

Hysterectomy: abdominal, vaginal or laparoscopic?

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Introduction

Hysterectomy is the commonest major gynaecological procedure^{1,2}. The optimal route of a hysterectomy will depend on several factors. The clinical indication; uterine size; uterine descent; presence of endometriosis, pelvic adhesions or adnexal masses; previous pelvic surgery; surgeon's and client's preference are among them. Although there are many methods of performing a hysterectomy, primarily there are three approaches; laparotomy, vaginal and laparoscopic routes.

In some instances, the optimal route is obvious; e.g., if the uterus is larger than 20-weeks, a total abdominal hysterectomy (TAH) may be the method of choice. While in malignancy a more radical approach with other additional surgical procedures would be needed. In uterine prolapse, with coexistent cystocele or rectocele a vaginal hysterectomy and repair would be the best approach to handle all the problems. Therefore, the route is obvious in some instances and there is no need for a debate on the optimal route in these situations.

However, there is a ubiquitous group of gynaecological conditions with menorrhagia or dysmenorrhoea where the uterus is less than 14-weeks with no descent, for

whom any one of the three main routes of hysterectomy can be applied. In such situations alternatives such as levonorgestrel-releasing intrauterine system (LNG-IUS) and endometrial ablation should also be considered. Hysterectomy was similar in terms of quality of life and psychological well-being when compared to LNG-IUS³. A systematic review found that hysterectomy is preferable to LNG-IUS and endometrial ablation in terms of clinical effectiveness and cost-effectiveness⁴. Despite being clinically effective and cost-effective hysterectomy is generally not considered an initial option owing to its invasiveness and the possibility of complications⁴.

However, in Sri Lanka, management in the form of LNG-IUS and endometrial ablation are virtually non-existent due to financial constraints in the public sector. As a result, a significant proportion of these women who could have been managed with these methods also undergo hysterectomy. Although statistics for Sri Lanka are not collated it can be presumed that the hysterectomy rate is relatively high.

Therefore, as hysterectomy is the commonest gynaecological major surgery, a Lower-Middle Income Country (LMIC) such as Sri Lanka must find out the

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optimal route in terms of cost-effectiveness for this ubiquitous group which can be operated in any one of the three main methods. In order to address this a multi-centre randomized controlled trial was done at

District General Hospital, Mannar and North Colombo Teaching Hospital, Ragama⁵. Figure 1 and Table 1 show the CONSORT diagram and the basic characteristics of the study groups.

