

NON-DESCENT VAGINAL HYSTERECTOMY USING BIPOLAR VESSEL SEALING SYSTEM VERSUS TOTAL LAPAROSCOPIC HYSTERECTOMY FOR BENIGN DISEASES OF UTERUS: A PROSPECTIVE INTERVENTIONAL STUDY

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ABSTRACT

Objective: The objective of the study was to compare the surgical outcomes of non-descent vaginal hysterectomy (NDVH) using bipolar vessel sealing system and total laparoscopic hysterectomy (TLH) with reference to intraoperative time, intraoperative blood loss, and post-operative pain.

Methods: The study was conducted on 100 patients who required hysterectomy for benign diseases of uterus and was fit to undergo both modalities of surgery (TLH/NDVH). 50 patients that underwent TLH and 50 patients that underwent NDVH with BipBIPVSS were part of Study Group.

Results: The mean intraoperative time taken in performing NDVH using Bipolar BIPVSS (28.06 min) was significantly less than the mean time taken in performing TLH (92.62 min). The intraoperative blood loss in NDVH with BIPVSS was 41.70 mL and TLH was 89.24 mL. The post-operative pain in both the study group was not statistically significant as both the groups had similar experience and $p > 0.05$. Post-operative major complication of bleeding in ovarian artery and hemoperitoneum was observed in a patient of NDVH with BIPVSS while one case of thermal rectal injury and one case of bladder injury were observed in TLH group.

Conclusion: The route and procedure of hysterectomy will depend on various factors; however, NDVH with BIPVSS has certain advantage over TLH as it takes lesser times, lesser blood loss and gives similar pain experience if not better than TLH.

Keywords: Non-descent vaginal hysterectomy, Total laparoscopic hysterectomy, Bipolar vessel sealing system, NDVH with BVS.

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INTRODUCTION

While hysterectomy continues to be one of the most common gynecological surgeries used for benign disease of uterus, technological advancement and improved surgical skills are making their pathway to increase the efficiency and efficacy of the procedure. This has encouraged gynecologists to perform minimally invasive surgery even for non-prolapse indications and thus total laparoscopic hysterectomy (TLH), robotic hysterectomy, and non-descent vaginal hysterectomy (NDVH) have started to gain popularity among the surgeons. Based on surgical indications and other factors TLH is a better alternative of abdominal hysterectomy [1]; however, it requires specialized setup, high-end equipment, skilled, and trained surgeons and thus becomes an expensive affair which could not be afforded by many patients in India. NDVH, on the other hand, can be performed with minimal invasion and provides easy access to the ligaments for surgeons to become a good alternative of abdominal hysterectomy and a cost-effective alternative of TLH [2]. The efficiency and efficacy the NDVH could further be increased with the usage of latest instruments such as bipolar vessel sealing system to minimize the intraoperative time, intraoperative blood loss, and post-operative pain experience [3].

Harry Reich performed the first TLH in 1988 [4], being one of the most renowned vaginal surgeons claimed vaginal route to be the first choice of approach for hysterectomy. In the modern world vaginal hysterectomy could be performed either with the usage of clamps and ligation of pedicles or with the use of various energy sources, that is, electrosurgical unit, harmonic device, and laser to coagulate and cut the tissue.

Bipolar vessel sealing system is an electrosurgery unit used for sealing blood vessels of the size up to 7 mm in diameter and thus

effective for sealing uterine artery (size -approximately 2 mm). It compresses, coagulates and seals the vessel using bipolar electrothermal energy [5]. Lateral thermal spread of BipVSS is only up to 2.5 mm and thus chances of thermal injury in Ureter, Bowel, and Pelvic tissues are minimal [6].

The objective of this study is to compare the surgical outcomes of NDVH using bipolar vessel sealing system and TLH with reference to intraoperative time, intraoperative blood loss, and post-operative pain.

METHODS

It was a hospital-based cross-sectional analytical study, conducted in the department of Obstetrics and Gynaecology of SHKM Government Medical College Nalhar, Nuh, Haryana. The study was instituted only after obtaining necessary clearance from Institutional Ethics Committee of the medical college vide letter number SHKM/IEC/2020/167 dated July 13, 2020. The study was conducted over a period of 20 months from October 2020 to May 2022. Considering the low patient footfall due to COVID-19 pandemic, it was decided to attain the feasible sample of 100 patients during the decided study period. All 100 patients were recruited from the outpatient department after fulfilling inclusion/exclusion criteria and those who required hysterectomy for benign diseases of uterus and were fit to undergo both modalities of surgery (TLH/NDVH). Before commencement of the study, 50 random numbers were selected for NDVH using BipVSS study group and rest 50 were selected for TLH study group to ensure unbiased allocation of study subjects of NDVH using BipVSS and TLH groups. All these surgeries were performed by same set of senior consultants with the similar level of expertise. Anonymity and confidentiality were maintained during data collection as well as data storage by keeping file containing identity related details password protected.

