

### Implementing patient safety in laparoscopic surgery: quality assessment and process analysis

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#### Cover Page



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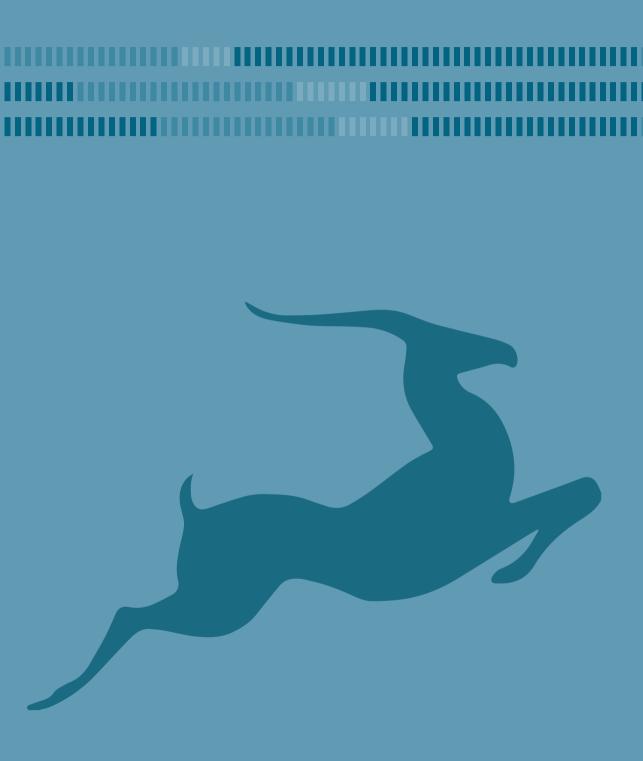
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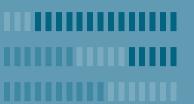
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# Chapter 3

## Clinical relevance of conversion rate and its evaluation in laparoscopic hysterectomy

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#### **Abstract**

**Study objectives:** To estimate the current conversion rate in laparoscopic hysterectomy (LH); to estimate the influence of patient, procedure, and performer characteristics on conversion; and to hypothesize the extent to which conversion rate can act as a means of evaluation in LH.

**Design:** Prospective cohort study (Canadian Task Force classification II-2).

**Setting:** The study included 79 gynecologists representing 42 hospitals throughout the Netherlands. This reflects 75% of all gynecologists performing LH in the Netherlands, and 68% of all hospitals.

Patients: Data from 1534 LH procedures were collected between 2008 and 2010.

**Intervention:** All participants in the nationwide LapTop registration study recorded each consecutive LH they performed during 1 year.

**Measurements and main results:** Conversion rate and odds ratios (OR) of risk factors for conversion were calculated. Conversions were described as reactive or strategic. The literature reported a conversion rate for LH of 0% to 19% (mean 3.5%). In our cohort, 70 LH procedures (4.6%) were converted. Using a mixed-effects logistic regression model, we estimated independent risk factors for conversion. Body mass index (BMI) (p = .002), uterus weight (p < .001), type of LH (p = .004), and age (p = .02) had a significant influence on conversion. The risk of conversion was increased at BMI >35 (OR 6.53; p < .001), age >65 years (OR 6.97; p = .007), and uterus weight 200 to 500 g (OR 4.05; p < .001) and especially >500 g (OR 30.90; p < .001). A variation that was not explained by the covariates included in our model was identified and referred to as the "surgical skills factor" (average OR 2.79; p = .001).

**Conclusion:** Use of estimated risk factors (BMI, age, uterus weight, and surgical skills) provides better insight into the risk of conversion. Conversion rate can be used as a means of evaluation to ensure better outcomes of LH in future patients.

#### Introduction

To spare women the customary abdominal incision, laparoscopic hysterectomy (LH) was adopted 20 years ago as a minimally invasive alternative to conventional abdominal surgery [1]. As a result, women are protected from the increased risk of blood loss, wound infection, and prolonged recovery [2]. If laparoscopy fails, the surgeon always has the possibility to "escape" by conversion to the conventional abdominal approach. Therefore, most gynecologists are of the opinion that conversion is inherent to laparoscopy and should not be regarded as an adverse event [3–5].

In previous publications, conversion rate was used to justify the feasibility of the laparoscopic approach [6]. However, to date, conversion rates in LH are still mentioned, yet no specific conclusions are drawn from these outcomes. As can be imagined, conversion that involves combined exposure to the general risk of the laparoscopic approach followed by an additional laparotomy is associated with substantially worse postoperative outcomes [7,8]. In addition, the indication for conversion is important. Several studies in the field of laparoscopic colorectal surgery have found that conversion because of an intraoperative adverse event ("reactive," e.g., a lesion of the ureter) is associated with higher postoperative morbidity than is conversion to prevent an adverse event in case of operative difficulties ("preemptive" or "strategic," e.g., adhesions) [9,10]. As a consequence, proper documentation of a conversion and its indication is essential.

In LH, strategic conversions can occur for a number of reasons. An enlarged immobile uterus and/or severe adhesions can obstruct sufficient visibility of the operative field. Furthermore, additional disease (e.g., a more advanced stage of cancer than expected) might dictate immediate conversion to the conventional approach. Also, patient risk factors such as (morbid) obesity might impede the laparoscopic approach; for example, the anesthesiologist is challenged to such an extent that conversion is required for patient safety. This subdivision into strategic and reactive conversions can provide information about indication, patient selection, and surgeon experience and skill. Therefore, we hypothesized that conversion rate may serve as a means of evaluation of the quality of a series of performed LH procedures.

In the past decade, quality assurance of the surgical process has been given increasing attention [11]. With the ultimate goal to improve quality of care, quality assurance enables evaluation and interpretation of variations in treatment, which in turn can be linked to treatment outcomes [12,13]. We believe that the importance of quality assurance in minimally invasive gynecology is currently underestimated. Given that in the near future an increasing number of LH procedures will be performed because of wider implementation of this surgical technique, the absolute number of conversions is likely to increase over time. To stay ahead of these developments and to answer the increasing demands of health inspectors,

professionals, and patients, it is essential to acquire better insight into conversion rate as a means of evaluation in LH

The objective of the present study was 3-fold. First, on the basis of prospectively obtained data, we estimated the influence of patient, procedure, and performer characteristics on conversion in LH. Second, because no systematic data on conversion rates is available at present, we performed a systematic search of the literature to provide a basis for evaluation. Third, supported by these two results, we hypothesize the extent to which conversion rate can act as a means of evaluation in laparoscopic hysterectomy.

#### Materials and methods

To provide a current estimate of the conversion rate in LH, we searched the literature on PubMed using the following terms: "hysterectomy," "laparoscopy," and "conversion." We limited the results to original observational studies and randomized controlled trials published after 2000, written in English, and with an available abstract. We excluded all publications concerning robotic (assisted) hysterectomy, single-incision, and/or radical hysterectomy because of oncologic indications. We also excluded studies that did not report the actual percentage of procedures converted to laparotomy. In cases in which the indication for conversion was clearly mentioned, we calculated the percentage of strategic conversions.

To estimate independent risk factors for conversion in LH, we analyzed the data obtained from the LapTop study (2008–2010), a prospective nationwide cohort in which 79 gynecologists in the Netherlands who performed LH procedures were enrolled and for 1 year registered each LH that he or she performed as a primary surgeon. This represented 75% of all gynecologists performing LH in the Netherlands, and 68% of hospitals (n = 42). Potential risk factors for conversion were identified and consisted of patient, procedure, and performer characteristics. In addition to the age of the patient and the indication for LH, these characteristics included body mass index (BMI), previous abdominal surgery including cesarean section, and ASA (American Society of Anesthesiologists) classification. Procedure characteristics included the type of LH performed (i.e., laparoscopic-assisted vaginal hysterectomy, supracervical laparoscopic hysterectomy [SLH], or total laparoscopic hysterectomy [TLH]), accompanying salpingo-oophorectomy, and uterus weight (in grams, weighed in the operating room). Performer characteristics included the actual number of LH procedures performed including the procedure to be registered. To ensure that all LH procedures performed were submitted, we double-checked 10% of the cases with the actual operating room statistics for each clinic. Parts of the collected data related to patient and surgeon factors as predictors of blood loss, operative time, and adverse events have been published elsewhere [14].

Adverse events were registered for type, severity (i.e., requiring repeat intervention or not), and moment of onset, according to the definitions and regulations as determined by the guidelines for adverse events of the Dutch Society of Obstetricians and Gynecologists [15]. Conversion to laparotomy was defined as an abdominal incision made after the laparoscopic start-up. Strategic conversions (e.g., due to inadequate visibility, adhesions, or additional disease) were differentiated from conversions to laparotomy because of an adverse event (reactive conversion). Additional information on the indication for conversion was to be reported in the comment section.

