CLINICAL RESEARCH

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| Published: 2015.03.17 | | One Hundred Seventy-Nine Consecutive Bariatric Operations after Introduction of Protocol Inspired by the Principles of Enhanced Recovery after Surgery (ERAS®) in Bariatric Surgery | | | | |
|---|--|---|---|--|--|--|
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| Background: Material/Methods: | | Obese patients are a very large high-risk group for complications after surgical procedures. In this group, opti- mized perioperative care and a faster recovery to full activity can contribute to a decreased rate of postopera- tive complications. The introduction of ERAS®-based protocol is now even more important in bariatric surgery centers. The results of our study support the idea of implementation of ERAS®-based protocol in this special group of patients. This analysis included 170 patients (62 male/108 female, mean BMI 46.7 kg/m ²) who had undergone lapa- roscopic bariatric surgery, and whose perioperative care was conducted according to a protocol inspired by ERAS® principles. Examined factors included oral nutrition tolerance, time until mobilization after surgery, re- quirements for opioids, duration of hospitalization, and readmission rate. | | | | |
| Cor | Results: During the first 24 postoperative hours, oral administration of liquid nutrition was tolerated by 16 patients and 163 (95.8%) were fully mobile. In 44 (25.8%) patients it was necessary to administer relieve pain. Intravenous liquid supply was discontinued within 24 hours in 145 (85.3%) patients. The cation rate was 10.5% (mainly rhabdomyolysis and impaired passage of gastric contents). The avera hospitalization was 2.9 days and the readmission rate was 1.7%. Conclusions: The introduction of an ERAS® principles-inspired protocol in our center proved technically possible for our patients, and allowed for reduced hospitalization times without increased rate of compliareadmissions. | | istration of liquid nutrition was tolerated by 162 (95.3%) 25.8%) patients it was necessary to administer opioids to nued within 24 hours in 145 (85.3%) patients. The compli- mpaired passage of gastric contents). The average time of the was 1.7%. otocol in our center proved technically possible and safe | | | |
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MEDICAL SCIENCE MONITOR

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Background

Bariatric surgery is currently the most rapidly developing type of surgery, with rapid growth in the number of procedures performed, in some countries reaching those for cholecystectomy [1]. This is caused by rising numbers of obese people in developed countries and by the fact that surgical treatment is currently the only known effective method for curing severe obesity [2,3]. Given the high rates of comorbidities, obese patients are a group with increased perioperative risk [4,5]. Thus, minimizing the trauma from the surgery itself is a key aspect of the treatment, which allows for quick recovery to full activity and may decrease the rate of perioperative complications. The concept of Enhanced Recovery After Surgery (ERAS®) developed by Kehlet has been gaining support worldwide for almost 20 years. The perioperative care pathway according to the ERAS® protocol has been well-documented for colorectal surgery [6-8]. It has been proven that the introduction of a modern multimodal perioperative care pathway allows for shortening of hospital stay, a lower rate of complications, and better quality of life after the surgical procedure [9]. The first reports on the introduction of this protocol in patients undergoing abdominal surgery have begun to appear and their findings are very encouraging [10,11]. Even though there are no clear guidelines for ERAS®-based perioperative care of patients operated on due to severe obesity, it seems that this pathway may contribute to shorter hospital stays and lower rates of complications. The aim of this study was to evaluate the implementation of an Enhanced Recovery After Surgery (ERAS®)-inspired protocol for bariatric patients at a high-volume laparoscopic center.

