

A SIX YEAR RETROSPECTIVE AUDIT OF CLINICAL AND SUBJECTIVE OUTCOMES OF SURGICAL VAGINAL PROLAPSE REPAIR WITH THE INSERTION OF MESH

Hypothesis / aims of study

Establish clinical and subjective outcomes of the use of Mesh for Vaginal Prolapse repair based on the Interventional Procedures Guidance (IPG) 267- Surgical Repair of Vaginal Wall Prolapse Using Mesh issued by the National Institute for Health and Clinical Excellence (NICE) – June 2008⁽¹⁾.

Study design, materials and methods

This was a retrospective audit from the 1st of January 2006 to the 31st of December 2011.

Forty five patients who had had a surgical vaginal prolapse repair with the insertion of mesh were identified by a local urogynaecology and theatre database. The audit department were able to retrieve 41 sets of notes. Clinical data was recorded into the NICE audit support tool issued alongside the guideline and data was entered into Excel worksheets. Subjective outcomes were established by posting a Prolapse Quality of Life questionnaire⁽²⁾ with an accompanying letter and prepaid envelope to 42 suitable patients (3 had deceased). There were two rounds of postage and out of 42 posted questionnaires we had a 76% response rate (32 questionnaires).

Results

There were 45 patients identified in the 6 years. The mean number of procedures performed / year were 6 (4 – 12) and the mean age of patient was 65.5 (41 – 84). The NICE audit support tool is divided into 6 domains:

Consent: At the time of introduction of mesh there were no information leaflets to hand to patients 0% (standard 100%), all the patients had a discussion with the surgeon prior to surgery (100%) and all the procedures were carried out by a gynaecologist with special expertise in the surgical management of pelvic organ prolapse (100%).

Baseline data: 100% of the patients had had a clinical assessment of prolapse at baseline. The type of prolapse in 59% was multi-compartment (anterior compartment most common 21/24) and single compartment in 41% (anterior most common 8/17). Prolapse staging was documented in 98% of the patients with 78% being stage 3 /4. The most common reported symptoms were of lower urinary tract symptoms (LUTS) 19/41. In 32% of women this was a redo prolapse repair in the same area, 41% had had a previous surgical repair of prolapse in a different area and in 44% (18/41) this was their first ever prolapse repair. Amongst the 41 patients there were 5 fit and healthy and 36 patients with collectively 46 co-morbidities the top three being overweight (55% 20/36), cardiac related (31% 11/36) and Respiratory (14% 5/36). Synthetic mesh was inserted in 89% of the women and 72% (31/43 meshes) had Prolift insertion.

Early adverse events: There was a 2% adverse event intra-operatively (1 bladder injury) and a 5% early, within 30 days, complication rate (1 urinary retention and 1 urinary tract infection).

Effectiveness at 6 months: 93% of the patients were seen within 6 months and 89% were examined. The clinical failure rate was 12% 4/34 (all anterior) and the occurrence of a new prolapse was 12% (all anterior). Mesh erosion rate was 6% 2/34 (posterior wall), 1 was treated conservatively with oestrogen, 1 was excised on two occasions in the outpatient clinic. Subjectively, 74% improved, 24% LUTS, 11% pain and 8% had the feeling of "something coming down".

Adverse events at 12 months: At one year follow up 31 patients were seen, there was no prolapse or adverse event in 65% of the patients n=20/31. Prolapse was present in 26% of the patients (n=8/31) with 16% being failure of the mesh (n=5/5 anterior) and 10% being a new prolapse (n=3/3 anterior). There was a 13% new mesh erosion rate n=4/31 (the two mesh erosions seen at 6/12 had healed well). The overall return to theatre for mesh related complications was 10% (n=4/41) these were for mesh excision for erosion n=3 and mesh excision for pain n=1.

Effectiveness at 12 months: Objectively at 12 months there was no prolapse 55% (n=17), a cystocele was seen in 26% (n=8), denovo incontinence was present in 13% (n=4), mesh erosion seen in 13% (n=4) and pain was present in 3% (n=1). There was no formal subjective outcome recorded.

The second part of the audit looked at subjective outcomes. The questionnaires returned ranged from 1 year to 6 years outcome. The response rate was 76%(n=32) and there was a 100 % return rate for year 2010 and 2011. The questionnaire covered 9 domains and in the 1st domain 81% (n=26) felt their general health was fair and above. The second domain concentrated on Prolapse impact and 50% answered not at all/ little. Overall the responses were positive in all the domains apart from frequency, backache and the use of pads.

Interpretation of results

The use of the NICE audit tool was useful to gather comprehensive information on each patient. The audit was invaluable in addressing areas below standard such as the availability of written information leaflets for the patients which has subsequently been addressed. Although mesh repair was used in 18 patients for a primary repair procedure the patients had been counselled appropriately based on the available evidence at the time of repair. Intra - procedural complications were low at 2% and overall the failure of repair at 16%, was acceptable compared to meta-analysis studies on failure of repairs with mesh (9 – 23%)⁽¹⁾. The denovo incontinence rate was acceptable 13% versus 15% and pain was positively low 3% versus 10%⁽¹⁾. The overall mesh erosion was 16% (6/38) and is higher than the 10% standard⁽¹⁾ but all 6/6 patients had a number of co-morbidities and 3/6 required mesh excision in theatre. Interestingly only 2/6 mesh erosions were seen at 6 months and the remainder at least 12 months later. This would suggest that at least one year follow up is important as mesh erosions can appear more than one year postoperatively especially in patients with co-morbidities.

Concluding message

Mesh vaginal prolapse repair is currently a hot topic of debate. It is essential to adhere to national guidance on the use of mesh in prolapse repair and to ensure adequate documentation. Patients should be fully informed on the issues and possible complications related to the use of mesh and encourage patients to visit reputable websites for further information. It is vital to be aware of national and international updates such as NICE and FDA guidance. This audit was a collaborative effort between the gynaecology and audit team and would not have been possible without their support. Large audit projects should be encouraged and supported as using a structured approach and collaborating with the audit department is invaluable.

References

1. National Institute for Health and Clinical Excellence 2008 Surgical repair of Vaginal wall prolapse using mesh. Interventional Procedure Guidance 267
2. Digesu A. et al (2005) P-QOL: a validated questionnaire to assess the symptoms and quality of life of women with urogenital prolapse. International Urogynaecology Journal 16: 3; 176 - 181

Disclosures

Funding: none **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** It was an audit with full audit lead approval **Helsinki:** Yes **Informed Consent:** Yes