The procedure and the patient and performer characteristics of this cohort were analyzed using statistical software (SPSS version 17.0; SPSS, Inc., Chicago, IL). The 95% confidence intervals (CIs) were calculated, and p < .05 was considered statistically significant. The distribution of continuous and ordinal variables was tested for normality using the Kolmogorov-Smirnov test. To describe non-normally distributed data the median, interquartile range (25th and 75th percentiles), and range (minimum and maximum values) were used. For the clinical relevance of the outcomes, we stratified a number of continuous variables: BMI (<25, 25–35, and >35), age (<45, 45–65, and >65 years), and uterus weight (<200, 200–500, and >500 g). As a reference category for categorical variables, we chose the most relevant category, preferably with the most cases. We used a mixed-effects logistic regression model to calculate the adjusted log odds ratio (OR) of each risk factor for conversion using statistical software (R-2 version 10.0) with the lme4-package [16]. In the case of a categorical variable, the OR was relative to the reference category. The variables included in the model had to either show a significant association in the univariable analysis or be marked as clinically important by the researchers.

The influence of surgical experience (number of LH procedures performed) was estimated in 2 ways. First, we estimated whether the risk of conversion is influenced by surgical experience, on a continuous scale per 10 consecutively performed procedures. Second, we estimated whether a dichotomous cutoff of >30 procedures influences the risk of conversion because this value is generally accepted as the individual learning curve [17,18].

We took into account that we observed multiple procedures for each surgeon [19]. Two procedures performed by the same surgeon tend to be "more similar" than 2 procedures performed by 2 different surgeons. We modeled this type of similarity by using a mixed-effects logistic regression model, thus including random contributions specific to each surgeon. The standard deviation (SD) of these random contributions (estimated at log odds of the exponent) capture differences between surgeons that are not explained by the included covariates of the model. Because our model corrects for all measurable patient and surgeon factors, this SD can be interpreted as an OR of factors that are not measurable as a number

with a unit such as the skills of the surgeon and the functionality of the complete operating team. Because the surgeon is ultimately responsible for the surgical procedure as a whole, we referred to this variation that is not explained by directly measurable factors as the "surgical skills factor." Using this approach, the calculated surgical skills factor can be used as an OR, describing the a priori difference in the risk of conversion between 2 randomly selected surgeons.

#### **Results**

From the literature search, we found a conversion rate in LH of 0% to 19% (Table 3.1) [20–52]. We found 33 relevant studies describing a total of 7827 procedures, of which 264 (3.5%) were converted to laparotomy. We calculated that 73% of conversions could be regarded as strategic in those studies that provided the reason for conversion.

A total of 1534 LH procedures were performed during the study (2008–2010). The mean experience (number of LH procedures performed) per gynecologist at the start of the study was 51 procedures (median, 28; range, 0–250). During the 12-month study, the mean (SD; range) number of LH procedures performed per year was 14.9 (10.7; 1–50).

A total of 70 LH procedures (4.6%; 95% CI, 4.3–4.9) were converted, of which 22 (31.4%; 95% CI, 22.9–40.0) were identified as a reactive conversion, and 48 (68.6%; 95% CI, 60.0–77.1) as a strategic conversion (Table 3.2). The primary reasons for a reactive conversion were uncontrollable bleeding (63.6%), internal organ lesions (13.6%), and technical failure of equipment (13.6%). Strategic conversions were primarily due to visibility or mobility problems as a result of altered anatomy (e.g., adhesions or myomas; 70.8%); a uterus too large to be removed in one piece in case of malignancy, and therefore contraindicated for morcellation; (14.6%); and anesthesiologic problems due to morbid obesity (BMI > 40; 10.4%).

In the course of the 1-year study, 42 gynecologists reported no conversions, whereas 46.8% of the performing surgeons had to convert to laparotomy at least once; their individual conversion rate ranged from 1.3% to 33.3%. Experience in more than 30 LH procedures did not correlate with the risk of conversion (p = .73). Moreover, the distribution between strategic and reactive conversions was not correlated with experience in more than 30 LH procedures (p = .17).

Overall patient and procedure characteristics are given in Table 3.3. The independent risk factors for conversion were BMI (p = .002), age (p = .02), uterus weight (p < .001), and type of LH (p = .004) (Table 3.4). Relative to the reference category of these risk factors, important categories were BMI >35 (OR, 6.53; p < .001), age >65 years (OR, 6.97; p = .007), uterus weight 200 to 500 g (OR, 4.05; p < .001), and uterus weight >500 g (OR, 30.90; p < .001). Compared

