

HYSTERECTOMY VS NO HYSTERECTOMY FOR UTERINE PROLAPSE IN CONJUNCTION WITH POSTERIOR INFRACOCOCYGEAL COLPOPEXY- A RANDOMISED PILOT STUDY 12 MONTHS REVIEW

Hypothesis / aims of study

Hysterectomy confers no advantage for reducing the incidence of recurrence of level one female pelvic organ prolapse (POP). Secondary hypothesis is that vaginal mesh erosion/ protrusion is not increased in the hysterectomy group.

Study design, materials and methods

Recurrence of POP is not uncommon after surgery for POP (1). Vaginal vault prolapse may be found in 1.8% of women who have hysterectomy for benign disease, but up to 11.6% when hysterectomy is performed for prolapse (2). Hysterectomy alone often fails to address the underlying deficiencies in pelvic support that cause uterovaginal prolapse. Vaginal hysterectomy at the time of prolapse surgery has not been proved to improve the durability of the repair and may in fact, increase morbidity, blood loss, operative time and duration of postoperative recovery and may result in pelvic neuropathy and further fascial/ligament degeneration. Synthetic graft augmentation offers an alternative, potentially more robust structural support but has a risk of mesh erosion when combined with hysterectomy(3).

Twenty-one women were recruited as a pilot study through a urogynaecology clinic, and were randomised by computer tables into 2 groups. Criteria for entry were uterine prolapse of at least grade 2 on POP-Q measures, with point D prolapsing to at least -4cm and point C to within 2cm of the hymen. Exclusion criteria were inability to give consent, abnormal bleeding, previous radiotherapy or cancer treatment, immune disorders or immuno-suppressant therapy. Subjects were consented after written information, underwent a POP-Q examination, demographic data was obtained and then completed the p-QOL questionnaire. Women in the conservation group underwent hysteroscopy with biopsy, posterior coccygeal colpopexy and any adjuvant prolapse surgery as necessary. The hysterectomy group underwent the same colpopexy procedure and associated prolapse surgery as necessary. Peri-operative data as well as a repeat examination and questionnaire were undertaken at 12 months. Categorical variables were compared with a two-sided Fisher's exact test & interval data with Student's t-test.

Results

Of the women recruited 5 datasets were unavailable as they had either moved overseas/ interstate or refused to return for follow-up. Of the 16 datasets available there were 9 in the vaginal hysterectomy group and 7 in the conservation group. Demographics are shown in Table 1. Peri-operative comparison in Table 2.

	Hysterectomy group	Conservation	p
Age	67 yrs	62 yrs	0.56
Parity	3.3	3.0	0.23
BMI	31	28	0.34
Previous pelvic surgery	2	1	0.12
Associated surgery			
Anterior fascial repair	4	3	0.11
Posterior repair	2	1	0.19
Sub-urethral sling	2	1	0.19
Anterior mesh repair	0	4	0.04

Table 1.

	Hysterectomy group	Conservation group	p
Blood loss	260mls	170 mls	0.04
Hospital stay	2.9 days	3.1 days	0.26
Days for catheter	1.2 days	1.5 days	0.17
Change in haemaglobin	-2.3 grams	-1.1grams	0.06
Duration of surgery	165 minutes	132 minutes	0.08
Pain scores Day 1 VAS 0-10	4.5	4.7	0.32
Return to activities	15 days	17.5 days	0.21
Mesh erosion at 12 months	2	0	0.07
Re-operation at 12 months	0	2	0.08

Table 2.

On examination point C was similar in both groups prior to surgery, +2.5cm (hysterectomy grp) vs +1.5cm (conservation grp), p=0.09. Post surgery at 12 months point C was -5.7cm (hysterectomy grp) vs -5.0cm (conservative grp), p= 0.23. Bp was similar between groups pre-operatively, +0.7cm vs -0.6cm,p=0.12 and post-surgery -2.2cm vs -2.4cm, p=0.36. Pre surgery point D was -1.8cm vs -3.3cm, p=0.09.

All parameters on the quality of life questionnaire improved in both groups with statistically significant improvement in bowels and lump sensation but no difference in bladder symptoms.

	Hysterectomy		Conservation		Difference of change Between groups
	Pre-op	Post-op	Pre-op	Post-op	P value
Urinary symptoms	13	5	14	6	0.24
Bowel/ Lump symptoms	12	3	12	2	0.34
Sexual symptoms	3	1	3	1	0.27
Affect on life	3.4	0.8	3.6	1.2	0.19
Role/ Physical limitations	8	2	10	2	0.26
Social limitations	3	1	4	1	0.31
Depression/Anxiety/ Emotion	6	2	7	1	0.18

Interpretation of results

Both groups improved both objectively as measured by point C and point Bp. TVL was no different. There was no difference in quality of life questionnaire parameters suggesting that undertaking a hysterectomy confers no advantage at the time of prolapse surgery. Re-operation rate was nil in hysterectomy group and 2 in the conservation group (1 apical , hysterectomy and 1 ant graft repair) .The mesh erosion rate was not statistically significant in these patients due to the low numbers. However it can still be an issue but was minor in terms of perceived morbidity. More anterior graft mesh was used in the conservative group which may have affected our final results.

Concluding message

This small pilot study suggests that recurrence is not increased significantly in the conservation group.However we accept that clinically hysterectomy may offer an advantage especially in cases where the cervix is longer than normal. Mesh erosion although still present is not a significant issue for patients. This may relate to the positioning of the mesh away from the vault incision retroperitoneally.

References

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Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	Yes
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Central and Northern Health Area Service, Adelaide, South Australia
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes

