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COMPARING THE ONE-YEAR OUTCOME OF THE USE OF GYNECARE PROLIFT(SYSTEM IN PELVIC ORGAN PROLAPSE (POP) SURGERIES PERFORMED IN 2008 AS COMPARED TO 2006 & 2007

Hypothesis / aims of study

30% of women worldwide are affected by pelvic organ prolapse (POP) and this is a condition which impairs the quality of life. Traditionally, pelvic reconstructive surgical techniques where conventional sutures are used were marred by a failure rate of up to 30% (1). The Gynecare Prolift® system is a Type I Polypropylene mesh devised to further enhance the durability of the repair thereby conferring long term pelvic floor support (2). The primary aim is to evaluate and compare the safety and efficacy of this mesh in patients operated in 2008 as compared to their counterparts in 2006/2007. The secondary aim is to establish if the learning curve and the experience of the pelvic surgeon has an impact on the peri-operative outcomes in these subjects.

Study design, materials and methods

This was a retrospective, non-funded review of all patients who had the Gynecare Prolift® mesh repair surgery from January 1st. 2006 till 31st. December 2008 in the Department of Urogynaecology. All patients were followed up to one year post-operatively. All operations were performed by the same urogynaecologist.

Results

There were a total of 254 patients; 95 patients in 2006; 74 patients in 2007 and 85 patients in 2008. Of this sum of patients, 128,106 and 20 patients had Total, Anterior and Posterior Prolift® respectively.

Interpretation of results

The patients with Total Prolift® had higher incidence of haematoma (p = 0.07), operative blood loss of more than 1000ml (p = 0.59), requiring blood transfusion (p = 0.25), UTI (p = 0.73), IDC ≥7 days (p = 0.76), rectal perforation (p = 1.0) as compared with the other two Prolift types. There were no cases of buttock pain in 2008 and thigh pain was significantly lower in 2008 as compared to 2006 and 2007 (p < 0.0001). There were no statistically significant differences in the mean operating time and hospital stay but clinically the blood loss, haematomas, bleeding greater than 1000ml, percentage of patients requiring blood transfusions (p = 0.09), duration of IDC ≥ 7 days (p = 0.27), wound dehiscence and re-operation rate were lower in 2008 in contrast to the years 2006 and 2007 (p = 0.43). Only 209 patients (82.3%) were available for review at one year. Nine patients (4.3%) had recurrent cysto-urethroceles. Two had recurrent uterine descent (22.2%) out of nine patients who had their uterus conserved with Total Prolift®. There were two (1.0%) cases of recurrent vault prolapse.

The subjective and objective cure rates at one year after Prolift® surgery in 2006, 2007 and 2008 were 92.1% and 92.1%; 97.0% and 92.4% and 100% and 97% respectively. The mesh erosion rate was remarkably lower in 2008 as compared to 2007 and 2006 (1.5% vs 6.1% vs 26.3%, p < 0.0001).

Concluding message

Gynecare Prolift® system of mesh incorporated pelvic reconstructive surgery is undoubtedly effective, beneficial and safe for the recipients. The learning curve and operating skill of the surgeon does improve the surgical outcome as both the peri and post-operative outcomes in 2008 were clearly better as compared to 2006 and 2007.

References

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Specify source of funding or grant	**Nil.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**SingHealth Centralised Institutional Review Board, 2010/021/D**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**SingHealth Centralised Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**