reduced post operative complications overall.

There was no difference in the reoperation rate between the two groups.

The operating time was longer in the laparoscopic group by 11,59 mins.

Post operative stay was significantly reduced with laparoscopic appendectomy (overall one day shorter stay).

Analgesic requirement was reduced as evidenced by reduced analgesic requirement, shorter time to return to normal activity.

In terms of cost in these meta-analyses there was no difference in the cost between the two groups.[2,3]

**What about in complicated appendicitis : Is laparoscopy still safe?**

In a meta-analysis the overall incidence of surgical site infection was lower with laparoscopic appendectomy. There was no difference in the rate of intraabdominal abscess. The conclusion was laparoscopic appendectomy is feasible and safe, it decreases the incidence of surgical site infection. It shortens hospital stay and the time to oral intake.[4]

Cost in the meta-analysis showed no difference however in a formal study addressing the issue of cost conducted in Spain. They looked at operating time, length of stay, post operative pain, complication rate and return to normal activity in an attempt to work out the total cost of each approach. This study found laparoscopic appendectomy had a shorter length of stay by one day. There was a faster return to activity by five days. The laparoscopic operation took longer by 30 minutes. The complications were significantly less in laparoscopic appendectomy 1,4%vs 10,6% p<0,001. Total cost of treatment was 150 euro more in the laparoscopic arm, but importantly this study did not look at the impact of the quicker return to normal activity. [5]

In conclusion I have demonstrated through high level evidence that laparoscopy is safe in appendicitis even complicated appendicitis. I have also demonstrated that the laparoscopic approach results in less complications especially wound infection. The drawback of laparoscopy is the slightly longer operating time and the cost. However these are offset by quicker return to work. Therefore laparoscopy is certainly the superior approach and the way forward in managing patients with appendicitis.

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# Is parathyroidectomy without sestamibi scan acceptable practice in 2018?

Dr Kinoo

## Introduction

Primary hyperparathyroidism (HPT) occurs when a pathological parathyroid gland secretes increased amount of parathyroid hormone (PTH), resulting in increased serum calcium with resultant symptoms of hypercalcaemia. Primary HPT is caused by a solitary adenoma in about 80% of cases; a double adenoma can occur in up to 12% of cases and hyperplasia in about 20% of cases. Carcinoma occurs in <1% of cases [1].

Operative approaches to treat Primary HPT include non directed bilateral neck exploration (traditionally regarded as gold standard with high success rates in expert hands), unilateral neck exploration and focused parathyroidectomy/minimally invasive radioguided parathyroid (MIRP) surgery (increasingly adopted by most centres and placing greater emphasis on pre-operative localisation) [1].

## The Role Of The Sestamibi Scan

The diagnosis of primary HPT is purely biochemical. The use of a Sestamibi scan is NOT to make or confirm this diagnosis. The role of this scan is merely to assist the surgeon in localizing the offending gland, allowing a more directed operative approach to the parathyroid gland.

How accurate is the Sestamibi scan in patients with primary HPT? False positive results are mainly due to underlying thyroid disease. False negative rates range between 12-25% and this accuracy of localisation for primary HPT depends on the primary pathology. The localisation rates for a single adenoma is the highest but varies [88-99% localisation] (for reasons discussed below). However hyperplasia will be missed in most cases [45% localisation] and double adenoma will rarely be localised [30% localisation]. Thus, although very specific, the overall sensitivity is reported to range between 80-100% [2].

## Reasons For Variable Sensitivities

The exact reason for uptake of the radiotracer in pathological parathyroids remains debatable; however, higher mitochondrial activity remains the major factor. Reasons for decreased rates of uptake may be due to biochemical, biological and technical factors (table 1). Biochemical factors include a low serum calcium, low serum PTH,

normal vitamin B levels and the use of calcium channel blockers. Biological factors include a small size gland, an adenoma with low oxyphil cell content compared to clear cell (as the oxyphil cell contains more mitochondria), P-glycoprotein membrane positivity and multiple gland disease.

Technical factors that improve rates of uptake include the use of dual isotope tracer subtraction imaging (to subtract the thyroid and exclude thyroid pathology), single-isotope dual-phase imaging (for thyroid uptake to washout).

Parathyroid imaging sensitivity is increased from 87% in 2 dimensional planar imaging to 95% in single photon emission computed tomography (SPECT) 3 dimensional imaging. The combination of SPECT with CT offers a potential advantage of better anatomical defining localisation of the scintigraphic findings. The $4^{th}$ dimension in 4D-CT refers to the administration of IV contrast giving excellent anatomy of the gland and surrounding structures [3] (table 2).

**Table 1**: Biochemical and biological factors affecting the likelihood of positive TS [3]

| FACTOR | HIGHER LIKELIHOOD OF +VE SESTAMIBI SCAN |
|---|---|
| Calcium level (mg/dl) | Greater than 11.3 |
| PTH level (pg/ml) | Greater than 160 |
| 25 Hydroxy Vitamin D (ng/dl) | Lesser than 25 |
| Use of Calcium Channel Blocker | Non-use |
| Mean weight of Adenoma (mg) | 1434 + 403 |
| Oxyphil cell content | Greater than 20% |

**Table 2**: Sensitivity for different pre-operative localisation studies [4]

| IMAGING MODALITY | SENSITIVITY (PERCENT) |
|---|---|
| Sestamibi | 71-79 |
| Sestamibi-SPECT | 70-81 |
| Ultrasound | 64-91 |
| 4D-CT | 83-95 |
| MRI | 40-85 |
| MET-PET-CT scan | 79-90 |

*SPECT: sestamibi-single photon emission computed tomography; CT: computed tomography; MRI: magnetic resonance imaging; N/A: not applicable; MET-PET-CT scan: 11C-methionine positron emission tomography and computed tomography*

## Conclusion

With a better understanding in physiology, improvements in imaging modalities and imaging techniques, and increase in sensitivity of Sestamibi scan in combination with

CT scan, the pre-operative use of Sestamibi scanning for localisation in primary HPT has to be encouraged.

The use of Sestamibi scan for MIRP surgery (together with intra operative PTH assays), has shown to decrease the rates of proceeding to bilateral neck exploration resulting in less complications (lower incidence of post-operative hypocalcaemia and nerve injuries) lower operative times, shorter hospital stays resulting in decreased costs. Its use in routine bilateral neck exploration also plays a role in identifying ectopic glands and thus facilitates operative accuracy [5, 6,7].

Patients with non localizing imaging or imaging showing more than one focus of activity can be planned for bilateral neck exploration upfront, preparing both surgeon and patient alike (*praemonitus, praemunitus*).

For recurrent and persistent disease or concomitant thyroid disease pre-operative localisation with a Sestamibi scan is invaluable as it increases success rates from 60% to 95% [8]. However, the use of Sestimibi scan for MIRP surgery without intra operative PTH assay is strongly discouraged as it increases the incidence of persistent and recurrent disease resulting in high rates of neck re-exploration and the complications that accompany it. The skewed notion that Sestimibi scanning will improve outcome in the hands of inexperienced surgeons should also be discouraged [9]!

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# **Argument for Radioisotope v/s Dye usage for sentinel node biopsy** in resource constraint environment

Prof Benn (Dye)

## Introduction

Involvement of the axillary lymph nodes is one of the most important prognostic factors in the treatment of breast cancer. While ALND remains the standard treatment for women, who have clinically palpable axillary nodes or positive nodes confirmed by ultrasound-guided fine needle aspiration or core biopsy, formal axillary dissection in the setting of the clinically or radiologically node negative axilla has slowly been replaced by sentinel lymph node biopsy (SLNB)(NSABP32).

## Background

The sentinel lymph node (SLN) is defined as the first regional lymph node that receives lymph flow from the primary tumour. It is the security guard (Sentinel) and the first (again Sentinel) that acts as the gatekeeper at the end of the driveway created by the body from the tumour. The sentinel lymph node (SLN) technique is based upon the observation that tumour cells migrate from a primary tumour to one or a few lymph nodes (LNs) before involving the remaining regional LNs. In the scenario of clinically node-negative breast cancer, a negative SLNB indicates that the involvement of the rest of the draining lymph nodes is unlikely, thereby reducing the need for more extensive axillary surgery

As the surgical treatment of breast cancer becomes less invasive; fewer indications for complete axillary node dissection (Z11; AMAROS) remain, with sentinel node biopsy remaining the reference-standard technique to supply clinicians with the vital information on which treatment decisions are based, achieving less morbidity than with ALND. Currently, even with improvements in molecular profiling affecting oncology decisions in breast cancer care management, the need for accurate axillary staging remains one of the most important diagnostic, prognostic, and local control procedure in the treatment of breast cancer. Understanding the mechanisms for finding the correct sentinel accurately and cost effective, with decreased the risk to patients is essential.

## Current Techniques

The conventional methods of SLNB identification are vital blue dye and/or a nuclear tracer such as technetium 99m (Tc-99m) sulfur colloid either together or alone. Both methods have limitations. Vital blue dye alone is logistically more accessible to use. It is

injected in the operating room while the patient is anaesthetised, and it is under the complete control of the surgeon. SLN identification rates are lower with blue dye alone, and it is associated with rare but serious allergic reactions or skin necrosis.
Many surgeons utilise with good success nuclear tracers alone. The Logistics associated with, its uses are more complicated. Many hospitals have licensing issues preventing injection in the operating room, requiring patients to go to the nuclear medicine department before the procedure for both the injection and imaging mapping, a time-consuming process and expensive process.

The added exposure of both patients and surgeons to radiation further complicates the usage choice. Access in rural and smaller communities to the nuclear tracer, as evidenced by an analysis of the Surveillance, Epidemiology, and End Results data (SEER)results in fewer SLNB procedures being performed in rural n areas. Reasons cited are a shortage of experienced surgeons, lack of training, and lack of technical support. Smaller community hospitals (similar to what we have in SA) may not have access to probes needed to perform sentinel lymph node biopsy, compounded further by lack of nuclear medicine facilities;  radiolabeled tracer as well as trained surgeons.
Sienna+ ®, a superparamagnetic iron oxide compound that can be detected using the Sentimag magnetometer and acts as both a tracer and a coloured dye, is an alternative mapping agent to identify sentinel lymph nodes. A meta-analysis published in the May 2016 edition of the Annals of Surgical Oncology analysed data from five European trials utilising this magnetic tracer, to determine whether the magnetic tracer is equivalent to standard methods of sentinel lymph node identification. The investigators concluded that Sienna was not inferior to conventional treatment methods. The detection rate difference per node between Sienna and the standard tracer technique was estimated to be 5.5 % (95 % CI 2.0–8.9), favouring Sienna with the detection rate difference per patient (  Sienna versus standard tracer) techniques was estimated to be 0.2 % (95 % CI 3.7 to 4.2).  Less concordance was seen the in negative nodes, with the Sienna method identifying more nodes overall. Most importantly,  high concordance in patients with positive nodes was observed.

The magnetic tracer has similar advantages as the blue dye technique; in that, the tracer is injected into the patient in the OR as soon as the patient is anaesthetised; both techniques under the surgeon's control; with resultant fewer logistical issues, and more convenience for both surgeon and patient. Lastly, with no radioactivity involved, and the associated risks thereof. All methods, have limitations. Those of the magnetic tracer include the fact that no metal instruments can be used as they will cause false-positive results. Disposable plastic instruments are supplied but present challenges in obese patients with a deep axilla. Some patients may experience brownish skin discolouration at the injection site. This tends to be much less noticeable than the blue discolouration that usually results from injection of isosulfan blue. Finally, the Sienna+ ® tracer was developed initially as an MRI contrast agent and may remain in the breast tissue after injection, potentially interfering with postoperative MRI.

Overall, several studies demonstrated that the use of Sienna is noninferior to Tc-99m radiotracer. They also reported that Sienna is safe, with no reported significant adverse reactions. This is an exciting new technology that may be an essential alternative to Tc-99m radioactive tracer in identifying sentinel nodes for axillary staging, and logistically, it may create more access to patients and surgeons in rural or underserved regions.

**Isotope**

A)Expensive

B) Requires access to nuclear medicine

c) Accurate

The use of radioisotope exposes patients and healthcare workers to radiation, is heavily controlled by legislation (both on the specific training for operators and on the subsequent disposal of medical waste), and provides poor preoperative spatial resolution on lymphoscintigraphy. As a result of the latter, some centres have stopped undertaking routine preoperative lymphoscintigraphy

**Dye**

Inexpensive

Can be done in theatre by the surgeon

Less accurate

Intraoperative blue dye injection can obscure the surgical field and frequently leaves a skin residue (tattoo stain), which can take months to fade and is occasionally permanent. There is also up to a 0.4 % risk of anaphylaxis, as a result of which some centres in the United Kingdom have stopped using blue dye.

**Sienna**

Fairly expensive

Can be done in surgery

Requires costly theatre equipment

**Combination**

The gold standard for SLNB is the combined technique, using both blue dye and radioisotope injection. The AMAROS trial ( 1,953 patients,) had an identification rate using the combined method of 97 %. This data is further confirmed by the ALMANAC trial data showing an identification rate of 96.0 %, with the use of the combined technique as opposed to 85.6 % when radioisotope or blue dye was used alone,

Comparatively the identification rate using blue dye alone varies from 65% to 94%, whilst using a dual method reaches 97% (Giuliano et al. 1994; Derossis et al. 2001).

2 out of 3; allows for better accuracy

My best-suggested options are dye and Sienna

**Costs**

Price of the SentiMag® device and the reusable probe is USD$39,975. The Sienna+® tracer costs $650 per vial.
The commonly utilised radioisotope is 99mTC antimony sulphur colloid, with a cost of about $100 per dose (data from Royal Brisbane and Women's Hospital Department of Nuclear Medicine, 12 May 2016).
Two dyes are available Patent Blue V (2.5%, 2ml) costing approximately $105 per dose, and Methylene Blue (1%, 5ml) costing roughly $35 per dose (personal communication, Royal Brisbane and Women's Hospital Central Pharmacy, 12 May 2016).
A 2012 study with a preoperative injection of 99mTc and lymphoscintigraphy incurred costs of USD$1,267 per patient.
This excludes additional costs of radioisotope handling, waste disposal, regulations, training, and licensing of operating theatre staff.

## Conclusion

The era of the historic axillary dissection is over. With Sentinel lymph node biopsy and if needed a minimal nodal sampling (7 lymph nodes equates to a dissection) being all that is required in the ultrasound node negative axilla; both in the early stage (primary surgery) and the post-primary chemotherapy ultrasound node negative axilla it is essential that the techniques we use to identify this important lymph node be safe and accurate.
For this reason, dye alone is not an option; due to the lack of facilities having access to radio-active isotope and radiation centres, other options need to be sought. It is my opinion that using 2 out of 3 of the substances allows for safe and accurate SLNB localisation. So I propose Sienna and blue dye at this stage as well as more research into safe; accurate and inexpensive new options for the future.

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# **Breast reduction and mammoplasty:** indications, successes and cost implication.

Dr Selahle

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**Breast reduction and mammoplasty: Indications, successes and cost implications.**

Breast reduction surgery is one of the commonly performed surgical procedures in South Africa after breast augmentation with a ratio of about 1:1.8 (breast augmentation : breast reduction).

This surgical procedure has evolved over many centuries, across different continents and the earliest reported case of breast reduction was performed for a patient with gynaecomastia by the Greek physician Paulus Aeginia in 70 AD.

The evolution of this surgical procedure over the years has brought about the following significant advances for modern day breast reduction surgery:

- Mechanical / Volumetric reduction in breast size
- Preservation of breast function through translocation of anatomically and physiologically intact nipple areolar complex (NAC)
- Achievement of aesthetically pleasing reduced breasts – by use of more accurate pre-operative geometric designs

The clinical indications of breast reduction ranges from the corrections of functional impairments on one side of the spectrum and to the achievement of cosmetically pleasing breasts on the other side of the spectrum.

The success of a breast reduction surgery is dependent on:

- Better patient selection
- Optimal peri-operative management of the breast reduction patient

The benefits of breast reduction surgery far outweigh its costs, and therefore the plastic surgery fraternity believes that breast reduction is not a cosmetic procedure but rather an essential functional operation.

# **Should small neuroendocrine tumours be treated** or observed?

Prof Ramos

Neuroendocrine tumours (NETs) arise from neuroendocrine cells which are located throughout the body. These cells typically produce hormones such as insulin, glucagon, gastrin and others. Tumours arising from these cells may thus lead to elevated levels of these hormones with consequent symptoms. Gastroenteropancreatic (GEPNETs) account for about two thirds of all NETs with the rest arising in the lung and other sites. The small bowel and pancreas are the commonest sites of NETs. The incidence of GEP-NETs appears to be increasing and they are the second most prevalent GIT tumour after colon cancer. There is certainly an increased diagnosis of NETs due to modern imaging however the true incidence is probably rising. Previously most NETs were diagnosed due to symptoms arising from increased production of hormones. This led to the belief that most NETs were functional. With most NETs now being diagnosed incidentally, it is apparent that most of these tumours are actually non-functional, the latter accounting for 60 to 90% of all NETs.

NETs are typically sporadic but arise in familial syndromes where more than one NET is found – these include Multiple Endocrine Neoplasms (MEN) of which there are two main types, MEN-1 and MEN-2 [3]. These are autosomal dominant inherited syndromes.

Most NETs are now diagnosed incidentally on endoscopy or imaging. Most of them are small and asymptomatic. Typically, the diagnosis of a NET has led to invasive treatment, either endoscopic or surgical resection. With better understanding of the natural history of these tumours, it is apparent that many of them have a benign behaviour with limited progression and no apparent effect on long-term survival and outcome. This is led to many questioning the need for active treatment of small asymptomatic NETs.

### Natural history of NETs

The biological behaviour and outcome of NETs is largely related to grade of tumour, stage and organ of origin. NETs generally have a better survival than other malignancies of the same organ (Fig. 1) although these are malignant tumours and carry a potentially significant mortality. The natural history of NETs is also affected by the organ of origin, with better survival being associated with those of the rectum, small intestine and stomach whereas those arising in the colon and pancreas have a worse prognosis.