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Table 3.1 Reported conversion rates in laparoscopic hysterectomy

| Source, year                      | Туре оf LH | Study design       | No. of<br>procedures | No. of<br>conversions | Conversion rate (%) | Strategic<br>conversion (%) |
|-----------------------------------|------------|--------------------|----------------------|-----------------------|---------------------|-----------------------------|
| Brummer et al [20], 2009          | Mixed      | Prospective cohort | 1686                 | 87                    | 5.2                 | 92                          |
| Candiani et al [21], 2009         | TLH        | Prospective cohort | 30                   | 0                     | 0                   | NA                          |
| Chang et al [22], 2005            | LAVH       | Prospective cohort | 225                  | 2                     | 6:0                 | 0                           |
| Chen et al [23], 2008             | LAVH       | Prospective cohort | 147                  | П                     | 2.0                 | 0                           |
| Daraï et al [24], 2001            | LAVH       | RCT                | 40                   | m                     | 7.5                 | 29                          |
| David-Montifiore et al [25], 2007 | Mixed      | Prospective cohort | 121                  | 23                    | 19.0                | 65                          |
| Donnez and Donnez [26], 2010      | Mixed      | Prospective cohort | 400                  | 0                     | 0                   | ΑΝ                          |
| Drahonovsky et al [27], 2010      | Mixed      | RCT                | 125                  | m                     | 2.4                 | Unknown                     |
| Erian et al [28], 2005            | SLH        | Prospective cohort | 100                  | 0                     | 0                   | NA                          |
| Garry et al [29], 2004            | Mixed      | RCT                | 920                  | 32                    | 3.5                 | 72                          |
| Ghezzi et al [30], 2010           | TEH        | RCT                | 41                   | 0                     | 0                   | NA                          |
| Ghomi et al [31], 2007            | SLH        | Prospective cohort | 09                   | П                     | 1.7                 | 0                           |
| Holub et al [32], 2001            | LAVH       | Prospective cohort | 271                  | m                     | 1.1                 | 33                          |
| Johnston et al [33], 2007         | Mixed      | Prospective cohort | 364                  | 4                     | 1.1                 | 75                          |
| Karaman et al [34], 2007          | Mixed      | Prospective cohort | 1120                 | 26                    | 2.3                 | 92                          |
| Kluivers et al [35], 2007         | Mixed      | RCT                | 27                   | 2                     | 7.4                 | 100                         |
| Kreiker et al [36], 2004          | LAVH       | Prospective cohort | 160                  | 5                     | 3.1                 | 100                         |
| Leung et al [37], 2007            | Mixed      | Prospective cohort | 143                  | П                     | 7.0                 | 100                         |
| Lieng et al [38], 2005            | SLH        | Prospective cohort | 43                   | П                     | 2.3                 | 0                           |

Table 3.1 continues on next page

Table 3.1 Continued

| Source, year                 | Type of LH | Study design       | No. of<br>procedures | No. of<br>conversions | Conversion rate (%) | Strategic<br>conversion (%) |
|------------------------------|------------|--------------------|----------------------|-----------------------|---------------------|-----------------------------|
| Long et al [39], 2002        | Mixed      | Prospective cohort | 104                  | m                     | 2.9                 | Unknown                     |
| Mourits et al [40], 2010     | TLH        | RCT                | 185                  | 20                    | 10.8                | 09                          |
| Mueller et al [41], 2011     | TLH        | Prospective cohort | 267                  | П                     | 0.2                 | 100                         |
| Muzii et al [42], 2007       | LAVH       | RCT                | 40                   | 2                     | 5.0                 | 0                           |
| Obermair et al [43], 2012    | TLH        | RCT                | 404                  | 24                    | 5.9                 | Unknown                     |
| Ottosen et al [44], 2000     | LAVH       | Prospective cohort | 40                   | 4                     | 10.0                | 75                          |
| Pan et al [45], 2008         | H_T        | Prospective cohort | 132                  | 6                     | 6.8                 | 100                         |
| Persson et al [46], 2006     | LAVH       | RCT                | 63                   | e                     | 4.8                 | 33                          |
| Schütz et al [47], 2002      | LAVH       | Prospective cohort | 28                   | 0                     | 0                   | ΑΝ                          |
| Seracchioli et al [48], 2002 | TLH        | RCT                | 09                   | П                     | 1.7                 | 0                           |
| Sesti et al [49], 2008       | LAVH       | RCT                | 50                   | 0                     | 0                   | NA                          |
| Shahid et al [50], 2011      | SLH        | Prospective cohort | 29                   | 0                     | 0                   | NA                          |
| Soriano et al [51], 2001     | LAVH       | RCT                | 40                   | т                     | 7.5                 | 100                         |
| Wang et al [52], 2005        | LAVH       | Prospective cohort | 62                   | 0                     | 0                   | ΑΝ                          |
| Total                        |            |                    | 7827                 | 264                   | 3.5                 | 73ª                         |

LAVH= laparoscopic-assisted vaginal hysterectomy; LH = laparoscopic hysterectomy; NA = not applicable; RCT = randomized controlled trial; SLH = supracervical laparoscopic hysterectomy.

