Quality assessment of laparoscopic hysterectomy

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Chapter 5

Case–mix variables and predictors for outcomes of laparoscopic hysterectomy: a systematic review

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Abstract

The assessment of surgical quality is complex, and an adequate case-mix correction is missing in currently applied quality indicators. The purpose of this study is to give an overview of all studies mentioning statistically significant associations between patient characteristics and surgical outcomes for laparoscopic hysterectomy (LH). Additionally, we identified a set of potential case-mix characteristics for LH. This systematic review was conducted according to the Meta-Analysis of Observational Studies in Epidemiology guidelines. We searched PubMed and EMBASE from January 1, 2000 to August 1, 2015. All articles describing statistically significant associations between patient characteristics and adverse outcomes of LH for benign indications were included. Primary outcomes were blood loss, operative time, conversion and complications. The methodological quality of the included studies was assessed using the Newcastle-Ottawa Quality Assessment Scale. The included articles were summed per predictor and surgical outcome. Three sets of case-mix characteristics were determined, stratified by different levels of evidence. Eighty-five of 1549 identified studies were considered eligible. Uterine weight and Body mass index (BMI) were the most mentioned predictors (described, respectively, 83 and 45 times) in high quality studies. For longer operative time and higher blood loss, uterine weight ≥ 250 to 300g and ≥ 500g and BMI ≥30 kg/m^2 dominated as predictors. Previous operations, adhesions, and higher age were also considered as predictors for longer operative time. For complications and conversions, the patient characteristics varied widely, and uterine weight, BMI, previous operations, adhesions and age predominated. Studies of high methodological quality indicated uterine weight and BMI as relevant case-mix characteristics for all surgical outcomes. For future development of quality indicators of LH and to compare surgical outcomes adequately, a case-mix correction is suggested for at least uterine weight and BMI. A potential case-mix correction for adhesions and previous operations can be considered. For both surgeons and patients it is valuable to be aware of potential factors predicting adverse outcomes and to anticipate on this. Finally, to benchmark clinical outcomes at an international level, it is of the utmost importance to introduce uniform outcome definitions.

Introduction

Laparoscopic hysterectomy (LH) is the most performed advanced gynecologic laparoscopic procedure, and its implementation has increased worldwide [1]. Currently, there is a growing concern regarding patient safety during complex endoscopic surgical procedures, including LH [2]. This has led to increased efforts to measure and assess the quality of surgical procedures [3]. Quality indicators are widely accepted performance measures used to monitor, evaluate and improve the quality of care [4]. Three different types of indicators are outcome, process, and structural quality indicators [5]. Outcome indicators refer to direct clinical outcomes and are the most used indicators to assess quality of surgical care. Process indicators measure the complete care system (e.g., multidisciplinary meetings). Structural indicators reflect the setting in which the care is provided (e.g., case volume). The assessment of surgical quality is very complex, and one of the main problems of the introduced quality indicators is the lack of case-mix correction. Case-mix variables are defined as characteristics that influence surgical outcomes and could potentially explain the differences in outcome among hospitals and/or surgeons. Therefore, for a reliable interpretation of surgical outcomes, a correction for case-mix is of highest importance [6]. To develop an accurate quality indicator for LH, more insight is needed into the patient characteristics that influence surgical outcomes. Yet, no international consensus has been reached on this issue. A great variety of published studies mentioned 1 or more predicting patient characteristics for LH, but no accurate overview of these characteristics is available. This is a challenging topic because different outcome definitions are used in literature and also other factors than patient characteristics (e.g., surgeon volume, type of procedures etc.) could potentially influence surgical outcomes. However, a clear summary of patient characteristics associated with surgical outcomes is first needed in order to continue the discussion about the essence of case-mix adjustment for reliable quality assessment.

The objective of this study is to identify patient characteristics that significantly influence the surgical outcome of LH. Additionally, we aim to compose a minimal set of potential case-mix variables for LH. This set should preferably be used in the development of (new) quality assessment tools and is the first step required to develop a valid and accurate quality indicator for LH.

Materials and methods

Data sources

This systematic review was performed according to the Meta-Analysis of Observational Studies in Epidemiology guidelines [7]. A search of the literature in PubMed and EMBASE was

performed from January 1, 2000 to August 1, 2015 to identify articles describing a statistically significant association between patient characteristics and surgical outcomes of LH.

A clinical librarian was consulted to define the search strategy, together with the primary researcher (S.R.C.D.). The exact search string is shown in Supplemental Appendix 1. All duplicate articles were removed. All references of selected articles were reviewed to identify other relevant articles. If additional eligible articles were identified, a new search string was composed by the research librarian to include these extra references as well. This was repeated until no new cross-references were found. At this point the search was considered as definitive (see Supplemental Appendix 1). We limited the results to human studies and studies written in English.

Study selection

The literature selection was performed independently by 2 authors (S.R.C.D. and E.M.S.). In case of uncertainty, a third author (F.W.J.) was contacted. After a first selection on titles and abstracts, the full text of the remaining articles were reviewed using the following exclusion criteria: LHs for oncologic indications, studies reporting no association between predictors and clinical outcomes, nonclinical studies (e.g., review, case report), and conference abstracts. If unexpected oncologic cases were included in the study population, only those studies with less than 5% oncologic cases were included.

Equal data from multiple publications based on the same cohort were only used once in the final analysis.

Predictors were defined as patient characteristics that were statistical significantly associated with adverse surgical outcomes. Our study focused only on patient characteristics as predictors, because these variables cannot be influenced in any way during the (pre)surgical process and are therefore suitable as case-mix characteristics. For this reason the type of LH, the use of different technical instruments (e.g., monopolar, bipolar, ultrasound, use of mobilizer etc.), preoperative medical treatment, surgeon's volume, and the number of surgeons performing the procedure were not included in our study.

Surgical outcomes included intraoperative blood loss, operative time, conversion to laparotomy, and complications. The definition of the surgical outcomes as mentioned by the authors in the included paper was applied. Hospital stay was not considered as a surgical outcome, because hospital discharge mainly depends on the (local) guidelines.

The included articles were summed per predictor and surgical outcome (Table 1). The surgical outcomes were depicted in 4 separated tables, including all selected articles with

the detailed predictor, the (detailed) outcome, the study population, the study design and the methodological quality (Table 2, 3, 4, 5).

This systematic review did not involve human subjects and was exempt from institutional board review.

Quality assessment

The methodological quality of the included studies was assessed according to the Newcastle-Ottawa Quality Assessment Scale (NO-QAS) [8]. This assessment scale assigns a specific study up to a maximum of 9 points, to include points for selection of the study groups, comparability of the groups and the ascertainment of outcome or exposure of the study. For example, a study was higher rated when correction for confounders or regression analysis was performed. The rating was done independently by the 2 review authors (S.R.C.D. and E.M.S.). Furthermore, the different study designs were reported: randomised controlled trial, prospective cohort study, retrospective cohort study, and case-control study.

Selection of case–mix variables

Per surgical outcome, 3 sets of case-mix characteristics were composed according to defined criteria of levels of evidence (Table 6; low, medium, and high). These criteria were based on the number of high quality studies (NO-QAS 9) and considerable quality studies (NO-QAS 8 or 7) as modified from Courrech Staal et al. [9]. Case-mix selection set 1 (low): all characteristics mentioned in ≥1 study with NO-QAS of 9 or ≥2 studies with NO-QAS 8 or 7; set 2 (medium): characteristics identified in ≥1 study with NO-QAS of 9 and ≥1 study with NO-QAS 8 or 7, set 3 (high): characteristics mentioned in ≥2 studies with NO-QAS of 9 or ≥4 studies with NO-QAS 8 or 7 (Table 6).

Results

Overview of studies

An overview of the literature selection is shown in Figure 1. The literature search yielded 1549 unique articles. After selection, 85 articles met the inclusion criteria and reported a significant association between specific patient characteristics and surgical outcomes. Of these 85 articles, 4 were randomized controlled trials, 29 prospective cohort studies, 47 retrospective cohort studies and 5 case-control studies (Table 2, 3, 4 and 5).

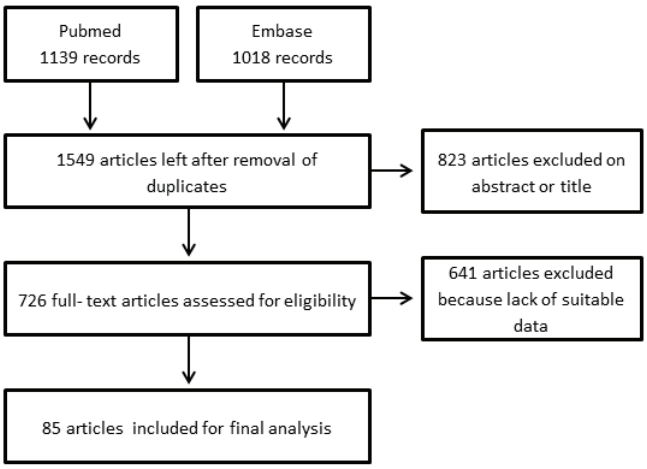

Figure 1 Flowchart of reviewed and selected studies.

Table 1 Number of found articles that showed a statistical significant association between the patient characteristics and surgical outcome

OUTCOME / PATIENT CHARACTERISTIC *(Predictor)*	Longer operative time	More blood loss	Increased complication rate	Increased conversion rate	Total
Uterine weight	47	21	7	8	83
BMI	21	11	8	5	45
Previous operations	3	na	7	6	16
Adhesions	3	3	4	2	12
Endometriosis	1	na	2	na	3
Age	3	1	4	1	9
Uterine descent	na	na	1	na	1
Menopause	1	na	na	na	1
Parity	1	1	2	na	4
Fibroid	na	na	na	1	1
Comorbidity *(previous stroke/TIA, DM, creatinine or platelet count, ASA score, hypertension)*	1	na	6	na	7
Smoking	na	na	2	na	2
Ethnicity	na	na	1	na	1
Total	81	37	44	23	185

DM = diabetes mellitus, na = not applicable.

The number of included articles per patient characteristic and surgical outcome is depicted in Table 1. Figure 2 demonstrates a graphical representation of the number of articles where a significant association between the patient characteristic (predictor) and surgical outcome was identified.

Uterine weight and body mass index (BMI) are by far the most mentioned patient characteristics influencing all surgical outcomes and described, respectively 83 and 45 times in the selected articles (Table 1 and Figure 2). Subsequently, previous operations, adhesions, and age were mentioned 16, 12, and 9 times, respectively, as predictor (Table 1).

