



TO COMPARE EFFICACY, OUTCOME AND COMPLICATIONS IN NON-DESCENT VAGINAL HYSTERECTOMY VERSUS TOTAL ABDOMINAL HYSTERECTOMY IN BENIGN UTERINE CONDITIONS: A RANDOMIZED CONTROL TRIAL

Obstetrics & Gynaecology

Dr. Ashwin Sontakke

Associate Professor, Department of Obstetric and Gynaecology, Government Medical College & KTS/BGW Hospital, Gondia, India.

Dr. Aparna Patil*

Junior Resident 3, Department of Obstetrics and Gynaecology, Government Medical College, Nagpur, India. *Corresponding Author

ABSTRACT

Introduction: Hysterectomy is the commonest major operation performed by gynaecologist through various approaches and techniques including vaginal, abdominal, laparoscopic and robotic hysterectomy. Non decent vaginal hysterectomy (NDVH) is less invasive, less time consuming and scar less surgery. This study was performed to evaluate the appropriate route of hysterectomy (abdominal or vaginal) in our hospital population for women with benign disease by comparing peri-operative and post-operative complications. **Objectives:** The objectives of the study are to compare intra and post-operative complications, efficacy, safety of abdominal hysterectomy with Non descent vaginal hysterectomy in benign uterine conditions. **Methodology:** A total of 106 cases with an indication of hysterectomy were selected, after randomization 53 underwent Non descent vaginal hysterectomy and rest 53 underwent total abdominal hysterectomy. These patients were further evaluated and statically analysed for various factors including age, parity, operative time, blood loss and intra and post-operative complications. Collected data was analysed. **Results:** There was no significant association was found between age, parity, socioeconomic status, residence and selection of procedure. Fibroid was the most common indication for hysterectomy. Patients of NDVH group were operated with minimal blood loss, in lesser duration, post-operative pain score and ambulation period in comparison to patients operated by total abdominal hysterectomy. Significant association was found for above four factors which highly influence the selection of procedure. post-operative complications were more in TAH group as compared to the NDVH group like wound discharge (7.5%), paralytic ileus (3.8%), and wound gape (3.8%) which was significant. Faster recovery was observed in group of NDVH. Follow-up complications like UTI were almost equal in both the groups. **Conclusion:** Non descent vaginal hysterectomy is safer, efficacious with lesser intra-operative and post-operative complications over total abdominal hysterectomy, thus demonstrating that the non-descent vaginal hysterectomy should be the choice of operation for benign uterine conditions with no adnexal pathology

KEYWORDS

Hysterectomy, Vaginal hysterectomy, Abdominal hysterectomy.

INTRODUCTION

Hysterectomy is the most common major gynecological operative procedure performed by gynecologists. There are many indications for Hysterectomy and can be performed by Abdominal, vaginal or laparoscopic route.¹ A large-scale survey has shown that 70-80% of hysterectomies are performed by abdominal route in the absence of uterine prolapse probably because most gynecologists prefer abdominal to other accepted routes of hysterectomy.² Abdominal route is mainly used for malignancies, bulky uterus, adhesions, tubo-ovarian pathologies and when removal of uterus is not possible through vaginal route, but it also comes with post-op complications like wound infection, paralytic ileus, incisional hernia, pain, prolonged hospitalization and delayed resumption of routine life.^{3,4} But now a days, d/t advancement in the medical sciences practitioners are moving towards the less invasive procedures that is total laparoscopic hysterectomy comes with lesser post-op complications and lesser duration of hospital stay, but it also requires special endoscopic equipments, highly skilled surgeon, medical/paramedical staff, anaesthetist with longer duration of operation with higher cost.^{5,6,7} Vaginal Hysterectomy was the first minimally invasive surgical approach for benign gynecological conditions. Previously vaginal approach was reserved for uterovaginal prolapse and non-prolapsed uterus was considered as a contra-indication, so general contra-indication to vaginal route must be re-evaluated as using several strategies i.e., vaginal hysterectomy in large fixed uterus can be facilitated by bisection, wedge more cellatin, myomectomy, debulking, coring and clamp less approach.⁸ Also, in vaginal hysterectomy, less operative time, early recovery, less pain, scarless surgery, less morbidity and early resumption of day-to-day activity.⁹ Most of the ovaries are visible & readily accessible during vaginal surgery. It is safe to perform BSO at the time of vaginal hysterectomy. Up to 97.5% of prophylactic oophorectomies can be completed vaginally.¹⁰ Objective of my study is to compare the outcome & complication rates of vaginal and abdominal hysterectomy done for similar conditions like benign & premalignant conditions of uterus in a non-prolapsed uterus.