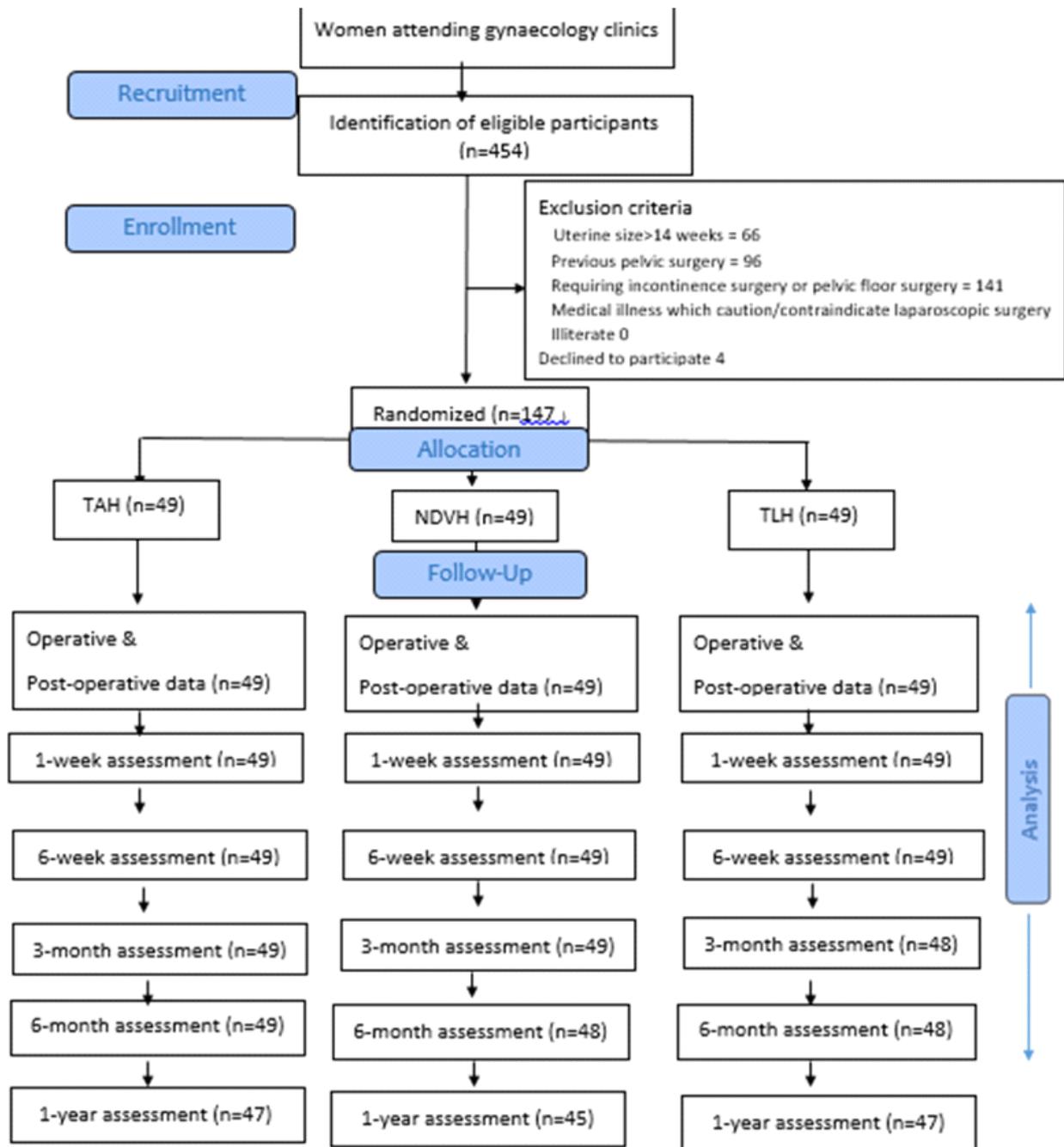


Figure 1. Participant flow diagram.

Obtained from 'Randomized controlled trial on non-descent vaginal hysterectomy and total laparoscopic hysterectomy versus total abdominal hysterectomy: a cost-effectiveness analysis' submitted to the *Journal of South Asian Federation of Obstetrics and Gynaecology*.

Table 1. Basic characteristics

	TAH (n=49)	NDVH (n=49)	TLH (n=49)	p value
Age (years) [mean, (95% CI)]	47.0 (45.6-48.4)	47.1 (44.8-49.5)	48.1 (46.2-50.1)	0.63 [#]
BMI (kg/m ²) [mean, (95% CI)]	26.4 (24.8-28.0)	25.7 (24.2-27.1)	25.0 (23.3-26.7)	0.51 [#]
Median parity (Q1-Q3)	2 (2-3)	3 (2-3.5)	3 (2-3.5)	0.20 [*]
Uterine weight (g) [median (Q1-Q3)]	124 (90-252)	111 (91-153)	141 (101-199)	0.16 [*]

[#] One-way ANOVA

^{*} Kruskal Wallis test

NDVH – non-descent vaginal hysterectomy, TAH – total abdominal hysterectomy, TLH – total laparoscopic hysterectomy

Obtained from 'Randomized controlled trial on non-descent vaginal hysterectomy and total laparoscopic hysterectomy versus total abdominal hysterectomy: a cost-effectiveness analysis' submitted to the *Journal of South Asian Federation of Obstetrics and Gynaecology*.

The optimal route of hysterectomy was studied in terms of operative time, hospital stay, complications, time to recover, quality of life, pelvic organ function and cost etc. which will eventually determine cost-effectiveness.

Operative time

Vaginal hysterectomy has a shorter operative time compared to laparoscopic hysterectomy and abdominal hysterectomy⁶. Data from studies involving LAVH or TLH versus TAH all suggest a shorter operative time for the latter although this may become insignificant when the learning curve has been overcome⁶⁻⁸. Data from our study showed that TAH [45 (36.5-60)] had the shortest operative time followed by NDVH [50 (35-65)] and TLH [93 (80-111)] (Table 2).

Post-operative hospital stay

It is generally accepted that VH has a shorter post-operative hospital stay compared to TAH^{6,9,10}. Similarly, a shorter hospital stay is seen for the laparoscopic route when LAVH or TLH is compared with TAH⁶⁻¹¹. There is conflicting evidence in terms of post-operative hospital stay between VH and LH with Morelli et al, suggesting a significant difference in hospital stay between LH and VH in favour of LH, and data from eVALuate trial and Ottosen not showing a significant difference between the two approaches^{9,12,13}. Our study

data showed that TLH [2 (1-3)] had the shortest post-operative hospital stay followed by NDVH [3 (2-3)] and TAH [3 (2-3)] (Table 2).

Complications

Trials by Benassi and Ottosen did not show a difference in the incidence of urinary tract, bowel and vascular injuries between VH and TAH^{6,9}. However all these studies were under-powered to detect a significant difference. Even a systematic review on the approach to hysterectomy by Nieboer et al was under-powered to detect a difference in visceral and vascular injuries between the two approaches, although fewer febrile episodes or unspecified infections [OR 0.42 (95% CI (0.21-0.83))] was observed in VH¹⁰. A lower post-operative pain score for TAH was observed by Silva-Filho AL, when VH was compared to TAH for women undergoing hysterectomy for uterine myoma¹⁴.

The abdominal arm of the eVALuate trial, designed to compare effects of laparoscopic hysterectomy with TAH showed a higher rate of major complications for laparoscopic hysterectomy [11.1% vs 6.2%, P=0.02]¹³. Most studies were under-powered to detect a difference in urinary tract injuries between LH and TAH when analysed separately. However when results were pooled together the risk of either a bladder or ureteric injury was significantly more in LH compared to

TAH [OR 2.41 (95% CI 1.21-4.82)]¹⁰. There was no significant difference in bowel or vascular injuries between LH and TAH¹⁰. The chance of intra-operative transfusion was lower in LH compared to TAH [OR 0.50 (95% CI 0.26-0.95)]¹⁰. The drop in haemoglobin level was also significantly less in LH compared to TAH with a mean difference of 0.55 g/dl (95% CI 0.28-0.82) suggesting an overall lower blood loss with LH¹⁰. The risk of wound or abdominal infection and febrile episodes or unspecified infection was also lower in LH compared to TAH, OR 0.31 (95% CI 0.12-0.77) and OR 0.67 (95% CI 0.51-0.88)¹⁰. Data from the eVALuate trial suggests that LH was less painful than TAH [visual analogue scale, 3.51 vs 3.88, P=0.02]¹⁶. Other studies also show that either LAVH or TLH is less painful or require lower analgesic doses than TAH^{7,14}.

The vaginal arm of the eVALuate trial, which compared effects of laparoscopic hysterectomy (n=336) with VH (n=168) was under-powered to detect a significant difference in major complications; urinary tract, bowel or vascular injuries¹³. The systematic review by Nieboer et al which included 1205 patients from seven trials showed that there were no significant differences in urinary tract, bowel or vascular injuries between LH and VH¹⁰. However when considering TLH, there were significantly more urinary tract injuries for TLH versus VH [OR 3.69, (95% CI 1.11 to 12.24); 440 women, 2 trials]¹⁰. Although there was no difference in the number of unintended laparotomies, blood loss [OR 2.76, (95% CI 1.02-7.42)] and need for blood transfusion [OR 2.07, (95% CI 1.12-3.81)] was higher in LH compared to VH¹⁰. TLH appears to be less significantly painful in both the immediate post-operative period and even after convalescence compared to VH¹².

Our study was also under powered to detect a difference in complications between the three routes (Table 2). In terms of major complications; there were three cases in the NDVH group and two in the TLH group which had to be converted to laparotomy. There were two bladder injuries in the NDVH group with one ureteric injury in the TLH group. One patient had a rectal injury in the NDVH group. There was no significant difference in the blood loss or change in haematocrit (pre-op – post-op) between the three routes. In terms of post-operative pain, TLH group had a lower pain score on the first two days after surgery (Table 2).

Time to recover and quality of life

When considering time to recover in days, VH and LH performs better than TAH, with a shorter recovery⁹. There is no significant difference between VH and LH when considering time to recovery⁹. Our study data shows that TLH [30 (25.5-45)] has the shortest time to recover followed by NDVH [32 (24.5-60)] and TAH [35 (30-45)] (Table 2 and Figure 2).

A better quality of life was observed in VH compared to TAH, although patient satisfaction was similar in the two groups^{6,14}. For LH versus TAH, the abdominal arm of the eVALuate trial demonstrates that quality of life is significantly better for LH at six weeks along with body image which is significantly improved for LH at six weeks and four months, but not 12 months¹³. Although Lumsden et al, found quality of life and patient satisfaction to be similar four weeks post-surgery in LAVH and TAH, Ellstrom and Nieboer both found quality of life to be better following TLH compared to TAH even at four years of follow up^{8,15,16}. Comparing TLH to VH, Morelli suggests an improved quality of life for TLH versus VH at six weeks post-operatively¹².

Costs

The eVALuate trial compared costs of TAH, VH and LH; but the two arms, abdominal (TAH versus LH) and vaginal (VH versus LH), were inherently different in terms of patient characteristics¹¹. There is no randomized trial which had directly compared costs between VH and TAH. There have been a few studies which have calculated costs for LH and TAH. The total direct costs of LH (\$ 3008) versus TAH (\$ 2680) in eVALuate trial was not statistically significant (95% CI \$-45 to \$661)¹¹.

Direct costs (\$3169) and indirect costs (\$1411) for TLH was compared with TAH; direct costs (\$ 3116) and indirect costs (\$2838), by Ellstrom in a study done in Sweden in 19988. It showed that there was a net saving for TLH versus TAH (\$ 4580 vs 5954) as although direct costs were similar, indirect costs had been halved. A systematic review on costs and effects of abdominal versus laparoscopic hysterectomy estimates total costs in LH to be \$3884 versus \$3312 in the TAH group¹⁷. The only comparison of cost between VH and LH is the vaginal arm of the eVALuate trial which calculated costs for VH (\$ 2203) versus LH (\$ 2911), with a mean difference of \$ 708 (95% CI \$477 to \$954)¹⁰.

Table 2. Clinical outcomes

	TAH (n=49)	NDVH (n=49)	TLH (n=49)	p value*
Anaesthetic time (min)	85 (65-100)	75 (64-100)	135 (116-152)	<0.001
Operative time (min)	45 (36.5-60)	50 (35-65)	93 (80-111)	<0.001
Post-operative hospital stay (days)	3 (2-3)	3 (2-3)	2 (1-3)	<0.001
Blood loss (ml)	150 (100-200)	150 (100-275)	150 (100-300)	0.51
Change in haematocrit	1.8 (0.8-3.8)	2.7 (1.2-5.1)	1.9 (1-3.2)	0.30
Pain score – Day 1	7 (5.5-8.2)	6 (5-7)	5 (4-6.8)	<0.01
Pain score – Day 2	4 (3-5.5)	3 (2-4.7)	3 (1-4)	<0.01
Pain score – Day 3	1.2 (0-4)	1 (0-2)	0 (0-2)	0.14
Time to recover (median, Q1-Q3) (days)	35 (30-45)	32 (24.5-60)	30 (25.5-45)	0.89 [‡]
QALYs (AUC)	8.63 (2-15.27)	9.97 (1.9-18.03)	13.84 (7.08-20.61)	
Complications				
No complications	42	41	37	
Laparotomy	0	3	2	
Blood transfusion	5	6	5	
Bladder injury	0	2	0	
Ureteric injury	0	0	1	
Rectal injury	0	1	0	
Post-operative fever	2	0	2	
Surgical site infection	1 [†]	1 [†]	0	
Urinary tract infection				

median (Q1-Q3)

* Kruskal-Wallis test

‡ log rank test

‡ ANOVA

Patients can have one or more complication

† Superficial incisional surgical site infection (SSI), the SSI incidence was 2.04% for TAH and NDVH. The SSI was 0% for TLH. Standardized infection rate (SIR) was 1.67 for TAH and NDVH [18]

NDVH – non-descent vaginal hysterectomy, TAH – total abdominal hysterectomy, TLH – total laparoscopic hysterectomy

Obtained from 'Randomized controlled trial on non-descent vaginal hysterectomy and total laparoscopic hysterectomy versus total abdominal hysterectomy: a cost-effectiveness analysis' submitted to the *Journal of South Asian Federation of Obstetrics and Gynaecology*.