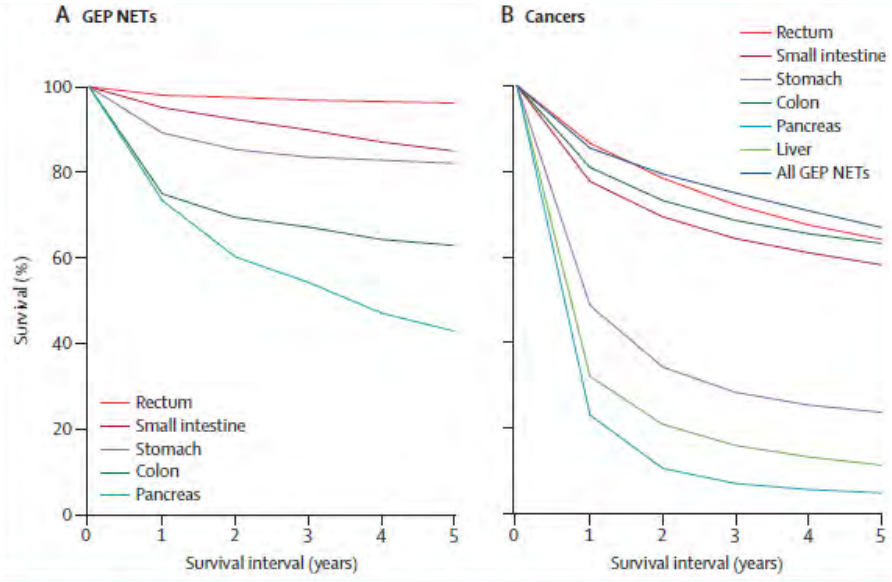


Fig 1. 5-year survival of GEPNETs and GEP cancers

## Grading of NETs

The natural history of NETs is strongly correlated with grading [6]. Grading classification has been defined and upgraded by the World Health Organisation (WHO), the last update for pancreatic NETs being in 2017 (Fig 2).

| WHO 1980 | WHO 2000/2004 | WHO 2010 | WHO 2017 |
|---|---|---|---|
| Islet cell tumour (adenoma/ carcinoma) | Well-differentiated endocrine tumour/carcinoma (WDET; WDEC) | Neuroendocrine tumour NET G1/G2 | Neuroendocrine tumour **NET G1/G2/G3** (Well differentiated neuroendocrine neoplasm) |
| Poorly differentiated endocrine carcinoma | Poorly differentiated endocrine carcinoma/small cell carcinoma (PDEC) | Neuroendocrine carcinoma NEC G3 large or small cell type | Neuroendocrine carcinoma **NEC G3** (Poorly differentiated neuroendocrine neoplasm), large or small cell type |
| | Mixed exocrine-endocrine carcinoma MEEC | Mixed adeno-neuroendocrine carcinoma MANEC | Mixed neuroendocrine-nonneuroendocrine neoplasm **MiNEN** |
| Pseudotumour lesions | Tumour-like lesions (TLL) | Hyperplastic and preneoplastic lesions | |

Fig 2 Comparison of the WHO classification of PNETs 2017

Grading is determined by the Ki-67 and mitotic index as shown in Fig 3.

| WHO Classification 2010 | | | WHO Classification 2017 | | |
|---|---|---|---|---|---|
| **Well Differentiated NET's** | **Ki67 index** | **Mitotic index** | **Well differentiated NET's** | **Ki67 index** | **Mitotic index** |
| NET G1 | <=2% | <2 /10 HPF | NET G1 | <3% | <2 /10 HPF |
| NET G2 | 3-20% | 2-20/10 HPF | NET G2 | 3-20% | 2-20/10 HPF |
| | | | NET G3 | >20% | >20/10 HPF |
| **poorly differentiated NEC's** | | | **poorly differentiated NEC's** | | |
| NEC | >20% | >2 /10 HPF | NEC | >20% | >2 /10 HPF |

Fig 3. Grading criteria for pancreatic NETs WHO 2017

## Survival in patients with NETs

This is determined by both grading and staging as shown in Fig 4. Patients with well differentiated tumours and early stage have a 75-85% 20-year survival. The size of the NET is not typically part of prognostic criteria attributed to these tumours however has an impact on the T staging of the tumour. As tumour size increases so does the T stage thus affecting the overall stage of the tumour.

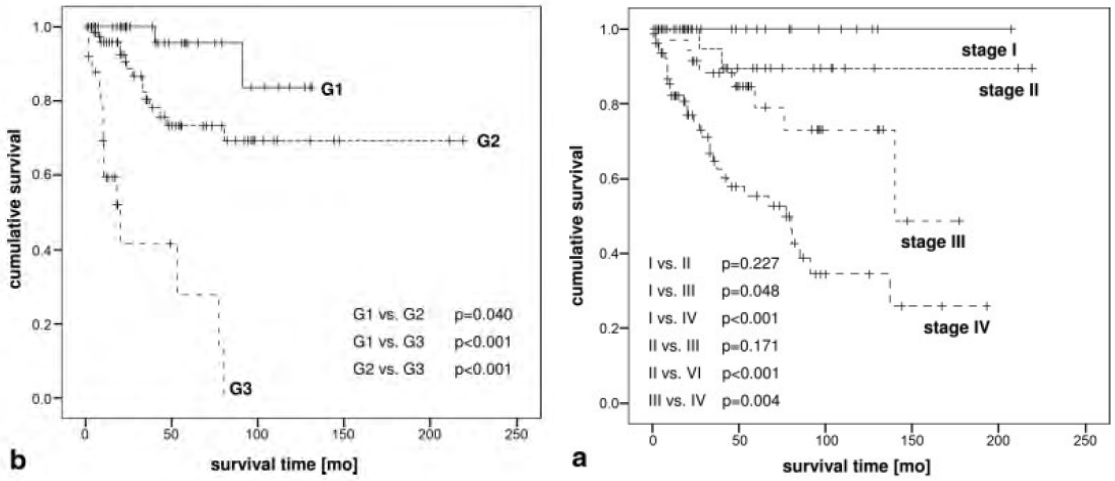


Fig 4. Cumulative survival of NET patients by grade and stage [4]

## Management principles

Complete surgical resection of NETs provides the patient with the best chance of cure or long-term survival. This is particularly true for NETs which are localised and have not metastasised, or which are locally advanced but remain amenable to complete resection. Surgical resection is also recommended for NETs which have metastasised and when complete resection of the primary as well as the metastases is possible.

## Can NETs be treated conservatively?

Data has emerged that many NETs do not show any progression or increase in size over the expected lifespan of the patient. This has led to the question as to whether it is necessary to treat all of these tumours. The following factors need to be taken into consideration when determining whether a particular NET should or should not be treated.

- Symptoms and or complications attributed to the tumour
- Patient fitness for surgery
- Functional status of the tumour
- Size of tumour
- Grade of tumour
- Stage of tumour
- Site of tumour

### Symptomatic and/or complicated tumours

These should be treated.

### Functional status

Functional tumours should be treated. Non-functional tumours can be considered for conservative therapy provided the other criteria are met.

### Size of tumours

Conservative treatment is only appropriate for smaller tumours which have not shown any progressive increase in size. There is no defined cut-off value of size, however tumours larger than 1-2 cm would generally be treated by surgical resection if appropriate. This does depend on the organ of origin of the tumour. In general, conservative treatment would only be appropriate for tumours less than 2 cm or, ideally, less than 1 cm.

### Grade of tumour

Conservative treatment is only applicable to low-grade tumours which would thus be limited to G1 or low G2 tumours, the latter being limited to those tumours with a Ki-67 of 5 or less. This figure however is not definitive and each case would need to be assessed individually. There would need to be an accurate assessment of grading thus FNA may not be appropriate and a core needle biopsy may be required in order to determine whether grading is being accurately assessed.

### Stage of tumour

Staging varies according to the organ of origin of the NET. In general however a small tumour would be classified as a Stage I, these typically being less than 1-2 cm in size. A higher stage would imply a larger or locally advanced or complicated tumour, these

characteristics precluding the option of conservative treatment provided that there are no contraindications to interventional therapy.

Staging however needs to be accurately performed. This may involve endoscopic assessment together with cross-sectional and NET-specific imaging (see below).

**Site of tumour**

Conservative treatment tends to be limited to tumours of the stomach, duodenum, pancreas, and possibly the rectum. Small intestine (SI) tumours are typically diagnosed when symptomatic or complicated. Occult lesions can be detected early with aggressive screening among patients with a family history of neuroendocrine tumours. Most patients with SI NETs have multifocal disease and one third present with stage III disease. Almost half of patients with SI NETs less than 10 mm in size have lymph node metastases. In view of these findings, all SI nets should be considered as aggressive disease and should be managed operatively with adequate surgical resection and lymphadenectomy.

**Diagnosis and imaging of NETs**

These tumours may be identified at the time of upper or lower GIT endoscopy, or at the time of imaging with ultrasound, CT or MRI. Blood investigations typically performed for these tumours include chromogranin A (CgA), gastrin, glucose and insulin, calcium and PTH. Urinary 5-HIAA should be measured in suspected small bowel NETs and carcinoid syndrome.

Apart from the cross-sectional imaging mentioned above, specific investigations in these patients may include endoscopic ultrasound (EUS) for upper GI, rectal and pancreatic NETs and imaging directed at identifying somatostatin positive tumours. These would include Octreoscan and Tektrotyd, as well as the Gallium – 67 PET/CT using dotatate, dotatoc etc. Low-grade tumours are more likely to exhibit somatostatin positivity whereas the higher grade tumours may be negative with this scan. FDG-PET is a useful staging investigation in these patients to exclude higher-grade tumours, as if this scan is positive, it implies a Ki – 67 of higher than 10%. Patients with FDG-PET positive tumours would not be considered for conservative therapy.

## Organ-specific management of NETs as per ENETS Guidelines

### Stomach

| | Type 1 | Type 2 | Type 3 |
|---|---|---|---|
| Proportion among g-NENs, % | 70–80 | 5–6 | 14–25 |
| Tumor characteristics | Often small (<1–2 cm), multiple in 65% of cases, polypoid in 78% of cases | Often small (<1–2 cm) and multiple, polypoid | Unique, often large (>2 cm) polypoid and ulcerated |
| Associated conditions | Atrophic body gastritis | Gastrinoma/MEN-1 | None |
| Pathology | G1–G2 NET | G1–G2 NET | G3 NEC |
| Serum gastrin levels | ↑ | ↑ | Normal |
| Gastric pH | ↑↑ | ↓↓ | Normal |
| Metastases, % | 2–5 | 10–30 | 50–100 |
| Tumor-related deaths, % | 0 | <10 | 25–30 |

Fig 5. Classification of gastric NETs

Only Type 1 gastric NETs (g-NETs) should be considered for conservative management if smaller than 1cm. Type 2 g-NETs can be resected endoscopically provided that metastases are not present. Type 3 g-NETs should be resected surgically.

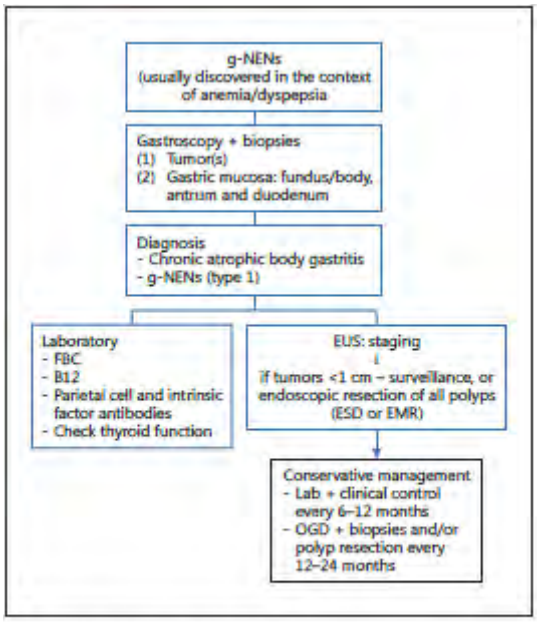


**Fig. 1.** Algorithm for type 1 g-NEN management. EUS = Endoscopic ultrasonography; FBC = full blood count; OGD = oesophageal gastroduodenal endoscopy.

Fig 6. Management algorithm for Type 1 g-NETs

## Duodenal NETs

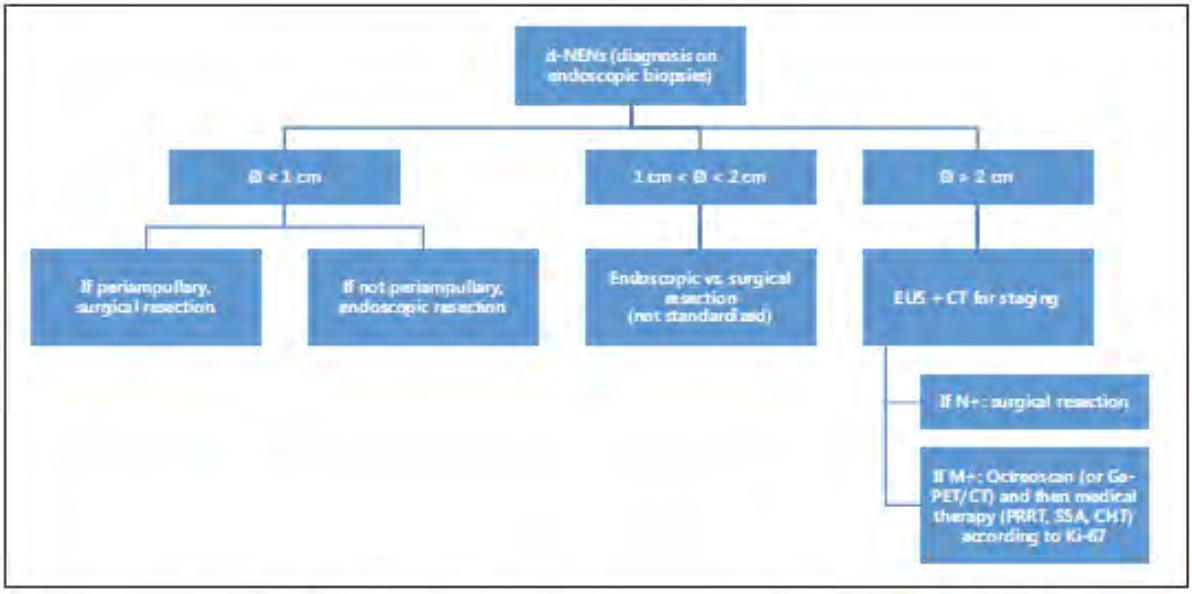


**Fig. 2.** Algorithm for d-NENs. EUS = Endoscopic ultrasonography; N+ = positive lymph nodes; M+ = positive for metastasis; CHT = chemotherapy.

Fig. 7 Management algorithm for duodenal NETs

## Small bowel NETs

| Disease | Localized | Regional | Distant | | |
|---|---|---|---|---|---|
| **Stage** | **I/II** | **III** | **IV** | | |
| TNM | T1–3N0M0 | T4N0M0<br>T1–4N1M0 | | TxNxM1 | |
| Surgical treatment | **Radical resection** | | **Radical resection with curative intent** | **Palliative resection** | **No resection** |
| | Local radical open (or in selected pts) laparoscopic resection* of<br>• primary tumor(s)**<br>• lymph nodes (dissection along the superior mesenteric root) | | Local radical open resection of<br>• primary tumor(s)<br>• lymph nodes (dissection along the superior mesenteric root)<br><br>In combination with:<br>• mets (liver) | Local radical open (in selected pts) laparoscopic resection of<br>• primary tumor(s)<br>• lymph nodes (dissection along the superior mesenteric root) | Due to:<br>• local inoperability<br>• comorbidity |
| Aim | Free from tumor | | Free from tumor | • To avoid local complications (obstruction, bleeding etc.)<br>• To possibly improve prognosis* | |

**Fig. 2.** Therapeutic algorithm for Si-NENs. Pts = Patients; mets = metastasis. *For details, see the text. **Caution: multiple primaries.

Fig 8. Management algorithm for small bowel NETs

## Appendiceal NETs

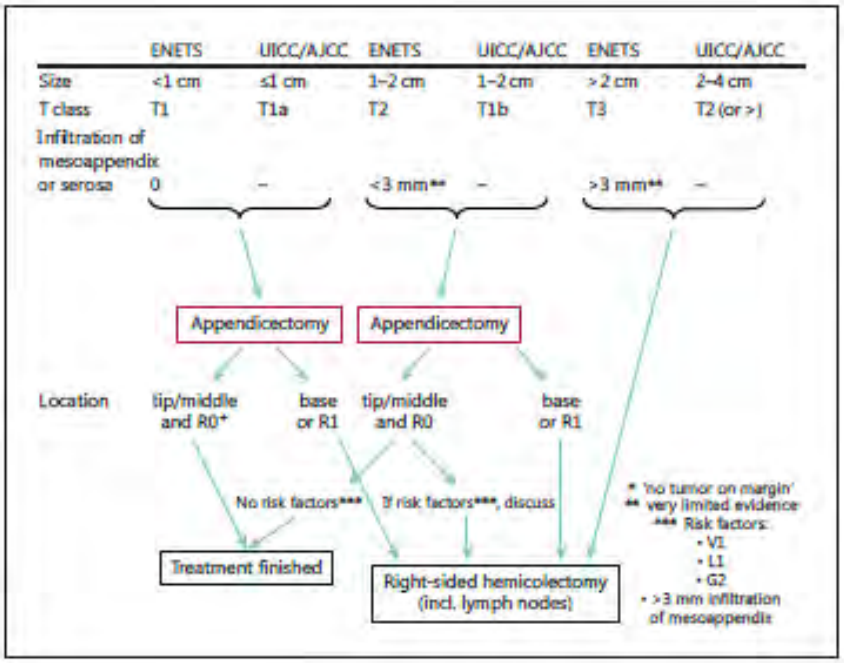


**Fig. 1.** Therapeutic algorithm for small appendiceal NET. V1 = Vascular invasion; L1 = lymphatic invasion; G2 = grade 2 tumor (Ki-67: 3–20%).