<sup>a</sup> Weighted average.

Table 3.2 Primary reason for strategic and reactive conversions (N = 1534)

| Variable                       | n (%)     | 95% CI    |
|--------------------------------|-----------|-----------|
| Strategic conversion           | 48 (68.6) | 60.0-77.1 |
| Visibility/mobility problems   | 34 (70.8) |           |
| Risk of spillage               | 7 (14.6)  |           |
| Anesthesiologic problems       | 5 (10.4)  |           |
| Reactive conversion            | 22 (31.4) | 22.9-40.0 |
| Uncontrollable bleeding        | 14 (63.6) |           |
| Internal organ lesion          | 3 (13.6)  |           |
| Technical failure of equipment | 3 (13.6)  |           |
| Total conversions              | 70 (4.6)  | 4.3-4.9   |

CI = confidence interval.

Table 3.3 Overview of primary patient and procedure characteristics and adverse events in total cohort  $(N=1534)^a$ 

| Patient characteristics               | Median     | IQR⁵      | Minimum-<br>Maximum |
|---------------------------------------|------------|-----------|---------------------|
| Age, yr                               | 46.4       | 41.7-51.1 | 13.0-89.3           |
| BMI                                   | 27.5       | 22.5-28.1 | 17.5-56             |
| Parity                                | 2          | 0-2       | 0-5                 |
| Uterus weight, g                      | 150        | 97-285    | 14-1600             |
| Indication for LH                     | No. (%)    |           |                     |
| Dysfunctional uterine blood loss      | 762 (49.7) |           |                     |
| Uterus myomatosus                     | 420 (27.4) |           |                     |
| (Pre)malignant endometrium or cervix  | 236 (15.4) |           |                     |
| Endometriosis                         | 34 (2.2)   |           |                     |
| Other (prophylaxis, sex change)       | 80 (5.2)   |           |                     |
| Previous abdominal surgical procedure |            |           |                     |
| None                                  | 918 (59.9) |           |                     |
| 1                                     | 397 (25.9) |           |                     |
| 2                                     | 143 (9.3)  |           |                     |
| >2                                    | 50 (3.3)   |           |                     |

| Procedure characteristics | Median | IQR⁵    | Minimum-<br>Maximum |
|---------------------------|--------|---------|---------------------|
| Operative time, min       | 110    | 90-134  | 32-344              |
| Conversions (N = 70)      | 120    | 100-175 | 34-330              |
| Blood loss, mL            | 100    | 50-200  | 0-2600              |
| Conversions (N = 70)      | 500    | 300-950 | 10-2500             |

Table 3.3 continues on next page

Table 3.3 Continued

| Procedure characteristics        | n (%)      |  |
|----------------------------------|------------|--|
| Type of LH                       |            |  |
| TLH                              | 957 (62.4) |  |
| LAVH                             | 185 (12.1) |  |
| SLH                              | 391 (25.5) |  |
| Bilateral salpingo-oophorectomy  | 362 (23.6) |  |
| Adverse events                   | n (%)      |  |
| Procedures with ≥1 adverse event | 116 (7.6)  |  |
| Infection                        | 12 (0.8)   |  |
| Internal organ lesion            | 29 (1.9)   |  |
| Vessel lesion                    | 8 (0.5)    |  |
| Wound dehiscence                 | 15 (1.0)   |  |
| Blood loss >1000 mL              | 43 (2.8)   |  |
| Venous thromboembolism           | 2 (0.1)    |  |
| Other                            | 21 (1.4)   |  |
| Seriousness                      |            |  |
| No (re)intervention needed       | 105 (6.8)  |  |
| Intervention needed              | 25 (1.6)   |  |
| Time of adverse event            |            |  |
| During procedure                 | 67 (4.4)   |  |
| On hospital ward                 | 36 (2.3)   |  |
| After hospital discharge         | 27 (1.8)   |  |

BMI = body mass index; IQR = interquartile range; LAVH = laparoscopic-assisted vaginal hysterectomy; LH = laparoscopic hysterectomy; SLH = supracervical laparoscopic hysterectomy; TLH = total laparoscopic hysterectomy.

with TLH, performing SLH significantly decreased the risk of conversion (OR, 0.32; p = .02). History of abdominal surgery, ASA classification, accompanying salpingo-oophorectomy, and indication for LH were not associated with conversion. Furthermore, surgical experience, measured both per 10 procedures on a continuous scale (OR, 0.95; p = .09) and with a cutoff of >30 procedures (OR, 0.60; p = .25 (the latter not given in Table 3.4), was also not significantly associated with conversion. Although our model corrected for all of these (measurable) covariates, it repeatedly calculated an influence of the "variation not explained by the covariates" (the SD of the random contributions) on the risk of conversion. Some immeasurable "environmental" factors consisting of factors related to the surgeon, the operating room team, or organizational factors were accountable for this effect and were therefore referred to as the surgical skills factor. The SD of these random contributions was, independent of the included covariates, estimated at a log odds of 1.03 (p = .001) for the risk

<sup>&</sup>lt;sup>a</sup> All continuous and ordinal variables given were not normally distributed.

