

Assessment of the quality of life following laparoscopic vs. abdominal hysterectomy

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Abstract

Hysterectomy is the main surgical procedure used in gynecologic non-malignancies. The aim of this study was to compare the benefits and risks of vaginal laparoscopic hysterectomy versus abdominal hysterectomy.

We focused on the results obtained during a randomized controlled comparative trial observing post-surgery quality of life in total laparoscopic hysterectomy as compared to total abdominal hysterectomy. The RAND-36 health survey was completed by the 60 patients during March 2014 - March 2015.

Results of our study suggest that, when feasible, total laparoscopic hysterectomy may be a beneficial intervention for patients suitable for abdominal surgical approach.

Keywords: *hysterectomy, laparoscopy, quality of life, postoperative health.*

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I. INTRODUCTION

As the most frequently performed among gynaecological interventions, hysterectomy has been the focus of intense research for development of new approaches. First introduced by Reich (Reich et al., 1989) vaginal laparoscopic hysterectomy has now become the most frequently applied alternative procedure to abdominal hysterectomy, and, context permitting, a preferred and advisable option mainly in instances involving gynaecologic non-malignancies (Claerhout & Deprest, 2005; Johnson et al., 2005).

Since its introduction, several variant approaches of laparoscopic hysterectomy have been developed, mainly laparoscopic hysterectomy involving laparoscopic occlusion of arteries in the uterus, laparoscopic-aided vaginal hysterectomy, consisting of vaginal hysterectomy preceded by laparoscopy not involving closing off of uterine arteries and, lastly, total laparoscopic hysterectomy, where vaginal surgery in the entire procedure only consists of removal of the uterus, previously freed by laparoscopic means (Johnson et al., 2005; Reich, 2007; Weizman, et al., 2015).

Unlike for laparoscopic interventions for other purposes, the strategy for laparoscopic hysterectomy has not yet been firmly established (Knook, Stassen, & Bonjer, 2001), for a number of possible reasons among which its longer duration (Maheux-Lacroix, Lemyre, Couture, Bernier, & Laberge, 2015). Not less importantly, more experience is required for mastering it (Torres et al., 2015), an extended learning time marked by higher incidence than for traditional abdominal hysterectomy of complications determined by injury of the urinary tract (Mäkinen et al., 2001) among its advantages, reduced loss of blood (Kale et al., 2014) and febrile morbidity may be noted, shortening hospitalization (Claerhout & Deprest, 2005).

This latter advantage prompted the recommendation in 2003 by a quality of life expert committee concerning application of a health survey (SF-36; RAND-36) in trials for comparative study of health status after hysterectomy (Korolija et al., 2004).

In what follows, we will focus on the results obtained during a randomized controlled comparative trial observing post-surgery quality of life in total laparoscopic hysterectomy as compared to total abdominal hysterectomy.

II. MATERIALS AND METHODS

1. Participants and procedure

The trial in question was a 1-year randomized study conducted in the “Sf. Ioan” Hospital, during March 2014 - March 2015. Trial subjects were included mainly based on the criterion of gynaecological indication for hysterectomy, with negative uterine biopsy. Exclusion criteria

consisted of subtotal hysterectomies, associated procedures, severe systemic conditions, emergency hysterectomies for severe anaemia, personal patient history of malignancy and multiple abdominal procedures (more than one). Written informed consent was required and study approval was obtained from the “Sf. Ioan” Hospital Ethics Committee.

After antibiotic prophylaxis, general anaesthesia was performed on all patients, who were also given anticoagulants during immobilisation (Barber, Neubauer, & Gossett, 2015). Surgery proper was performed by general surgeons with advanced skills in laparoscopic strategies (Copăescu, Munteanu, Iosifescu, Ginghină, & Dragomirescu).

Initially, laparoscopic hysterectomy procedures had been intended as total laparoscopic hysterectomy procedures. Procedures applied were further divided into laparoscopy assisted vaginal hysterectomy, laparoscopic hysterectomy, and total laparoscopic hysterectomy, performed as outlined above (Claerhout & Deprest, 2005). Instrumentation consisted of an optical port at umbilicus or upper level on the xypho-umbilical line, as well as two 2 additional trocars (Garry, 2005).