Fig 9. Management algorithm for appendiceal NETs

## Rectal NETs

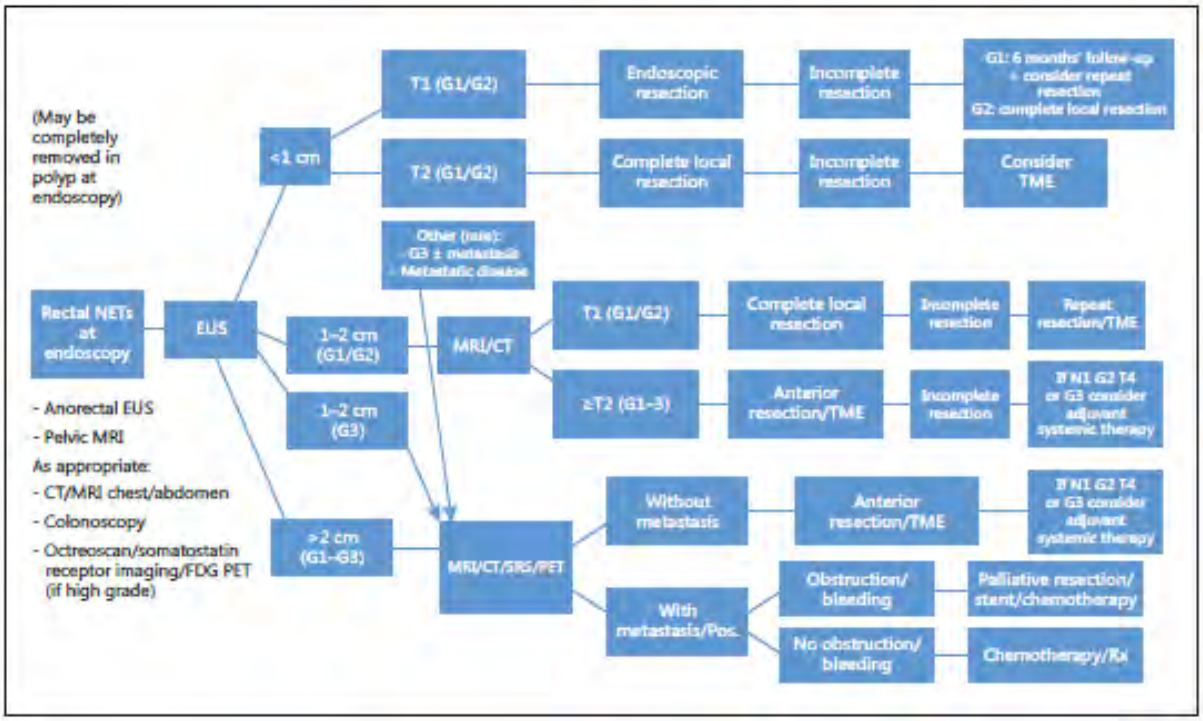


Fig 10. Management algorithm for rectal NETs

## Pancreatic NETs

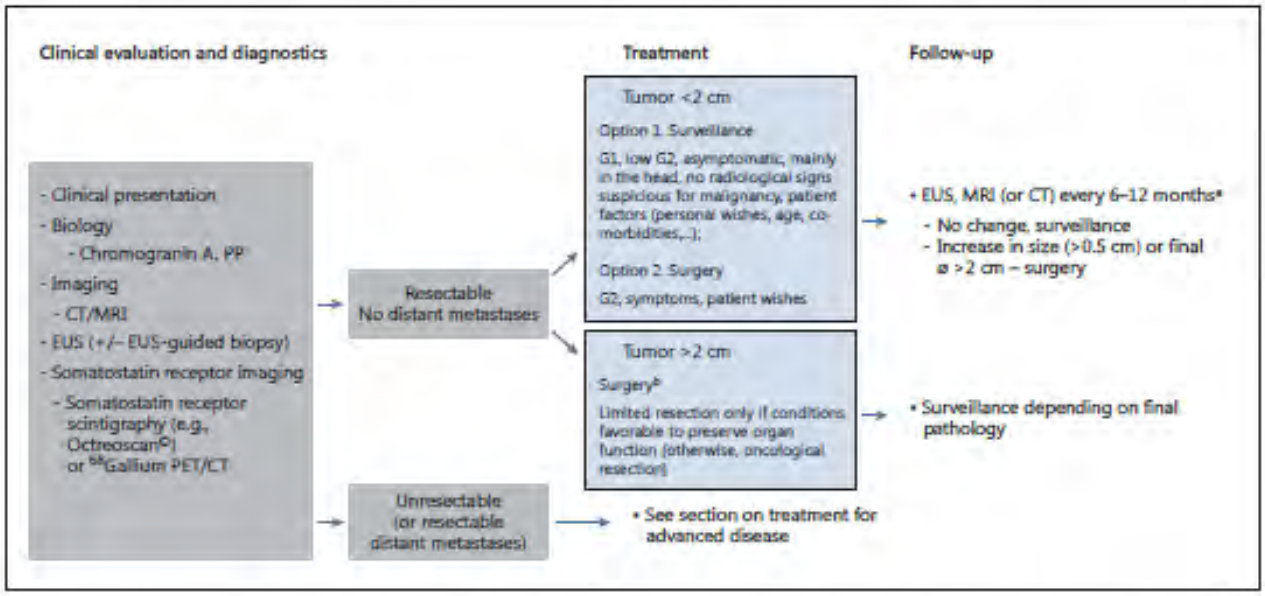


**Fig. 3.** Algorithm for treating NF-P-NETs. [a] If low Ki-67 value and stability after the initial 6 monthly evaluations. [b] Specific additional tests may be required to accurately stage the tumor (e.g. intraoperative US, intraoperative frozen section).

Fig 11. Management algorithm for pancreatic NETs

## Multiple Endocrine Neoplasia (MEN) Type 1 and 2

Patients with these syndromes have multiple tumours in different organs. The decision to resect these tumours is thus largely based on whether they are functional, symptomatic or complicated. Non-functional tumours, particularly those in the pancreas, should probably be treated conservatively as the natural history of this disease is for recurrence and or the appearance of new tumours. Pancreatic nets in MEN 1 patients are typically multifocal thus conservative therapy is recommended. Functional NETs however should be resected.

## Follow up of patients selected for conservative treatment

These patients should be under surveillance for possible disease progression. Type I gastric NETs can be monitored by endoscopy every 1 to 2 years and specific imaging should there be an indication of disease progression. Pancreatic nets which are visible on transabdominal ultrasound can be assessed on an annual basis. Should the lesions not be well seen on ultrasound, abdominal CAT scan, MRI or EUS may be indicated.

### Summary and take-home messages

NETs are being diagnosed more frequently due to a probable increase in incidence as well as increased diagnosis with modern imaging and endoscopic modalities. The majority are non-functional. All functional, symptomatic and/or complicated NETs should be treated by endoscopic or surgical resection as appropriate. There is however a place for nonoperative conservative treatment of small nets provided that these are not functional or symptomatic. This typically only applies however to small Type I gastric, duodenal, pancreatic and possibly rectal NETs. All small-bowel NETs should be resected.

When conservative surgery is selected, patients need to be carefully monitored with endoscopy and/or imaging as appropriate in order to exclude disease progression.

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# **Management of colorectal liver metastases.** How far should we go?

Eduard Jonas

Surgical Gastroenterology Unit, University of Cape Town and Groote Schuur Hospital

## Introduction

Globally the incidence of colorectal cancer (CRC) is increasing and it is currently the third leading cause of cancer death in the world (1). A significant percentage of patients will present with metastatic disease during the course of the disease, diagnosed at the time of diagnosis of the primary tumour (synchronous detection) or at a later stage (metachronous detection). Liver metastases are the most common with population-based studies showing that around 25% of patients diagnosed with CRC will turn out to have liver metastases during the course of the disease (2, 3). Around 25% of patients will present with extrahepatic metastases, with lung metastases being the most frequent, followed by peritoneal metastases and distant lymph node metastases (4). Ovarian, adrenal, bone and brain metastases are rare and usually occur in the presence of liver, lung or peritoneal metastases.

## Indications for curative intended intervention of colorectal cancer liver metastases

A subset of patients with metastatic CRC has limited disease, as opposed to pancreas, gastric and oesophageal cancer where any metastatic disease is usually an indication of extensive systemic disease. In this subgroup of patients cure and long-term survival is possible if intervention can render the patient tumour-free. This is the rationale behind offering patients with CRC liver metastases (CRCLM) curative-intended intervention.

Historically, only tumour characteristics such as number, size and distribution of metastases were regarded to assess resectability of patients with CRCLM. Evidence was weak, based on small retrospective case series from low-volume centres in the 1970s and 1980s. A one centimetre tumour-free margin was regarded as essential and extrahepatic metastases were regarded as an absolute contraindication to liver resection. As larger outcome study results became available, the components of these criteria were challenged, resulting in less restrictive criteria (5). The criteria focus on the future liver remnant (FLR) with resectability being defined as the ability to perform a

complete ($R_0$) resection (≥1 mm tumour-free margin) while preserving a FLR sufficient for maintenance of post-operative function and regeneration (>20-25% of the total parenchymal volume in a healthy liver). The FLR had to have intact arterial and portal supply and biliary and venous drainage. Tumour factors such as distribution and number of CRLM, the presence of extrahepatic disease and progress on chemotherapy are at most regarded as relative contraindications and should be assessed individually in patients. Although overall survival of patients with CRCLM operated on according to current criteria is significantly better than patients treated with oncologic treatment only, purely resectability-based criteria are a poor predictor of tumour-free survival with hepatic recurrence occurring in 50-60% of patients.

## Pushing the boundaries for curative intervention

From a surgical perspective, patients with CRCLM can be divided into three therapeutic groups, namely readily resectable, unresectable but with the potential to convert to resectable, or initially unresectable and unlikely to ever become resectable. In patients initially not resectable, conversion strategies are designed to address the specific cause of unresectability, namely creating a tumour-free FLR in cases where resection is precluded by the extent of segmental engagement and liver volume manipulation in the event of insufficient FLR volume. Advances in interventions have been aimed at offering more patients the possibility of cure.

Tumour-directed therapies (staged resections, local ablation and chemotherapy) are used in isolation or in combination with volume manipulation of the FLR (portal vein ligation (PVL), portal vein embolization (PVE) and associating liver partition and portal vein ligation for staged hepatectomy (ALPPS)). Liver transplantation for CRCLM has in recent years been revived as an alternative where no combination of the current techniques can achieve a tumour-free state.

## Extrahepatic metastases

In parallel to advances in CRCLM treatment there have been encouraging developments in the treatment of extrahepatic metastases, in particular for lung and peritoneal metastases. Although there are no generally accepted guidelines for treatment of pulmonary CRC metastases an increase in the number of patients offered treatment directed at lung metastases has been observed (6). Although there is reasonable consensus that combined cytoreductive surgery and hyperthermic intraperitoneal chemotherapy (CRS/HIPEC) is a curative-intended treatment option and that decisions should be made in a multidisciplinary team (MDT) setting, it is based on very low levels of evidence (7). Results of treatment, however, are encouraging (Table 1).

**Table 1** Median and 5-year OS and operative mortality for patients operated for liver, lung and peritoneal metastases

| Metastatic | Median OS | 5-year OS (%) | Operative mortality |
|---|---|---|---|

| location | (months) | | (%) |
|---|---|---|---|
| Liver | 36-74 | 36-58 | 0.9-2.8 |
| Lung | 36.2-70.1 | 38.3-78 | 0-1.3 |
| Peritoneal | 30.1-48 | 15-58 | 1-8 |

OS overall survival

**Diagnostic assessment for CRCLM**

Optimal management of CRCLM starts with good imaging using high-resolution modalities with high sensitivity and specificity for detection and characterization. MRI with hepatocyte-specific contrast (Gd-EOB-DTPA, Primovist®) has been shown to be the superior imaging modality (8). It must be emphasized that metastases, regardless of the time point of detection, are probably present at the time of diagnosis of the primary tumour and therefor potentially detectable. Early detection and accurate staging of metastases is a prerequisite for optimal treatment planning. For example, in the case of liver metastases definitive management of limited hepatic disease, and in planned staged procedures, the first operation can be combined with the primary tumour operation.

**How far should we go?**

Much of the advances in curative treatment for CRCLM in the last two decades were technique-based, having pushed the boundaries in terms of what is technically feasible. Although still in clinical use, treatment algorithms based on technical resectability alone are outdated. Recent advances in the understanding of metastatic patterns in CRC have identified a number of other clinical and molecular factors that influence the aggressiveness of metastatic disease and may need to be considered in decision-making (9). Differential metastatic patterns for CRC depending on the location of the primary tumour, classified as right- versus left-sided tumours or from midgut versus hindgut origin have been reported (4). Liver and lung metastases are more frequent in left-sided (hindgut origin) cancers, whereas peritoneal metastases more often occur in right-sided (midgut origin) tumours. There is also a differential response of tumours to chemotherapy with mutations from left-sided RAS wild type tumours having better outcomes, as measured by OS, progress-free survival (PFS) and response rate, compared to metastases from RAS wild type right-sided tumours (10). Although left-sided colon and rectal cancer have a higher incidence of liver metastases, liver metastatic right-sided colon cancer has a higher number of metastases, as well as more extensive segmental involvement, resulting in a worse survival (4).

These factors will need to be incorporated in treatment algorithms. The concept of oligometastatic disease (OMD) that appreciates the fact that different organ metastases

influence survival differently is a step in the right direction (11). Although the exact definition of OMD in CRC is still imprecise, it is an important development, classifying metastases on an organ-level into those with a more favourable (liver, lung, peritoneum, nodes and ovaries) and those with a less favourable (bones and brain) prognosis. According to the ESMO guidelines OMD may be characterised as tumour disease at up to 2 or occasionally 3 sites and 5 or sometimes more lesions, predominantly visceral and occasionally lymphonodal. In patients with synchronously detected metastatic disease the primary tumour counts as one tumour site and metastatic site includes the more favourable prognosis sites (liver, lung, peritoneum, nodes and ovary). Patients with multiple bone and brain metastases are, with some exceptions, excluded from a classification of OMD.

Although there will certainly be further advances in curative intended techniques, the next important phase in curative intended treatment of CRCLM will be the creation of treatment algorithms where technical resectability and clinical and oncological parameters will be integrated in individual patient-specific multiple modality treatment regimes (12). To optimize assessment and therapeutic decision-making, treatment decisions are ideally made in multidisciplinary treatment (MDT) conferences settings or tumour boards with input from liver and colorectal surgeons, radiologists, pathologists and oncologists.

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# **Open pancreaticoduodenectomy** is associated with high morbidity and significant mortality. Does laparoscopic resection improve outcomes?

Dr Brand

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**Abbreviations**

MIPD *Minimally invasive pancreaticoduodenectomy (laparoscopic)*

OPD *Open pancreaticoduodenectomy*

Although pancreaticoduodenectomy (PD) was initially performed by Kausch in 1909 and popularized by Allen Whipple in 1935, the operation was traditionally regarded with significant skepticism due to high mortality and morbidity rates, ranging from 0.5-12% and 30-68% respectively. The first laparoscopic cholecystectomy was performed 30 years ago, and since then we have rapidly progressed with few operations not being amenable to laparoscopic surgery and the first laparoscopic PD was described in 1994.(1)

Whereas some major laparoscopic hepatopancreaticobiliray procedures have shown clear benefit to the patient such as two/three segment non-anatomical liver resections, and other have shown moderate benefit or equivalence, such as pancreaticoduodenectomies.

Most benefit from less post operative pain, earlier mobilization, shorter hospital stay and improved cosmesis. However initially there were concerns regarding the extent of oncological resection, adequate lymph node staging, and peritoneal seeding as a result of the pneumoperitoneum. The cost of a laparoscopic procedure exceeds open surgery, however, the overall cost with fewer hospital days, earlier return to work and lower incidence of complications that require an operation such as incisional hernias are difficult to cost accurately. Intuitively when one considers all of these factors there may be cost equivalence.

**MIPD vesrsus OPD**

A meta-analysis which focused on all types of laparoscopic pancreatic resections, primarily distal pancreatectomies but included two studies compared MIPD and OPD. Though small numbers the results were overwhelmingly in favour of laparoscopic distal pancreatectomies, but could not determine superiority for MIPD. (2) A more recent

systematic review of MIPD compared to open OPD of 11 retrospective studies published between 2009 and 2013 included 869 patients demonstrated the following outcomes(3):

- MIPD has longer operative time (MD 105 min, 95% CI 49.73 to 160.26 min, p<0.001, $I^2$ =93%)
- MIPD has reduced intraoperative estimated blood loss (MD 2361.93 ml, 95% CI 2519.22 to 2204.63 ml, p<0.001, $I^2$ =94%)
- No statistical difference in mortality (OR 0.82, 95% CI 0.37 to 1.85, p= 0.64, $I^2$ =0%)
- No statistical difference between MIPD and OPD in terms of overall morbidity (OR 0.73, 95% CI 0.53 to 1.00, p= 0.05, $I^2$ =10%
- No significant statistical difference between MIPD and OPD in the incidence of neither overall pancreatic fistula (OR 0.96, 95% CI 0.65 to 1.44, p= 0.86, $I^2$ =0%)
- Length of stay was shorter by 2.64 days for the MIPD group, and the difference was statistically significant (MD 22.64 d, 95% CI 24.23 to 21.05 d, p= 0.001, $I^2$ =78%
- Oncological outcomes were not significantly different between the two groups: number of lymph nodes harvested MD 1.15, 95% CI 22.02 to 4.32, p= 0.48, $I^2$ =83%; R0 resection margins R0 resections, OR 0.57, 95% CI 0.31 to 1.04, p= 0.07, I2 =40%

Laparoscopic PD remains controversial. A worldwide survey which included 435 surgeons from 50 countries to determine opinions regarding minimally invasive pancreas surgery, only 10% responded that they thought MIPD was superior to OPD. (4) A recent study compared matched MIPD to OPD concluded that MIPD is associated with higher morbidity, primarily as a result of more severe pancreatic fistula and thus LR should only be considered only in patients with a low risk of pancreatic fistula. (Dokmak 2015) Conversion from MIPD to OPD remains relatively low at 9%. (Gumbs 2011)

## Alternative PD techniques

*Hybrid technique*

Hybrid technique which involves laparoscopic resection phase and open reconstruction phase have been shown to be similar outcome to OPD.(7)

*Robotic pancreaticoduodenectomy*

A single center study compared 211 robotic performed PD's to 817 OPD their conclusion was that once the learning curve had been achieved morbidity rates were similar between the two procedures. (8)

## Conclusion

MIPD is a technically challenging procedure limited to small pancreatic head tumors. No randomized control trial has been completed comparing MIPD to OPD, and case series have diverse outcomes so that there is no consensus on whether or not MIPD is an appropriate option. Furthermore no cost analysis has been performed to determine whether or not MIPD is economically justifiable. For now the jury is out and most surgeons will continue with OPD's.

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# **PPI v/s Surgery for GORD** in 2018

## Prof Kgomo (PPI)

Gastro- oesophageal reflux is a normal physiological process and is necessary for normal gastrointestinal function; it is when it causes troublesome symptoms and or complications that it becomes a disease.

Any form of successful treatment should take this into consideration and not totally eliminate gastro-oesophageal reflux but make it asymptomatic and avoid complications.

Symptoms of GORD are divided into oesophageal and extra-oesophagel. Oesophageal symptoms are themselves divided into typical and atypical.

The typical symptoms are heartburn and regurgitation, the presence of these symptoms makes the diagnoses of GORD with no need for further investigation except in few cases.

Atypical and extra-oesophageal symptoms are many, non-specific and their presence does not make a diagnosis without further testing.

The purpose of treating GORD is to improve quality of life and prevent complications. Complications of this disease include Barrett's oesophagus, adenocarcinoma, peptic strictures, bleeding and cardiopulmonary problems.