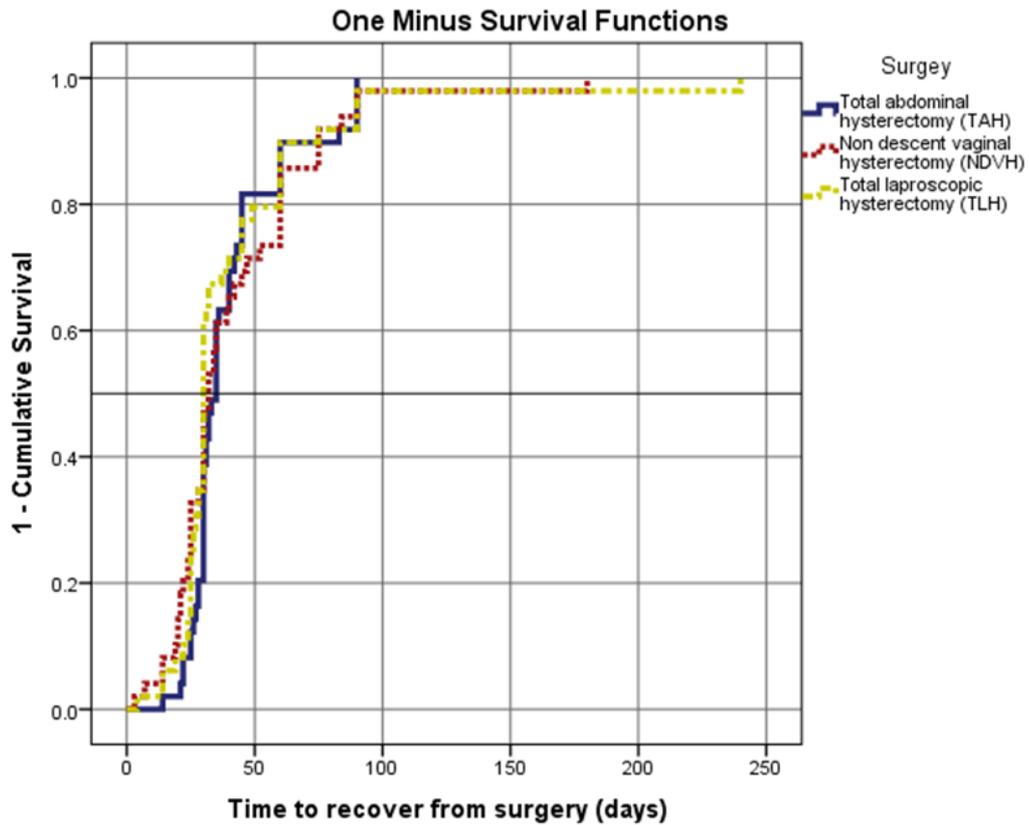


Figure 2. Kaplan-Meier survival analysis.

Obtained from ‘Randomized controlled trial on non-descent vaginal hysterectomy and total laparoscopic hysterectomy versus total abdominal hysterectomy: a cost-effectiveness analysis’ submitted to the *Journal of South Asian Federation of Obstetrics and Gynaecology*.

Micro-costing was done to analyse costs in our study¹⁸. It showed that there was a significant difference in direct costs (mean, 95% CI) between the three groups [TAH \$ 659 (632-687), NDVH TLH \$ 800 (622-1116), \$ 752 (719-795) (p=0.03)]. There was no difference in costs for the worst case and best case scenarios (Table 3).

Cost-effectiveness

Typically the cost-effectiveness ratio that compares two alternatives is calculated as the difference in costs (net costs) between the alternatives divided by the difference in outcomes (net effectiveness)¹⁹. In the eVALuate trial, the incremental cost per QALY gained was \$ 471,789 between LH and VH¹¹. When considering the abdominal arm of eVALuate trial, an incremental cost per QALY gained of \$ 46893 between LH and TAH¹¹. Similarly the incremental costs for reducing one patient with major complications between LH and TAH was \$35750¹⁷. Cost-

effectiveness trials between VH and TAH were not found in literature.

Our trial used time to recover as the denominator to calculate cost-effectiveness. The incremental cost-effectiveness ratio (ICER, 95% CI) for the study setting showed that it was \$ 11 (TAH dominance to 351) for TLH. It was preferable to do a TAH instead of a NDVH [TAH dominance (TAH dominance to \$ 477)]. The probability of cost-effectiveness at a threshold of 3 USD/day were 1.15% and 0% for NDVH and TLH. The corresponding values at a threshold of 10 USD/day were 14.1% and 4.2% for NDVH and TLH respectively (Figure 3).

