Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and **Reproductive Biology**

journal homepage: www.elsevier.com/locate/ejogrb

Full length article

Formal institutional guidelines promotes the vaginal approach to hysterectomy in patients with benign disease and non-prolapsed uterus

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ARTICLE INFO

Article history:

Received 12 November 2020 Received in revised form 17 February 2021 Accepted 20 February 2021 Available online xxx

Keywords:

Benign gynaecological pathology Laparoscopic assisted vaginal hysterectomy Non-Prolapsed uterus Promoting vaginal route for hysterectomy Surgical decision algorithm Vaginal hysterectomy



ABSTRACT

Objectives: This study was undertaken at the Department of Obstetrics and Gynaecology of the Charlotte Maxeke Johannesburg Academic Hospital to determine if the use of formal guidelines and a standardised surgical technique would increase the rate of vaginal hysterectomy (VH) and result in an overall decline in open abdominal hysterectomy (AH).

Study Design: All women admitted between July 2001 and December 2014 for hysterectomy due to benign conditions, meeting the guidelines criteria (vaginally accessible uterus, uterus \leq 12 weeks size or \leq 280 g on ultrasound examination and pathology confined to the uterus) were included. The surgical route was determined using the Unit surgical decision tree algorithm. In cases where the pathology was not confined to the uterus or success in VH was uncertain, laparoscopic assisted vaginal hysterectomy (LAVH) was performed. The VH procedures were performed by the residents in training, under the supervision of specialists with large experience in vaginal surgery. In addition to the patient characteristics and surgical approach to hysterectomy, length of hospital stay, intra-operative and immediate post-operative complications were also recorded and analysed.

Results: A year before the initiation of the study, the percentage of all VHs undertaken in the Department was 9.8 % (mainly performed for utero-vaginal prolapse). During the study period, 1143 vaginal procedures (1017 VHs and 126 LAVHs) were performed. The most common indications were cervical dysplasia, uterine fibroids, dysmenorrhoea or abnormal uterine bleeding, adenomyosis, endometrial hyperplasia and chronic pelvic pain. Introducing a formal clinical decision tree algorithm and a standardised surgical technique resulted in an increase in the rate of VH to 48.4 % and overall decline in open AH from 91.2%-51.6%. Thus, the VH/AH ratio increased from 1/9 at the beginning of the study (July 2001) to 1/1 by its end (December 2014). In all cases, VH was performed without the need to convert the vaginal to the abdominal route.

Conclusion: The use of institutional guidelines for determining the hysterectomy route and a standardised VH technique resulted in an increased number of performed VHs. This provided an essential opportunity for residents to acquire, improve and maintain the skills required to safely perform VH.

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Introduction

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https://doi.org/10.1016/i.eiogrb.2021.02.019 0301-2115/© 2021 Elsevier B.V. All rights reserved.

Globally, hysterectomy serves as the most common treatment for benign uterine conditions [1,2]. Hysterectomy can be performed *via* the abdominal, vaginal, or laparoscopic route, with or without robotic assistance. The advantages provided by both vaginal and laparoscopic hysterectomy (VH and LH, respectively)







over abdominal hysterectomy (AH) include less postoperative pain and need of analgesia, shorter hospital stay, more rapid recovery and return to daily activities, and reduced hospital charges and therefore cost [3–7]. However, VH is associated with fewer intraoperative and postoperative complications as compared with AH or laparoscopic hysterectomy (LH), either total laparoscopic hysterectomy (TLH) or laparoscopy-assisted vaginal hysterectomy (LAVH) [8–10]. Despite this, AH remains the chosen route for benign uterine conditions, worldwide. This preference is largely due to a lack of experience in VH, resulting in surgeons' reluctance to perform VH, especially in patients without uterine prolapse, ignoring the fact that a vast worldwide literature has demonstrated its applicability in benign diseases such as uterine fibroids, in those with previous laparotomies, caesarean sections, as well as in nulliparous women [11–16].