Several other patient characteristics were only mentioned once or a few times in the selected articles: parity, endometriosis, uterine descent, menopause, presence of fibroids, ethnicity, previous stroke, smoking, diabetes mellitus, American Society of Anesthesiologists (ASA) score, hypertension, creatinine serum, and platelet count (Table 1).

The selected articles and predictors are shown in detail per surgical outcome (blood loss, operative time, conversion and complications) in Table 2, 3, 4 and 5.

Predictors for longer operative time

Respectively, 47 and 21 studies reported a significant association between prolonged operative time and high uterine weight and high BMI.

The most mentioned detailed associations for prolonged operative time were uterine weight ≥ 250 to 300 grams and ≥ 500 grams and BMI ≥ 30 kg/m^2. Previous operations and adhesions

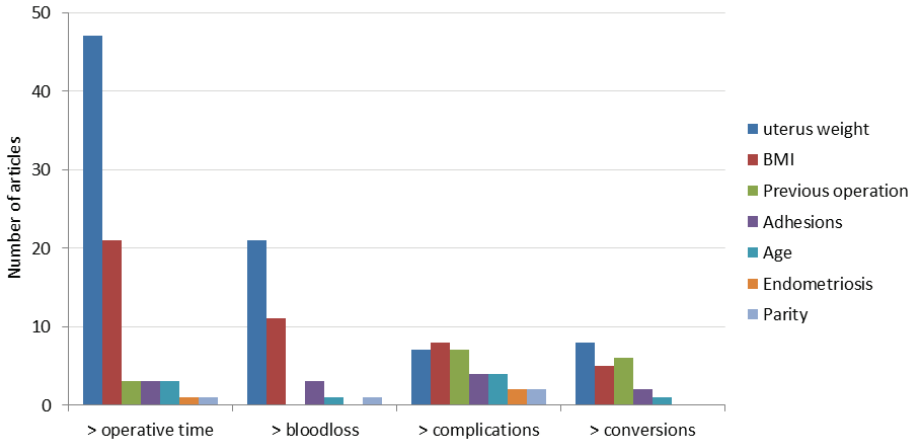

Figure 2 Number of selected articles that showed a statistical significant association between the patient characteristic and outcome *(including only the characteristics which are mentioned more than twice).*

were also considered as relevant predictors, both mentioned in 3 studies (Table 2). Three studies found older age to be associated with prolonged operative time.

Predictors for increased blood loss

For the outcome increased blood loss, 21 articles observed a significant association with larger uterus and 11 articles with higher BMI (Table 1), whereas uterine weight ≥ 500 g and BMI ≥ 30 kg/m^2 were mentioned the most (Table 3). In addition, 3 different studies found that the presence of adhesions also had an impact on blood loss.

Predictors for increased complication rate

For complications, patient characteristics varied widely, but uterine weight, BMI, previous operations and adhesions predominated (Table 4). Also, the predictor age was mentioned in 4 different studies. A considerable difference was found among described ages, and no consistent cutoff value could be found. Endometriosis was mentioned as a significant predictor in 2 studies. Furthermore, comorbidity (e.g., diabetes mellitus, previous stroke, ASA score), smoking, ethnicity, and uterine descent were mentioned in 1 or 2 studies rated as high quality (NO-QAS 8-9).

Predictors for increased conversion rate

For conversion (Table 5), the least studies showing a significant association with patient characteristics were found (a total of 23 studies, Table 1). Uterine weight, BMI and previous operations were the most mentioned significant predictors. Adhesion, age, and presence of fibroids were also found in 1 or 2 studies.

Selection of case–mix characteristics

Three different sets of case-mix variables per surgical outcome are depicted in Table 6.
The number of case-mix variables depends on the preferred level of evidence criteria. Looking at the lowest level of evidence criteria (set 1), a great variety of case-mix characteristics can be selected: uterine weight, BMI, adhesions, previous operations, age, endometriosis, uterine descent, smoking, transient ischemic attack/stroke, diabetes mellitus, and ASA score. When selecting the highest composed level of evidence criteria (set 3), less case-mix characteristics were observed: uterine weight, BMI, previous operations, and adhesions.
In all defined levels of evidence (low, medium, and high; Table 6), uterine weight and BMI remained selected as relevant case-mix characteristics for all surgical outcomes.

Table 2 Longer operative time: predictors in detail

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
Uterine weight	≥ 250-300g	Giep, 2010 [14]	589 RALH, LAVH and LSH	[C]	9
		Kondo, 2011 [15]	2092 TLH and LAVH	[C]	6
		Boggess, 2009 [16]	152 RALH	[B]	8
		Kriplani, 2012 [17]	110 TLH	[C]	6
		Surgit, 2012 [18]	68 TLH	[B]	7
		Hussain, 2012 [19]	85 LSH	[B]	7
		Wong, 2011 [20]	97 LAVH	[C]	6
		Wattiez, 2002 [21]	240 TLH	[D]	7
		Mebes, 2012 [22]	52 LH	[C]	7
		Dassel, 2015 [23]	1004 LH	[C]	8
		Catanzarite, 2015 [24]	7630 LH	[C]	8
	≥500g	Payne, 2010 [25]	256 RALH	[C]	8
		Ark, 2009 [26]	367 LAVH	[C]	7
		Chang, 2005 [27]	225 LAVH	[B]	8
		Fiaccavento, 2007 [28]	684 TLH	[C]	7
		Shahid, 2011 [29]	29 LASH	[B]	7
		Wang, 2004 [30]	189 LAVH	[B]	7
		Ferrari, 2000 [31]	31 LAVH	[B]	6
		Wong, 2010 [32]	588 LAVH	[C]	7
	≥750-800g	Shiota, 2011 [33]	629 LAVH	[C]	6
		Chang, 2008 [34]	181 LAVH	[B]	7
	Increase/100g	Twijnstra, 2012 [35]	1534 LH	[B]	9
	Longitudinal >9cm or uterine volume >370ml on ultrasound	Carugno, 2014 [36]	558 RTH	[C]	9

Table 2 continues on next page

Table 2 ***Continued***

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
	Not defined	Uccella, 2013 [11]	712 TLH	[C]	7
		Condous, 2007 [37]	75 TLH	[B]	7
		Shashoua, 2009 [38]	70 TLH and RATLH	[C]	8
		Song, 2010 [39]	15 SPA-LAVH	[B]	6
		Chou, 2011 [40]	56 LAVH	[B]	6
		Paek, 2011 [41]	100 SPA-TLH	[C]	7
		Lin, 2014 [42]	100 RATLH	[C]	8
		Bojahr, 2006 [43]	1692 LASH	[C]	6
		Payne, 2010 [44]	100 RALH	[C]	8
		Gyr, 2001 [45]	48 TLH	[D]	6
		Shin, 2011 [46]	168 TLH and LAVH	[C]	6
		Ghomi, 2007 [47]	59 LSH	[B]	6
		Tu, 2005 [48]	167 LAVH	[C]	8
		McClellan, 2007 [49]	100 LSH	[B]	8
		Song, 2013 [50]	21 SPA-TLH	[B]	6
		Erian, 2008 [51]	400 LSH	[B]	7
		Göçmen, 2012 [52]	60 TLH	[C]	6
		Heaton, 2010 [53]	379 TLH	[D]	6
		Jahan, 2015 [54]	100 LAVH	[C]	7
		Mueller, 2012 [55]	567 TLH	[B]	6
		Paraiso, 2013 [56]	52 LH and RALH	[A]	9
		Sendag, 2014 [57]	36 RALH	[C]	7
		Wang, 2015 [58]	512 tVNOTEH and LAVH	[C]	7
		Estrade, 2015 [59]	40 SPA-LSH	[B]	6

Table 2 continues on next page

Table 2 *Continued*

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
BMI	BMI ≥ 30 kg/m^2	Chopin, 2009 [60]	1460 TLH	[C]	9
		Giep, 2010 [14]	589 RALH, LAVH and LSH	[C]	9
		Morgan-Ortiz, 2013 [61]	209 TLH	[B]	7
		Carugno, 2014 [36]	1290 TLH and RALH	[C]	9
		Morsi, 2013 [62]	186 LAVH and LH	[C]	7
		Harmanli, 2013 [63]	970 LSH and TLH	[C]	7
		Surgit, 2012 [18]	68 TLH	[B]	7
		Heinberg, 2004 [64]	270 TLH	[C]	8
		Mikhail, 2015 [65]	3812 LAVH and TLH	[C]	7
	Not defined	Siedhoff, 2012 [66]	834 TLH and LSH	[C]	8
		Shashoua, 2009 [38]	70 TLH and RALH	[C]	8
		Bardens, 2014 [67]	194 LH	[C]	8
		Ghomi, 2010 [68]	421 LAVH and LSH	[C]	8
		Brummer, 2011 [69]	1679 LH	[B]	8
		Payne, 2010 [44]	100 RALH	[C]	8
		Kriplani, 2012 [17]	110 TLH	[C]	6
		Göçmen, 2012 [52]	120 TLH and RALH	[C]	6
		Heaton, 2010 [53]	379 TLH	[D]	6
		Shah, 2015 [70]	26609 LH	[C]	9
		Dassel, 2015 [23]	1004 LH	[C]	8
		Catanzarite, 2015 [24]	7630 LH	[C]	8
Adhesions	Adhesion score (adhesion severity combined with extent of adhesions)	Chiu, 2015 [71]	216 RLH and TLH	[C]	8
	Dense adhesions	Paek, 2011 [41]	100 SPA-TLH	[C]	7
	Extensive pelvic adhesions	Hsu, 2007 [72]	236 LAVH	[C]	6

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Table 2 *Continued*

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
Previous operations	Previous history of myomectomy	Carugno, 2014 [36]	2580 LH, TLH and RALH	[C]	9
	Previous laparotomy	Ghomi, 2010 [68]	421 LAVH and LSH	[C]	8
	Not defined	Shin, 2011 [46]	168 TLH and LAVH	[C]	6
Age	≥41 years	Giep, 2010 [14]	589 RALH, LAVH and LSH	[C]	9
	Not defined	Ghomi, 2010 [68]	421 LAVH and LSH	[C]	8
	>50 years	Catanzarite, 2015 [24]	7630 LH	[C]	8
Endometriosis	Pelvic endometriosis	Song, 2012 [73]	2012 LAVH	[C]	8
Menopause	Premenopausal women	Yavuzcan, 2013 [74]	87 LH	[B]	7
Parity	Nullipara	Wong, 2011 [20]	297 LAVH	[C]	6
Comorbidity	Diabetes Mellitus	Catanzarite, 2015 [24]	7630 LH	[C]	8
	Hypertension	Catanzarite, 2015 [24]	7630 LH	[C]	8
	ASA score 3-4	Catanzarite, 2015 [24]	7630 LH	[C]	8