It was preferable to do a TAH instead of either a NDVH or a TLH in the worst case scenario which considered probable complications and prolonged hospital stay with readmissions (Table 3). The probability of cost-effectiveness were unchanged at 0.2% and 0% for NDVH and TLH at a threshold of 3 USD/day and 10 USD/day (Figure 3).

Table 3. Economic evaluation comparing NDVH and TLH to TAH

	TAH	NDVH	TLH	Significance# (p)
Time to recover	40.43 (34.91-45.95)	41.73 (33.31-50.16)	41.06 (31.06-51.07)	0.98*
Direct cost (mean, 95% CI)	659 (632-687)	800 (622-1116)	752 (719-795)	0.03*
Incremental effect (mean, 95% CI)		-1.09 (-11.82 to 8.04)	-0.58 (-13.16 to 9.02)	0.03
Incremental cost (mean, 95% CI)		143 (-49 to 470)	94 (49 to 142)	0.03
ICER (mean, 95% CI)		TAH dominant (TAH dominant to 477)	11 (TAH dominant to 351)	
<i>Worst case</i>				
Incremental effect (mean, 95% CI)		-11.84 (-20.94 to -4.92)	-11.05 (-22.46 to -3.12)	0.47#
Incremental cost (mean, 95% CI)		637 (403-1096)	64 (599-702)	0.72#
ICER (mean, 95% CI)		TAH dominant (TAH dominant to TAH dominant)	TAH dominant (TAH dominant to TAH dominant)	
<i>Best case</i>				
Incremental effect (mean, 95% CI)		2.99 (-5.12 to 10.42)	3.90 (-6.69-12.16)	0.054#
Incremental cost (mean, 95% CI)		-355 (-469 to -148)	-349 (-371 to -320)	0.76#
ICER (mean, 95% CI)		NDVH dominant (TAH dominant to 874)	TLH dominant (TAH dominant to 686)	

Student's T test

* ANOVA

NDVH – non-descent vaginal hysterectomy, TAH – total abdominal hysterectomy, TLH – total laparoscopic hysterectomy

Obtained from 'Randomized controlled trial on non-descent vaginal hysterectomy and total laparoscopic hysterectomy versus total abdominal hysterectomy: a cost-effectiveness analysis' submitted to the *Journal of South Asian Federation of Obstetrics and Gynaecology*.

