FAST TRACK PELVIC SURGERY – WHAT IS EVIDENCE BASED?

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Evidence Based Medicine, EBM

- A group of clinicians and epidemiologists based at McMaster University, Canada: “…It’s about integrating individual clinical expertise and the best external evidence…” Sackett et al. Evidence based medicine: what it is and what it isn’t. BMJ 312:71, 1996


- “…EBM clearly has a place, it does not have all the answers…”

- Well?
EBM and Randomized Clinical Trial, RCT

- Experimental methods (RCTs) are "gold standard" for evaluation


- However - there are several limitations related to RCTs within surgical research
RCTs and surgical research – limitations and problems


1. History – does not favour RCTs
2. Technical problems
   - learning curve
   - surgeons’ experience / skills
   - surgeons’ preferences
   - patients preferences
   - blinding: procedure / outcome assessores
   - exact defination of the procedure
3. More general level problems
   - external validity low
   - surgeons unrepresentative / enthusiasts
   - setting atypical (e.g. univ. hospital)
   - patients atypical: inclusion / exclusion criterias
   - treatment atypical – better care
   - not large enough – infrequent outcomes
   - outcome far in the future (follow-up time)
Thus - RCTs generally offer an indication of the efficacy of an intervention rather than its effectiveness in everyday practice.

Observational studies generate clinical uncertainty, generate hypothesis, and allow identification of the structures, processes and outcomes that should be measured in a trial.

Black N. Why we need observational studies to evaluate the effectiveness of heath care. BMJ 1996;312:1215-8
Level of evidence

A. Strong evidence – several high quality studies with uniform results
B. Moderate evidence – at least one good quality study and several modest studies
C. Scant evidence – at least one good quality study
D. No evidence – expert opinion
Cochrane Database

- Fast track surgery and gynecology: 0.
- Day care surgery and gynecology: 1 – IUD; not relevant
- Prolapse surgery: 11 hits, 5 related to gynecology
- Ambulatory gynecological surgery: 23 hits – mostly anesthesiological studies
- Office procedures: 123 hits
Definitions

- Fast track: 24-48 hr
- Day surgery: during the same day
- Office surgery?
One-stop gynecological clinics

- Menorragia / postmenopausal bleeding services (UK)
  - transvaginal ultrasound / outpatient hysteroscopy / endometrial biopsy
  - patient satisfaction high (Abu JJ et al. BJOG 2001)

- Infertility (endoscopy based: transvaginal hydrolaparoscopy - Belgium, UK)
  - patients tolerate minimal access procedures better than traditional investigations (Tahir MM et al. BJOG 1999, Gordts et al. Human Reproduction 2002)
Common procedures done by fast-track setting


1. Hysteroscopy
2. Colposcopy – cervical loop excision
3. Endometrial ablation
4. Laparoscopy
5. Sterilization
6. Suburethral sling insertion
7. Peri-urethral injection
8. Infertility investigations
9. Oocyte collection
Newer developments in ambulatory gynaecological procedures


1. Vaginal hysterectomy
2. Prolapse repair under local anesthetic
3. Oncology
1. Hysteroscopy, operative hysteroscopy

- There is a consensus that hysteroscopy can be offered as a first-line office diagnostic procedure (Campo et al. Human Reproduction 2005)

- RCTs have demonstrated the superior efficacy, safety, cost-effectiveness and patient satisfaction of office hysteroscopy compared with its day-case counterpart (Marsh F et al. BJOG 2004, Kremer C et al. BMJ 2000)

- Operative hysteroscopy: “…the choice of approach depends on the endoscopic experience of the gynecologist and the availability of equipment…”
2. Colposcopy – cervical loop excision

- The see-and-treat strategy
- Obs. the risk of preterm delivery in subsequent pregnancies
- No RCTs comparing outpatient with inpatient or day-case cervical loop excision

3. Endometrial ablation

- Most endometrial ablation techniques are performed as day surgery
- Thermal balloon ablation is feasible in the outpatient setting (Clark TJ et al. Fertility and Sterility 2004)
4. Laparoscopy and
5. Sterilization

- Observational studies: minilaparoscopy under local anaesthesia has been used successfully (Zupi E et al. J Am Ass Gyn Laparoscopists 1999)

- Hysteroscopic sterilization and COCHRANE: 0.

  - RCT: difficult to perform? - N=89; ratio 2:1 was undertaken
  - 81% successful bilateral device placement
  - When successful greater overall patient satisfaction
  - However, the devices cannot be bilaterally placed in all cases and some women do not tolerate the procedure awake
6. Suburethral sling insertion

- Scandinavia vs. the rest of the world
  - TVT vs conventional methods
  - TOT vs TVT: RCTs on going (Finland, Austria)

- Local anesthesia, peroperative stress test etc.

- "Cook book" by Ulf Ulmsten
7. Peri-urethral injection

- ‘...as an outpatient procedure, provided that the patient is eligible for the ambulatory setting...’ Kuhn A Schweizerische Rundschau fur Medizin Praxis (Review) 2004

8. Infertility investigations

- HSG, saline infusion sonohysterography, THL (transvaginal hydrolaparoscopy)

9. Oocyte collection
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1. Vaginal hysterectomy

Litterature:

2. Bran DF et al. AORN Journal 1995
5. El-Shawarby SA, Kelleher C BJOG 2007
6. Penketh et al. BJOG 2007
1. Vaginal hysterectomy

  - A cross-sectional analysis a total 23,191 records
  - Conclusion: of the three techniques examined (TAH, LAVH, VH) vaginal hysterectomy provides the best patient outcomes, with the shortest hospital stays and lowest complication rates, at the lowest cost.

  - N=412; 93 % were discharged within 12 hours of admission

- Penketh R, Griffiths A, Chawathe S. A prospective observational study of the safety and acceptability of vaginal hysterectomy performed in a 24-hour day case surgery setting. *BJOG 2007;114:430-6*
  - N=71; nonprolapse indication: intraoperative complication rate 1.4 % / readmission rate 6.2 %
1. Vaginal hysterectomy

However – at present time no RCTs available comparing conventional and fast track approach.
2. Prolapse repair under local anaesthetic

Next speaker from Denmark – I hope…since…
At least five studies published between 2001–2007?

Kuhn A, Gelman W, O’Sullivan S, Monga A. The feasibility, efficacy and functional outcome of local anaesthetic repair of anterior and posterior vaginal wall prolapse.


- N=130, minimum st II prolapse (KA, KP or both)
- Mean follow-up 30 months
- 98.4 % found the procedure very acceptable and would recommend it to a friend
3. Oncology

- The role of ambulatory laparoscopic techniques in gynecological oncology is not well defined
- Staging
- Radical hysterectomy
- Second-look laparoscopy following chemotherapy
Benefits / drawbacks

- Number of women treated increases
- Exposure to hospital infections decreases
- Less disruption to personal life
- Potential cost-savings
- Rapid return to daily activities / work

- Risk management mandatory
- Pain control (26 %)
- Minor medical problems after discharge (23 %)
- Re-attend rate 8 % (general surgery)

- 25 procedures, 13 hospitals, N= 5069*
Conclusions

- Enough evidence to critically evaluate our treatment procedures / habits

- Many factors influence the present and local practicities (traditions, equipments, individual skills etc.)

- Evidence based vs best possible practice