

PELVIC ORGAN PROLAPSE SURGERY IN ENGLAND, 13 YEAR TREND: HAS FDA & MHRA MESH REPORTS AFFECTED PRACTICE?

Hypothesis /aims of study

To quantify changes in the operative practice for the surgical treatment of pelvic organ prolapse (POP) in women in England. To review the impact of the 2008 and 2011FDA's Obstetric and Gynecology devices advisory committee report, and the 2012 MHRA report on safety/adverse effects of mesh for pelvic organ prolapse, and ascertain their impact on the trends of prolapse surgery in England.

Study design, materials and methods

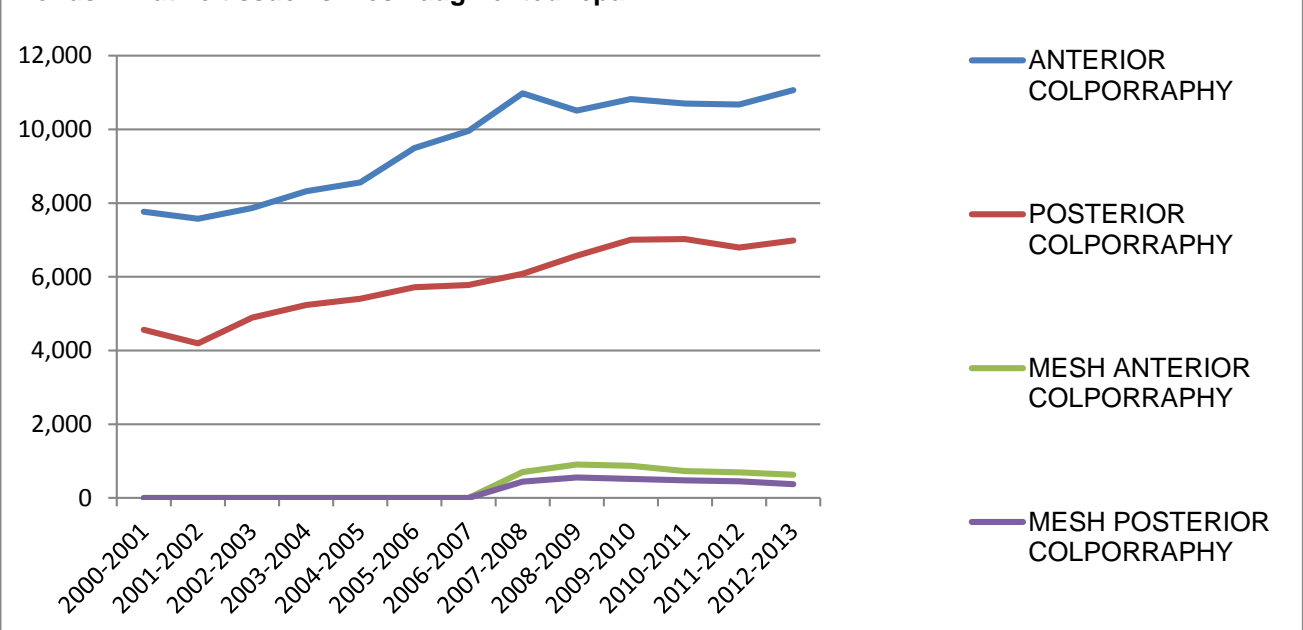
A comprehensive analysis of trends of surgical procedures for POP in England spanning 13 years from 2000 to 2013 was performed. A review of the Hospital Episode Statistics (HES) database dataset was performed (1). Operations were coded using the office of population censuses and surveys surgical operations and procedures, fourth edition (OPCS-4). Data of all admissions within the period were reviewed by selecting specific 4-character OPCS-4 codes referring to all procedures for POP. Summary tables were constructed for the main operations per year and the numbers of the procedures were extracted then plotted by year demonstrating the trends. Analysis was then performed dichotomising the data pre and post regulatory agencies report years.