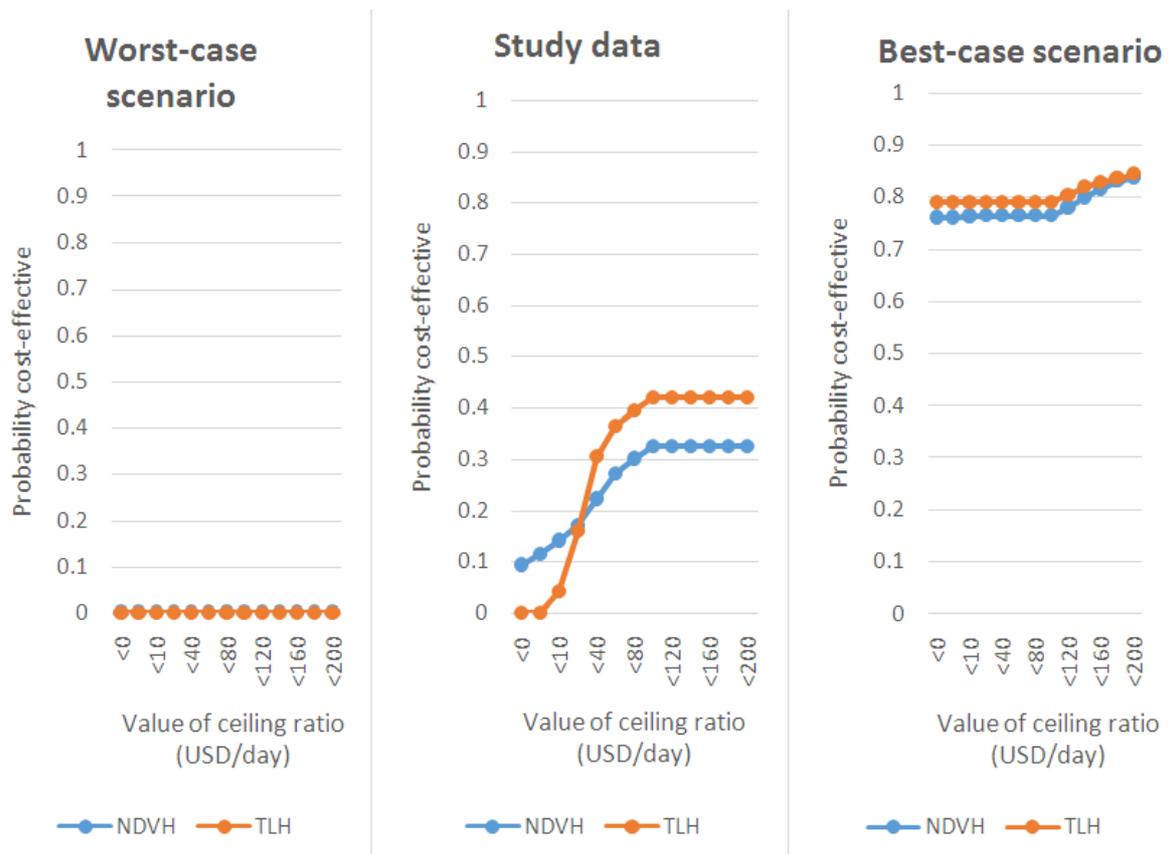


Figure 3. Cost-effectiveness acceptability curves for study data, worst-case scenario and best-case scenario.

Obtained from ‘Randomized controlled trial on non-descent vaginal hysterectomy and total laparoscopic hysterectomy versus total abdominal hysterectomy: a cost-effectiveness analysis’ submitted to the *Journal of South Asian Federation of Obstetrics and Gynaecology*.

The best case scenario which considered optimal conditions with no complications and readmissions showed that NDVH and TLH were both superior to TAH (Table 3). The probability of cost-effectiveness at a threshold of 3 USD/day were 76.1% and 79% for NDVH and TLH. The probability of cost-effectiveness at a threshold of 10 USD/day were 76.3% and 79% for NDVH and TLH respectively (Figure 3).

This result illustrates the fact that alternate routes; NDVH and TLH would be superior to the conventional TAH in specialist centres whereas the generalist would be better off confining himself to the usual TAH.

Urinary function

A review on the effects of hysterectomy on vesico-urethral function by Long confirms the hypothesis that hysterectomy is likely to improve lower urinary tract symptoms (LUTS)²⁰. Roovers et al. found a higher prevalence of urge incontinence after VH compared with TAH and subtotal hysterectomy (STAH)²¹.

However this study was also an observational study which did not control for confounders such as asymptomatic prolapse. A prospective multi-centre observational study also found that a significant number of patients had been treated for micturition symptoms after VH compared to TAH [18 versus 8%; P=0.02; adjusted OR 3.8, (95% CI 1.2-11.6)]²². There was no RCT in published literature that has compared lower urinary tract symptoms (LUTS) for VH versus TAH. In a RCT on pelvic organ function in patients undergoing TLH versus TAH by Kluivers et al, it was found that TLH was superior to TAH with respect to LUTS one year after hysterectomy²³. There has not been any study on urinary function for VH versus LH.

Validated Sinhala and Tamil ICIQ-FLUTS questionnaire was used to analyse urinary symptoms^{24,25}. There was an improvement [median (IQ1-IQ3)] in urinary flow symptoms [TAH 2 (1-4) vs 1 (0-3), p<0.001; NDVH 3 (2-5) vs 2 (0.5-4), p<0.001; TLH 1 (1-4) vs 1 (0-3), p<0.05], urinary voiding symptoms [TAH 0 (0-0) vs 0(0-0), p=0.20; NDVH 0 (0-1) vs 0 (0-0.8), p<0.05;

TLH 0 (0-0) vs 0 (0-0), $p < 0.05$] and urinary incontinence symptoms [TAH 0 (0-2) vs 0 (0-2), $p = 0.06$; NDVH 0 (0-3) vs 0 (0-3), $p < 0.001$; TLH 0 (0-3) vs 0 (0-2), $p < 0.05$] at 1-year (TAH $n = 47$, NDVH $n = 45$, TLH $n = 47$). There was no significant difference among the three different routes in terms of urinary flow symptoms [TAH 0 (0-1), NDVH 0 (0-1), TLH 0 (0-2), $p = 0.56$], urinary voiding symptoms [TAH 0 (0-0), NDVH 0 (0-0), TLH 0 (0-0), $p = 0.64$] and urinary incontinence symptoms [TAH 0 (0-0), NDVH 0 (0-1), TLH 0 (0-1), $p = 0.35$] at 1-year.

