

IS LEVATOR AVULSION A PREDICTOR FOR CYSTOCELE RECURRENCE FOLLOWING ANTERIOR VAGINAL MESH?

Hypothesis / aims of study

Traditional anterior colporrhaphy commonly yields low success rates, especially in women with an abnormal levator shelf (1). Current evidence suggests that transobturator mesh may lower recurrence rates (2). It seems that such implants may partly or completely compensate for the added recurrence risk conveyed by pelvic floor trauma. Such an effect may justify the use of mesh as primary or secondary intervention, despite the substantial complications associated with mesh implants, such as chronic pain, dyspareunia and erosion. However, even with mesh use, recurrence rates in women with avulsion of the puborectalis muscle may still be unacceptably high (2). This study was designed to determine whether avulsion is a risk factor for recurrence following anterior compartment transobturator mesh placement.

Study design, materials and methods

This study is a retrospective analysis of data obtained in clinical audit projects performed at three tertiary Urogynaecology units, assessing subjective and objective outcomes following transobturator mesh use for cystocele repair. All patients had a standardized interview, a clinical assessment using the ICS POP-Q, along with a 4D transperineal ultrasound using Voluson 730 expert and Voluson i systems (RAB 8-4 MHz transducer). All ultrasound images were analysed offline using proprietary software (4D View v 10), with the computer operator blinded against all clinical data. A clinical recurrence was defined as a cystocele \geq Stage 2 (ICS POP-Q), a significant cystocele on ultrasound was defined as maximum bladder descent to 10 mm below the symphysis pubis, or lower. Levator trauma was identified by tomographic ultrasound (see Figure 1) by the senior author as previously described (3), blinded against all other data, including ultrasound appearances in the midsagittal plane. We did not perform formal power calculations due to a lack of pilot data.

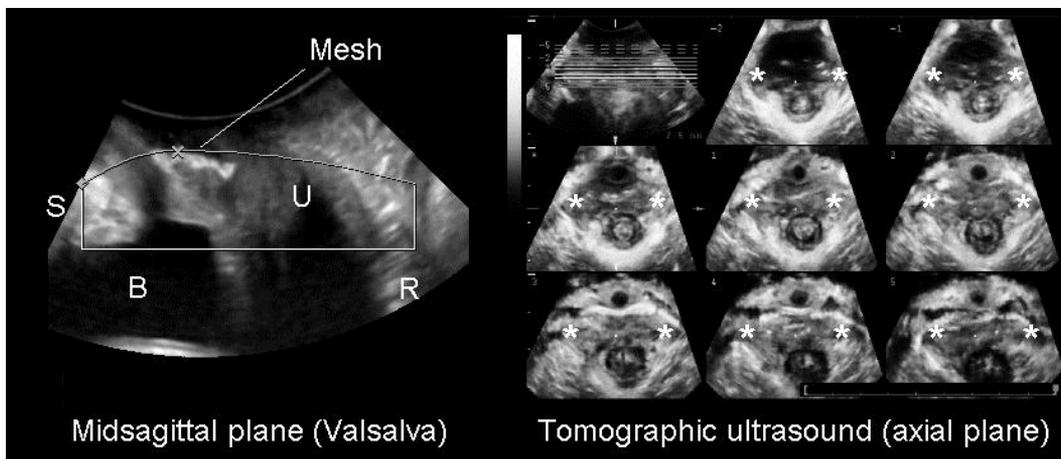


Figure: Pelvic floor ultrasound demonstrating successful cystocele reduction after anterior mesh placement (evident in the midsagittal plane on the left) in a patient with bilateral avulsion (visible on tomographic imaging on the right, avulsion indicated by *). S=symphysis pubis, B=bladder, U= uterus, R= rectal ampulla.

Results

220 patients had anterior vaginal mesh placement (68 Anterior Prolift™, 152 Perigee™). Mean age was 64.4 (32-89), median vaginal parity was 3 (0-10). Mean BMI was 28.1 (18-49). 105 patients (48%) had had a previous hysterectomy, 72 (33%) a previous vaginal repair procedure. 29 women (13%) had a concomitant hysterectomy, 29 (13%) a sacrospinous colpopexy, 72 (33%) a suburethral sling, 68 (31%) a posterior vaginal repair and 78 (35%) a posterior compartment mesh. Patients were seen at an average of 2.1 years (6 weeks - 5.6 years). Most were satisfied with the outcome (n= 181, 85%) whilst 23% of patients (n=51) had symptoms of recurrence, such as the sensation of a vaginal lump, or a dragging sensation. On clinical examination, the mean POPQ Ba was -1.8 (-3 to $+3$), with 70 patients (32%) having a clinical recurrence of \geq Stage 2. We found erosions in 22 patients (10%).

On pelvic floor ultrasound, maximum descent of the bladder was measured at a mean of 1.9 ($+21$ to -38) mm below the symphysis pubis, with 55 (25%) women having a cystocele recurrence as defined above. 83 patients (38%) were diagnosed with an avulsion of the puborectalis muscle on tomographic ultrasound, of which about half were bilateral (n=42), with a slight preponderance of right-sided trauma (n=69, 32% vs. n=56, 26%).

In one patient, ultrasound datasets could not be retrieved due to clerical error, leaving 219 datasets for analysis of the relationship between levator trauma and subjective / objective recurrence after mesh placement. Differences between groups did not reach significance for symptom recurrence ($P=0.311$ on Chi^2 test) and clinical recurrence (37% vs. 29%, $P=0.18$ on Chi^2 test) when compared to those without levator avulsion. This also was the case for point Ba (-1.63 for avulsion vs. -1.92 for intact levator, $P=0.13$).

	Symptoms	Mean Point Ba	≥ Stage 2 cystocele	Mean cystocele descent on US (mm)	Significant cystocele on US
Avulsion (n= 83)	22/83 (27%)	-1.63	31/83 (37%)	-4.1	29/83 (35%)
No avulsion (n= 136)	28/136 (21%)	-1.92	39/136 (29%)	-0.8	26/136 (20%)
P-value	0.311	0.13	0.18	0.072	0.009 OR 2.27

Table: Subjective and objective outcomes after mesh implantation in women with and without levator avulsion (n=219), at a mean follow-up of 2.1 years. * Confidence Interval 1.23 to 4.21.

On analysing ultrasound measurements, there was a trend towards increased bladder descent in women with avulsion (4.1mm vs. 0.8mm below the symphysis pubis, $P=0.072$). This relationship reached significance on considering significant cystocele on ultrasound (29/83 [35%] vs. 26/136 [19%], $P=0.009$ on Chi^2) with an odds ratio of 2.27 (Confidence Interval 1.23-4.21) in women with avulsion. Since only the last analysis reached significance, we limited subgroup analysis to the outcome measure of 'significant cystocele on US'. There was a significant effect of avulsion on recurrence in the Perigee group, mean follow-up of 1.8 years (24/64 [38%] vs. 19/87 [22%], $P=0.035$ on Chi^2 , OR 2.15, CI 1.05- 4.38). This association did not reach significance in the Prolift group at a mean follow-up of 2.7 years (5/19 [26%] vs. 7/49 [14%], $P=0.24$ on Chi^2 , OR 2.14 (CI 0.62- 7.54).

Interpretation of results

Levator avulsion was found to be a significant predictor of cystocele recurrence in this group of 219 women seen at an average of 2 years after anterior compartment mesh placement (OR 2.27). As demonstrated previously, the optimal outcome measure, i.e., the one providing maximum power, was the finding of a significant cystocele on pelvic floor ultrasound. Although this effect remained significant in a subgroup of women with Perigee meshes, this was not the case for the Prolift group, likely due to insufficient power.

Concluding message

Avulsion of the puborectalis muscle more than doubles the risk of cystocele recurrence after anterior compartment transobturator mesh. This implies that mesh implantation in such patients does not fully compensate for the effect of levator trauma on recurrence risk.

References

1. Ultrasound Obstet Gynecol 2010;36:76-80.
2. Int Urogynecol J 2011; in print
3. Ultrasound Obstet Gynecol 2009;33:698-703.

Specify source of funding or grant	Nil
Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	SWAHS HREC (Nepean Campus),Townsville HREC and Gold Coast Hospital HREC
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes