Izkušnje z uvajanjem in skladnostjo delovanja z ERAS® protokolom v majhnem ginekološkem onkološkem centru

Experience involving the implementation and compliance with the ERAS® at a small gynecologic oncology centre

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Ključne besede:
ERAS®, ginekološka onkologija, ginekološka kirurgija

Key words:
ERAS®, gynecologic oncology, gynecologic surgery

Članek prispel / Received
15. 5. 2019
Članek sprejet / Accepted
25. 2. 2020

Naslov za dopisovanje / Correspondence
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Izvleček

Namen: *V prispevku želimo predstaviti rezultate izvajanja in skladnosti z ERAS® protokolom za pospešeno okrevanje po operaciji na manjšem ginekološko-onkološkem oddelku.*

Metode: *Na oddelku za ginekološko onkologijo in onkologijo dojk UKC Maribor smo leta 2015 s pomočjo multidisciplinarnega tima uvedli ERAS® protokol. Izvedli smo prospektivno opazovalno študijo z namenom izvajanja protokola in primerjave podatkov s kohorto iz leta 2005, pri kateri ERAS® protokola nismo uporabljali. Rezultati kliničnih izidov bolnic so bili analizirani v obdobju od leta 2015 do konca leta 2017.*

Rezultati: *Obravnava bolnic po protokolu ERAS® je pokazala jasne koristi*

Abstract

Purpose: *To present the results of implementation and compliance with enhanced recovery after surgery (ERAS®) in a low-volume gynecologic oncology department.*

Methods: *In the Department of Gynecologic and Breast Oncology (Maribor, Slovenia) the ERAS® protocol was prepared by a gynecologist, anesthesiologist, and abdominal surgeon in 2015. A prospective observational study was developed with the aim of implementing the protocol and to compare the data with a historical cohort from 2005. Clinical audit results were analyzed from 2015 until the end of 2017.*

Results: *The ERAS® protocol showed clear benefits for patients who un-*

za bolnice, ki smo jih zdravili zaradi ginekoloških malignomov ali večjih benignih tumorjev. Korist se je kazala predvsem v kratkem staležu v polintenzivni enoti, krajši hospitalizaciji in nizki stopnji ponovnega sprejema na oddelek po odpustu. Pooperativna slabost je bila prisotna le v prvih 24 urah. Stopnja pooperativnih zapletov je bila nizka. Večja odstopanja od protokola so bila prisotna le pri 6,8 % bolnic. Odstopanja od protokala so bila povezana z močnimi osebnimi prepričanji kirurga. V spremljani skupini smo opazili nizko stopnjo epiduralne postavitve katetra (14 %), predvidoma zaradi pomanjkanja strokovnega znanja / navade. Ob načrtovani resekciji črevesja z anastomozo se je abdominalni kirurg vedno odločil za drenaže zaradi osebnega mnenja / navade. Drenaža je bila v povprečju odstranjena drugi pooperativni dan, brez anastomotičnega puščanja.

Zaključek: *Glavni razlogi za neupoštevanje protokola ERAS® pri vodenju bolnic so bili povezani predvsem z močnimi osebnimi mnenji / navadami izvajalcev protokola. Izvajanje potencialnih multicentričnih raziskav in spodbujanje sprememb klinične prakse na nacionalni ravni bi lahko izboljšalo skladnost z novimi protokoli.*

derwent surgery for gynecologic malignancies or large benign tumors. The patients had short hemi-intensive unit stays, short hospitalization stays, and low re-admission rates. Post-operative nausea if present, persisted only during the first 24 h. The rate of post-operative complications was low. Complete non-adherence was present in only 6.8 % of patients and was associated with the opinion of the surgeon. A low rate of epidural catheter placement was observed (14 %) and was likely associated with a lack of expertise and habit. When bowel resection with anastomosis was planned and performed, the abdominal surgeon elected for drain placement in all cases, again due to opinion and habit. The drains were removed on the second post-operative day and no anastomotic leakage was noted.

