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## **Health-related quality of life and postoperative recovery in fast track hysterectomy.**

Running title: *Fast track hysterectomy and quality of life*

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## **Abstract**

*Objective:* To determine whether health-related quality of life (HRQoL) and postoperative recovery of women who undergo abdominal hysterectomy in a fast track program under general anesthesia (GA) differ from women who receive spinal anesthesia with intrathecal morphine (SA).

*Design:* Secondary analysis from an open randomized controlled multicentre study.

*Setting:* Five hospitals in south east Sweden.

*Population:* 180 women admitted for abdominal hysterectomy for benign disease were randomized; 162 completed the study, 80 to GA and 82 to SA.

*Methods:* HRQoL was measured pre-operatively using the EuroQoL EQ-5D and the Short-Form-36 health survey (SF-36) questionnaires. EQ-5D was used daily for one week; thereafter once weekly for four weeks and again six months after operation. SF-36 was completed at five weeks and six months. Dates of commencing and ending sick leave were registered.

*Main outcome measures:* Changes in HRQoL; duration of sick leave.

*Results:* HRQoL improved significantly faster in women after SA than after GA. Sick leave was significantly shorter after SA than after GA (median 22.5 vs. 28 days). Recovery of HRQoL and duration of sick leave were negatively influenced by postoperative complications. In particular, the mental component of HRQoL was negatively affected by minor complications, even six months after the operation.

*Conclusions:* Spinal anesthesia with intrathecal morphine provided substantial advantages in fast track abdominal hysterectomy for benign gynecological disorders by providing faster recovery and shorter sick leave compared with general anesthesia.

## **Keywords**

Abdominal hysterectomy; Anesthesia; Fast track program; Quality of Life; Randomized study.

## **Abbreviations**

ANOVA	analysis of variance
ASA	American Society of Anesthesiologist classification of physical status
GA	general anesthesia
HRQoL	health related quality of life
MCS	mental component summary
PCS	physical component summary
SA	spinal anesthesia with intrathecal morphine
SD	standard deviation

## **Introduction**

Most hysterectomies are carried out to eliminate disturbing gynecological symptoms and consequently improve quality of life (1). Measuring health-related quality of life (HRQoL) is an important way to monitor clinical outcome following such operations. Previous studies have shown substantial improvement in HRQoL regardless of mode of hysterectomy (2-4).

Fast track surgery strategy combines various programs to optimize postoperative rehabilitation of patients. These include giving detailed preoperative information about the perioperative period, optimized opioid-reduced pain management, early mobilization and enteral nutrition (5). Regional anesthesia is often used in fast track surgery to further diminish surgical stress response and facilitate early recovery (6). In obstetrics and gynecology spinal anesthesia is commonly used and intrathecal opioids prolong analgesic effects (7,8).

Studies concerning fast track in general surgery have shown reduced length of hospital stay and postoperative morbidity (9) but have not taken HRQoL into account. The use of a fast track program in connection with hysterectomy has not been much studied to date (10-12). Considering the advantages of fast track programs reported from experience with general surgery, it seemed important to investigate the concept in gynecological surgery and the conceivable associations between use of fast-track and postoperative recovery and HRQoL.

We conducted the open, randomized, multicenter trial “general anesthesia (GA) vs. spinal anesthesia with intrathecal morphine (SA) in fast track abdominal hysterectomy” (“GASPI” study), to compare efficacy of GA and SA in women scheduled for abdominal hysterectomy for benign gynecological conditions. In prior articles, we have reported the primary objective of the trial – duration of hospital stay – and secondary objectives concerning postoperative symptoms (13,14). The present report focuses on HRQoL outcomes and postoperative recovery.

The objective of this study was to determine whether women who undergo GA for abdominal hysterectomy compared to SA in a fast track program differ regarding postoperative recovery and improvement in HRQoL.

## **Material and Methods**

Details of the “GASPI” study design, methods and material including CONSORT flow chart of participants, have been reported (13,14). The study was approved by the Regional Ethical Board at Linköping University and was registered in ClinicalTrial.gov Protocol Registration System (NCT00527332) with initial release September 7, 2007.

<http://clinicaltrials.gov/show/NCT00527332>).

Briefly, in a multicenter trial encompassing five hospitals in the south east health region of Sweden women with benign gynecological diseases, who were scheduled for abdominal hysterectomy in a fast track program, were randomized to have the operation performed under general anesthesia (GA) or spinal anesthesia with intrathecal morphine (SA).

Decisions about mode of hysterectomy and skin incision were made by the surgeon prior to the randomization. The participating surgeons were free to perform the hysterectomies using their customary techniques.

Both modes of anesthesia (GA and SA) were standardized and given in conventional ways. The fast track program specified that there would be no use of sedatives for premedication, i.v. fluid restriction, analgesics based on non-opioids, pre-emptive antiemetic therapy using acupuncture wrist bands, early start of enteral nutrition and mobilization and standardized criteria for discharge. The standardized modes of anesthesia and the content of the fast track program are described in previous published articles (13,14)

Preoperatively, the women completed two questionnaires concerning HRQoL (the EuroQoL EQ-5D and the Short-Form-36 (SF-36)). During the stay in hospital the research nurses and the ordinary nursing staff encouraged the women to fill in the questionnaires according to the study protocol. The research nurse contacted the patient by telephone the day after discharge and then once weekly until the 5-week outpatient visit. The purpose of these contacts was firstly to disclose possible side-effects of the medication under investigation and early detection of complications and secondly to remind the participant to complete the questionnaires. At the 5-week visit emphasis was on registration of complications and information of the *de facto* sick leave. If the sick leave was not concluded at that time the research nurse kept in contact with the patient regularly until sick leave had come to an end. Per- and postoperative complications within five weeks were registered and characterized as major or minor complications.

The patient was eventually contacted by the research nurse six months postoperatively by telephone and a semi-structured interview performed. Besides, the patient completed the HRQoL questionnaires at that time and mailed these by post to the research nurse.

To measure perceived health the patient completed the EQ-5D form preoperatively, daily during the first week after surgery, then once weekly until the 5-week postoperative visit and finally at the 6 month postoperative follow-up .

EQ-5D comprises five dimensions of health (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Each dimension comprises three levels (no problems, some/moderate problems or extreme problems). A unique EQ-5D health state is defined by combining one level from each of the five dimensions. This health state can give rise to a specific health profile and be converted into a weighted health state index by applying scores from EQ-5D value sets elicited from general population samples, to calculate HRQoL (15). The weighted health state index is on a scale from -0.594 to 1. Zero indicates the state of death and 1 good health. A figure less than 0 should indicate a state worse than death. This cannot, for obvious reasons, be translated into a clinical categorization, but for the purpose of tracing and analyzing changes in “health state” over time this makes sense scientifically. For this reason we have not transformed values below zero to zero in this study.

To assess health status and quality of life the SF-36 Health Survey was used preoperatively, at 5 weeks and 6 months postoperatively. The SF-36 questionnaire is a widely used and robust measure of HRQoL in patients and has been translated and validated under Swedish circumstances (16-18).

The SF-36 contains 36 items and measures perceived health status by assessing eight health components (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health). Sum scores are calculated and analyzed to every single component. Additionally, physical component summary (PCS) and mental component summary (MCS) is calculated separately (19). The summary components encompass 35 of the 36 items in the form; 21 in the PCS and 14 in the MCS. A high score represents a better HRQoL.

In the analyses of associations between complications and HRQoL the SF-36 and EQ-5D measurements at five weeks and six months were used. The analysis of SF-36 was limited to the summary component scores, PCS and MCS.

At discharge from the hospital the patient was granted sick leave for 14 days. On the basis of patient demand, the sick leave was prolonged at the telephone contact with the research nurse by at most seven days at a time until the patient was able to return to work or she felt

herself sufficiently recovered. Duration of the sick leave was defined as the time from the day of surgery to the day of return to work (same extent of work as preoperatively). Women, who were on sick leave for other reasons than the hysterectomy, were unemployed or had disability pension were excluded from the analysis of sick leave.

