

Deciding the Appropriate Route and Method of Hysterectomy for Women with Benign Diseases: A Cross-sectional Study at a Tertiary Care Hospital, India

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ABSTRACT

Introduction: Different factors may influence the route of hysterectomy for benign indications. Each of the three main approaches of hysterectomy has its own set of risks and benefits. A rational and evidence-based decision to select a right method for a particular patient is necessary to bring about the best possible outcome with least complications.

Aim: To compare three groups of hysterectomy, i.e., laparotomy for Total Abdominal Hysterectomy (TAH), Non-descent Vaginal Hysterectomy (NDVH) and Total Laparoscopic Hysterectomy (TLH), with regard to the patient and clinical factors, surgical outcomes and complications, in order to decide the optimum route and method of hysterectomy in a patient with benign disease.

Materials and Methods: In this hospital-based cross-sectional study, 120 women, with 40 patients each in the TAH, NDVH and TLH groups, were admitted due to benign gynaecological conditions in a tertiary care hospital in Kolkata, India from May 2013 to April 2014. They were operated, and then followed-up at 6-12 weeks after surgery. All the relevant information, e.g., clinical diagnosis, operating time, intraoperative blood loss,

length of stay in hospital, postoperative pain score, intraoperative and postoperative complications, etc., were recorded. Data were analysed statistically by simple proportions and statistical tests, i.e., Chi-square test and F-test.

Results: The most common indication for hysterectomy was benign diseases in all the groups, 47.5%, 40% and 37.5%, respectively in the TAH, NDVH and TLH groups. The mean operating time (minutes) was significantly higher in the TLH group (163.5) as compared to the TAH (75.03) and NDVH groups (84.88) ($p=0.039$). A significantly lesser mean intraoperative blood loss (mL) was observed in the NDVH (85.67) and TLH groups (98.63) as compared to the TAH group (168.47) ($p=0.021$). The observations in regard to other surgical outcome parameters, i.e., postoperative pain score, hospital stay, were also favourable in the NDVH or TLH group. The complication rate was higher in the TAH group (22/40 or 55%) as compared to the NDVH (14/40 or 35%) and TLH (17/40 or 42.5%) groups.

Conclusion: NDVH or TLH is the preferred method over TAH in case of benign uterine disease due to lesser operative morbidity and faster recovery.

Keywords: Comparative, Fibroid, Non-descent vaginal hysterectomy, Total abdominal hysterectomy, Total laparoscopic hysterectomy

INTRODUCTION

Hysterectomy is one of the most frequently performed major surgical procedures worldwide in gynaecology. Hysterectomy can be performed vaginally, abdominally, laparoscopically or as Laparoscopic Assisted Vaginal Hysterectomy (LAVH). They are performed for different benign conditions like uterine fibroids, endometriosis, adenomyosis, uterine prolapse, abnormal uterine bleeding, etc., and for malignant diseases as well [1].

The incidence of hysterectomy varies worldwide. Among the industrialised nations, the number of hysterectomies performed annually ranges from about 100,000 (UK) to more than 600,000 (USA) [2]. The incidence is much lower in the developing nations. A study done in rural Haryana, India among married women >15 years of age reported the incidence rate of hysterectomy as 7% compared to 10-20% in the western countries [3]. In India, approximately 2,310,263 hysterectomies are performed every year [4].

Factors that may influence the route of hysterectomy for benign indications include the uterine size and shape, vaginal space and accessibility to the uterus, extent of extrauterine disease, the need for any concurrent procedure, training and experience of the surgeon, available hospital technology, devices and support, scheduled or emergency cases, and the woman's choice [1].

Each of the three main approaches of hysterectomy has its own set of risks and benefits. The American College of Obstetricians

and Gynaecologists (ACOG) committee on gynaecologic practice concluded that vaginal hysterectomy is the approach of choice whenever feasible, based on its better outcomes, cost-effectiveness and lower complication rates [1]. When it is not feasible to perform a vaginal hysterectomy, the surgeon must choose between laparoscopic hysterectomy or abdominal hysterectomy. The surgeon should take a rational and evidence-based decision after critically evaluating all types of hysterectomy to select a right method for a particular patient to bring about the best possible outcome with least complications.

There are very few studies on this debating issue reported from India [5,6]. Moreover, most of those studies had the limitations for absence of adequate information on patient and clinical factors. With the above background, the present study was undertaken to compare the patient and clinical factors, surgical outcomes and complications of three groups of hysterectomy, i.e., laparotomy for TAH, NDVH and TLH in order to decide the optimum route and method of hysterectomy in a patient with benign disease.

