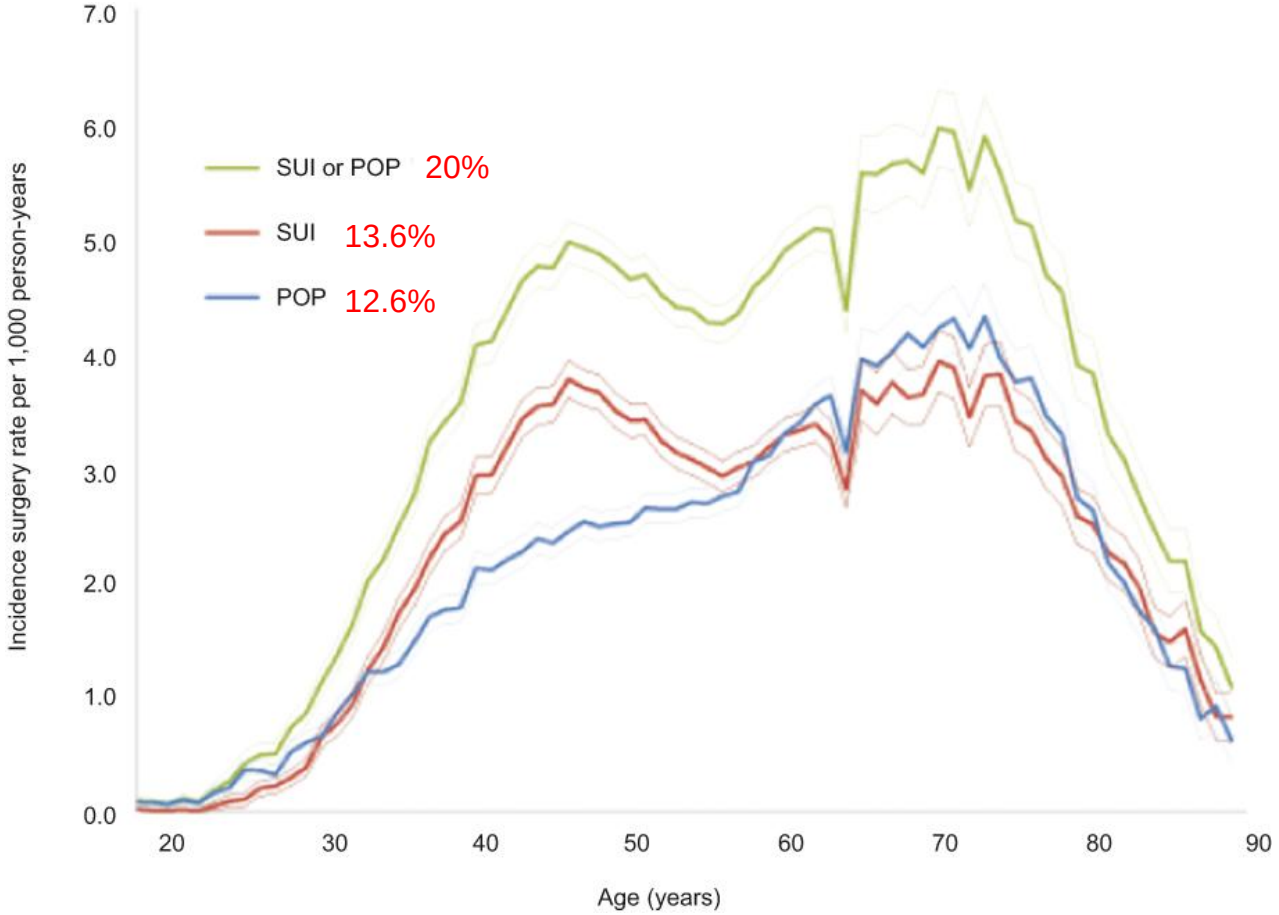
UNIVERSITY OF HELSINKI
FACULTY OF MEDICINE

Vaativa laskeumakirurgia – mitä sanoo EBM?

Tomi Mikkola
HYKS Naistenklinikka

Lifetime risk of POP surgery



- In 2007-11 evaluated 10,177,480 US women
  - 57,755 POP surgeries – by age 80 lifetime risk 12.6%

Wu et al. Obstet Gynecol, 123;1201-6, 2014

Recurrent rates after POP surgery

- With native tissue repair approximately 30%
  - anterior compartment up to 50-60%
    - Level I (apical) defect in 60%
- Native tissue repair results poor
  - improve native tissue repair – not in the past 100yrs
  - use of mesh – particularly in recurrent POP
- Rational of using mesh
  - abdominal hernia repairs
    - mesh standard of care in hernia repair
    - long development of material/methods

Olsen et al. Obstet Gynecol 1997
DeLancey et al. 2006
Amato et al. Cochrane 2009

Mesh in POP surgery

- First vaginal mesh for POP surgery approved by FDA in 2002
  - rapid increase in use after 2005
  - also laparoscopic/robotic techniques evolved
    - by 2009 surpassed the abdominal approach
- Flaws in the initiation of vaginal mesh surgery
  - no routine follow-up/ report of adverse events
  - industry driven training/marketing of “simple kits”
  - “in my hands” one center publications

Abed et al. Int J Urogynecol 2011
Skoczylas et al. Int J Urogynecol 2014

FDA warnings

Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication

"*erosion of mesh through the vagina is the most common and consistently reported mesh-related complication from transvaginal POP surgeries using*"

"*Both mesh erosion and mesh contraction may lead to severe pelvic pain"*

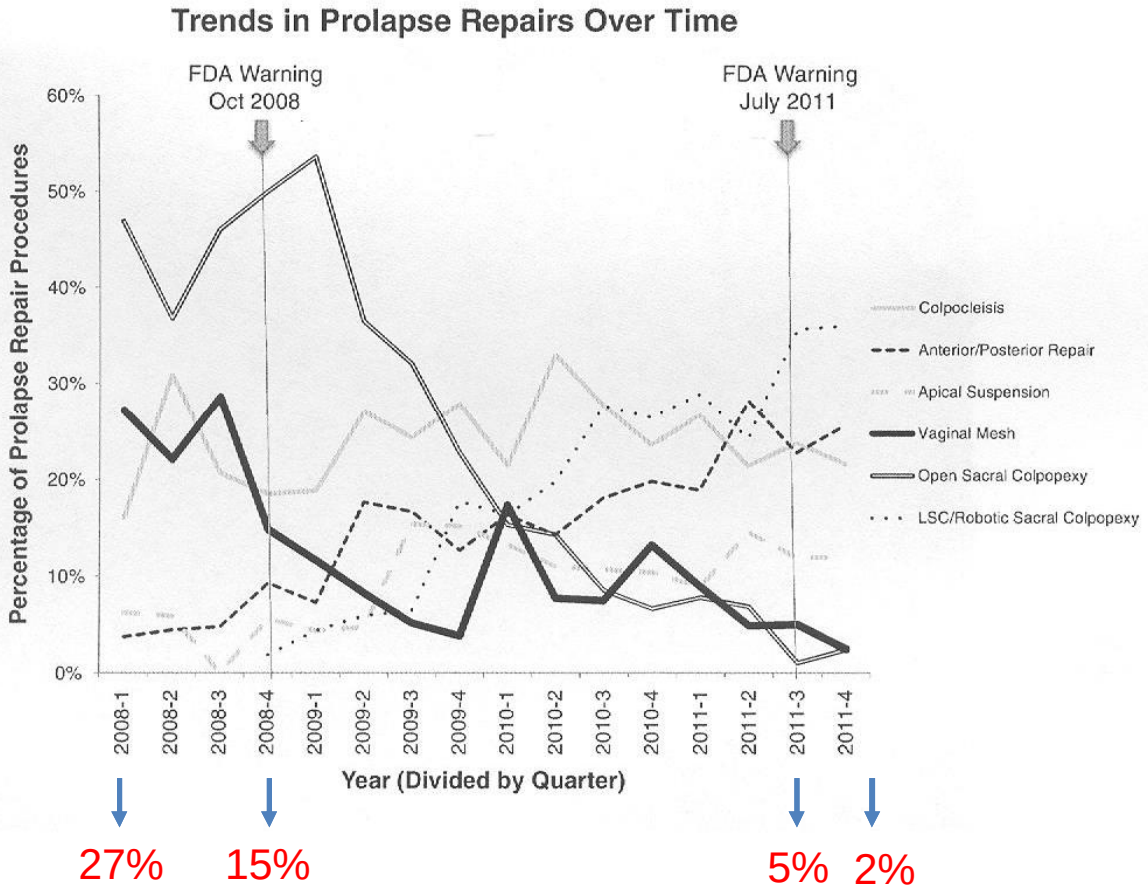
FDA 2008 and 2011

- Systematic review of complications
  - wound granulation 8%
  - erosion 10%
  - dyspareunia 9%

Abed et al. Int J Urogynecol 2011

FDA warnings

Fig. 1 Trends in prolapse repairs from 2008 to 2011 at the University of Pittsburgh Medical Center ($n = 1{,}385$ prolapse repairs)



Vaginal mesh use decline p=0.001

Skoczylas et al. Int J Urogynecol 2014

Where are we today?

