An update on the current treatment controversies for stress urinary incontinence and pelvic organ prolapse

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Hysterectomy or uterine preservation

Native tissue or mesh

Minimal access or open

Concomitant surgery?

Recurrences?

Mesh removal surgery??
• Natural history progression of prolapse and incontinence
• 20% Lifetime risk of surgery
• High re-operation rates (up to 30%)

- Wu JM et al.. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. Obstet Gynecol. 2014
• 1963 polypropylene mesh hernia repair
• 1987 Lichtenstein reports outcomes of 6000 hernia repairs
• Safety of mesh in hernias
• 1992 Mesh colpopexy (Timmons et al.)
• 1996 Vaginal mesh for recurrent prolapse
  (TM Julian et al)
• 1996 ProteGen sling approved  
  (Boston Scientific) - woven polyester sling  
• 1998 J & J clearance for Gynecare TVT  
• 1996-2008 Numerous FDA approved  
  transvaginal mesh kits (FDA’s 510(k) process)
• FDA enforcement report – higher than expected rates of vaginal erosion and dehiscence
• By 2003 BS settles more than 700 cases of ProteGen (undisclosed)
Authors' conclusions

The data on sub urethral sling operations remain too few to address the effects of this type of surgical treatment. Few trials are reported by authors in a complete fashion and most information came from abstracts presented in annual meetings. The broader effects of suburethral slings could not be established since trials did not include appropriate outcome measures such as general health status, health economics, pad testing, third party analysis and time to return to normal activity level. Data obtained from thirteen trials did not provide reliable estimates because of their sizes, and heterogeneity of designs, populations studied, and types of comparisons made.

Reliable evidence on which to judge whether or not suburethral slings are better or worse than other surgical or conservative management is currently not available.
NICE Guidance

Stresses the need to inform women of the lack of long term outcomes data
Adequately powered randomised controlled trials are urgently needed.

344 randomised
5 years outcomes
1.7 % mesh complications; 81% cure rates
**Vaginal Mesh for Prolapse: A Randomized Controlled Trial**

Iglesia, Cheryl B. MD; Sokol, Andrew I. MD; Sokol, Eric R. MD; Kudish, Bela I. MD; Gutman, Robert E. MD; Peterson, Joanna L. RN; Shott, Susan PhD

Obstetrics & Gynecology: August 2010 - Volume 116 - Issue 2 - p 293-303

**CONCLUSION**: At 3 months, there is a high vaginal mesh erosion rate (15.6%) with no difference in overall objective and subjective cure rates. This study questions the value of additive synthetic polypropylene mesh for vaginal prolapse repairs.
Beginning of the storm

Ivilina Pandeva
IUGA Symposium 30 June 2019
• 2005 – 2008: The FDA receives over 1,000 reports of transvaginal mesh injuries
• 2008: FDA first vaginal mesh safety alert
• 2008 – 2010: The FDA continues to receive over 2,800 adverse event reports of vaginal mesh injuries.
Urethral TOT mesh exposure
FDA Safety Communication:
Date issued: July 13, 2011,

..from Jan. 01, 2008 through Dec. 31, 2010, the FDA received 2,874 additional reports of complications associated with surgical mesh devices used to repair POP and SUI, with 1,503 reports associated with POP repairs and 1,371 associated with SUI repairs. Although it is common for adverse event reporting to increase following an FDA safety communication, we are concerned that the number of adverse event reports remains high.

The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are not rare.

From 2008 – 2010, the most frequent complications reported to the FDA for surgical mesh devices for POP repair include mesh erosion through the vagina (also called exposure, extrusion or protrusion), pain, infection, bleeding, pain during sexual intercourse (dyspareunia), organ perforation, and urinary problems. There were also reports of recurrent prolapse, neuro-muscular problems, vaginal scarring/shrinkage, and emotional problems. Many of these complications require additional intervention, including medical or surgical treatment and hospitalization.

FDA 2011 recommends implants for POP reclassification from moderate to high risk

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An Indiana jury hit Johnson & Johnson (NYSE:JNJ) subsidiary Ethicon with a $35 million verdict in a product liability lawsuit brought over its Prolift pelvic mesh.

Jury hits Ethicon with $3.25 mln verdict in mesh case
I told my husband he could sleep with someone else: Mother-of-two, 43, can no longer have sex and depends on a mobility scooter after being fitted with controversial vaginal mesh implant

Vaginal mesh left me in agony. When will women's health be taken seriously?

Kath Sansom

Hundreds of women left with health in ruins after bladder mesh ops, so why is treatment still offered?
Executive Summary

1. Robust clinical governance must surround treatment, the decision to use mesh and the surgical approach used.
2. Evidence of involvement in multi-disciplinary team working, audit activity, reporting of adverse events.
3. Informed consent is a fundamental principle underlying all healthcare.
4. The lack of extended long term follow up and related outcome data, including information on quality of life and activities of daily living, should be addressed.
5. Good information is essential to good patient care.
6. Improving awareness of clinical teams of the possible symptoms of mesh complications together with good communication skills, (including good listening and empathy) is an essential part of good clinical care.
7. A review of the different sources of evidence led us to express concern in the use of the transobturator rather than the retropubic approach.
8. Concern both for effectiveness and adverse events, at the use of transvaginal mesh in surgery for pelvic organ prolapse.

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NHS ENGLAND MESH WORKING GROUP REPORT

includes evaluation of both the efficacy and the extent and causes of adverse incidents and complication rates associated with these types of surgery:
• Higher complication and re-operation rate
• No vaginal mesh in primary pelvic floor repair
• The results supported the use of mesh procedures for incontinence, although further research on longer term outcomes would be beneficial
- HES data between 2007-2015
- 5.9% were readmitted at least once within 5 years for further mesh intervention
- 9.8% complication rate within 5 years of the mesh procedure
'Scandal' of vaginal mesh removal rates revealed by NHS records

Traumatic complications mean one in 15 women fitted with the most common type of mesh support will require surgery to extract it, figures suggest

- Vaginal mesh implants: ‘I really thought I was dying’
Transvaginal mesh use should be suspended, health groups say

Alliance of six state and territory consumer bodies say full audit of complications is needed

Transvaginal mesh inquiry criticises Australia's medical device regulation

Failure to protect women receiving the mesh implants cast health professionals in ‘very poor light’, inquiry finds
Update on the Independent Medicines and Medical Devices Safety Review: Written statement - HCWS841

Baroness Cumberlege has reported to the Department of Health and Social Care an early finding of her review relating to surgical mesh. Following a number of engagement meetings with patients she has concluded that there should be a pause without delay in the use of surgical mesh for stress urinary incontinence (SUI).

High vigilance restrictions on use of vaginal mesh

On 10 July 2018, NHS Improvement and NHS England wrote to all acute trusts advising of the immediate implementation of a high vigilance restriction period regarding vaginal mesh.

For the majority of patients, mesh surgery should not be performed during this period of high vigilance restriction.

For some patients, mesh procedures may be the only viable treatment option. This includes cases where clinicians judge there is clinical urgency to carry out the procedure and no suitable alternative exists, and/or where delay would risk harm to the patient. However, this treatment should only be used in carefully selected patients who understand the risks and have given fully informed consent.
So where are we NOW?
Urinary incontinence and pelvic organ prolapse in women: management

NICE guideline [NG123]  Published date: April 2019

- multidisciplinary teams
- urodynamic testing in urinary incontinence
- absorbent products for urinary incontinence
- medicines for overactive bladder
- botulinum toxin A for overactive bladder
- surgical procedures for stress urinary incontinence.

- assessment and management of pelvic organ prolapse
- management of coexisting urinary incontinence and pelvic organ prolapse
- assessment and management of complications associated with mesh surgery for urinary incontinence or pelvic organ prolapse.
Surgical management of stress urinary incontinence

- Colposuspension (Open or Laparoscopic)
- Autologous fascial sling
- Paraurethral bulking if above options not acceptable
- Retropubic sling - permanent and may not be removed fully. TOT unless RPR contraindicated
• Vaginal hysterectomy
• Pelvic floor repair
• Sacrospinous fixation
• Mesh sacrocolpopexy (Laparoscopic or open)
• colpocleisis
Managing complications associated with mesh surgery

- Regional MDT
- Limited evidence on atrial and complete mesh removal
- Significant complications of mesh removal surgery
- Symptoms recurrence
- Mesh centres
Mesh introduced to overcome the shortcomings of native tissue repairs

Vaginal mesh remains suspended

Knock on effect on abdominal mesh surgery
Lessons learnt?

- More and more women request mesh removal
- Robust MDT process to manage these complex patients
PRIMUM NON NOCERE

FIRST DO NO HARM

Hippocratic Oath