Matjes in de urogynaecologie: indicaties, resultaten, risico's of terug naar de Burch?

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Disclosures

Grants, honoraria to institution from Ferring, Medtronic, Astellas

Frederik Paulsen chair

Medtronic OptiLuts chair

Minority shareholder P2solutions (smart textiles) without salary

MMK, Burch....





Burch has a learning curve which is significant higher than MUS, however is not based on EBM but on common sense.

Volume and experience seem to matter

Pubo-Vaginal Sling (PVS)



1998: TVT revolution, MUS

1998: TVT revolution: Mid urethral slings (MUS)

Minimal invasive, almost no-scalpel Local anesthesia possible Short operating time and day-stay clinic possible

See 1 do 1 principal Short learning curve: TOT/TVT: 10-30d

Success was the "tension free" principle Burch colposuspension and pubovaginal slings disappeared Mesh systems started in **2000** with TVM

2004-2005 Update of mesh systems

Better understanding what to do, what not to do

Variety of mesh systems have been on the market

4000 à 5000 Prolapse repairs annually...

2014

MESH POSITION STATEMENT

NZAGS Position Statement on Hernia Mesh Repairs by Steven Kelly, General Surgeon, Christchurch on behalf of the Executive, New Zealand Association of General Surgeons (NZAGS)

Interview on surgical mesh on Radio New Zealand

Another "unfortunate experiment" is how one woman is describing New Zealand's handling of surgical mesh. Yesterday MedSafe announced that from January 4 mesh implants will not be used for pelvic organ prolapse or urinary incontinence because of the risks. It will still be used for other surgeries, including hernia repair. ACC has paid out more than \$13 million in injury claims to hundreds of patients who had problems with the mesh in the past decade. Some of the injuries include the mesh eroding in the body, binding with other tissue, and causing extreme pain. Co-founder of the "Mesh Down Under" online support group Carmel Berry joins us. Listen Here

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Bekkenbodemmatjes: Ernstige complicaties vereisen terughoudend gebruik transvaginale mesh

Na onderzoek naar problemen met de behandeling van bekkenbodemverzakkingen met transvaginale mesh roept de Inspectie voor de Gezondheidszorg (IGZ) gynaecologen, urologen en chirurgen op terughoudend te zijn bij het gebruik van deze mesh.

Berichtgeving FDA over vaginale bekkenbodemmatjes en de gevolgen daarvan voor Nederland

Op woensdag 17 april 2019 maakt de Amerikaanse toezichthouder FDA bekend dat alle transvaginale bekkenbodemmatjes (mesh) in de Verenigde Staten van de markt gehaald moeten worden https://www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants

Infecties en pijn

'Hoop is weg' voor honderden vrouwen met bekkenbodemmatjes

22 november 2019 17:25 Aangepast: 14 februari 2020 14:51

New Zealand bans vaginal mesh implants

Ministry of Health asks suppliers to stop marketing the mesh until they have proven its safety

▲ Vaginal mesh implants have been banned in New Zealand pending further investigation. Photograph: Emily Critchfield/Duke Health

Kristien Bonneu w 22 ww 2019 Q 18 5

Christ'l kreeg een bekkenbodemmatje ingeplant, maar dat liep fout: "Ik kan niet meer zitten, stappen of fietsen"

Mesh shrinkage, what is this?

Mesh retraction, also known as mesh shrinkage or mesh contraction

Reduction of the surface area of the original implanted mesh

Mesh shrinkage, what is this?

- Any foreign body inserted in our tissues generates chronic inflammation
- Inflammatory reaction depends on: Individual
 - Type of foreign material
 - Mono/polyfilament
 - Amount of foreign body
 - Mesh size
 - Pore size
 - Erosion and/or infection
- This inflammatory response is suggested to be the cause of mesh shrinkage

Mesh shrinkage, consequeces?

- Pain and dyspareunia due to inflammation and folding

- Recurrence of prolapse due to diminished mesh-coverage and folding

- Folding happens where lateral traction is seen

Prevalence of shrinkage according to literature

How to treat shrinkage

- 1) Close erosions early to decrease inflammation
- 2) Anti-inflammatory drug?
- 3) Alleviate traction by cutting i.e. 1 mesh arm to decrease traction

4) Mesh excision :

location of the pain ++ removal of the body of the mesh if needed often major surgery!

