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Mr Gans Thiagamoorthy

Consultant Gynaecologist and Urogynaecology Subspecialist

Mesh-free Biological Urogynaecology

Mr Gans Thiagamoorthy

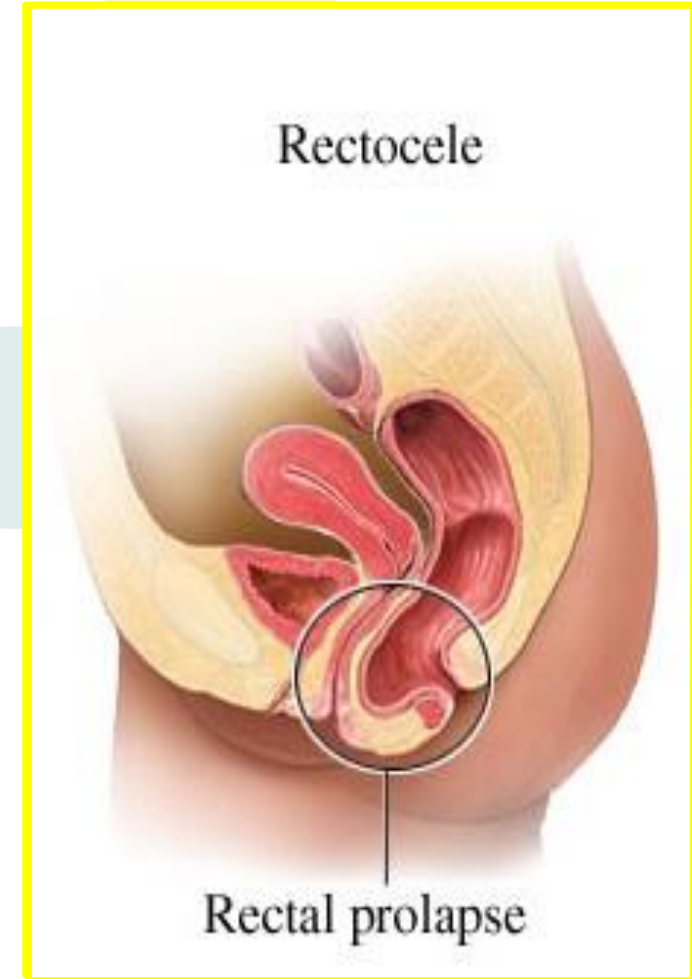
MBBS MRCOG

Consultant Obstetrician & Gynaecologist

Urogynaecology Subspecialist

Urinary incontinence and Urogenital prolapse

- Prevalence of urinary incontinence 12.8 - 46.0%
Hannerstad 2000, Botlero 2008, Onwude 2009
- Half of these women are affected by stress incontinence
Hannerstad 2000
- Prolapse is the herniation of the uterus, bladder or rectum into the vagina
- Secondary to weakness of the vaginal wall or supports of the uterus
- Both have a negative impact on QoL
Coyne et al 2003
- Women have a 11% lifetime risk of surgery for incontinence or prolapse with a re-operation rate of 29%
Olsen et al 1997



Precedent for Using Mesh

- Initial success of TVT mesh
- Meta-analysis by EU Hernia Trialists Collaboration (n=4005)
- Patients undergoing open groin hernia repair

Ulmsten 1996

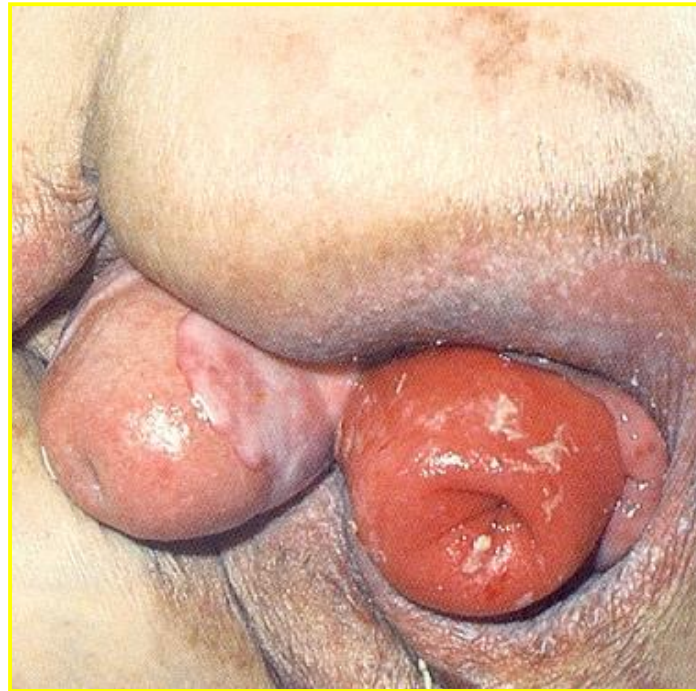
Mesh
Recurrence rate
1.4%

Vs
(P<0.001)

Non Mesh
Recurrence rate
4.4%

Br J Surg 2000

Poor inherent tissue



Vaginal Mesh: Prospect Study

- Two multicentre randomised controlled trials

Native tissue repair Vs synthetic mesh or biological graft

- 1348 women included and followed over 2 yrs
- No difference in POP-SS or QoL at 1 & 2 years
- Cumulative mesh complications in 12% of women
- Augmentation of vaginal repair with mesh or graft material did not improve outcome