It is divided into erosive (20-30%) (EGR) and non erosive which is the more frequent of the two at 60-70%) (NERD).

**Erosive GORD is** graded according Los Angeles criteria from A to C, Grade B and C may require long term PPI.

**The non-erosive reflux is further divided into**:

- True NERD where acid exposure test (AET) is abnormal with a positive symptom index (SI).
- Hypersensitivity NERD; where AET and SI are positive.
- Functional NERD; both AET and SI are normal.

Medical management if instituted correctly is successful in 70-85% of the cases. These consist of life style modification and the use of proton pump inhibitors. Of the remaining 15-30% not responding to treatment, most are because the diagnosis is incorrect and one may have to exclude Non-Acid reflux, Bile reflux, and eosinophilic

oesophagitis. It may be due to genetic variation where one PPI may need to be changed to another for effect. It may be there is a barrier defect between the stomach and the oesophagus in which case surgery may be indicated. It is this small group of patients that require alternative form of therapy such as psychosocial, neuro-modulation and surgery.

Surgery is specifically indicated only in patients with barrier defects such as hiatus hernia or those with a large reflux burden such as regurgitation.

Proton pump inhibitors as a class have been found to be safe and there are no double blind control studies showing significant side effects in years, they are therefore the preferred mode of treating GORD by far. Life style modification has a beneficial effect whichever way one looks at it.

Extra oesophageal manifestations respond to much higher doses than standard oesophageal symptoms.

# **Laparoscopic v/s open surgery** for perforated peptic ulcer

Dr Nair (Laparascopy)

With the recognition of the pathogenesis of peptic ulcer disease (PUD), the widespread eradication of Helicobacter Pylori, the prophylactic use of proton-pump inhibitors and the rational use of nonsteroidal anti-inflammatory drugs, the worldwide incidence of complicated peptic ulcer disease has decreased in the past few decades. Although, in Sub-Saharan Africa, Rickard et al[1] reports that there has not been a substantial drop in the incidence of perforated peptic ulcers (PPU) with 35% of the surgeries performed for PUD being for perforations. PPU is associated with significant morbidity and mortality rate especially when open repair (OR) is performed. This was confirmed in the local data from Grey's Hospital in Pietermaritzburg[2]. Of the 101 patients managed with PPU, most of whom underwent open repair, during the period of 2010 to 2016, the superficial surgical site infection rate was 8.9% and deep surgical site infection rate was 13.9%. Post-operative pneumonia was found in 17.8% of the patients and mortality rate was 15.8%.

The operative management for PPU involves the control of intraperitoneal contamination and closure of the perforation. The choice of surgical technique, laparoscopy vs. laparotomy, varies depending on the patient's preoperative clinical status, location of the perforation, and surgeon's expertise and preference. Numerous techniques have been described on how to close PPU, however in Grey's hospital, we endeavour to close the perforation with a pedicled omentoplasty as described by Cellan-Jones et al[3], irrespective of whether we are performing the surgery open or laparoscopic.

Mouret et al[4] and Nathanson et al[5] published the first results of successful laparoscopic repair of perforated peptic ulcer (LR) in 1990. However, open surgery remained the primary approach for multiple reasons: surgeon inexperience with laparoscopy and inadequate evidence attesting safety or superiority of laparoscopic repair.

Within the last two decades, we have seen rapid and successful application of laparoscopic surgery for elective procedures such as cholecystectomy, anti-reflux procedures and hernia repairs. Laparoscopic surgery has also been shown to be effective in emergency surgery for appendicitis even with generalized peritoneal contamination. Minimally invasive surgery has displayed significant benefit over open

operation with decreased hospital length of stay, time to return of bowel function, and postoperative pain, among other variables. There has also been an improvement in the laparoscopic skills, techniques and equipment available thus making LR a more feasible option for the surgeon. Knowledge on setting up laparoscopic equipment has also improved with the nursing staff, thus allowing laparoscopic surgery to be performed as an emergency even after normal working hours.

The proportion of LR being performed within the United States ACS NSQIP population has nearly tripled from 4.5% in 2010 to 11.4% in 2016[6]. Smith et al[7] also revealed in a retrospective cohort study from Australia looking at patients being managed with PPU from 2011-2015, that 65% of their patients were started laparoscopically with a conversion rate of only 15%. Palanivelu et al[8] was even able to successfully proceed and perform definitive surgeries for 12% of his patient cohort, with none requiring conversion. These results indicate that more surgeons are utilizing laparoscopic approach to repair PPUs. This can be attributed to generally decreased morbidity associated with laparoscopic surgery, increase in the surgeon's confidence in performing laparoscopic surgery and increased study data pertaining to safety and efficacy of the technique. Thus I would like to recommend that we consider laparoscopic repair for PPU as procedure of choice in patients who can tolerate a pneumoperitoneum.

Skeptics of LR will complain that it takes longer to perform, as evidenced by the LAMA trial by Bertleff et al[9], where LR was found on average to be 25 minutes longer than OR. The LAMA trial was a randomized control trial (RCT) from Netherlands during the period of 1999 to 2005, consisting of 101 patients. It's important to note however that this trial was performed in the early 2000s, when surgeons were not as proficient as they are now. In this trial, the surgeons found laparoscopic suturing to be more technically challenging, especially when trying to perform a pedicled omentoplasty with intracorporeal suturing. Thorough laparoscopic irrigation was also found to be more time consuming. However, as surgeons are becoming more capable in laparoscopic surgery including laparoscopic suturing, later studies have shown no significant difference in operative time, with comparable reoperation and leak rates. PPU repair techniques have also been modified without adding any additional harm to the patients. Ge et al[10] in a newer RCT from China, with 119 patients for the period of 2010 to 2014, revealed similar operative times between LR and OR, when they employed simple suture repair of PPU without pedicled omentoplasty. No significant difference in leak rates were found. Single stitch repair and sutureless repair with biodegradable patch[14] and fibrin glue has also been researched to improve operative times.

Recent meta-analyses by Tan et al[11] and Zhou et al[12], which included the above mentioned RCTs, showed that the LR group has significantly lower post-operative pain

scores and analgesic requirements. Zhou et al[12] also revealed that the LR group had shorter nasogastric tube duration with earlier resumption of diet, with less risk for post-operative ileus. These factors contribute to the patients having a faster recovery, which has resulted in a shorter length of hospital stay. The LAMA trial[9] exhibited median length of hospital stay to be 6.5 days in the LR group and 8 days in the OR group. Quicker recovery also has an economic impact for the patient, as they can get back to work faster.

Vakayil et al[13], in a retrospective cohort study of 12 years (2005 to 2016) using the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database, displayed that LR was associated with a lower rate of superficial surgical site infections (1.5% LR versus 4.2%) and lower rate of wound dehiscence and deep surgical site infections (0.3% LR versus 1.6%). Due to the decreased number of wound complications encountered with LR, we can surmise that patients undergoing LR, have better quality of life and less risk of developing incisional hernia in the future.

The previous suspected risk of inducing sepsis by increasing bacterial translocation while establishing a pneumoperitoneum, was only demonstrated in animal studies, and no difference in post-operative sepsis or mortality rates were exhibited in humans.

Laparoscopic repair has previously been associated with high costs, but in the public sector where theatre time is not billed per minute. The cost of the disposable equipment used in LR is R2220 which is much lower than the cost incurred by the hospital, for the extra day of hospital stay, which is R8154 per day in Grey's hospital. An earlier discharge does also mean, freeing up a bed for another patient, in a public service system that is constantly struggling with bed shortages.

Most of the above mentioned studies comparing LR and OR, used patients with Boey score of 0 or employed propensity-score matching to accommodate for selection bias. However, Palanivelu et al[8] and Smith et al[7] demonstrated that LR was successful in patients presenting more than 24 hours since onset of symptoms with no significant difference in patient outcomes.

Thus, in view of the overwhelming evidence, showing the efficacy, safety, improved outcomes favouring LR. I would like to recommend that we consider LR in all PPU patients who are haemodynamically stable and has no significant comorbidities (ASA 1 and 2).

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# **Laparoscopic v/s open surgery** for perforated peptic ulcer

## Dr Human (OPEN)

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When a patient present with a perforated peptic ulcer, the surgeon needs to ask a few questions:

1. Is the performance of an operation indicated?
2. Is the patient stable enough to undergo a definitive ulcer operation?
3. Is an omental plication sufficient or is a definitive ulcer operation indicated? Which definitive ulcer operation is indicated?
4. Should the procedure be performed laparoscopically or by laparotomy?

Surgery is the mainstay of management of a perforated duodenal ulcer. Mouret et al first described laparoscopic intervention for perforated duodenal ulcers in 1990. Subsequently, this approach has found wide acceptance and has been successfully incorporated into the surgical armamentarium at many hospitals. Laparoscopic management has obvious benefits in reducing the size of the incision resulting in better cosmesis, reducing the incidence of postoperative wound infection, and the occurrence of incisional hernias. When faced with a patient with suspected or documented perforated ulcer disease, the surgeon should now consider whether a laparoscopic repair would benefit the patient.

One of the major factor in this decision-making is the laparoscopic expertise of the surgeon. Although many studies comparing laparoscopic repair with open repair have been published, controversy remains regarding the clinical utility of laparoscopic techniques for the treatment of perforated peptic ulcer disease. It has been postulated that the minimally invasive approach involves less operative stress and results in decreased morbidity and mortality but is this really true for all patients.

The decreasing incidence of peptic ulcer perforation has diminished the use of the surgical treatment of this condition. Clinical data mostly report retrospective studies, whereas prospective trials are primarily uncontrolled, thereby providing a low level of evidence. In view of experimental data demonstrating the efficacy of pneumoperitoneum compared with laparotomy in experimental models of intra-abdominal sepsis, the laparoscopic approach to PPU is of considerable interest.

There are several recent meta-analyses:

Stravos et al. reviewed the current literature (4 randomized trials (289 patients)) that compared the laparoscopic approach with open sutured repair of perforated ulcer.

Analysis of outcomes did not favor either approach in terms of morbidity, mortality, and reoperation rate. Although odds ratios seemed to consistently support the laparoscopic approach. Results did not determine the comparative efficiency and safety of laparoscopic or open approach for perforated peptic ulcers.

During their meta-analysis Tan et al. analyzed 5 RCTs investigating (549 patients). There were no significant differences between these two procedures in some primary outcomes including overall postoperative complication rate, mortality, and reoperation rate.

Subcategory analysis of postoperative complications showed that laparoscopic repair had also similar rates of repair site leakage, intra-abdominal abscess, postoperative ileus, pneumonia, and urinary tract infection as open surgery, except of the lower surgical site infection rate ($P < 0.05$). There finding was similar: laparoscopic surgery is comparable with open surgery in the setting of repair for perforated peptic ulcer. The obvious advantages of laparoscopic surgery are the lower surgical site infection rate. Recommendation: more higher quality studies should be undertaken to further assess the safety and efficacy of laparoscopic repair for peptic ulcer disease.

Sandhya et al mentioned the following as indications for (conversion to) an open procedure:

- Cardiovascular instability has been a published indication for conversion to an open procedure.
- Relative indications for conversion:
    - An ulcer greater than 6 mm in diameter or an ulcer with extremely friable edges
    - Posterior location of the ulcer, inadequate localization
    - Inadequate instrumentation
    - Presence of a perforated gastric ulcer that may need an open procedure for definitive surgery in cases of suspected malignancy
    - Prognostic factors resulting in conversion are shock at the time of presentation (50% conversion rate in patients in shock as opposed to an 8% conversion rate in patients without shock) and the time lapse between perforation and presentation (33% conversion rate in patients presenting more than 24 hours after perforation, compared with no conversion in patients presenting earlier than 24 hours after perforation).

Sandhya et al. has probably summed up more than 80% of the patients that we see in our setting.

In one of the more recent meta-analysis Chunhua et al. noted the following: fewer studies that compared laparoscopic repair with open repair for PPU have been published in the past few decades; however, a consensus on the best approach has not been reached.

To resolve these debates, Chunhua et al performed this updated meta-analysis to try to summarize the highest quality of data from studies that compared laparoscopic repair and open repair (analyzed 24 NRS and 5 RCTs).

Because high heterogeneity was found in most of the outcomes, they tried to reduce the influence of the heterogeneity by excluding some of the data in order to get reliable conclusions that are based on the best available data in the literature currently:

The feeling of **pain** is subjective; therefore, they used the days of analgesic use or the dosages to estimate the level of pain in patients. Minimally invasive surgery results in a less painful recovery: this was confirmed in the NRS. But RCTs did not reach the same conclusion but indicated less analgesic use in the LR group. In general, patients may suffer less pain after LR, but further investigations are needed.

**$CO_2$ pneumoperitoneum** is very important for laparoscopic procedures. However, the increased intra-abdominal pressure with $CO_2$ pneumoperitoneum is associated with an increased risk of bacteremia and sepsis and increased bacterial translocation from the peritoneal cavity into the bloodstream may cause pneumonia. In the previous studies, pneumonia has been found to occur more often in patients who undergo LR than OR even when the operative times were similar in both groups. The present analysis demonstrated a similar pneumonia rate between the LR group and OR group. This benefit of LR may neutralize the disadvantages of $CO_2$ pneumoperitoneum. Further validations are needed.

Because laparoscopic suture and peritoneal cavity lavage are technically more difficult, suture-site leakage and intra-abscess occur more frequently after LR. The present analysis did not demonstrate any significant differences between the two approaches. Similar incidences of urinary tract infection, difficulty with gastric emptying, gastrointestinal bleeding, pleural effusion and burst abdomen were found between the two groups; however, these symptoms were investigated in only a few studies.

Chinchau et al.'s analysis demonstrated a lower mortality rate in the LR group in the NRS. In patients with PPU, mortality is associated with sepsis and inflammation. Because inflammation has been alleviated after elective laparoscopic surgery, this minimally invasive approach for PPU, which is an emergency condition, is correlated more closely with patient risk factors than surgical complications. Thus, the selection bias of patients may lead to a higher mortality rate after OR. And in the analysis of

RCTs, the **mortality** was similar between the two groups. Therefore, more RCTs are needed to confirm these findings

The main cause for reoperation following surgery is suture-site leakage. Chinchau et al found the reoperation rate was similar between the LR and OR approaches. This outcome indicates that LR has become safer with improvements in the skill of surgeons and laparoscopic instruments.

In conclusion, Chinchau et al, combining the results of RCTs and NRS, LR is a feasible and safe option for PPU. Compared with OR, LR are associated with similar outcomes and complications. Moreover, the reoperation rate and the operative time are similar between the two groups, However, further high-quality multicenter RCTs are needed to confirm the benefits of LR.

**$CO_2$ Insufflation** in laparoscopic surgery has metabolic and physiological effects. $CO_2$ insufflation of the peritoneal cavity in the presence of peritonitis has been shown in rat models to cause an increase in bacterial translocation from the peritoneal cavity to the bloodstream (Sandhya et al). Naesgaard et al have shown that the incidence of postoperative pneumonia was significantly higher in patients undergoing laparoscopic repair of a perforated duodenal ulcer as compared with the open procedure. This pulmonary complication could not be attributed to time from perforation, because the time interval was the same in both groups. Controlled trials to study the effects of pneumoperitoneum on infectious complications will be necessary to more clearly define the true risks and benefits of laparoscopic repairs. Differences if any between patients undergoing open surgery and patients initially explored laparoscopically and subsequently converted to open may also shed more light on this problem. Currently some authors state that laparoscopy is more dangerous in a situation of prolonged peritonitis.

| cardiovascular | Respiratory | Others |
|---|---|---|
| ↓ Venous return | ↓ lung volumes FRC | ↓renal function |
| ↓cardiac output | ↑ airway resistance | ↑ risk of regurgitation |
| ↑ SVR | ↓ pulmonary compliance | ↑ ICP |
| ↓ BP | ↑ airway pressure | ↓ CPP |
| Brady/tachycardia | ↑risk of barotraumas | |
| | ↑ V/Q mismatch | |

Table 1: Physiological effects of a pneumoperitoneum

| Respiratory | Cardiovascular | Others |
|---|---|---|
| • Hypercarbia & Acidosis<br>• Pneumothorax<br>• Atelectasis<br>• Subcutaneous emphysema<br>• Pneumomediastinum<br>• Pleural effusion | • Arrhythmias<br>• Hypotension<br>• Cardiac arrest<br>• Deep-vein thrombosis<br>• Pulmonary oedema<br>• Myocardial infarction<br>• Gas embolism | • Shoulder pain<br>• Retinal haemorrhage<br>• Oliguria<br>• Transient ischemic attack<br>• Bowel ischemia/oedema<br>• Hypothermia<br>• Necrotizing fasciitis<br>• Tumour inoculation |

Table 2: Metabolic effects of $CO_2$ insufflation during pneumoperitoneum

Sanabria A. et al. in collaboration with the Cochrane library has made a review in 2010. They showed that there was a tendency to a decrease in septic intra-abdominal complications, surgical site infection, postoperative ileus, pulmonary complications and mortality with laparoscopic repair compared with open surgery, none of these were statistically significant. However, there was a tendency to an increase in the number of intra-abdominal abscesses and re-operations, but without statistical significance. This finding could be related to surgeon experience in laparoscopic surgery. It is not possible to draw any conclusions about suture dehiscence and incisional hernia with the two procedures

Some authors specifically recommend open surgery in presence of septic shock, a Boye score of 3 or in patients with absolute contraindications for pneumoperitoneum. Di Saverio suggest open surgery in presence of perforated and bleeding peptic ulcers, unless in stable patients with minor bleeding and in presence of advanced laparoscopic suturing skills available.

Babu et al. discussion: A systemic review of three randomized control studies (315 patient) comparing the open and laparoscopic duodenal perforation repair failed to suggest difference in the abdominal septic complications, pulmonary complications, morbidity, mortality, and reoperation rate. A Cochrane systemic review of 56 studies could not suggest the better technique between the two open and laparoscopy approaches.

The size of perforation is a factor for conversion to the open procedure, the rate of conversion is 12.4% in some study. The leakage rate and operative time was also more in laparoscopy group in some studies. There was less need of postoperative analgesia and better mobilization of the patient in postoperative period in laparoscopic approach and the cost of surgery of open and laparoscopy was almost similar.

Recent trials have shown that the patient with Boey score 3 and age more than 70 years and perforation duration more than 24 hours should undergo open surgery (Shelat et al and Kuwabara et al)

CONCLUSION:

In view of an increased interest in the laparoscopic approach, further randomized trials are considered essential to determine the relative effectiveness of laparoscopic and open repair of PPU.

There are however a few facts to remember: most meta-analysis failed to suggest difference in the abdominal septic complications, pulmonary complications, morbidity, mortality, and reoperation rate when comparing open and laparoscopic repair of perforated peptic ulcers.