Material and Methods

There were 179 bariatric surgical procedures performed at our center between April 2009 and March 2014. Four patients who refused to be treated according to the ERAS®-inspired protocol were excluded from the study, as well as 3 patients who were transferred to intensive care after the procedure due to respiratory failure (patients spend in ICU 7-22 days, and has been mechanically ventilated for the period of 5-12 days), along with 2 patients who were reoperated on within 24 hours due to bleeding or anastomosis dehiscence – the first patient had repeat surgery 10 hours after primary surgery due to signs of hypovolemic shock caused by bleeding from the staple line, the second was in surgery for 23 hours due to the presence of the symptoms of peritonitis caused by the leakage after LSG. Further analysis included 170 patients (108 women and 62 men) whose mean age was 42.5 years (range 18-68 years), and whose BMI averaged 46.7 kg/m² (35.0-63.4). The demographic characteristics of the patients are presented in Table 1. There were 164 (96.5%) patients diagnosed with comorbidities

of obesity. A total of 92 laparoscopic Roux-en-Y gastric bypass (LRYGB) procedures and 78 laparoscopic sleeve gastrectomies (LSG) were performed.

The research study included a group of patients undergoing bariatric surgery due to severe obesity. The indication for surgery was a BMI >40 kg/m² or 35 kg/m² for patients with comorbid conditions. Patients were qualified for 1 of 2 procedures: laparoscopic Roux-en-Y gastric bypass (LRYGB) or laparoscopic sleeve gastrectomy (LSG). By qualification to the operation we have taken into consideration presence of diabetes mellitus (patients qualified to LRYGB), presence of gastro-esophageal reflux disease (GERD) (patients qualified to LRYGB) and patients' personal references. All the operations have been performed by the same team of surgeons. Patients included in the study gave informed consent to the introduction of the ERAS® protocol, which was presented to them 14 days before their admission in the outpatient department. The study excluded patients who did not consent to ERAS®-inspired protocol-based care, patients transferred to intensive care immediately following the procedure, and patients who required reoperation in the early postoperative period. We analyzed the tolerance of oral nutrition, time until mobile, length of hospitalization, number and type of postoperative complications, requirement for opioids, and readmission rate within a 30-day postoperative period.

Patients were qualified for treatment through an outpatient health assessment, which included cardiology, pulmonology, endocrinology, and anesthesiology examinations. At 14 days before surgery, patients received written information about the proposed postoperative treatment and a list of dietary recommendations to be observed. They were also asked to attempt to lose weight and, if necessary, to guit smoking. All patients were admitted to the hospital during the 24 hours before the procedure. On that day they were provided information on the stages of the treatment; the perioperative care plan, including a description of each day after the procedure; and they were told the planned discharge date. Additionally, the patients' families were asked to participate in postoperative rehabilitation. The procedure was performed through laparoscopy. The patients received injections of bupivacaine solution at the sites of trocar placement, and Transversus Abdominis Plane - block (TAP-block) was used in some patients. Nasogastric tubes and drains were not left in after surgery. Short-acting anesthetics were used for general anesthesia. To prevent postoperative nausea and vomiting (PONV), ondansetron and dexamethasone were administered intravenously at the end of the surgery, and passive oxygen therapy was used in the first postoperative hours. Once the patients returned from the recovery room, they were allowed to drink clear liquids. Liquid nutrition was added to their diet on the following day. To prevent renal failure caused by rhabdomyolysis, diuresis was monitored in

Table 1. Demographic characteristics of the groups.

| Total number of patients | 170 | 170 | | |
|-----------------------------------|------------------------------|--------------------------|--|--|
| Number of men/women | 62 (36.5 | 62 (36.5%)/108 (63.5%) | | |
| Mean age | 42.5 yea | 42.5 years (18–68 years) | | |
| Mean BMI | 46.7 kg/m² (35.0–63.4 kg/m²) | | | |
| Comorbidites | | | | |
| Type 2 diabetes | 64 | (37.6%) | | |
| Type 1 diabetes | 2 | (1.2%) | | |
| Glucose intolerance | 19 | (11.2%) | | |
| Hypertension | 124 | (72.9%) | | |
| Dyslipidemia | 129 | (75.9%) | | |
| Fatty liver | 125 | (73.5%) | | |
| Cardiovascular diseases | 43 | (25.2%) | | |
| Respiratory system diseases | 40 | (23.5%) | | |
| Osteoarthritis | 86 | (50.6%) | | |
| Varicose veins of the lower limbs | 63 | (37.1%) | | |

Table 2. Discharge criteria.