50 patients who underwent NDVH and 50 patients that underwent TLH were included in the study after taking detailed history and performing general and systemic examinations. Malignancy was ruled out using clinical examination, Pap smear and/or endometrial, and endocervical biopsy. Pre-anesthetic fitness was taken prior to surgery. Data collection variables included demographic variables (Age, Parity, and Surgical indication); and variables pertaining to intra-operative (Blood Loss and Intra-Operative Time) and post-operative pain.

Study participants included patients above the age of 35 years having benign diseases of uterus such as fibroid, endometrial and endocervical polyps, adenomyosis, dysfunctional uterine bleeding, and chronic pelvic inflammatory disease. Patients of abnormal uterine bleeding not responding to medical management for ≥ 6 months, patients with uterine size on per-vaginal examination ≤ 12 weeks, and patients with previous history of tubectomy done for female sterilization were also included in the study.

Study participants having Uterine size >12 weeks, Narrow subpubic angle, Restricted Uterine mobility, Complex/simple adnexal cyst ≥ 5 cm, Uterovaginal prolapse, and Suspicion of genital malignancy were excluded from the study. Patients requiring additional surgical procedures in addition to hysterectomy, patients with history of previous abdominal surgeries, patients with history of Abdominal Koch's and patients not giving consent for the mode of surgery were also excluded from the study.

All cases of NDVH using bipolar vessel sealing system and TLH were done under general anesthesia using standard operating techniques. After Lithotomy position cleaning and draping was done, cervix was held with Vulsellum and circular incision was taken around the cervix. Pubovesical ligament was cut to push up the bladder and pouch of Douglas was open posteriorly. Cardinal ligaments, uterosacral ligaments, and uterine artery were cut after clamping and coagulating with bipolar vessel sealing system. Uterine myomectomy, debulking, and bisection were performed on case-to-case basis. Uterus was delivered by clamping, coagulating and cutting the round ligament, infundibular pelvic ligament, and tuboovarian ligament using bipolar vessel sealing system. Vaginal vault was closed using continuous interlocking suture. Same electrothermal energy source was used in both NDVH with BipVSS and TLH.

Primary outcome measures included statistically significant differences in the operating time, intraoperative blood loss, post-operative pain after 24 and 48 h of surgery and post-operative complications between the two groups (TLH and NDVH). Operating time was calculated as the time taken from skin incision to placement of last abdominal or vaginal closure sutures. Estimated blood loss was calculated on the basis of weight of the final mops counts and blood in suction apparatus. Post-operative pain after 24 and 48 h of surgery was scaled according to visual analog scale of 0–10 to measure mild, moderate, and severe pain.

Statistical analysis

Data collected were entered into Microsoft excel 7, then data were analyzed using Statistical Package for the Social Sciences 20.0 software package. Categorical variables have been expressed as the numbers of cases and percentage value. Independent t-test and Chi-square test were applied and $p < 0.05$ was considered statistically significant.

RESULTS

As mentioned in Table 1, the demographic constituent of both the study group was comparable where more than half of the patients in both study groups was between 41 and 50 years. Patients within the age range of 30–40 years were between 12% and 14% in NDVH and TLH groups, respectively. There were 26% patients between the age group of 51 and 60 in NDVH group while 30% of the patients were in 51–60 age group in TLH study group. About 6% patients were above the age of 61 years in both the study groups.

Most of the patients were multiparous in both the study group (74% in NDVH group and 66% in TLH group). Only one patient was nulliparous in TLH study group and rest all the patients had parity between 1 and 3.

As Table 2 shows, the most common indication of surgery was fibroid of uterus in above 40% patients in both the study groups which was then followed by adenomyosis in 26% of the patients in NDVH group and 22% in TLH group. Postmenopausal bleeding was only seen in one patient in NDVH group.

As shown in Table 3, NDVH using bipolar vessel sealing system was completed in 40 min for 88% of the patients while took little longer to complete within 80 min for 12% of the patients. TLH surgery took more than 2 h for most of the patients (86%) and was completed within 2 h for 14% of the patients in TLH group.