In spite of the benefits offered by VH, globally still 70–80% of hysterectomies have been shown to be carried out *via* the abdominal approach, according to all large-scale surveys, except when treating utero-vaginal prolapse [17–27]. This latter indication accounts for about 10 % of all hysterectomies conducted

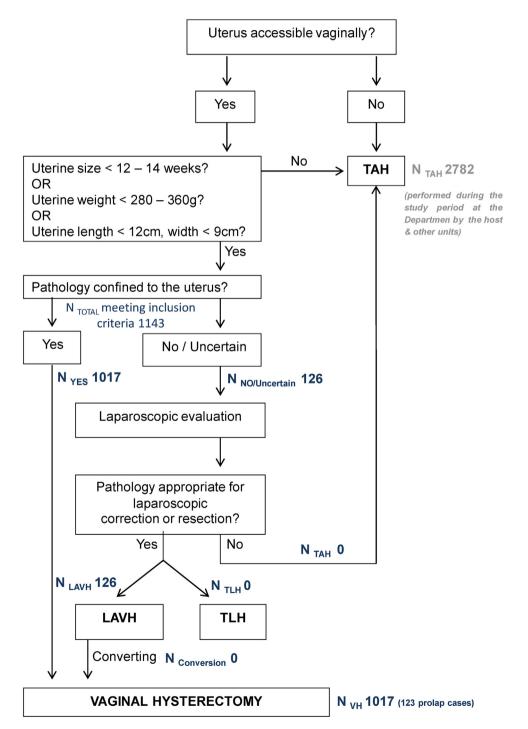


Fig. 1. Formal Unit decision algorithm used for determining the route of hysterectomy for benign disease (approach based on clinical examination and pelvic ultrasonography). N indicates the number of cases included during the study in each category. Abbreviations: LAVH, laparoscopically-assisted vaginal hysterectomy; TAH, total abdominal hysterectomy; TLH, total laparoscopic hysterectomy; VH, vaginal hysterectomy.

worldwide [27,28]. The rate of LH has been increasing, without a significant reduction in AHs. This increase in LH has thus been incurred at the expense of VH. Assessing current trends in resident hysterectomy training, Burkett *et al.* concluded that there is an increase in endoscopic approach, including robotic hysterectomy (RH), while VH is becoming inappropriately replaced and underutilised [29]. However, this highlights a fundamental problem currently facing clinical gynaecology, namely insufficient VH training/practice due to the inadequate experience of junior trainers in VH, and the consequent lack of appreciation of the benefits afforded by VH.

In this study, we investigated the possibility of increasing the number of VHs performed by residents – and thus the improvement of their proficiency in the procedure – through the incorporation of formal hysterectomy guidelines (a surgical decision tree algorithm) and standardised VH technique into the resident training programme.

Materials and methods

The study was approved by the Ethics Committee of the University of Witwatersrand (ref. Nr: M150462) and realized at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). CMJAH is a tertiary-level academic hospital and a referral centre for the eastern and western areas of greater Johannesburg. The Department of Obstetrics and Gynaecology is associated with the University of the Witwatersrand, and is thus a provider of training to undergraduate and postgraduate students. Guidelines (Fig. 1) were introduced as part of academic programme to improve teaching among the residents.

All patients admitted between July 2001 and December 2014 (the period covered by the study) due to benign conditions, meeting the inclusion criteria (*i.e.* vaginally accessible uterus, uterine size equivalent to \leq 12 weeks of gestation or \leq 280 g on ultrasound examination, pathology confined to the uterus; Fig. 1) were included. According to the guidelines set by the Unit, nulliparous women, women without uterine descent, women with previous pelvic surgery or caesarean section, women requiring salpingo-oophorectomy, and women with persistent cervical dysplasia after previous large loop excision of the transformation zone (LLETZ) or endometrial hyperplasia without atypia on endometrial sample were also included.

Women with utero-vaginal prolapse who underwent VH were also included in the study but analysed separately. The surgical route was determined using the study surgical decision tree algorithm (Fig. 1). In cases where the pathology was suspected not to be confined to the uterus or success of the vaginal route was uncertain, LAVH was performed.

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All the VH procedures were performed by the residents in training, under the supervision of the head of the Unit (A.C.) or specialists within the Unit with thorough experience in vaginal surgery. During the study period, a standardised surgical technique [30] was used, for both VH and LAVH. A brief description of the VH and LAVH used in the study is shown in Panel 1. All patients received prophylactic antibiotics intra-operatively.

The patient characteristics at inclusion, the indications for hysterectomy, the weights of the uteri, the length of hospital stay, and intra-operative and immediate post-operative complications, among those who underwent VH and LAVH were recorded and analysed. The operative time was calculated as the time that elapsed from the first cut to the closure of the abdominal incisions in cases of LAVH, or of the vaginal vault in cases of VH. Descriptive statistics were engaged for socio-demographic characterisation of the study population. All continuous data were compared using the Student *t*-test. The Chi-square test and Kruskal-Wallis test were used to compare the difference between LAVH and VH groups. Pearson's correlation coefficient was calculated to assess the relationship between the clinic and/ or demographic factors of the patients. The results were considered to be statistically significant if a p-value <0.05 was obtained (CI 95 %).

Results

A total of 3925 women underwent hysterectomy during the study period in our department: 2782 (70,8%) had AH, 1017 (26%) VH, and 126 (3,2%) LAVH. A year before the beginning of the study, the percentage of VH in our Institution was 9.8 % of all hysterectomies. The procedure was mainly performed for uterovaginal prolapse. Introducing formal guidelines, a surgical decision tree algorithm, and a standardised surgical technique resulted in an increase in the rate of VH to 48.4 %, and an overall decline in open AH from 91.2%–51,6% (Fig. 2). Thus, VH to AH ratio increased from 1:9 at the beginning of the study (July 2001) to 1:1 by its end (December 2014). A sharp increase in LAVH was observed from July 2001 to December 2004, reaching a maximum of 10.8 %, and dropping to 1,25 % by the end of the period studied (December 2014). As experience was gained with VH, the total number of VH increased with a decrease in the need for LAVH (Fig. 2).

After following the surgical decision tree algorithm, 1017 VHs and 126 LAVHs were performed in the department during the study period. Thus, a total of 1143 patients submitted to minimally invasive procedures (VH or LAVH) were included in the study. The cases who underwent AH (2782 patients) mainly included women with cervical and endometrial malignancies, and patients with abnormal uterine bleeding not responding to medical treatment and the uterine size exceeding 12 weeks of gestation on clinical

Panel 1

VH and LAVH techniques used in the study.

VH:

- 2. Patient placement in dorsal lithotomy position with her feet in stirrups
- 3. Exposure of the cervix, circular incision around the cervico-vaginal junction
- 4. Opening of the anterior and posterior peritoneum, preferentially before the clamping, cutting and ligating of the utero-sacral and cardinal ligaments
- 5. Clamping, cutting and ligating of the uterine vessel pedicle, containing the uterine artery and vein, and the broad ligament peritoneum anterior and posterior to these vessels, with a 0 or 2.0 delayed absorbable suture
- 6. Clamping, cutting and ligating of the remaining portion of the broad ligament attached to the uterus (containing the round and ovarian ligaments, the proximal part of the fallopian tube and blood vessels) with 0 or 2.0 delayed absorbable suture
- 7. Closing the peritoneum and the vaginal
- 8. Insertion of the urine catheter and vaginal plug

- 1. Laparoscopic assessment of the pelvic organs, release of adhesions, treatment of endometriosis where necessary, and freeing the adnexa
- 2. VH as described above, with laparoscope left in situ to assess the progress and any complication of the procedure
- 3. Laparoscopic assessment of haemostasis and removal of the blood clots and debris

^{1.} General or regional (spinal) anaesthesia

I AVH·

Abbreviations: LAVH, laparoscopic-assisted vaginal hysterectomy; VH, vaginal hysterectomy.

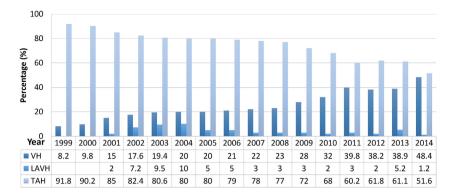


Fig. 2. Vaginal hysterectomy (VH), laparoscopically-assisted vaginal hysterectomy (LAVH) and total abdominal hysterectomy (TAH) presented as a percentage of all hysterectomies performed at the Department of Obstetrics and Gynaecology of the Charlotte Maxeke Johannesburg Academic Hospital during the period July 1999 – December 2014.

Table 1

Patient characteristics.

Hysterectomy approach (number of the patients)	VH (n = 1017)	LAVH (n = 126)
Mean age (SD), years	50.1 (11.9)	43.9 (9.3) *
Parity (SD), number of children	2.7 (1.3)	1,9 (1.0) *
Median uterus weight measured after the surgery (range), g	70.0(20–380)	100.4 (25–420) *

* VH vs. LAVH group p-value<0.0001; Abbreviations: LAVH, laparoscopic-assisted vaginal hysterectomy; SD, standard deviation; VH, vaginal hysterectomy.

Table 2

Indications for hysterectomy.

Indication	VH group, n(%)	LAVH group, n(%)	p-value
Cervical dysplasia	541 (53.1)	49 (38.8)	0.0026
Multifibroid uterus	397 (39.0)	43 (34.1)	0.29
Heavy menstrual bleeding	30 (2.9)	16 (12.6)	< 0.0001
Post-menopausal bleeding	18 (1.8)	2 (1.5)	1.00
Adenomyosis	17 (1,7)	6 (4.8)	0.033
Dysfunctional uterine bleeding	9 (0.9)	1 (0.8)	1.00
Endometrial polyp, hyperplasia	8 (0.8)	1 (0.8)	1.00
Chronic pelvic pain	6 (0.6)	1 (0.8)	0.56

Abbreviations: LAVH, laparoscopic-assisted vaginal hysterectomy; n, number; VH, vaginal hysterectomy.Note: Patients could have more than one indication each.

Table 3

Comparison of operation time (not including anaesthetic time) post-operative course between VH for prolapse, VH for non-prolapse indications and LAVH.

Hysterectomy approach	VH (n = 1017)	VH prolapse (n = 123)	VH non-prolapse (n = 894)	LAVH (n = 126)
Median operation time (IQR), minutes	30.1 (20–90)	29.4 (20–50)	30.9 (20–45)	67.2 (50–90) *
Median hospital stay (IQR), days	2.1 (2–4)	2.1 (2–4)	2.1 (2–4)	2.1 (2–4)
Median number of opiate injections required (IQR)	3.0 (2–4)	3.0 (2–4)	3.0 (2–4)	3.0 (2–4)

* p-value < 0.001 when compared with LAVH group; Abbreviations: IQR, interquartile range; LAVH, laparoscopic-assisted vaginal hysterectomy; n, number; VH, vaginal hysterectomy.

evaluation or 280 g on ultrasound examination. The patient characteristics, including the uterine weight, for all the VHs and LAVHs are presented in Table 1. The most common indications were cervical dysplasia, uterine fibroids and heavy menstrual bleeding, followed by post-menopausal bleeding, adenomyosis, dysfunctional uterine bleeding, endometrial hyperplasia and chronic pelvic pain (Table 2). In all cases, the procedure was successfully performed in terms that there was no need for conversion to open abdominal hysterectomy. The mean time required for LAVH was 67.2 min, significantly longer compared to VH for prolapse, 29,4 min, or VH for non-prolapse indication, 30,9 min as well (p < 0.001; Table 3). The postoperative hospital stay and the convalescence time were similar for VH (prolapsed uterus), VH (non-prolapsed uterus) and LAVH procedures – 2.1 days (range 2–4 days), respectively. There was no statistically significant

difference regarding the postoperative pain and the need of analgesia between the patients submitted to VH and those from the LAVH group (Table3).

Vaginal hysterectomy for utero-vaginal prolapse was performed in 123 (10,7%) of the 1143 patients. The patients with prolapse were older than their non-prolapsed counterparts, had an increased parity and had significantly lower uterine weights with a median of 42,5 g (range 20–103) compared to 90,4 g (range 20–380) for those without prolapse and 100,4 g for those who underwent LAVH (25–420), p < 0.001 (Table 4). When patients with non-prolapsed uterus submitted to VH were compared with the women who underwent LAVH, there was no significant difference in uterine weight (Table 4).

Intra-operative and immediate post-operative complications are presented in Table 5. Five bladder perforations (0.43 %)

Table 4

Patient characteristics between VH for prolapse, VH for non-prolapse and LAVH groups.

Hysterectomy approach	VH prolapse (n = 123)	VH non-prolapse (n = 894)	LAVH (n = 126)
Mean age (SD), years	63.1 (9.4)	49.2 (11.2)	43.9 (9.3)*
Median parity (range), number of children	4 (1-7)	2 (0-5)	2 (0-4)*
Median uterus weightmeasured after the operation (range), g	42.5	90.4 (20-380)	100.4 (25-420)*
	(20 - 103)		

* p-value < 0.001 when compared with VH prolapse group; Abbreviations: LAVH, laparoscopic-assisted vaginal hysterectomy; n, number; SD, standard deviation; VH, vaginal hysterectomy.

Table 5

Complications occurring intra-operatively and in the immediate postoperative period in VH and LAVH group.

Complications		VH (n = 1017)	LAVH (n = 126)	p-value
Major	Urinary tract damage			
-	Bladder injury	3 (0.3 %)	2 (1.6 %)	0.10
	Ureteric injury	0	0	
	Haemorrhage necessitating blood transfusion and relook laparotomy	4 (0.4 %)	1 (0.8 %)	0.44
	Bowel damage	0	0	_
	Deep vein thrombosis	0	0	_
	Minor	Pyrexia requiring antibiotics	0	0
		Wound sepsis	0	0
Wound dehiscence		0	0	_
Conversion to open	abdominal hysterectomy	0	0	-

Abbreviations: LAVH, laparoscopic-assisted vaginal hysterectomy; n, number; VH, vaginal hysterectomy.

occurred during the study period, 3 in the VH group and 2 in LAVH group. Five patients (0.43 %) had a relook laparotomy due to a bleeding in the immediate post-operative period, 4 in VH and 1 in LAVH group respectively. There were not bowel injuries or other complications (Table 5).

Discussion

This study demonstrates that the use of formal guidelines, a clinical decision tree algorithm, and a standardised surgical technique, as well as the incorporation of these guidelines into the residents training programme, can increase the rate of VH and result in an overall decline in open AH and LAVH. This study is in agreement with other large studies, which indicate that, the implementation of a clinical pathway and hysterectomy guidelines can be associated with a decrease in the proportion of hysterectomies performed abdominally [31-34]. In our Institution, the proportion of hysterectomies performed abdominally decreased from 91.2%-51.6% and those performed vaginally increased from 9.8%–48.4% from the beginning of the study in July 2001 its end in December 2014 (Fig. 2). The VH to AH ratio, therefore, was increased from 1:9 to 1:1. Based on this, it seems that as much as 40 % of feasible vaginal procedures were replaced by a more invasive approach. AH, when the surgical decision algorithm was not used.

Between 2014 and 2019 the rate of VH has been sustained and remains the same (unpublished data). We agree with Moen et al. that, improving the use of VH among our residents can only be achieved by addressing the key issues of training and maintaining skills in the technique and by increasing awareness of the scientific evidence supporting its use [15].

AH rates worldwide remain very high [28], despite welldocumented evidence that VH has distinct benefits over other routes [3-7,31-36]. However, some surgeons remain reluctant to change their practice patterns, and continue to select the abdominal route for most operations without documenting that the vaginal route is contraindicated The surgical decision tree algorithm in Fig. 1 offers gynaecologic surgeons a structured approach for selecting the appropriate surgical technique. Another reason for the extremely high rates of AH seen today is that well-established evidence-based guidelines for hysterectomy are ignored by practising gynaecologists [21,31–34] which results in the abdominal route being chosen based on the surgeon's personal preference, in many circumstances without patient being informed about the VH option [37]. This arbitrary approach is not justifiable: there are significant differences in the medical outcome of VH as compared with TAH and LH [3,6–8,46,49]. The American Association of Gynaecologic Laparoscopists (AAGL) recommends that surgeons without the requisite training and skills required for the safe performance of VH or LH should enlist the aid of colleagues who do, or should refer patients requiring hysterectomy to such individuals for their surgical care [38].

