

30-Day Postoperative Outcome in Patients Undergoing Extensive Gynaecological Surgery

Jacob Thomasson¹, Ulf Schött^{2*} and Peter Bansch¹

¹*Institution of Clinical Sciences Lund, Lund University and Skane University Hospital, Department of Anaesthesiology and Intensive Care, Lund, Sweden*

²*Associate Professor, Institution of Clinical Sciences Lund, Lund University and Skane University Hospital, Department of Anaesthesiology and Intensive Care, Lund, Sweden*

***Corresponding Author:** Ulf Schött, Associate Professor, Institution of Clinical Sciences Lund, Lund University and Skane University Hospital, Department of Anaesthesiology and Intensive Care, Lund, Sweden.

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Abstract

Purpose: Extensive gynaecological surgery is the treatment of choice for advanced ovarian cancer and borderline ovarian tumours. Postoperative complications are common and contribute to patient suffering and medical costs. The purpose of this prospective observation study was to investigate complications and subjective parameters, such as pain and nausea, in patients undergoing extensive cytoreduction surgical procedures at our hospital to lay ground for future improvement.

Methods: Patients undergoing elective laparotomy for suspected advanced ovarian cancer and borderline ovarian tumours were included. Pre- and intra-operative parameters were drafted from anaesthesiology records. Medical records provided data regarding postoperative complications. Pre-formatted inquiries were answered by patients on the first, third, fifth and 30th postoperative day.

Results: Twenty-three patients were included in the study. Fifteen patients experienced complications within 30 days postoperatively, with a total of 38 complications recorded in the study. Only 2 patients experienced severe complications. The most common complications were urinary tract infection (5 patients) and delayed gastric emptying (5 patients). Significant differences in operative time, perioperative intravenous fluid use, perioperative lactate and length of stay were found between patients suffering from complications compared to patients with an uncomplicated postoperative course.

Conclusions: Postoperative complications following extensive cytoreduction surgical procedures are common and further research and resources should be devoted to their prevention, detection and treatment. Postoperative pain management was satisfactory while nausea management could be improved.

Keywords: *Ovarian Cancer; Laparoscopy; Cytoreduction Surgical Procedures; Postoperative Complications; Ovariectomy; Salpingectomy*

Abbreviations

AOC: Advanced Ovarian Cancer; ASA: American Association of Anesthesiologists Physical Status Classification; BOT: Borderline Ovarian Tumours; CD: Clavien-Dindo; DGE: Delayed Gastric Emptying; IDS: Interval Debulking Surgery; IV: Intravenous; NACT: Neo-Adjuvant Chemotherapy; MCCI: Modified Charlson Comorbidity Index; PCA: Patient-Controlled Analgesia; PDS: Primary Debulking Surgery; EDA: Epidural Analgesia; POCD: Postoperative Cognitive Dysfunction; POVN: Postoperative Nausea and Vomiting; SAS: Surgical Apgar Score; SCS: Surgical Complexity Scale; TH-BSO: Total Hysterectomy-Bilateral Salpingo-Ovariectomy; UTI: Urinary Tract Infection

Introduction

Although massive progress has been made in the field of minimally invasive surgery, including the use of laparoscopic and robotic techniques in the field of gynaecology [1], operations for some diagnoses still rely on the use of open techniques which grant surgeons an extensive view over anatomical circumstances and the ability to manipulate tissue with their own hands. One example is the use of extensive cytoreduction surgical procedures in treatment of advanced ovarian cancer (AOC) [2,3], where surgeons must be able to identify carcinosis using both hands and eyes. Often, multiple procedures are necessary to achieve optimal results for the patients. These may include total hysterectomy-bilateral salpingo-ovariectomy (TH-BSO), peritoneal and diaphragm stripping, omentectomy, para-aortic and pelvic lymphadenectomy, splenectomy and bowel resections, depending on the current state of the patient's disease. This procedure, with the exception of lymphadenectomy, is also recommended in patients with borderline ovarian tumours (BOT) [4] although fertility-preserving surgery or primary laparoscopic approaches are feasible alternatives in fertile women [5,6].