Level of evidence 3

How to prevent shrinkage, prevent inflammation

Inflammatory reaction depends on:

Individual Type of foreign material Mono/polyfilament Amount of foreign body/Mesh size Pore size Erosion and/or infection

Conclusion:

use type 1 monofilament, macroporous and low weight prolene

avoid opening vagina and erosions (estrogens, abdominal technique, subtotal hysterectomy)

Level of evidence 2

How to prevent shrinkage, prevent traction

Correct placement is necessary, appropriate training

Avoid mesh-arm lateral traction

Avoid mesh bends, folds, during placement, mesh must lie flat

Avoid mesh fixation with traction

Mesh fixation with absorbable sutures to prevent folding at shrinkage

Level of evidence 3

Mesh or no mesh, if yes make abdominal approach (open, laparoscopic, robotic)

Mesh only in failures:

YES because this makes risks acceptable NO because second surgery is less blood vessels, higher risk of erosion and infection NO because i.e. urologists are used to perform sacrocolpopexy with mesh as a primary solution and this surgery is considered the gold standard in the literature

Mesh or no mesh, if yes make abdominal approach (open, laparoscopic, robotic)

AGE:

Older women need mesh Less risk of dyspareunia More risk erosion Younger women need mesh Less risk erosion More risk dyspareunia More need for strong repair

Xxxxx

Genitale prolaps: prothesemateriaal gebruiken of herstel met lichaamseigen weefsel?¹

K. Everaert^{2, 5}, A.S. Goessaert², T. Hamerlynck³, D. Van De Putte⁴, P. Pattyn⁴, S. Weyers³

Beslisboom heelkundig prolapsherstel.

Prolaps uteri: graad 2< 3 en de patiënte staat open voor een hysterectomie

Hysterectomie, bij voorkeur langs de vaginale weg of laparoscopisch

Prolaps uteri: graad 2< 3 en de patiënte wenst geen hysterectomie

- Hysteropexie met prothesemateriaal
- · Bij een gecombineerde cysto- of rectocele: bij voorkeur vaginaal
- Indien enkel prolaps uteri: laparoscopische hysteropromontoriopexie

Prolaps uteri: graad ≥ 3

- Vaginale hysterectomie met colposuspensie langs de vaginale weg, ofwel subtotale hysterectomie laparoscopisch met colpopromontoriopexie (voorkeur bij seksueel actieve vrouwen)
- Indien geen coïtusactiviteit en/of uitgesproken atrofie: bij voorkeur colposuspensie door middel van sacrospinosumfixatie

Topprolaps: graad 2-4

- · Laparoscopische colpopromontoriopexie met prothesemateriaal
- Indien geen coïtusactiviteit en/of uitgesproken atrofie: bij voorkeur vaginale sacrospinosumfixatie

Cystocele: graad 2-3

- Vaginale colporraphia anterior, bij voorkeur zonder mesh
- Prothesemateriaal overwegen bij actieve vrouwen en/of vrouwen < 50 jaar en/of cystocele graad 3 of hoger
- Prothesemateriaal zeker overwegen bij recidief of een uitgesproken lateraal defect

Rectocele: graad 2-3

- Vaginale colporraphia posterior, bij voorkeur zonder prothesemateriaal
- Prothesemateriaal overwegen bij actieve vrouwen en/of vrouwen < 50 jaar
- Prothesemateriaal zeker overwegen bij recidief
- Geassocieerde enterocele en/of intussusceptie en/of rectumprolaps: open of laparoscopische ventrale rectopexie

Enterocele: graad 2-3

- · Vaginale enterocelecorrectie, bij voorkeur met prothesemateriaal
- Indien geen coïtusactiviteit en/of uitgesproken atrofie: bij voorkeur sacrospinosumfixatie

Totaalprolaps

- Vaginale hysterectomie met colporraphia anterior/posterior en sacrospinosumfixatie
- Indien nog seksueel actief: bij voorkeur laparoscopische subtotale hysterectomie met colpopromontoriopexie met prothesemateriaal

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Easy for prolapse but what with surgery for SI: Back to the Burch?

- 1) Long record of publications and long follow up (+/-50y)
- 2) Treats cystocoele up to grade 2 in same operation
- 3) No mesh needed
- 4) Can be done laparoscopic or robotic

Burch, MMK, Cochrane 2017

Open retropubic colposuspension is an effective treatment modality for stress urinary incontinence especially in the long term. Within the first year continence rate is 85% to 90%. After five years, approximately 70%.

Newer MUS sling procedures look promising in comparison with open colposuspension but their long-term performance is limited and closer monitoring of their adverse event profile must be carried out.

Burch colposuspension is associated with a lower risk of voiding dysfunction compared to traditional PVSsling surgery and the retention risk is comparable to MUS.

Laparoscopic/robotic colposuspension should allow speedier recovery but its relative safety and long-term effectiveness is not yet known, although most studies confirm its efficacy and safety.

<u>BUT :</u>

Burch colposuspension is associated with a higher risk of secondary pelvic organ prolapse compared to sling operations and anterior colporraphy: Rectocele has been noted in 11-25% and enterocele in 4-10% of patients followed-up 10-20 years.

What are the surgical issues with this type of surgery

Intra-operative:

Bleeding (correct opening Retsius, bleeding pelvic veins best solved by putting Burch sutures)

Hitting the bladder with non-resorbable sutures

Overcorrection and its consequences: retention, internalization meatus "fingerspitzengefühl"

Postoperative

Reducing anterior compartment prolapse and consequenses (1/4-1/5)

DVT, lung embolism

Osteitis pubis (use transverse fascia instead of Cooper/periostum, up to 2.5% after MMK)

Indications today, impact on need for training?

