

## DOES VAGINAL SURGERY ALTER THE RELATIONSHIP BETWEEN PROLAPSE AND PROLAPSE SYMPTOMS?

### Hypothesis / aims of study

Recurrence after surgery for female pelvic organ prolapse is common. However, many patients seem to remain asymptomatic even if there is objective prolapse recurrence, and it is commonly observed that objective recurrence rates are substantially higher than recurrence of symptoms of prolapse (1,2). This may be due to denervation of the vaginal surface, or possibly evidence of a simple placebo effect. In order to test the hypothesis: "The relationship between objective prolapse and prolapse symptoms is altered by vaginal prolapse surgery" we undertook a retrospective observational study.

### Study design, materials and methods

We conducted a retrospective analysis of the clinical and ultrasound datasets of 892 patients seen for multichannel urodynamic testing and/ or clinical assessment between January 2005 and July 2008. All underwent a standardised local nonvalidated interview, prolapse assessment using the ICS POP-Q staging system and 4D translabial ultrasound (US) using a Voluson 730 expert system with RAB 8-4 Mhz transducer, as previously described; see Figure 1 (3). Symptoms of prolapse were defined as the symptom of a lump or a dragging sensation, with no attempt made to quantify bother or severity. Significant cystocele on US was diagnosed if the leading edge of the bladder was found at 10 mm below the symphysis pubis (SP) or lower, a significant uterine prolapse if the uterus was at the level of the SP or lower, a significant enterocele if small bowel was detected at the level of the SP or lower, and significant rectal descent if the rectal ampulla was at 15 mm below the SP or lower (3).

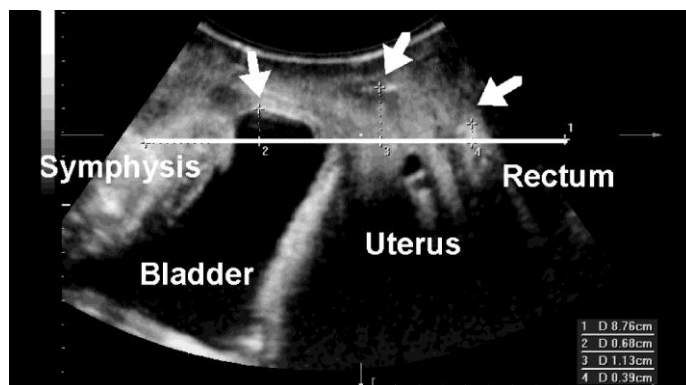


Figure 1: Ultrasound assessment of prolapse: measurements are relative to the inferior margin of the symphysis pubis on maximal Valsalva. Arrows indicate leading edge of cystocele (left), uterus (centre) and rectal ampulla (right).

### Results

Of 892 women included in the database between May 2005 and July 2008, 135 were excluded due to missing or insufficiently detailed information on previous surgery, leaving 757. All subsequent analysis refers to this group. Mean age at assessment was 54.8 (range, 26-81). Patients presented with stress incontinence (n=535, 70.7%), urge incontinence (n=523, 69.1%), frequency (n=384, 50.7%), nocturia (n=385, 50.9%), voiding dysfunction (n=170, 22.5%) and symptoms of prolapse (n=335, 44.3%).

The majority of women had at least one vaginal birth (n=685, 90.5%), 29 (3.8%) had all their children by Caesarean Section, and 43 (5.7%) were nulliparas. Two hundred forty two (31.9%) had had a previous hysterectomy (abdominal or vaginal) and 160 (21.1%) previous incontinence procedures. Overall, 171 patients (22.6%) had previously undergone a vaginal procedure potentially affecting the innervation of vaginal walls such as vaginal repairs, vaginal hysterectomy or sacrospinous fixation. Two women had refused clinical examination, leaving 755. A significant cystocele (ICS POP-Q stage 2 or higher) was detected in 281 women (37%), a uterine prolapse in 51 (7%), an enterocele in 31 (4%) and a rectocele stage 2+ in 202 (27%). In total, we found a prolapse of stage 2 or higher in 375 women (50%).

Ultrasound data was available in 731 women. A significant cystocele was found in 302 women (41%), a significant uterine prolapse in 111 women (15%), a significant enterocele in 115 women (16%) and significant rectal descent (rectal ampulla 15 mm below the SP or lower) in 264 women (36%). In total, 452 women (62%) were found to have significant prolapse according to ultrasound criteria.

	Asymptomatic	Symptomatic	Total
No prior vaginal surgery and significant clinical prolapse*	98 (35%)	182 (65%)	280
Prior vaginal surgery and significant clinical prolapse	34 (36%)	61 (64%)	95

Table 1: Relationship between significant prolapse on clinical examination (n=375) and symptoms of prolapse, comparing women with and without previous vaginal surgery. \* ICS POP-Q stage 2+.

	Asymptomatic	Symptomatic	Total
No prior vaginal surgery and significant prolapse on US	136 (41%)	198 (59%)	334
Prior vaginal surgery and significant prolapse on US	51 (43%)	67 (57%)	118

Table 2: Relationship between significant prolapse on ultrasound (n=452) and symptoms of prolapse, comparing women with and without previous vaginal surgery.

There was a highly significant relationship between symptoms of prolapse on the one hand and stage2+ prolapse on clinical assessment ( $X^2= 125.9$ ,  $P < 0.001$ ) as well as prolapse on ultrasound ( $X^2= 91.2$ ,  $P < 0.001$ ). Previous vaginal surgery did not modify these relationships (see Tables 1 and 2);  $P$  for modification= 0.44 for clinical prolapse and  $P= 0.86$  for prolapse on ultrasound.

#### Interpretation of results

Previous surgery affecting the anterior or posterior vaginal wall does not seem to affect the relationship between objective prolapse and reported symptoms of prolapse. Denervation of vaginal walls is unlikely to be a sufficient explanation for the commonly observed discrepancy between subjective and objective success rates after prolapse surgery. It seems reasonable to assume that this discrepancy may be a manifestation of the Placebo effect. This should be taken into account when designing trials evaluating prolapse surgery. Subjective outcomes are likely to be confounded by placebo effect and therefore likely to provide inferior power relative to objective outcome measures.

#### Concluding message

Previous vaginal surgery does not seem to influence the relationship between objective prolapse and reported symptoms of prolapse.

#### References

1. Obstetrics & Gynecology 2007;109 (6):1424-33.
2. International Urogynecology Journal 2008; 19:1593-1601.
3. Ultrasound in Obstetrics & Gynecology 2007;29:688-691.

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<b>Is this a clinical trial?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>Yes</b>
<b>Specify Name of Ethics Committee</b>	<b>SWAHS HREC</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>No</b>