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Research Article

Enhanced Recovery After Surgery (ERAS) for Para-aortic Lymphadenectomy-A New Trend to Consider?

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Abstract

Background: Enhanced recovery after surgery (ERAS) is a multimodal approach aiming to improve rehabilitation after surgery. In gynecologic malignancies, para-aortic lymphadenectomy (PAL) is indicated for either diagnostic or therapeutic finalities. Minimally invasive surgery (MIS) constitutes the cornerstone for ERAS programs.

Methods: This retrospective study conducted between November 2006 and January 2018, aims to analyze the role of ERAS implementation for patients undergoing PAL. Starting 2016, an ERAS protocol was implemented for all the patients in our institution. All patients who underwent PAL for gynecologic malignancies were included in this study. To analyze the impact of this implementation on the surgical outcomes (length of hospital stay (LOS)) and the post-operative complications, we compared the patients who

underwent PAL within ERAS protocol between 2016 and 2018 "ERAS Group" to the patients who underwent PAL prior to this implementation (between 2006 and 2015) "Prior to ERAS group" Results: A total of 193 patients were identified. "ERAS Group" was associated with a significant decrease of median LOS (2 days vs. 3 days, p<0.001) and a significant increase in earlier post-operative discharges: OR=29.62 [13.58-64.64], p<0.001. Two factors were independently associated with early postoperative discharge: Implementation of the ERAS protocol (OR=25.64 [8.14-80.71], p<0.0001) and the endorsement of the extraperitoneal technique for PAL (OR=5.92 [2.10-16.68], p=0.0008). There was no difference in intra-operative complications rate between groups (p=0.497). More postoperative complications were found in the "ERAS group" (23% vs 10%, p=0.017) but this difference was not significant for severe complications (p=0.277) and lymphocele rate (p=0.248).

Conclusions: Implementing ERAS protocols for patients undergoing minimally invasive PAL is an independent factor improving early recovery and decreasing the LOS without increasing severe complications.

Keywords: Enhanced recovery after surgery; Para-aortic lymphadenectomy; Gynecologic malignancy; Minimally invasive surgery

1. Introduction

Enhanced recovery after surgery (ERAS) is a multimodal approach aiming to improve functional rehabilitation after surgery. Introduced in the 1990s by Kehlet [1-3] for colorectal surgery, its implementation in gynecologic surgery is recent. It is applied for benign [4-6], premalignant [7], and malignant conditions [8-10]. In addition, the ERAS society have established and recently updated the guidelines for pre-operative, intraoperative and post-operative care in gynecologic malignancies [11-13]. Owing to its advantages (less blood loss, shorter hospital stay, shorter recovery and fewer complications), minimally invasive surgery (MIS) has progressively replaced the traditional open surgery over the last 20 years [14, 15]. Widely adopted in the treatment and staging of patients with gynecologic malignancies, MIS constitutes an important pillar of the ERAS programs. Despite the debate concerning the role of para-aortic lymphadenectomy (PAL), it is still indicated for high risk endometrial cancers [14, 16, 17], early stage ovarian cancers [18, 19] and advanced stage cervical cancers [20, 21]. Dargent and Querleu confirmed the feasibility and safety of laparoscopic PAL in gynecologic malignancy [22, 23]. Furthermore, robotic assisted PAL proved to be a reproducible, safe technique that is not associated with an increase in the rate of intra-operative and post-operative complications [24-26]. Our before and after study analyses the outcome of the implementation of ERAS protocols in patients undergoing PAL for gynecological malignancies. The main objective is to analyze the impact of ERAS on the length of stay (LOS) and the post-operative complications.