A $CO_2$ pneumoperitoneum has systemic and metabolic effects, that can undo the advantage of minimal access surgery in a patient with peritonitis and shock.

Recent trials have shown that the patient with Boey score 3 and age more than 70 years and perforation duration more than 24 hours should undergo open surgery (Shelat et al and Kuwabara et al).

In the South African state sector most patients present late (often more than 24 hours post perforation), already in septic shock, thus often with a high Boey score.

Our theatre time is precious, every second count. A prolonged laparoscopic case with a minimal experience surgeon might help the patient in front of us to get a better cosmetic result, but at what cost? I did my first open omentopexy as a second-year intern, and my first laparoscopic repair as a surgery consultant, should the patient wait for my laparoscopic expertise, at what cost?

Limiting surgical delay is of paramount importance in treating patients with PPU. In fact from the Danish Clinical Register of Emergency Surgery, a cohort study including 2668 patients showed that every hour of delay from admission to surgery was associated with an adjusted 2-4 per cent decreased probability of survival compared with the previous hour. Might cosmesis, decrease wound sepsis and earlier mobilization in one patient, lead to the mortality of your second patient with a perforated peptic ulcer on your list? Ever heard of ERAS… post laparotomy, organize some physiotherapy.

In a resource restricted environment every patient should count, get to theatre earlier if possible. In our setting every intern or junior doctor can save a life – by doing a laparotomy and omental patch. By saving a life surgically – a junior doctor might just fall in love with surgery… and become a superhero surgeon.

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# **Open v/s endoscopic/video assisted surgical treatment** of zenkers diveticulum

Prof Joseph (Endoscopy)

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**Optimal and effective surgical patient management under budgetary and resource constraints- doing more with less.**

1. Debate on: Open v/s Endoscopic/ video assisted surgical treatment of Zenker's diverticulum. Argue for Endoscopic/ Video assisted as the best.

Proposal:
Endoscopic treatment for Zenker's is better than open surgery with reference to the following:

- ❑ Optimal and Effective Surgical Management
- ❑ Budgetary and Resource constraints
- ❑ Doing more with less

For the purposes of this discussion the endoscopic technique includes laser assisted and stapler assisted diverticulotomy only. Flexible endoscopic diverticulotomy is not widely used and further reports are needed for objective assessment.

Literature review and personal results (reported below) demonstrate similar outcomes for both open and endoscopic surgery with the latter having fewer complications, shorter theatre time and reduced hospital stay. [1,2,3,4]

Porter and Lee have reported the importance of surgical risk, recovery and early return to full function with minimum morbidity and disability to patients in the Harvard Review. [5]

These authors note that there are 3 main areas that matter to patients undergoing surgery:

1) Risk and Result of Surgery
2) Recovery and Rehabilitation
3) Outcome and Disability

Endoscopic surgery offers the optimal and effective approach in achieving these patient requirements and is a better than open surgery in a resource and budgetary constrained environment.

**Overall costs are lower in the endoscopic surgery. [6]**

Where staples are used instead of laser the additional cost of the stapler disposables is offset by reduced theatre time (30 mins vs 90 mins) and hospital stay (1 day vs 5 days). It may be argued that state hospitals do not benefit from reduced theatre time as cases are not charged on a time basis. However the resulting more efficient use of resources from reduced theatre time (more cases done per operating day per staff contingent) is an advantage. Similarly reduced hospital stay releases beds for other admissions.

Endoscopic laser surgery uses standard theatre equipment (ENT state hospital units) except for a diverticuloscope that is required for this technique. Requirements such as sutures, drains and dressings required in the open approach are not needed in laser diverticulotomy.

The laser may be used by other disciplines, optimising effective resource utilisation.

Budgetary and resource constraints result in staff shortages and pressure on beds in hospitals. The reduced theatre time and hospital stay associated with endoscopic Zenker's surgery results in more effective use of these limited resources with more theatre time for other cases plus efficient bed utilisation. State facilities can therefore do more (theatre cases and hospital admissions) within their current restraints.

- ❑ Optimal and Effective Surgical Management

This will be discussed with reference to the areas that matter most to patients as noted in the Harvard Review.[5]

- Risk and Result of Surgery
- Recovery and Rehabilitation
- Outcome and Disability

**Personal series 89 patients with minimum 2years follow up:**

**Analysis:**

Most patients in 6th and 7th decade: Age 61 to 80 years

Co morbid disease in 58% (mainly cardiovascular and diabetes).

Previous surgery with recurrence in 18 patients: 20%

| **Previous Surgery 20%** | **Patients 18** | | |
|---|---|---|---|
| Open | 12 | 66.7% | 1 septicaemia po |
| Closed | 6 | 33.3% | 5 staples (1=2x)<br>1 laser (2x) |
| | | | |
| Interval to recurrence | 9 | 50% | < 12 months |

| | | | |
|---|---|---|---|
| | 9 | 50% | > 12 months |

12 (66%) of the 18 previous operations were by open technique and 6 endoscopic (5 staples and 1 laser). These patients had all recurred within 2 years.

Revision surgery for recurrence in personal series was 4.5%.

**Protocol for endoscopic vs open**

| POST OP | ENDOSCOPIC | OPEN |
|---|---|---|
| **Fluid intake** | Immediately 1st 24 hrs | Nil Per Os 3 days |
| **Pureed diet** | 3 days | 5 – 7 days |
| **Soft diet** | 4 – 10 days | 10 days + |
| **Hospital Stay** | 1 day | 7 – 10 days |

**Recovery:**

Shorter stay than open surgery and early return to function (optimal and effective).
Patients are more comfortable as they are permitted to swallow immediately (liquids) and eat soft diet within 4 days.
Discharged home next day provided no surgical emphysema or temperature.
Open technique requires nil orally for 3 to 5 days and neck drain (removed day 2 or 3).

The Cochrane systematic review and analysis concludes that while both the open and endoscopic approaches have similar outcomes the endoscopic procedure is associated with reduced hospital stay, less morbidity and more rapid return to function.[1]

**Risk and Results:**

The endoscopic approach reduces risk and improves recovery and rehabilitation as required for optimal and cost effective care as described in the Harvard Review.[5]

Results are similar for both approaches with fewer complications reported for the endoscopic approach.[2, 3, 6]

Complications (risk) and Results in Personal Series 6.7% (Up to 14% Reported)[2, 3, 6]

| Complication | History |
|---|---|
| LEAK (3 cases) | 1 required surgery.2 settled on conservative Rx |
| AIR | Surgical emphysema. Simultaneous G scope. Previous HH repair |

| | |
|---|---|
| DENTAL | Crown incisor |

| **Successful** | **91.1%** |
|---|---|
| Recurrence | 8.9% |
| Revision Laser | 4.5% |

**Advantages over Open surgery**

Endoscopic surgery for Zenker's vs open:

Shorter Theatre Time

Shorter Hospital Stay

Swallow immediately

> Endoscopic surgery has equivalent results to open surgery with fewer complications (less risk) reported [2, 3, 6] (and in own series) with a shorter recovery period and return to normal eating. These factors are important to patients when assessing cost effective, optimal patient care.[5]

The endoscopic approach is therefore superior to open surgery in meeting the requirements for the optimal and effective surgical management of Zenker's.

58% of patients have comorbid disease. Endoscopic surgery for Zenker's is quicker, safer and less traumatic than open surgery. These benefits are an advantage in patients with comorbid disease.

**Budget and Resources: Endoscopic vs Open Surgery**

Reduced cost (theatre time, disposables, sutures, drains and ward stay).[6]

The endoscopic technique is a clean procedure, strict sterility is not required. Savings on linen and skin preparation are also possible.

Uses standard resources with the following additional requirements vs open:

LASER safety (Standard in ENT departments, no additional resources needed).

Instruments (1 endoscope). Other equipment is standard in ENT.

Stapler cost (recurring in staple technique. Offset by shorter theatre time and fewer disposables, drains and sutures).

Most requirements are met by standard theatre resources with the exception of an endoscope in laser diverticulotomy and the stapler in the staple technique.

The more effective use of time releases constrained resources for other (non Zenker's) patient surgery and hospitalization (beds) for other admissions.

Note that flexible endoscopic diverticulotomy is not widely used at present and further reports are needed for an objective assessment. It is not included in this discussion.

## Conclusion

Endoscopic Zenker's surgery is the more effective and optimal alternative to open surgery due to reduced risk, quicker recovery and similar success rates vs open surgery.

It has a positive effect on resource and budgetary constraints by allowing more efficient use of resources plus cost savings. Theatre time is less, therefore more operations (other cases) are possible. More bed days are available in hospitals; thus meeting the requirement of doing more with less.

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# **Long term outcome of bariatric surgery:** Is it good, bad or indifferent?

Dr Lubbe

## Introduction

Since the recognition of obesity as a chronic worldwide epidemic, and with increased evidence for the high mortality associated with excessive weight, bariatric surgery has emerged as the most effective treatment strategy available to clinicians. Decreased weight associated life expectancy is mostly attributable to cardiovascular disease and malignancy, and the remarkable remission rates of Type 2 Diabetes (T2D) in patients undergoing bariatric surgery has resulted in it increasingly being referred to as 'metabolic surgery' (MS).(1-3)

A multitude of both endoscopic and surgical techniques have been employed to assist with weight loss and treatment of weight associated comorbid diseases, and the laparoscopic approach has revolutionized surgical treatment of obesity.(4) The classic Roux and Y gastric bypass (RYGB) is currently the second most commonly performed procedure after a worldwide surge in Sleeve gastrectomy procedures in the 21st century.(5) Gastric banding (GB) and biliopancreatic diversion and duodenal switch procedures (BPD-DS) are often also offered in high volume metabolic surgery centers. Two high-quality randomized controlled trials (RCTs) were recently reported, comparing RYGB with SG, and showing no clinically relevant difference between SG and RYGB five years post-operatively. There was however a trend toward more weight loss (3.6kg) after RYGB in the study by Peterli et al.(6, 7) The mechanisms by which selected procedures result in weight loss and resolution of comorbidities has not been definitively established, but includes restrictive, malabsorptive and neuroendocrine changes initiated after intervention.(8, 9)

## Obesity and metabolic surgery in South Africa

In South Africa, 70% of adult females are classified as overweight (BMI >25 kg/m2), and 42% as obese (BMI >30 kg/m2), the highest recorded numbers in Sub-Saharan Africa, and the third highest numbers globally.(10) From 1980-2015, the largest jump in obesity prevalence has been seen in men between the ages of 25-29 years who are living in countries with a low-middle sociodemographic index (SDI).(11) The trend is likely due to the increased availability and widespread consumption of affordable diets, high in salt and sugar, and low in nutrients.(12) Health-care providers in South Africa are thus progressively faced with increasing numbers of patients where obesity co-exists with malnutrition, commonly referred to as the overfed but

undernourished (obesity) paradox.
MS has been performed in the private sector in South Africa to a limited extent due to funding difficulties, but results are comparable to international centers.(13, 14) The resource constrained public health environment poses an even bigger challenge to governmental MS programs, but the advantageous weight, metabolic and QOL outcomes after surgery, as well as an increasingly obese public patient population, has led to reports also from academic centers.(15)

**Cost of obesity and treatment options**

The 1998 South Africa Demographic and Health Survey (SADHS) data revealed that 87% of T2D, 68% of hypertension, 61% of endometrial cancer, 45% of ischemic stroke, 38% of ischemic heart disease, 31% of kidney cancer, 24% of osteoarthritis, 17% of colorectal cancer, and 13% of postmenopausal breast cancers, were attributable to a raised BMI.(16) The development of serious comorbidities places immense strain on Health Care Providers, although specific cost analyses is not available for South Africa currently. Data on the cost of obesity to Health Care is derived from the US and United Kingdom (UK), where the combined medical costs associated with treatment of preventable obesity related diseases are estimated to increase by 48-66 billion US dollars per year in the Americas, and by 2 billion pounds per year in the UK by 2030.(17) Treatment options include lifestyle modification (exercise and diet), medication and metabolic surgery.(18) Measures such as lifestyle modification and medication are plagued by limited loss of body weight as well as weight recidivism (the regain of lost weight).(19, 20) Increased physical activity and healthier eating habits as primary preventative ways to curb the obesity and 'diabecity' epidemics, have resulted in a tax levy on the distribution and sale of sugar sweetened beverages (SSB's), instituted by countries such as Mexico, Brazil and France.(21) The South African government is currently forging ahead with 'sugar tax', but this strategy might be limited by its failure to affect consumption at clinically significant levels, and the degree of weight loss in patients with extreme degrees of obesity and medical comorbidities does not reach levels seen after metabolic surgery.(22)

**Long-term outcomes after metabolic surgery**

Most robust long-term data on MS is derived from the Swedish Obesity Study (SOS).(23) This nationwide population based comparison, initiated in 1987 and including 1879 matched patient pairs, compares outcomes after best medical therapy vs. MS (GB, SG or RYGB). After 10 years the percentage weight loss from baseline was 3% for the medical therapy group, and 25% for patients undergoing RYGB.(24) After two years, 22% of patients with T2D were in remission in the medical therapy group, as compared to 72% in the surgery group.(25) At 16 years follow-up cumulative overall mortality was analyzed, and after multivariate analysis, surgery was associated with a 30% risk reduction for death.(2) The favorable effect

of metabolic surgery on life expectancy, although seen in the first few years after operation, became statistically significant 13 years after the surgery was performed. Evidence on the effect of MS on weight loss and T2D is now available from 11 randomized controlled trials (RCT).(26-28) The 2012 STAMPEDE study was a landmark report, emphasizing the role of metabolic surgery in the treatment of weight associated comorbid disease.(3) This was a single-center study including 150 obese patients with T2D randomized to either intensive medical therapy or MS (SG or RYGB). After 12 months of follow-up the primary end-point of glycemic control was achieved in 12% of patients in the medical therapy group, 37% of patients in the SG group, and 42% of patients in the RYGB group (P=0.002). The average number of anti-diabetic, lipid-lowering and antihypertensive medications increased in the medical therapy group, but decreased significantly in both surgery groups. This effect has been sustained at 3 years and 5 years after randomization.(29, 30) Comparison of outcomes after MS with those after lifestyle modification (including medication), consistently find MS superior, as demonstrated in several metaanalyses.( 31-33) After surgery, patients lost more body weight, had higher remission rates of T2D and metabolic syndrome, greater improvements in quality of life (QOL) and reductions in medicine use, when compared to non-surgical treatment. Percentage weight-loss after MS (from baseline) depends on the type of procedure performed, and varies between 17.3% and 33.8% 2-5 years after surgery.(34) Complete remission of T2D can be expected in 78% - 82% of diabetics after MS.(35) Further evidence for diabetes remission after surgery is abundant, also for patients with a BMI of 30-35 kg/m2.(36-38) Results are best for patients with recent onset diabetes (< 4 years), but also held true for cases where diabetes was long-standing at the time of operation.

**The cost of metabolic surgery**

Interpretation of reports assessing the cost effectiveness of metabolic surgery is complicated by the wide variety of systems used for analysis. In general, metabolic surgery performed for a BMI >35 kg/m2, with-or without comorbidity, is cost effective, while surgery performed for a BMI >50 kg/m2, with obesity related comorbidity, carries a cost saving (39). In a recently published Australian cost-utility analysis, assuming a willingness to pay $70,000 (R762,000) per quality-adjusted life year (QALY), the probabilities of surgery being cost- effective were 75% for RYGB and 71% for SG.(40) Subgroup analysis showed that bariatric procedures are less costeffective for older cohorts of patients, and for patients with T2D, surgery was more cost-effective in comparison with usual care.

Cost analysis publications for bariatric surgery, originating from developing countries, are limited. Zanela et al., using discrete event simulation in a Mexican cohort, found a return on investment after 6.8 years. (41) At 10 years follow-up, total costs for the surgical group were 52% less than the group undergoing conventional therapy. Return on investment decreased to 4.4 years for patients with

T2D undergoing metabolic surgery. In a Korean study, metabolic surgery in severely obese individuals (BMI 30-40 kg/m2) was analyzed. (42) The starting age of the cohort was 30 years old, the cycle length was 1 year, and non-surgical interventions included a physician visit, exercise, diet, and pharmacotherapy. The incremental cost effectiveness ratio (ICER) was US$1,771/QALY, translating to R25,190/QALY.

## Conclusion

Maximum weight loss after MS is generally reached at postoperative year 2, and beyond this time period weight regain can be observed in all procedures. In a small number of patients weight can return to pre-operative values at 15 years of follow up, resulting in a return of weight associated comorbidities. The survival benefit gained by the years of improved weight and metabolic control, is however still present in these patients, it seems that some of the metabolic effects prevail in patients despite weight regain.

The fact that MS is currently the most effective treatment strategy available for weight control and treatment of T2D, cannot be denied. South Africa has not been spared the obesity and 'diabeticy' epidemics, and our public patient population can benefit from access to MS. There are limited studies available reporting MS surgery outcomes in South Africa, and large volume studies investigating long-term outcomes and cost-effectiveness is needed, especially in the South African context.

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# **Reductive v/s Malabsorptive surgery** for morbid obesity. Which is more efficient and cost effective?

Dr Folsher (Malabsorptive)

The number of obese people worldwide, as well as the absolute levels of obesity, is increasing. According to the WHO, South Africa ranks 44 in the global obesity stakes, but that still translates to 26,8% of adults considered obese (BMI>30). (WHO 2017)

Treatments of obesity, apart from surgery, are usually ineffective for long term weight reduction. Worldwide, bariatric surgery has therefore grown in tandem with this obesity epidemic. (Chang 2014)

**A move from Obesity surgery to Metabolic surgery**

Rates of comorbidity reduction are high after bariatric surgery. Combined with the worldwide explosion in especially type II diabetes, the focus of this surgery has shifted to improvement of medical conditions. (Chang 2014) This culminated in the publication of the latest guidelines for the use of metabolic surgery in type II diabetes in 2016. (Rubino 2016) These guidelines, endorsed by all the major diabetic societies in the world, suggest metabolic surgery as the primary treatment for all Type II diabetics with BMI > 40, and strong consideration to be given to this treatment for BMI > 35. As a result of this, it has become imperative to find the most effective and efficacious procedures not only for weight loss, but even more importantly for comorbidity resolution.