MATERIALS AND METHODS

This study was carried out at tertiary level teaching hospital. This was randomized control trial carried out over a period of 20 months. A total of 106 Cases admitted to gynaecological ward requiring hysterectomy for benign diseases were selected randomly and were divided into two groups according to the type of surgery. In group A, 53 patients were

subject to total abdominal hysterectomy and in Group B another 53 patients were subject to vaginal hysterectomy. Before recruiting the eligible patient in the study informed consent was taken from the patient. Particulars of the patients were noted according to prescribed proforma. Detailed history was taken including patient's age, parity, weight, menstrual history and presenting complaints. A complete general, physical and pelvic examination was performed. All the routine investigations were done. Pre-operative USG was done to assess the size of fibroid or any adnexal pathology. All the patients were informed about the disease and the surgical procedure and also consent was taken for conversion of NDVH to TAH (if needed). Blood loss was calculated by noting the number of Mops used during surgery. Measurement of Mops use in present study was 34 cm x 24 cm. On an average ¼ soaked Mops contain 20 ml, ½ soaked 40 ml and fully soaked 100 ml. This was rough estimation of blood loss. Data was collected and comparison between two groups was done with the parameters duration of the surgery, estimated intra-op blood loss, need of blood transfusion, time of ambulation, complications (wound infection/ fever), pain score on day 3, duration of hospital stay. All the patients were advised to attend the outpatient department two weeks after discharge from hospital to note their wellbeing or any late complications like vaginal discharge, urinary/bowel symptom

Inclusion Criteria

1. Uterus Size <16 Weeks (non-pregnant uterus)
2. Pathology confined to uterus
3. Adequate vaginal access
4. Uterine mobility
5. Non-descended uterus
6. Non-scarred uterus

Exclusion Criteria

1. Extrauterine diseases
- a) Adnexal pathology
- b) Severe endometriosis
2. Fixed/ immobile uterus due to adhesions
3. Previous pelvic surgeries
4. Malignant conditions
5. Bulky uterus due to multiple fibroids/ big fibroids and adenomyoma
6. Prolapsed uterus
7. Nulliparity
8. Narrow vagina

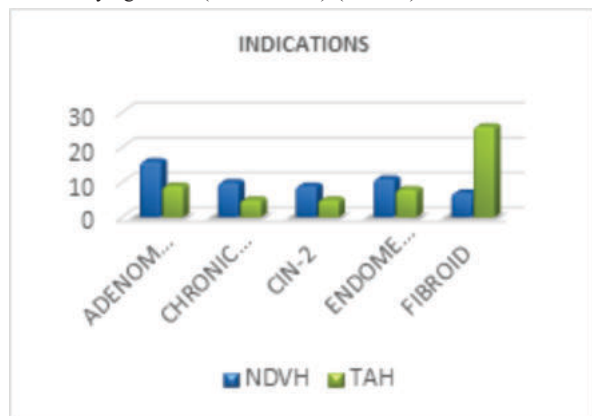
9. Narrow pubic arch (<90°)

Statistical Analysis

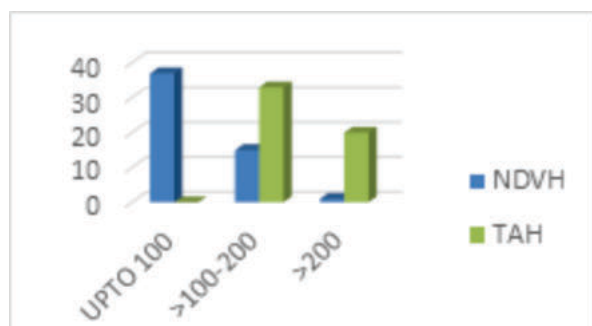
- A) Collected data was entered into Microsoft Excel software and coded
- B) Charts and tables were prepared using Microsoft word and excel software.
- C) Analysis was done using SPSS software version 18.0 by using unpaired t-test and chi-square test. Open EPI version 2.0 was used for assessing the confidence interval

RESULTS

Most of the patients in NDVH and TAH group (54.7% and 37.7%) belonged to age group of >50 years and second highest age group was 41-45 years, 10 (18.9%) in NDVH group while 15 (28.3%) subjects were in TAH group. The association between age factor and type of operation was found to be not significant (p value > 0.05). Majority of that maximum cases that is 29 (54.7%) from NDVH group and 37 (69.8%) in TAH group, presented to us were belonged to parity 1 to 2. There was no significant association between parity and type of operation. In this present study, this table states that according to modified Kuppaswami classification maximum cases were from upper lower class that is 39.6 % from NDVH group and 54.7 % from TAH group. In our study maximum patients were uneducated 35.8 % from NDVH group and 41.5% from TAH group. In our study it was found that maximum patients, who were undergone hysterectomy belonged to AUB-L (FIBROID) with 7 % in NDVH group and 49 % in TAH group. (Fig 1). When duration of operation was measured, it was observed that approximately three-fourth of the subjects were operated in less than one hour in NDVH group, that is 45 (84.9%) required < 60 min time while majority of cases that is 38 (71.6 %) from TAH group required 60-90 min time. The difference in surgical time was statistically significant (P value 0.001). (Table. 1)

**Fig 1. Indication For Hysterectomy****Table 1: Comparison Of Operative Period In Both Groups**

DURATION OF SURGERY	NDVH		TAH	
	No.	%	No.	%
<60	45	84.9	11	20.75
60-90	07	13.2	38	71.6
>90	01	1.8	04	7.5
Total	53	100	53	100
Mean ± Std. Deviation	60.717 ± 13.03749		69.08± 10.40867	
P-VALUE	0.001 (Highly-significant) **			

**Fig 2: Comparison Of Intra-operative Blood Loss**

It was observed that majority of cases from NDVH group i.e 37 (69.8%) had blood loss up to 100ml, while majority of cases from TAH group i.e 33 (62.26%) had blood loss 200 to 300 ml, that of only 1 case (1.8 %) from NDVH group had blood loss >200 ml. The difference in intra-operative blood loss was statistically significant (P value 0.000). (fig. 2). majority of patients from both group i.e 46 (86.7%) from NDVH and 35 (66%) from TAH group did not require transfusion, followed by almost 07 (13.2%) from NDVH group and 12 (22.6%) from TAH group required one blood transfusion. The difference in intra-operative blood transfusion was statistically significant (P value 0.000).

DURATION OF SURGERY	No	Mean ± Std. Deviation	P-Value
NDVH	53	60.717 ± 13.03749	0.001 (Highly-significant) **
TAH	53	69.08 ± 10.40867	
AVERAGE BLOOD LOSS	No	Mean ± Std. Deviation	P-Value
NDVH	53	103.776 ± 40.5835	0.000 (Highly-significant) **
TAH	53	211.5094 ± 51.7537	
AMBULATION	No	Mean ± Std. Deviation	P-Value
NDVH	53	38.9057 ± 4.49899	0.000 (Highly-significant) **
TAH	53	53.2264 ± 5.01015	
PAIN SCORE ON DAY 3	No	Mean ± Std. Deviation	P-Value
NDVH	53	3.7358 ± 0.68363	0.000 (Highly-significant) **
TAH	53	5.3585 ± 0.68203	
HOAPITAL STAY	No	Mean ± Std. Deviation	P-Value
NDVH	53	5.5849 ± 1.27753	0.000 (Highly-significant) **
TAH	53	8.717 ± 3.38195	

In our study, 106 surgeries performed the complications were as follows:

2 patients (3.8%) from TAH group had intra-operative bladder injury and 1 patient (1.8%) had ureter injury. Whereas 1 case (1.8%) from NDVH group had vault hematoma. The difference in intra-operative complications was statistically significant (P value 0.000). TAH group patients had different post-operative complications like 2 cases (3.8%) had paralytic ileus, 2 cases (3.8%) had wound gape, and 4 cases (7.5%) had wound discharge. However, 1 case (1.8%) from each group had complaints of UTI.