| Adequate pain control with oral analgesia |
|--|
| Full mobilization patient drinks at least 1.5L of liquids daily and tolerates oral intake of a liquid diet |
| No evidence of infection (neither systemic, nor of the operated site) |
| Normal diuresis |
| Normal body temperature |
| Post-discharge support for the first 3 days after discharge |
| No other contraindications to discharge |

the 24 hours after surgery, and if it was low, it was stimulated through intravenous administration of liquids and a loop diuretic. In the first postoperative hours, respiratory rehabilitation and mobilization of the patients (sitting up, walking close to the bed) were initiated. The following day the patients were encouraged to spend at least 6 hours out of bed walking and were subject to a routine panel of laboratory tests, including a creatine phosphokinase test (CPK). Non-steroidal anti-inflammatory drugs and paracetamol were used for pain management, and in the case of complaints of severe pain in the first hours after surgery, small doses of morphine were administered upon request (patient-controlled analgesia [PCA]). The discharge criteria included full mobilization, oral ingestion of an appropriate amount of liquid nutrition without the need for intravenous administration, appropriate diuresis, adequate post-discharge support (e.g., a family member), and the lack of objective contraindications for discharge (Table 2). Upon discharge, all patients received dietary recommendations, subcutaneous low-molecular-weight heparin injections, and vitamin supplements. The first outpatient follow-up was scheduled 7 days after surgery. Table 2 shows the ERAS protocol adopted at our center.

Results

The median operation time in case of LSG was 97 minutes (63–187 min.) and the median operation time in case of LRYGB was 128 min (90–364 min).

Liquids were introduced through oral administration within the first 5 postoperative hours for all patients in the study group and it was well-tolerated by 128 (75.3%) patients. Patients who did not tolerate fluids receive antiemetic drugs (Ondansetron 4

 Table 3. Enhanced Recovery after Surgery inspired protocol in obese patients adopted in the 2nd Department of General Surgery in Cracow.

| Before admission to the hospital | Standardized information about planned treatment Cardiological, pulmonological, endocrinological and anesthesiological examinations – qualification for surgery Gastroscopy, <i>H. pylori</i> test Dietary recommendations, recommendations to reduce body mass and quit smoking |
|-----------------------------------|---|
| Day of admission | Detailed conversation with the patient and their family about each treatment phase Anesthesiological consultation Bath, unlimited ingestion of liquids, dinner Thromboprophylaxis |
| Day of operation | No liquid ingestion 2–3 hours before the procedure Single prophylactic antibiotic dose, Laparoscopic surgery, Injection of trocar placement sites with bupivacaine or TAP-block Use of short-acting anesthetics PONV prophylactics Oxygen therapy by mask after the procedure Oral administration of liquids Treatment of pain Monitoring of diuresis and liquid intake Early mobilization in the evening (standing up and short walks) Thromboprophylaxis |
| 1 st postoperative day | Follow-up examinations Treatment of pain Monitoring liquid intake (about 1500 ml) Discontinuation of intravenously administered liquids Enhancement of diet Thromboprophylaxis Full mobilization |
| 2 nd postoperative day | Continuation of treatment from the previous day Removal of catheters Full mobilization (several hours of walks) Planning of discharge |
| Day of discharge | Dietary recommendations Examination of surgical wounds Monitoring of liquid intake Evaluation of pain treatment Prescription of thromboprophylactical treatment, pain treatment, vitamin supplements |
| 7 th postoperative day | Evaluation of wounds, removal of stitches, planning of subsequent follow-up visits |

mg i.v.) and they received fluids within the next 6 hours once again. On the first postoperative day, oral administration of liquids was tolerated by 162 (95.3%) patients.

All patients were mobilized on the day of the surgery (sitting up on the bed with legs down) and 136 (80%) were able to stand up from their beds without assistance. Within the first 24 postoperative hours, 163 (95.8%) of the patients were fully mobilized.