- Positive aspects
  - studies required prior to introducing new products
    - development of products – less mesh, apical support, etc.
    - evaluation of subjective results
    - more multicenter large scale studies (?)
  - centralization of mesh surgery started
    - hopefully less “wannabe” POP-surgeons
    - discussion/recommendations about skills and volume
  - more critical in patient selection
    - mainly in recurrent POP

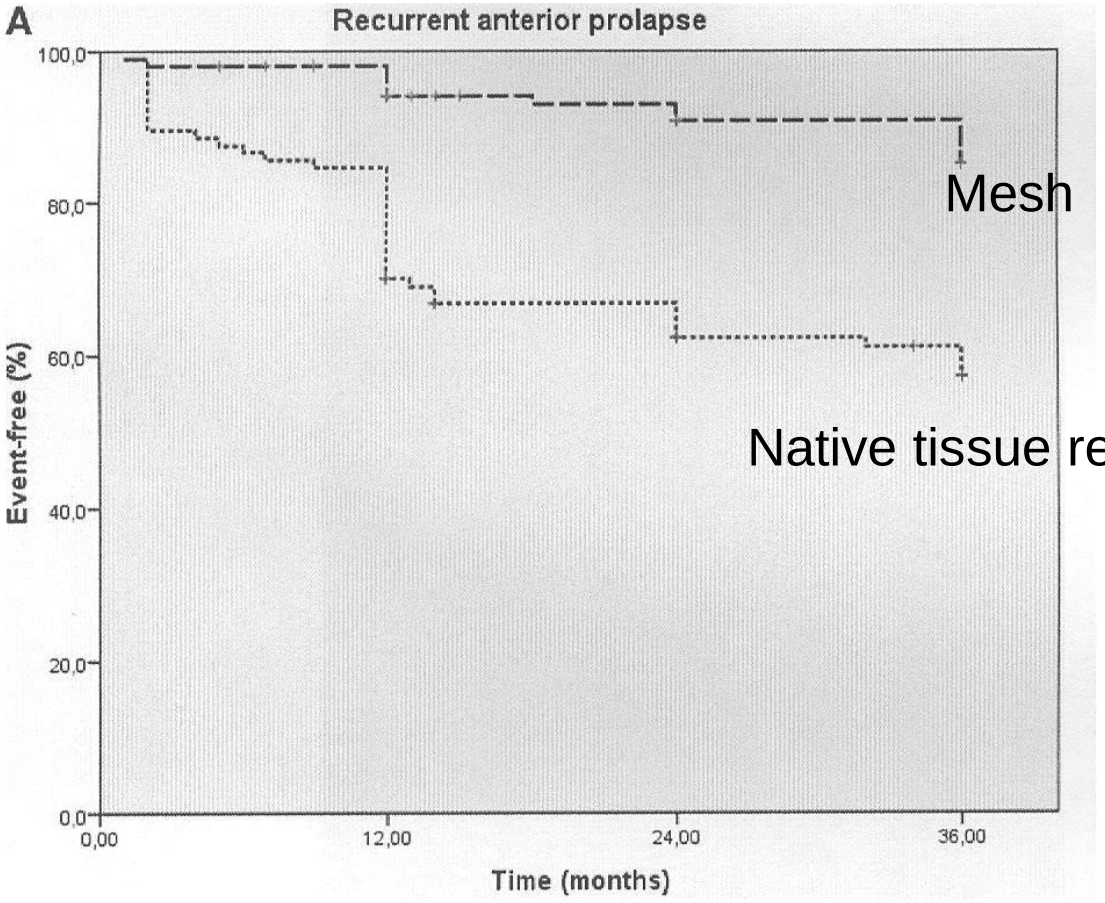
Where are we today?