**Types of metabolic surgery: Restrictive vs malabsorbtive**

Traditionally, bariatric surgery procedures were divided into procedures that reduce the quantity of food that can be ingested (restrictive) and those that reduce the quantity of food that is absorbed (malabsorbtive). With increasing knowledge of the physiological effects of the procedures, it is clear that hormonal, microbiotical and GIT changes are much more complex than this binary approach suggests. (Rubino 2014)

1. Laparoscopic Adjustable Gastric Banding (LAGB): This is a purely restrictive, nominally reversible procedure where a band around the top of the stomach creates a small (15-25ml) gastric pouch which empties slowly into the remaining stomach. The rate of emptying can be adjusted by inflating a balloon in the band. It is a technically simple procedure.
2. Laparoscopic Roux en Y Gastric Bypass (LRYGB): This is both a restrictive and malabsorbtive procedure. The stomach is transected to create a small pouch,

and a Roux en Y limb of varying length is joined to this. The procedure requires advanced laparoscopic skills.

3. Laparoscopic Sleeve Gastrectomy (LSG): This is anatomically an (irreversible) restrictive procedure, but it has hormonal effects beyond purely restrictive. A 32-44 Fr bougie is passed along the lesser curve of the stomach, and the larger curvature of the stomach is stapled off over this and removed. It is an easier procedure than the LRYGB.
4. Biliopancreatic Diversion (with or without Duodenal Switch) (BPD/DS): This is a technically complex and demanding mostly malabsorptive procedure. A sleeve gastrectomy is done and the duodenum joined up to the bypassed small intestine.
5.

**How should results of bariatric surgery be assessed?**

It follows from the above than any evaluation of metabolic surgery should look at resolution of comorbidities, especially diabetes, with accompanying increase in life expectancy and QALY's. Short and long term weight loss, measured as a percentage of excess weight lost (%EWL), is the second endpoint. This should then be balanced with the risks of the surgery. (Chang 2014) The costs and cost-effectiveness of the procedures can then be assessed.

**Results: Weight loss**

LAGB has the worst long term results, with 45% EWL after 2-5 years, and the majority of patients not achieving 50% EWL, considered a benchmark In addition, recidivism increases over longer periods.(Wolfe 2016). LRYGB has the best results of the commonly performed procedures, with between 62 and 72% EWL after 2-5 years. This appears to hold true in the long term, up to 15 and 20 years.(Sjostrom 2013, Puzziferri 2014) Long term results for LSG are awaited, but initial 2-4 year EWL is about 65%(Puzziferri 2014).

**Results: Diabetes**

LAGB achieves 28,6% longer term remission in meta-analysis. This is much poorer than the 66,7% quoted in the same analysis for RYGB. (Puzziferri 2014) Laparoscopic Sleeve Gastrectomy has promising short term results, comparable to that of RYGB. (Franco 2011) However, the results need to be confirmed in the long term. BPD has the highest rate of remission, >80%.

**Results: Other comorbidities**

In general, the less weight loss, the less resolution of other comorbidities like hypertension and dyslipidaemia. LAGB has rates one half to a third of that demonstrated by RYGB.(Shostrom 2013, Franco 2011) Five year results for LSG are scarce, and it is quite impossible to tease out the actual rate of remission.(Noel 2017, Schauer 2018)

**Complications**

The US Bariatric Outcomes Longitudinal Database (BOLD) figures for one year complication rate in 57 000 operations reviewed is: LAGB 4,6%, LSG 10,8%, LRYGB 14,9% and BPD 25,7%.(DeMaria 2010) This is probably representative of true results. LAGB has a lower complication rate at initial surgery, but develops complications at a rate of approximately 2%/year thereafter. In sleeve gastrectomy, there is a conversion rate of between 20 and 35% in the long term, due to complications or weight regain.(Felsenreich 2018)

**Cost and cost effectiveness**

All bariatric surgery is cost effective compared to conservative measures for T2DM and weight loss.(Chang 2014, Hoerger 2010, Schauer 2017, Rubino 2016) LRYGB is the most cost effective, giving the best QALY to expense ration with a ratio of $7000/QALY as opposed to $11000/QALY for LAGB, and sleeve gastrectomy somewhere in-between.(Hoerger 2010) Rubino, in definitive treatment algorithm, notes: ***RYGB is a well-standardized surgical procedure, and among the four accepted operations for metabolic surgery, it appears to have a more favourable risk-benefit profile in most patients with T2D.***(Rubino 2016) The BPD is very expensive and less cost effective due to the higher morbidity and mortality, as well as repeated treatment needed for nutrient deficiencies.

**What about South Africa?**

It is attractive to postulate that a LSG is better for South Africa, as there is less risk of long term nutritional deficiencies and internal hernia. However, overall results does not support this, and there is a very high (20-35% or more) risk of a further procedure being needed. The high long term complication and revision rate makes the LAGB a poor procedure for any country.

**Conclusion:**

Restrictive bariatric procedures tend to be easier, with less short term complications. However, in the long term the weight loss, resolution of comorbidities, safety and efficacy of the malabsorbtive procedure remains the best.

The LRYGB requires advanced skills, but this should not be a reason not to do the best, proven and efficacious operation

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# **Reductive v/s Malabsorptive surgery** for morbid obesity. Which is more efficient and cost effective?

Dr Loots (Reductive)

**The case for reductive surgery: a more efficient and cost-effective option.**

For bariatric surgery operations to be sustainable it requires a simple, effective, reproducible operation that is time efficient with a low complication and readmission rate. The laparoscopic sleeve gastrectomy (LSG) fulfills these criteria.

Restrictive operations have taken the baritric scene by storm on two occasions. In the first wave of restrictive operations, the lapaoscopic gastric banding (LB) made a surge and then quickly dissipated. The second wave was marked by the rise of the LSG. Current evidence points to it that it satisfies the above requirements and is here to stay. The Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) has been tested against the LSG and fails to satisfy these criteria.

**1. LSG is the most commonly performed primary operation for bariatric surgery.[1]**

In 2016, 72% of all bariatric patients operated underwent LSG's and 23% had a LRYGB (three times less). This is a staggering figure. It reflects the sentiment amongst surgeons performing these operations. Possible influencing factors are the high efficiency, low technical complexity of the LSG, which makes it attractive as a first line operation. It has a higher reproducibality and is easier to perform and to teach.

The rate of decline in the use of the laparoscopic band (LB) and the infrequent use of a Bilio-pancreatic diversion procedure (BPD) requires consideration. The LB are known for lower success rates in reversal of medical risk factors and higher re-operation rates. The BPD is complex and overly aggressive and is marred with malabsorbtive problems. A price too high to pay for many. Surgeons are low in its uptake because of its complexity and high post-operative maintenance.

The LSG has inreased in popularity and some of the benefits are explained below. It is perceived as a conservative operation because the gastro-intestinal tract continuity is maintaned. It is effective as proven by a growing body of evidence including randomised control trials reaching 5 years or more. And probably one of its main attractions is that it can later be converted to almost any of the malabsorptive

operations should the need arise. Reoperation rates are similar to those with LRYGB. LRYGB are mostly re-operated for internal hernias or late ulcer perforation.

**2. The LSG and LRYGB have the same weight loss at five years.[2,3]**

Two recently published randomized studies have set the precedent. Both the LSG and LRYGB are equivalent in weight loss efficiency.

The Swiss Multicenter Bypass or Sleeve Study (SM-BOSS) showed that the excess BMI loss was not significantly different at 5 years. The LSG group had 61.1% excess weight loss, wheras the LRYGB had 68.3% excess weight loss. They concluded that “there was no significant difference in excess BMI loss between laparoscopic sleeve gastrectomy and laparoscopic Roux-en-Y gastric bypass at 5 years of follow-up after surgery.” This came as a surprise to some.

The Finnish SLEEVEPASS Randomized Clinical Trial concluded that when assessing the percentage excess weight loss at 5 years, the difference was not statistically significant, based on the prespecified equivalence margins.

The chapter of the long term efficacy of the LSG as a standalone operation that is effective for weight loss can therefore be laid to rest for at least the next 5 years.

**3. The cost factor.[4,5]**

Cost is mainly influenced by what happens on the day of the operation, the length of hospital stay and readmissions which are influenced directly by complication rates.

A low to middle income country (Iran) studied the cost comparison between the two operations. We can extraplolate from their figures. The direct cost of services for a LRYGB was $ 2991 in their public sector and $4221in their private sector. For a LSG, it was $ 1952 in their public sector and $ 3177 in their private sector. The authors concluded that the LSG procedure when compared to LRYGB was cost effective both in the public and private sectors.

The explanation may lie in the reduced time it takes to perform an LSG, which translates into less theatre minutes. It has less complications in the short and long term requiring less ER visits and hospital admissions. The fewer nutritional complications means less follow-up and fewer laboratory tests and nutritional supplements.

LRYGB has more serious complications, including a higher mortality rate compared to the LSG. The Swedish Obese Subjects study's long-term problems have shown an increased risk for suicide, falls and fractures, and alcohol/substance abuse. More worrying complications include bowel obstruction, which can be life-threatening; stomal ulcers can bleed or perforate; gastric dumping syndromes and severe hypoglycemia.

The LSG has higher reflux rates. This is mostly will managed by a proton-pump inhibitor. In our institution's experience we have converted 1 out of 53 LSG patients to a LRYGB. A small price to pay. The Two European RCT's looked at this and it seems that patients in the early learning curve of a surgeons career suffered more. There were less reflux symptoms when more experienced surgeons performed the LSG. Operation volume may therefore play a role although this remains speculative at this stage.

LRYGB patients have an increased rate of hospital admissions (65% at six years, with 25% of these associated with partial or complete intestinal obstruction) and reoperations for a variety of gastrointestinal problems, including internal hernias.

Another study compared LSG and LRYGB head to head and found readmissions more common after LRYGB compared with SG (6.1% versus 3.8). This was statistically significant. Nausea, vomiting, and dehydration were more commonly a reason for readmission after LSG than LRYGB. Postoperative pain, bleeding, intestinal obstructions, and wound occurrences were more commonly a cause for readmission for LRYGB than for LSG.

This warrants careful consideration. The risk for internal hernia with a LRYGB will frequently result in a patient with abdominal pain admitted for at least a CT scan. This esclates costs and potentially burdens an already overburdened public health sector. LSG readmission could be readily managed on an outpatient basis if proper protocols are followed.

**4. Diabetes remissions and other disease remission.[6,7]**

The STAMPEDE trial compared both the LSG and the LRYGB over a five-year period against best medical care for patients with type 2 diabetes and a BMI of 27 to 43. The outcome data showed that bariatric surgery with intensive medical therapy was more effective than intensive medical therapy alone in decreasing, or in some cases resolving, hyperglycemia.

Looking at it in a bit more detail.

| | LRYGB | LSG | Medical |
|---|---|---|---|
| Body weight | 23% | 19% | 5% |
| Triglyceride | 40% | 29% | 8% |
| Use of insulin | 35% | 34% | 13% |
| Quality-of-life measures (score) | 17 | 16 | 0.3 |

However, 10 years follow up after LRYGB have shown a weight loss closer to 50% of excess body mass and resolution of type 2 diabetes at only 50%. This is a problem, as revision of gastric bypass is one of the most difficult clinical situations that face bariatric surgeons. For better glucose control a very distal gastric bypass is sometimes undertaken with serious and often worse malnutrition ensuing.

On the other hand a sleeve gastrectomy can be converted to a duodenal switch (or single anastomosis duodeno-ileostomy [SADI] or stomach intestinal pylorus–sparing [SIPS] procedure), achieving closer to a 90% chance of remission, or even better. This is an attractive option because the surgeon is left with choice. Reversing a LRYGB is hazardous and avoided by most, but our experience has shown that converting a LSG can be readily performed for the minority of patients that do require it.

## Conclusion[7]

In summary, “the choice of surgical procedure should be based on evaluation of the risk-to-benefit ratio in individual patients, weighing long-term nutritional hazards versus effectiveness on glycemic control and cardiovascular disease risk.” The LSG fulfill this criteria more often, more consistently and in a more cost-effective manner than a LRYGB.

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# **Laparoscopic** v/s open inguinal hernia repair

Dr Bougard (Laparoscopy)

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**Defining the Terms of Reference**

Inguinal Hernia Surgery represents a vastly heterogenous group of procedures and the terminology may be confusing. Open Inguinal Hernia surgery may encompass both mesh repairs and tissue repairs and may be anterior or posterior in approach, or may be single layer or bilayer repairs.[1] Laparo-endoscopic surgery may include Totally Extraperitoneal (TEP) or TransAbdominal PrePeritoneal (TAPP) or Extended view Totally extraperitoneal (eTEP). For the purposes of this debate I have simplified the question to be whether an endoscopic approach should be the gold standard for the public sector in South Africa.

Similar heterogeneity is demonstrated by our patients whose hernias range from simple asymptomatic and unilateral to complex, symptomatic and multi-recurrent. Surgeons skills are also variable and the environments and supporting facilities in which they practice are not comparable.

**Disclaimers:**

It would be naive to promote a single tool or approach for every patient, surgeon and circumstance. Surgeons who specialise in one particular method of hernia repair appear to have reasonable outcomes with that technique. [2]. I will discuss some of the specific circumstances where literature is able to guide us towards one avenue or another for the best possible outcomes for our patients.

There is no substitute for common sense and safe practice principles which should always prevail. I do encourage every surgeon interfacing with a patient to be honest about what is best, whether you are in a position to offer it or not, and what their options are. Tailored choices and true informed consent make the best bedfellows for optimal results. [1]

Biases do exist in interpreting literature. These range from lack of consistent definitions for pain, variations in competency of surgeons and differences in training protocols. Registry data, though traditionally belonging to a “lower” class of evidence, may actually provide a far better sense of real world outcomes. [3]

**Pros and Cons of Open and Laparoscopic Approaches**

Both the open anterior mesh repair and the posterior laparoscopic repair have their strengths and weaknesses. It is important to understand where these differences lie in order to ascertain which approach may be particularly suited under specific clinical conditions.

The differences can be summarised in this table below.

**TABLE 1. Pros and Cons of Laparoscopic and Open Anterior Groin mesh repairs**

| | OPEN MESH | LAPAROSCOPIC |
|---|---|---|
| PRO | Spinal or local anaesthesia<br>Short learning curve<br>Reproducible results<br>Less seroma | Minimal Tissue trauma<br>Better QOL outcomes<br>Rapid recovery<br>Early return to work<br>Less acute pain<br>Less analgesia required<br>Globally lower costs<br>Less SSI<br>Less Haematoma formation<br>Lower incidence nerve injury<br>Less severe chronic pain<br>Less post surgery numbness |
| CON | More acute Pain<br>More Chronic Pain<br>Return to work<br>Return to activities | Long learning curve (50-100 cases)<br>Special Equipment<br>Difficult under regional<br>Potentially higher OR costs * |
| NEUTRAL | Total Morbidity<br>Recurrence<br>Reoperation rate<br>Intestinal Lesion frequency<br>Urinary bladder lesions<br>Major vascular lesions<br>Urinary retention<br>Testicular problems | |

The key differences are mapped out in both meta-analyses of RCT's and confirmed by large registry cohorts. [3, 4, 5, 6, 7, 8, 9] The laparoscopic approach has the advantage of physics and biomechanics as well as a precise view of the anatomy of the

myopectineal orifice. These factors may translate into some of the clinical advantages demonstrated. [10] The most important patient related outcome benefits with laparoscopic surgery are the reduction in both acute and chronic pain, the rapid recovery and quicker return to work, activities and sport and a decrease in surgical site sepsis and haematoma formation. [1,3]

**South African Public Sector Context**

Whenever evolving techniques are discussed, the issue of resources is foremost. It is important to understand that this is a dynamic matter. Whilst the purse is finite, the allocation of those resources is dynamic. We should therefore be advocating for allocation of resources to a large proportion of our patients whose short-term and long-term outcomes will be influenced by the approach offered.

Its is also important to view resource distribution in a broad based manner and not according to traditional silos of “operative costs” for example. The upstream and downstream costs of the entire patient care journey should be considered when making a judgement on such resource allocation.

It is the obligation of every doctor to be the patient’s health advocate. This imperative could not be more critical than in the context of our public sector patients. If we look at our patient demographics we note that our patients often have heavy manual work to perform. They have contractual labour terms and no work is no pay. Therefore the social dictum is that they need to return as breadwinners as rapidly as possible. [7, 8, 11]
On the matter of equipment and cost, the equipment (laparoscopic stack and instruments) required to perform this procedure should be available in every hospital employing a specialist surgeon. There are a number of procedures such as laparoscopic cholecystectomy, laparoscopic appendicectomy amongst others which mandate a laparoscopic gold standard for the sake of improved patient outcomes. The equipment required for a laparoscopic groin hernia operation is standard and no special requirements exist. The consumables amount to a single piece of 15x15cm flat mesh and therefore need not increase costs at all. Some studies include tackers, balloon cannulas and disposable instruments which skew the costs inappropriately. [7]

As far as anaesthesia is concerned, a general anaesthetic is a safer more predictable technique. When costs are compared to costs of surgery directly the cost difference is negligible. [11]
On the matter of training and skills, I concede that not every surgeon can safely learn and practice laparoscopic groin surgery. It is a technically demanding operation with a long learning curve. Skills acquisition and translation will take some time and some effort. This training should be structured and licence to practice should be outcomes based. However, I remain convinced of the great aptitude of South African surgeons

and believe that with structured training and wider uptake of laparoscopy as a gold standard, these procedures will become fairly straight forward.

Africa has its own unique resource challenges. Despite that, we should not accept second best for our patients. In my opinion, if anyone deserves the best possible procedure, it would be our patients.

**Difficult Cases**

It seems that the evidence weighs in favour of a laparoscopic approach for our patients. Especially given the social circumstances our public sector patients have to contend with. The question is whether the laparoscopic approach is feasible and safe under challenging circumstances.

**Previous Surgery**

The laparoscopic approach is feasible and safe in experienced hands for patients who have undergone lower abdominal surgery or pelvic radiotherapy. Specifically after caesarian section, TEP is often possible without increased complications. Case selection and surgical skill should be the tenets of decision making under these circumstances. [12; 11; 7; 8]
Recurrent hernias
If the initial operation was an open repair, then the operation for a recurrence should be a laparoscopic repair, and vice versa, [11 ,8] Repeat laparoscopic repair is only feasible when the surgeon has a high level of experience in laparoscopic hernia repair.[11] TAPP repair of recurrent inguinal hernia after prior TEP or TAPP may be performed, but only by experts in TAPP. [7]

**Bilateral**

Laparoscopic repair is the preferred option, from a patient outcome and cost-effectiveness perspective [11]

**Incarcerated/strangulated hernias**

These hernias can be safely repaired laparoscopically. This allows assessment of the viscus involved and resection rate may be lower in laparoscopic cases. If the viscus has been reduced by the time of open exploration, it will need to be inspected. Placing the laparoscope through the deep ring is a cheap and convenient option. Incarcerated femoral hernias may be safely repaired via the TAPP or TEP repair.[7]] Mesh placement after bowel resection is possible, in clean contaminated situations.[11] Laparoscopic repair should be avoided in the setting of peritonitis or an infected abdominal wall.[7]

**Hernias in women**

A laparoscopic approach is recommended in inguinal hernias in women,[6, 7] The existence of a femoral hernia should be excluded in all cases of groin hernias in women.Women have a higher rate of recurrence of 'inguinal hernias' because of higher occurrence of femoral hernias (overlooked or de novo) [8]

**Hernias in obesity**

No evidence exists for the preferential use of any particular approach in morbidly obese patients.[6] The operation is more difficult with either approach.

