

THE USE OF GYNECARE PROLIFT® SYSTEM IN THE SURGICAL TREATMENT OF FEMALE PELVIC ORGAN PROLAPSE

Hypothesis / aims of study

To evaluate the safety and efficacy of Gynecare Prolift® system (Johnson & Johnson Medical Ltd.) for patients who had surgical treatment for advanced or recurrent female pelvic organ prolapse (POP).

Study design, materials and methods

This is a retrospective review of patients who had undergone Prolift surgery performed from 1st January 2006 to 31st December 2007 by a senior urogynaecologist. Patients were then assessed for peri-operative complications, late complications, cure and recurrent prolapse rates.

Results

142 patients were included in this study: 76 in 2006, 66 in 2007 respectively. In both groups, patients who had Total Prolift formed the majority of the patients (40.7% and 51.5%). In 2006, 5 (3.5%) patients sustained major intra-operative complications that required blood transfusion: 2 cases of vault haematoma, 1 case of pelvic wall haematoma, 1 with vaginal wall haematoma, 1 patient with gluteal exit wound bleed. In comparison, there was only 1 case of haemorrhage from the ovarian pedicle in 2007 and all of them had undergone total Prolift surgery. However this observation is not significant.

The incidence of thigh and buttock pain is significantly lower in 2007 as compared to 2006 18.2% vs 34.2% (p=0.031) and 9.1% vs 23.7%, (p=0.021) respectively.

However, there is significant longer operating time in 2007 as compared to 2006 (83.0 ± 25.78 minutes and 71.7 ± 29.14 minutes, p=0.016). There is no significant difference in terms of blood loss, fever rates and duration of hospital stay between the 2 groups. Mean duration of indwelling catheterization was 2.89 ± 2.77 days in 2006 and 2.67 ± 2.38 days in 2007 and 6.7% of patients in 2006 and 3.0% in 2007 had urinary retention for more than 1 week.

A total of 11 (8.4%) recurrent cystourethroceles were detected in all patients who underwent Prolift surgery, with 6 cases (8.57%) in 2006 and 5 (8.2%) in 2007. There was only 1 recurrent rectocele among the total Prolift patients in 2006. Two recurrent uterine descend was detected in patients (in 2006) who underwent total Prolift surgery and had their uterus conserved (2/8, 25%).

At one-year, the incidence of *de novo* SUI and *de novo* urge was 11.1%, 8.2% (p=0.594) and 8.5%, 2% (p=0.14) in 2006 and 2007 respectively. By comparison, mesh erosion was significantly higher in 2006 (25%) as compared to 2007 (8.2%, p=0.018).

The success rate for patients who underwent total Prolift surgery was 77.4% for 2006 and 87% for 2007 and the success rate for patients who underwent posterior Prolift was 100% for both years.

Interpretation of results

This review affirmed that the Prolift surgery is effective for treating female POP. The study also noted that the successful outcome of the surgery is significantly dependent on the skill and experience of the surgeon (more experience 2007).

Concluding message

The safety of Gynecare Prolift® is shown to have manageable adverse effects and excellent short-term cure rates. Total Prolift was reported to have higher peri-operative complications and lower cure rates for those patients who had uterine conservation.

References

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Specify source of funding or grant	Nil
Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Institutional Review Board KK Women's & Children's Hospital
Was the Declaration of Helsinki followed?	No
This study did not follow the Declaration of Helsinki in the sense that	The declaration was not applicable because this was a retrospective review therefore did not involve human experimentation.
Was informed consent obtained from the patients?	No