Due to the extensive nature of this type of surgery, postoperative mortality and morbidity are important factors to take into account. In patients with AOC, reported 30-day postoperative morbidity range from 11 to 67% [7] with a mean postoperative mortality of 2.8% ranging from 0 to 6.7% [8]. Several predicting factors have been proposed, of which the most studied include age, co-morbidity and extent of surgery. The latter has been standardized by Aletti, *et al.* in the form of Surgical Complexity Scale (SCS) [9]. Other proposed factors are preoperative albumin levels [11], presence of ascites, splenic involvement [12] and preoperative tetranectin concentrations [13], a protein involved in the activation of plasminogen into plasmin in the fibrinolytic system.

Due to the high risk for postoperative complications in these patients, studies imply the importance for individual assessment when selecting the optimal treatment, especially in elderly patients [11]. Primary debulking surgery (PDS) followed by adjuvant platinum-based chemotherapy is the current standard, although a recent review concludes that neo-adjuvant chemotherapy (NACT) combined with interval debulking surgery (IDS) is a viable alternative to PDS especially in patients with bulky disease [14]. A phase III trial included in that review (EORTC 55971) shows lower rates of postoperative haemorrhage, venous thromboembolism and infections in patients undergoing NACT prior to surgery with no significant difference in overall survival, progression-free survival or Quality of life.

In cases of borderline ovarian tumors, few studies exist regarding postoperative complications. A recent study comparing the use of laparotomy and laparoscopy in these patients showed a postoperative morbidity rate of 19.7% in the laparotomy group, compared to 18.2% in the laparoscopy group, although this study is too small to draw any major conclusions [15].

Postoperative pain management is a vital part in the treatment process in patients undergoing extensive surgery as it inarguably leads to diminished patient suffering and faster postoperative recovery. Due to the relatively large incision in the abdominal wall, pain at the site of incision can affect deep breathing and lead to delayed ambulation and a slower rate of recovery from atelectasis, thus increasing the length of stay and the risk for developing pneumonia. Other commonly observed adverse postoperative events in these patients are infections, gastrointestinal complications, nausea and vomiting and less common, cardiac ischemic events [16]. Opioids, local anaesthetics and acetaminophen are used in different combinations and administrative routes to manage postoperative pain in patients undergoing extensive surgery. Intravenous opioids, epidural analgesia (EDA) or a combination of both are most commonly used, either as a continuous infusion, intermittent doses or patient-controlled analgesia (PCA). A prospective randomized study on 120 patients by Tsui, *et al.* concludes that EDA is superior to opioids via PCA in patients undergoing gynaecological laparotomy [17]. EDA also has advantages since systemic opioids are more likely to increase the risk for postoperative paralytic ileus, sedation, respiratory suppression and nausea and vomiting [18]. Postoperative nausea and vomiting (POVN) contributes to patient suffering and can affect patient recovery due to decreased calorie intake, dehydration and electrolyte imbalance.

In this study, we prospectively investigated the 30-day postoperative outcome regarding complications and several subjective parameters in patients undergoing extensive gynaecological cancer surgery. The purpose of this study was to identify the frequency of postoperative complications, to identify perioperative parameters related to complications and to receive patient input regarding subjective postoperative parameters such as pain, nausea and experience of medical care to lay ground for future improvements.

Materials and Methods

All patients gave their informed and written consent to participate and the study were approved by the Regional Ethical Board, Lund, Sweden according to DNRs 2015/916 and 2015/405. The work was carried out in accordance with the Code of Ethics of the World Medical Association (Helsinki Declaration) of 1975, as revised in 1983. The study was a prospective screening study. No power analysis was performed.

Inclusion criteria for the study were patients suffering from confirmed or suspected gynaecological malignancy planned to undergo elective operation via midline laparotomy.

Anaesthesia was standardized and performed with Fentanyl, Propofol, Rocuronium for induction and Sevoflurane for maintenance. For intraoperative analgesia, epidural Mepivacaine with Morphine was used, alternatively Fentanyl where epidural analgesia could not be performed or was insufficient.