- Negative aspects
  - in some countries mesh use completely stopped
    - results of native tissue repair remain poor
    - seeking arguments to not use mesh hardly improves patient care
  - “hostile” debate about the rational of using vaginal vs. laparoscopic/robotic mesh (or no mesh)
    - instead we need objective data
  - patients who require mesh for POP are afraid
- More importantly – where should we go?

Key questions

- Should we discard vaginal mesh in POP surgery?
  - back to native tissue repair?
- Should we use mainly laparoscopic/robotic approach?
  - do we have data?
- What type of mesh to use?
  - current development/understanding?
- Patient/surgeon selection?
  - risk factors?

Native tissue repair vs. mesh

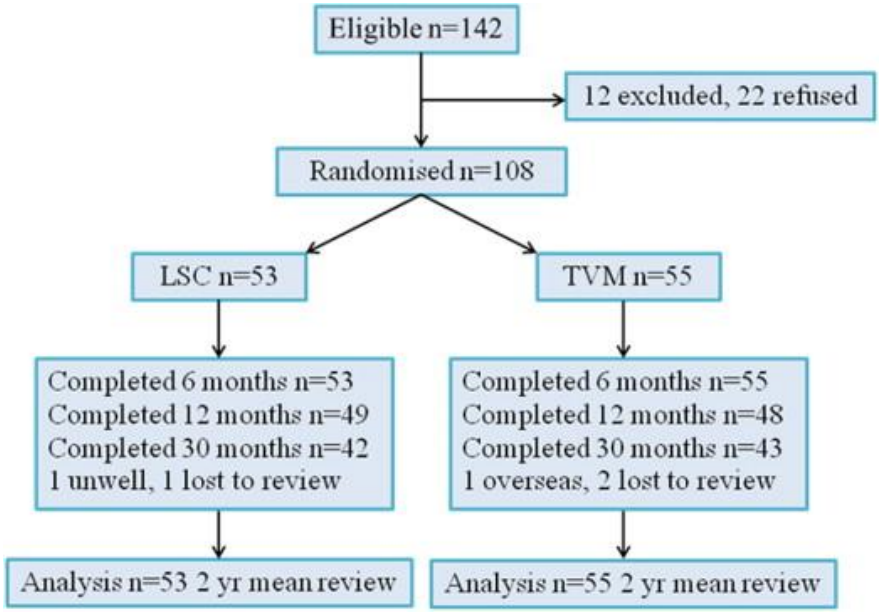


p<0.0001

- 202 women - anterior colporraphy vs. tailored mesh
  - in 3 year follow-up failure if POP-Q Aa/Ba stage II

Nieminen et al. Am J Obstet Gynecol, 2010

Laparoscopic/robotic approach?



- Only one randomized study LSC vs. TVM
  - 1 erosion in LSC vs. 5 in TVM
  - satisfaction 87% in LSC vs. 79% in TVM
  - operating time 97min in LSC vs. 50min in TVM
  - LSC better? – in hands of an expert laparoscopist
- Robot in POP surgery – expensive "toys for the boys"

Maher et al. Am J Obstet Gynecol 2011
Paraiso et al. Obstet Gynecol 2011

What type of mesh to use?

- Type I macroporous (pore size > 75µm)
- Vaginal mesh retraction correlates with pain
  - is it contraction/shrinkage or folding?
  - also partially behind erosions?
- Mesh size!
- Apical support!

Rogowski et al. Int J Urogynecol 2013

Mesh/patient/surgeon selection

- Prolift® vaginal mesh (n=294)
  - anterior 71 (24%)
  - posterior 110 (37%)
  - anterior and posterior/ total 113 (38%)

- Independent risk factors for mesh exposure (12%)
  - smoking OR 3.1 (1.1 – 8.7)
  - total mesh OR 3.0 (1.2 – 7.0)
  - Surgeons experience OR 0.5 (0.3 – 0.8) per 10yrs

Withagen et al. Obstet Gynecol 2011

Nordic TVM Group

- 12 month RCT - colporraphy (n=189) vs. Prolift® anterior (n=200)
- POP-Q stage 0-1 and symptomless
  - colporraphy 35% vs. TVM 61% (p< 0.001)
- Erosion needing surgical revision
  - colporraphy 0 vs. TVM 6 (3%) (p< 0.03)