RALH = robot-assisted total laparoscopic hysterectomy, LAVH = laparoscopic assisted vaginal hysterectomy, LSH = laparoscopic supracervical hysterectomy, TLH = total laparoscopic hysterectomy, LASH = laparoscopic subtotal hysterectomy, SPA = single-port access, tVNOTEH = transvaginal natural orifice transluminal endoscopic hysterectomy.
[A] = randomized controlled trial, [B] = prospective cohort study, [C] = retrospective cohort study, [D] = case-control study.
NO-QAS = Newcastle-Ottawa Quality Assessment Scale.

Table 3 More blood loss: predictors in detail

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
Uterine weight	≥250-300g	Hussain, 2012 [19]	85 LSH	[B]	7
		Kriplani, 2012 [17]	110 TLH	[C]	6
		Surgit, 2012 [18]	68 TLH	[B]	7
		Dassel, 2015[23]	1004 LH	[C]	8
	≥500g	Payne, 2010 [25]	256 RALH	[C]	8
		Ark, 2009 [26]	367 LAVH	[C]	7
		Chang, 2005 [27]	225 LAVH	[B]	8
		Fiaccavento, 2007 [28]	684 TLH	[C]	7
		Huang, 2014 [75]	109 SPA-LH	[B]	7
		Wang, 2004 [30]	189 LAVH	[B]	7
		Wong, 2010 [32]	588 LAVH	[C]	7
	≥750-800g	Shiota, 2011 [33]	629 LAVH	[C]	6
		Chang, 2008 [34]	181 LAVH	[B]	7
	Increase/100g	Twijnstra, 2012 [35]	1534 LH	[B]	9
	Not defined	Uccella, 2013[11]	712 TLH	[C]	7
		Condous, 2007 [37]	75 TLH	[B]	7
		Chou, 2011 [40]	56 LAVH	[B]	6
		Yen, 2002 [76]	61 LAVH	[B]	6
		Song, 2013 [50]	21 SPA-TLH	[B]	6
		Jahan, 2015 [54]	100 LAVH	[C]	7
		Wang, 2015 [58]	512 tVNOTEH and LAVH	[C]	7

Table 3 continues on next page

Table 3 *Continued*

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
BMI	BMI ≥ 30 kg/m^2	Shen, 2002 [77]	670 LAVH	[C]	7
		Harmanli, 2013 [63]	970 LSH and TLH	[C]	7
		Morgan-Ortiz, 2013 [61]	209 TLH	[B]	7
		Surgit, 2012 [18]	68 TLH	[B]	7
		Heinberg, 2004 [64]	270 TLH	[B]	8
	Not defined	Siedhoff, 2012[66]	834 TLH and LSH	[C]	8
		Twijnstra, 2012 [35]	1534 LH	[B]	9
		Bardens, 2014 [67]	194 LH	[C]	8
		Ghomi, 2010 [68]	421 LAVH and LSH	[C]	8
		Brummer, 2012 [78]	1679 LH	[B]	9
		Dassel, 2015[23]	1004 LH	[C]	8
Adhesions	Adhesion score (adhesion severity combined with extent of adhesions)	Chiu, 2015 [71]	216 RALH and TLH	[C]	8
	Extensive pelvic adhesions	Hsu, 2007 [72]	236 LAVH	[C]	6
	Vesicouterine peritoneum adhesions	Lee, 2000 [79]	50 LAVH	[B]	6
Age	Not defined	Lin, 2014 [42]	100 RATLH	[C]	8
Parity	Nullipara	Wong, 2011 [20]	297 LAVH	[C]	6

RALH = robot-assisted total laparoscopic hysterectomy, LAVH = laparoscopic assisted vaginal hysterectomy, LSH = laparoscopic supracervical hysterectomy, TLH= total laparoscopic hysterectomy, SPA= single-port access, tVNOTEH = transvaginal natural orifice transluminal endoscopic hysterectomy.
[A] = randomized controlled trial, [B] = prospective cohort study, [C] = retrospective cohort study, [D] = case-control study.
NO-QAS = Newcastle-Ottawa Quality Assessment Scale.

