804

Burton C[1], Toozs-Hobson P[1], Latthe P[1], Parsons M[1]
1. *Birmingham Womens Hospital*

GOVERNANCE OF NEW PROCEDURES: THE USE OF THE BSUG DATABASE IN EVALUATING SHORT TERM OUTCOMES FOLLOWING I-STOP POSTERIOR INTRAVAGINAL SLINGPLASTY FOR PROLAPSE..

Hypothesis / aims of study

In the UK novel procedures are required to have specific governance protocols in place to review outcomes. The I-stop mesh system (CL Medical, France) has been introduced to perform posterior intravaginal slingplasty (IVS) for vaginal vault and posterior compartment prolapse with enterocele. The original description of IVS used a multifilament mesh with high reported mesh complications (1). The I-stop uses a monofilament, macroporous polypropylene mesh. We introduced this procedure to replace the IVS tunneller, because of the long term mesh complications, and to replace sacrospinous fixation, because of the high rate of anterior prolapse due to alteration of vaginal axis.

This paper sets out to demonstrate the role of the British Society of UroGynaecology (BSUG) surgical database in reviewing the short term success of I-stop in correcting vaginal vault and posterior wall prolapse.

Study design, materials and methods

BSUG database review of all cases of I-stop posterior intravaginal slingplasty performed in a tertiary unit by 3 consultant urogynaecologists. All patients completed a standard assessment and were entered on the BSUG database. Analysis was performed using the different characteristics available on the BSUG database. Success was defined subjectively on a 7 point scale and also as anatomical cure (grade 0-1 prolapse on POP-Q assessment). One of the unique features of the BSUG database is the ability to analyse follow up data by a variety of matrices.

Results

35 women had the procedure between July 2008 and Dec 2010.

The indication for surgery was prolapse in all cases and additional functional bowel issues in 4. In 13 cases, there was significant vault prolapse, and the remainder of the cases had significant posterior prolapse with rectoenterocele.

The mean age was 66 years (range 28-85) and mean BMI was 27 (range 18-38).34 patients had previous surgery – 91% hysterectomy (13 TAH, 19 VH), 37% pelvic floor repairs. 1 had surgery for rectal prolapse (Delormes procedure and rectopexy).

32 women had concomitant prolapse procedures at the time of I-stop insertion. 2 had anterior repairs, 24 had posterior repairs and 6 had both.

There were no intra operative complications. Average length of hospital stay was 2.6 days (range 1-5)

Planned review in clinic was at 3 months (range 6 weeks-1 year)

Table 1 Pre and post operative POP-Q assessment

Grade of prolapse	Ant wall pre op	Ant wall post op	Vault pre op	Vault post op	Post wall pre-op	Post wall post-op
0	7	10	0	**22***	1	**24***
I	10	14	22	**12***	3	**6***
II	12	8	10	0	26	4
III	5	2	2	0	4	0
IV	1	0	1	0	1	0

*anatomical cure of prolapse

83% of women with no vault or posterior prolapse on follow-up reported their prolapse as much better or very much better. Of the 5 women who did not report such improvement, 3 had significant anterior prolapse.

Overall 82% of patients reported their prolapse as much better or very much better following surgery.

Four women developed post operative complications. 2 had temporary buttock pain, 1 had a mesh extrusion at vault at 3 month review which was excised and 1 had a wound infection requiring oral antibiotics.

1 patient has had further abdominal surgery for vault prolapse and recurrent enterocele at I year post-op. A second patient reported no improvement despite objective evidence of reduction in the POPQ scores. The vault was found to be -4 and she is awaiting a sacrocolopexy and rectopexy. A third patient who had previously had a Delormes and a rectopexy subsequently developed further rectal prolapse at 30 months requiring an abdominal repair. The vaginal prolapse remained controlled but the tape had to be divided to access the rectum for the rectopexy and a sacrohysteropexy was performed to replace the tape

Analysis using the BSUG database tools suggested that low BMI may be associated with poorer subjective results and that mesh support may depend on native tissue. There was no trend observed by age. Likewise analysis of time of surgery suggested that there was little or no learning curve for this surgery.

Interpretation of results

None of the 34 women who had insertion of I-stop had significant vault prolapse on post-operative review.

Surgery was “successful” using a combined objective and subjective measure in 74%. If the 3 women with post-operative anterior prolapse are excluded the success rate increases to 81%.

We would view as laparoscopic sacrocolpopexy as the “gold standard”. The 6% re-operation however is in keeping with the literature for apical surgery and we feel this procedure has been demonstrated through our governance protocol as an acceptable alternative. Our decision on surgical approach will depend on patient characteristics and the patient’s preferences.
NICE encourages clinicians performing this surgery in the UK to collect long-term data on clinical outcomes as part of clinical governance. However current health policy restricts surgeons’ ability to review patients routinely outside of clinical trials. We have moved from a 6 week to 12 week follow up to collect all short-medium term complications. The additional matrix analysis on the BSUG database has provided quick and easy additional information that may help improve patient selection and has identified areas for further observation outside the realms of a formal RCT.

Concluding message

Posterior I-STOP is a minimally invasive vaginal procedure to correct vault prolapse. It may be particularly useful in treating prolapse in older, frailer patients for whom abdominal surgery would not be appropriate. The initial results following surgery are encouraging but larger series are needed and long term outcomes need to be assessed.
Use of the BSUG database has enhanced our ability to assess outcomes in patients outside clinical trials. It has also facilitated easy feed back on safety and outcome to the governance committee at our institution. We would strongly recommend that such tools are adopted to allow robust outcome measures to be recorded with all new devices as well as assess outcomes of routine procedures.

References

1. Baessler K, Hewson AD, Tunn R, Schuessler B, Maher CF. Severe mesh complications following intravaginal slingplasty. Obstet Gynecol 2005; 106: 713-6

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**this was not a research study**
Was the Declaration of Helsinki followed?	**No**
This study did not follow the Declaration of Helsinki in the sense that	**this was not a research study.**
Was informed consent obtained from the patients?	**No**