<sup>&</sup>lt;sup>b</sup> IQR (25<sup>th</sup> and 75<sup>th</sup> percentiles).

of conversion. Therefore, between 2 randomly selected surgeons, on average, an intrinsic OR of 2.79 (Exp[1.03]) on the risk of conversion was present. The multivariable analysis was based on 1292 cases because 242 cases were excluded because of at least 1 missing parameter (15.7%). These excluded cases included 5 converted procedures.

Table 3.4 Risk factors and adjusted ORa for conversion to laparotomy in LHb

| Variable                                  | No. of procedures | Conversions<br>(% of total) | Adjusted<br>OR | 95% CI      | p value |
|---|-------------------|-----------------------------|----------------|-------------|---------|
| Age, yr                                   |                   |                             |                |             | .02     |
| <45                                       | 528               | 16 (3.0)                    | 1.0            | Reference   |         |
| 45–65                                     | 689               | 40 (5.8)                    | 1.39           | 0.68-2.83   | .37     |
| >65                                       | 75                | 9 (12.0)                    | 6.97           | 1.72-28.27  | .007    |
| Body mass index                           |                   |                             |                |             | .002    |
| <25                                       | 531               | 13 (2.4)                    | 1.0            | Reference   |         |
| 25–35                                     | 653               | 36 (5.5)                    | 1.90           | 0.90-4.00   | .09     |
| >35                                       | 108               | 16 (14.8)                   | 6.53           | 2.27-18.78  | <.001   |
| Uterus weight, g                          |                   |                             |                |             | <.001   |
| <200                                      | 760               | 19 (2.5)                    | 1.0            | Reference   |         |
| 200-500                                   | 408               | 24 (5.9)                    | 4.05           | 1.87-8.79   | <.001   |
| >500                                      | 124               | 22 (17.7)                   | 30.90          | 11.72-81.48 | <.001   |
| Previous abdominal surgical procedures    |                   |                             |                |             | .54     |
| None                                      | 773               | 38 (4.9)                    | 1.0            | Reference   |         |
| ≥1  | 519               | 27 (5.2)                    | 1.20           | 0.65-2.22   |         |
| ASA classification                        |                   |                             |                |             | .12     |
| I   | 903               | 35 (3.9)                    | 1.0            | Reference   |         |
| II  | 357               | 24 (6.7)                    | 1.4            | 0.68-2.72   |         |
| III/IV                                    | 32                | 6 (18.8)                    | 5.39           | 1.12-25.84  |         |
| Type of LH                                |                   |                             |                |             | .004    |
| TLH                                       | 787               | 42 (5.3)                    | 1.0            | Reference   |         |
| SLH                                       | 343               | 11 (3.2)                    | 0.32           | 0.12-0.83   | .02     |
| LAVH                                      | 162               | 12 (7.4)                    | 2.07           | 0.80-5.36   | .13     |
| Bilateral salpingo-oophorectomy           |                   |                             |                |             | .07     |
| No  | 1014              | 52 (5.1)                    | 1.0            | Reference   |         |
| Yes                                       | 278               | 13 (4.7)                    | 0.39           | 0.13-1.16   |         |
| Indication                                |                   |                             |                |             | .79     |
| Dysfunctional uterine bleeding            | 656               | 28 (4.3)                    | 1.0            | Reference   |         |
| Uterus myomatosus                         | 361               | 23 (6.4)                    | 0.83           | 0.39-1.75   |         |
| (Pre)malignancy,<br>endometrium or cervix | 176               | 13 (7.4)                    | 1.61           | 0.51-5.06   |         |
| Endometriosis                             | 31                | 1 (3.2)                     | 1.01           | 0.09-10.83  |         |
|   |                   |                             |                |             |         |

Table 3.4 continues on next page

Table 3.4 Continued

| Variable                                     | No. of procedures | Conversions<br>(% of total) | Adjusted<br>OR    | 95% CI    | p value |
|--|-------------------|-----------------------------|-------------------|-----------|---------|
| Other (e.g., sex change, prophylaxis)        | 68                | 0                           | NA <sup>c</sup>   |           |         |
| Surgical experience, continuous <sup>d</sup> |                   |                             | 0.95              | 0.89-1.01 | .09     |
| Surgical skills factor                       |                   |                             | 2.79 <sup>e</sup> |           | .001    |

ASA = American Society of Anesthesiologists; CI = confidence interval; LAVH = laparoscopic-assisted vaginal hysterectomy; LH = laparoscopic hysterectomy; NA = not available; OR = odds ratio; SLH = supracervical laparoscopic hysterectomy; TLH = total laparoscopic hysterectomy.