2. Methods

2.1 Study design

This retrospective study was conducted between November 2006 and January 2018 at the Paoli-Calmettes Institute (Marseille, France), a tertiary cancer center. ERAS protocols were endorsed in our institution in 2016, and were implemented for all the patients with no exceptions. We previously reported our experience in gynecologic surgery [27]. All patients who underwent a PAL for gynecologic malignancies (vaginal, cervical, endometrial and ovarian cancers) with no associated procedures were included in the study. To analyze the effect of implementing ERAS protocols for patients

undergoing PAL, we compared our cohort of patients who underwent PAL after the implementation of the ERAS protocols "ERAS Group" (2016-2018) to those who underwent the same procedure prior to the endorsement of ERAS protocols (2006-2015). Surgical approaches included conventional laparoscopy and robotic assisted laparoscopy. Surgical techniques included both trans-peritoneal and extra-peritoneal approaches. PAL was performed up to the left renal vein cephalad, the ureter and gonadic pedicles laterally and the common iliac bifurcation caudally. In 2017 and after the publication of Azais and al, [28], we changed our practice for locally advanced cervical cancers (LACC) limiting our PAL to the inferior mesenteric artery cephalad. For the trans-peritoneal approach, we followed a 10 step standardized technique that we previously published [29].

For the extra-peritoneal approach: the procedure starts with a standard trans-peritoneal laparoscopy to rule out peritoneal carcinomatosis and perform a peritoneal fluid sampling. Then, a single incision is performed on the patient's left side between the iliac crest and the last rib. A single port device is then inserted. The extraperitoneal space is insufflated. The procedure is then conducted using the same landmarks than the transperitoneal approach. At the end of the procedure, a marsupialization of the peritoneum under trans-peritoneal laparoscopic control is often performed [30]. Patients under 18 years of age, patients having a history of para-aortic surgery, radiation therapy or patients who underwent PAL associated to other procedures (hysterectomy, pelvic lymphadenectomy) were excluded from the study. PAL performed via laparotomy and patients admitted to the intensive care unit for more than one night were also excluded from the analysis.

Data collected included: age, comorbidities, body mass index (BMI), American Society of Anesthesiologists (ASA) score, personal medical and oncologic history, surgery related data (surgical technique, level of PAL, operative time, volume of blood loss, per-operative complication), number of lymph nodes removed, post-operative data (complications, readmission rates and LOS). LOS was defined as the number of nights spent at the hospital from admission to discharge. Early postoperative discharge was defined as LOS $\leq$ 2 days [27]. The Clavien-Dindo classification was used to grade the complications. The return to intended oncologic treatment (RIOT= time between PAL and adjuvant treatment in days) has also been evaluated.

All the members of our medical team underwent a thorough training according to the implementation of the ERAS protocols, including the recently published recommendations and guidelines [11-13]. Written protocols detailing the three phases of ERAS were distributed to all caregivers. The highlights of the preoperative phase are the proscription of bowel preparation and preoperative sedation, and allowing patients to drink clear fluids up to 2h before surgery. The Intra-operative phase is characterized by the prophylaxis for post-operative nausea and vomiting, the maintenance of a "zero fluid" balance and the use of opioid sparing strategies (trunk blocks and oral analgesia (acetaminophen, NSAIDs and level II opioids)). No drains were used and no nasogastric tubes were kept after surgery completion. The post-operative phase consisted of the use of an opioid sparing strategy for analgesia, encouraging the patients to start drinking clear fluids 2h post-operatively and to get out of bed for at least two hours on the evening of surgery. Nurse-led post discharge follow-up were carried up to 30 days' post operatively to detect the slightest complication and to evaluate the compliance of the patients to the ERAS

related post discharge instructions. The study protocol was approved by the institutional review board and the French data protection authority [CNIL declaration number: 2174848]. All included patients provided written informed consent.