Due to the requirement of data for every moment of measurement in the repeated measures analysis of variance (ANOVA) missing data in the questionnaires with repeated measures were managed in the following way: In the SF-36 a missing cell was substituted by the truncated mean value of the other items in the specific subscale for the individual. If all cells in a subscale were missing the cells were substituted by the truncated mean value of each cell in the group. In case a questionnaire was missing completely on one occasion, each cell was substituted by the truncated mean value of the cell for the group on that occasion. Missing cells for the SF-36 on all three occasions made up 0.44% and a complete SF-36 was missing in 2.26% (11 of 486 cases). Concerning EQ-5D, missing data were found in 38 cases on the 14 occasions of assessment (1.68%). In these cases the weighted health state index was substituted by the mean value of the group. Overall the frequency of missing data was equally distributed between the GA and SA groups.

Women were included between March 2007 and June 2009. Only those women who declared that they wanted to participate in the GASPI study completed the SF-36 and the EQ-5D forms preoperatively, but during the period March 2008 to June 2009, all women admitted to the hospitals for benign hysterectomy were asked to fill in the forms prior to recruitment in the GASPI study. Thus, 84 women who did not want to or could not for various reasons participate in the GASPI study completed the forms and constitute the group of non-participating women.

### *Statistical analysis*

Power calculation of sample size was based on the primary outcome of the GASPI study, i.e. duration of hospital stay, and has been reported (13). No specific power calculations were done for secondary outcome measures.

Continuous data are expressed as median and (range) or mean and (one standard deviation (SD)). The descriptive mode of measures of central tendency and dispersion is stated in the text. Nominal data are presented as numbers and percentage.

Yates' corrected  $\chi^2$  test and Fisher's exact test were used to analyze categorical data. Continuous data were analyzed by means of a Mann-Whitney U-test in univariate analysis. Repeated measures analysis of variance (ANOVA) was used to analyze data measured on more

occasions. Significance level was set at  $p < 0.05$ . All analyses were carried out according to intention-to-treat principles. In addition, per protocol analyses were performed and reported.

The computer software StatView for Windows, SAS Institute Inc. Copyright © 1992-1998. Version 5.0.1 was used.

## Results

Baseline demographic and clinical data have been presented previously (13).

According to EQ-5D, perceived health status at baseline was similar in the two groups. The SA group recovered significantly faster as concerned improvement in HRQoL than the GA group (Figure 1). Per protocol analysis was similar for this aspect.

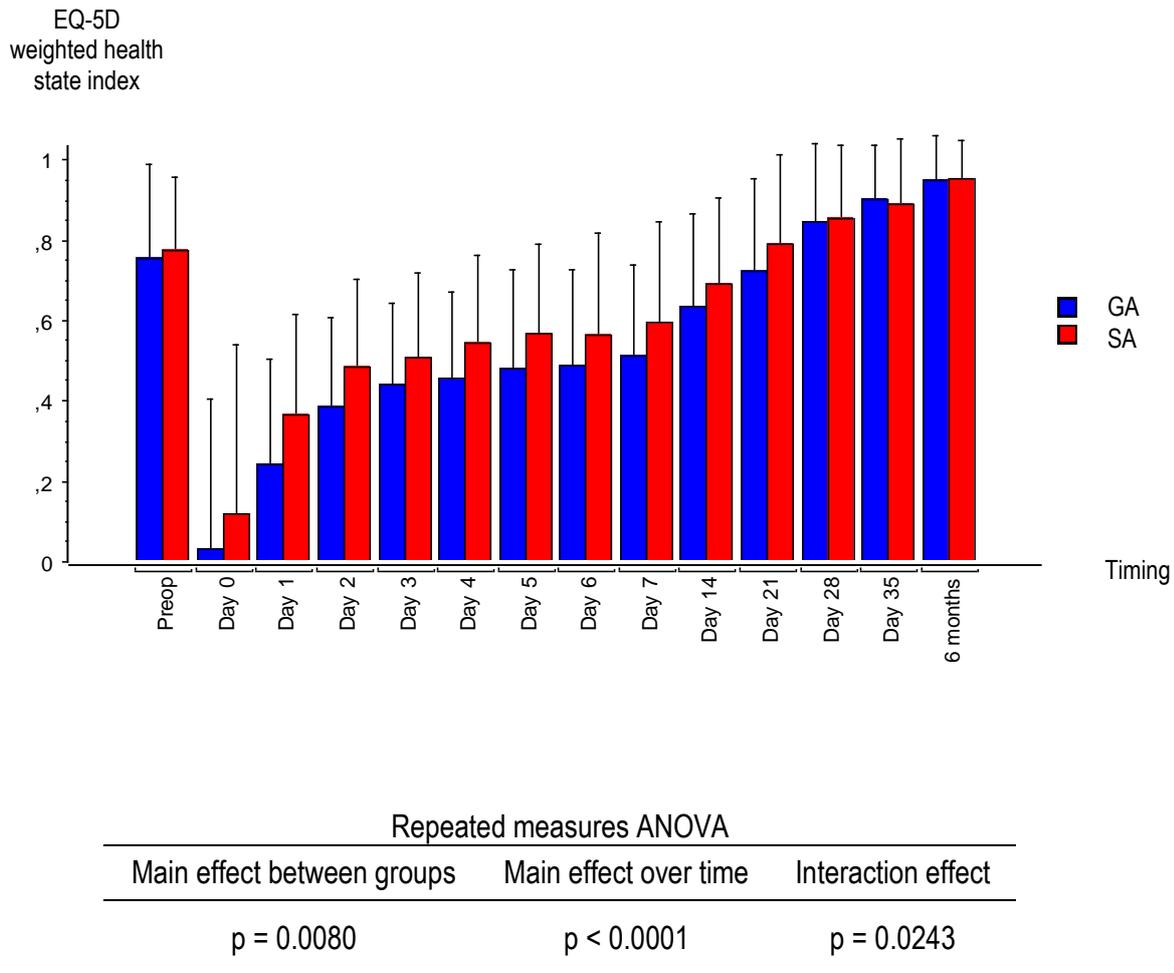


Figure 1: Illustration of EQ-5D weighted health state index in relation to occasion of measurement. Boxes represent means and bars represent 1 SD. The preoperative EQ-5D assessment did not differ significantly between the two groups. Results of the repeated measures ANOVA from Day 0 to the 6 months assessment are presented in the table below the diagram. GA = general anesthesia. SA = spinal anesthesia including intrathecal morphine.

No significant differences were observed between the two groups in any of the SF-36 subscales or component summary scores at baseline except for mental health (p=0.0466). Repeated measures ANOVA concerning SF-36 measured on the three occasions showed that SA was

associated with a better perceived health status than GA concerning bodily pain, vitality, social functioning, role emotional, mental health and MCS (Table 1). On per protocol analyses only bodily pain reached significance in favor of SA.

Details about number and type of complications are presented in Table 2. In total, 29 women (37%) in the GA group had a complication of some kind, which was not significantly different from 28 (34%) in the SA group. Minor complications were disclosed in 23 (29%) women in the GA and 24 (29%) in the SA group, whereas major complications occurred in eight (10%) and five (6%) women, respectively. Per protocol analyses showed similar results. Two women were registered as having a major as well as a minor complication. This did not differ significantly among women with and without a previous laparotomy, mode of hysterectomy or skin incision (data not shown).

At the 5-week evaluation there was a significant difference between women with and without complications concerning PCS (mean score (1 SD): 36 (7) vs. 40 (8),  $p=0.0020$ ), MCS (45 (13) vs. 51 (11),  $p=0.0023$ ) and EQ-5D (0.82 (0.18) vs. 0.94 (0.11),  $p<0.0001$ ).

The significant differences seen at the 5-week assessments concerning PCS and MCS had vanished at the 6-month evaluation. The scores of EQ-5D were still significantly different at 6-months between women with and without complications (0.94 (0.09) vs. 0.96 (0.11),  $p=0.0166$ ).

The occurrence of minor complications had a significant negative impact on EQ-5D outcome ( $p=0.0001$ ) and MCS ( $p=0.0034$ ), but not PCS ( $p=0.0705$ ) at the 5-week assessment. At the 6-month assessment occurrence of minor complications still had a negative impact on MCS outcome ( $p=0.0377$ ), whereas PCS ( $p=0.2032$ ) and EQ-5D ( $p=0.0564$ ) were unaffected.

Considering the occurrence of major complications the outcomes of the EQ-5D and PCS were significantly negatively affected ( $p=0.0095$  and  $p=0.0117$ , respectively) at the 5-week assessment, whereas MCS was unaffected ( $p=0.5254$ ). At the 6-month assessment, the occurrence of the major complications still affected the EQ-5D outcome and PCS negatively ( $p=0.0465$  and  $p=0.0362$ , respectively) and the MCS outcome was unaffected ( $p=0.4460$ ).

Of the women 151 received a sick leave, 73 in the GA and 78 in the SA group. Seven women had disability pension and four were on sick leave for other reasons. There was a significant difference in duration of sick leave between the groups. Median duration in the SA group was 22.5 days (2-258) compared with 28 days for the GA group (7-81); ( $p=0.0059$ ). The per protocol analysis was similar. Complications prolonged the duration of sick leave in general. Women with a registered complication had sick leave duration of median 31 days (6-258). The corresponding sick leave in women without any complication was 22 days (2-60),

( $p=0.0005$ ). This difference was mainly attributed to minor complications (29 days (6-258) vs. 23 days (2-60);  $p=0.0071$ ), whereas the difference between those with and without major complications was not significant (31 days, (13-45) vs. 28 days, (2-258);  $p=0.2557$ ).

The 84 women in the non-participating group were compared with the study group regarding age and preoperative assessments of EQ-5D and SF-36. There were no differences between the groups in these aspects (data not shown).

## **Discussion**

This study demonstrated significant advantages of spinal anesthesia with intrathecal morphine compared with conventional general anesthesia in fast track abdominal hysterectomy regarding improvement in HRQoL and rate of postoperative recovery. Spinal anesthesia with intrathecal morphine contributed to a significantly faster recovery of HRQoL and a shorter sick leave. The HRQoL recovery was strongly associated with the extent of complications.

A multicentre setting was used to ensure better generalizability of the results. Baseline demographic and clinical data for the women showed no significant differences, which indicates that the randomization process had worked well. Analysis of the participating and non-participating women concerning age, and HRQoL measures did not show any difference, which again indicated that the results may apply on a wider scale.

Quality of life is a broad term, covering both HRQoL and non-health or environment-based quality of life (20). HRQoL encompasses domains of life directly affected by changes in health. In this study HRQoL was measured by two methods, EQ-5D and SF-36. EQ-5D is a standardized measure of health status developed by the EuroQol Group, in order to provide a generic measure of health (15). It is applicable to a wide range of health conditions and interventions. Besides, the EQ-5D develops an index which facilitates ranking of the state of health. SF-36 is a generic short-form health measure that has been proven useful in surveys of general and specific populations for differentiating health benefits by a wide range of different interventions (21). The SF-36 creates a health profile that enables comparison within different dimensions of HRQoL. Thus, using two different generic measures of health status further strengthens our results on HRQoL.

There is solid evidence that using fast track strategies will improve clinical outcomes in general abdominal surgery (22), but the issue of HRQoL has not previously been focused upon. Previous studies on QoL in association with abdominal hysterectomy have shown distinct long-term improvements in QoL (2,3,23). There are few publications concerning fast track hysterectomy and none of them focuses on HRQoL (10-12,24). Considering the advantages seen in clinical outcomes following fast track programs it would be reasonable to believe that the HRQoL would also be improved earlier in such a program.

We have demonstrated an association between hysterectomy in a fast track setting and improvement of HRQoL. Use of regional anesthesia to diminish surgical stress response and facilitate early recovery has been a part of fast track programs (6). Spinal anesthesia adding opioids intrathecally prolongs analgesia postoperatively (7,8) and could therefore further

improve early recovery and HRQoL. To our knowledge only three previously published studies, including our own, have compared SA and GA for abdominal hysterectomy (13,24,25), but HRQoL was not covered in the context of those studies. We showed a significant difference between SA and GA with respect to recovery of HRQoL, in particular in the early postoperative period. Women in the SA group recovered faster. In previous studies concerning abdominal hysterectomy and quality of life the measurements were conducted a minimum four weeks postoperatively and do not reflect the immediate postoperative period (1-3,26,27). Improvements in HRQoL were found in these studies, similar with our results, but we also found a remaining difference in the mental components of the HRQoL still six months after the operation favoring women in the SA group. This might imply that an early faster recovery in general may accelerate the mental recovery in particular, or that spinal anesthesia including intrathecal morphine influences the mental recovery differently than general anesthesia within six months after surgery.

Complications registered in this study were comparable to those presented by others (2,3,26,28,29). We found an association between occurrence of complications and lower perceived health status. This may indicate that women with complications have a slower speed in improvement of HRQoL and may not have recovered to the same extent half a year after the operation as women without complications.

There was considerable differences in how minor and major complications influenced HRQoL. This may be interpreted as minor complications mainly exerted an influence on mental functions and to a lesser degree the physical functions. This effect seemed to persist six months after the operation. In contrast, occurrence of major complications influenced physical dimensions of HRQoL and to lesser degree the mental dimensions. Major complications usually develop in connection with surgery or in the immediate future whereas minor complications often occur after discharge from hospital when the individual is trying to regain normal daily activities. The woman probably worries about the discomfort and seeks medical advice. Minor complications therefore might be experienced mentally as more annoying and thus influence the mental dimensions of the HRQoL.

Sick leave is a blunt measure of postoperative recovery and is influenced by medical factors but also by factors not directly related to patient recovery such as governmental regulations, local traditions, economy and patient expectations. Previous studies have shown associations between postoperative complications and sick leave, and postoperative recovery in terms of general well-being and sick leave (29,30). Sick leave was significantly prolonged in

association with occurrence of complications (30). Women with shorter sick leave rated their general well-being higher and had a faster recovery than those with longer sick leave (29).

All citizens in Sweden are covered by a national health insurance covering economic reimbursement during sick leave. There are, so far, no national guidelines concerning length of sick leave after hysterectomy. Duration of sick leave is supposed to reflect length of time needed to recover full working capacity. This implies that attention be given to physical as well as mental dimensions. In this study the women themselves decided when they were capable of returning to work and sick leave was prolonged in a standardized manner. Sick leave in the SA group possibly reflects a faster recovery of HRQoL. One woman in the SA group had a prolonged sick leave (258 days) due to neuralgic pain in the hip and thigh following several attempts to apply spinal anesthesia. Sick leave found in this study was considerably shorter than that usually reported after abdominal hysterectomy (28-31) and even after laparoscopic and vaginal hysterectomy (32). Complications, in particular minor, prolonged the sick leave. This is similar to results from previous studies (29,30). At the same time it was the group with minor complications that experienced their HRQoL impaired even in the long-term.

In conclusion, spinal anesthesia including intrathecal morphine in fast track abdominal hysterectomy enhanced recovery of HRQoL and reduced sick leave compared with surgery under general anesthesia. Occurrence of complications influenced recovery of HRQoL adversely. Preventive measures should be considered to improve HRQoL as quickly as possible. Such measures should include strategies to reduce complications after surgery.

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## **Disclosure of Interests**

None.

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Table 1. SF-36 subscales and summary scores. A high score represents a better health-related quality of life.