Sexual function

An observational study over six months by Roovers et al. found a reduction in sexual problems after vaginal, total or subtotal hysterectomy²⁶. Galyer et al. also evaluated differences in libido and genital sexual sensitivity and found that the type of hysterectomy made no difference at 12-months²⁷. Radosa et al. did an observational cohort study on VH versus TLH versus supra-cervical laparoscopic hysterectomy (SLH) and found that there was a significant improvement post-hysterectomy regardless of the approach²⁸. Kluivers also confirmed these findings on a RCT between TLH and TAH²³.

Vaginal and sexual symptoms were analysed using validated Sinhala and Tamil ICIQ-VS questionnaire²⁹. There was an improvement [median (IQ1-IQ3)] in vaginal symptoms [TAH 6 (2-8) vs 4 (0-8), $p < 0.001$; NDVH 6 (4-8.5) vs 5 (0-8), $p < 0.001$; TLH 4 (2-10.5) vs 4 (0-10), $p < 0.001$]. There was an improvement in sexual symptoms only in the TLH group [TAH 0 (0-11.5) vs 0 (0-14), $p = 0.08$; NDVH 0 (0-0) vs 0 (0-0), $p = 0.46$; TLH 0 (0-0) vs 0 (0-4), $p < 0.05$]. There was no significant difference among the three different routes in terms of vaginal symptoms score [TAH 2 (0-2), NDVH 0 (0-2), TLH 0 (0-2), $p = 0.33$] and sexual symptoms [TAH 0 (0-0), NDVH 0 (0-0), TLH 0 (0-0), $p = 0.52$] at 1-year 30.

Bowel function

Prospective studies have failed to demonstrate an adverse bowel function after hysterectomy. Prior et al. observed that six months after hysterectomy, constipation was more likely to disappear in 60% of patients with pre-operative bowel symptoms while de novo symptoms occurred in 10%³¹. Weber et al. found no significant changes in bowel function 1 year after

hysterectomy³². Kluivers et al. found no difference in TAH versus TLH at one year of follow up³¹. There has been no RCT comparing TAH versus VH or TLH versus VH.

Bowel symptoms [median (IQ1-IQ3)] improved at 1-year for TAH ($p = 0.001$), NDVH ($p < 0.001$) and TLH ($p < 0.05$). There was no significant difference among the three different routes in terms of bowel symptoms at 1-year [median (IQ1-IQ3)] [TAH 0 (0-1), NDVH 0 (0-2), TLH 0 (0-2), $p = 0.30$].

Conclusion

There is a dilemma on how to assess clinical outcomes following a surgical procedure. Many indicators that have been used to compare outcomes for different routes of hysterectomy. Available evidence and study data suggests that TLH and NDVH is favourable to TAH in terms of post-operative hospital stay, time to recover, quality of life and cost-effectiveness. The operative time and cost appears to be more for TLH. There is inadequate data to suggest a difference in complications between the routes although early evidence suggested more urological injuries with TLH. There is also no difference in pelvic organ symptoms between the three routes. The study data further suggests that alternate routes would be preferable for specialist centres whilst the conventional TAH would be more suited for the generalist.

In an era where quality of care is an evolving area of interest, studies such as this which deals with post-operative convalescence are of importance, especially as it is from a low-resource setting. Patient reported outcome measures are vital as they consider the patient's viewpoint and functionality, something that cannot be assessed by clinical evaluation or investigations. One of the major findings was that there was an improvement in pelvic organ symptoms at 1-year with no significant difference between the three routes.

Adequate emphasis should be laid on cost; quality of life; and post-procedural convalescence in addition to conventional clinical indicators. A change in attitude among gynaecologists, appropriate allocation of resources, and refining postgraduate training are also required when selecting surgical options for women with benign uterine conditions in addition to patient factors and logistical factors in the health care system.

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