#### Discussion

In most cases (69%), strategic considerations are the reason for converting LH to the conventional abdominal approach. Visibility and/or mobility problems are the primary reason for this type of conversion, whereas uncontrollable bleeding is the primary adverse event leading to a reactive conversion. As reported in other studies, BMI and uterus weight have been confirmed as independent risk factors for conversion [53–55]. However, a new effect demonstrated in our study is that this risk increases with BMI > 35 (approximately 6.5-fold), age >65 years (approximately 7-fold), uterus weight 200 to 500 g (approximately 4-fold), and uterus weight >500 g (approximately 30-fold). However, performing SLH, compared with TLH, decreases the risk of conversion (approximately 3-fold). Surgical experience did not directly correlate with the conversion rate. However, we identified the presence of an intrinsic factor influencing the risk of conversion, which we referred to as the surgical skills factor.

Most LH procedures (>95%) are completed laparoscopically as planned. To facilitate an increase in this rate and further improvement of the quality assurance in LH, in our opinion, conversion rate can be considered a means of evaluation. In general, conversion should be viewed as a phenomenon inherent to laparoscopic surgery, being a calculated risk and a sign of good surgical judgment [56]. Nevertheless, from a quality control point of view, just as registration of adverse events is mandatory in every clinic, this registration should also include the number of conversions and their indication. A subdivision into strategic and reactive conversions will be helpful in daily practice because reactive conversion is associated with a higher risk of postoperative adverse events and prolonged hospital stay [9,10]. In

<sup>&</sup>lt;sup>a</sup> Relative to the reference category in case of a categorical variable.

<sup>&</sup>lt;sup>b</sup> The mixed-effects logistic regression model was based on 1292 cases because 242 cases were excluded because of ≥1 missing parameter.

<sup>&</sup>lt;sup>c</sup> Could not be calculated because there were no conversions. This did not affect the adjusted OR of all other covariates.

<sup>&</sup>lt;sup>d</sup> Per 10 consecutive procedures performed.

<sup>&</sup>lt;sup>e</sup> Average OR.

addition, while strategic conversions potentially are the result of suboptimal preoperative patient evaluation, an insufficiently trained surgeon and operating team might be the cause of either a strategic or reactive conversion. Such registration can be used as an additional means of evaluation of LH in which preeminently the rate of strategic conversions can provide information about patient selection, indication, and surgical skills of the gynecologist and the operating team.

Furthermore, each clinic should evaluate the ratio of vaginal hysterectomies, abdominal hysterectomies, and LH procedures performed over the years. Ideally, on hypothetical grounds, the rate of vaginal hysterectomies must remain steady while an optimum rate of LH should be reached, with subsequent low numbers of primary abdominal hysterectomy procedures [25,57–63]. To accomplish this, we must ensure and further improve the quality of the surgical procedure (in this case, LH) by using additional means of evaluation of the procedure such as the conversion rate and its subdivisions. It can be imagined that surgeons could fear such a measurement and therefore might refrain from the laparoscopic approach in some cases. However, this will deprive patients of the advantages of a minimally invasive approach, consequently obscuring the true indication for the abdominal approach. We would like to stress that the need to perform a conversion will always remain. Moreover, proper registration can be both a means of evaluation and a helpful tool for each surgeon. As a consequence, opportunities are provided that eventually might enable reduction in both the conversion rate in LH and the rate of abdominal hysterectomies as a whole.

With regard to the risk factors for conversion, a number of studies have reported a correlation between surgical experience and conversion rate [4,5,53,64]. However, in the present study we found no significant increase in the risk of (strategic or reactive) conversions in the group of less experienced gynecologists (<30 procedures). This is most probably the result of various teaching or mentorship programs that gynecologists who are novices to LH are now obliged to attend, thereby protecting patients from an increased risk of adverse outcomes and conversions [65].