Conclusions: *The main reasons for non-adherence to the ERAS® protocol in a low-volume department were largely associated with strong personal opinions and habits. Conducting prospective multicenter research and promotion of clinical practice changes on a national level could improve compliance with the novel protocols.*

INTRODUCTION

The enhanced recovery after surgery (ERAS®) or ''fast-track'' surgery protocols have been widely studied and implemented to various degrees in everyday clinical practice since the first publications in colorectal surgery (1-3). The main aim of ERAS® is a reduction in hospital stay with an associated reduction in costs, but also to identify and reduce the physical stress response with multi-organ dysfunction provoked by the surgery. The ERAS® Society was formed and defined the multimodal peri-operative protocols for different surgical fields to achieve faster recovery for patients undergoing major surgery. The ERAS® Society recommendations for pre- and intra-operative care in gynecologic/oncology surgery have been developed and were published in 2016 (4, 5). As a general overview, the protocol de-escalates the use of pre-operative laxatives, and supports the use of fluids up until a few hours before surgery and soon after the surgical procedure. The protocol also limits intravenous fluid use and decreases antimicrobial therapy in comparison to standard pre- and peri-operative therapy. As part of the surgical therapy, minimally invasive surgery is the preferred mode of treatment and the protocol suggests the avoidance of routine drainage and nasogastric tube. Furthermore, early patient mobilization post-operatively is suggested (4, 5). Our Department for Gynecologic and Breast Oncology at the University Medical Centre (Maribor, Slovenia) is a small gynecologic oncology center with approximately 50-60 new endometrial cancer patients, 40-50 ovarian borderline and invasive cancer patients, and 10 cervical cancer patients per year with 2-3 primary surgeons performing all of the surgeries. The department offers diagnostics for suspected gynecologic malignancies, surgical treatment of confirmed and suspected pre-malignant and malignant lesions as well as larger benign tumors, and provides palliative care for the patients. The department is an

ESGO and CEEGOG member and participates in multicenter studies.

Although there is emerging evidence of the benefits of the ERAS® protocols, the heterogeneity of evidence and the fact that change in practice is usually slow and challenging suggests that the implementation of and compliance with ERAS® is still challenging (6,7). We present our experience of commencing and sustaining the program in a department and university hospital that has a small patient volume and close personal working relationships which create unique circumstances for research and practical clinical development.

METHODS

After a careful literature and congress report review, some parts of the so called ''fast-track'' protocols were occasionally introduced in a stepwise fashion in our department late in 2013. Specifically, mechanical bowel preparation was omitted, starting with early liquid oral intake and avoiding prophylactic drainage and early mobilization. Antibiotic prophylaxis and thromboprophylaxis were already standard of care at that time. However, major personal concerns were expressed by some gynecologic surgeons, abdominal surgeons, and anesthesiologists, and thus the newly introduced clinical practice was stopped.

To proceed with implementation, a structural program was designed. First, a meeting with an abdominal surgeon, who was experienced and educated in ERAS®, and an anesthesiologist, who predominantly worked at our operating room, was arranged. Together, we prepared a hospital-specific protocol for our patients who were undergoing major surgery for malignant or benign large tumors. The protocol was written and defined as follows: (i) pre-operative counseling for the patients; (ii) pre-operative mild laxatives and no mechanical bowel preparation; (iii) 2 dcL of sweet tea at 6 o'clock on the morning of surgery for all patients; (iv) placement of an epidural catheter for patients undergoing a laparotomy if no contraindications exist; (v) regular application of analgesics from two different groups (paracetamol and metamizol) with patient-controlled application of opioid analgesics, introduction of oral analgesics as soon as possible, and locoregional analgesia for laparotomies; (vi) personalized intravenous liquids of no more than 3 liters within 24 h after surgery; (vii) controlling of glucose and potassium levels 3 h after surgery and correction, if necessary; (viii) regular antiemetic prophylaxis with up to 3 different antiemetic drugs; (ix) introducing liquid oral intake on the evening after surgery; (x) avoidance of routine drainage (only for bleeding control in selective patients for 24 h); (xi) avoidance of a nasogastric tube; (xii) early mobilization, preferably a few hours after surgery; and (xiii) use of a minimally-invasive approach and careful surgical technique. The recommended therapy was written on special stickers for user-friendly purposes. It is worth mentioning that our patients usually spend the first 24 h after surgery in a hemi-intensive care unit (if there was no need for peri0operative intensive care unit referral), led by gynecologists.

The educational meetings were performed for gynecologists in our Division of Gynecology and Perinatology and for our nurses and operating nurses, as well as our physiotherapist. We intended to conduct a prospective observational study of all consecutive patients undergoing surgery by one surgeon in a 6-month timeframe to obtain the informed consent from the patients, as was suggested by other members of the team. The study was therefore designed with the purpose to structurally introduce the protocol to everyday clinical practice. The Institutional Review Board approved the protocol. Following collection, we then compared the data with data from a cohort of consecutive patients operated in a 6-month period in 2005 before implementation of any parts of the ERAS® protocol. Patient paper documentation was clearly marked with a colorful sticker (fast track protocol). The data were analyzed with Chi-square tests for ordinal and non-parametric Mann-Whitney or Kruskal-Wallis test for nominal parameters. A P-value <0.05 was set as statistically significant. IBM SPSS statistics (version 22) was used for statistical analysis. The results are presented as fractions and median values with minimum and maximum values, as appropriate.

