Gynecological Surgery

ORIGINAL ARTICLE Open Access

Comparison of laparoscopy-assisted vaginal hysterectomy as endoscopic single-station surgery and conventional laparoscopic hysterectomy—surgical effects on safety and quality of life

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Abstract

Background: To extend the benefits of minimally invasive surgery, an increasing enthusiasm has emerged for the laparo-endoscopic single-site surgery (LESS). The idea of LESS is to allow inserting multiple laparoscopic instruments through only one umbilical incision instead of multiple abdominal incisions.

Methods: Sixty patients from three different centers in Germany were randomized (1:1) to conventional laparoscopic hysterectomy ($n = 31$) or LESS hysterectomy ($n = 29$). The study focused in particular on the safety and efficacy of both techniques.

Results: The mean operative time was comparable in both groups (68.2 vs 73.6 min., $p = 0.409$; 95% CI − 18.69–7.12). No differences were seen regarding estimated blood loss ($p = 0.915$; 95% CI − 21.02–18.88), intra- and postoperative complications ($p = 0.944$), and wound infection rates ($p = 0.944$). Patients within the LESS group experienced significantly less pain in the first 24 h postoperatively ($p = 0.006$); the pain scores at 3, 5, 7 days and 2 months postoperatively were comparable.

Conclusion: LESS hysterectomy is a reliable and safe option in gynecologic surgery. Compared to conventional laparoscopic hysterectomy, LESS surgery demonstrated comparable surgical properties in regard to blood loss, duration of surgery, and intra-/postoperative complications. Notably, patients undergoing LESS hysterectomy experienced some less pain postoperatively.

Keywords: Gynecological surgery, Laparo-endoscopic single-site surgery, Hysterectomy

Introduction

Since the early 1990s, minimally invasive surgery (MIS) has been rapidly implemented into a variety of surgical disciplines. The main advantage of MIS is the absence of a large abdominal wound, which results in fewer wound-related complications, less postoperative pain, and a shorter hospital stay [1]. In an effort to extend these benefits, an increasing enthusiasm has emerged for the laparo-endoscopic single-site surgery (LESS). In LESS, multiple laparoscopic instruments are placed through one single abdominal incision at the place of the umbilicus.

The hypothesis is that a single incision technique might offer advantages over the standard multi-port laparoscopy such as decreased abdominal wall trauma, following diminished postoperative pain, and improved cosmesis [2–4].

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The potential drawbacks of single-port approaches are a larger umbilical incision and the proximity of the instruments resulting in a technical challenge, especially for advanced surgery [5, 6]. It was only in 1991 that Pelosi et al. performed the first LESS hysterectomy, more than 20 years after the first publication on the LESS procedure in 1969 [7]. Currently, some studies have shown the feasibility of LESS surgery in many benign gynecologic procedures [8]. However, it remains debatable whether this new technology has added value over the existing conventional laparoscopic techniques and whether it should be broadly implemented for hysterectomy.

The trend for minimal invasive surgery dominates in a variety of surgical disciplines [9]. Complication rates such as visceral (0.04–0.075%) and vascular (0.04–0.075%) injury as well as postoperative hernia (0.02%) have been demonstrated to be very low [10–13]. Furthermore, patients reported less pain after laparoscopic surgery [9].

Conventional laparoscopic approaches, however, are associated with tissue trauma correlating with number and size of used ports [2, 3]. LESS is preferred among women undergoing gynecologic surgery who have cosmetic concerns about skin incisional scarring. Furthermore, this approach results in comparable clinical outcomes compared to standard laparoscopic surgery. LESS has been reported showing lower morbidity and better cosmesis [2, 11, 14] and thus has recently emerged as a growing trend in minimally invasive surgery including total hysterectomy.