Altman et al. N Engl J Med 2011

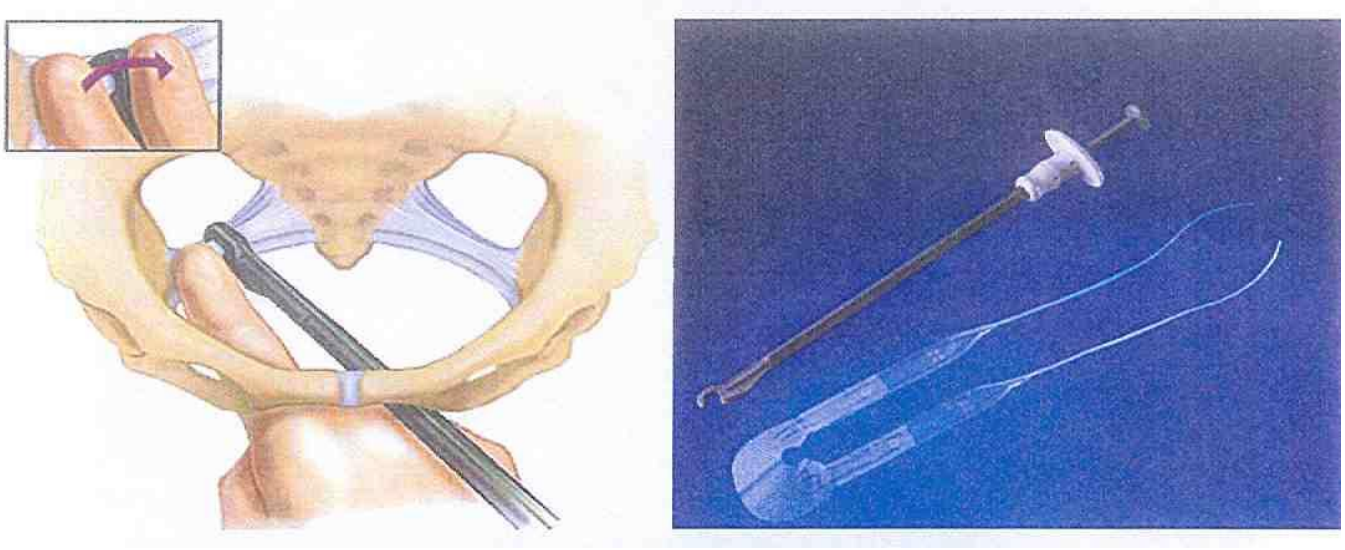
Importance of apical support

POP surgery 1999 (n=3244)	Re-operation after 10 years
Anterior colporraphy	20%
Anterior colporraphy and apical support	11% (p< 0.01)
Posterior colporraphy	15%
Posterior colporraphy and apical support	10%

Eilber et al. Obstet Gynecol 2013

Advanced vaginal approach

- Smaller vaginal mesh with apical support
  - Uphold® - after dissection the suturing device is used to pull the mesh through the sacrospinous ligament, medial to the ischial spine



- Preliminary data from one center/surgeon
  - median follow-up 12 (0.4–30.9) months - promising anatomical and QoL results
  - erosion 2.6 %

Vu et al. Int Urogyn J 2012

Nordic TVM Group

- Prospective, multicenter (24 clinics – Sweden, Norway, Denmark, Finland), open-label, single cohort feasibility study of Uphold LITE ®
- Inclusion - primary or recurrent ≥ stage 2 prolapse of the middle compartment (vaginal/uterine) with or without cystocele
- Primary outcome – complications
- Secondary outcome – anatomy and symptoms

Conclusions

- Native tissue repair results poor
  - particularly in anterior/apical defects
- Mesh in recurrent POP surgery is needed
- Laparoscopic sacrocolpopexy is an option
  - particularly in posterior/apical defects
- In vaginal approach small/light mesh with apical support

Conclusions

- The use of mesh in pelvic reconstructive surgery need to be centralized
  - sufficient volumes/skills
- More high quality multicenter studies needed
  - the ideal method in POP surgery remains to be developed

Clinical approach

- Good diagnostic and native tissue repair skills
  - colpocleisis and sacrospinous fixation should not be forgotten
- Mesh mainly in recurrent POP surgery
  - apical support crucial
- Both vaginal and laparoscopic methods should be used
  - vaginal mesh mainly in anterior/apical defects
  - laparoscopic mesh mainly in posterior/apical defects