

## HIATAL BALLOONING IS AN INDEPENDENT RISK FACTOR OF PROLAPSE RECURRENCE

### Hypothesis / aims of study

Female pelvic organ prolapse is a common condition, and recurrence after surgical treatment is considered a significant clinical issue. A number of predictors of prolapse have been described in the literature, including patient age, preoperative prolapse stage and avulsion of the puborectalis muscle(1). There is some evidence that the size of the genital hiatus may also be a predictor. In this study we used data obtained in clinical audit projects in order to identify predictors of prolapse recurrence. The aim was to explore the potential of a recurrence prediction model for use in clinical practice to help select patients for mesh surgery.

### Study design, materials and methods

This study utilizes patient and ultrasound data obtained in the context of four separate clinical audit projects of subjective and objective outcomes after Anterior Colporrhaphy +/- mesh augmentation. Appointments consisted of a standardised interview, an ICS POP-Q clinical examination along with a 4D translabial pelvic floor ultrasound using GE Kretz Voluson 730 expert and Voluson I systems(1). Recurrence was defined in three ways: 1.) recurrent symptoms of a vaginal lump or dragging sensation, 2.) Ba at -1 or lower on ICS POP-Q, and 3.) a cystocele reaching to 10 mm below the symphysis pubis on Valsalva, or lower.

Ultrasound data analysis was performed using proprietary software, (GE Kretz 4D View 10.0, Kretz Medizintechnik, Zipf, Austria), blinded against all clinical data. Avulsion of the puborectalis muscle was diagnosed on tomographic ultrasound as previously described(2). In short, a patient was rated as positive for an avulsion defect if three axial plane slices at the level of the plane of minimal dimensions and 2.5 and 5 mm cranial were deemed abnormal in a volume obtained on maximal Pelvic floor muscle contraction. Hiatal dimensions were determined in the plane of minimal hiatal dimensions, using rendered volumes of 2 cm thickness to account for the non- euclidean nature of the plane of minimal dimensions(3). We then tested potential predictors of recurrence (age, BMI, follow- up interval, previous surgery, pre-operative prolapse grading, avulsion and hiatal area on Valsalva) against subjective and objective recurrence using logistic regression modelling techniques. The area under the receiver operating characteristic (AUC ROC) curve corresponding to the best multivariate logistic regression model was calculated to summarise its predictive performance.

Variable	Univariate		Multivariate	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Mesh	0.47 (0.29 to 0.78)	0.0035	0.40 (0.23 to 0.68)	0.0007
Age (years)	0.98 (0.96 to 1.00)	0.0534	-	-
BMI	1.02 (0.98 to 1.07)	0.3912	-	-
Prev. hysterectomy	0.94 (0.61 to 1.46)	0.7951	-	-
Prev. incontinence surgery	0.53 (0.14 to 2.01)	0.3494	-	-
Length of follow-up (years)	1.08 (0.95 to 1.23)	0.2252	-	-
Avulsion	2.19 (1.39 to 3.43)	0.0006	1.93 (1.19 to 3.12)	0.007
Hiatal area on Valsalva (cm <sup>2</sup> )	1.04 (1.01 to 1.06)	0.0081	1.04 (1.01 to 1.06)	0.01

Variable	Univariate		Multivariate	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Mesh	0.59 (0.36 to 0.99)	0.0444	0.41 (0.23 to 0.75)	0.003
Age (years)	1.00 (0.98 to 1.02)	0.9698	-	-
BMI	1.00 (0.95 to 1.04)	0.8502	-	-
Prev. hysterectomy	1.09 (0.69 to 1.72)	0.7146	-	-
Prev. incontinence surgery	1.11 (0.32 to 3.8)	0.8702	-	-
Length of follow-up (years)	0.90 (0.79 to 1.03)	0.1194	-	-
Avulsion	3.45 (2.15 to 5.53)	<.0001	2.95 (1.77 to 4.91)	<.0001
Hiatal area on Valsalva (cm <sup>2</sup> )	1.08 (1.05 to 1.11)	<.0001	1.07 (1.04 to 1.11)	<.0001

Table 1: Univariate and multivariate analysis of recurrence risk after anterior colporrhaphy (n= 334) at an average follow-up of 2.51 years). Panel A shows estimates using clinical recurrence (ICS POP-Q stage 2+) as the outcome, Panel B shows estimates using recurrent cystocele on ultrasound (bladder at least 10 mm below symphysis pubis) as the outcome.

