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June 2014 Update #20

Vaginal Mesh Controversies

The use of vaginal mesh has recently come under intense scrutiny after the FDA July 2011 Public Health Notification and re classification to a high risk class III product (concern at adverse events and the non superiority of prolapse outcomes), with the subsequent class legal actions and the withdrawal from the market of Johnson & Johnson, Boston & Bard mesh kits.

There have now been three generations of vaginal mesh, the first being multifilament heavy polypropylene mesh (with an erosion rate of around 20%), the second of monofilament heavy polypropylene mesh (erosion rate around 10%), and the third of monofilament light polypropylene mesh (erosion rate around 5%).

A meta-analysis of second generation vaginal mesh by Haya in 2013 found only 5 RCT's for currently available mesh kits. Mesh exposure was reported at 14%, however 49% of these reported ongoing pelvic pain and dyspareunia.

The major advantage of the Elevate third generation system is the anchorage of the mesh arms directly to the sacrospinous ligament, creating a backward force of the mesh and hence reducing the forward pressure on the vaginal epithelium with less mesh erosions.

Studies of the Anterior Elevate mesh system have reported success rates of 87.7% at 12 months (Stanford 2013, n=112) with a mesh erosion rate of 6.3%. The Posterior Elevate mesh system has a success rate of 92.5% (Lukban 2012, n= 139), with an erosion rate of 6.5%.

My own results of Elevate from 2012-4 are reported in tables 1 & 2. Mesh should now only be used by those doctors experienced in its use and the management of complications, as well as undertaking long term follow up of their results. Patients at high risk of prolapse recurrence should be informed of the benefit of mesh, as well as the additional risks associated with synthetic grafts.

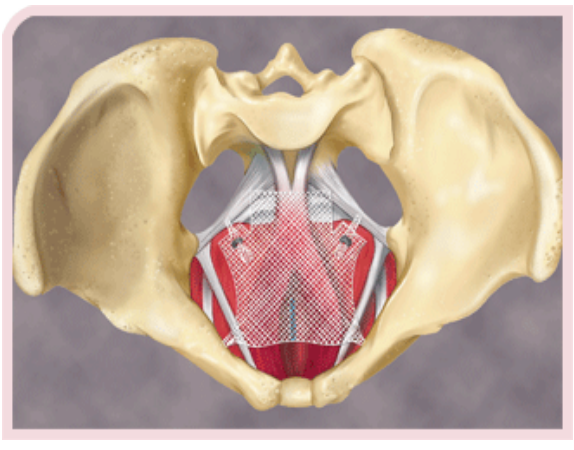


Table 1: Results of 92 Elevate Cases

Age	64.0
Weight	72.7
Parity	2.8
Surg. time (min)	62.4
Blood loss (mls)	157
Home (days)	3.0
6 wk cure	56/60 (93.3%)
6 mth cure	32/40 (80%)

Table 2: Complications

Stress Incontinence	3/40 (7.5%)
Urgency	3/40 (7.5%)
UTIs	2/40 (5%)
mesh erosion	0/40

Obstetrics Update

1. Non Invasive Prenatal Testing (NIPT):
NIPT is a new maternal blood test that determines fetal chromosomes by assessing cell free fetal DNA which can be identified in the maternal plasma from five weeks post-conception, with the level increasing with gestational age, and then disappearing after the birth. Studies have found NIPT to have a high sensitivity and specificity (98-100%) for trisomy 21. The positive predictive value is lower at 20-100%. Therefore those women with a positive test should have the karytype confirmed by invasive testing such as CVS or amniocentesis. NIPT offers the advantage of a negative test enabling invasive testing to be avoided. Currently testing is send overseas to the USA for a cost of around $600 to the patient.

2. Preeclampsia predictive testing:
Such testing would allow early identification of patients with appropriate treatment and transfer to appropriate centres. Recent advances involve multiparametric approaches such as:
- increase in mean arterial pressure
- uterine artery diastolic notch from increased uteroplacental resistance
- reduced biomarker PAPPA (placental protease)

Markers in development include:
- increased cystatin C (renal function marker)
- increased PTX3 (inflammatory marker)
- reduced PIGF (placental growth factor).

3. Vit D. Vitamin D deficiency:
This may also be a risk factor for pregnancy related conditions including pre-eclampsia, hypertension, cardiovascular diseases and pre-term labour, as well an childhood rickets. Supplementation of 1,000IU is recommended at levels of less than 75nmol/l, which can occur in up to 30% of low risk women (without dark skin & with sunlight exposure). Calcium intake should also be greater than 1000mg per day. Repeat levels should be performed at 28 weeks. (PTO)

Obstetrics Update (cont.)

