

VAGINAL VERSUS ABDOMINAL HYSTERECTOMY IN PATIENTS WITH HISTORY OF PREVIOUS PELVIC SURGERY

Protocol of Thesis

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INTRODUCTION

Hysterectomy is the most common non-pregnancy related gynaecologic surgical procedure performed in the United States. It has been estimated that one in three women will have a hysterectomy by the age of 60 (*Farquhar and Steiner, 2002*).

Most hysterectomies in the UK are abdominal (70-90%). Only 10-30% of cases are performed as vaginal hysterectomies and less than 5% are laparoscopic or laparoscopically assisted vaginal hysterectomies (*Mares, 2002*).

A Cochrane review on the surgical approach to hysterectomy for benign gynaecological disease, published in 2006, concluded that vaginal hysterectomy should be performed in preference to abdominal hysterectomy, where possible (*Johnson et al., 2006*).

The Cochrane review of 27 randomized controlled trials found that vaginal hysterectomy meant a shorter stay in hospital compared with abdominal hysterectomy, a speedier return to normal activities for the patient and fewer unspecified infections or febrile episodes. There was no evidence of benefits for laparoscopic hysterectomy compared with vaginal hysterectomy and the operating time was increased for laparoscopic hysterectomy (*Johnson et al., 2006*).

Vaginal hysterectomy scored the most points in terms of patient satisfaction and well-being. *Ottosen et al.* randomised study showed that vaginal hysterectomy should be considered the primary method for hysterectomy (*Ottosen et al., 2000*).

Despite the fact that vaginal hysterectomy is acknowledged to be the fastest and least expensive technique available to achieve removal of the uterus and cervix, it is used in only 23% of the hysterectomies performed in the United States. Traditionally, many surgeons have avoided vaginal hysterectomy or used it only in carefully selected patients. Until recently, the procedure was rarely used in patients who have difficult anatomy with limited visibility, including those with a narrow vagina without uterine descent, an expanded lower uterine segment, a bulky uterine fundus, extensive pelvic adhesions, or a history of prior pelvic radiation. Other commonly cited contraindications to the vaginal approach included nulliparity, obesity or previous pelvic surgery (*Kives et al., 2003*).

Contraindications to vaginal hysterectomy include uterus more than 12 weeks size, restriction of uterine mobility, adnexal pathology, cervix flush with the vagina, inaccessible cervix, vesicovaginal and/or rectovaginal fistula repair and invasive cancer of the cervix. *Davies et al*, reviewed 500 cases of hysterectomy; 76% were by the abdominal route in the absence of an absolute contraindication to vaginal hysterectomy. Reasons given for not taking the vaginal route were absence of prolapse in 76%, presence of fibroid in 45%, and need for oophorectomy in 43%. *Quinlan* in South Africa has performed vaginal hysterectomy for large fibroids on a large number of black women who were expected to have an android pelvis and a narrow sub-pubis; the narrow sub-pubic angle was never a problem in them (*Sheth S.S., 2005*).

The presence of adnexal disease generally contraindicates vaginal hysterectomy and indicates a laparoscopy-assisted vaginal hysterectomy or an abdominal hysterectomy. Adnexectomy for

benign disease is possible vaginally at the time of vaginal hysterectomy, however, provided that any adhesions have been removed, access to the adnexa is not difficult, and the intervention is attempted by surgeons with significant experience of vaginal hysterectomy with bilateral salpingo-oophorectomy. Given the author's success at performing bilateral adnexectomy vaginally and without laparoscopic assistance for mobile dermoid or serous ovarian cysts at the time of vaginal hysterectomy, and the benefits of this approach affords to patients. **Sheth S.S.** sought to broaden the scope of the procedure to include adnexectomy for endometrial cysts of the ovary. His decision was supported by trial results published in the evidence-based Cochrane database and elsewhere, which distinctly favor the vaginal route as the technique of choice, when appropriate, for hysterectomy (**Sheth S.S., 2009**)

Currently 20% or more of deliveries are carried out by caesarean section in most countries. With this trend likely to flourish, it is conceivable that the surgeon of tomorrow will have increasingly to confront the problem of hysterectomy in patients with one or multiple previous caesarean sections. **Coulam and Pratt** say that the chief concern in this group of patients is the risk of injury to the bladder and the difficulty in gaining through the scarred anterior cul-de-sac. **Carpenter and Silva** compared vaginal and abdominal hysterectomies after previous pelvic surgery and they concluded: 'vaginal hysterectomy following pelvic operation is technically easy and without increase in morbidity'. **Kovac et al.** have discussed the role of laparoscopic assisted vaginal hysterectomy, which is more invasive than vaginal hysterectomy for these patients. (**Sheth S.S. and Allahbadia G.N. 2002**).

AIM OF THE WORK

To assess the efficacy and safety of vaginal hysterectomy compared to abdominal hysterectomy in women with previous pelvic surgery.

PATIENTS AND METHODS

Setting:

- The study will be carried out in Ain-Shams University Maternity Hospital.

Study group:

- Women admitted for Hysterectomy for a benign disease.

Type of study:

- Prospective randomized clinical trial.

Statistical analysis:

Analysis Plan:

Sample size statement:

27 cases in each group would allow a difference of 28 % points in rate of complications assuming that the rate is 51 in 1st group with the power of 90%, using 5% significance level (Rate of success; can be obtained from published studies =28% difference).

Confidence interval= 95% Accuracy of ± 28 percentage point

Sig level 5% Power: 90%

Required sample size: =27 in each group

Comparison of data will be performed using Chi-Square test X^2 and Fisher's Exact Test (results will be presented as percentages and the corresponding P value). Unpaired (student') t test will be used to test the difference about mean values parametric data, results will be presented as mean and standard deviation, non parametric data will be analyzed using Mann-Whitney test (data presented as median and IQR).

The data will be coded, entered and processed on computer using SPSS program (version 15). The level $P < 0.05$ will be considered the cut-off value for significance.

Population:

- Includes **54 patients** undergoing hysterectomy, divided randomly into 2 groups:
 1. **Group 1 (The case group):** This group consisted of **27 patients** undergoing vaginal hysterectomy.
 2. **Group 2 (the control group):** This group consisted of **27 patients** undergoing abdominal hysterectomy.

For both groups: All patients will have a history of previous abdominal gynecologic or obstetric operation. Types of pelvic operations are:

- Ovarian cystectomy.
- Oophorectomy & Salpingo-oophorectomy.
- Salpingectomy, tubal sterilization.
- Myomectomy.
- Cesarean section.
- Other operations.

Inclusion criteria for both groups:

1. 1st or 2nd degree uterine descent.
2. Uterine size < 16 weeks.
3. Benign pathology.
4. Vaginal canal should be ample.
5. Posterior & lateral vaginal fornices should be wide and deep.
6. Subpubic angle > 90°.

Exclusion criteria for both groups:

1. Cervix flushed with the vagina.
2. Narrow vagina.
3. Uterine size > 16 weeks.
4. Absent uterine descent with no adequate mobility.
5. Pelvic mass.
6. Pelvic Malignancy.
7. Previous successful repair of vesicovaginal fistula.

Methods:

Complete preoperative assessment including:

- History.
- Examination including evaluation of pelvic support and evaluation of the pelvis.
- Investigations.
- Examination under anaesthesia: to confirm prior findings and to assess uterine size, mobility, descent, culdesac and vaginal adequacy. The decision is then made whether to proceed vaginally or abdominally randomly.

Method of Randomisation: Computer generated program.

Operative methods:

- Group 1(case group):patients undergoing vaginal hysterectomy.

-Group 2(control group):patients undergoing abdominal hysterectomy.

Then each patient in the study will be tested for the following endpoints:

- Operative blood loss and the need for blood transfusion.
- Pre&postoperative hemoglobin & hematocrit change.
- Hollow organ injury.
- Urinary retention or urinary tract infection.
- Postoperative hospital stay.
- Any postoperative complications including:
 - Need for analgesics.
 - 1ry or 2ry haemorrhage.
 - Postoperative infection and febrile morbidity.
 - Wound infection in abdominal hysterectomy.
 - The need for readmission.
 - The need for laparotomy.

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VAGINAL VERSUS ABDOMINAL HYSTERECTOMY IN PATIENTS WITH HISTORY OF PREVIOUS PELVIC SURGERY

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ABSTRACT

Objective: To assess the efficacy and safety of vaginal hysterectomy compared to abdominal hysterectomy in women with previous pelvic surgery.

Study design: 54 patients undergoing hysterectomy for benign conditions were randomised to either vaginal or abdominal group. Each group of patients shares the character of having previous pelvic surgery.

Results: Participants in the vaginal hysterectomy group had a shorter operating time (73.7 min vs. 107.8 min; $p < 0.001$), less blood loss (563 ml vs. 1219 ml; $p < 0.001$), smaller drop in hemoglobin (0.86 gm vs. 1.8 gm; $p < 0.001$), earlier discharge from hospital, lower hospital cost, quicker return to normal activities and improved quality of life. Complication rates were not statistically different between the two groups.

Conclusion: Vaginal hysterectomy appear to be the preferred hysterectomy technique for women with previous pelvic surgery and every gynecological surgeon should be familiar with this procedures.

1. INTRODUCTION:

Hysterectomy is the most common non-pregnancy-related gynaecologic surgical procedure performed in the United States, with one in three women having a hysterectomy by the age of 60 [1]. Most hysterectomies in the UK are abdominal (70–90%) with only 10–30% performed vaginally and less than 5% laparoscopically [2].

The 2005 Cochrane review of surgical approaches to hysterectomy for benign gynaecological diseases concluded that, where possible, vaginal hysterectomy (VH) should be performed in preference to abdominal hysterectomy (AH) [3]. When compared to AH, VH is associated with fewer unspecified infections/febrile episodes, shorter hospital stay and quicker return to normal activities. There was no evidence of benefits for laparoscopic

hysterectomy (LH) compared with VH, while the operating time was increased in LH [3].

Despite the fact that vaginal hysterectomy is acknowledged to be the fastest and least expensive technique available to achieve removal of the uterus and cervix, it is used in only 23% of the hysterectomies performed in the United States. Traditionally, many surgeons have avoided vaginal hysterectomy or used it only in carefully selected patients. Until recently, the procedure was rarely used in patients who have difficult anatomy with limited visibility, including those with a narrow vagina without uterine descent, an expanded lower uterine segment, a bulky uterine fundus, extensive pelvic adhesions, or a history of prior pelvic radiation. Other commonly cited contraindications to the vaginal approach included nulliparity, obesity or previous pelvic surgery [4].

Currently 20% or more of deliveries are carried out by caesarean section in most countries. With this trend likely to flourish, it is conceivable that the surgeon of tomorrow will have increasingly to confront the problem of hysterectomy in patients with one or multiple previous caesarean sections. *Coulam and Pratt* say that the chief concern in this group of patients is the risk of injury to the bladder and the difficulty in gaining through the scarred anterior cul-de-sac [5].

The current study assessed the safety and efficacy of vaginal route for hysterectomy in comparison with the abdominal route in patients with previous pelvic surgery which make a significant challenge for the majority of gynaecologists.

2. MATERIALS AND METHODS

The study was carried out in Ain-Shams University Maternity Hospital over a period of 20 months from December 2010 to August 2012. Ethical approval was granted from the local scientific research committee on August 2010.

Women waiting to undergo a hysterectomy procedure for benign disease were approached, recruited and gave their written consent to participate after receiving information on the study (by ME). 54 consecutive cases who underwent hysterectomy for benign disease underwent preoperative assessment and were randomly assigned to one of the following two groups:

- Group 1 (The case group): This group consisted of 27 patients underwent vaginal hysterectomy (VH, n = 27).
- Group 2 (the control group): This group consisted of 27 patients underwent abdominal hysterectomy (AH, n = 27).