MATERIALS AND METHODS

A hospital-based cross-sectional study was conducted in the Department of Obstetrics and Gynaecology, Calcutta National Medical College and Hospital, a tertiary care hospital in Kolkata, India from May 2013 to April 2014. Ethical clearance for doing this study was obtained from the Institutional Ethics Committee (No. CNMC/445/P,

dated 11.02.13). Informed consent for performing the hysterectomy procedure and for participating in the study was obtained from all the eligible women.

Inclusion criteria: All women admitted in above-mentioned hospital for hysterectomy due to benign gynaecological conditions during the study period were included in the study.

Exclusion criteria: All the cases requiring intraoperative conversion of the procedure were excluded from the study.

Study Procedure

Total of 120 consecutive patients were included in the study after following the above criteria, with 40 patients each in TAH, NDVH and TLH groups.

The women were included in the vaginal (NDVH) group if the uterine size was ≤ 14 weeks with adequate mobility, adequate vaginal access and presence of adnexal pathology like benign ovarian cyst of < 8 cm. The women were included in the laparoscopy (TLH) group if there was previous history of < 2 pelvic surgeries and no contraindication for general anaesthesia [7-9]. No strict inclusion criteria was followed for assigning a patient to the abdominal (TAH) group.

Most of the relevant information was recorded at the time of hospital stay, i.e., background information, ultrasound report including all relevant clinical examination, clinical diagnosis, operating time, intraoperative blood loss, length of stay in hospital, postoperative pain score, intraoperative and postoperative complications. Follow-up information, i.e., days required to return to normal household activities, was recorded at the Outpatient Department (OPD) 6-12 weeks after surgery.

Uterine volume (in cm^3) was calculated by preoperative ultrasound measurement using a simplified prolate ellipsoid formula by multiplying length by breadth by antero-posterior diameter by 0.542 ($L \times W \times AP \times 0.542$) [10]. Uterine fibroid volume, when present, was calculated separately in similar way and added to the uterine volume to get the total volume. Although an intramural fibroid was included in the total uterine volume.

Operating time was calculated from the beginning of incision to the placement of final abdominal or vaginal closure suture. Intraoperative blood loss was estimated: (i) by weighing dry swabs and blood-soaked swabs and subtracting the values (1 mL blood=19 mg approximately); combined with the volume of blood in the suction apparatus in case of TAH and NDVH; and (ii) by subtracting the volume of irrigation fluid from the total amount of fluid in the suction apparatus in case of TLH. Length of stay in hospital was defined as the total number of days from the day of surgery to the day of discharge from hospital. Postoperative pain was assessed on the postoperative day 3 by a 10 cm Visual Analog Scale (VAS).

STATISTICAL ANALYSIS

Data were analysed statistically by simple proportions and statistical tests, i.e., chi-square test and F-test. The trial version of SPSS, version 21.0 (IBM Corp., Armonk, New York, United States) was used to analyse data.

RESULTS

This study was conducted on 120 women. While considering background characteristics of the patients [Table/Fig-1], the commonest age group noted was 40-45 years in all the three study groups. The mean parity of the patients was highest in the NDVH group (2.7). History of previous Cesarean Section (CS) was absent among patients in the NDVH group. The proportion of patients with history of previous pelvic surgery (e.g., tubectomy, ovarian cystectomy, surgery for ectopic pregnancy, etc.,) was lowest (30%) in the NDVH group.

Background characteristics	Hysterectomy approach		
	TAH n (%) (n=40)	NDVH n (%) (n=40)	TLH n (%) (n=40)
Age group (Years)			
<40	6 (15)	7 (17.5)	15 (37.5)
40-45	29 (72.5)	25 (62.5)	20 (50)
46-50	5 (12.5)	6 (15)	4 (10)
>50	-	2 (5)	1 (2.5)
Mean (\pm SD)	41.95 (\pm 2.0)	42.98 (\pm 4.8)	41.8 (\pm 3.5)
Parity			
0	2 (5)	-	-
1	7 (17.5)	2 (5)	6 (15)
2	22 (55)	17 (42.5)	20 (50)
≥ 3	9 (22.5)	21 (52.5)	14 (35)
Mean (\pm SD)	2.07 (\pm 1.9)	2.7 (\pm 3.0)	2.47 (\pm 1.9)
History of previous CS	4 (10)	-	5 (12.5)
History of previous pelvic surgery	18 (45)	12 (30)	21 (52.5)
Associated co-morbid condition			
Hypertension	5 (12.5)	4 (10)	3 (7.5)
Diabetes mellitus	3 (7.5)	2 (5)	2 (5)
Heart disease	1 (2.5)	2 (5)	-
Obesity (BMI ≥ 30)	3 (7.5)	1 (2.5)	3 (7.5)
Anaemia (Hb < 9 gm%)	6 (15)	3 (7.5)	2 (5)
Hypothyroidism	1 (2.5)	1 (2.5)	2 (5)