After analyzing our results and the decision to implement the ERAS® was made, the clinical audit system was

prepared. Thus far, we have analyzed the consecutive patients who underwent major surgery at our department from the second half of 2015 when the first systematic implementation started until the end of 2017. The results are presented as fractions, median values with minimum/maximum values, and average values with standard deviations, when appropriate.

RESULTS

In the experimental timeframe of 6 months in 2015, a total of 39 consecutive patients were included and compared with a cohort of 40 consecutive patients in 2005. There were no statistically significant differences regarding the diagnosis (ovarian cancer, uterine cancer, or benign large tumors) and FIGO stage for malignant tumors between the experimental years (2005 and 2015). The age of the patients did not differ (59.7±12.2 years [2005] vs. 62.8±11.3 years [2015], P=0.239).

Significantly more patients underwent a laparoscopic approach in 2015 (1/40 [2.5%] in 2005 vs. 17/39 [43.5%] in 2015 P=0.000). Approximately the same number of patients had a hysterectomy with or without an adnexectomy (19/40 [47.5%] in 2005 vs. 19/39 [48.7%] in 2015); however, more extensive cytoreductive surgery was more frequent in 2015 (4/40 [10.0%] in 2005 vs. 13/39 [33.3%] in 2015; P=0.026). Planned bowel resection was performed in 2 patients in 2005 and in 1 patient in 2015. The median operating time was 129 min (range, 65-195 min) in 2005, whereas it was 122.1 min (range, 40-265 min) in 2015 (P=0.169). There were no significant differences in the intra-operative complication rates. The results are presented in Table 1.

Table 1. *Comparison between the cohort of consecutive patients followed by classic peri-operative treatment in 2005 and patients, followed by hospital-specific ERAS® in 2015, in the same timeframe*

		2005	2015	P value
Diagnosis	Uterine malignancy	22/40 (55.0 %)	22/39 (56.4 %)	0.865
	Ovarian malignancy	9/40 (22.5%)	10/39 (25.6 %)	
	Large benign tumors	9/40 (22.5 %)	7/39 (17.9 %)	
FIGO stage	FIGO stage I/II	20/29 (68.9 %)	25/32 (78.1 %)	0.834
Associated medical conditions		25/40 (62.5 %)	32/39 (82.0 %)	0.003
Median intra-operative blood loss		202 mL (from 0 to 1200)	275 mL (from 0 to 3700)	0.764
Rate of intra-operative transfusion		5/40 (12.5 %)	4/39; (10.3 %)	0.754
Rate of post-operative transfusion		10/40 (25.0 %)	3/39 (7.7 %)	0.038
Drainage		26/40 (65.0 %) Median duration 6 days (from 0 to 16)	3/39 (7.7 %) Median duration 2 days (from 1 to 2)	0.000 0.005
Median time of intravenous opioid analgesics Laparotomy only		3 days, from 0 to 9 3.0 days, from 1 to 9	1 day, from 0 to 2 1.0 day, from 0 to 2	0.000 0.000
Median time of intravenous analgesia Laparotomy only		3.5 days, from 2 to 21 4.0 days, from 3 to 21	2 days, from 1 to 5 3.0 days, from 1 to 5	0.000 0.026
Complete restriction of solid/liquid oral intake		1 day (from 0 to 6 days)	No patients	
Median time for introduction of solid food		3 days (from 2 to 8 days)	2 days (from 1 to 2)	0.000
Rate of post-operative ileus		1/40 (2.5 %)	2/39 (5.1 %)	0.541
Median hemi-intensive care unit stay Laparotomy only		3 days (from 1 to 7) 3.5 days, from 1 to 7	1 (from 1 to 2) 1.0 day, from 1 to 2	0.000 0.000
Median hospitalization stay Laparotomy only		10 days (from 2 to 25) 10.0 days, from 5 to 25	4 days (from 2 to 17) 6.0 days, from 2 to 17	0.000 0.000
Rate of post-operative complications		10/39 (25.6 %)	4/39 (10.3 %)	0.077
Rate of post-operative antibiotic prescription		11/39 (28.2 %)	8/31 (20.5 %)	0.429
Rate of 30 days re-admission		2/32 (6.3 %)	4/39 (10.3 %)	0.546