As stated in Table 4, blood loss for more than half of the patients in NDVH using Bipolar vessel sealing system group (54%) was <30 mL while all the patients in TLH group had more than 30 mL of blood loss. 30–60 mL of blood loss was observed in 26% patients of NDVH group and in 40% patients of TLH group. About 16% patients of NDVH group and 50% patients of TLH group had a blood loss between 60 mL and 90 mL. 2% patients of NDVH group and 4% patients of TLH group had more than 120 mL of blood loss. The mean intraoperative blood loss in

Table 1: Demographic factors

Age (years)	NDVH using bipolar vessel sealing system (n=50) (%)	TLH (n=50) (%)
30–40	06 (12)	07 (14)
41–50	28 (56)	25 (50)
51–60	13 (26)	15 (30)
61–70	02 (4)	03 (6)
>70	01 (2)	0 (0)
Parity	NDVH using Bipolar Vessel Sealing System (n=50)	TLH (n=5)
Nulliparous	0 (0)	01 (2)
Para 1–3	13 (26)	16 (32)
Multiparous	37 (74)	33 (66)

Yate's Chi Square Test was applied, Chi-square value=(0.063), Degree of freedom-5, $p > 0.05$ (0.99995), Result-statistical non-significant

Table 2: Surgery indication

Indications	NDVH using bipolar vessel sealing system (n=50) (%)	TLH (%)
Fibroid uterus	22 (44)	24 (48)
Adenomyosis	13 (26)	11 (22)
Dysfunctional uterine bleeding	08 (16)	09 (18)
Endometrial polyp	03 (06)	02 (04)
Chronic pelvic inflammatory disease	03 (06)	04 (08)
Post-menopausal bleeding	01 (02)	00 (00)

Table 3: Mean operative time

Mean operative time (Minutes)	NDVH using bipolar vessel sealing system (n=50) (%)	TLH (n=50) (%)
0–40	44 (88)	00 (00)
41–80	06 (12)	04 (08)
81–120	00 (00)	24 (48)
>120	00 (00)	16 (32)
	00 (00)	06 (12)

Independent t Test was applied, t-value = (-16.42605), p value= <0.00001 , Result-statistical highly significant

this study for NDVH with BIPVSS group has been 41.7 mL and 89.24 mL for TLH group.

As per Table 5, 22% patients of NDVH group and 32% patients of TLH group had severe postoperative pain until after 24 h after surgery which continued in 2% patients of NDVH group and in 4% patients of TLH group. Moderate pain was reported until after 24 h after the operation in 68% and 62% of the patients and continued for 48 h in 34% and 32% in NDVH group and TLH group, respectively. About 10% patients of NDVH group 6% patients of TLH group complained of mild pain after 24 h of surgery. About 64% patients of both the groups continued to have mild pain until after 48 h.

In both the study groups, all the patients were ambulated within 8 h of the surgery and were discharge on 3rd operative day. A follow-up was done after 1 week and thereafter every fortnight for next 3 months.

Post-operative complication was observed in a patient of NDVH group where the patient developed hemorrhagic shock after the surgery. On examination and investigation hemoperitoneum was confirmed and exploratory laparotomy was performed. Intraoperative bleeding from left ovarian vessel was found along with broad ligament hematoma. Ovarian vessel was ligated and hematoma was drained. Patient recovered well after laparotomy.

Two major complications were reported in TLH group, where one patient presented with peritonitis on the 3rd post-operative day. On exploratory laparotomy, perforation in rectum was found probably due to thermal injury and was successful managed by colostomy. Another patient of TLH group was discharged on 3rd post-operative day in stable condition. During the follow-up visit on 11th post-operative day, the patients complained of the abdominal pain with spontaneous urination without any urinary complain or dribbling of urine. On USG, small amount of ascitic fluid was present in abdominal cavity which was increasing gradually. On retrograde CT urogram bladder injury was diagnosed and bladder was repaired successfully.

DISCUSSION

Conventional vaginal hysterectomy is still the procedure used by most gynecologist for benign disease of uterus as it is affordable, safe, and less time-consuming procedure in comparison to TLH [2] but it is associated with more intraoperative blood loss and post-operative pain. With the advancement of electrosurgical instruments, it has now

become even more effective as it has further reduced the operative time, blood loss, and post-operative pain in NDVH [7].

In this study, the most common indication has been fibroid uterus in both the groups (NDVH with BIPVSS as 44% and TLH with 48%), which is comparable to Nimbannavar *et al.* study [8] but Nagar *et al.* study had adenomyosis as the most common indication in both the group [9].