As presented in Fig. 1, if there is suspicion of pathology outside of the uterus, or the physician is not sure about the likely success of VH, LAVH can and should be performed. The laparoscopic component of VH aims to restore pelvic anatomy and free the adnexa. Nothing is gained by continuing the dissection laparoscopically, since not only does this considerably and unnecessarily prolong the surgery but it may also increase the risk of visceral damage and haemorrhage [48,49].

An interesting observation during the study period was that as VH increased, the need of LAVH decreased. With initially increasing use of LAVH the surgeon becomes more confident in the preoperative assessment of operability by a history, bimanual examination and pelvic sonar and more confident to operate "blind" (VH), discovering that the laparoscopic component is most often superfluous. When focus is directed towards VH, the need for laparoscopic assistance decreases as experienced with VH is gained (Fig. 2). This finding is opposed to other studies, which have shown that if the focus is directed to LH, there is a resulting significant reduction in rates of VH to below 10 %, without perceptible impact on AH rates [21,39,40]. The advent of robotic hysterectomy (RH) may also contribute to declines in VH rates [41].

Our results are also in agreement with other studies, which demonstrated that VH required significantly shorter operating time compare to LH [3–8]. The postoperative hospital stay and the convalescence time were identical for LAVH and VH. The

postoperative pain and the need of analgesia did not differ between the two groups (Table 3).

Our results of 0.3 % and 1.6 % bladder injuries during VH and LAVH, respectively, are comparable to previously reported incidences of 0.6–2.5% [35,42–44]. There were no injuries to the bowel recorded. Conversion to laparotomy has been found by others to be higher during LH as opposed to VH [45,46]. The absence of conversion in our series may be due to the fact that all the cases were performed in one centre under the supervision of experienced vaginal surgeons in which a residency programme actively sought to teach VH.

In the immediate postoperative period, our 5 patients required a relook laparotomy for bleeding. These five patients (0.4 %) received blood transfusions, 4 in VH and 1 in LAVH groups respectively (Table 5) which is much less compared to other large studies, which reported postoperative haemorrhage of 0.9 - 2.5% [33,42,43,46].

In a survey performed among South African practising gynaecologists about preferred and implemented methods of hysterectomy, 46 % of the responders indicated lack of training and experience as the main reason of not performing VH [47]. Less emphasis on vaginal surgery in resident training programmes, the absence of clear guidelines for selecting appropriate candidates for VH as shown in Fig. 1, and the lack of patient knowledge about surgical options results in the low rates of VH seen today. Several studies have shown that VH can be successfully performed in 90–100% patients with benign disease by use of a formal decision-making process to determine the correct route [31–34,48,49].

Regarding training of VH during residency, it is important to distinguish between proficiency and exposure. In a survey about resident opinions on VH training performed in United States of America, 75 % of the responders indicated that, in order to achieve proficiency during residency, more than 20 cases of VH are necessary [50]. The American College of Obstetrics and Gynaecology (ACOG) requests the number of 15 cases to be performed before completing the residency programme. In Nigeria, VH is underutilised as most centres hardly conduct more than five VHs in a year [51]. The situation in South Africa is similarly problematic because the South African College of Medicine (CMSA) requires only five VHs to be performed during a residency programme of four years. With these numbers, exposure is achieved but not proficiency. The future gynaecologist, not proficient to perform VH, may be inclined to perform hysterectomy by the abdominal route when it could be safely performed vaginally. This lack of proficiency also increases the likelihood of litigation should complications arise.

The programme introduced by our unit has been tested extensively, as more than 1000 hysterectomies have been safely performed vaginally during the period studied. By increasing the rate of VH in our institution, we achieved greater exposure and training at resident level, providing the possibility of true proficiency that could be passed to others.

Conclusion

This study provides proof of the concept that introducing formal institutional guidelines and using a standardised surgical technique can significantly increase the number of VHs in patients with benign gynaecological conditions and without uterine prolapse. In addition to the benefits that patients have, this strategy enables an increasing number of residents to perform VH and obtain the necessary proficiency.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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