Up to the end of 2017, a total of 139 patients were followed by hospital-specific ERAS and in only 10 of 149 patients (6.7 %) did the surgeon adopt a classic peri-operative strategy. Among those patients followed by ERAS®, 65 of 139 (46.8 %) underwent surgery for endometrial cancer, 6 of 139 (4.3 %) underwent surgery for cervical cancer, 45 of 139 (32.4 %) underwent surgery for ovarian cancer, and the remaining 23 of 139 (16.5 %) underwent surgery for large benign tumors. Approximately one-half of the patients were operated on laparoscopically (71/139 [51.1%]), among whom 10 were converted to laparotomy (14.1%) following intra-operative frozen section results, a uterus too large for vaginal extraction, or intra-operative surgical or anesthetic complications. Extensive cytoreductive surgery was performed in 38 of 139 (27.3%) patients, radical hysterectomy was performed in 5 of 139 (3.6%) patients , hysterectomy with pelvic/paraaortic lymphadenectomy was performed in 23 of 139 (16.5%) patients, and hysterectomy with or without adnexectomy was performed in 72 of 139 (51.8%) patients. The cytoreductive surgery was radical with no macroscopically residual tumor in 33 of 38 (86.8%) patients. Planned bowel resection was performed in 8 of 139 (5.8%) patients. Only 34 of 139 (24.5 %) patients did not have co-morbidities. The clinical outcomes are presented in Table 2.

Table 2. *Clinical audit of hospital-specific ERAS® (2.5 years)*

Median and average intra-operative blood loss	100,0 mL (from 0 to 3700) 270.9 ± 535.4
Intra-operative blood transfusion rate	10/139 (10.1 %)
Post-operative blood transfusion rate	9/139 (6.5 %)
Post-operative drainage Median time of drain placement Drainage after bowel resection Median time of drain placement after bowel resection	24/139 (17.6 %) 0.5, from 0 to 10; 1.4±2.1 8/8 (100%) patients 2.0 days (from 1 to 4)
Epidural catheter	11/139 (7.9 %); patients with laparotomy 10/68 (14.7 %)
The median time and average time of intravenous analgesia Laparotomy only	2.0 days (from 1 to 15) 2.8±2.2 days 3.0 (from 1 to 15); 3.6±2.5
The median time and average time of opioid intravenous analgesia Laparotomy only	1. day (from 0 to 15) 1.4±1.6 days 1.0 (from 0 to 15); 1.6±1.9
Median time and average time for liquid oral intake	1.0 day (from 0 to 15) 1.4±1.6 days
Median time and average time for solid food intake	2 days (from 0 to 11) 2.0±1.0
The median time and average time of duration of post-operative nausea	0 days (from 0 to 4) 0.29±0.7
The rate of post-operative ileus	6/139 (4.3 %)
Post-operative antibiotic therapy (with or without clinically evident infection)	29/139 (20.9 %) Median duration 1.5 days (from 0 to 17)
Median time and average time spent in hemi-intensive care unit Laparotomy only	1. (from 0 to 14) 1.3±1.3 1.0 (from 1 to 5); 1.4±0.9
Median and average hospitalization stay Laparotomy only	4.0 days (from 1 to 46) 5.6±5.0 days 5.0 (from 2 to 22); 6.6±3.9
Re-admission rate 30-days after discharge	10/139 (7.2 %)

Twenty-two of 139 (15.8%) patients had a post-operative complication, among whom 6 (26.1%) had infections, 2 (8.7 %) had major bleeding, 1 (4.3 %) had a major medical complication, 1 (4.3 %) had a bowel perforation, and 1 (4.3%) had a thermal injury involving the ureter after radical hysterectomy. There were 5 of 139 (3.6%) patients who needed re-admission to the hemi-intensive care unit. Two post-operative deaths occurred, with 1 secondary to bowel perforation (the patient had ovarian cancer and underwent

neoadjuvant chemotherapy with several medical co-morbidities, including compensated primary liver cirrhosis) and 1 was secondary to unrecognized acute paraneoplastic hyponatremia with advanced FIGO stage III endometrial cancer. There were no cases of dehiscence of bowel anastomosis when planned bowel resection was performed.

DISCUSSION

The results from an observational cohort study, including consecutive patients within the same 6-month timeframe in 2005 before the introduction of the ERAS® protocol, were compared prospectively to patients in 2015 and showed a shorter hemi-intensive care unit stay and a shorter hospitalization stay with no increase in the re-admission rate when the hospital-specific ERAS® protocol was implemented. Although significantly more patients were operated on laparoscopically in 2015, a minimally-invasive approach was defined as part of the protocol and the benefits were still clearly demonstrated compared to the patients undergoing a laparotomy. The results are comparable to published data (8-12).