We repeatedly found that the risk of conversion is significantly influenced (OR, 2.79; p = .001) by the presence of an intrinsic factor that, independent of experience, represents surgical skills and the functionality of the operating team. Although this assessment might be somewhat precarious, others have also stated that as a predictor for surgical outcome, surgical skills seem to have a more important role than surgical experience alone and that therefore should not be ignored [66]. Similarly, it has been argued that measuring structures and processes of care, which incorporate individual skills, may be a better means of evaluation than the conventional focus on outcome measurements [67,68]. If we compare testing proficiency in surgery with driving a car, we can state the following metaphor: Not only that the driver has

acquired a driver's license (i.e., completed a learning curve) and how many times he or she has driven a car before determine the outcome of the drive, but also the skills of the driver (or the instructor) and the functionality of the car influence the outcome of each ride. Thus, in our opinion, although easier to assess, surgical experience should not solely be used as a safeguard to prevent conversion. On the contrary, we should be aware of the presence of such an intrinsic surgical skills factor influencing the risk of conversion.

Although studies have been published on ORs that were adjusted for the influence of BMI on conversion rate, our study provides stratified groups rather than an OR per point increase, which makes it clinically more relevant [53,55]. This stratification is, in our opinion, more useful in daily practice and will enable better informed consent.

Some claim that conversion rate is related more to the shape of the uterus rather than its weight (e.g., myomas) [55]. Although we think that shape certainly may influence the outcome, our analysis showed a strong independent association between conversion and uterus weight. With respect to the influence of age on conversion, some studies state no correlation [53,55,69]. However, a recently published nationwide study showed an increasing conversion rate in elderly patients [70]. Furthermore, the significant influence of age >65 years can be explained by a relatively high conversion rate associated with premalignant indications within this subgroup (12.3%; data not shown). Although apparently this combination has an increased risk of (strategic) conversion, it is important to note that most patients in this subgroup can benefit from the advantages of the laparoscopic approach. Moreover, because the premalignant indication shows a trend toward a higher risk of conversion, this explains in part why performing SLH seems to be associated with a significantly lower risk of conversion. Furthermore, in theory, the lack of colpotomy in SLH, often regarded as a difficult surgical step, facilitates lower conversion rates. However, SLH should not be performed at the expense of a proper indication.

On the basis of our findings, we suggest when counseling about the laparoscopic approach that one should be aware of the aforementioned patient risk factors and evaluate one's personal (i.e., team) tendency to convert. When in doubt, one should ask for expert help or refer the patient. However, if past performance is reassuring, challenging patients should also be offered the laparoscopic approach.

The overall conversion rate of 4.6% in LH in our cohort is representative for the Netherlands: 75% of the Dutch gynecologists who perform LH fully participated in the study, and the patient and procedure characteristics were similar to the data we found in the literature [20,29]. However, this figure is somewhat higher than the 3.5% conversion rate identified in our literature review. This is probably because our cohort represents a country as a whole, reflecting daily practice rather than the specific experience of a single surgeon or

center. A limitation of the present study is the influence of possible selection bias because all gynecologists decided according to their individual criteria whether to perform the hysterectomy laparoscopically rather than abdominally or vaginally. However, this reflects the actual clinical situation in which all gynecologists try to use proper indication criteria to the extent of their surgical experience and skills. Furthermore, patient characteristics in our cohort are comparable with those of other large studies [20,29] (Table 3.3). In addition, in collecting our data, we had to rely on each individual gynecologist who submitted each performed procedure. We did not identify any missing procedures during the double-check. In our study design, registration of diagnostic laparoscopy followed by abdominal hysterectomy might potentially have led to underreporting of the number of conversions. However, we cannot think of any indication justifying this option as an optimal treatment, and, based on our definition for conversion (stated in the study protocol), even such a procedure should have been registered as a conversion.

In conclusion, because the present study provides data collected from many centers rather than a single (experienced) center, the results could be interpreted as applying nationwide. We therefore suggest that, supported by our literature review, a conversion rate of <5% can serve as a reference for future comparison. If a hospital exceeds this percentage, it should conduct an audit of its converted LH procedures. The questions to be asked would include the following: Did intraoperative adverse events occur? Were indications properly made? Were the skills of the surgeon and the functionality of the operating team adequate? In addition, the subdivision between strategic and reactive conversions enables better identification of conversions that could be avoided. Furthermore, the balance between strategic (70%) and reactive (30%) conversion provides information on the implementation of the abovementioned risk factors in the indication for LH. Therefore, conversion rate in general, and the rate of strategic conversions in particular, represent a tool for evaluation of LH. Thus, additional insight into the indications for conversion can be acquired, enabling further improvement in the outcomes in LH and preventing unnecessary conversions in future patients.

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