Glazener et al, 2017



Scientific Committee on Emerging and Newly Identified Health Risks

SCENIHR

Opinion on

The safety of surgical meshes used in urogynecological surgery

**Scottish Independent Review
of the use, safety and efficacy
of transvaginal mesh implants
in the treatment of stress
urinary incontinence and
pelvic organ prolapse in
women**

Final Report March 2017



NICE National Institute for
Health and Care Excellence



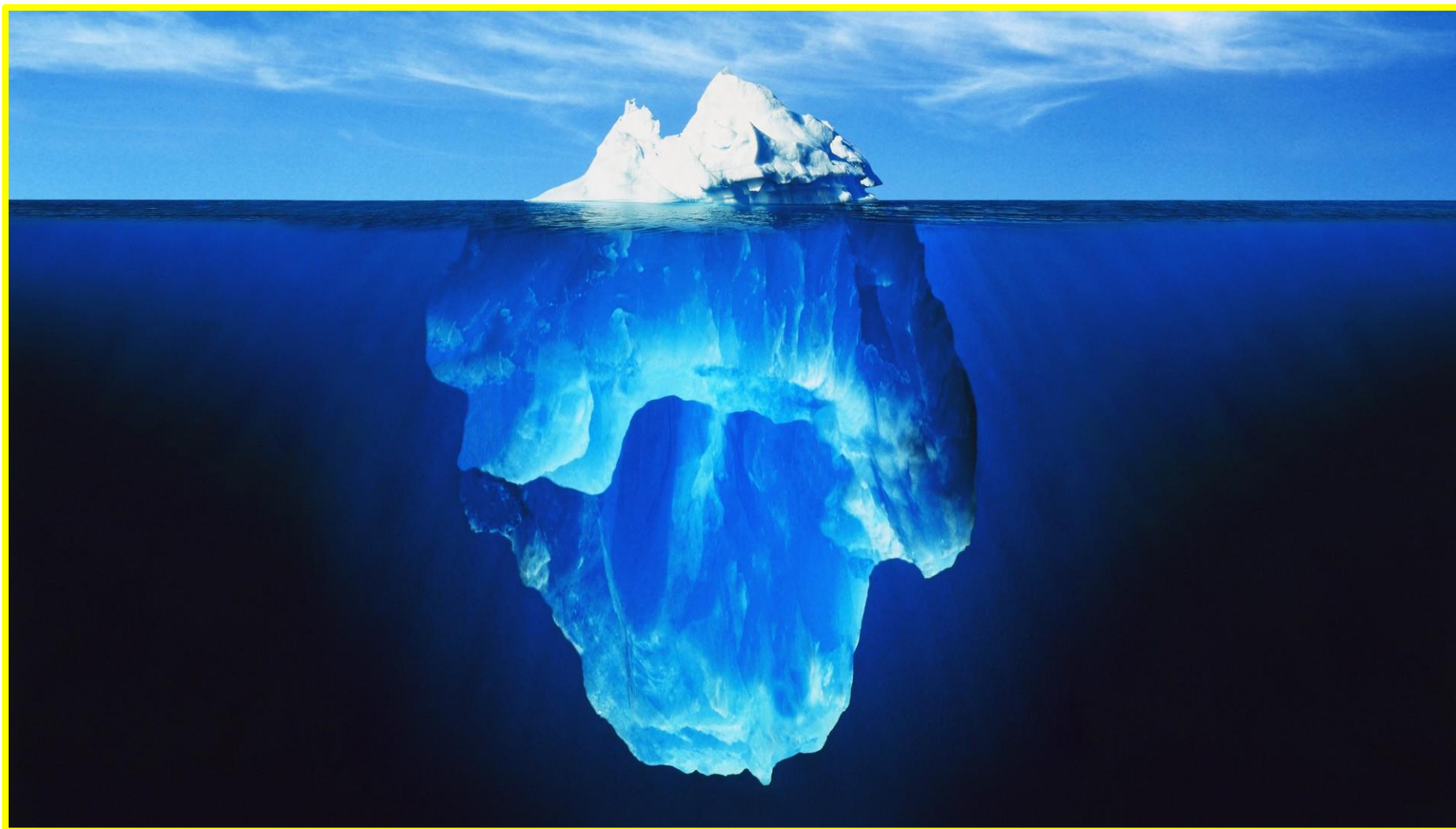
Royal College of
Obstetricians &
Gynaecologists



THE BRITISH ASSOCIATION
OF UROLOGICAL SURGEONS

Mesh Oversight Group Report

July 2017

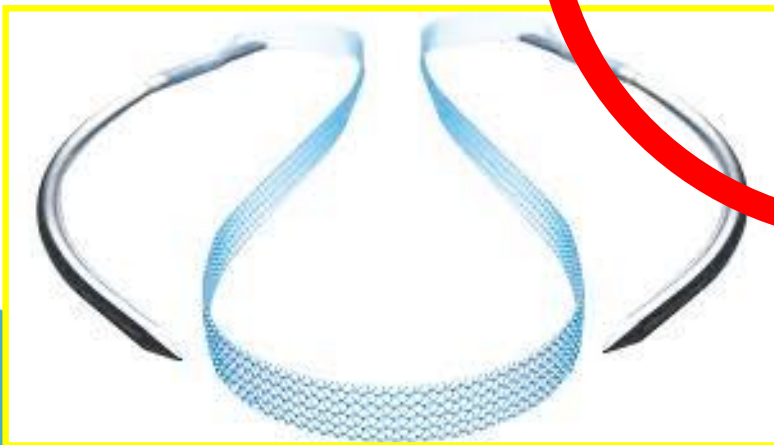
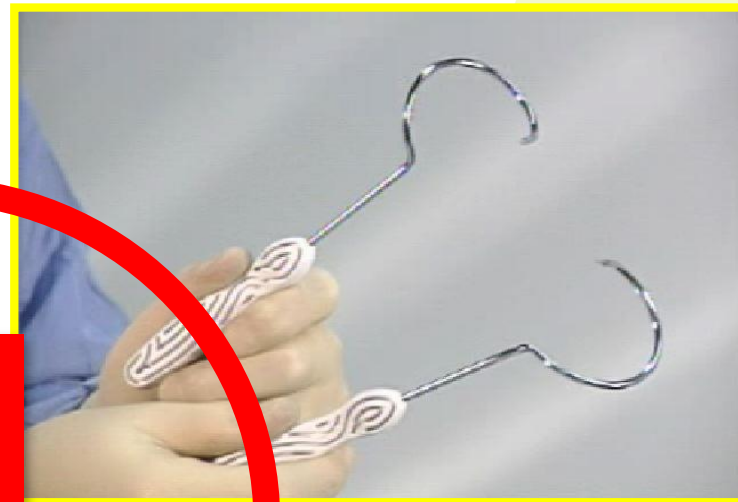
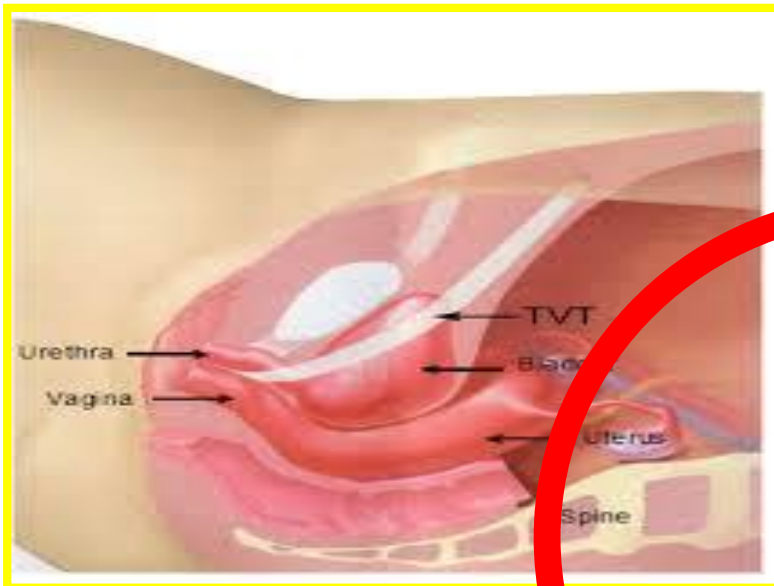


Transvaginal mesh repair of anterior or posterior vaginal wall prolapse

- Serious well-recognised safety concerns
- Evidence of long-term efficacy being inadequate
- Anterior or Posterior vaginal prolapse mesh should only be used in the context of research

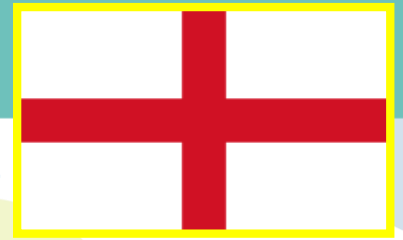
NICE, December 2017

TVT and Transobturator tapes



NHSE Pause- July 2018

- Government announced a 'pause' in the use of surgical mesh/tape to treat stress urinary incontinence (SUI) and vaginal prolapse where the mesh is inserted through the vaginal wall
- Surgeons should only undertake prolapse or urinary incontinence surgery if they are:
 - Appropriately trained
 - Work in a MDT
 - Undertake operations regularly
 - ?Subspecialist ?Tertiary centre ?Adequate Caseload
- Surgeons report every procedure to a national database
- A register of operations is maintained to ensure every procedure is notified and the woman identified who has undergone the surgery
- Reporting of complications via MHRA is linked to the register





UTERINE PROLAPSE



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Uterine prolapse

- Decreased awareness of prolapse in those undergoing vaginal hysterectomy compared to uterine sparing prolapse surgery ($p < 0.05$)

Roovers 2004

- Vaginal hysterectomy has the least risk of complications and re-operation of all prolapse operations
- On this basis, advised vaginal hysterectomy for uterovaginal prolapse rather than any abdominal/laparoscopic procedure

Scottish Independent Review 2017



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APICAL/VAULT PROLAPSE

Apical/Vault prolapse

- Sacrospinous ligament fixation- low morbidity
- Sacrocolpopexy (SC) mesh has a low but still not insignificant morbidity

6th ICI 2016

- SC with porcine graft comparable to synthetic mesh outcomes at mid to long-term follow-up

Altman 2006

- SC with autologous grafts are equally effective as with synthetic mesh

Quiroz LH 2008



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ANTERIOR/POSTERIOR VAGINAL PROLAPSE