2.2 Statistical analysis

All statistical analysis was performed using the SAS® 9.3 software, and statistical significance was set at a p value of 0.05. Patients' characteristics were described using frequencies for categorical variables and means (+/- standard deviations) or median [min-max] for quantitative variables. Chi-square or Fisher's exact tests (categorical variables) and Wilcoxon's tests (quantitative variables) were used to compare the characteristics of the "ERAS group" and "prior to ERAS group". Odds Ratios (OR) after univariate and multivariate analysis were used to evaluate the impact of the ERAS implementation on the early discharge. The other covariates in the multivariate logistic regression included: the surgical approach (extraperitoneal vs trans-peritoneal), the number of lymph nodes resected (>11 vs ≤11), the upper limit of the lymphadenectomy (infra- vs supra-mesenteric) and the BMI (25-30 vs >30 vs <25). An analysis of the morbidity (LOS, complications, consultations in postoperative period and readmissions) was also performed in the subgroup of patients who underwent an extraperitoneal approach.

3. Results

3.1 Population description

A total of 193 patients who underwent PAL for gynecologic malignancies were included in the study. 98 patients were treated before the implementation of the ERAS protocols ("Prior to ERAS" Group) and 95 patients were treated after the implementation of ERAS protocols ("ERAS Group"). Table 1 shows patients and surgical characteristics. There was no significant difference in terms of age, BMI or ASA score between the two groups. However a significant difference was noticed in the surgical indications (p=0.004). A higher proportion of cervical cancer (88%) and a lower proportion of endometrial cancer (8%) were found in the "prior to ERAS" group compared to the "ERAS Group" in which 76% of the cases were cervical cancers and 23% were endometrial cancer

In the "ERAS group", the extraperitoneal approach for PAL was significantly more performed (82% vs. 65 %, p=0.008). After implementation of the ERAS protocols and the subsequent changes in our therapeutic protocols in cervical cancer patients infra-mesenteric PAL was more prevalent in the "ERAS group"(63% vs. 8%, p<0.0001). This evolution in our trends was reflected by a lower number of lymph nodes removed (9 vs 12, p<0.0001) and a shorter operative time (129 vs 180, p<0.0001) in the "ERAS group" (Table 1). No difference was observed between the two groups in terms of intra-operative transfusion rates.

3.2 ERAS implementation and postoperative complications

The characteristics of the postoperative period are shown in Table 2. The ERAS protocol was associated with a significant decrease in the median LOS (2 days vs. 3 days, p<0.001) and a higher rate of early postoperative discharge (83% vs. 14%; p < 0.001). Furthermore, four patients were treated in an ambulatory setting (same-day-discharge) in the "ERAS group". There was no difference in intra-operative complications between the two groups. Post-operative complications were more frequent in the "ERAS group" (23% vs 10%, p=0.017). However, this difference was not significant for grade 3 complications (p=0.277) nor for lymphocele rates (p=0.248). There was no difference in the rate of post-operative consultations and hospital

readmissions. Almost all grade 3 complications consisted of lymphoceles treated with radiologic guided drainage (Grade 3A), except for 3 cases of infected lymphoceles that required surgical management (Grade 3B). There were no grade 4 complications reported during the study period. No significant difference in the Return To Intended Oncologic Treatment (RIOT) between the two groups (p=0.21).

3.3 ERAS and LOS

The "ERAS group" was significantly associated with a higher rate of "early discharge" than the other group (OR=29.62 [13.58-64.64], p<0.001). The multivariate analysis (Table 3) confirmed this finding and showed that the two factors independently associated with "early post-operative discharge" are the Implementation of the ERAS protocols (OR=25.64 [8.14-80.71], p<0.0001) and the endorsement of the extraperitoneal approach (OR=5.92 [2.10-16.68], p=0.0008).

3.4 Extraperitoneal approach

When analyzing patients that were treated exclusively with the extraperitoneal technique, we found that after ERAS implementation, this technique is associated with a decrease of median LOS (3 vs.1, p<0.001) and a higher rate of early postoperative discharge (90% vs. 19%). On the other hand, an increase in the rate of mild (grade 1 and 2) complications was also observed in this subgroup (27% vs 9%, p=0.008).

