EVIDENCE BASED SURGERY – THE GOOD, THE BAD AND THE UGLY

Peter Pockney
Colorectal and General Surgeon
CONFLICTS OF INTEREST

I provide “fee for service” medical services
- Private Practice
- Medicare

I currently have, or have had recently, research funding support from
- John Hunter Hospital Charitable Trust
- Cancer Institute NSW
- HNE LHD
- CSSA
- Colleagues and Public Donation
- Ethicon
I currently receive industry hospitality and entertainment for CME activities
- Ethicon
- Applied Medical
- Sanofi
- Others

I have previously received entertainment and support for training (courses, hospitality etc) from industry including
- Ethicon
- Bard
- Cook Medical
- THD Labs
- KCI
- Others
THIS TALK

- Surgical Progress and Evidence
  - The good, the bad and the ugly
  - The surgical evidence conundrums
Evidence Based Surgery – The Good

- Peri-operative Care
- Treatment Paradigms
- Stopping interventions that don’t work
EVIDENCE BASED SURGERY - THE BAD

- “new” operations
- Case series
- “Experience”
EVIDENCE BASED SURGERY – THE UGLY

- New technologies
- Restricting Practice
- Continuing Practice
The Good – Progress in Care

- Peri – Operative Care
- Treatment Paradigms
- Stopping things that don’t work

“The rest of the text has stood the passage of time remarkably well, although it has all been subjected to careful scrutiny in the light of modern practice”
ABDOMINO PERINEAL RESECTION OF THE RECTUM

1994
- Indication: for tumours <10cm from the anal verge
- Post operative radiotherapy for involved margins
- No mention of total mesorectal excision
- Blood: 4 – 6 Units x-match, used liberally (not a surgical priority to minimise losses)
- Stay – 2-3 weeks
- Oral intake: fluids when stoma works
- Drains out – Abdominal 5-7 Days, Perineum 10-14 days
- Sutures out: 7-14 days

2014
- For tumours <5cm from the verge (lower in some)
- Neo-adjuvant chemoradiotherapy to increase clear margins
- Total Mesorectal Excision (Laparoscopic)
- Blood: G&S, rarely transfused
- Stay 5-7 days
- Oral intake: free oral intake day of surgery
- Drains – none
- Sutures - degradeable
PERI-OPERATIVE CARE

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Evidence

- All these changes have been based on high quality evidence (RCTs, well designed cohort studies, cross sectional studies)
“...the Companion to Specialist Surgical Practice has aspired to meet the needs of surgeons in higher training and practicing consultants who wish contemporary, evidence–based information on the subspecialist areas relevant to their general surgical practice...”

“Where possible, all contributors have attempted to identify evidence based references to support key recommendations within each chapter.”
EVIDENCE BASED SURGERY – THE BAD
Evidence Based Surgery – the bad

- Case Series
  - Individual surgeons enthusiasm creates a vogue for an operation or technique that is not justified by time
    - Numerous examples: Anal fistula plugs, Coronary artery stents, coronary artery ligation, etc
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‘New operations’
- When you have a new hammer, every task looks like a nail
  - Laparoscopic Aortic Aneurysm Repairs, Lap Whipples,
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Experience
- I do it like this and I have never had a recurrence/complication/leak/fistula etc
  - So why do I get these....?
EVIDENCE BASED SURGERY – THE UGLY

- Technology
  - Unproven by trials
  - Industry pushed
  - Glamour
  - “Leadership”
  - Status

- From small to large – laparoscopic humidifiers to Da Vinci robots
  - Intra abdominal mesh repairs for incisional and midline hernias
  - Inadequately evaluated joint replacements
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  - Some things are truly personal (feel, familiarity, length of experience)
  - For some things the evidence just doesn’t help, and probably won’t
EXAMPLE

- Inguinal Hernia Surgery
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  - Four basic approaches
**Example**

- Inguinal Hernia Surgery
  - Four basic approaches
    - Open mesh repair (aka Lichtenstein)
    - Open non mesh repair
    - Laparoscopic trans abdominal repair (TAPP)
    - Laparoscopic totally extra-peritoneal repair (TEP)
Example

Inguinal Hernia Surgery

- Four basic approaches
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  - Open non mesh repair
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- Multiple trials, multiple systematic reviews and meta analyses
Open vs Open with Mesh

- Shouldice etc vs Lichtenstein etc

- Cochrane Database of Systematic Reviews 2002(4): CD002197
  - Mortality – no difference, low incidence
  - Pain >3/12 – Mesh better than no mesh, Odds Ratio 0.68 (95% Conf Interval 0.47-0.98)
  - Recurrence - Mesh better than no mesh, OR 0.37 (CI 0.26 – 0.51)
But..

- **Expert Case Series**
  - Shouldice type repairs match the Mesh repairs (expert surgeon effect) so

- Sutured repairs (by experts) are still ‘allowed’ by guidelines e.g. European Hernia Society

- How do you get to be an “expert” if, by implication, your learning curve will be as a non-expert, and hence likely with a higher recurrence rate
Open vs TEP Repair vs TAPP

- Important Outcomes
  - Dead vs Not Dead – No difference
Open vs TEP repair vs TAPP

- Chronic Pain
  - TAPP and TEP better than Open
    - Relative risk 0.66, 95% CI 0.51 – 0.87, P=0.003
  - TAPP better than Open
    - Relative Risk 0.66, 95% CI 0.5 – 0.87, p=0.003
  - Open no different to TEP
    - RR 0.81, 95% CI 0.45 – 1.44, p=0.465
Open vs TEP Repair vs TAPP

- Recurrence of Hernia
  - TAPP = Open,
    - Rel Risk 1.14, 95% CI 0.78 – 1.68, P=0.49
  - TEP worse than Open (and by implication, worse than TAPP)
    - Rel Risk 3.72, 95% CI 1.66 – 8.35, P=0.001
Eklund et al, BJS, 2006, 1060 - 1069
41.6% of all the TEP vs Open repairs in the meta analysis

1 surgeon (of 22) responsible for 1/3 (7 of 21) of all recurrences – reported in 2009 (Annals of Surgery, 2009, 33 – 38)

With that surgeon excluded, this trial had a RR between Open and TEP of 1.3-2.4, p=0.109, hence not significant, but still in favour of open

Would it be enough to alter the meta analysis – cleverer person than me would need to test, but I doubt it
**Open vs TEP Repair vs TAPP**

- Serious adverse events (operative complications)
  - Open and TEP equal, TAPP worse than Open or TEP
    - TEP vs Open: Rel Risk 1.05, 95% CI 0.85 – 1.3, P=0.667
    - TAPP vs Open: Rel Risk 1.47, 95% CI 1.18 – 1.84, P<0.001

Pick your risk
- Open – Pain
- TAPP – Complications
- TEP - Recurrence
So....do I want an expert open surgeon to do a non mesh repair, or
? 

- So….do I want an expert open surgeon to do a non mesh repair, or
- A regular surgeon (with 10 – 15 years training and experience) to do a TAP repair and guarantee no major complications or
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A better than average surgeon to do a TEP repair
THANK YOU