**567**

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# CAN BALLOONING OF THE LEVATOR HIATUS BE CORRECTED SURGICALLY?

Hypothesis / aims of study

Hiatal ballooning, i.e., excessive distensibility of the levator hiatus, seems to be an independent predictor of female pelvic organ prolapse (FPOP) (1). This is not surprising since the levator hiatus is the largest potential hernial portal in the abdominal envelope. Data obtained in young, nulliparous women and in older women without symptoms or signs of prolapse suggest that a 'normal' hiatus should measure <25 cm2 on Valsalva (2), a value that is exceeded by the vast majority of women presenting with FPOP. A larger hiatus implies that any surgically placed support structure (sutures, mesh arms etc) would be exposed to increased stress during the period of wound healing, heightening the risk of support failure.

We hypothesize that permanent reduction of the levator hiatus may help reduce recurrence rates after pelvic reconstructive surgery. In order to determine whether a band of mesh placed in the ischiorectal fossa, surrounding the levator ani, can reduce hiatal area, we undertook a pilot surgical intervention trial. The concept is a development based on a procedure designed for fecal incontinence (3).

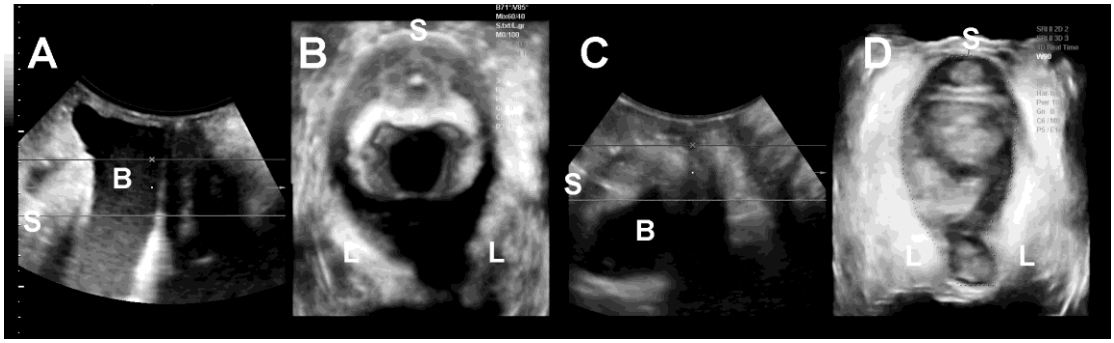


*Figure: Hiatal reduction from 35 cm2 to 22 cm2 3 months after insertion of a puborectalis sling. Midsagittal (A) and axial (B) view on Valsalva before anterior repair, transobturator sling and sacrospinous fixation; midsagittal (C) and axial (D) view on Valsalva 3 months after the procedure. S= symphysis pubis, B= bladder, L= levator ani.*

Study design, materials and methods

We enrolled 20 patients on our waiting list for prolapse repair in a prospective surgical pilot study at two tertiary Urogynaecology units. Patients were aware that this was a Phase I trial which was IRB- approved, and they provided written consent. The entry criteria were 1) patient due for prolapse repair, and 2) hiatal ballooning of 35 cm2 or more. After completion of standard prolapse repair, a postanal tunnel was created via two 2 cm incisions 3 cm posterior and lateral to the anus. A piece of mesh was cut diagnonally from a 6 in x 6 in patch of polypropylene (2.5 cm wide, with the central portion between 3 and 3.5 cm wide). This strip was placed through the postanal tunnel and retrieved by a Stamey or Pereyra needle passed through the obturator foramen, through an incision located at the site of a transobturator sling incision. After retrieval the distal end of the strip was sutured to the inferior surface of the inferior pubic ramus. Patients were followed up at 5-6 weeks and 3 months after the procedure. Hiatal area on Valsalva was measured offline in cine volume datasets obtained using a Voluson 730 expert system with RAB 8-4 Mhz transducer (2). We did not perform formal power calculations due to an absence of pilot data in the literature.