**Sportsman's hernia**

Laparoscopic mesh repair is effective in sportsman's' hernias and is the preferred method for early return to the sports field. [11]

**High Risk for Chronic Pain**

Laparoscopic techniques should be preferred to open mesh or non-mesh repair to reduce acute pain and the risk of chronic pain.[7, 11, 8]

Risk factors for chronic pain are listed below. Patients falling into these categories should be offered a laparoscopic approach:[3, 7]

**Preoperative groin pain**

Preoperative chronic pain conditions not related to the groin
Early postoperative pain
Recurrent hernia
Age <50 years
Female gender
Surgical complications such as seroma, wound infection, bowel or bladder injury, bowel obstruction

**Key messages:**

Always use mesh
The exception being grossly contaminated and dirty wounds.

A good surgeon should be familiar with multiple techniques.
Plan your initial approach but have a backup plan.

Laparoscopy is the aspirational standard for outcomes BUT the approach must be tailored according to the clinical scenario, skills and equipment available.

The benefits/ differentials in numbers between open and lap are very small.

Informed consent should be key to decision making.
Make sure the patient understands the options and implications.

A laparoscopic approach should be offered as first line treatment to certain groups of patients (fat, female, recurrent, bilateral, sportsman, chronic pain) or they should be advised that it is the standard of care.

Laparoscopy should NOT be offered in the following situations (no patient consent, no skills, no equipment, no backup plan)

Excellent training and a high caseload are the foundations of good surgery
Every surgeon should enter their results into a registry and audit their outcomes

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# **Laparoscopic** v/s open inguinal hernia repair

Dr Jann Kruger (OPEN)

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**Introduction**

Open Hernia Surgery was performed since the ancient times.
Consequently the experience with open repair is vast.
The following information about the history of hernia repair is taken from Legutko J et al (1):
Five eras of groin hernia treatment are described: 1. Ancient Egypt time to the 15th century. In the Papirus of Ebers a swelling that comes out with coughing is described. 2. During the era of the Renaissance, 18th -19th century, many anatomical discoveries were made. The treatment results were completely unsatisfactory. Astley Cooper said:" no disease treated surgically involves from surgeon so broad knowledge and skills as hernia and its many variants. The 3.era span from 19th century to the middle of the 20th century. It was the time of hernia repair under tension. Anesthesia as well as anti- and aseptic procedures were introduced. It was the time of the high ligation of the sac and the narrowing of the internal ring. However the outcomes were still pure, the recurrence rate after 4 years 100% and the postoperative mortality 7%.
Then Bassini came along, introduced the reconstruction of the posterior wall of the inguinal canal and the results improved.
E. Shouldice from Canada performed the imbrication of the transverse fascia, strengthened the posterior wall by four layers of fascia and aponeurosis of the oblique muscles. Consequently the recurrence rate dropped to 3%.
After this time of major developments the 4th era began, the era of tensionless hernia repair. In 1935 Carothers discovered the synthetic polymers. The first tensionless hernia repair was described by Lichtenstein. He used mesh to strengthen the posterior wall of the inguinal canal. He performed 1000 procedures with Marlex mesh and did not have one recurrence after 5 years of follow up.
In 1975 Rene Stoppa introduced a preperitoneal repair with Dacron mesh. Recurrence rate 1.4%.
With the introduction of the flat-mesh Lichtenstein also started using the Marlex mesh plug in 1968 for inguinal and femoral hernias.
In the 20th century we have entered the latest era of groin hernia treatment: the laparoscopic inguinal hernia repair .

## How to choose the optimal repair for the patient

If we are in the process of choosing the optimal hernia repair technique we have to consider the following points:

- Skills of surgeon, learning curve
- Type of patient: young-old, normal-increased BMI, comorbidities, elective - emergency situation,...
- primary - recurrent hernia
- Availability of equipment and meshes

## Skills of the surgeon

We know that the number of a procedure performed by a surgeon determines his/her skills and outcomes (2).
I like to assume that at least in the public sector of the health system in South Africa the open Lichtenstein procedure is more commonly taught and performed than the laparoscopic hernia repair.
Therefore more expertise is present in the open approach to the groin hernia.
The learning curve is an important factor in a resource and time constraint environment.
The Lichtenstein procedure with a learning curve of about 40 cases (5) or the ONSTEP procedure which a learning curve of about 10 cases in the hands of an experienced surgeon ( 4) fits in very well with the described situation.
In comparison the learning curve for the laparoscopic procedure can take up to 80-100 cases depending.(5)
Also the Stoppa procedure compares better with a learning curve of about 30 cases (8)

## Different types of open repairs

The open Lichtenstein procedure can be performed in any patient in any situation because it can be used with any type of anesthesia ( general, regional, local). It can be applied in an elective or in an emergency situation. The Lichtenstein procedure can be used for small hernias as well as complicated large, incarcerated or even strangulated hernias.
The ONSTEP and Stoppa technique can also be used for the same indications. Unlike the Lichtenstein procedure these two techniques are placing the mesh pre-peritoneal which means they are a combination of the laparoscopic and the open technique. Additionally the mesh is placed on the " right" side of the defect, meaning the mesh is in front of the defect not behind.

The ONSTEP ( Open new simplified totally ExtraPeritoneal) repair is performed through a 5cm incision in the middle lower abdomen and does not use any fixation. The advantages are short operating time, short recovery time, it can be done under local anesthesia, it has a low incidence of chronic postoperative pain syndrome and a good cosmetic result.(7) The recurrence rate is less than 1% after one year follow up.(3)
The Stoppa technique is similar to the ONSTEP procedure. A Dacron mesh is inserted into the pre-peritoneal space via a skin incision in the lower abdomen. Recurrence rate is 1.4%. (1)
Another version of the open inguinal hernia repair is the plug repair. However it seems that the incidence of erosions with plug repair is significantly higher than with flat mesh. Therefore it is not recommended anymore.(2)
In a study from China,2014 (6) TEP and open extraperitoneal repair are shown to be equivalent in most outcomes. TEP is followed by a shorter hospital stay, quicker return to work, less urinary problems, open procedure has a lesser incidence of peritoneal tears.

**Availability of equipment and meshes**

In an environment where the health system is under extreme financial pressure it might be problematic to rely on the availability of sophisticated laparoscopic equipment. It is of utmost importance to be familiar with open inguinal hernia surgery. However there should not really be a problem with the availability of meshes. The recurrence rate is simply to high in groin hernia repairs without meshes. There is also a whole range of meshes on the market and certainly cheaper once can be found.

## Conclusion

In a resource constraint environment an open pre-peritoneal approach is probably the most suitable approach. It appears at the moment that there is not much difference between laparoscopic and open pre-peritoneal procedures in the short and longterm. However most of the recent studies comparing open and laparoscopic procedures claim that the postoperative course, faster recovery and lower incidence of postoperative chronic pain syndrome are more of an advantage with the laparascopic procedures.(9)

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# **Ethical and medicolegal consequences of healthcare** rationing under budgetary constraints

Dr Household

This is a particularly vexed topic that has entertained some of the wisest scholars, bioethicists and economists and I am none of these. However, I will reflect on the challenge that increasingly faces all healthcare systems across the world and not only in Gauteng or South Africa, which is the infinite nature of the need for healthcare and the finite nature of the resources available to provide that healthcare. In addition, the advances in medicine over the last century while they have increased the lifespan and quality of life of many people, they have at the same time exponentially increased the cost of healthcare over the last century.

Against this the World Health Organization (WHO) constitution of 1948 declares health as a fundamental human right and determines that all member states should strive to provide Universal Health Coverage (UHC) to their citizens. UHC means that all citizens and communities can use the promotive, preventive, curative and palliative health services they need, of sufficient quality to be effective, while ensuring that the use of these services does not expose the user to financial hardship.[1]

The South African Constitution in the Bill of Rights indicates in 27(1)(a) that, *"Everyone has the right to have access to health care services, including reproductive health care"* and further in 27(1)(c) that *"no-one maybe refused emergency medical treatment."* In 27(2) it is indicated that, *"the State must take reasonable legislative and other measures within its available resources, to achieve the progressive realization of each of these rights."*[2] The interpretation of the right to healthcare has been tested on several occasions in South African courts. The Constitutional Court ruled in 1997 in a landmark judgement by Judge Chaskalson with the concurrence of two other Constitutional Court judges that the State's failure to

[1] http://www.who.int/health_financing/universal_coverage_definition/en/

[2] The Constitution of the Republic of South Africa, Act 108 of 1996

provide renal dialysis for all patients suffering from chronic renal failure was not a breach of the obligations imposed on it by Section 27 of the Constitution.[3]

Interesting extracts from the judgement are firstly an extract from a Canadian court judgement which is as follows, *"the inescapable fact is that if governments are unable to confer any benefit on any person unless it confers an identical benefit on all, the only viable option would be to confer no benefit on anybody"* and secondly the statement by Judge Chaskalson that, *"However the right to life may become defined, there is in reality no meaningful way in which it can be constitutionally extended to encompass the right indefinitely to evade death"*.

In a judgement made in an English court regarding the National Health Service in the United Kingdom also referred to in this Constitutional Court judgement, there is a telling quote which is as follows, *"Difficult and agonizing judgements have to be made as how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgement which a court can make."*[4] The *"agonizing judgements"* refers to the decisions made every day by health authorities and health professionals in countries across the globe which reflect the fact that as stated in the introduction that the need for health services outstrips the available resources.

So, if it is accepted that the ability to provide health care will be less than the need however it is defined and that it is legally and ethically justified to limit the degree to which health care can be provided to an individual and a population, ration healthcare, then there is the question of how this should and can be done?

To be able to consider this question more adequately, it is necessary to reflect briefly on the bioethical principles that guide the systems and processes that have been utilized to make these difficult decisions. Ethics is defined as the discipline of dealing with what is good and bad and with moral duty and obligation.[5] Biomedical ethics is a more recent development within the healthcare professions evolving through codes of medical and nursing ethics, research ethics and reports of government commissions. In biomedical ethics

[3] Constitutional Court of South Africa Case CCT 32/97 Thiagraj Soobramoney versus Minister of Health (Kwazulu-Natal)

[4] Sir Thomas Bingham from the judgement R v Cambridge Health Authority 1995

[5] Merriam-Webster's Collegiate Dictionary 11th Edition

two types of ethical theory predominate, consequentialism and deontological theories.[6] A detailed discussion of these theories is both beyond the scope of this lecture and this presenter, but it is useful to highlight briefly the concepts of both.

Consequentialism is the moral theory that actions are right or wrong according to their consequences and the most often utilized in health issues is utilitarianism. Utilitarianism maintains that the moral rightness of actions is determined by their consequences, in particular the maximization of the value resulting from the action. In contrast, deontological ethical theory maintains that obligation and right are independent of the concept of good. Right actions are not determined exclusively by the production of good consequences, that is that some actions are right or wrong for reasons other than the consequences.[7]

In large measure as a health manager, I have utilized a utilitarian approach to decision making. The principle of utility indicates that an action is justified if it produces more "good" than any alternative action and that this will determine if an action is morally right or wrong. Utilitarianism can be further divided into act utilitarianism and rule utilitarianism with the difference between the two stated simply being that the *"act utilitarian"* applies the principle of utility directly and the *"rule utilitarian"* applies a set of moral rules and a moral code to the principle of utility in decision making. I would classify myself as a rule utilitarian.

The basic moral principles on which biomedical ethics are based, are autonomy, nonmaleficence, beneficence and justice and while each is relevant to healthcare for the purpose of this lecture I will only concentrate on aspects of beneficence since many public health policies relate to this principle such as cost-and risk-benefit analysis. ***Costs*** are the resources required to bring about a benefit and ***risk*** refers to the possible future harm, where harm is defined as a negative impact on life, health and welfare.

Cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA) are often used in decision-making regarding health policies. Cost-effectiveness analysis measures the benefit in non-monetary outcomes such quality-adjusted life years

[6] Principles of Biomedical Ethics Chapter 2 Types of Ethical Theory 3rd Edition Beauchamp and Childress 1989

[7] Principles of Biomedical Ethics Chapter 2 Types of Ethical Theory 3rd Edition Beauchamp and Childress 1989

(QALYs - cost per year of life saved). Cost-benefit analysis measures both the benefits and costs (benefit-cost ratio) in monetary terms. A CEA is best used to compare programs of policies with the same aims. For example, if two therapeutic procedures have an equal outcome but one is less expensive, then that procedure is more cost-effective. In contrast, a CBA allows the evaluation or comparison of a policy with different aims in monetary terms.

Risk analysis identifies the risks of a policy or intervention. Risk assessment estimates the probability of a consequent negative event and a risk-benefit assessment assesses risk in relation to possible benefits. Risk management is the response to the analysis and assessment of risk. For the purposes of medical decision-making and health policy, the acceptability of the risks set against the likelihood and degree of the risk and possible benefits must be determined. For example, policies should be put in place that reduce the risk of medico-legal claims against health facilities and health workers.

I will proceed with this as the basis for the consideration of the rationing of healthcare which by necessity occurs when the environment is resource constrained. Rationing is an uncomfortable word with varied meanings and definitions[8]. When related to healthcare it implies that potentially beneficial treatment is denied to a patient.[9] In South Africa, as in many countries social services such as public healthcare and education depend on funding from a common pool, which is almost exclusively derived from tax revenue. Attempting to meet all the healthcare needs would potentially overwhelm the requirements of other social services and societal needs. For this reason, a degree of rationing or the often used less uncomfortable word, prioritization, is necessary and inevitable.

Rationing can occur at many levels. Macro-allocation occurs at a national level where decisions are taken on how funds are allocated to functions such as health, education and welfare services amongst others. In South Africa this process for the public sector occurs annually with the allocation of budgets to national and provincial departments on the basis of an equitable share formula and conditional grants based on priorities outlined in strategic and annual performance plans and over the annual rolling three-year Medium-Term

[8] Kelidar I, Mosadeqhrad AM, Jafari-Sirizi M Rationing in health systems: A critical review. Med J Repub Iran 2017;31:47

[9] Truog RD, Brock DW, Cook DJ et al for the Task Force on Values, Ethics and Rationing in Critical Care (VERICC) Rationing in the intensive care unit. Crit Care Med 2006; 34(4):958-963

Expenditure Framework (MTEF), first introduced in South Africa in the 1998. The National Treasury states that the MTEF provides Government with a tool to manage the tension between competing policy priorities and budget realities by integrating the top-down resource envelope with bottom-up sector programs. If one analyses this statement it is clear that this is a macro-allocation prioritization or rationing process.[10]

Micro-allocation occurs at the level of an individual with a decision of whether or not an individual patient will receive a scarce medical resource. It is clear that restrictive macro-allocation decisions will result in more situations in which individual patients must be denied potentially beneficial treatments.[11] Micro-allocation is in many instances the prerogative of the medical practitioner although most would not like to admit that they ration healthcare.

The Oregon Health Plan[12] in the United States is probably one the most often quoted examples of rationing of health services which resulted from the State of Oregon in the early 1990's facing escalating medical expenditure for Medicaid recipients in the face of budget deficits. A not unfamiliar situation considering the state of South African provincial budgets. The macro-allocation in this plan balanced state healthcare spending against competing social goods such as education and infrastructure but further at another level of macro-allocation traded providing a larger range of healthcare services to less than half the population for providing a basic level of healthcare to all Oregonians living in poverty. The plan utilized a prioritized list of services developed by a Health Services Commission consisting of consumers and providers of health services which ranked healthcare services for coverage according to their benefit to the entire population served, which was a clear utilitarian approach. The prioritized list was developed ranking conditions and treatments according to four factors – cost, duration of benefit, likelihood to alleviate symptoms or death and the views of citizens on the seriousness of symptoms and functional limitations. The list was criticized for exclusions that were regarded as counter intuitive and amended in a series of adjustments. In truth as time went on the plan was watered down due to political pressures and US Federal Government restrictions but the principles involved are instructive in the consideration of rationing in healthcare.

[10] National Treasury MTEF Guidelines http://www.treasury.gov.za

[11] Scheunenmann L, White DB The Ethics and Reality of Rationing in Medicine Chest 2011; 140(6):1625-1632

[12] Oregon Health Plan An historical overview Oregon Department of Human Services July 2006

Seen from an economic perspective, the use of QALYS is the best metric to measure benefit from a particular healthcare intervention. However, rationing by maximizing QUALYs is limited by methods to quantify the quality of life. Nevertheless, the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom uses QUALYs to guide coverage decisions. The NICE website defines one QUALY as equal to 1 year of life in perfect health which it is indicated is often measured in terms of the person's ability to carry out the activities of daily life, and freedom from pain and mental disturbance.[13]

So, what is the situation in South Africa with the current two-tier national health system comprising the public and private health sectors that provides healthcare to the South African population? In the private sector that serves an estimated 16% of the population, economic rationing while not overtly mentioned is practiced as the ability to access private health care is based largely on the ability to pay for the service. The high cost of private healthcare has been the subject of the Health Market Inquiry[14] that released a draft report on 5th July 2018. The World Health Organization told the HMI hearings in February 2016 that South Africa has one of the most expensive private healthcare systems in the world.

The report provides some interesting insights into what drives the need for private healthcare services although there is no reference to factors other than funding that exclude South Africans for accessing the private health sector. The report which states that, "*practitioners (doctors) typically have more information than payers for, or recipients of health care which they describe as information asymmetry. The health practitioner in most cases advises of the need for a service and then provides the service. Since providers are typically paid by volume of services provided, a revenue-maximizing professional will tend to recommend more, rather than fewer services, which is supplier-induced demand",* highlights how the ethical principle of autonomy, which implies a free informed choice, is infringed by this information asymmetry.

From multivariate modelling the HMI Report concludes, *"that there is sufficient evidence to confirm that rates of hospital admission are positively associated with the levels of both doctors and hospital beds after adjusting for clinical and demographic*

[13] NICE website https://www.nice.org.uk/glossary?letter=q

[14] Health Market Inquiry Provisional Findings and Recommendations Report Competition Commission South Africa

*factors."*[15] This suggests that the supply-side pressures rather than the defined health need are determining the level and cost of private healthcare in South Africa and that resource constraints are vested in the consumer and possibly the funders rather than the providers of the services.

