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ABDOMINAL SACRAL HYSTEROPEXY: CLINICAL OUTCOMES COMPARED TO ABDOMINAL SACRAL COLPOPEXY WITH CONCURRENT HYSTERECTOMY.

Hypothesis / aims of study
We hypothesized that abdominal sacral hysteropexy (ASH) is comparable to abdominal sacral colpopexy with concurrent hysterectomy (ASC/TAH) in patients presenting with uterovaginal prolapse. Our primary outcome was an assessment of patient improvement.

Study design, materials and methods
We identified all patients who underwent ASH or ASC/TAH for Stage 2 or greater pelvic organ prolapse in our urogynecology unit from January 2007 to December 2008. Patients were excluded if they had had prior use of intra-abdominal or vaginal graft or vaginal apical prolapse repair. Those undergoing concurrent rectopexy were also excluded. A total of 29 patients were eligible, 20 ASH and 9 ASC/TAH. Patients were assessed preoperatively and at 1 year with history, examination (pelvic organ prolapse quantification system (POPQ)) and validated questionnaires (Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ-7)). A consent process was utilised for patients who had not had their 1 year followup at the commencement of the study. At 1 year patients also completed a Global Impression of Improvement question, a 7 point Likert scale ranging from “very much better” to “very much worse” recently validated in prolapse patients.

The primary outcome measure was impression of improvement. Patients were considered improved if they answered “very much better” or “much better”. Secondary outcome measures were anatomical cure, change in symptoms and complications including mesh erosion. Anatomical cure was defined separately for the apical, anterior and posterior compartments. Symptom change was assessed using change in total scores and symptom subscale scores of the PFDI-20 and PFIQ-7.

Statistical analysis was performed using STATA version 10.0 (Stata-Corp, College Station, Texas, USA). Continuous data were analysed using paired and unpaired t-tests for parametric data, Wilcoxon sign rank test for non-parametric data. Categorical data were analysed using Fishers exact test. A p value <0.05 was considered statistically significant..

Post-hoc analysis revealed that for a power of 80% with alpha of 5%, and the clinically meaningful difference at 15%, we would need to recruit 100 patients to each treatment group to show equivalence for a composite outcome of success as discussed below.

Results
29 patients were eligible for the study, 20 ASH patients and 9 ASC/TAH patients. 1 ASH patient declined participation and 1 ASH patient was unable to be contacted therefore pre- and post-operative data were available for 27 patients. There were no differences in baseline characteristics between groups.

Mean operating time for ASH and ASC/TAH was 192 min and 239 min respectively (p=0.06). There was a trend for lower blood loss in the ASH group (193ml (ASH) vs 333 ml (ASC/TAH)) but this did not reach statistical significance (p=0.15). 2 patients, both ASC/TAH, required blood transfusion although this was not directly related to the hysterectomy. Hospital stay did not differ significantly between the groups (p=0.08). Operative and post-operative complications were rare. 3 mesh erosions occurred, all in the ASC/TAH group, at a mean of 5.3 months (range 3-8 months). 2 of these occurred in the presence of polypropylene mesh and were managed successfully with vaginal excision of the mesh. One of these patients did not attend for further followup appointments following excision of the mesh and is excluded from further outcomes analysis.

Mean follow up was 19 months (range 10-33 months). Both groups exhibited high levels of improvement, 89% ASH and 87% ASC/TAH (p 0.9). Of the 3 patients that were not improved, all indicated they were “a little bit better”. None of these patients were considered failures based on POPQ assessment.

Anatomical cure was defined separately for the apical, anterior and posterior compartments as follows; apical cure as point C/D + (TVL -2) ≤0, anterior/posterior cure as point Aa/Ba or Ap/Bp >-2. Based on these definitions, anatomical cure occurred in 7/18 (39%) ASH and 5/8 (63%) ASC/TAH patients (p 0.3). All failures were Stage 2 and predominantly occurred in the anterior compartment, with no apical failures noted. Of the 14 patients considered failed on POPQ, only 2 indicated on their followup questionnaire that they were “somewhat” bothered by their bulge symptoms (POPDI subscale question number 3).

Symptom change was shown in both groups with the greatest statistically significant results noted in the pelvic organ prolapse subgroups of both the PFDI-20 (ASH -31.9, p<0.001, 95% CI 18.4-45.5; ASC/TAH -31.0, p=0.008, 95% CI 10.8-51.3) and PFIQ-7 (ASH -42.4, p=0.004, 95% CI 15.1-70.8; ASC/TAH -46.4, p=0.037, 95% CI 17.5-75.2). These changes were also clinically significant. There were no differences in total mean change in scores when groups were compared.

Reoperation occurred in 3 ASH patients. I patient required posterior vaginal repair with fascial replacement (pelvicol) for recurrent Stage 2 prolapse. 2 patients required mid-urethral sling placement for persistent SUI diagnosed as intrinsic sphincteric deficiency 4 ASH patients were investigated post-operatively for abnormal uterine bleeding. All investigations and pathology was benign. There were no pregnancies reported.

Interpretation of results

This study shows that, in patients undergoing ASH and ASC/TAH for uterovaginal prolapse, overall improvement occurs in 87-89%. Given the small absolute difference of 2% between patient groups this is likely to represent a true result and further studies using the same primary outcome are unlikely to show a clinically meaningful difference.

Although anatomical cure rates were low in both groups (ASH 395, ASC/TAH 63%) only 2/14 "failed" patients experienced symptoms referable to the recurrent prolapse. More recently, the concept of a composite outcome of success incorporating absence of bulge symptoms with anatomical outcomes has been proposed.(1) Using this definition, 83% ASH and 100% ASC/TAH patients in our study would be considered "cured". The significance of asymptomatic Stage 2 recurrence at 1-2 year follow up is unknown and requires longer term follow up.

Mesh erosion occurred in 33% of patients in the ASC/TAH group, with none in the ASH group. Current literature provides conflicting results with respect to the risk of mesh erosion with concurrent hysterectomy. One study, a secondary analysis of the CARE trial, suggested that concurrent hysterectomy increased the risk of mesh erosion with an OR 4.9 (2), whilst a retrospective study did not show this increase.(3)

Concluding message

Abdominal sacral hysteropexy remains a viable alternative for women undergoing pelvic reconstructive surgery who wish to retain their uteri, providing comparable rates of overall improvement and symptom change. Avoiding hysterectomy decreases the risk of mesh erosion but may increase the risk of subsequent recurrent prolapse, specifically in the anterior compartment. We are planning to undertake a prospecitve, multicentre cohort study with composite outcome of success as the primary outcome under investigation.

References

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