2. Instruments

The RAND-36 health survey (a generic questionnaire for measurement of health-related quality-of-life) was used for the assessment. Assessment is achieved by means of 8 scales (graded 0-100) measuring subjective health, therefore resulting in a possible total score ranging 0-800 (from poorest to the best ideally quality of life). The 8 scales were assessed by standardised scoring algorithms and summated ratings (DeCherney, Bachmann, Isaacson, & Gall, 2002).

3. Outcome

3.1. Primary study outcome

According to design, the primary study outcome searched was quality of life. As mentioned above, the RAND-36 health survey was used for the assessment. Following randomization, patients were requested to fill in baseline measurements, whereas post-surgery measurements were performed at 1, 2, 4, 6, and 12 weeks. Questionnaires were filled in without professional assistance and then returned by mail.

3.2. Secondary study outcomes

In addition to the primary outcome specified above, the study also yielded secondary outcomes, namely peri- and postoperative development concerning complications, surgical

details and finally the duration of hospitalization. Necessary prospective data were collected by means of a standardized case record form filled in by both performing surgeon and researchers.

Data included intervention times and the amount of blood loss, recorded by the anaesthesiology team. The former was calculated starting with the first incision up to completion of the last suture of the skin from, whereas the latter was derived from total blood loss in suction, draping and gauzing.

Complications were defined as surgery and post-surgery adverse effects and did not refer to transfers from laparoscopy to laparotomy, which were described separately, according to study design. All complications were recorded in case-record templates for 6 consecutive weeks immediately after surgery, in line with a predefined list and ad-hoc for the following 6 weeks, on condition of reasonable relationships to hysterectomy. Information collected also included data related to re-operations, major and minor anaesthesia problems, potential visceral damage and thromboembolism. As far as bleeding complications were concerned, 4 groups were established, namely major hematoma not requiring surgery, major hematoma requesting surgery, haemorrhage with transfusion and blood loss above 1000 dL with no transfusion.

Infection complications were split into several categories, respectively defined as surgical site infections in need of local drainage, urinary tract infections during the first 6 weeks requiring antibiotic treatment in the hospital or at home by the GP (general practitioner), pelvic infections with pus drainage or fever and ultrasound confirmed abscess, and radiograph confirmed chest infections. An additional category consisted of other infections such as serious infusion site infection.

To be considered complications, instances of fever were defined as 38°C or higher temperatures measured on 2 time points at minimum 12 hours intervals, occurring beyond the first day after surgery. Complications related to vaginal stump were established as post-surgery stump dehiscence or vaginal bleeding. Wound dehiscence was further defined as visceral herniation, irrespective of restoration.

Local protocols were applied for post-surgery care, with no interference from the research team. Removal of the urinary catheter was performed the next morning following surgery. Haemoglobin measurements were conducted before the intervention and on the first day after surgery. Information concerning medication given in the first 3 post-surgery days was gathered from respective nursing charts.

Administration of analgesics was in line with a standardised post-anaesthesia protocol based on a 0- 10 visual analogue pain scale, with patients receiving analgesics for pain scores. Discharge from the hospital occurred on cessation of fever, lack of need for systemic analgesics, normal defecation and micturition and restored capacity to mobilize, eat and drink.

3.3. Procedure

Prior to study start, the research team calculated the sample size for administration of the RAND-36 questionnaire for measurement of the quality of life. At the same time, the decision was made to consider differences of 15 per scale (Rock, 2001) as clinically relevant. For a standard 20 deviation, a 0.05 type I error and 80% power, 30 patients were included per study group.

Data collected were analysed based on intention-to-treat. Analysis consisted of calculation of correlations among patients' characteristics at baseline (age, body mass index, and ASA [American Society of Anaesthesiologists] score). Statistical significance of differences in medical outcome were tested between the 2 treatment groups, by means of the t test for normally distributed data and the Mann Whitney U test for data non-normally distributed.

IV. RESULTS

According to Table 1 of the study, 60 women were randomized in two groups, allocating 30 to the study of results after the abdominal intervention and 30 after the laparoscopic intervention. Both groups displayed a statistically significant BMI and ASA score correlation (laparoscopic hysterectomy with $r=0.42$, abdominal hysterectomy with $r=0.58$), whereas all other correlations for patient characteristics were ≤ 0.33 .

Table 1. Patient characteristics and surgical indications.

Parameters		LH (n=30)	AH (n=30)
Age		44 [32-62]	46 [34-62]
BMI		26 [20-34]	28 [22-34]
ASA score		1 [1-3]	1 [1-3]
Primary indication for surgery	Bleeding disorders	24	28
	Other	6	2

In the abdominal hysterectomy group Cronbach's alpha for RAND-36 with the 8 scales was $\alpha = .78$. The Cronbach's alpha for the 8 scales of RAND-36 calculated in the laparoscopic hysterectomy group was $\alpha = .88$. In Table 2 are presented the observed and estimated scores from 2 to 12 weeks after surgery, as well as the observed baseline and 1-week scores of the total RAND-36 score.

Table 2. RAND – 36 level

Parameters RAND-36	Differences (LH > AH)	After surgery effect per week	Baseline
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Physical functioning	7.2 (-0.3-15.9)	3.8 (3.5-4.2)	0.12 (-0.06-0.27)
Social functioning	6.8 (-1.8-15.7)	3.5 (2.5-4.0)	0.34 (0.13-0.56)
Role physical	1.7 (-7.7-11.1)	4.5 (3.2-5.8)	0.05 (-0.02-0.17)
Role emotional	1.4 (-13.4-16.5)	2.2 (1.2-3.2)	0.15 (0.00-0.32)
Mental health	3.2 (-2.8-9.9)	0.6 (0.2-1.4)	0.35 (0.16-0.54)
Vitality	11.8 (4.7-19.3)	2.2 (1.4-2.6)	0.26 (0.12-0.43)
Bodily pain	8.2 (-0.1-17.4)	3.2 (2.4-4.2)	0.37 (0.16-0.54)
General health	0.0 (-7.8-7.8)	0.22 (-0.13-0.57)	0.48 (0.26-0.68)
Total RAND-36	47.28 (-4.9-101.5)	18.3 (15.6-23.5)	0.23 (0.04-0.38)

Providing data on the procedures, intra-surgery complications in the laparoscopic hysterectomy group mainly consisted of one bladder injury determined by post C-section scarring; this was treated by laparoscopic suturing. The group including abdominal hysterectomy patients recorded 2 severe allergic reactions of unknown origin. Both groups showed equal drops in haematocrit and haemoglobin.

In comparison to the abdominal hysterectomy group, the laparoscopic group included a significantly lower number of patients requiring opioid treatment in the first 2 days post-surgery ($p < 0.01$, i.e. 34% vs. 67%). In addition, there were fewer laparoscopic hysterectomy patients requiring antiemetics ($p < 0.07$, i.e. 7% vs. 22%). Notably, no patient in either group needed opioids or antiemetics on the third post-surgery day. Regarding discharge on days 2, 3, or 4 after surgery, 64% of the patients in the laparoscopic hysterectomy group were discharged, as compared to 36% of the patients in the abdominal hysterectomy group ($p < 0.03$).

Regarding complications, in week one after surgery, 3 cases of vaginal urinary loss caused by urethra fistula was noted in the laparoscopic hysterectomy group, which was successfully treated by insertion of a double-J catheter for 4 weeks. On the other hand, two bladder fistulas were noted in the abdominal hysterectomy group. In 92% of laparoscopic hysterectomy patients and 91% of abdominal hysterectomy patients, myoma or adenomyosis were revealed through histological tests.

V. DISCUSSION

A randomized controlled trial has been conducted to establish differences in quality of life following total laparoscopic hysterectomy and total abdominal hysterectomy in patients suitable for both types of interventions. Laparoscopic hysterectomy has been largely recommended by a significant difference reported concerning post-surgery vitality (Nieboer, et al., 2009; Nieboer, Hendriks, Bongers, Vierhout, & Kluivers, 2012), persisting over the entire recovery period up to 12 weeks after surgery. The vitality level is assessed by means of questions on energy loss and fatigue, considered important factors during post-hysterectomy, with fatigue

known for twice more frequent occurrence and persistence than pain (Pinto, McIntyre, Almeida, & Araújo-Soares, 2012).

Confirming previous reports, performance of the laparoscopic procedure was noted to be longer, with equal or favourable results versus abdominal hysterectomy concerning all other parameters.

In the context of 15% to 30% lifetime risk of patients of hysterectomy internationally as well as of a largely variant rates among the three hysterectomy approaches mentioned above (Reichen & Lebec, 2007), assessment of quality of life is of utmost importance in hysterectomy research (Darwish, Atlantis, & Mohamed-Taysir, 2014; Lee, Wen, Lin, & Lin, 2009). This is further advocated by the fact that most hysterectomies are the intervention of choice in cases of benign indications and improved quality of life is the main reason prompting development of the laparoscopic approach. Therefore, quality of life should be a primary concern of reports resulting from laparoscopic hysterectomy research. Results of the present study suggest that, when feasible, total laparoscopic hysterectomy may be a beneficial intervention for patients suitable for abdominal surgical approach.

References

- Barber, E. L., Neubauer, N. L., & Gossett, D. R. (2015). Risk of venous thromboembolism in abdominal versus minimally invasive hysterectomy for benign conditions. *American journal of obstetrics and gynecology*, 212(5), 609-e1.
- Claerhout, F., & Deprest, J. (2005). Laparoscopic hysterectomy for benign diseases. *Best Practice & Research. Clinical Obstetrics & Gynaecology*, 19(3), 357–75.
- Copăescu, C., Munteanu, R., Iosifescu, R., Ginghină, O., & Dragomirescu, C. [Laparoscopic hysterectomy]. *Chirurgia* (Bucharest, Romania: 1990), 102(2), 161–7. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/17615917>.
- Darwish, M., Atlantis, E., & Mohamed-Taysir, T. (2014). Psychological outcomes after hysterectomy for benign conditions: a systematic review and meta-analysis. *European Journal of Obstetrics, Gynecology, and Reproductive Biology*, 174, 5–19.
- DeCherney, A. H., Bachmann, G., Isaacson, K., & Gall, S. (2002). Postoperative fatigue negatively impacts the daily lives of patients recovering from hysterectomy. *Obstetrics and Gynecology*, 99(1), 51–7. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/11777510>.
- Fanning, J., Kesterson, J., Davies, M., Green, J., Penezic, L., Vargas, R., & Harkins, G. (2013). Effects of electrocautery and vaginal closure technique on postoperative vaginal cuff dehiscence. *JSL: Journal of the Society of Laparoendoscopic Surgeons*, 17(3), 414.