Table 4 Increased complication rate: predictors and outcome in detail

Predictor	Detailed predictor	Detailed outcome	Reference, Year	Study population	Study design	NO-QAS
Uterine weight	>250 g	Urinary tract infection and blood transfusions	Catanzarite, 2015 [24]	7630 LH	[C]	8
	≥500g	Total complications and intra-operative haemorrhage ≥1000mL	Brummer, 2011 [69]	1679 LH	[B]	8
		Events requiring active treatment or prolonged hospital stay	Chang, 2005 [27]	225 LAVH	[B]	8
		Postoperative minor complications	Fiaccavento, 2007 [28]	684 TLH	[C]	7
	≥750-800g	Intraoperative complications	Shiota, 2011 [33]	629 LAVH	[C]	6
	Increase/100g	Adverse events defined by the Dutch Society of Obs and Gyn.	Twijnstra, 2012 [35]	1534 LH	[B]	9
	Not defined	Secondary haemorrhage	Paul, 2014 [80]	1613 TLH	[C]	6
BMI	BMI < 20 kg/m^2	Infection (urinary, wound of intra-abdominal)	Osler, 2011 [81]	1331 LH	[B]	9
		Vaginal spotting, major complications and vaginal bleeding	Jeung, 2010 [82]	248 TLH	[A]	9
	BMI ≥ 30 kg/m^2	Major complications	Morgan-Ortiz, 2013 [61]	209 TLH	[B]	7
		Febrile event (not defined)	Brummer, 2011 [69]	1679 LH	[B]	8
		vaginal spotting, major complications and vaginal bleeding	Jeung, 2010 [82]	248 TLH	[A]	9
		Minor intraoperative complication; vaginal or uterine perforation	Kondo, 2012 [83]	2271 LAVH, TLH and SLH	[C]	7

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Table 4 ***Continued***

Predictor	Detailed predictor	Detailed outcome	Reference, Year	Study population	Study design	NO-QAS
	Not defined	Complication severity; Dindo-Clavien grade 1 or 2 vs grade 3 or higher	Siedhoff, 2012 [66]	834 TLH and LSH	[C]	8
		Postoperative complications	Bardens, 2014 [67]	194 LH	[C]	8
		Overall complications	Catanzarite, 2015 [24]	7630 LH	[C]	8
Previous operations	≥2 caesarean sections	Bladder injury	Song, 2012 [73]	2012 LAVH	[C]	8
	1 vs none and ≥3 vs none	Adverse events defined by the Dutch Society of Obs and Gyn.	Twijnstra, 2012 [35]	1534 LH	[B]	9
	Previous caesarean section	Bladder injury	Brummer, 2011 [69]	1679 LH	[B]	8
		Cystomy	Rooney, 2005 [84]	433 LAVH	[D]	6
		Major complication particular cystotomy	Wang, 2010 [85]	574 LH	[B]	8
	Previous laparotomy or caeseran section	Bladder injury	Lafay Pitter, 2009 [86]	1501 LH	[C]	7
	Not defined	Fever (undefined)	Ghomi, 2010 [68]	421 LAVH and LSH	[C]	8
Adhesions	Extensive vs none	Short-term post-operative complications (requiring re-operation)	Wallwiener, 2013 [87]	1952 TLH and LSH	[B]	9
	Adhesiolysis	Bowel injury	Brummer, 2011 [69]	1679 LH	[B]	8

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Table 4 *Continued*

Predictor	Detailed predictor	Detailed outcome	Reference, Year	Study population	Study design	NO-QAS
	Moderate or severe adhesions	vaginal spotting, major complications and vaginal bleeding	Jeung, 2010 [82]	248 TLH	[A]	9
	Severe adhesions	Pelvic cellulitis	Chang, 2011 [88]	195 LAVH	[D]	7
Age	Younger patient	Short-term post-operative complications (requiring re-operation)	Wallwiener, 2013 [87]	1952 TLH and LSH	[B]	9
	<55 years	Pelvic infection, haematoma or abscess	Brummer, 2011 [69]	1679 LH	[B]	8
	>60 years	Medical complications	Hanwright, 2013 [89]	6190 LAVH and TLH	[C]	8
	Younger age	Overall complications	Catanzarite, 2015 [24]	7630 LH	[C]	8
Endometriosis	Severity of endometrioses (highest incidence stage III/IV)	Vaginal cuff abscess	Patzkowsky, 2013 [90]	545 LH and RALH	[C]	8
	Not defined	Major complication	Brummer, 2011 [69]	1679 LH	[B]	8
Parity	Nullipara	Not defined	Wong, 2011 [20]	297 LAVH	[C]	6
	No previous vaginal delivery	Bladder injury	Lafay Pitter, 2009 [86]	1501 LH	[C]	7
Uterus descent	No descent (vs first degree)	Major complications	Garry, 2004 [91],	920 LH	[A]	9

Table 4 continues on next page

Table 4 *Continued*

Predictor	Detailed predictor	Detailed outcome	Reference, Year	Study population	Study design	NO-QAS
Smoking	Active smoker	Medical complications	Hanwright, 2013 [89]	6190 LAVH and TLH	[C]	8
	History of smoking	vaginal spotting, major complications and vaginal bleeding	Jeung, 2010 [82]	248 TLH	[A]	9
Comorbidity	Previous stroke/TIA	Medical complications	Hanwright, 2013 [89]	6190 LAVH and TLH	[C]	8
	Diabetes mellitus	vaginal spotting, major complications and vaginal bleeding	Jeung, 2010 [82]	248 TLH	[A]	9
	Diabetes mellitus	Postoperative urinary retention	Liang, 2009 [92]	150 LAVH	[A]	8
	Higher serum creatinine or platelet count	Surgical site infection	Mahdi, 2014 [93]	15549 LH	[C]	8
	ASA score 2	Pelvic cellulitis	Chang, 2011 [88]	195 LAVH	[D]	7
	ASA score 3-4	Overall complications and blood transfusions	Catanzarite, 2015 [24]	7630 LH	[C]	8
	Previous stroke/ TIA	Overall complications	Catanzarite, 2015 [24]	7630 LH	[C]	8
Ethnicity	Non-white ethnicity	Deep or organ/space surgical site infection	Mahdi, 2014 [93]	15549 LH	[C]	8

LAVH = laparoscopic assisted vaginal hysterectomy, TLH = total laparoscopic hysterectomy, LSH = laparoscopic supracervical hysterectomy, RALH = robot-assisted total laparoscopic hysterectomy.
[A] = randomized controlled trial, [B] = prospective cohort study, [C] = retrospective cohort study, [D] = case-control study.
NO-QAS = Newcastle-Ottawa Quality Assessment Scale.