Several reports suggest the feasibility of LESS surgery in benign gynecologic surgery [8]. However, it still remains unclear whether this new technology has added value over the existing conventional laparoscopic technique and if it seems necessary to implement this new technique into hysterectomy procedures. In Germany, hysterectomy incidence reaches 2.13/1000 per year, and in the USA almost 5.4/1000 per year [15]. The majority of hysterectomies in Germany are performed by vaginal surgery or by laparoscopy, while only 15.7% will be performed by open abdominal surgery. Laparoscopic hysterectomy shows advantages in comparison to vaginal hysterectomy because of access to the ovaries and fallopian tubes, as well as the inspection of the whole abdomen. Although LESS hysterectomy is well-established in some countries, e.g., Korea [16], no data regarding to the proportion of LESS hysterectomy in Germany are available.

Hysterectomy in general is one of the most performed advanced surgeries in gynecology with approximately 600,000 procedures a year in the USA [13]. There are only a few prospective trails and meta-analysis in the literature that evaluate LESS in gynecological surgery. As a result, defining the surgical approach with the most advantages is essential. In this light, the aim of this study is to provide a systematic review and meta-analysis of the current comparative studies specifically evaluating LESS hysterectomy compared to conventional laparoscopy. We particularly focused on safety and effectiveness of both techniques.

Methods

In a prospective randomized multi-center trial, 64 patients from three centers in Germany (University Medicine Greifswald, Dept. of Gynecology; Hospital Damme, Dept. of Gynecology; Medical University Aachen, Dept. of Gynecology) were randomized (1:1) to conventional laparoscopic hysterectomy ($n = 32$) or LESS hysterectomy ($n = 30$). Only patients with benign diseases were included in this trial. The trial was approved by the Ethical Committee (BB 119/11, 30.11. 2011) Medicine University Greifswald. Every patient gave written informed consent.

Patients were excluded from this trial, if they had a lower midline incision, undergoing peritoneal dialysis, ASA > 3, prior umbilical hernia repair, or malignancy of female genital tract. Four patients were excluded because of screening failures. All patients received routine preoperative care including detailed demographic, medical and surgical history, general and gynecological examination, blood examination, and Quality of Life and Pain Scale Survey. All surgeons performed the same technique LAVH, using SILS™ Port or conventional laparoscopy. The following advised products, at least one Cambridge articulating instrument, were used during each surgery: SILSPT12, LF5544, SILSDISSECT36, 5 mm or 10 mm Laparoscope of choice. Five milliliter of 1% Xylocaine has been injected into the skin at the conclusion of the procedure.

Conversion to standard laparoscopic hysterectomy or by introducing an additional lateral port was at the discretion of the surgeon. The investigator specified if an intraoperative device/instrument malfunction occurred, estimated blood loss, any other intraoperative findings or adverse events, and if there was a conversion to standard laparoscopic hysterectomy or laparotomy. The routine postoperative care was prescribed according to the investigator's standard of care.

The investigator reported any postoperative complications that occurred. A physical examination was conducted post-surgery, but prior to the patient discharge. Current medications, post-treatment status of main symptoms, and evaluation of pain score were recorded.

All patients received steri-strips placed on the traditional hysterectomy sites regardless of which arm of the study they were randomized into as described above. The patients were instructed not to remove the steri-strips until they came in for their 1-week visit. The steri-strips were removed after the 1-week pain score and SF-36 have been administered so as not to bias them.

Results

Patients' characteristics

Overall, 60 patients were available for analysis. The baseline characteristics of patients are summarized in Table 1. Patients in both groups were similar in terms of age. Median age was 45 years (range, 24–62) and median body mass index (BMI) reached 24.5 kg/m^2 (range, 17.2–49 kg/m^2). There was no statistically significant difference between the two groups.

Indication for hysterectomy were hypermenorrhea ($n = 37$, 61.7%), atypical hyperplasia ($n = 7$, 11.7%), dysmenorrhea ($n = 9$, 15%), and postmenopausal bleeding ($n = 2$, 3.3%). Diagnosis was not available in five cases. Further, 56.7% of all patients ($n = 34$) experienced prior abdominal (laparoscopy or laparotomy) surgery.