Anterior/Posterior Prolapse

- Native tissue repair- ‘Double breasted technique’

Fairclough 2017
- Absorbable biological graft (Permacol) vs Native tissue repair
 - Improved QoL and at median follow-up 487 days, no subjective prolapse concerns

Araklitis, BSUG abstract 2016
- “Further research is required to determine whether surgical technique and type of graft used impact surgical outcome and complications”

Nguyen 2008

Obliterative surgery: Colpocleisis

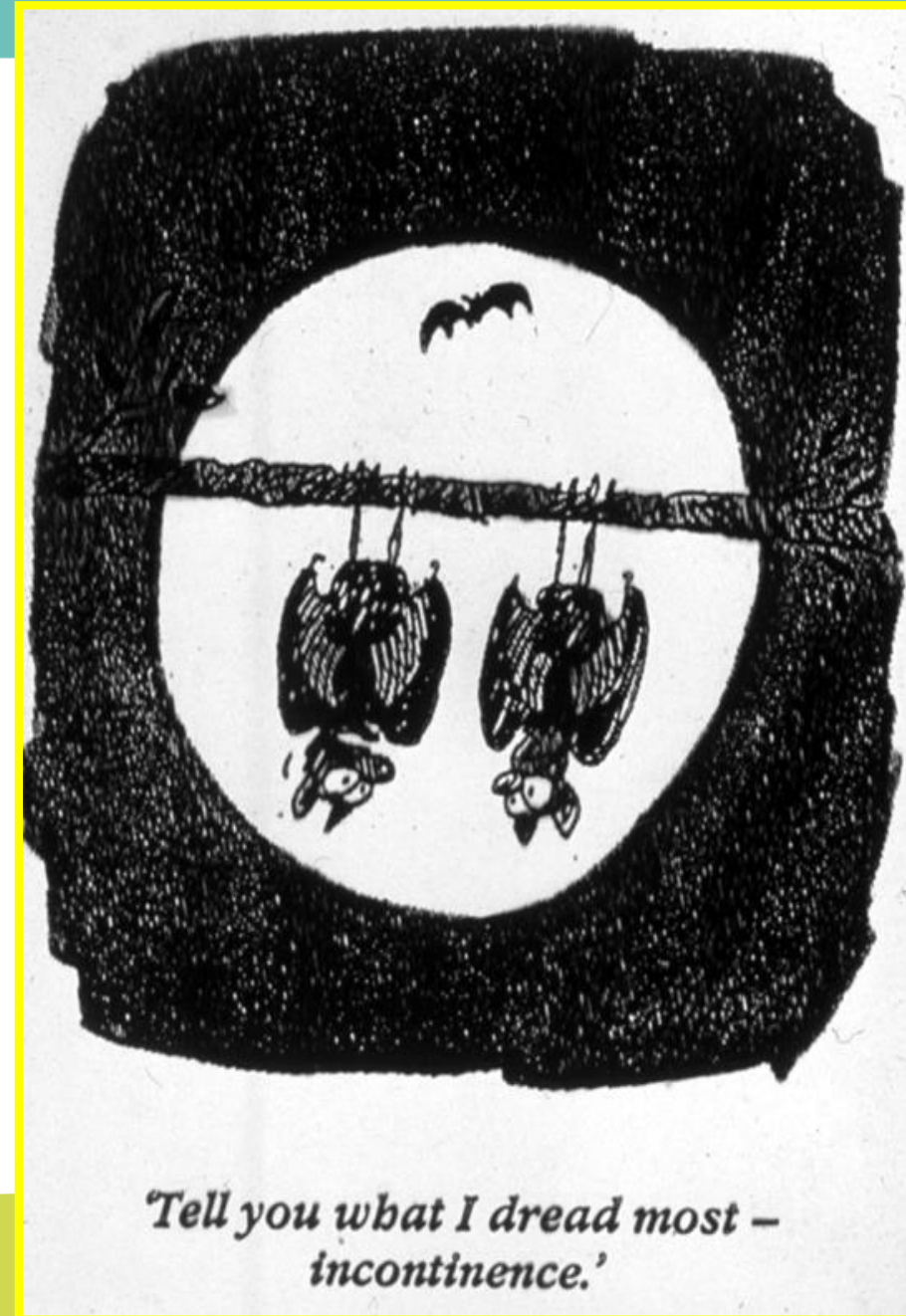
Advantages

- Quick (~40minutes operating)
- Success rate almost 100%
FitzGerald et al 2005
- Associated with high patient satisfaction
Glavind et al 2005
Wheeler et al 2005

Disadvantages

- No further intercourse
- Associated with increased incidence of SUI but rate of re-operation unknown
FitzGerald et al 2005
- Pyometra may develop in women retaining their uterus
Roth et al 2007