[Table/Fig-1]: Distribution of the patients among three hysterectomy groups according to background characteristics (n=120).
 Figures in the parentheses indicate percentages; TAH: Total abdominal hysterectomy; NDVH: Nondescent vaginal hysterectomy; TLH: Total laparoscopic hysterectomy; CS: Cesarean section

While considering clinical characteristics of the patients [Table/Fig-2], fibroid uterus was found to be the most common clinical diagnosis in all the three groups (47.5%, 40% and 37.5% in the TAH, NDVH and TLH groups, respectively). In the NDVH and TLH groups, 50% or more patients (21 and 20, respectively) had uterine volume of 150 cm^3 or less.

Clinical characteristics	Hysterectomy approach		
	TAH (n=40) (%)	NDVH (n=40) (%)	TLH (n=40) (%)
Clinical diagnoses			
Fibroid uterus	19 (47.5)	16 (40)	15 (37.5)
Adenomyosis	9 (22.5)	11 (27.5)	10 (25)
Abnormal uterine bleeding	5 (12.5)	9 (22.5)	10 (25)
Chronic cervicitis with moderate dyskaryosis	4 (10)	3 (7.5)	3 (7.5)
Pelvic endometriosis	3 (7.5)	1 (2.5)	2 (5)
Uterine volume (cm^3)*			
≤ 150	11 (27.5)	21 (52.5)	20 (50)
151-300	19 (47.5)	16 (40)	18 (45)
301-400	6 (15)	2 (5)	2 (5)
>400	4 (10)	1 (2.5)	-

[Table/Fig-2]: Distribution of the patients among three hysterectomy groups according to clinical characteristics (n=120).
 Figures in the parentheses indicate percentages; *Uterine volume refers to total volume; which includes uterine volume and uterine fibroid volume

Statistically significant differences ($p < 0.05$) were found among three groups in regard to mean operating time, mean intraoperative blood loss, postoperative length of stay in hospital and postoperative pain score. Overall, NDVH or TLH was found to be superior procedure than TAH in terms of surgical outcomes [Table/Fig-3].

No major intraoperative complications were noted in all the three groups, except one case of bowel injury in the TLH group and one

case of bladder injury each in the TAH and NDVH groups. In regard to postoperative wound infection, statistically significant difference was found among three groups ($p=0.039$). The rate of port infection was quite high in the TLH group (6 or 15%), whereas no one in the NDVH group had postoperative wound infection [Table/Fig-4].

Surgical outcomes	TAH (n=40) (%) Mean (SD)	NDVH (n=40) (%) Mean (SD)	TLH (n=40) (%) Mean (SD)	F-value (df1, df2)	p-value
Operating time (minutes)	75.03 (7.54)	84.88 (23.18)	163.5 (16.34)	327.68 (2, 117)	0.039
Intraoperative blood loss (mL)	168.47 (44.96)	85.67 (20.39)	98.63 (23.97)	79.05 (2, 117)	0.021
Length of stay in hospital from surgery to discharge (days)	7.13 (0.40)	4.38 (2.77)	3.5 (1.45)	95.49 (2, 117)	0.001
Postoperative pain score (on postoperative day 3)	6.975 (0.8)	2.975 (0.97)	2.575 (0.96)	283.51 (2, 117)	0.001

[Table/Fig-3]: Comparison among three hysterectomy groups according to surgical outcomes (n=120). <0.05 statistically significant; p-values based on F-test

Complications	TAH (n=40) (%)	NDVH (n=40) (%)	TLH (n=40) (%)	χ^2 -value (df)	p-value
Intraoperative complications					
Bladder injury	1 (2.5)	1 (2.5)	-	-	-
Bowel injury	-	-	1 (2.5)	-	-
Postoperative complications*					
Requirement of blood transfusion	9 (22.5)	4 (10)	3 (7.5)	4.47 (2)	0.1069
Febrile morbidity	5 (12.5)	4 (10)	4 (10)	0.17 (2)	0.92
Urinary Tract Infection (UTI)	4 (10)	5 (12.5)	3 (7.5)	0.56 (2)	0.76
Wound infection	3 (7.5)	-	6 (15)	6.49 (2)	0.039

[Table/Fig-4]: Distribution of the patients among three hysterectomy groups according to complications (n=120).