The difference in post-operative complications was statistically significant (P value 0.000)

DISCUSSION

This randomized control trial was carried out to study the to compare safety, efficacy between Non-Descent Vaginal Hysterectomy and Total Abdominal Hysterectomy. Advantage and disadvantage for abdominal and vaginal hysterectomy for non-descent uterus were also studied in the department of obstetrics and gynecology over the period of 18 months at tertiary health care Centre Nagpur with study population of 106 cases with 53 in each group. Following were the important observations, which have been enumerated upon. In our study the maximum hysterectomy either TAH or NDVH is being performed between age group of > 50 years. However previous studies conducted by study L.Pranathi, Y.Madhavi¹¹ had surgeries performed in both TAH and NDVH group were belonged to age group of 46 to 50 years. In the present study, no significant association was found between age as similarly observed by Deshpande et al¹² and L Benassi et al¹³ who did a prospective, randomized study. In our study maximum patients were found with parity 2 followed by multiparity (para 3 and 4). Though higher parity and advancing age are the favorable factors for vaginal hysterectomy but no statically significant association was found similarly found in pooja jain et al study¹⁴. In our study according to socioeconomic status maximum patient belonged to upper lower class in both NDVH and TAH group, according residence patient belonged to both rural and urban region with near about equal distribution, according to education status most of the patient were uneducated however there was no significant statistical association seen between socioeconomic status, parity, education status and region of residence. This observation was similar to previous studies^{14,15,16}. In our study, It was observed that most common indication for hysterectomy observed was fibroid uterus (31%) of total 106 cases followed by adenomyosis (19.8%), followed by endometrial hyperplasia followed by PID and CIN, cases selected randomly for type of hysterectomy, hence

statistical significance could not be obtained for indication of type of hysterectomy, which is comparable to the study conducted by Neerja G et al¹⁷ showed maximum cases of hysterectomy were operated for fibroid uterus (47%), DUB (19%), adenomyosis (5%) and endometrial hyperplasia (4%). A similar study performed by Rupali D et al¹⁶, showed fibroid as the most common indication for hysterectomy (68%). In our study most cases undergone hysterectomy having uterine size between 8 to 12 weeks i.e 64.1% in NDVH and 73.5 % in TAH, however as this is randomized study there was no statistical significance obtained for the type of hysterectomy. In our study When duration of surgery was analyzed it was observed that maximum patients from NDVH group i.e (84.9%) was operated in less than one hour whereas only 20.75% in TAH group. It was also observed that almost (71.6%) cases from TAH group required surgical time of 60 to 90 min while up to (13.2%) of cases from NDVH group required surgical time of 60-90 min. The mean duration of surgery required for NDVH group is 60.71 and that of TAH group is 69.08. The mean difference for duration of operation in NDVH and TAH group was highly significant (p value = 0.001) which indicates that the time used for surgery by NDVH and TAH methods were different and influences the selection of the procedure. Henceforth, the technique of Non-Descent Vaginal Hysterectomy (NDVH) is better than conventional abdominal hysterectomy when duration of operation is considered. In the Study performed by Sanita Kayastha and colleagues¹⁸ the mean duration of surgery of TAH was 96.8 min and that of VH was 89 min (p value=0.0192). Another study by Sunanda Bharatnur¹⁹ in majority of cases (72%) the maximum operating time was between 60-120min in abdominal hysterectomy group where as in NDVH Group (68%) the time taken was 60min.

In our study it was observed that during surgery there was a minimal blood loss in NDVH as compared to abdominal hysterectomy. In our study maximum cases from NDVH group had blood loss <100 ml while that of TAH group blood loss is between 100-200 ml. Furthermore, it was statistically interpreted that blood loss during operation is one of the important factors which influenced the selection of the procedure. In the study by Deshpande et al¹², mean blood loss was significantly less amongst non-descent vaginal hysterectomy cases as compared to total abdominal hysterectomy. Bing Chen, Dong Ping Ren, Jing-Xuan Li, Chun-Dong Li²⁰ who compared outcomes of vaginal and abdominal hysterectomy procedures in women also concurred with their results showing intraoperative blood loss was significantly less in the Vaginal Hysterectomy (Mean 30.4 ml) group compared with the abdominal hysterectomy (Mean 70.3 ml) group²⁰. Similar results were also observed in the study by Sanita Kayastha and Singh A¹⁸.

Need for intra-operative blood transfusion has been observed in both groups, TAH group cases required more blood transfusion than NDVH. However, most of the cases did not require any transfusion, which was statistically significant. This is in accordance with the study by Chakraborty S et al²¹. In our study intra operative complications while performing non descent vaginal hysterectomy were less as compared to the total abdominal hysterectomy. Moreover, Intraoperative complication showed ureteric injury (1.9%) and bladder injury (3.8%) was significantly high among Total abdominal hysterectomy cases as compared to non-descent vaginal hysterectomy cases, while vault hematoma was seen in one case (1.9%) in non-descent vaginal hysterectomy. N. Fatima Shanthini, G. K. Poomalar, M. Jayasree, A. Bupathy found that Bladder injury occurred in 1 case in VH (1.9%) and in 4 cases in TAH (2.3%). Ureter injury occurred in 1(0.6%) case in TAH group., determined by significant associations (p value 0.05)²². In present study, post-operative complications were more after abdominal hysterectomy in comparison to the other group. Majority of the patients in after abdominal hysterectomy complained of pain, fever (1.8%). Abdominal distension, paralytic ileus (3.8%) and wound infection that is wound discharge (7.5%) and wound gape (3.8%) were observed and those (3.8%) subjects respectively needed resuturing and reopening in TAH group while none in the study group. A study by Neerja G et al¹⁷ showed that no major postoperative complications were encountered in any of the cases operated through vaginal route. Also, this is in accordance with study by Iftikhar R²³ and Bharatnur S¹⁹ who observed that the incidence of UTI was more in TAH as compared to NDVH. Similarly, Iftikhar R²³ found paralytic ileus in only abdominal group. Furthermore, in our study satisfaction score that is visual assessment score by likert scale done, which interpreted pain score on day 3, about (33.9%) of the cases from NDVH and only 1 case (1.8%) from TAH had pain score between 2-3 (mild pain) ,

whereas (41.5%) of cases from TAH group had pain score >6 (severe pain) it was statistically interpreted that intensity of pain in post-operative period and above discussed factors are most important factor which influences the selection of the procedure. In our study, mean ambulation time for NDVH group is 38 hours and that of TAH group is 53 hours and mean duration of hospital stay for patients of NDVH group was approximately 5 days while that of TAH group was 8 days which was significantly more than NDVH group. This could be because of many factors including more pain and requirement of analgesics, more patients developed post-operative febrile illness and paralytic illness in patients with TAH group requiring prolonged hospital stay and delayed ambulation in TAH group. These observations were similar to previous studies^{12,13,21}. Henceforth, the technique of Non-Descent Vaginal Hysterectomy (NDVH) which showed less intra and post-operative complications and morbidity is considered better than conventional abdominal hysterectomy

CONCLUSION

Our study was done to provide objective evidence to assist Gynecological surgeons in their selection of the most appropriate method of hysterectomy and to provide data to permit patients to make an informed decision about their preferred type of hysterectomy. It is observed that compared to TAH group NDVH group had less operative time, less intra operative blood loss, less post-operative pain and requirement of analgesics. Compared to TAH group NDVH group had less mean ambulation time, hospital stay and fewer post – operative complications. Hence, it can be elementary concluded that Non-Descent Vaginal Hysterectomy superior over Abdominal Hysterectomy with patient favorable outcome and must be the choice of operative procedure amongst the two surgeries.

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