Fluid therapy consisted of a baseline intravenous (IV) infusion of 2.5% glucose at 1 ml/kg/h and Ringer's Acetate at 4 ml/kg/h, which could be increased if needed. Colloid infusions were given in form of Albumin 5%, Albumin 20% or Dextran 70 (Macrodex®) at the discretion of the anaesthetist. Erythrocyte concentrate was used to maintain haemoglobin levels above 80 g/L. Blood plasma and fibrinogen was used when blood tests or the clinical situation suggested lack of coagulation factors.

Patients were graded according to American Association of Anesthesiologists Physical Status Classification (ASA), Modified Charlson Comorbidity Index (MCCI) and Performance Status (WHO). Intraoperative data, including length of surgery, blood loss, intraoperative IV-fluids, arterial blood gas values and Surgical Apgar Score (SAS) was collected. Following surgery, Surgical Complexity Score (SCS) was calculated from records provided by the surgeon. Complications arising during hospital stay were actively sought out through journal reviews and regular patient visits and recorded and graded according to the Clavien-Dindo (CD) [19] classification to provide a measurement of their individual severity.

Additionally, to register patient experiences, questionnaires were designed to evaluate subjective parameters such as pain, nausea, well-being and experience of medical care. Patients were asked to answer these questionnaires on the first, third and fifth postoperative day. Thirty days following surgery, patients were contacted by phone and interviewed according to a similar pre-defined questionnaire. In cases of unplanned contact with health care or readmission during the 30-day postoperative period, medical records were retrieved and included in the results. Readmission due to planned chemotherapy was not included in the results. Postoperative complications were pre-defined (See table 3 below). In cases where neither international nor national unanimous definitions existed, complications were defined according to local routines and best knowledge.

Statistics

Mann-Whitney U-test and Students T-test were used to test for statistical significance in between groups regarding perioperative data. $P < 0.05$ was considered significant. Normality tests (Shapiro-Wilk) were performed to decide which test was relevant for each set of data. Data analysis was performed using SPSS software version 22.0.0.0 (IBM Corp. Armonk, NY, US).

Results and Discussion

During the ten weeks study period, 25 patients met the inclusion criteria. 2 patients declined participation, leaving 23 patients that could be included in the study. Questionnaire response rates were 96% (Day 1), 91% (Day 3), 91% (Day 5) and 83% (Day 30). Data regarding length of stay was missing in 2 patients and perioperative arterial blood gas analysis (ABGs) were missing in 3 patients.

Median age was 61.0 years (range 34 - 82). Five patients had ASA I, 15 ASA II and 3 ASA III. Eleven (48%) patients had pre-existing comorbidities (MCCI > 0) with 9 patients MCCI 1, 1 patient MCCI 2 and 2 patients MCCI 2; and 8 (35%) patients had symptomatic disease (WHO > 0) with 7 patients WHO 1, and 1 patient WHO 3 at the time of surgery. Fifteen (65%) patients were diagnosed with malignant disease prior or following surgery, 2 (9%) were diagnosed with borderline tumours and the remaining 6 (26%) had benign disease.

Various intra- and post-operative data are presented in table 1, then split into whether patients had postoperative complications or not (table 2, with significance p value - notations). Significant differences in perioperative parameters between patients who suffered from postoperative complications and patients without complications were found. Operating time, postoperative IV-fluids, total perioperative IV-fluids and perioperative lactate were longer/larger in patients with postoperative complications. The length of stay was also significantly greater in patients suffering from postoperative complications.

Surgical Complexity	Low-complex n = 10 (43%)	Intermediate-complex n = 9 (39%)	High-complex n = 4 (17%)	Total n = 23 (100%)
Operative time (min)	142 88 - 306 (103 - 194)	311 133 - 376 (243 - 365)	393 358 - 411 (353 - 424)	289 88 - 411 (201 - 301)
Blood loss (ml)*	200 50 - 500 (139 - 321)	800 300 - 3500 (281 - 1807)	1050 750 - 1500 (591 - 1584)	500 50 - 3500 (376 - 1020)
Intraoperative IV- fluids (ml)	2285 1260 - 3320 (1873 - 2711)	4455 3120 - 6950 (3726 - 5316)	6020 5375 - 8940 (4003 - 9175)	3830 1260 - 8940 (3098 - 4725)
Postoperative IV- fluids (ml)	1995 1200 - 4200 (1555 - 2881)	3320 1800 - 5045 (2561 - 4231)	4330 2825 - 5410 (2533 - 5915)	2825 1200 - 5410 (2490 - 3566)
Total perioperative IV- fluids (ml)	4325 3000 - 6950 (3538 - 5482)	7850 6500 - 9500 (7036 - 8810)	10900 8200 - 13250 (7326 - 14299)	6950 3000 - 13250 (5742 - 8142)
Perioperative colloids (ml)	0 0 - 750 (- 3 - 403)	1000 500 - 2700 (748 - 1751)	2125 1100 - 2350 (1019 - 2831)	750 0 - 2700 (550 - 1271)
Perioperative erythrocyte transfusion (ml)	0 0 - 0 0%	0 0 - 3000 44%	750 0 - 1000 75%	0 0 - 3000 30%
Perioperative aB - lactate (mmol/mml)*	1.2 0.9 - 1.9 (0.6 - 1.5)	2.4 1.4 - 7.3 (1.1 - 4.3)	3.1 2.2 - 3.3 (2.1 - 3.7)	2.0 0.9 - 7.3 (1.6 - 3.0)
SAS median (range)	7 (4 - 8)	5 (3 - 6)	4.5 (3 - 6)	6 (3 - 8)
Macroscopic radicality (n)	7 (70%)	8 (89%)	4 (100%)	19 (83%)

Table 1: Perioperative data.

Median, range, (95% confidence interval). Median, range, percentage of patients who received perioperative erythrocyte transfusion.

	Patients without complications n = 8 (35%)	Patients with complications n = 15 (65%)	p - value
Age	64 44 - 82 (54 - 74)	59 34 - 78 (53 - 66)	0.373‡
ASAI/II/III n (%)	2/5/1 (25/63/13)	3/10/2 (20/67/13)	0.875
WHO 0/1/2/3 n (%)	7/1/0/0 (88/13/0/0)	8/6/0/1 (53/40/0/7)	0.190
MCCI 0/1/2/3 n (%)	5/1/0/2 (63/13/0/25)	6/8/1/0 (40/53/7/0)	0.776
Preoperative ascites N (%)	4 (50%)	7 (47%)	0.925
Operation time min	133 88 - 305 (97 - 221)	358 89 - 411 (242 - 358)	0.003
Blood loss ml	250 50 - 3500 (- 298 - 1635)	750 200 - 1500 (464 - 962)	0.101
Intraoperative IV- fluids ml	2690 1260 - 4700 (1857 - 3958)	4270 1800 - 8940 (3355 - 5538)	0.060‡
Postoperative IV- fluids ml	1845 1200 - 4020 (1455 - 3028)	3200 1200 - 5410 (2781 - 4114)	0.023‡
Total perioperative IV- fluids ml	4825 3000 - 8600 (3507 - 6805)	7850 3000 - 13250 (6391 - 9397)	0.020‡
Perioperative colloids ml	375 0 - 1600 (5 - 957)	1000 0 - 2700 (654 - 1626)	0.070‡
Perioperative erythrocyte infusion ml	0 0 - 1500 13%	0 0 - 3000 40%	0.357
Perioperative aB - lactate mmol/ml	1.2 0.9 - 1 - 9 (0.9 - 1.8)	2.4 1.2 - 7.3 (1.8 - 3.6)	0.006
SCS median (range)	2.5 (2 - 6)	5 (0 - 12)	0.065
SAS median (range)	6.5 (3 - 8)	5 (3 - 7)	0.076
Length of Stay days	4.5 3 - 8 (3.6 - 6.2)	8 4 - 30 (6.0 - 15.3)	0.013

Table 2: Patients with and without postoperative complications.

Median, range, (95% confidence interval). Median, range, percentage of patients who received perioperative erythrocyte transfusion. ‡ Students T - test.

Postoperative complications are presented in table 3. The most frequent complications found were urinary tract infection and delayed gastric emptying in 5 cases each. Five complications did not fit to our predetermined definitions. These were nevertheless included as they were considered as a deviation from the normal postoperative course.

Urinary tract infection	5	II
Delayed gastric emptying	5	I
Pleural effusion	4	IV, IIIa, I, I
Paraesthesia	3	I
Paralytic ileus	2	IIIb, II
Sepsis	2	II
Intra-abdominal infection	2	II
Postoperative haemorrhage	1	IV
Secondary ventilation	1	IV
Intra-abdominal abscess	1	IIIa
Acute myocardial infarction	1	II
Arrhythmia	1	II
Pneumonia	1	II
Pulmonary oedema	1	II
CVC-infection	1	II
Renal failure	1	I
Psychosis	1	I
Other		
Vaginal tip haematoma	1	I
Haematuria	1	II
Bowel obstruction	1	I
Stomal necrosis	1	IIIa
Ascites	1	IIIa
Total	38	

Table 3: Postoperative Complications.

N: number of patients. *CD:* Clavien Dindo scale 1-IV.

Twenty-one (91%) patients primarily received preoperative EDA as a part of intra- and postoperative analgesia and the remaining two patients received PCA with IV opioid infusion. Postoperative pain management regime had to be altered in 8 (35%) patients due to insufficient or unwanted effect of the epidural analgesia. Reported median pain in rest on postoperative day 1, 3, 5 and 30 was 3 (range 1 - 6), 2 (1 - 8), 3 (1 - 4) and 1 (1 - 4) respectively. Median pain in motion was 6 (1 - 10), 5 (2 - 8), 4 (1 - 8) and 2 (1 - 3) respectively. Median patient estimation of analgesic efficiency was 8 (3 - 10), 8 (4 - 10), 8 (4 - 10) for postoperative day 1, 3 and 5 respectively and median nausea was 5 (1 - 10), 5 (1 - 10) and 3 (1 - 10). 9 (39%), 6 (26%) and 6 (26%) patients reported vomiting during the last 24 hours when answering questionnaires on respective postoperative days. All questionnaire data are shown in Figures 1-4 with boxplot/ median/SD and 95% confidence intervals shown. We did not perform intragroup comparisons between days only descriptive statistics are given due to the small patient number and limitations of our questionnaire (see below).

Within 30 days postoperatively, 7 (30%) patients suffered from complications requiring medical attention after hospital discharge (table 3). 5 (22%) patients were readmitted within 30 days after surgery and underlying diagnoses for readmission were vaginal tip haematoma, pleural effusion, bowel obstruction, intra-abdominal abscess and ascites. 7 (30%) patients reported suffering from bowel discomfort following discharge, 2 (9%) patients reported problems with memory and concentration, 3 (13%) patients reported paraesthesia, 7 (30%) patients reported suffering from pain-related discomfort and 6 (26%) patients reported problems with nausea following hospital discharge.

In this study, we prospectively studied postoperative outcome following extensive gynaecological surgery. Patient satisfaction with analgesia and treatment by medical staff was high, whereas nausea and vomiting was regarded as more problematic.

The frequency of complications recorded in the study (65%) is in the higher interval compared to other studies regarding postoperative complications in AOC and BOT [7,15]. It is important to realize that the rate of complications recorded is dependent on how they are defined in the study design, where an overgenerous inclusion of complications less relevant to the well-being of the patient will contribute to this estimation in the same degree as a life-threatening complication. To stratify the severity of complications, the Clavien Dindo [19] classification was used, a well-proven scale that ranks postoperative complications in an objective and reproducible manner according to the type of interventions required to treat them.

Only two patients developed life-threatening complications, but their intraoperative course did not obviously differ from that of other patients. Furthermore, since the study size was too small, we cannot draw any conclusions about contributing factors or predictions regarding which patients are more likely to develop severe complications. Although life-threatening complications are most feared and cumbersome for the patient, less severe complications contribute to patient suffering and require more medical resources compared to patients with an uneventful postoperative course. Since these less severe complications are frequent, developing measures to detect, avoid and treat them would be of value for a large number of patients.

When evaluating a treatment with such a high rate of complications, it is of utmost importance to take the risk-benefit ratio into account. In our study population, 19 (83%) patients were radically treated, with no macroscopically residual disease, which is the optimal result regarding overall survival [2,3]. In the light of this, many patients would probably accept the relatively high risk related to this type of treatment. Nonetheless, efforts must be made to further reduce risks and improve outcome.

The most frequent complications recorded were urinary tract infection (UTI) and delayed gastric emptying (DGE). Even these less severe complications can lead to further suffering for the patient if not diagnosed and treated in time. UTI can lead not only to discomfort for the patient but also to pyelonephritis and urosepsis, whereas DGE can lead to decreased calorie intake, nausea and vomiting. It is therefore important to further study the extent of these and other less severe complications in order to decrease patient suffering and to improve the postoperative course.

Perioperative factors that differed significantly between patients suffering from complications and patients without postoperative complications were largely dependent on the extent and complexity of surgery. It is reasonable to assume that high complex surgery leads to longer operations and thus greater evaporation from the surgical area and possibly greater blood loss. This in turn may lead to increased haemodynamic stress with lactate generation and the requirement of larger volumes of IV-fluids. No significant correlation between SCS and postoperative complications was found in this study, but this is probably due to insufficient statistical power. On the other hand, our results indicate that the patients who developed complications underwent longer surgeries, needed more perioperative IV-fluids and had higher perioperative lactate values supports the likeliness that these patients underwent more complex surgery. Surgical complexity is a relatively well-studied risk factor for developing postoperative complications [9], and even though our study population is too small to stratify a possible risk, it is important for the responsible surgeon to be aware of contributing risk factors to be able to choose the optimal treatment for the patient. This is also noteworthy in the discussion regarding whether debulking surgery followed by chemotherapy may be favorable for some patients whereas shorter interval surgery combined with NACT may be preferred for others to decrease the rate of postoperative complications.

Subjective data was recorded using self-defined questionnaires; the reason for collecting this type of data was to assess effectiveness of analgesic and antiemetic treatment throughout the treatment process. We believe that the subjective well-being of the patient plays an important role in the recovery process, and some studies suggest that patient satisfaction is a predictor of survival in some malignant diseases [20-22]. Even if it may not improve hard outcome directly related to surgery, it is an important goal from an ethical point of view. Our results show that postoperative pain management (figure 1) was interpreted as satisfactory. Even though 35% of patients had to modify their initial pain management, patient satisfaction was high (median 8 on postoperative day 1, 3 and 5), suggesting adequate pain relief.

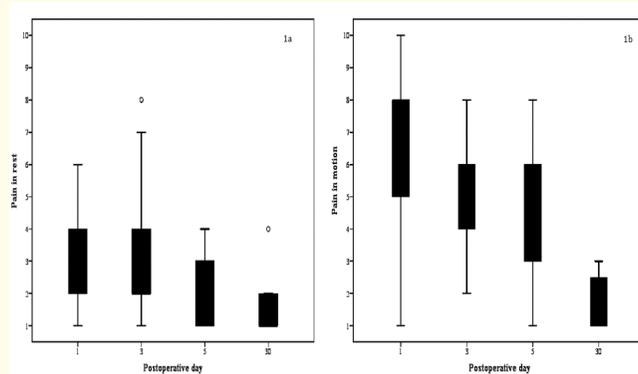


Figure 1: Pain in rest and pain in motion on postoperative. Visual Analogue Scale day 1, 3, 5 and 30.

Postoperative nausea and vomiting (PONV) was common (figure 2), although varied greatly in intensity between patients and no single contributing factor could be identified in this study. Causes for PONV are multimodal [23], with opioid usage being an important factor. Reducing the need for opioids in these patients by optimizing analgesia with non-opioid drugs and regional analgesia is one approach while antiemetic treatment and choice of analgesic drugs are two other important factors in reducing PONV. Despite all attempts to reduce PONV, it is still a major contributor to patient suffering and hopefully, more effective methods to reduce it will be available in the future.