Figures in the parentheses indicate percentages; *Multiple responses; p-values based on χ^2 -test

During the follow-up visits, it was reported that only one-fifth (8 or 20%) of the patients in the TAH group returned to normal household activities in <2 weeks after surgery, whereas the results were much favourable in the NDVH and TLH groups (28 or 70% and 26 or 65%, respectively) [Table/Fig-5].

Time taken to return to normal household activities after surgery	TAH (n=40)	NDVH (n=40)	TLH (n=40)
<2 weeks	8 (20)	28 (70)	26 (65)
≥2 weeks	32 (80)	12 (30)	14 (35)

[Table/Fig-5]: Distribution of the patients among three hysterectomy groups according to time taken to return to normal household activities after surgery (n=120).

Figures in the parentheses indicate percentages

DISCUSSION

The route of choice for hysterectomy has been a source of debate for a long time. The current evidence-based clinical practice guidelines favour the use of minimally invasive approaches (vaginal/laparoscopic) for benign gynaecologic disease [1, 11]. The use of vaginal hysterectomy, though preferred, may be limited in patients with concurrent pelvic disease, a large uterus or in patients lacking uterine descent.

In the present study, most of the patients in all the three groups belonged to the 40-45 years of age with the mean ages ranged from 41.8 (± 3.5) years in the TLH group to 42.98 (± 4.8) years in the NDVH group. The EVALUATE study [12] had reported almost similar findings regarding the mean ages of the patients, ranging from 40.82 (± 6.46) years in the VH group in the vaginal trial to 41.68 (± 7.15) years in the LH group in the abdominal trial.

The mean parity of the patients ranged from 2.07 (± 1.9) in the TAH group to 2.7 (± 3.0) in the NDVH group. Most of the patients in the NDVH group were of parity 3 and higher. The tissue resilience, free space in the parametrial tissue made the vagina roomy for the surgical procedure of NDVH. Other studies [13,14] had also reported higher mean parity in the NDVH group.

In this study, no one had history of previous CS in the NDVH group. History of previous pelvic surgery was present in 52.5% patients in the TLH group, followed by the TAH and NDVH groups (45% and 30%, respectively). However, in the EVALUATE study [12], none of the patients in any study group had history of previous CS, whereas almost similar proportions of patients in each group (63% in the AH/LH group in the abdominal trial and 61.5% in the VH group in the vaginal trial) had history of previous pelvic surgery. Other studies [13,15] had reported history of previous CS and previous pelvic surgery in lesser proportions of patients in the NDVH/VH group. Additional surgical skill is an essential requirement in any method of hysterectomy. In respect to the presence of associated co-morbid condition, all the three groups were comparable in the present study.

The most common indication for surgery was fibroid uterus in all the three groups, followed by adenomyosis and abnormal uterine bleeding. Other studies also support these findings [3,14-17]. Another study from India [5] reported Dysfunctional Uterine Bleeding (DUB) (45%) as the most common indication for VH and myoma (45%) for TAH.

In the present study, 25% patients in the TAH group had uterine volume of >300 cc. The maximum volume of uterus removed through abdominal route was 1502.42 cc. The large abdominal incision and easy accessibility facilitated the removal of enlarged uterus with greater volume. The maximum volume of the uterus removed via vaginal route was 467.71 cc. In this case, removal of a large uterus with fibroid was facilitated by trisection of uterus and vaginal myomectomy. The maximum volume of uterus removed laparoscopically was 370.32 cc. Case selection for TLH had to be done more carefully as the center did not have the facility of a morcellator.

The mean operating time (minutes) was significantly longer in the TLH group (163.5 \pm 16.34) than the other two groups, i.e., NDVH (84.88 \pm 23.18) and TAH (75.03 \pm 7.54) ($p<0.05$). In the initial phase of the study, the TLH procedures required more operating time due to the slow learning curve. In the NDVH group, the operating time was prolonged in cases where additional debulking procedures (like bisection, trisection, coring procedure, myomectomy, etc.) were required. Many variables are considered important to decide the operating time namely the experience and expertise of the team, theatre resources (energy sources used), patient factors, etc., [15-17].