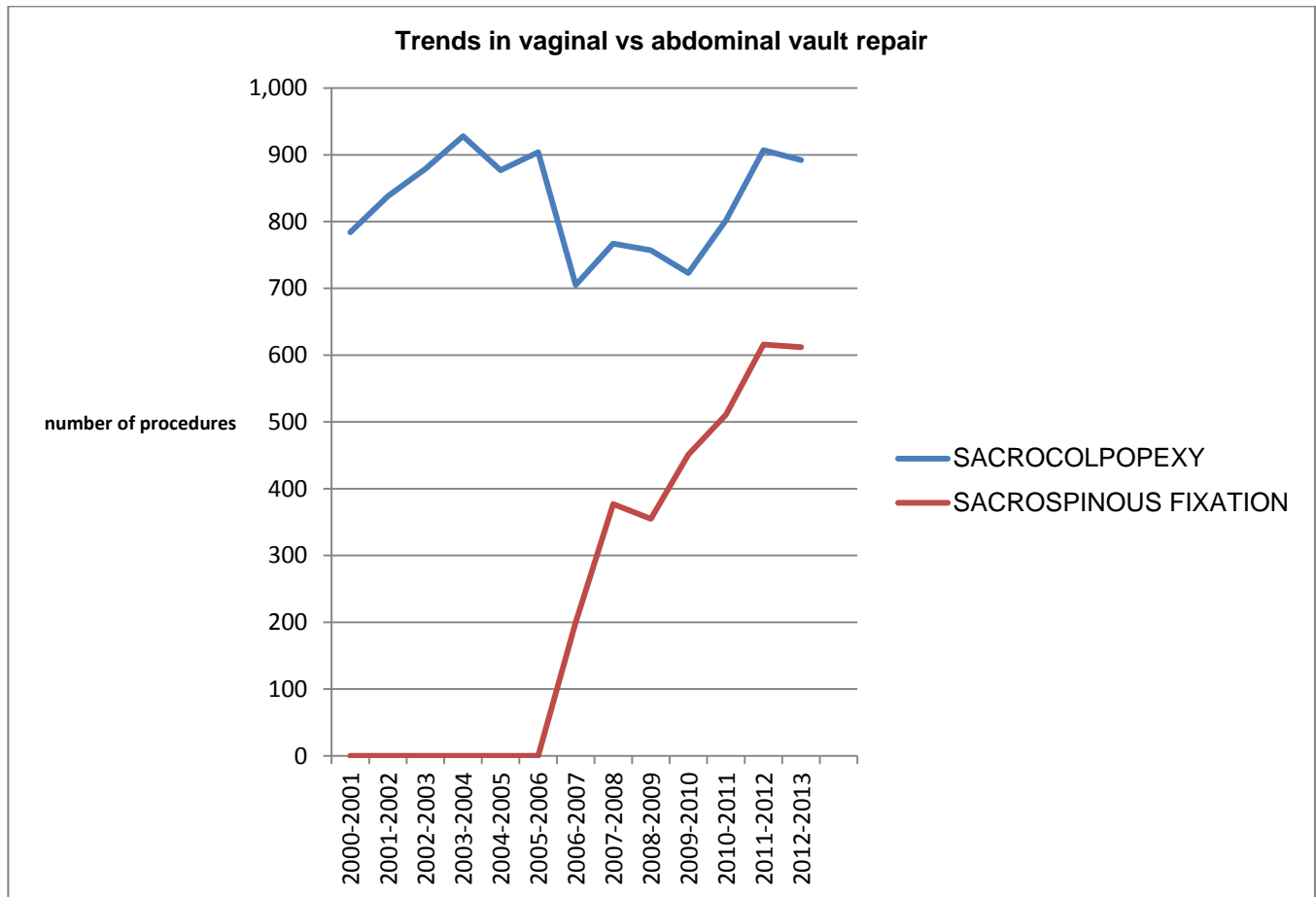
Results

Table 1 below depicts the data of the main procedures performed for POP for the duration of the study and their summary statistics.

Main POP Procedures	Median number of procedures per year	Range
Vaginal Hysterectomy	6933	6345-8513
Anterior Colporrhaphy	9960	7575-11065
Mesh Augmented Anterior Colporrhaphy	717	628-908
Posterior Colporrhaphy	5777	4191-7023
Mesh Augmented Posterior Colporrhaphy	464	372-554
Anterior & Posterior Colporrhaphy	6350	4780-7177
Sacrocolpopexy	838	705-928
Sacrospinous Fixation	451	200-616
Vault prolapse repair abdominal route	52	29-94
Mesh augmented Vault prolapse repair abdominal route	158	86-205
Vault prolapse repair vaginal route	114	60-176
Mesh augmented Vault prolapse repair vaginal route	163	129-210
Perineorrhaphy	1546	1274-3824

Trends in native tissue vs mesh augmented repair





Data for the use of Mesh to augment pelvic floor repair procedures commenced in the 2007/8 with mesh repairs accounting for 6% of anterior and posterior wall prolapse repairs. Year on year there was a 1% increase in mesh repair proportion to the total number of repairs reaching a Peak at 2008. From then there has been a reduction in the use of mesh repairs with the steepest drop by 2.5% in 2012/2013. The rates of Sacrospinous fixation and sacrocolpopexy overall continue to rise year on year.

Interpretation of results

There have been relative rises in the rates of procedures such as vaginal hysterectomy, anterior and posterior colporrhaphy enterocoele repairs. Commencing in 2007 augmenting anterior and or posterior vaginal wall prolapse occurred with a steady rise but this rise was cut short from 2009 with significant reduction in more recent years. There seems to be some correlation with the regulatory agency caution in their reports from 2008, 2011 and more recently 2012. On the other hand sacrocolpopexy and sacrospinous fixation procedures have had a steady rise.

Concluding message

There has been a reduction in the use of mesh augmentation when compared to use of native tissue repairs in anterior and posterior vaginal wall prolapse in women in England from this 13 year review which may have been a response to the FDA & MHRA reports

References

1. Department of Health, UK. Hospital Episode Statistics. Available online at <http://hesonline.nhs.uk> (Accessed March 2014)
2. <http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf>
3. <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con205383.pdf>

Disclosures

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