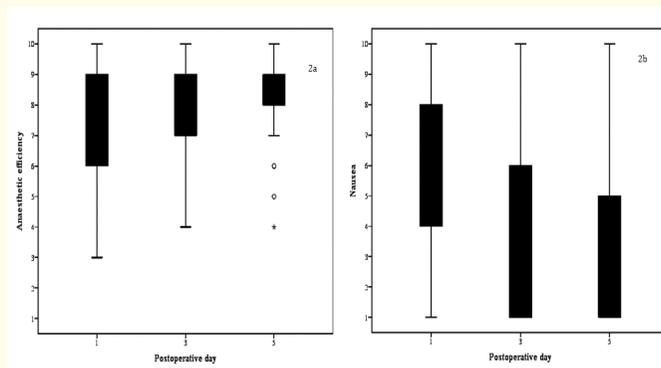


Figure 2: Anaesthetic efficiency on postoperative- and nausea at day 1, 3 and 5. For respective scale see text.

Regarding postoperative memory and concentration (figure 3), patients report a slight negative impact, predominately on the first and third postoperative day. 30-days postoperatively, only 2 (9%) patients reported remaining problems with memory and concentration after hospital discharge. This correlates well with prevailing knowledge about postoperative cognitive dysfunction (POCD) [24], where a significant proportion of patients, especially elderly, are cognitively affected primarily during the first week after major surgery. In our study, we did not use specific tools for examining POCD, and therefore our results cannot be validated or compared to others.

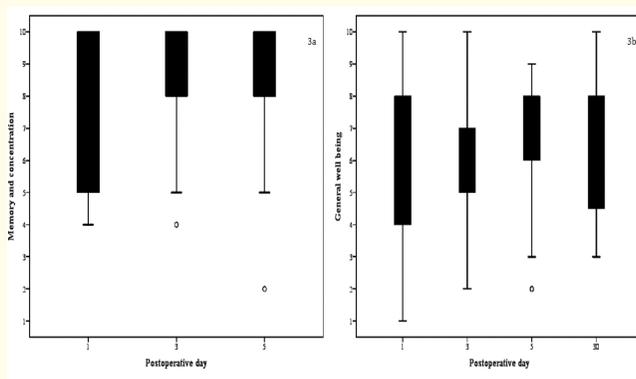


Figure 3: Memory and concentration and general well-being on postoperative on postoperative day 1, 3, 5 and 30. For respective scale see text.

Another factor that probably influences patient well-being and recovery is the treatment by medical staff (figure 4), which was generally considered to be satisfactory. This is encouraging information that in itself may contribute to further improvement of patient care, since personal performance usually improves with positive feedback.

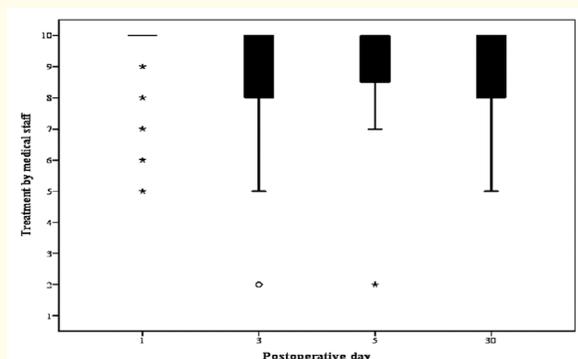


Figure 4: Treatment by medical staff on postoperative day 1, 3, 5 and 30.

Noteworthy is that subjective parameters included in the study are prone to error due to a number of reasons. As parameters, only were measured once a day by the use of a questionnaire, the variance of pain, nausea and other subjective experiences throughout the day were not recorded. Also, the subjective scale is interpreted differently among patients and is thus complex to compare in-between patients and studies. Additionally, questionnaires developed for this study have not been validated, which makes it difficult to compare our results to other data.

Conclusion

A relatively large number of patients suffered from postoperative complications following extensive gynaecological surgery at our hospital. Operating time, lactate values and the amount of IV-fluids given were identified as contributing factors to postoperative morbidity. Surgical complexity is probably another important factor, but the study size was too small to draw any long going conclusions. Patient satisfaction was generally high. As intended, we improved our knowledge regarding objective and subjective postoperative problems which can be used as a basis for future improvement.

Conflict of Interest

There are no financial interest or any other conflict of interests for any of the authors.

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