Many studies done in last few years suggest that the mean operating time in NDVH is significantly less than the mean time taken in TLH [10,11]. In this study, TLH took a mean operating time of 94.26 min which is comparable to the study done by Nagar *et al.* [9] but the study done by Murali and Khan [11] suggests mean operating time for TLH was 120 min. Mean Operating time for NDVH without BIPVSS takes 40 min as per study done by Murali and Khan [11] and 37min as per the study done by Balakrishnan and Dibyajyoti [12].

NDVH operating time can further been reduced if BIPVSS is used as conventional suturing ligature is replaced by electrosurgical instrument to clamp, coagulate, and cut. The mean operating time in NDVH with BIPVSS in this study has been 28.06 min which is significantly less than the mean operating time 92.62 min in TLH group. The difference in the mean operating time in both study group of this study is statistically highly significant as the $p < 0.00001$. The literature published in FOGSI Focus Vaginal Surgeries [3] also suggest the reduced mean operating time of 20 min (range 15–35 min) in NDVH with BIPVSS.

Blood loss in any of the gynecological surgery is unavoidable; however, gynecologists are continuously striving to contain the blood loss with the help of technological advancement and improvement in surgical skills. Studies have proven that the blood loss in NDVH has been lesser than TLH and this can further be reduced if NDVH is performed using BIPVSS [13]. As per the study by Murali and Khan [11], the mean blood loss in NDVH has been 50ml while it was 120ml in TLH. Roy *et al.* study also suggests that NDVH took least operative time and significantly lesser blood loss ($p = 0.02$) compared to TLH [7].

In this study, the mean blood loss in NDVH with BIPVSS was observed to be 41.7 mL while the mean blood loss reported in TLH group was 89.24 mL. The difference in the blood loss of the two study groups has been highly significant and the $p < 0.00001$. This is comparable to the literature published in FOGSI Focus Vaginal Surgeries [3] which suggests that NDVH with bipolar vessel sealing systems decreased blood loss by an average of 48 mL.

Post-operative pain is a matter of concern in all surgeries and studies suggest that NDVH causes more pain in comparison to TLH due to inflammation and edema in pedicles [9,12]. However, as per this study the usage of BIPVSS has reduced the severity and duration of the postoperative pain because thermal hemostasia reduces inflammation and inflammatory mediators. This has also been published in FOGSI Focus Vaginal Surgeries [3]. The postoperative pain in both the study groups in this study has been comparable and statistical significance cannot be established as $p > 0.05$ after 24 h as well as after 48 h of the surgery. Initial studies by Clavé *et al.* also suggest that patients that undergone VH using BiClamp® experience less post-operative pain [13,14].

Table 4: Mean intraoperative blood loss

Mean intraoperative blood loss (mL)	NDVH using bipolar vessel sealing system (n=50) (%)	TLH (n=50) (%)
<30	27 (54)	00 (00)
30–60	13 (26)	08 (16)
60–90	08 (16)	28 (56)
90–120	01 (02)	10 (20)
>120	01 (02)	04 (08)

Independent t-test was applied, t-value=(-9.4508), p value=<0.00001, Result-statistical highly significant

Table 5: Post-operative pain

Post-operative pain	NDVH using bipolar vessel sealing system (n=50)		TLH (n=50)	
	After 24 h of surgery	After 48 h of surgery	After 24 h of surgery	After 48 h of surgery
Mean VAS Score (After 24 h and after 48 h)				
Mild (1–3)	05 (10%)	32 (64%)	03 (06%)	32 (64%)
Moderate (3–6)	34 (68%)	17 (34%)	31 (62%)	16 (32%)
Severe (>6)	11 (22%)	01 (02%)	16 (32%)	02 (04%)

Chi-square test was applied, Chi-value=1.5644 for 24 h and 0.3636 for 48 h, p value=>0.05 (0.457401 for 24 h 0.833753 for 48 h), Result-statistical not significant

Limitations

This study had the limitation as the sample size in the study was small to apply the results to general population and some parameters had 0 and <5 patients and thus had difficulty in applying statistical tests.

CONCLUSION

The route and procedure of hysterectomy will depend on various factors such as surgical indication, surgical setup, surgeon's preference, and even patients' preference, NDVH with BIPVSS has certain advantage over TLH as it takes lesser times, causes lesser blood loss and gives similar pain experience if not better than TLH.

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AUTHORS' CONTRIBUTION

All the authors have contributed equally.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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