Characteristics	**Prior to ERAS Group (n=98)**	**ERAS Group (n=95)**	**p-value**
Age (Min-max)			
Median	50.00 [23-79]	53.00 [25-85]	0.279
BMI (%)			
<25	54 (56)	58 (61)	0.786
25-30	28 (29)	24 (25)	
>30	14 (15)	13 (14)	
ASA score (%)			
Score 0	0 (0)	1 (1)	0.48
Score 1-2	88 (94)	89 (94)	
Score 3	6 (6)	5 (5)	
Surgical indications (%)			
Cervical cancer	86 (88)	72 (76)	**0.004**
Endometrial cancer	8 (8)	22 (23)	
Ovarian cancer	3 (3)	0 (0)	
Vaginal cancer	1 (1)	1 (1)	
Surgical technique (%)			
Transperitoneal	34 (35)	17 (18)	**0.008**
Extraperitoneal	64 (65)	78 (82)	
Surgical time (min)			
Median [Min-Max]	180 [120-370]	129 [64-259]	**<.0001**

Number of lymph nodes			
Mean (+/- SD)	13.9 (+/- 7.47)	9.4 (+/- 4.69)	**<.0001**
Median [Min-Max]	12 [1-49]	9 [1-25]	
≤ 11 (%)	46 (47)	67 (71)	**0.0009**
> 11 (%)	52 (53)	28 (29)	
Level of the Lymphadenectomy(%)			
Supra mesenteric	88 (92)	35 (37)	**<.0001**
Infra mesenteric	8 (8)	60 (63)	
Intra- operative transfusion (%)			
No	96 (98)	95 (100)	0.498
Yes	2 (2)	0 (0)	

Prior to ERAS, Patients who had surgery before implementing the enhanced recovery after surgery program; ERAS Group, Patients operated within the enhanced recovery after surgery program; Age, years; BMI (Body mass index; Kg/m2); ASA (American Society of Anesthesiologists); min (minutes); SD (Standard deviation)

Table 1: Patients and surgical characteristics before and after ERAS implementation.

Implementations	**Prior to ERAS group (n=98)**	**ERAS group (n=95)**	**p-value**
Length of stay			
Median [Min-Max]	3 [2-8]	2 [0-10]	**<.0001**
Early post-operative discharge (≤ 2 days) (%)			
No	84 (86)	16 (17)	**<.0001**
Yes	14 (14)	79 (83)	
Intra-operative complications (%)			
No	96 (98)	95 (100)	0.498
Yes	2 (2)	0 (0)	
Post-operative complications (%)			
No	87 (90)	73 (77)	**0.017**
Yes	10 (10)	22 (23)	
Post-operative Complication severity (%)			
Grade 1	1 (10)	6 (27)	0.544
Grade 2	3 (30)	6 (27)	
Grade 3	6 (60)	10 (45)	
Severe post operative complications (%)			
No	91 (94)	85 (89)	0.277
Yes	6 (6)	10 (11)	
Lymphocele (%)			

No	88 (90)	80 (84)	0.248
Yes	10 (10)	15 (16)	
Consultation in post operative period* (%)			
No	86 (90)	81 (85)	0.368
Yes	10 (10)	14 (15)	
Readmission to the hospital for post operative complications (%)			
No	93 (97)	85 (89)	
Yes	3 (3)	10 (11)	**0.042**
RIOT (days)			
Median [Min-Max]	29 [12-60]	32 [13-67]	0.21

Abbreviations: Prior to ERAS: Patients who had surgery before implementing the enhanced recovery after surgery program; ERAS group, Patients operated within the enhanced recovery after surgery program; *consultation unrelated to further treatments; RIOT: return to intended oncologic treatment

Table 2: Descriptive analysis: Morbidity before and after implementation of ERAS.