Our clinical audit results confirmed that the hospital-specific ERAS® protocol was feasible and implemented in the vast majority of cases with only 6.7 % of patients for whom the surgeon opted for non-adherence to the protocol, and due to personal decisions, managed the patients according to classic peri-operative pathways. Partial implementation or struggling with compliance to the protocols has been described for other disciplines in addition to gynecology (2, 3, 13, 14). Reasons for non-adherence to the protocols included difficulties in multidisciplinary collaboration, discontinuing the protocol after completion of the protocol, and lacking financial support.

The adherence to ERAS® in our department was most prominent in introducing liquid oral intake within the first 24 h after surgery, administration of intravenous opioid analgesia only within 24 h after surgery, all patients having sweet liquid in the morning of surgery, a minimally-invasive approach when feasible, and successful routine post-operative antiemetic prophylaxis. The results clearly show the benefits of the ERAS® protocol with a short hemi-intensive care unit stay, short hospitalization rate, low re-admission rate, and low complication rate, as well as a short duration of post-operative nausea, and a low rate of post-operative paralytic ileus. Previously published reviews of the literature have mostly presented benefits or non-inferiority of ERAS® protocols compared with a classic peri-operative approach; however, there is still a marked heterogeneity between the studies and protocols, a lack of prospective randomized trials, and a lack of the assessment of individual interventions to outcome improvements (6, 15).

Unfortunately, only 14 % of patients who underwent laparotomies had epidural catheter placement. In the last 2 years our hospital has experienced a sudden shortage of anesthesiologists, thus resulting in a large number of anesthesiologists from other institutions coming sporadically to our operating rooms. The anesthesiologists determined epidural catheter placement based on their expertise in the method and/or habit. The regular application of 2 different non-opioid analgesics and patient-controlled opioid analgesic use only when the pain persisted showed excellent pain control with the need for opioid analgesics only within the first 24 h after surgery in the majority of patients, even when laparotomy was performed. A multimodal approach to pain relief is one of the most important parts of ERAS®; however, the use of invasive locoregional methods was not clearly demonstrated with some conflicting results especially for ovarian cancer patients (16, 17).

As stated, routine drainage was placed only for blood control and usually removed 24 h after surgery when the gynecologist placed drains (16 of 139 patients). When abdominal surgeons performed bowel resection with anastomosis, drains were placed as the discretion of the abdominal surgeon. Drains were placed in all 8 patients; however, removed in a median of 2 days. No dehiscence of the anastomosis was observed. Again, although the protocol clearly opposed routine drainage, according to published data for abdominal surgery (18), the personal opinion of the surgeon was the reason for non-adherence to the protocol. It is important to emphasize that our Department of Abdominal Surgery has not adopted a structural ERAS® protocol.

As presented, non-adherence to the protocol or parts of the protocol was associated with strong personal opinions/habits or a lack of personal expertise. This problem is even more prominent in small-volume departments where research is associated with a small number of participants and the need for prolonged time to obtain sufficient numbers for strong local evidence. Smaller hospitals are associated with personal acquaintances between team members which sometimes is a benefit when trying to make clinical practice improvements; however, it may also be an obstacle when personal disagreements exist. To make successful clinical practice changes and sustain the changes after implementation, quality improvement programs are widely used to achieve change by applying a systematic approach (19). The ERAS® Society emphasized that to successfully adopt the program, three requirements should be met, as follows: a written ERAS® protocol; an audit system prepared to review protocol compliance and clinical outcomes; and an ERAS® team formed to promote adherence to the program (20). As published, it is evident that without a structural program, even interdepartmental spread of innovations, although adopted within one department closely related to another (such as from an Abdominal Surgery Department to a Gynecology Department) do not occur spontaneously (21). With respect to our department, much work is planned, including the formation of an official hospital ERAS® team, plus promotion of the protocol to related departments and also at a national level. In Slovenia, the national gynecologic associations have yet to discuss or recommend the changes in peri-operative protocols.

CONCLUSION

Our results further support the ERAS® protocol for major gynecologic surgery. Non-adherence to the protocol in our low-volume department was usually associated with strong personal opinions/habits. Due to the heterogeneity of results and lack of RCT in the field, further research is warranted for small departments and a multicentre design is the optimal approach. Multicenter studies with strict protocols and activation of changes at the national level might be the solution for better compliance with the novel protocols.

There are no conflicts of interests for each author. There was no financial support from industry.

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