

ARE WE DOING TOO MANY VAGINAL HYSTERECTOMIES WITH ANTERIOR COLPORRHAPHY? VALIDATION OF INTRAOPERATIVE CERVICAL TRACTION AND PRELIMINARY RESULTS OF AN OBSERVATIONAL CLINICAL STUDY

Hypothesis / aims of study

Vaginal hysterectomy is still the standard practice of many surgeons despite the descent of the uterus itself being a result of, not a cause of, pelvic organ prolapse (POP). However, there is lack of evidence suggesting that a concomitant vaginal hysterectomy improves the outcome of POP surgery [1]. It is common practice in the UK to assess the need for a vaginal hysterectomy at the time of vaginal prolapse surgery, in theatre [2]. The value of inter-operative assessment has never been proven. Correction of prolapse is the primary aim of surgery, and hysterectomy may be an unnecessary step in the procedure [3]. The aim of this study was to evaluate the surgical outcome of uterine preservation during anterior colporrhaphy in patients with significant uterine descent, after the application of validated traction under anaesthesia.

Study design, materials and methods

1. Validation of intra-operative cervical traction force:

10 Gynaecologists were asked to apply the degree of cervical traction they would apply to decide whether they would perform a vaginal hysterectomy concomitant to anterior colporrhaphy. Traction was applied on a Volsellum through a strain gauge instrument to measure the force. The gynaecologist did not look at the reading and the mean (mid-quartiles) traction force was calculated.

2. Observational study:

Patients with symptomatic anterior compartment prolapse (stage II or more), awaiting anterior colporrhaphy and with POPQ point C (cervix) no less than – 3cm from the introitus were offered participation in the study. These patients were asked to complete a vaginal symptoms questionnaire (ICIQ-VS) and a preoperative POP-Q score was documented.

Patients recruited in the study had the agreed 'standard downward cervical traction' applied intra-operatively and an intra-operative POP-Q score was documented. Hysterectomy was not performed if the cervix remained at point C \leq + 2 cms. The patients who qualified for the study had a simple, pubocervical fascia plication anterior repair only.

Patients were reviewed 8 -12 weeks following surgery, when a further questionnaire was completed and POP-Q score recorded. We expect the uterus to be 2 or more centimetres lower postoperatively in not more than 5% of cases. The sample size calculation is based on comparison of this 5% with a hypothesised value of 12%. We will require approximately 123 participants for the study to have 80% power using a cut-off for statistical significance of 5%.

Results

Results of validation of intra-operative cervical traction force: The mean traction demonstrated by the 10 Gynaecologists was 3.6 kgs and was the traction force applied to all patients who participated in the observational study.

Results of the observational study:

Table 2: Demographic features of the patients

| | |
|-----------------------------|------------|
| Patients | |
| Mean Age (yrs) (SD) | 60.9 (9.3) |
| Median Parity (range) | 2 (1 - 7) |
| Mean BMI (S.D) | 26.7 (2.9) |
| Previous prolapse surgery | 3 patients |
| Hormone replacement therapy | 2 patients |

30 patients were recruited in the study and all patients had at least stage 2 uterine prolapse as per ICS definition when the 3.6 kgs traction was applied under anaesthesia. One patient was withdrawn when the examination under anaesthesia revealed stage 3 uterine descent (C= +3 cm). Only one patient was found to have a stage 2 uterine 'prolapse' and had to have a subsequent vaginal hysterectomy after their initial anterior repair. One patient had an early failure, needing a repeat anterior repair.

Table 3: Table showing the preoperative, intraoperative and post operative subjective and objective findings.

| | Pre op | Intra op | Post op | P value |
|---------------------------------|--------|----------|---------|----------|
| Vaginal symptoms (0 -53)- mean | 24.9 | - | 8.6† | p<0.0001 |
| Quality of life (0-10)-mean | 4.4 | - | 2.8 | p=0.18 |
| Aa (mean) | 0.46 | 0.48 | - 1.5† | p<0.0001 |
| Ba (mean) | 0.47 | 0.52 | - 1.5† | p<0.0001 |
| C(mean) | -4.71 | - 0.05† | - 4.5 | p<0.0001 |

† Significantly different from pre op findings.

Interpretation of results

Our findings show that if a vaginal hysterectomy was not performed, there was no significant change in point C both pre operatively and when the patient was seen 8 -12 weeks post operatively (table 3). This is despite the presence of a significant difference in point C when the 3.6 kg pull was applied intraoperatively.

There was an improvement in the vaginal symptoms postoperatively. In a recent survey of Gynaecologists in our region 67.8% would have performed a hysterectomy on this particular group of patients, when only one (3.3%) of them subsequently required a vaginal hysterectomy. Intra-operative judgement as to whether a vaginal hysterectomy is required may be misleading and could result in an unnecessary major procedure, with its morbidity, and higher costs to health services. Recruitment continues into this study.

Concluding message

Apparent uterine descent with cervical traction under anaesthesia may not be helpful in assessing the need for vaginal hysterectomy at the time of anterior repair, and many unnecessary vaginal hysterectomies may be performed using this unproven test.

References

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| <i>Specify source of funding or grant</i> | None |
| <i>Is this a clinical trial?</i> | Yes |
| <i>Is this study registered in a public clinical trials registry?</i> | No |
| <i>Is this a Randomised Controlled Trial (RCT)?</i> | No |
| <i>What were the subjects in the study?</i> | HUMAN |
| <i>Was this study approved by an ethics committee?</i> | Yes |
| <i>Specify Name of Ethics Committee</i> | Frenchay Research Ethics Committee |
| <i>Was the Declaration of Helsinki followed?</i> | Yes |
| <i>Was informed consent obtained from the patients?</i> | Yes |