Effect	**Odds Ratio [95% CI]**	**p-value**
Comparing « ERAS group » and « Prior to ERAS group »	**25.64 [8.14-80.71]**	**<.0001**
Comparing the Extraperitoneal and transperitoneal approaches	**5.92 [2.10-16.68]**	**0.0008**
Comparing the Number of Lymph Nodes removed (> 11 vs ≤ 11)	1.02 [0.40-2.57]	0.972
Comparing the Level of Lymphadenectomy (Infra versus Supra mesenteric)	1.30 [0.41-4.13]	0.660
Comparing BMI 25-30 vs < 25	0.40 [0.15-1.09]	0.072
Comparing BMI >30 vs < 25	1.01 [0.29-3.57]	0.982

Abbreviations: Prior to ERAS group: Patients who had surgery before implementing the enhanced recovery after surgery program; ERAS group: Patients operated with the enhanced recovery after surgery program; BMI, Body Mass Index (Kg/m^2)

Table 3: Multivariate analysis for early post-operative discharge (≤ 2 days).

Implementations	**Prior to ERAS group (n=64)**	**ERAS group (n=78)**	**p-value**
Length of stay (days)			
Median [Min-Max]	3 [2 - 7]	1 [0 -10]	**<.0001**
Early post operative discharge (%)			
No	52 (81)	8 (10)	**<.0001**
Yes	12 (19)	70 (90)	
Post-operative complications (%)			
No	58 (91)	57 (73)	**0.008**

Yes	6 (9)	21 (27)	
Severity of Post-Operative Complications (%)			
Grade 1	0 (0)	6 (29)	0.339
Grade 2	1 (17)	5 (24)	
Grade 3	5 (83)	10 (48)	
Severe post-operative complications (%)			
No	59 (92)	68 (87)	0.334
Yes	5 (8)	10 (13)	
Lymphocele (%)			
No	58 (91)	63 (81)	0.10
Yes	6 (9)	15 (19)	
Consultation in the post-operative period* (%)			
No	55 (89)	65 (83)	0.367
Yes	7 (11)	13 (17)	
Readmission to the hospital for post-operative complications (%)			
No	59 (95)	68 (87)	0.106
Yes	3 (5)	10 (13)	

Abbreviations: Prior to ERAS group: Patients who had surgery before implementing the enhanced recovery after surgery program; ERAS group: Patients operated within enhanced recovery after surgery program; *consultation unrelated to further treatments

Table 4: Morbidity analysis before and after implementation of ERAS in patients treated with the extraperitoneal approach.

4. Discussion

Our results suggest that implementing ERAS protocols for patients undergoing isolated PAL for gynecologic malignancy is an independent factor associated with a reduction of LOS without increasing the rate of severe postoperative complications (OR=25.64 [8.14-80.71], p<0.0001). This study also shows that the extra-peritoneal approach seems to be an independent factor in decreasing the LOS (OR=5.92 [2.10-16.68], p=0.0008). These results are in line with the results of Hudry et al. but non concordant with the results of the STELLA trial [24, 31] in which there was no difference in peri-operative complications and LOS between trans-peritoneal and extra-peritoneal techniques. The ERAS group was significantly associated with more postoperative complications, however the complication rate was consistent with what's reported in literature [32, 33]. The rate of severe complications (grade 3 and 4) was 8.3%, without a significant difference between the two groups. The higher rate of mild complications (grade 1 and2) in the "ERAS group" can be explained by the systematic nurse led post-operative follow up that was established only after ERAS implementation. Regardless of complications, there was no significant difference in the RIOT between the two groups. This novel metric that helps evaluate the impact of the treatment on the oncologic outcome [34].