The public health sector which provides healthcare to the balance of the population, an estimated 84%, reflects a very different picture with continued and oft publicized failures to provide quality and safe healthcare. It is instructive to consider what constitutes a quality health service and then to analyze the failures in this area in the public health sector. According to the World Health Organization quality health care must meet the following criteria in six areas[16]:

- **Safe.** Deliver health care that minimizes risks and harm to service users, including avoiding preventable injuries and reducing medical errors and that is trustworthy and reliable
- **Effective.** Provide services based on scientific knowledge and evidence-based guidelines.
- **Timely.** Reduce delays in providing and receiving health care.
- **Efficient.** Deliver health care in a manner that maximizes resource use and avoids waste.
- **Equitable.** Deliver health care that does not differ in quality according to personal characteristics such as gender, race, ethnicity, geographical location or socioeconomic status.
- **People-centered.** Provide care that considers the preferences and aspirations of individual service users and the culture of their community.

Clearly measured against these six criteria, the South African public health sector overall currently falls short in almost every area and while it would be simple to indicate that it is solely a resource issue, it would be difficult to sustain this argument. The South African public health sector reflects the broader challenges facing government in the country with a lack of leadership, management capacity and systems hampering the delivery of quality healthcare.

While the country faces a burgeoning burden of disease driven by the high levels of infectious diseases, non-communicable diseases, violence and injury, the

[15] Health Market Inquiry Provisional Findings and Recommendations Report Competition Commission South Africa Chapter 8 Page 399 paragraph 55.
[16] Quality of Care A process for Making Strategic Choices in Health Systems World Health Organization 2006

failure of management and administration of resources allocated to the public health sector has increased the pressure on the services. This is evidenced by the increasing frequency of irregular, fruitless and wasteful expenditure reported by the Auditor-General of South Africa as well as well documented cases of fraud, wastage and corruption in health departments across the country indicating that the precious health rand is not being optimally utilized to meet the need for public health services.

Two examples of the health rand being wasted are illustrative such as the Gauteng Department of Health where the previous MEC for Health, Brian Hlongwa, faces charges of corruption and money laundering relating to two tenders worth R1,4 billion. The North-West Department of Health which has been in the spotlight for alleged corrupt practices involving healthcare delivery since February 2018 when details were revealed of a R30 million pre-payment to Gupta-linked healthcare company Mediosa with another R150 million to follow. The health minister Dr Aaron Motsoaledi visited the province in early March 2018 where he described the contract between the North-West Department of Health and Mediosa as, *"an ATM card for the Guptas to withdraw money from the department*"

In the light of this, the first step is to ensure that funds allocated for the delivery of public health services are indeed utilized for that purpose. The next step is to ensure that the personnel in the health departments whose remuneration consumes over 65% of the public sector health spend are essential to provide health services. Thirdly, the equipment, medical consumables, pharmaceuticals and infrastructure essential to provide the basic package of services at the various levels of care must be determined. In determining steps two and three understanding that the resources even after having excluded wastage of whatever origin, will be insufficient to meet the need as defined by the burden of disease outlined above, a utilitarian process will be required to prioritise the resources required to deliver the services that are deemed necessary. The key to this process is that it: (i) must meet the requirements of transparency, (ii) be based on reasoning according to information and principles that all can accept as relevant, (iii) have procedures for appeal and review of individual decisions, (iv) have oversight by a legitimate institution and (v) involve meaningful public support.[17] [18]

[17] Daniels N, Sabin J. Limits to health care: fair procedures, democratic deliberation, and the legitimacy problem for insurers. Philos Public Aff. 1997;26(4);303-350

[18] Daniels N Accountability for reasonableness BMJ 2000;321 (7272):1300-1301

The National Health Insurance Bill[19] published on 21st June 2018 indicates in Clause 25(1) that the National Minister of Health may appoint, a (Health) Benefits Advisory Committee that it appears is tasked to undertake this process. The question is whether the composition of this committee meets the criteria of a *"legitimate institution"* as mentioned above. Membership, appointed by the National Minister of Health, includes all the heads of medical schools, a member from the World Health Organization, nine members nominated by the provincial health departments, a member from the Council for Medical Schemes and two members from the hospital association. Clause 25(5) indicates that the Benefits Advisory Committee must determine (a) the health service benefits and types of services to be reimbursed by the Fund at each level of care, (b) detailed and cost-effective treatment guidelines that take into account the emergence of new technologies and (c) in consultation with the Minister and the Board, the health service benefits. It is a concern that the composition and structure of this committee falls short of the requirements outlined in the previous paragraph considering the power and consequences of decisions to be made by this committee. In addition, a Stakeholder Advisory Committee outlined in Clause 27 comprised of representatives from the professional and research councils, statutory bodies, labour, business, non-governmental and civil society organizations is tasked with providing comments and advice on the health service benefits offered by the Fund. A concern is that while the appearance of this committee is that of a wide representative stakeholder committee, whether the mechanism will be effective in ensuring *"meaningful public support"*.

Failure to implement a rational ethics-based system of this nature results in implicit or covert rationing with the doctor often the "rationer" of last resort. Nevertheless, despite adherence to these principles for ethical priority setting based on sound rule utilitarian decision-making, the emotive nature of rationing life-saving medical therapies may provoke a public outcry. Faced with a choice that effectively consigns an individual to death, individuals seek to deny moral responsibility for their role in the choices made. At this stage the impulse to rescue the individual, say a child with a rare disease requiring a very costly medical therapy may override the ethics-based utilitarian decision and by public subscription or donation funds will be spent or allocated which on even a rule-based utilitarian basis could have been allocated elsewhere to the greater good. An example of this outside the health field could be the efforts made without regard to the rescue of trapped miners, which on the basis of consideration of the greater good would have been better spent on improving general mine

[19] National Health Insurance Bill Government Gazette 21st June 2018 No. 635

safety but the unacceptable moral and emotional consequence would have been the death of the trapped miners.

Finally, the concern of health professionals is the potential for medico-legal action against a health professional for failing to provide therapeutic interventions that would have prevented the harm or death of an individual. The reassurance in these instances lies within the Constitutional Court ruling outlined at the outset of this lecture that, *"However the right to life may become defined, there is in reality no meaningful way in which it can be constitutionally extended to encompass the right indefinitely to evade death"* and further that, *"Difficult and agonizing judgements have to be made as how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgement which a court can make."* Thus, in the absence of acts of medical negligence or willful omission, given that resources are limited and that a fair, transparent and ethical process adhering to the principles of distributive justice has been followed to reach the decision to withhold or not provide a particular therapeutic intervention, a legal action seeking to prove medical malpractice or negligence will fail.

I understand that not all may agree with the views that I have outlined and that some of you may contest the moral and ethical basis for the conclusions that I have drawn. I resorted to these debates with myself and my colleagues when faced by decisions of this nature both as a practicing pediatrician and later when heading two provincial health departments. I welcome the fact that the organizers of this meeting have seen fit to place the topic on the agenda and I would encourage ongoing debate on these difficult issues that increasingly face health professionals in South Africa today.

# **Ethical and medicolegal consequences of healthcare** rationing under budgetary constraints

Prof Mcquoid-Mason

## Introduction

This paper deals with the ethical and medico-legal consequences of harm caused to patients by healthcare administrators and providers because of healthcare rationing under budgetary constraints.[1] Liability for harm under these circumstances raises the following issues: (a) the ethical liability of healthcare administrators for causing budgetary constraints; (b) the legal liability of healthcare administrators when causing budgetary constraints; (c) the ethical liability of healthcare practitioners when providing healthcare services during budgetary constraints; and (d) the legal liability of healthcare practitioners when providing healthcare services during budgetary constraints. The paper will end with some scenarios based on real or hypothetical situations for consideration by readers or participants.

## Healthcare rationing under budgetary constraints

It is common knowledge that certain entities in the provincial public healthcare systems are almost dysfunctional because of budget overruns, negligence, maladministration, corruption and indifference by healthcare administrators and some healthcare practitioners.[2] The Esedimini tragedy involving the deaths of over 143 mentally ill patients[3] and the oncology crisis in KwaZulu-Natal which has caused the death of about 300 to 500 women who were originally suffering from treatable cervical cancer,[4] have been widely publicized. Both these tragedies have in part emanated from budgetary constraints caused by maladministration and corruption on the part of public sector health administrators and their political superiors.

It is intended to deal with the ethical and legal liability of both the healthcare administrators for causing the budgetary constraints and the healthcare practitioners working in a resource-starved environment.

## Ethical liability of healthcare administrators for causing budgetary constraints

Healthcare administrators who are registered with the HPCSA are subject to the ethical rules of the HPCSA whether they are acting in administrative or professional roles.[5] MECs responsible healthcare who are political appointments and are registered with the HPCSA or South African Nursing Council are also subject to the ethical rules of their professional bodies.[5]

The Public Finance Management Act[6] and Public Service Act[7] state that heads of department are responsible for the day-to-day management of public entities – not the MECs.[4] However, if MECs or politicians interfere in the day-to-day management by the heads of departments – as happened during the Esedimini tragedy and allegedly in the KZN oncology crisis – they will be held personally ethically and legally liable.[4] Healthcare administrators need to ensure that ethically their conduct is in line with the bioethical principles of patient autonomy, beneficence, non-maleficence and justice or fairness.[8] While patient autonomy may be limited by resource constraints in the public sector patients should still be informed about the limited choices available to them and allowed to decide which they want to choose.[9] When alternative health services are available (e.g. a health service is offered by an NGO) patients should be informed about them.[9] Health administrators who do not respect patient autonomy – even when it is limited – may also be violating the other principles of beneficence, non-maleficence and justice or fairness.[8] Health administrators who cause budgetary constraints through maladministration, negligence, indifference or corruption will be violating all four of the bioethical principles.[8]

## Legal liability of healthcare administrators when causing budgetary constraints

Healthcare administrators who cause budgetary constraints and harm to patients through maladministration, negligence, indifference or corruption may be criminally or civilly liable in law.[2] If they intentionally cause the death of patients – i.e. they subjectively foresee that their conduct may lead to the deaths of patients and proceed with their conduct regardless (e.g. by transferring patients to unregistered healthcare facilities for mentally ill patients or not repairing oncology machines) – they will be liable for murder.[9] If they negligently cause the death of patients – i.e. there is no legal intention but they objectively ought to have foreseen that their conduct may cause death – they will be guilty of culpable homicide.[9] If they intentionally injure patients or aggravate their illness they may be criminally liable for assault. However, while there is not criminal liability for negligently causing such injury or illness, civil liability may arise.[9]

If healthcare administrators are found to have intentionally contributed the death of patients through unlawfully causing shortages of resources, they may be sued by the dependents of such patients for actual and sentimental damages suffered.[2] If they negligently contribute to the death of patients through unlawful conduct causing scarce resources, they may be sued by the patients' dependents for pecuniary loss - not sentimental damages.[2] If they intentionally injure patients or aggravate their illness through their unlawful conduct causing resource shortages, they may be sued by the harmed patient for pecuniary loss and sentimental damages.[2] If they negligently cause such injury or illness by unlawfully causing a scarcity of resources, the harmed patient can sue them for the pecuniary loss suffered plus pain and suffering.[2]

## Ethical liability of healthcare practitioners when providing healthcare services during budgetary constraints

Ethically healthcare practitioners are required to comply with the ethical standards of their professional bodies - even when there is a shortage of resources (e.g the HPCSA or SA Nursing Council). The most useful framework for determining whether healthcare practitioners are following the ethical standards of their professions is to measure their conduct against the bioethical principles.[8] Thus when faced with a shortage of resources practitioners need to ask themselves whether they are:

(a) Respecting the autonomy of their patients – within the resources available – by informing them of the limited options that can be offered and allowing them to choose.

(b) Acting to the benefit of their patients – by doing the best they can within the limited resources.

(c) Not harming their patients –by ensuring that they use the limited resources in a manner that does not harm their patients.

(d) Treating all patients justly and fairly – by ensuring that there is a fair distribution of the limited resources amongst them without unfair discrimination.

## Legal liability of healthcare practitioners when providing healthcare services during budgetary constraints

The test of whether a healthcare practitioner is legally liable is judged by how a reasonably competent practitioner in his or her field would have

behaved in a similar situation.[11] In the case of budgetary constraints and shortages of resources the test will be:

> Has the healthcare practitioner conducted himself or herself in the manner that a reasonably competent practitioner in the same field, faced with the same shortage of resources, would have acted.[12]

If the answer is in the affirmative the healthcare practitioner concerned will not be held legally liable. If the answer is in the negative they will be liable for the types of damages mentioned above (see above para 4). The court will decide whether or not such healthcare practitioner had acted lawfully based on the evidence of the medical experts. However, the court always has the discretion to make up its own mind on whether or not such evidence is tenable.[13]

## Conclusion

Ethically healthcare administrators and political appointees registered with professional bodies can be held liable for unlawfully causing budgetary constraints. Legally healthcare administrators who unlawfully contribute to budgetary constraints causing harm to patients may be criminally and civilly liable. The professional bodies may discipline healthcare administrators and practitioners registered with them, if such practitioners contravene the body's ethical rules when providing healthcare services during budgetary constraints. Healthcare practitioners who fail to act like reasonably competent practitioners in their field of practice when faced with similar budgetary constraints may be criminally and civilly liable for their conduct.

## Scenarios

**Scenario 1: Who is liable - the healthcare administrators or the healthcare practitioners and workers?**

P, who is 23 years old and at full-term pregnancy presents at a district hospital. Her transfer from a district hospital to a provincial hospital is delayed by 3 hours because of lack of transport. At the provincial hospital, a fetal monitor is not available as only 4 of the 12 are functional. Only 4 midwives are available for the 9 women in the labour ward where P is in labour with a cervical dilation of 5 cm. After 45 minutes in the labour ward, P is given the first available monitor because she had a previous caesarean section with a stillborn child. The monitor shows severe fetal distress. All 4 theatres are busy, with the first one available in only 20 - 30 minutes' time. P is sent to theatre but the porters wait 40 minutes for a lift before she arrives there. The lifts regularly malfunction and are

continually repaired rather than being replaced or upgraded. P is taken to theatre and, within 15 minutes of her arrival, is anaesthetised and the C-section commenced. The uterus is found to be ruptured, with the fetus in the abdomen. Attempts to resuscitate the child are unsuccessful. The baby could have been saved if the inter-hospital transfer had been quicker, the fetal state had been detected earlier, and there had not been a 40-minute delay for a lift. Management has regularly over a number of years been informed by clinicians at the provincial hospital of long delays in inter-hospital transfers, shortage of labour ward staff, deficiencies in fetal monitoring, and malfunctioning lifts. The excuse for these shortcomings has been lack of funds. However, the provincial health budget has been overdrawn for some years because of maladministration such as unlawful tendering practices, wasteful expenditure on travel, entertainment and study tours, high expenditure on consultants, etc., which has led to substantial cuts in expenditure on the provincial health care services.

Who is liable for what?

1. The hospitals?
2. The hospital administrators?
3. The ambulance drivers?
4. The midwives?
5. The porters?
6. The obstetricians?
7.

**Scenario 2: The Esedimini tragedy**

Mentally ill patients were transported from private psychiatric facilities 'like cattle on the back of open bakkies, to ill-equipped and unlicensed NGOs, where unqualified staff had no idea how to care for them' and 143 patients died. Evidence showed that the former MEC for health and other public health officials had ignored 'protests, pleas, warning after warning, and even court action by activists'. The former MEC in her evidence said: 'I cannot carry personal blame because I wasn't working for myself. I was an elected official'.[3]

Could the former MEC and responsible health officials be liable:

1. Ethically? If so, for breaching which ethical principles?

2. Criminally? If so, for which crimes?

3. Civilly? If so, for what damages?

## Scenario 3: The Oncology crisis

A provincial hospital purchases two state of the art oncology machines that can each treat 100 patients a day. The purchase includes a five-year service contract to ensure that the machines operate properly. At the end of the five years, the MEC for health refuses to renew the contract. An ex-employee of the department of health establishes a company that is unqualified to service the machines. The department of health contracts the newly formed company to fix them – but it is unsuccessful. The provincial heads of health departments are complicit with the MEC's in making the decisions. Hundreds of cancer patients, who in the past would have been treated with the two hospital oncology machines within two weeks of being diagnosed, now have to wait for nine months for treatment. Their cancer progresses from treatable to terminal and they die. The hospital's oncology staff leave to join the private sector because they can no longer treat cancer patients ethically and effectively as they lack the necessary equipment.[4]

Are the MEC and heads of departments ethically and legally liable? If so, for what? If not, why not?

## Scenario 4: The Paediatric ICU – failing to do more with less

A provincial hospital ICU has a paediatric ICU where the ratio of nurses is one nurse to five neonates (1:5). The recommended ratio is 1:1. A 16 week-old neonate has a tracheostomy tube on which she is dependent for ventilation. The tube becomes displaced and this is not noticed by the nurses. The neonate suffers cerebral hypoxia with irreversible brain damage and is reduced to a persistent vegetative state. The parents sue the hospital for the negligence of the nurses. The hospital defends the action. It alleges that because of a shortage of resources, instead of a 1:1 ratio there was a 1:5 ratio in the paediatric ICU. Thus the limited resources meant that and the nurses could not be held liable for negligence.[12]

1. If you were the judge how would you decide the case?
2. Would you hold the hospital liable? Why or why not?
3. If you would hold the hospital liable, what kind of damages would you award?

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3 Kotze A, Lopez Gonzalez L and Malan M. Life, death and political gain. Mail & Guardian 2018: January 26 to February 1: 15.

4 McQuoid-Mason DJ. Public health officials and MECs for health should be held criminally liable for causing the death of cancer patients through their intentional or negligent conduct that results in oncology equipment not working in hospitals. S Afr J Bioethics Law 2017: 10(2): 83-85.

5 Health Professions Act No. 56 of 1974.

6 Public Finance Management Act No. 1 of 1999.

7 Public Service Act No. 103 of 1994.

8 Beauchamp TL & Childress JF. Principles of Beomedical Ethics. 3rd ed: New York: Oxford University Press 1989.

9 Section 6 of the National Health Act No. 61 of 2003.

10 McQuoid-Mason DJ. Esidimeni deaths: Can the former MEC for health and public officials escape liability for the deaths of mental health patients on the basis of obedience to superior orders or because the officials under them were negligent? S Afr J Bioethics Law 2018: 11(1): 5-7.

11 Cf. Van Wyk v Lewis 1924 AD 438.

12 Collins v Administrator, Cape 1995 (4) SA 73 (C).

13 Michael vs *Linksfield* Park Clinic (Pty) Ltd 2001 (3) SA 1188 (SCA).