Results

Mean age of study participants was 59.6 (28.5-88.4) years. Body mass index was 29.5 (21-43). All were vaginally parous, 4/20 reported a previous vaginal operative delivery. 9/20 had previously had a hysterectomy, 7 an incontinence or prolapse procedure. Patients suffered from symptoms of prolapse (n=20), stress incontinence (n=11), urge incontinence (n=15), frequency (n=10), nocturia (n=10) and symptoms of voiding dysfunction (n= 11). All had a symptomatic prolapse ICS POP-Q stage 2+ (stage 3+, n=15) on clinical assessment (cystocele, (n=16), uterine prolapse (n=8), vault prolapse (n=7), rectocele or recto- enterocele (n=14). 11/20 were diagnosed with an avulsion (6 bilateral). Mean hiatal area on Valsalva was 42.5 (35- 60) cm2, with 11/20 showing severe ballooning >40 cm2.

Patients underwent surgery between August 2010 and February 2011. Concomitantly, we performed 9 vaginal hysterectomies, 12 vault suspension procedures, 16 anterior repairs, 4 with mesh augmentation (Perigee$^{TM}$), 16 posterior repairs and 10 suburethral slings. There were no cases of vaginal or rectal/ anal perforation due to the needle passage, and no other major intraoperative complications due to the puborectalis sling. There was no significant bleeding from skin incisions or on needle passage. Minor technical issues included two cases of inadvertent subpubic passage of the needle and several mesh dislodgments from the needle on mesh retrieval, necessitating additional needle passes. In one case, a concomitant sacrospinous colpopexy resulted in perforation of the rectal ampulla. This was recognised intraoperatively and followed by an uneventful recovery after suture removal. Postoperatively we observed one case of potential compression of the inferior rectal nerve (burning peri-anal pain) and one case of stool impaction one week after surgery. The former was 90% improved at the 3 month follow-up, with the patient declining division of the puborectalis sling, the latter resolved after an enema, without further sequelae at 6 months.

One patient could not be followed up prior to abstract submission due to an overseas trip. She reported an uneventful postoperative course. The remaining 19 were seen at an average follow-up of 101 days. Patients were mostly satisfied with their surgery (16/20, 80%) and considered themselves improved or cured (17/20, 85%). Five (25%) reported symptoms of recurrent prolapse. Apart from the above- mentioned instance of nerve compression, there was no chronic pain related to the mesh implant or its fixation to the inferior pubic rami, and no de novo symptoms of obstructed defecation. We saw 11 cases of recurrent prolapse (ICS POP-Q stage 2 or worse). The average Ba was at –1.2, C at -5.7 and Bp at -2.3. On ultrasound, there were five cases of recurrent cystocele, three cases of significant rectal hypermobility, and four recurrent true rectoceles. The mean hiatal area on Valsalva was reduced by a mean of 12 cm2, to 30.7 cm2 ($P < 0.0001$, $t = 7.32$).

Interpretation of results

The puborectalis sling represents an attempt to reduce the area of the levator hiatus in order to decrease the load placed on native tissue or implants during wound healing after prolapse surgery. It is performed as an adjunct, after completion of a prolapse procedure. We present early follow-up data on a pilot series of 20 patients, undertaken to provide 'proof of concept'. This study has provided such proof: clearly, it is possible to substantially reduce hiatal area with a sling placed through the ischiorectal fossa, exterior to the levator ani. The average reduction after 3 months was about 12 cm2, from an average preoperative area of 42.5 to 30.7 cm2. While this pilot study was not designed or powered to allow an estimate of recurrence rates, results so far are encouraging, given that all patients suffered from marked or severe ballooning, and that more than half had avulsions. This pilot study has been extended to 50 patients to allow power calculations for a subsequent randomised controlled trial to determine the effect of this procedure on prolapse recurrence.

Concluding message

The 'Puborectalis sling' procedure is a minimally invasive technique that results in a significant reduction of the size of the levator hiatus at the 3 month mark. In this pilot series of 20 patients there were no major complications. We are currently completing an extended pilot study of n=50 to determine whether there is any effect on prolapse recurrence rates.

References


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| ***Specify source of funding or grant*** | **Nil** |
| ***Is this a clinical trial?*** | **Yes** |
| ***Is this study registered in a public clinical trials registry?*** | **No** |
| ***Is this a Randomised Controlled Trial (RCT)?*** | **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** |
| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |