New Surgical Realities—Implementation of An Enhanced Recovery After Surgery Protocol for Gynecological Laparoscopy: A Prospective Study

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Abstract

Background

Multimodal rehabilitation allows optimization of functional recovery in surgery patients by reducing the post-operative stress and hospital stay duration, without increasing the morbidity and mortality. It is reportedly successful in other surgical disciplines, and guidelines for its application to gynecological surgery are available; however, most evidence for these guidelines is derived from observational and/or retrospective studies. Therefore, this study aimed to investigate the applicability of an enhanced recovery after surgery (ERAS) protocol in laparoscopic gynecological surgery and its influence on the postoperative stay, morbidity, mortality and readmission, through a prospective approach.

Methods

This prospective cohort study was performed on 90 patients who underwent laparoscopic hysterectomy for benign causes from October 2017 to October 2019. Patients in whom the ERAS (ERAS group, $n = 30$) and traditional (control group, $n = 60$) protocols were implemented were compared. All patients were followed for six months.

Results

The groups were homogeneous and did not differ significantly with respect to the demographic characteristics (age, ASA score, body mass index), surgical indications, and surgery types. Adherence to the ERAS protocol was over 99%. The postoperative hospital-stay durations were 1.73 days ($r = 1-3$) and 2.97 days ($r = 2-6$) in the ERAS and control groups ($p = 0.000$). No significant intergroup differences were observed in the rates of complications and readmissions.

Conclusions

The ERAS protocol is applicable in laparoscopic gynecological surgery and can be implemented with good adherence. This can allow optimization of patient recovery by reducing the hospital stay duration, without increasing the rates of morbidity, mortality, or readmission.

Introduction

The practice of multimodal surgical rehabilitation, also known as the intensive recovery program, “fast-track surgery”, or “enhanced recovery after surgery” (ERAS), first emerged at the end of the 20th century with works by Kehlet et al. [1] and Bardram et al [2]. Although ERAS or fast-track surgery protocols were first adopted for colorectal surgeries, the good outcomes obtained have allowed their extension to other specialties.

These programs have a multidisciplinary approach, and their main objective is to improve patient recovery after surgery. To achieve this, patient involvement is fundamental, and it is necessary to develop a pathway that addresses the preoperative assessment and optimization, patient nutrition, surgical analgesia, the surgery itself, and postoperative management.

Currently, there are reference guidelines for the implementation of these protocols within gynecological surgery [3, 4]. However, part of the evidence for the application of different techniques and procedures is derived from studies in other surgical specialties [5]. Therefore, this study aimed to assess the implementation of an ERAS protocol in patients undergoing laparoscopic hysterectomy in a level III center.

The main objective of this study was to achieve the implementation of an ERAS protocol in laparoscopic gynecological surgery. The secondary objectives were to assess its influence on the postoperative stay and the morbidity, mortality, and readmission rates. We assess patients’ adherence to ERAS protocol too.

Material And Methods

Patients

This prospective cohort study enrolled 90 patients who presented to the Hospital Regional Universitario de Málaga from October 2017 to October 2019. Patients who were scheduled for a laparoscopic hysterectomy for benign causes were included, while those who required conversion to open surgery, resided outside our province, and whose ASA score was > II were excluded.

These patients were categorized into two groups: 1) the ERAS group (n=30, patients in whom the ERAS protocol was implemented) and 2) the control group (n=60, patients in whom the traditional protocol was implemented). All patients were followed for six months.

Pre-surgical visit

Pre-surgical visits are one of the pillars of our protocol. During this visit, patients were informed of the procedure to be performed, and the procedure itself was optimized for surgery. Pre-surgical visits were always managed by a gynecologist from our surgery unit.

Surgery

The surgeries themselves were performed by the gynecological surgery unit of our hospital, and were attended by at least one senior surgeon. Furthermore, all personnel involved in the process, i.e., the surgeons, anesthesiologists, and nurses, received specific training on the phases and procedures defined in the ERAS protocols. Likewise, our center's protocol was also developed by adapting the evidence gathered in the available clinical guidelines (Table 1) [3,4,6].

Table 1. The ERAS Protocol.