Surgical outcomes

The mean operative time was comparable in both groups (68.2 vs 73.6 min., $p = 0.409$; 95% CI − 18.69–7.12). This difference was not statistically significant. There were no conversions to additional trocars or to laparotomy.

Within the two groups, no differences were seen regarding estimated blood loss ($p = 0.915$; 95% CI − 21.02–18.88), intra- and postoperative complications ($p = 0.944$), and wound infection rates ($p = 0.944$). Only one patient within the control group obtained blood transfusions after surgery ($p = 0.337$). Patients within the LESS group experienced significantly less pain 24 h postoperatively ($p = 0.006$), while pain scores at days 3, 5, 7, and 2 months postoperatively were comparable. The required pain medication at time of discharge was comparable within the two groups ($p = 0.602$). Furthermore, the median duration

Table 1 Patients' characteristics

	Total	LESS	cLS	*p* value
Number of patients, *n*	60	29	31	
Age at surgery, median (years), range	45.0 (24.0–62.0)	45.0 (24.0–62.0)	46.5 (30.0–55.0)	0.728
BMI, median (kg/m^2), range	24.5 (17.2–49.0)	24.4 (21.0–31.1)	24.7 (17.2–49.0)	0.554
Prior abdominal surgery, median (*n*), range	34 (56.7)	16 (55.2)	18 (58.1)	0.821
Laparoscopy	23 (38.3)	10 (34.5)	13 (41.9)	0.553
Laparotomy	19 (31.7)	9 (31.0)	10 (32.3)	0.919
Indication for surgery				
Atypical hyperplasia, *n* (%)	7 (11.7)	2 (6.9)	5 (16.1)	
Hypermenorrhea, *n* (%)	37 (61.7)	21 (72.4)	16 (51.6)	
Dysmenorrhea, *n* (%)	9 (15.0)	2 (6.9)	7 (22.6)	
Postmenopausal bleeding, *n* (%)	2 (3.3)	2 (6.9)	0	
Not available, *n* (%)	5 (8.3)	2 (6.9)	3 (9.7)	
Surgical outcome				
Operative time, mean (min)	70.7	73.6	68.2	0.409
Blood loss, mean (ml)	0	106.7	105.0	0.915
Intraoperative complications, *n* (%)	0	0	0	–
Conversion rate, *n* (%)	0	0	0	–
Postoperative outcome				
Postoperative complications, *n* (%)	2 (3.3)	1 (3.4)	1 (3.1)	0.944
Wound infection, *n* (%)	2 (3.3)	1 (3.4)	1 (3.1)	0.944
Blood transfusion, *n* (%)	1 (1.6)	0	1 (3.1)	0.337
NRS–pain score, mean				
24-h postoperative		4.89	5.84	0.006
At day 3		3.36	3.55	0.667
At day 5		1.96	2.33	0.356
At day 7		1.85	1.38	0.411
2-month postoperative		0.43	0.11	0.154
Required pain medication at time of discharge, *n* (%)	11 (18.6)	6 (21.4)	5 (16.1)	0.602
Hospital stay, median (days), range		4 (2–13)	3 (2–10)	0.551

of hospital stay was comparable in both groups, reaching 3 days (range, 2–10) within the control group and 4 days (range, 2–13) within the LESS group ($p = 0.551$).

Discussion

In this randomized trial, we evaluated safety and effectiveness of LESS hysterectomy compared to the conventional laparoscopic hysterectomy. Our findings confirm the findings from three meta-analyses, defining LESS hysterectomy as a safe surgical procedure [6, 8]. The primary aim of the trial was to evaluate the blood loss during surgery. In both arms, blood loss was comparable. Our findings showed that the LESS hysterectomy had no higher rate of intraoperative complications. Furthermore, no differences with regard to conversion-rate to laparotomy were observed. In the LESS approach, no additional port was needed. In other trials, a frequency of 3.5% to additional port was denoted [17]. Our results demonstrated that LESS hysterectomy was comparable to conventional laparoscopic hysterectomy, mainly depending on the experience of the surgeon. All participating surgeons were certified as MIC-II-III by the German Study Group for Gynaecologic Endoscopy (Arbeitsgemeinschaft Gynäkologische Endoskopie: AGE). Additionally, we demonstrated that the operative time was comparable in both groups which has been confirmed in recent trials [6, 8, 17, 18].

Patients within the LESS group experienced significantly less pain 24 h postoperatively ($p = 0.006$), while pain scores were comparable at days 3, 5, 7, and 2 months postoperatively. The required pain medication at time of discharge was comparable within the two groups ($p = 0.602$).

Postoperative pain is an important issue regarding hysterectomy. The fast recovery after laparoscopic hysterectomy allows better performance also in outcome patient settings. Oral pain medication such as paracetamol or novamin is commonly sufficient for postoperative pain treatment in these patients. Our finding that patients reported less pain 24 h postoperatively confirms the results from other trials [18].

The strength of this study includes the randomized study design and the homogeneity of the included patients. A high BMI index limit was not an exclusion criteria (range, 17.2–49 kg/m^2). The participating surgeons were well experienced and qualified for the trial. As a limitation of this study, it can be considered that the patients of the LESS arm were not given a mock-incision [19]. However, for ethical reasons, this was not permitted in the study design.

The results of the trial show that the LESS hysterectomy is a feasible and safe surgical procedure in gynecologic surgery. Though, we did not find any significant differences in postoperative pain. Directly and 24 h after LESS hysterectomy, a significant lower pain score was observed. This difference was not observed when analyzing only the RCTs. Furthermore, the mean difference did not exceed 1.09 and studies have shown that a mean difference of 2 points on a 10-point scale should be considered as clinically relevant [17]. In addition, it cannot be excluded that enrolled patients in the study are biased with respect to their pain outcomes as, except in one study, the included patients were not blinded to the type of surgery. One single randomized controlled trial applied accurate blinding [20]. Patients and anesthesiology staff who measured the postoperative pain scores did not know which type of approach had been performed, while similar pain scores were found. Cosmetic outcomes are also suggested as an important improvement in the single-site approach, but surprisingly, only a few studies on LESS hysterectomy reported on this topic [14, 21, 22].

Conclusion

Taken together, our study demonstrates that LESS laparoscopy-assisted vaginal hysterectomy is a reliable and safe setup in gynecologic surgery. Compared to conventional laparoscopic hysterectomy, LESS surgery demonstrated comparable surgical properties in regard to blood loss, duration of surgery, and intra-/postoperative complications. Notably, patients undergoing LESS hysterectomy had less pain within the first 24 h after surgery. However, this difference was only about one point in the pain score ($p = 0.006$), which is statistically significant but can presumably be considered without clinical relevance.

Abbreviations

AGE: German Study Group for Gynaecologic Endoscopy; BMI: Body mass index; LESS: Laparo-endoscopic single-site surgery; MIS: Minimally invasive surgery

Acknowledgements

Not applicable.

Authors' contributions

AM, BH, HE, SK-R, JS, DT, IM-H, and DK collected and analyzed the data. MBS and TK analyzed the data. AM, MBS, and DK developed the concepts, designed the study, and wrote the manuscript. All authors read and approved the final manuscript.

Funding

Not applicable.

Availability of data and materials

The dataset supporting the conclusions of this article is available in the Department of Gynecology and Obstetrics at the University Medicine Greifswald, Greifswald, Germany.

Ethics approval and consent to participate

The study was approved by the Ethics Commission of the Greifswald Medical Faculty (BB 119/11, 30.11.2011). Approval and declarations of consent are available at the Medical Faculty Greifswald.

Consent for publication
All authors have read and accepted the final manuscript and agreed to its publication.

Competing interests
The authors declare that they have no competing interests.

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Received: 14 May 2018 Accepted: 7 August 2019
Published online: 16 August 2019

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