The most commonly reported complication was retroperitoneal lymphocele which is in agreement with literature review representing 0 to 50% of the complications related to PAL [35-38]. No modifiable factors were identified that can decrease the rate of lymphocele [35]. However, performing a PAL up to the left renal vein increases the risk of lymphocele because of the proximity to the lymphatic collectors [39]. The extraperitoneal approach also tends to increase the risk of lymphocele. Knowing that the benefit of the marsupialization of the peritoneum is still controversial, we did not perform it systematically and thus we cannot analyze it's effect in this study [23, 40]. The shorter operative time in the "ERAS group" is associated with the surgeon's experience in MIS, the larger number of patients who underwent an extraperitoneal approach and the difference in surgical indications between the two groups, in accordance with other publications where a trend of decrease LOS was observed [24]. Following the results published by Azais and al. [28], we performed more infra mesenteric PAL in the "ERAS group" than in the "Prior to ERAS group" (63% vs. 8%, $p<0.001$). Our study confirms that the benefit risk balance is in favor of a therapeutic de-escalation (limiting the lymph node dissection between the common iliac bifurcation to the inferior mesenteric artery) and that is in line with what's published by Leblanc et al. [41].

Our study's major limitation is its retrospective aspect which might cause a selection bias concerning the post-operative complications. Another important factor is the change in our surgical practice which might bias the number of lymph nodes removed and the operative time. We did not evaluate the post-operative pain and the patient's satisfaction in our study, but literature review shows a high satisfaction rate (89%) in the case of ERAS protocol in gynecologic oncology [42]. The major strength of this study is the radical change in our practice in 2016 with the inclusion of all of our patients in the ERAS program. Due to this abrupt change in practice, it was possible to demonstrate a real impact of ERAS program on LOS. Moreover, the large number of patients in our cohort emphasizes the feasibility and the safety of ERAS implementation in complex gynecological surgery. Literature shows that MIS associated with ERAS protocols allows patients undergoing hysterectomy with pelvic lymphadenectomy with or without PAL to be treated in an ambulatory setting. In our ERAS cohort, four patients underwent PAL in an ambulatory setting without an increase in per or postoperative complications. Our experience shows that the association of MIS with ERAS protocols is an important cornerstone in changing the trend from early discharge to same-day-discharge for patients undergoing complex surgeries for gynecologic malignancies [43].

5. Conclusion

MIS is a pillar of the ERAS program. Next to disease stage, the patient general status and the procedure complexity, the two factors found to influence the results are mainly the implementation of ERAS protocols and the surgical approach. This study shows that the extraperitoneal approach for laparoscopic PAL is independently associated with an early post-operative discharge. But more importantly, it shows that implementing ERAS protocols for patients undergoing minimally invasive PAL is an independent factor decreasing the LOS and may constitute a safe step to move to same-day-discharge for patients undergoing complex surgeries for gynecologic malignancies. Further larger prospective studies are required to confirm these results.

Ethics Approval and Consent to Participate

This work was approved by our institutional review board (IPC - Comité d'Orientation Stratégique). All

procedures performed in this study involving human participants were done in accordance with the French ethical standards and with the 2008 Helsinki declaration. All included patients provided written informed consent before surgery.

Consent for Publication

Not applicable.

Availability of Data and Material

Administrative data and clinical data are compiled in a common database and are available to editors and peer reviewers.

Authors' Contributions

Eric Lambaudie, Gilles Houvenaeghel, Clément Brun, Camille Jauffret-Fara, Mellie Heinemann, Guillaume Blache, Laura Sabiani and Marion Faucher have contributed patients to the trial. Isabelle Masquin, Mellie Heinemann and Eric Lambaudie have contributed to the literature search. Christophe Zemmour, Isabelle Masquin, Mellie Heinemann andEric Lambaudie have contributed to the study design. Camille jauffret-Fara, Isabelle Masquin and Mellie Heinemann have contributed to the data collection. Isabelle Masquin, Mellie Heinemann, Christophe Zemmour, Houssein El Hajj and Eric Lambaudie have contributed to the data analysis, data interpretation; writing and reviewing of final manuscript. All authors approve final version of paper for submission.

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