<p>Pre-operative</p> <p>Inform the patient of her surgery and the protocol to be followed in the consultation</p> <p>Give up tobacco, alcohol and ACHOs 4 weeks before surgery, correcting anaemia</p> <p>Carbohydrate-rich diet the day before surgery</p> <p>6-hour fast for solids and 2-hour fast for clear liquid</p> <p>Abdominal and vaginal shaving (if necessary) of the patient.</p> <p>No mechanical bowel preparation</p>
<p>Intraoperative</p> <p>Anaesthetic induction and anaesthetic maintenance with short-acting agents.</p> <p>Maintain temperature 36°C +/- 0.5 (thermal blankets, hot sera)</p> <p>Pneumatic compression stockings</p> <p>Antibiotic prophylaxis</p> <p>Fluid therapy in continuous perfusion balanced solution. (3-5 ml/kg/h for laparoscopy). Maintain Euvolemia</p> <p>Haemodynamic optimisation through objective-guided fluid therapy (FGO) in risk patients.</p> <p>Postoperative nausea and vomiting prophylaxis with double therapy.</p> <p>No drainage. No nasogastric tube.</p> <p>Infiltration of the laparoscopy ports with Bupivacaine</p>
<p>Immediate post-operative</p> <p>Active temperature maintenance. Maintenance of FiO2 0.5 2 hours after the end of the operation.</p> <p>Analgesia according to the operation. Minimum morphic administration. AVOID OPIOIDS</p> <p>Restrictive fluid therapy.</p> <p>Start of oral tolerance at 6 hours post-surgery, If positive oral tolerance, liquid diet in the evening and removal of intravenous fluids.</p> <p>Beginning of mobilization and prophylaxis of the thromboembolism. at 6 hours after surgery</p>
<p>Post-operative</p> <p>Blood test the morning after the intervention</p> <p>Normal balanced diet according to tolerance.</p> <p>Removal of bladder catheter 12-24 h after surgery</p> <p>Active mobilization</p> <p>Oral analgesia according to protocol. Avoiding morphs. Breathing incentive.</p>

Follow-up

After discharge, the patients underwent an in-person check-up one month after the surgery, and were followed for up to six months to confirm a return to normal activity and to rule out any complications. All post-operative complications were classified according to the Clavien–Dindo classification [7].

Outcomes

Main outcome:

- Achieve the implementation of an ERAS protocol in laparoscopic gynecological surgery.

Secondary outcomes:

- Assess ERAS protocol influence on the postoperative stay and the morbidity, mortality, and readmission rates.
- Assess patients' adherence to ERAS protocol

Statistical analysis

All statistical analyses were performed using the SPSS package v25 (IBM). Qualitative variables were described by counts and frequencies, while quantitative variables were described by means, medians, and ranges. The patient characteristics and distribution were compared between the two groups by using the Student's *t*-test and the χ^2 test. The level of statistical significance was set at $\alpha = 0.05$.

Ethical approval

All the patient were informed and consented to the elaboration and publication of this review. Similarly, the ethics committee of our centre gave its approval

Results

The total adherence to the designed protocol was higher than 99%, based on the evaluation of 14 items from the entire process (Table 2).

Table 2. Adherence to protocol

	Group ERAS
Pre-operative counseling	100%
6-hour fasting	100%
Compression stockings	100%
Antibiotic prophylaxis	100%
Restrictive fluid therapy	100%
Nausea and vomiting prophylaxis	100%
Active heating	100%
Avoiding drainage	100%
NSAIDs as contributors	100%
Laparoscopic port infiltration	100%
Tolerance 6h after surgery	100%
Removal of bladder catheter 1st PO	100%
Avoiding the use of opiates	96.67%
Active mobilisation 1st PO	96.67%
Total Adherence	99.52%

As shown in table 3, the ERAS and control groups were homogeneous with respect to the demographic characteristics (age, ASA, and body mass index), surgical indications, and type of surgery.

Table 3. Group characteristics

	ERAS (n30)	Traditional protocol (n60)	p-value
Age (years)			
Mean (+/- SD)	42.97(+/- 7.88)	43.07(+/- 9.51)	NS
Median (Min/Max)	45 (24/56)	44,5(21/60)	
ASA score			
ASA I (%)	46,7	36.7	NS
ASA II (%)	53.3	63.3	
BMI (kg/m2)			
Mean (+/- SD)	25.83(+/- 3.66)	26.60(+/- 5.14)	NS
Median (Min/Max)	25 (20/34)	25(17/39)	
Surgical indication (%)			
Symptomatic myoma	66.7	63.3	NS
Gender Identity Disorder	23'3	25	
Others	10	11.7	
Surgical procedures (%)			
Total hysterectomy	40	46.7	NS
Subtotal hysterectomy	60	53.3	

Abbreviations: BMI body mass index, SD standard deviation

The mean hospital stay duration was 1.73 days (r=1–3) in the ERAS group and 2.97 days (r=2–6) in the control group protocol (p = 0.000). Up to 40% of the patients in the ERAS group were discharged from the hospital on the first postoperative day.

The incidence of postoperative complications was 6% in the ERAS group and 20% in the control group; this difference was not statistically significant (p = 0.1). In the subgroup analysis of complications (Clavien–Dindo I, II, and III), no significant intergroup differences were observed as well. Furthermore, no grade IV complications were reported. The analysis and distribution of complications is shown in Table 4.

Table 4. Complications recorded in both groups

	ERAS (n30)	Traditional protocol (n60)	p-value
Total	2 (6%)	12(20%)	NS
Grade I	1(3%)	6(10%)	NS
Grade II	1 (3%)	5 (8.33 %)	NS
Grade III	0	1 (1.6 %)	NS
		Vaginal cuff dehiscence	
Readmission in relation with postoperative complications	0	1(1.6 %)	NS
		Vaginal cuff dehiscence	
<i>According to Clavien Dindo Classification</i>			

Discussion

Our study showed that the implementation of an ERAS protocol in gynecological laparoscopic surgery is feasible and decreases the hospital stay duration, without increasing the rates of readmission and complications associated with the surgery.

Despite the fact that ERAS protocols are becoming the new standard for the management of gynecological surgery, much of the evidence and procedures are derived from protocols and studies performed in other surgical specialties [5]. Moreover, studies comparing these protocols in gynecological surgery are usually observational in nature and/or compare the ERAS group with retrospective control cohorts [8,9]. As indicated by Groot et al. [10] in their review and meta-analysis of published studies, the main problem in gynecological surgery is the reliance on observational studies that carry a high risk of bias.

Although it is true that there are clinical trials that have attempted to validate these protocols, these are mainly focused on oncological surgery and their results are inconsistent. For instance, Dickson et al. [11] found no significant differences in the hospital stay duration between the ERAS and traditional protocols, while Ferrari et al. [12] reported a shorter hospital stay duration for the ERAS protocol as compared to the standard protocol.

There are two main difficulties associated with the implementation of the ERAS protocol. One, the need to coordinate and train multiple professionals from different specialties requires a great deal of collaboration from everyone involved in the process. It is essential to reach a protocol that is agreed upon and adapted to the reality of each center and that allows the traceability of each of its items. Reviewing compliance with these items and identifying possible failures or problems are fundamental to the implementation phase, because adherence is directly related to the success of the ERAS program, as shown by several studies [13,14].

Second, our study population initially rejected the reduction in the hospital stay duration, believing that they could receive less attention than necessary for their procedure. Therefore, pre-surgical re-education of patients should be prioritized in order to resolve the doubts and fears that the new protocol may generate. It is also important to design a personalized follow-up

calendar for the patients. In our case, all these visits were scheduled and managed by gynecologists during the implementation process; in some studies, the nursing staff has been trained to coordinate these actions on a larger scale and with a greater number of patients, once the implementation process has been completed. Furthermore, the follow-up visits were performed in person. With a view of expanding the scale of the program, the possibility of including telephone visits after the first 30 days following surgery has been considered in order to combine both actions, as recommended in the literature [15].

Our study has some limitations, including its sample size and the absence of a cost study. However, we believe that its strengths outweigh its weaknesses: it is a prospective study with homogeneous groups, a long-term follow-up, and an adherence-to-the-ERAS-protocol rate of above 99%.

Conclusion

Our study shows that the implementation of an ERAS protocol, and the evidence developed in other surgical specialties regarding it, is also applicable in gynecological laparoscopic surgery. Therefore, it is a feasible option for optimizing the recovery of our patients and reducing their hospital stay, without increasing the rates of complications and readmissions.

List Of Abbreviations

ERAS: Enhanced recovery after surgery

BMI: Body mass index,

SD: Standard deviation

Declarations

Ethics approval and consent to participate

All the patient were informed and consented participate in this study. Similarly, the ethics committee of our centre gave its approval

Consent for publication

All the patient were informed and consented to the elaboration and publication of this review.

Availability of data and material

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request (jcvilches@sego.es)

Competing interests

Nothing to declare

Funding

Nothing to declare

Authors' contributions

JCV Conception & design of study, data collection, manuscript preparation , patient recruitment ; BTS data collection , patient recruitment ; EVM Conception & design of study , BSP Statistical analysis, manuscript preparation; JJJ Conception & design of study, manuscript preparation .All authors read and approved the final manuscript.

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