Administration of morphine through the PCA system was necessary in 44 patients (25.8%) due to pain in the first hours after surgery. The total dose did not exceed 40 mg in any of the patients. After the first 24 postoperative hours, opioids were necessary in only 5.8% of patients.

Intravenous liquid administration was discontinued within 24 hours of the procedure in 145 patients (85.3%), during the second postoperative day for another 15 patients (8.8%), and during the following days for the remaining 10 patients (5.9%).

Complications occurred in a total of 18 patients (10.5%). The most frequent complications were rhabdomyolysis (Grade I according to the Clavien-Dindo classification), which occurred in 10 patients (2 of whom presented clinical symptoms) and PONV (Grade I, Clavien-Dindo classification) in 10 patients.

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Table 4. Postoperative complications.

| Total | 18 | (10.5%) | | | |
|---|----|---------|--|--|--|
| Rhabdomyolysis | 10 | (5.9%) | | | |
| PONV | 10 | (5.9%) | | | |
| Abnormal passage of gastric content lasting over 48 hours | 6 | (3.5%) | | | |
| Infection of the surgical site | 2 | (1.1%) | | | |
| Urinary tract infection | 2 | (1.1%) | | | |
| Fever of unknown etiology | 1 | (0.6%) | | | |
| The numbers do not add up to 100% as some patients experienced more than one complication | | | | | |

The abnormal passage of gastric contents lasting over 2 days and not requiring reoperation (Grade I, Clavien-Dindo classification) occurred in 6 patients (5 after LSG and 1 after LRYGB). Infection of the surgical site occurred in 2 patients (Grade I, Clavien-Dindo classification). Urinary tract infection (Grade II, Clavien-Dindo classification) was diagnosed in 2 patients, and 1 patient exhibited a fever of unknown etiology for 3 days (Grade II, Clavien-Dindo classification). Data on complications are presented in Table 4.

The mean duration of hospitalization was 2.9 days (range 1–12). It should be emphasized that the standard hospitalization duration in this group of patients before implementation of the ERAS-inspired protocol was 5.3 days. Within the first 30 postoperative days, 3 patients (1.7%) required readmission due to abnormal passage of gastric contents and dehydration (2 patients) and pneumonia (1 patient). There was no need for reoperating in any of the participants and no deaths occurred in the first 30 postoperative days.

The group of patients is in the constant follow up in our center. All the patients are invited for follow-up visits every 12 months. The group of patients in follow-up after 12 months is 86%, after 24 months is 78% and after 36 months 63%.

After 12 months, we learned that 1 patient had died, due to deep vein thrombosis that began 3 months after the operation.

Discussion

Our results confirm the effectiveness and safety of the ERAS[®]inspired protocol introduced for bariatric surgery in our center in Eastern Europe. There are some reports of similar efforts in the current literature [11–13]. Although the authors are unanimous in affirming that an ERAS[®] protocol allows for shortened hospitalization without increased rates of complications, there are still no clear guidelines as to postoperative care in patients operated on due to severe obesity. There has been only 1 randomized trial study published comparing the ERAS protocol to traditional clinical care, showing the advantages of applying ERAS[®] [14], but this study was limited in scope, featuring only patients who underwent LSG. In a comprehensive review from 2013, Elliot argued that even though the introduction of ERAS[®]-based programs and reductions of hospitalization lengths are possible, the conclusions as to the effectiveness of ERAS[®] are based on studies of select groups of patients and cannot be assumed to extend to patients operated on for severe obesity [12].

