A Six Year Retrospective Audit of Clinical and Subjective Outcomes of Surgical Vaginal Prolapse Repair with the Insertion of Mesh

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Objectives


Methods

- Retrospective audit from the 1st of January 2006 to the 31st of December 2011.
- Local Urogynaecology and theatre database identified 45 patients who had had a surgical vaginal prolapse repair with the insertion of mesh
- The audit department were able to retrieve 41 sets of notes.

Role of the clinical team

- Collection of clinical data from the patients’ notes using the NICE audit support tool issued alongside the guideline.
- The NICE audit criterion is divided into 6 domains
  1. Consent
  2. Baseline data
  3. Adverse events (Intraprocedural and within 30 days)
  4. Effectiveness (6 months)
  5. Adverse events (12 months)
  6. Effectiveness (12 months)
- Data entry into Excel worksheets and analysed

Role of the audit team

- Postage of the Prolapse Quality of Life questionnaire (PQOL) (3) with an accompanying letter and prepaid return envelope to 42 suitable patients (3 had deceased). There were two rounds of postage.
- Scoring the PQOL questionnaires responses and formulating a report.

General Results

Mean number of procedures / yr = 6 (4 – 12)
Mean age of patient = 65.5 yr (41 – 84).

1) Consent: Written information 0%, written consent 100%, surgery by an experienced surgeon 100%.
2) Baseline data: Multi compartment prolapse present in 59% and 74% were stage 3/4. History of previous prolapse repair in 73% of patients. There were 46 comorbidities in 36 patients. Synthetic mesh was inserted in 89% of the women and 72% had Prolift insertion.
3) Early adverse events: 2% intraoperatively (1 bladder injury) and a 5% early complication rate (1 UTI, 1 retention)

Clinical Results

4) Clinical effectiveness at 6 months

- No prolapse
- Recurrence
- New prolapse

6% 82% 12%

Failure: 4
New: 2
6/6 Anterior

2 Posterior erosions = Erosion rate 6%  
***FDA erosion rates = 10%***

Patients’ reported outcomes no / 38

| Improved | 74% |
| LUTS     | 24% |
| Pain     | 11% |
| SCG      | 8%  |

5) Adverse events and 6) Effectiveness at 12 months

- 31 patients seen at 12 /12
- Completely well 65%
- Prolapse(8) 26% Failure 5/31 Anterior New 3/31 Anterior
- Denovo incontinence 13%

Erosion (4) = 13%

Pain (1) = 3%

Mesh related return to theatre = 10% 3 erosion 1 pain

Subjective outcomes at 12 months

The response rate was 76%(n=32) with 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.

Conclusions

Mesh vaginal prolapse repair is currently a hot topic of debate. It is essential to be aware of FDA updates and NICE guidance on the use of mesh. Our results relating to early and long term outcomes were within national and international standards. Large audit projects should be encouraged and supported as using a structured approach and collaborating with the audit department is invaluable.

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References:
1) Surgical Repair of Vaginal Wall Prolapse using Mesh- IPG 267 NICE June 2008
2) FDA Update- Mesh for POP - based on MAUDE (Jan 08 – Dec 10) 2011