Table 5 Increased conversion rate: predictors in detail

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
Uterine weight	≥500g	Kondo, 2011 [15]	2092 TLH and LAVH	[C]	6
		Song, 2012/2011 [73,94]	2012 LAVH	[C]	8
		Twijnstra, 2013 [95]	1534 LH	[B]	9
		Ferrari, 2000 [31]	31 LAVH	[B]	6
	≥750-800g	Shiota, 2011 [33]	629 LAVH	[C]	6
	Uterus width on ultrasound 8-10cm	Leonard, 2005 [96]	416 TLH	[C]	8
	Not defined	Park, 2011 [97]	288 TLH	[C]	7
		Wallwiener, 2013 [87]	1956 LSH and TLH	[B]	9
BMI	BMI ≥ 30 kg/m^2	Shen, 2002 [77]	670 LAVH	[C]	7
		Song, 2012 [73]	2012 LAVH	[C]	8
		Harmanli, 2013 [63]	970 LSH and TLH	[C]	7
		Twijnstra, 2013 [95]	1534 LH	[B]	9
	Not defined	Leonard, 2005 [96]	416 TLH	[C]	8
Previous operations	Previous history of myomectomy	Song, 2012/2011 [73,94]	2012 LAVH	[C]	8
	Caesarean section	Song, 2011 [94]	2012 LAVH	[C]	8
		Wang, 2010 [85]	574 LH	[B]	8
		Jo, 2013 [98]	300 LESS (LAVH and TLH)	[C]	6
	3 laparotomies	Lafay Pitter, 2009 [86]	1501 LH	[C]	7

Table 5 continues on next page

Table 5 *Continued*

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
	History of adhesion-causing abdominopelvic surgery	Leonard, 2005 [96]	416 TLH	[C]	8
Adhesions	Pelvic adhesions	Park, 2011 [97]	288 TLH	[C]	7
	Minor vs none and extensive vs none	Wallwiener, 2013 [87]	1952 LSH and TLH	[B]	9
Age	>65 years	Twijnstra, 2013 [95]	1534 LH	[B]	9
Fibroids	Lateral fibroid measuring > 5cm	Leonard, 2005 [96]	416 TLH	[C]	8

TLH = total laparoscopic hysterectomy, LAVH = laparoscopic assisted vaginal hysterectomy, LSH = laparoscopic supracervical hysterectomy, LESS = laparoendoscopic single-site hysterectomy.
[A] = randomized controlled trial, [B] = prospective cohort study, [C] = retrospective cohort study, [D] = case-control study
NO-QAS = Newcastle-Ottawa Quality Assessment Scale.

Table 6 Selection of case-mix variables per surgical outcome; stratified per level of evidence criteria

	Sets of case-mix characteristics		
	Set 1 (Low) *Level of evidence criteria:* **≥1 study with NO-QAS 9 or ≥2 studies with NO-QAS 8 or 7**	**Set 2 (Medium)** *Level of evidence criteria:* **≥1 study with NO-QAS 9 and ≥1 study with NO-QAS 8 or 7**	**Set 3 (High)** *Level of evidence criteria:* **≥2 study with NO-QAS 9 or ≥4 studies with NO-QAS 8 or 7**
Operative time	Uterine weight BMI Adhesions Previous operations Age	Uterine weight BMI - Previous operations Age	Uterine weight BMI - - -
Bloodloss	Uterine weight BMI	Uterine weight BMI	Uterine weight BMI
Complication	Uterine weight BMI Previous operations Adhesions Age Endometriosis Uterus descent Smoking TIA/Stroke Diabetes Mellitus ASA score	Uterine weight BMI Previous operations Adhesions Age - - Smoking - Diabetes Mellitus -	Uterine weight BMI Previous operations Adhesions - - - - - - -
Conversion	Uterine weight BMI Previous operations Adhesions Age	Uterine weight BMI - Adhesions -	Uterine weight BMI Previous operations - -

NO-QAS = Newcastle-Ottawa Quality Assessment Scale.

Discussion

In this review we aimed to identify predictors for surgical outcomes of LH. These predictors can be used as case-mix correctors for quality assessment and serve to correctly compare the outcomes of clinicians. We observed that most studies of high quality described a statistically significant association between higher BMI, high uterine weight, and less favorable surgical outcomes. Also, adhesions and previous operations seemed to be important predictors for the outcome of LH. These 2 characteristics are closely linked to each other, because previous operations are obviously associated with pelvic adhesions [10]. The strong association between larger uterine weight and all surgical outcomes for LH can inherently be explained by a larger blood supply in large uteri, the need of morcellation, and inadequate visibility

during surgery, which can also lead to prolonged surgery and more complications [11]. Higher BMI was found to be a predictor for longer operative time, more blood loss, and higher risk for complications and conversion. The laparoscopic entry and actual procedure can be more difficult in obese women. However, as has been shown in different studies, LH in obese women and for large uteri is still a safe and feasible approach and should be considered before the abdominal approach [11, 12].

Based on our search, a case-mix correction for at least uterine weight and BMI is strongly recommended when assessing surgical quality of LH. It remains debatable which level of evidence criteria a patient characteristic should meet before being selected as valid case-mix characteristic. However, even when we consider the highest level of evidence (Table 6), BMI and uterine weight remain relevant predictors for all surgical outcomes.

Previous operations and adhesions can also be considered as potential case-mix factors. However, the difference in severity of adhesions makes it more complex to use for a quality assessment tool and quality indicator. Age is also mentioned as predictor in a number of high quality studies for the outcomes complications, operative time, and conversion. However, both younger and older ages are observed as predictors, and no specific cut-off point is observed, which makes a case-mix correction difficult. Furthermore, comorbidity characteristics (e.g., diabetes mellitus, ASA score, transient ischemic attach/stroke), smoking, and uterine descent should be further explored, as only 1 or 2 studies did mentioned these factors, however these are studies of high quality.

Pelvic endometriosis is often mentioned as a level of difficulty of LH and therefore expected to be highly associated with worse surgical outcomes. However, unexpectedly, the appearance of endometriosis did not seem to be an important predictor in the literature, because only 3 articles showed a significant association with longer operative time and more complications. A possible explanation is the difficulty in consistently determining the stage of endometriosis and therefore was not included as a registered patient characteristic in the studies. In addition, LH alone is generally not the primary treatment for (deep infiltrating) endometriosis (e.g., in case of bowel or bladder involvement), and therefore a large proportion of endometriosis cases were probably excluded in the study population of the eligible articles. Furthermore, it is well known that the appearance of endometriosis is closely correlated with pelvic adhesions, which is more often found to be a predictor.

Strengths and limitations

The major weakness of our study is the fact that our conclusions are only based on the number and quality of identified articles and that a more in-depth analysis of the data was

not possible. Our intended design was to pool the results with meta-analysis to determine strong evidence. Most included studies are studies had a different main objective from our search query, and therefore only very limited data for analysis were available (e.g., no means, no standard deviations) and an enormous heterogeneity in outcomes was observed. For this reason it was also not possible to identify all studies that did not find a significant difference between patient characteristics and outcome, because most articles only described the statistically significant data in the results section. However, because we were able to select more than 80 articles, our data do give a clear overview of the importance of certain patient characteristics in the outcome of LH. In addition, it is clear that a case-mix correction for some patient characteristics is indispensable to compare surgical outcomes correctly. We are also aware that reporting bias may play a role in the interpretation of our results. Our selected list of patient characteristics includes only those characteristics that have been reported in literature, and possibly also other characteristics not mentioned in literature, are associated with certain surgical outcomes. In addition, other well-known factors or diseases are inherently associated with our found characteristics (e.g., hypothyroidism with BMI).

A subject for future debate is how to apply case-mix adjustment for quality assessment tools. Several issues need to be taken into account as cut-off values of certain characteristics and how to weight these case-mix variables.

Another important issue regards the problem in the definitions of clinical outcome in literature. For example, the definition of a complication varies per study. This inconsistency makes it more difficult to properly compare clinical outcomes and thus surgical quality, and therefore we mentioned all used definitions for complications in our results (Table 5). In our opinion it is of the utmost importance to achieve an international consensus on uniform outcome definitions and to implement them worldwide. An attempt was made in a recently published study that gives a multidisciplinary consensus on the definition of conversion [13].

Measuring quality of healthcare interventions is a complex and difficult issue. To obtain and develop a validated and accurate quality assessment tool for LH, our study is the first necessary step, and case-mix adjustment is indispensable [6]. At the current time, quality assessment is a much-discussed issue and ranking lists of “best hospital” and “top surgeons”

are available to everyone. These data are widely interpreted by the media and patients as reliable quality measurements of performance data of hospitals and surgeons. However, the differences in patient population between hospitals and surgeons are usually ignored. Therefore, these quality-ranking lists provide the clinician, the insurance company, and the patient with a certain false sense of security. This is especially important for teaching and referral hospitals, because more challenging and more complex patients are treated in these clinics.

Our study gives an overview of all patient characteristics that influence the surgical outcome of LH. This is an important issue, not only for quality assessment but also for patient counselling and surgical scheduling. Based on these results surgeons will be able to better predict operative time, blood loss and risk for complications or conversion and anticipate on those issues. Furthermore, evidence-based knowledge of case-mix characteristics can be important considering medicolegal issues.

In conclusion, BMI, uterine weight, adhesions and/or previous surgery are the main predictors for surgical outcomes of LH. For future development of outcome quality indicators of LH and to correctly compare surgical outcomes, a case-mix correction is suggested for at least uterine weight and BMI. For both surgeons and patients it is of great value to be aware of potential factors predicting worse clinical outcomes and to anticipate on them. Finally, to benchmark clinical outcomes, it is of highest importance that similar (international) definitions are developed.

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Supplemental Appendix 1

Complete search strategy

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