At our center, for reasons of safety, every patient is consulted before surgery by a surgeon, pulmonologist, endocrinologist, and anesthesiologist. A similar scheme was described by other authors who consider preoperative examination of the patient a necessary condition for the safety of the operation [15–17]. Moreover, the patient is informed in detail about the steps of the planned treatment, which is known to lower both anxiety and the perceived degree of postoperative pain, and may even positively impact the healing of surgical wounds [18-20]. An important element of the protocol is the application of the laparoscopic technique, which causes less surgical trauma than traditional techniques, speeding recovery to full activity and shortening the length of hospitalization [21,22]. All patients were operated on through laparoscopic surgery, without need for conversion in any patients. Local anesthesia was administered through routine procedures locally at the trocar insertion sites and through a transverses abdominis plane (TAP-block). This enabled a partial elimination of strong opioids administration [15,23], which, while still necessary in some patients, was only applied on the first postoperative day and in small doses in the PCA scheme. It seems that the combination of non-steroidal anti-inflammatory drugs with paracetamol is sufficient in most patients [15,24]. Proper postoperative pain management paired with the administration of the antiemetic drugs ondansetron, droperidol, and dexamethasone (towards the end of the procedure) limit the occurrence of postoperative nausea and vomiting [15,24,25]. McCarty showed that a single steroid dose at the end of the procedure was a factor predicting earlier discharge [24]. PONV occurred in 5.9% of patients. Avoiding this complication and introducing proper treatment of pain are necessary for early mobilization [4]. Early mobilization after surgery lowers the complication rate and contributes to shortened hospital stay [9,26]. According to Smart, failure to mobilize the patient on the day of the operation has a negative impact on the results of treatment with the ERAS® protocol, and prolongs hospitalization [27]. Over 95% of patients in the study group were fully mobilized within 24 hours of surgery, similarly as in other reports [4,15]. Postoperative complications occurred in 10.5% of patients, a rate comparable to those reported in other studies [11,13,15,17,24]. It should be stressed that a significant number of patients diagnosed with complications in our study group were diagnosed with rhabdomyolysis, which manifested through heightened CPK and myoglobin, as well as a requirement for large doses of diuretics, crystalloids, and mannitol. In other publications this complication was not included because routine postoperative CPK tests were not performed. Also requiring special comment are patients with abnormal gastrointestinal passage (6 patients). We observed that this complication occurs more frequently in patients undergoing LSG vs. LRYGB, and that these complications last longer after LSG compared to LRYGB. Problems with the passage of gastric contents persisted from 4 to 13 days in the 5 patients after LSG, and in 2 of these patients they were the cause of readmission. This complication was also reported in other papers [28,29]. Importantly, the group did not include reoperated patients and patients requiring IT, thus the character of complications is slightly different than in other studies. The discharge criteria adopted at our center (Table 2) are similar to those presented by other authors [12,15,16,30]. The mean time of hospitalization was 2.9 days (range 1-12 days), longer than in other reports [15,16,24,30]. The main cause for this difference is that most of the patients came from remote locations, and also because patients were admitted on the day before surgery. Dos Santos observed that the distance between the patient's residence and the hospital is a factor influencing

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length of hospital stay. Patients whose home was further than a 2-hour car ride stayed 24 hours longer at the hospital on average [15]. McCarty has an even more radical view on this matter; he is hesitant to operate on patients who live further than 100 miles away from his center and directs them to centers closer to their place of residence [24]. We are convinced that in the case of readmission, it is safer for the patient to be placed at the center where the original surgery was performed. The readmission rate in the analyzed group was 1.2%, which is lower than others have reported [13,15,24]. This is undoubtedly linked with longer hospitalizations in our group, and it is possible that some patients who remained longer in the hospital had thus avoided readmission. Although postoperative complications after this type of procedure develop rather early, they manifest within 24 hours of surgery in only 45-60% of all cases [11,13]. Thus, a higher readmission rate can be expected in the group of patients discharged within 24 hours of surgery. Geubbels argued that although any patient operated on for severe obesity is eligible for the ERAS care pathway, not all are appropriate candidates for discharge within 24 hours of surgery [13].

Conclusions

The introduction of the ERAS[®] protocol at our center located in Eastern Europe was technically possible and safe for the patients. The results presented here show that over 85% of patients fulfilled discharge criteria within 24 hours of the procedure. Extended (although relatively short) hospital stays were often the result of the concern that geographical constraints would result in rehospitalization in a different center, rather than serious concerns about the possibility of complications. Overall, our experience suggests that average hospital stays could be shortened even further without increased risk of complications or readmission.

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