- Garry, R. (2005). The future of hysterectomy. *BJOG: An International Journal of Obstetrics and Gynaecology*, 112(2), 133–9.
- Hays, R. D., Sherbourne, C. D., & Mazel, R. M. (1993). The RAND 36-Item Health Survey 1.0. *Health Economics*, 2(3), 217–27. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/8275167>.
- Johnson, N., Barlow, D., Lethaby, A., Tavender, E., Curr, L., & Garry, R. (2005). Methods of hysterectomy: systematic review and meta-analysis of randomised controlled trials. *Bmj*, 330(7506), 1478.
- Kale, A., Aksu, S., Terzi, H., Demirayak, G., Turkyay, U., & Sendag, F. (2014). Uterine artery ligation at the beginning of total laparoscopic hysterectomy reduces total blood loss and operation duration. *Journal of Obstetrics and Gynaecology: The Journal of the Institute of Obstetrics and Gynaecology*, 1–4.
- Kluiwers, K. B., Hendriks, J. C., Mol, B. W., Bongers, M. Y., Bremer, G. L., de Vet, H. C., ... & Broilman, H. A. (2007). Quality of life and surgical outcome after total laparoscopic hysterectomy versus total abdominal hysterectomy for benign disease: a randomized, controlled trial. *Journal of minimally invasive gynecology*, 14(2), 145-152.
- Knook, M. T., Stassen, L. P., & Bonjer, H. J. (2001). Impact of randomized trials on the application of endoscopic techniques for inguinal hernia repair in The Netherlands. *Surgical Endoscopy*, 15(1), 55–8. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/11178764>.
- Korolija, D., Sauerland, S., Wood-Dauphinée, S., Abbou, C. C., Eypasch, E., Caballero, M. G., ... Neugebauer, E. (2004). Evaluation of quality of life after laparoscopic surgery: evidence-based guidelines of the European Association for Endoscopic Surgery. *Surgical Endoscopy*, 18(6), 879–97.
- Lee, C. F., Wen, F. H., Lin, S. S., & Lin, H. M. (2009). Changing quality of life in hysterectomized women. *Journal of the Formosan Medical Association*, 108(5), 414-422.
- Maheux-Lacroix, S., Lemyre, M., Couture, V., Bernier, G., & Laberge, P. Y. (2015). Feasibility and Safety of Outpatient Total Laparoscopic Hysterectomy. *JSLs: Journal of the Society of Laparoendoscopic Surgeons*, 19(1).
- Mäkinen, J., Johansson, J., Tomás, C., Tomás, E., Heinonen, P. K., Laatikainen, T., ... Sjöberg, J. (2001). Morbidity of 10 110 hysterectomies by type of approach. *Human Reproduction (Oxford, England)*, 16(7), 1473–8. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/11425832>.
- Nieboer, T. E., Hendriks, J. C. M., Bongers, M. Y., Vierhout, M. E., & Kluiwers, K. B. (2012). Quality of life after laparoscopic and abdominal hysterectomy: a randomized controlled trial. *Obstetrics and Gynecology*, 119(1), 85–91.
- Nieboer, T. E., Johnson, N., Lethaby, A., Tavender, E., Curr, E., Garry, R., ... & Kluiwers, K. B. (2009). *Surgical approach to hysterectomy for benign gynaecological disease*. The Cochrane Library.

- Pinto, P. R., McIntyre, T., Almeida, A., & Araújo-Soares, V. (2012). The mediating role of pain catastrophizing in the relationship between presurgical anxiety and acute postsurgical pain after hysterectomy. *Pain, 153*(1), 218–26.
- Reich, H. (2007). Total laparoscopic hysterectomy: indications, techniques and outcomes. *Current Opinion in Obstetrics and Gynecology, 19*(4), 337-344.
- Reich, H., DeCaprio, J., & McGlynn, F. (1989). Laparoscopic hysterectomy. *Journal of Gynecologic Surgery, 5*(2), 213-216.
- Reichen, J., & Lebrec, D. (2007). The future treatment of portal hypertension. *Best Practice & Research. Clinical Gastroenterology, 21*(1), 191–202.
- Rock, J. A. (2001). Quality-of-life assessment in gynecologic surgery. *The Journal of Reproductive Medicine, 46*(5 Suppl), 515–9. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/11396385>.
- Torres, D., Lang, T. G., Pasic, R., Biscette, S., Gunaratnam, B., & Shiber, L.-D. J. (2015). Identifying the rate-limiting step in total laparoscopic hysterectomy in a training hospital. *Journal of Minimally Invasive Gynecology*.
- Weizman, N. F., Einarsson, J. I., Wang, K. C., Vitonis, A. F., & Cohen, S. L. (2015). Vaginal Cuff Dehiscence: Risk Factors and Associated Morbidities. *JSLS: Journal of the Society of Laparoendoscopic Surgeons, 19*(2).