### Results

334 women were seen a minimum of 3 months (range, 0.26- 6.39 years, mean 2.51 years) after Anterior Colporrhaphy +/- mesh augmentation. 87 had had a traditional anterior colporrhaphy, 143 a Perigee, 67 an Anterior prolift, and 37 an Anterior Elevate mesh. 86/334 patients (26%) complained of recurrent symptoms of prolapse. Objective evidence of recurrence on clinical examination (Ba= -1 or worse) was seen in 141 women (42%), and on ultrasound a significant cystocele (lowermost point of the bladder at 10 mm below the symphysis pubis, or worse) was seen in 113/334 (34%).

Table 1 gives univariate and multivariable results for the prediction of a) clinical cystocele recurrence (ICS POP-Q stage 2+) and b) sonographic cystocele recurrence (bladder at least 10 mm below the symphysis on Valsalva). None of the tested predictors were predictive of recurrent symptoms of prolapse, likely due to a lack of power. Mesh, avulsion, and hiatal area were significant univariate predictors (and remained significant in the multivariate models) for both clinical recurrence and recurrence on ultrasound. The AUC ROCs for the multivariate models were 0.65 and 0.73 for clinical recurrence and recurrence on ultrasound respectively.

We included a term for the interaction between avulsion and mesh in a secondary analysis, on the basis of weak evidence in this dataset (p=0.087) that mesh may be more effective in women with avulsion. The predicted probability of recurrence with respect to hiatal area, avulsion status, and mesh use based on this secondary analysis is shown in Figure 1.

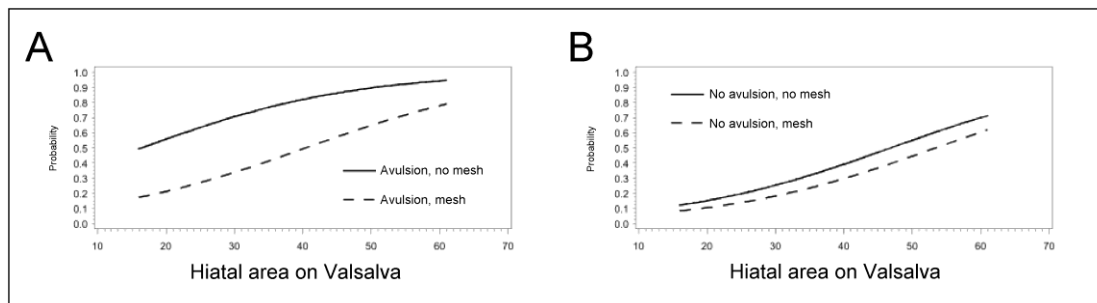


Figure 1: Risk of prolapse recurrence at 2.5 years after anterior colporrhaphy in women with (A) and without avulsion (B) relative to hiatal area and mesh use.

### Interpretation of results

In this series of 334 patients on average 2.5 years after cystocele repair, we found that the state of the patient's pelvic floor was by far the strongest predictor of recurrence. Avulsion is associated with an odds ratio of approx. 3 for recurrence on ultrasound, whilst hiatal area on valsalva conveyed an additional 7% per cm<sup>2</sup> for the likelihood of recurrence. This effect of an enlarged hiatal area seems largely independent of the risk conveyed by avulsion. This implies that both factors in combination may effectively distinguish patients in whom conventional surgery is likely to fail, suggesting that mesh augmentation may be advisable.

### Concluding message

Recurrence risk after Anterior Colporrhaphy is largely determined by the state of the patient's pelvic floor. The likelihood of recurrence may vary from 12% to over 90% in a patient with a given degree of cystocele, depending on the two main predictors avulsion and hiatal ballooning. Both should be determined prior to prolapse surgery, especially if mesh use is contemplated.

### References

1. Dietz H. Pelvic Floor ultrasound in prolapse: what's in it for the surgeon? *Int Urogynecol J* 2011;22:1221-32.
2. Dietz H, Bernardo M, Kirby A, Shek K. Minimal criteria for the diagnosis of avulsion of the puborectalis muscle by tomographic ultrasound. *Int Urogynecol J* 2011;
3. Dietz H, Wong V, Shek KL. A Simplified method for determining hiatal biometry. *Aust NZ J Obstet Gynaecol* 2011;DOI: 10.1111/j.1479-828X.2011.01352.x

### Disclosures

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