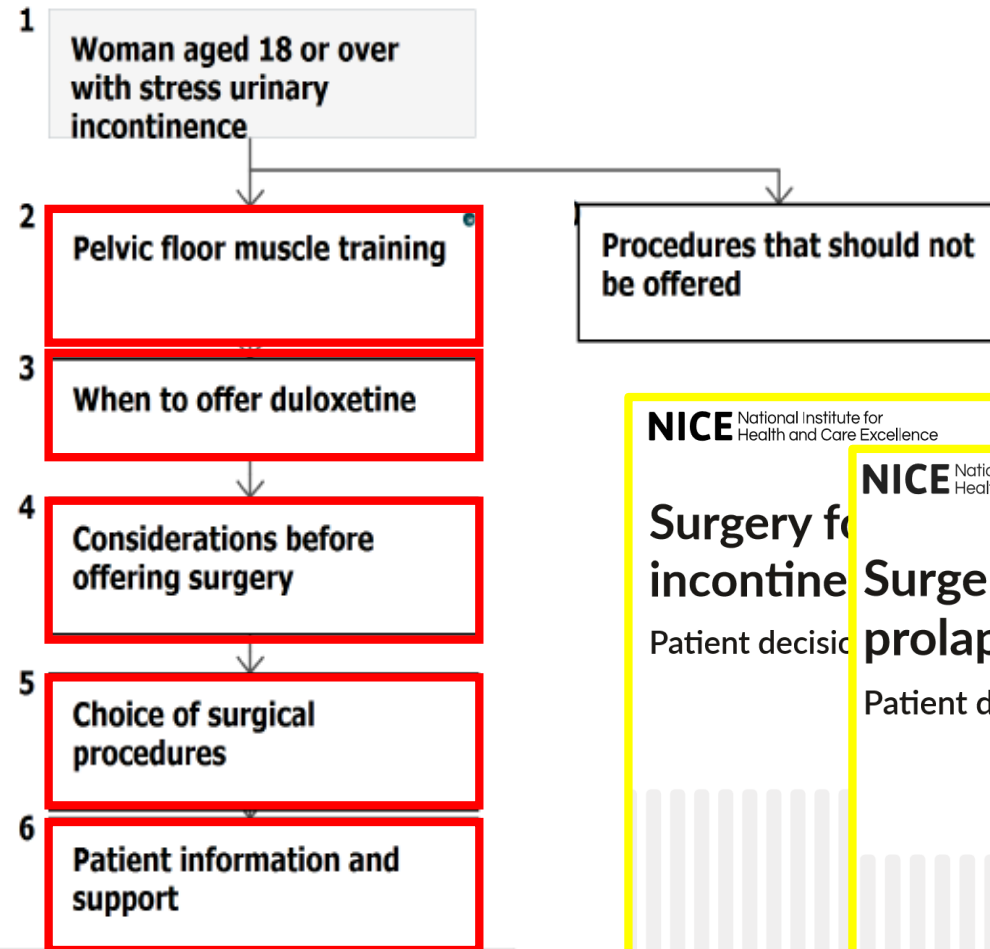
STRESS URINARY INCONTINENCE



Managing stress urinary incontinence in women

NICE Pathways

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Surgery for stress urinary incontinence
Patient decision aid

NICE National Institute for Health and Care Excellence



Surgery for vaginal prolapse
Patient decision aid

NICE National Institute for Health and Care Excellence



Surgery for vaginal vault prolapse
Patient decision aid



Duloxetine

- Duloxetine reduces incontinence episode frequency by 60%

Cardozo et al 2004

- May be offered as second-line therapy if:
 - women prefer pharmacological to surgical treatment
 - are not suitable for surgical treatment
- Women must be counselled about adverse effects

NICE 2013

- High incidence of side effects, especially nausea, results in discontinuation in up to 68 % of patients

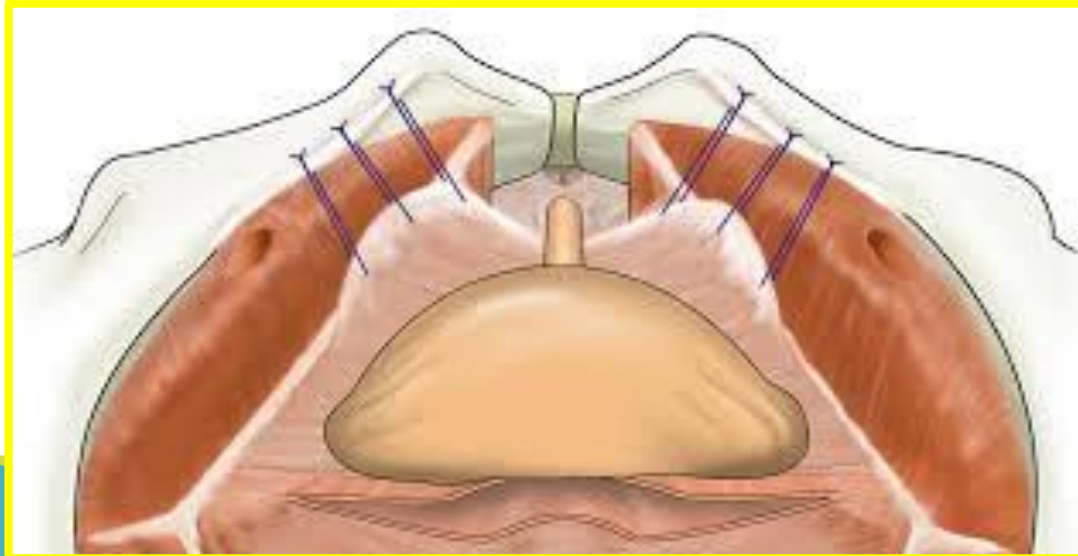
Duckett 2007

Colposuspension

- 71-100% cure rate
- Open colposuspension recommended as an effective treatment for primary or recurrent stress urinary incontinence (**Grade A**)
- Associated with higher risk of pelvic organ prolapse compared to sling operations and anterior colporrhaphy

6th ICI 2016

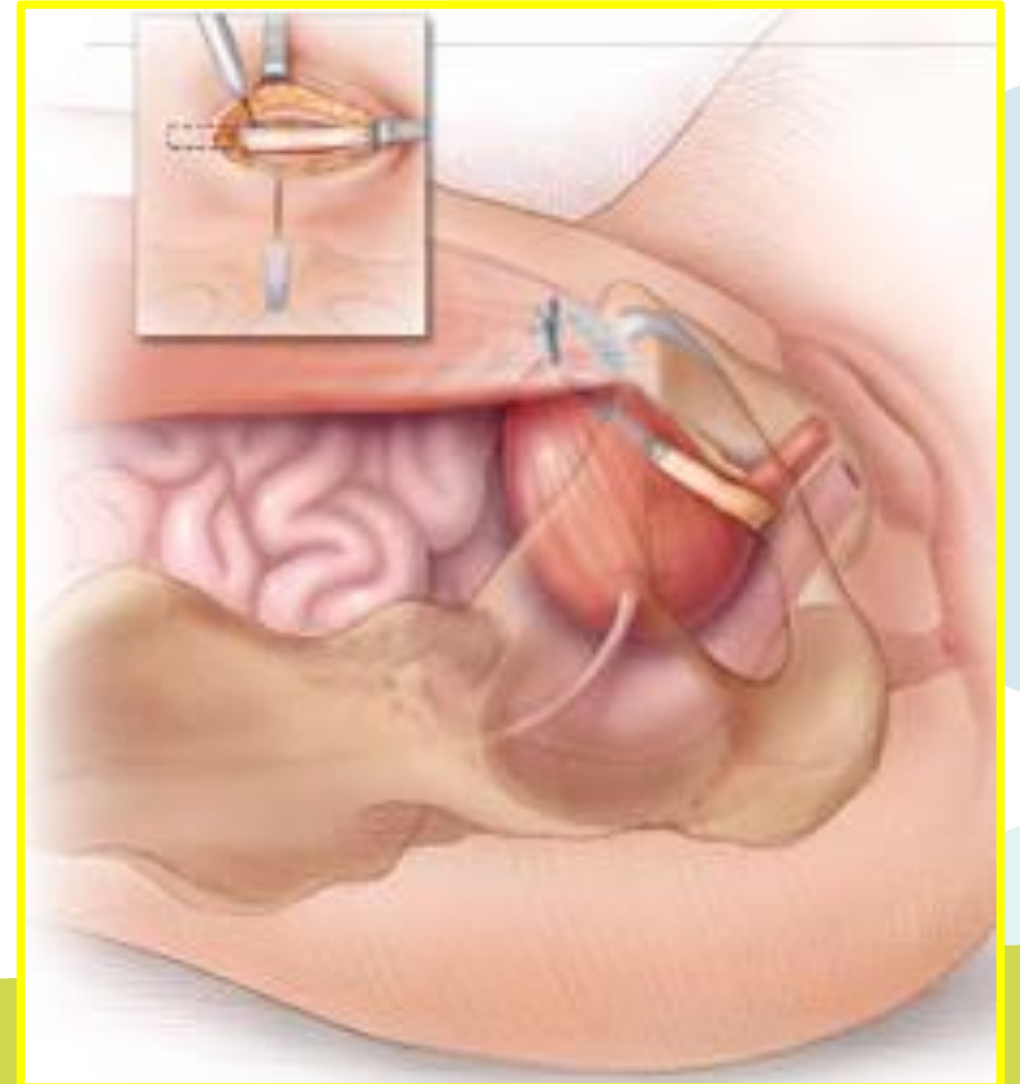
Cochrane 2016



Traditional Sling Procedures

- Autologous rectus fascial sling is the most widely evaluated biological sling
- Similar cure rate to open colposuspension, but the pattern of complications may vary
 - Albo 2007, Rehman 2011
- Recommended as an effective treatment for SUI which has longevity (Grade A)

6th ICI 2016



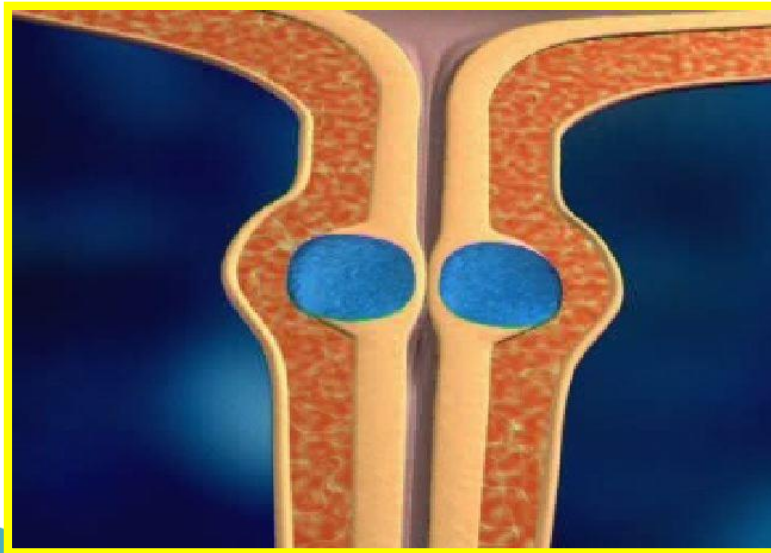
TVT Results: 17 year data

- Only available from Scandinavia
- Recruited from 3 centres: Jan 1995 – Oct 1996
- 58 of original 90 patients contacted
 - 93% objective cure
 - 79% subjective cure
 - 8% subjective improvement
 - 98% would recommend the operation
 - 2% late tape protrusion (was asymptomatic)

Nilsson et al 2013



Periurethral Bulking Agents



Periurethral Bulking Agents

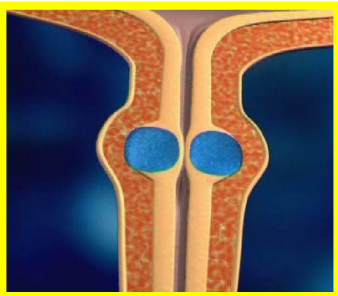
- Used for the past 30 years, more than 10 substances reported safe e.g. Bulkamid

Advantages

- NICE guideline approved
- Minimally invasive
- Performed under local
- Low morbidity
- Reduced incidence of voiding difficulties and 'de novo' D.O.

Disadvantages

- Lower efficacy than slings and colposuspension
- Repeat procedures may be required
- Cost
- Complications include migration and abscesses

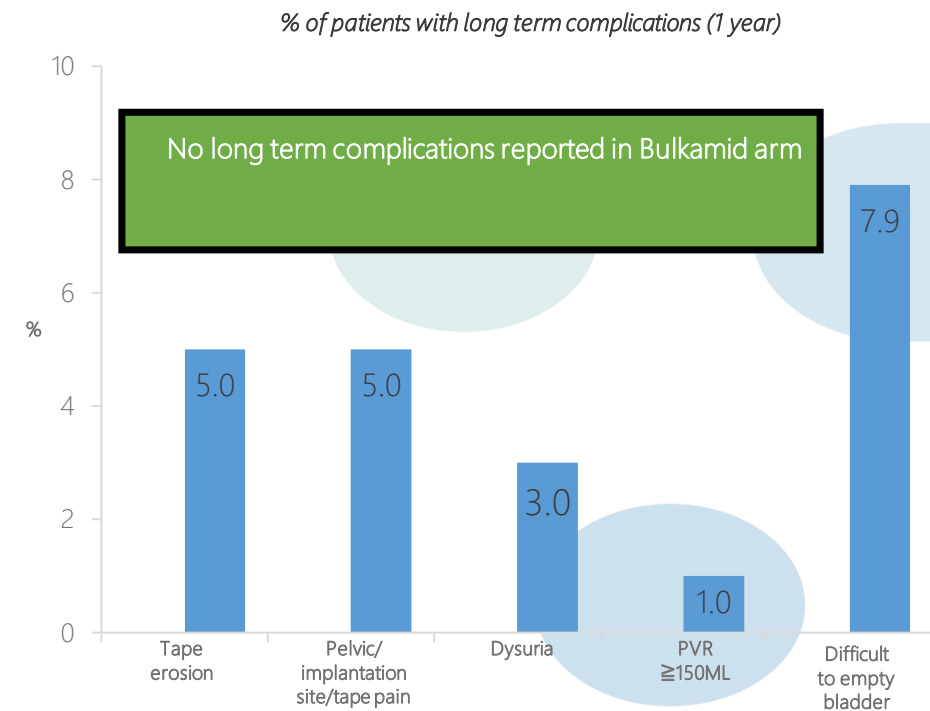
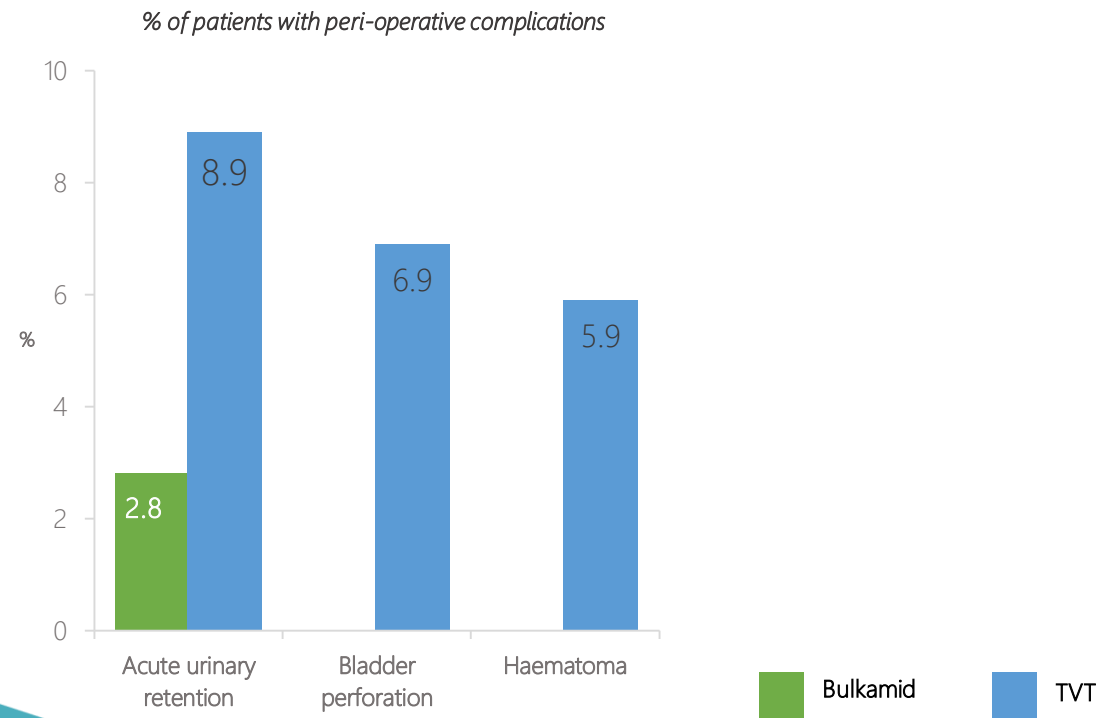