For both groups: All patients had a history of previous abdominopelvic gynaecologic or obstetric operation. Types of operations were: Ovarian cystectomy, Salpingo-oophorectomy, Salpingectomy, Myomectomy, Cesarean section and Appendectomy.

Inclusion criteria for both groups included: 1st or 2nd degree uterine descent, Uterine size $\leq$ 16 weeks, Benign pathology, Vaginal canal should be ample, Posterior & lateral vaginal fornices should be wide and deep and Subpubic angle $> 90^\circ$.

Patients with Cervix flushed with the vagina, Narrow vagina, Uterine size > 16 weeks, Absent uterine descent, No adequate uterine mobility, Pelvic mass, Pelvic Malignancy or Previous successful repair of vesicovaginal fistula were excluded from the study.

Participants had complete preoperative assessment by full history, complete examination and Examination under anaesthesia to confirm prior findings and to assess uterine size, mobility, descent, culdesac and vaginal adequacy. The decision was then made whether to proceed vaginally or abdominally after fulfilling the inclusion criteria randomly.

Total of 64 patients were examined, 10 patients were excluded after examination under anaesthesia for causes such as narrow vagina, uterine size > 16 weeks, no uterine mobility and absent uterine descent, and all underwent abdominal hysterectomy but were excluded from the study.

The remaining 54 patients fulfilled the inclusion criteria and were included in the study and were divided into two equal groups; 27 patients underwent vaginal hysterectomy and 27 patients underwent abdominal hysterectomy.

Participants had general, spinal or epidural anaesthesia. Heaney's technique was used in the vaginal hysterectomy group with or without debulking techniques such as myomectomy, morcellation, bisection, polypectomy or coring. It was common to encounter adhesions between the bladder and cervix in some patients, and this did make the surgery technically more difficult. Sharp dissection was attempted initially, keeping as close to the cervix as possible, to minimize the chances of bladder injury. In some patients a technique was very useful if dense adhesions prevented access to the uterovesical fold of the peritoneum was the lateral window technique or utilization of the uterocervico broad ligament space as shown by **Sheth**. where the dense adhesions in the midline, the lateral space between the leaves of the broad ligament adjoining the uterocervical border near the isthmic notch (the uterocervico broad ligament space) was usually free of adhesions [6].

2.1. Outcome measures

The primary outcome measures were the operative time and blood loss while the secondary outcome measures were the hospital stay and intra- and post-operative complications. each patient in the study was tested for the following endpoints:

The total operative time was calculated and it was defined as time from initial mucosal incision to closure of the vaginal cuff with satisfactory haemostasis (in group 1, VH group), and time from skin incision to skin closure (in group 2, AH group).

Operative blood loss was estimated by weighing the swabs (by the anaesthetist and auxiliary theatre staff). Concomitant procedures had separate calculation of operative time and blood loss. The postoperative haemoglobin and haematocrit were measured for all participants at 24 h after the procedure.

Hospital stay was identified for each case (less or more than 48 h) and, in cases of delayed discharge; the reason was identified and recorded. Complications were reported, e.g. the need for blood transfusion, urinary bladder injury or conversion to laparotomy.

2.2. Sample size and statistical analysis

27 cases in each group would allow a difference of 28 % points in rate of complications assuming that the rate is 51 in 1st group with the power of 90%, using 5% significance level (Rate of success; can be obtained from published studies =28% difference).

Confidence interval= 95%, Accuracy of ± 28 percentage point, Sig level 5%, Power: 90%. Required sample size: 27 in each group

Comparison of data will be performed using Chi-Square test X^2 and Fisher's Exact Test (results will be presented as percentages and the corresponding P value). Unpaired (student') t test will be used to test the difference about mean values parametric data, results will be presented as mean and standard deviation, non parametric data will be analyzed using Mann-Whitney test (data presented as median and IQR). The data will be coded, entered and processed on computer using SPSS program (version 15). The level $P < 0.05$ will be considered the cut-off value for significance.

3. RESULTS

Fifty four consecutive cases over a period of 20 months who underwent hysterectomy for benign disease were included in this study; 27 cases underwent vaginal hysterectomy and 27 cases underwent