SF-36 subscales	Time lapse						Repeated measures ANOVA		
	Baseline		5-weeks		6-months		Main effect between modes of anesthesia	Main effect over time	Interaction effect
	GA	SA	GA	SA	GA	SA			
Physical functioning	83 (21)	87 (15)	78 (21)	80 (19)	92 (14)	96 (9)	$p = 0.0792$	$p < 0.0001$	$p = 0.7889$
Role physical	65 (43)	70 (40)	14 (29)	19 (36)	88 (28)	90 (29)	$p = 0.2890$	$p < 0.0001$	$p = 0.8864$
Bodily pain	60 (28)	67 (26)	45 (20)	54 (24)	90 (20)	91 (18)	$p = 0.0204$	$p < 0.0001$	$p = 0.1532$
General health	76 (19)	76 (21)	81 (18)	81 (19)	85 (17)	85 (19)	$p = 0.9575$	$p < 0.0001$	$p = 0.9663$
Vitality	55 (24)	60 (24)	49 (23)	58 (22)	75 (21)	80 (19)	$p = 0.0210$	$p < 0.0001$	$p = 0.5233$
Social functioning	79 (23)	83 (23)	68 (25)	77 (22)	92 (15)	96 (10)	$p = 0.0248$	$p < 0.0001$	$p = 0.3395$
Role emotional	78 (37)	86 (31)	69 (43)	76 (41)	87 (31)	96 (17)	$p = 0.0297$	$p < 0.0001$	$p = 0.9332$
Mental health	73 (18)	78 (17) *	79 (16)	81 (20)	85 (17)	90 (12)	$p = 0.0495$	$p < 0.0001$	$p = 0.5284$
Physical component summary score	46 (11)	47 (9)	38 (7)	39 (9)	54 (6)	54 (7)	$p = 0.3263$	$p < 0.0001$	$p = 0.6146$
Mental component summary score	46 (12)	48 (11)	47 (11)	50 (13)	51 (9)	54 (6)	$p = 0.0229$	$p < 0.0001$	$p = 0.9412$

Figures indicate mean (1 SD). Round figures are presented for clarity. GA = general anesthesia. SA = spinal anesthesia with intrathecal morphine.

No significant differences were observed in subscales between the two groups at baseline except for "Mental health". (\*  $p=0.0466$ ; Mann-Whitney U-test).

Table 2. Number and type of complications within 5 weeks after abdominal hysterectomy.

Complications	GA (n = 80)	SA (n = 82)
<u>Major complications</u>		
Heavy bleeding, exceeding $\geq 1000$ ml	2 (2.5%)	2 (2.4%)
Blood transfusion (no. of women)	3 (3.8%)	0 (0%)
Bladder injury	1 (1.3%)	2 (2.4%)
Reoperation due to bladder injury	0 (0%)	1 (1.2%)
Reoperation due to retained surgical towels	1 (1.3%)	0 (0%)
Retroperitoneal and subcutaneous emphysema	1 (1.3%)	0 (0%)
Pulmonary embolism	0 (0%)	1 (1.2%)
Post-dural puncture headache	0 (0%)	1 (1.2%)
<u>Minor complications</u>		
UTI	6 (7.5%)	5 (6.1%)
Fatigue	1 (1.3%)	0 (0%)
Pain/neuralgia	5 (6.3%)	4 (4.9%)
Urticaria	1 (1.3%)	1 (1.2%)
Urinary catheter at discharge (no. of women)	2 (2.5%)	2 (2.4%)
Cholecystolithiasis	1 (1.3%)	0 (0%)
Abdominal wound complications*	10 (12.5%)	12 (14.6%)
Vaginal bleeding/vaginal hematoma	3 (3.8%)	2 (2.4%)
Treatment for anemia	1 (1.3%)	1 (1.2%)
Constipation	1 (1.3%)	1 (1.2%)
Sore throat	0 (0%)	1 (1.2%)
Vaginal and oral candidiasis	0 (0%)	1 (1.2%)

Figures denote number and (%). GA = general anesthesia. SA = spinal anesthesia with intrathecal morphine.

\*seroma, hematoma, infection and/or superficial wound dehiscence.

No statistically significant differences were observed in any of the variables between the groups (Yates' corrected  $\chi^2$  or Fisher's exact tests as appropriate).