Bulkamid vs TVT: Complications

Peri-operative complications

N=224

Complications at 1 year



Freitas et al 2019

Voice Your Choice

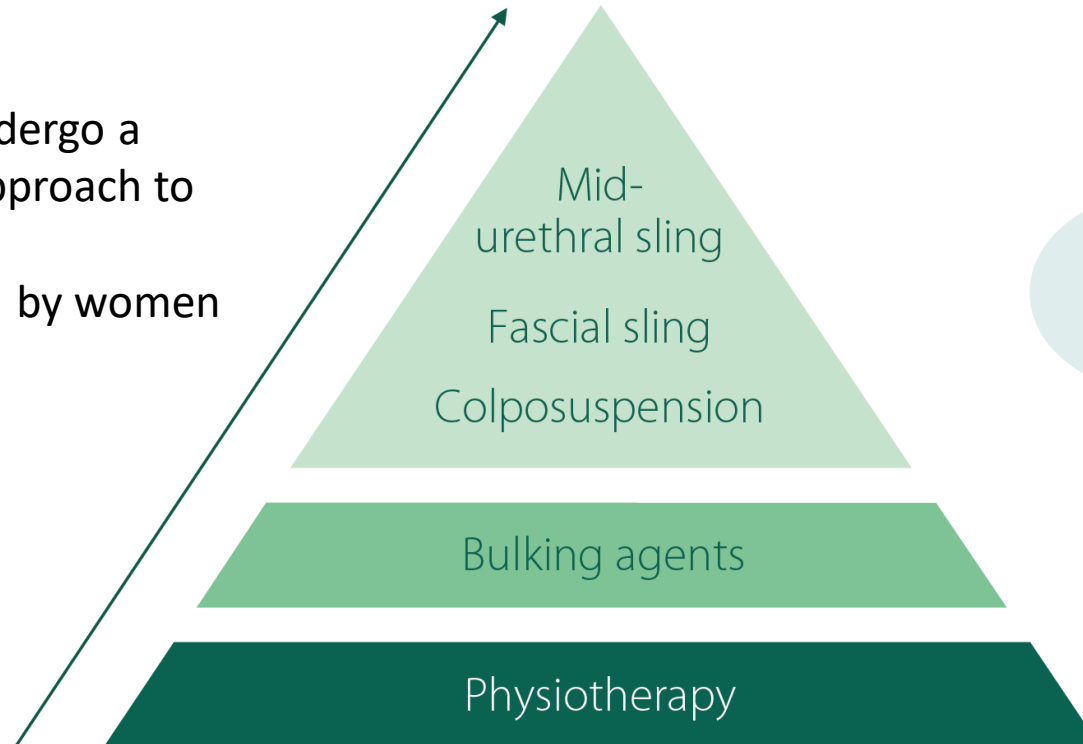
Given the choice, women will choose a less invasive procedure even if it means a lower cure/improvement⁶

Reid et al 2019



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A desire to undergo a hierarchical approach to treatment was expressed by women



74%

of women
opted for a
bulking agent
as a primary
procedure

N=212

WHAT ELSE?

Stem cells have been used to engineer a pubourethral ligament or in sphincter regeneration to correct the underlying aetiology

Tran and Damaser 2015

A few non-randomised studies show encouraging results

- 123 women with transurethral injections
 - At 1 year: 79% completely dry and 21% improved
 - Significant improvement in Sphincter thickness and contractility and Quality of life

Mitterberger et al 2007

- Adipose derived stem cells derived sling inserted suburethrally in rats
 - Two months post sling implantation leaks significantly reduced

Wang et al 2015

Prevention is better than cure



Education regarding:

- PFMT
- Risks of Obesity
- Optimal fluid intake
- Activities of daily life
- Excessively prolonged second stage

Conclusion

- Native tissue repair with the appropriate technique and conservative measures can reduce recurrence
- Biological grafts have been shown to have:
 - Equal efficacy as mesh
 - Improvements over native tissue repair for redo pelvic floor surgery
- Urethral bulking has a good satisfaction rate with extremely low morbidity
- Not all mesh is bad
 - With appropriate governance MUS & ASC mesh can still be used safely
- In the future, laser or stem cell therapy may prove beneficial