<u>High volume centers today:</u>

Burch replacing MUS if legal or insurance based needed or if MUS is to expensive (UK, US, New Zeeland, ASIA, Africa)

Most EU-centers today are low volume centers:

To solve mesh sling complications (bladder/urethral erosion) After or when present urethral diverticula or other urethral surgery Patients anxious for mesh

So rare indications, little opportunities to learn it

Burch, PVS, MUS, injectables....

PHD THESIS

DANISH MEDICAL JOURNAL

Surgical treatment for urinary incontinence in women

- Danish nationwide cohort studies

Margrethe Foss Hansen

This review has been accepted as a thesis together with two previously published papers one manuscript by University of Southern Denmark 31 October and defended on 9 December 2016.

Tutors: Kim Oren Gradel, Gunnar Lose and Ulrik Schiøler Kesmodel.

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Burch, PVS, MUS, Injectables....

Burch, PVS, MUS, injectables....

Table 9 Uni- and multivariate analyses of variables potentially involved in cure, ICIQ-SF (Frequency, Amount and Impact)

Variables	Fr	Frequency		Amount		Impact		
	Univariate analysis	Multivariate analysis	Univariate analysis	Multivariate analysis	Univariate analysis	Multivariate analysis		
	Odds ratio (95%, CI)	Odds ratio (95%, CI)	Odds ratio (95%, CI)	Odds ratio (95%, CI)	Odds ratio (95%, CI)	Odds ratio (95%, CI)		
Surgeon volume								
LOW	Reference	Reference	Reference	Reference	Reference	Reference		
Low Medium	Reference 2.25 (0.86-5.88)	Reference 1.95 (0.57-6.58)	Reference 0.44 (0.17-1.1)	Reference 0.39 (0.15-1.04)	Reference 1.3 (0.49-3.46)	Reference 1.03 (0.3-3.58)		
Low Medium High	Reference 2.25 (0.86-5.88) 2.59 (1.11-5.99)	Reference 1.95 (0.57-6.58) 4.51 (1.21-16.82)	Reference 0.44 (0.17-1.1) 0.86 (0.39-1.9)	Reference 0.39 (0.15-1.04) 0.64 (0.17-2.25)	Reference 1.3 (0.49-3.46) 1.42 (0.61-3.33)	Reference 1.03 (0.3-3.58) 1.83 (0.48-6.94)		
Low Medium High Department volume	Reference 2.25 (0.86-5.88) 2.59 (1.11-5.99)	Reference 1.95 (0.57-6.58) 4.51 (1.21-16.82)	Reference 0.44 (0.17-1.1) 0.86 (0.39-1.9)	Reference 0.39 {0.15-1.04} 0.64 {0.17-2.25}	Reference 1.3 (0.49-3.46) 1.42 (0.61-3.33)	Reference 1.03 (0.3-3.58) 1.83 (0.48-6.94)		
Low Medium High Department volume Low	Reference 2.25 (0.86-5.88) 2.59 (1.11-5.99) Reference	Reference 1.95 (0.57-6.58) 4.51 (1.21-16.82) Reference	Reference 0.44 (0.17-1.1) 0.86 (0.39-1.9) Reference	Reference 0.39 (0.15-1.04) 0.64 (0.17-2.25) Reference	Reference 1.3 (0.49-3.46) 1.42 (0.61-3.33) Reference	Reference 1.03 (0.3-3.58) 1.83 (0.48-6.94) Reference		

Women treated by a medium- (adjusted OR 1.82; 95% CI 1.01-3.28, "frequency") or high-volume surgeon (1.98; 1.18-3.32, "frequency") had an increased probability of cure compared with women treated by a low-volume surgeon.

Open / Laparoscopic / Robotic

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REVIEW ARTICLE

WILEY Crodynamics OICS

Burch colposuspension

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Burch has a learning curve which is significant higher than MUS, however is not based on EBM but on common sense Training in both open and laparoscopic Burch colposuspension should nowadays be provided in fellowship and training programs worldwide.

The NICE guidelines include amongst their recommendations that laparoscopic Burch colposuspension is not recommended as a routine procedure for the treatment of SUI in women. It was highlighted, that the procedure should be performed only by surgeons with appropriate training as well as expertise working in a multidisciplinary team, and women should be advised about the limited evidence.

Conclusion

Do not mix up abdominal versus vaginal mesh implants.

Do not mix up prolapse mesh versus stress incontinence mesh.

Mesh prolapse surgery indications are well understood, if mesh is used do the abdominal approach and do not open the vagina.

Mesh always tension free.

MUS (TVT/TOT) is the golden standard for treating SI with a short learning curve.

Burch and PVS for limited series of indications (MUS complications, post urethral surgery, urethral diverticula, post radiotherapy).

Surgery like open/lap/Robotic Burch colposuspension has a learning! It is major surgery and has significant complications.

I do not believe that we can return to good old Burch colposuspension without educational programs and I doubt we need to move back from MUS to Burch. Both types of surgery have their indications.