The mean intraoperative blood loss (mL) was highest in the TAH group (168.47 \pm 44.96), followed by the TLH (98.63 \pm 23.97) and NDVH (85.67 \pm 20.39) groups. In the NDVH group, the blood loss was apparently less due to routine use of vasopressin injection as a haemostatic procedure. In the TLH group, correct surgical steps and effective tissue coagulation using the energy sources (bipolar) had contributed to reduced intraoperative blood loss.

This study had calculated the postoperative length of stay in hospital to reduce the bias due to hospital policy on when to admit patients preoperatively. Hospital stay (days) was significantly shorter in the NDVH and TLH groups (4.38 \pm 2.77 and 3.5 \pm 1.45, respectively) than the TAH group (7.13 \pm 0.40) ($p<0.05$). This has a significant impact in a busy tertiary care teaching institute, where demand is always greater than the available resources. The reduced hospital stays of the patients enabled rapid turnover of beds and lower hospital expenses. Other studies support the above findings [5,15,17].

According to VAS, the postoperative pain score on day three was significantly lower in the TLH (2.575 \pm 0.96) and NDVH groups (2.975 \pm 0.97) as compared to the TAH group (6.975 \pm 0.8) ($p<0.05$). Hence, early postoperative mobilisation of the patients and lesser need of analgesia were observed in the NDVH and TLH groups in

the present study, although all the patients in the three study groups were encouraged for ambulation in the first postoperative day. In the EVALUATE study [12], AH was more painful than LH two days following the operation in the abdominal trial ($p=0.0003$).

In the present study, the overall complication rate was higher in the TAH group (22/40 or 55%) as compared to the NDVH (14/40 or 35%) and TLH (17/40 or 42.5%) groups. However, in the EVALUATE study [12], the incidence of major intraoperative complications was higher in the LH group. Surgeon's experience and expertise, case selection and energy sources used are the important determinants for the complications.

No major postoperative complication was noted in any group, and none of the patients required unintended laparotomy/relaparotomy. Although the number of patients requiring blood transfusion was more in the TAH group (9 or 22.5%), the difference between three groups in regard to postoperative blood transfusion was not statistically significant. It is not uncommon to transfuse blood postoperatively, as most of the patients are referred to this tertiary care center after a long period of failed therapy. The above findings are closely supported by other studies [5, 17].

The proportions of patients who had febrile morbidity during the postoperative period were almost similar in all the three groups ($p=0.92$). However, in the EVALUATE study [12], the incidence of febrile morbidity was higher in the LH group (5%) when compared to the AH group (3.1%) in the abdominal trial. Most other studies had reported febrile morbidity in all the groups [5, 16, 17]. Postoperative Urinary Tract Infection (UTI) though observed in all the groups, the rate was highest in the NDVH group (12.5%). Strict adherence to the aseptic procedure reduced the occurrence in later part of the study. The relatively high occurrence of port infection observed in the TLH group was mostly due to prolonged operating time. This problem was mainly faced in the cases operated during the initial phase of this study.

During the follow-up visits, it was reported that only one-fifth (20%) of the patients in the TAH group returned to normal household activities in <2 weeks after surgery, whereas the results were much favourable in the NDVH (70%) and TLH (65%) groups. The patients in the NDVH and TLH groups were also found to be happier than the patients in the TAH group. This might be due to less postoperative pain or discomfort and early postoperative recovery. Candiani M et al., observed that the resumption to work was not significantly different between the VH and LH groups [15].

Limitation(s)

First, it was done in a single hospital with fewer patients. Second, randomisation was not done. Lastly, long term postoperative outcomes were not considered.

CONCLUSION(S)

Each method of hysterectomy has its own place depending on individual patient. The cases with huge abdominal mass or with history of previous pelvic surgery are better treated with TAH. However, the procedures of NDVH and TLH have got superiority over traditional procedure of TAH in terms of complications and surgical outcome. Both these procedures had comparative outcome in terms of reduced

intraoperative blood loss, shorter duration of hospital stay, lesser analgesia and early postoperative recovery. From the psychosocial point of view also, patients' acceptance for the procedure of NDVH or TLH was more compared to that of TAH. Moreover, high demand of beds in a busy tertiary care teaching institute adds to the beneficial attributes of NDVH and TLH over TAH.

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