4. Glucose Challenge testing in Pregnancy:
Guidelines are due to be changed later this year to detect gestational diabetes with greater accuracy with a single fasting 75g 2 hour GTT at 26-28 weeks. Earlier testing at 20/40 is recommended for groups with moderate to high risk factors for GDM:

- Ethnicity: Asian, Indian subcontinent, Aboriginal, Torres Strait Islander, Pacific Islander, Maori, Middle Eastern, non-white African
- BMI > 25kg/m2
- Previous GDM
- Previously elevated blood glucose level
- Maternal age ≥40 years
- Family history DM (1st degree relative with diabetes or a sister with GDM)
- Previous macrosomia (baby with birth weight > 4500 g or > 90th centile)
- Polycystic ovarian syndrome
- Medications: corticosteroids, antipsychotics

The new diagnostic values in pregnancy are:
- Fasting ≥ 5.1mmol/L
- 1 hr ≥ 10.0mmol/L
- 2 hr ≥ 8.5mmol/L

Gynaecology Update

1. Conventional pap smears to be phased out by 2016:
In 2009, approximately 770 women were diagnosed with cervical cancer and there were 232 deaths from cervical cancer in 2010. In Australia, 80% of women with cervical cancer have not been screened or have not had regular screening tests.
Australia has the world's first national school-based HPV vaccination programme, and the MSAC has now recommended from 2016 the establishment of the world's first national cervical screening programme in a vaccinated population, using a primary HPV test, to prevent cervical cancer as follows:

- five-yearly cervical screening using a primary human papillomavirus (HPV) test with partial HPV genotyping and reflex liquid-based cytology (LBC) triage, for HPV vaccinated and unvaccinated women starting at age 25 through to 69 years of age, with exit testing of women 70 to 74 years of age;
- self-collection of an HPV sample, for an under-screened or never-screened woman, which has been facilitated by a medical or nurse practitioner (or on behalf of a medical practitioner) who also offers mainstream cervical screening;
- invitations and reminders to be sent to women 25 to 69 years of age, and exit letters to be sent to women 70 to 74 years of age, to ensure the effectiveness of the program; and
- the de-listing of the Medicare Benefits Schedule (MBS) items for the existing cervical cancer screening test MBS items over a 6 to 12 month transition period.

Gynaecology Update (cont.)

2. New OCP's VTE risk:
A recent meta-analysis reported a greater risk of VTE in women taking new-generation combined OCs containing desogestrel (Marvelon), gestodene (Femodon) and drospirenone (Yaz, Yasmin) compared with those containing levonorgestrel, norgestrel or norgestimate. In addition, two large studies (one Dutch case–control study and one Danish cohort study) reported that the risk of VTE is nearly doubled in patients taking combined OCs containing desogestrel, gestodene and drospirenone compared with those taking levonorgestrel. The studies also confirmed a higher risk of VTE during the first year of OC use irrespective of the formulation, with the risk more than halved in the second year of use.

A recent French review of the cyproterone acetate (Diane-35) found a negative risk–benefit profile for the threat of VTE.

A recent meta-analysis of studies published from 1967 to 2009 reported a 3–4-fold greater risk of VTE in women taking any OC compared with non-users. The absolute risk of VTE is about 10 per 10,000 woman years for women taking OCs containing desogestrel, gestodene, drospirenone or cyproterone acetate.

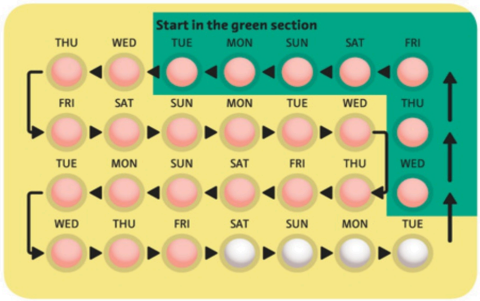
Care should be taken when prescribing OCs in women with risk factors that increase the risk of VTE such as:

- obesity
- age over 35 years
- smoking

Absolute contraindications are:

- previous history of VTE
- coronary artery disease
- cerebrovascular disease
- uncontrolled hypertension
- severely impaired liver function
- malignancy of the breast or genital tract.

Women with a history of VTE should be screened for thrombophilia before starting a combined OCP. Advise patients to continue taking their OC and, if a patient is tolerating the regimen, there is generally no need to discontinue use at this time.



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