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Randomized Controlled Trial of Enhanced Recovery After Surgery Protocols in Live Kidney Donors: ERASKT Study

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Background: Enhanced recovery after surgery (ERAS) pathways represent a comprehensive approach to optimizing perioperative management and reducing hospital stay and cost. In living donor kidney transplantation, key impediments to postoperative discharge include pain, and opioid associated complications such as nausea, vomiting, and the return of gastrointestinal function. **Methods:** In this randomized controlled trial, living kidney transplantation donors were assigned to either the ERAS or control group. The ERAS group patients received 15 preoperative, 17 intraoperative, 19 postoperative element intervention. The control group received standard care. The ERAS group received a multimodal opioid sparing pain management including an intraoperative transverse abdominis plane block. Our primary outcome measure was postoperative opioid consumption. The secondary outcome measures were postoperative pain scores, first oral intake, and hospital length of stay. **Results:** There were no significant differences in demographics between the 2 groups. The ERAS group had a statistically significant reduction in total postoperative opioid consumption calculated in intravenous morphine equivalents (24.2 ± 20.2 versus 71 ± 39.5 mg, $P < 0.01$). Postoperative pain scores were significantly lower ($P < 0.001$) from 1 h postoperatively to 48 h. Surgical time was 45 min shorter ($P = 0.037$). Intraoperative PlasmaLyte administration was lower (PlasmaLyte: 1444 ± 907 versus 2168 ± 1347 mL, $P = 0.049$). Time to tolerating regular diet was shorter by 2 h ($P < 0.008$), and length of hospital stay was decreased by 10.1 h. **Conclusions:** The ERAS group experienced superior postoperative analgesia and a shorter length of hospital stay compared with controls.

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More than 6900 living donor kidney transplants are performed every year, comprising about 30%–35% of all kidney transplants.[1] Donors are usually healthy individuals. However, living donor nephrectomy is not without potential postoperative complications. Postoperative pain side effects of opioids, such as nausea and vomiting and delayed return of bowel function, can prolong discharge and functional recovery. Enhanced recovery after surgery (ERAS) protocols represent an established strategy to minimize postsurgical complications and improve outcomes. The fundamental objectives of ERAS pathways are to reduce postoperative opioid consumption, enhance pain management, minimize the duration of hospitalization, decrease morbidity and mortality rates, and improve patient satisfaction. ERAS protocols achieve these objectives by meticulously optimizing every facet of the preoperative, intraoperative, and postoperative care phases.

ERAS pathways were first introduced in 1995 to guide postcolorectal surgery care.[2] Since then, ERAS pathways have increasingly been applied to other surgical procedures. Several studies have explored the potential benefits of ERAS in kidney transplantation.[3-5] However, most studies have focused on implementing a single or a few elements within the ERAS framework. The novelty of this study lies in its implementation of a 57-point ERAS protocol within a randomized controlled trial (RCT) framework. The objective of this study was to evaluate the effect of a ERAS protocol in

living kidney donors. The primary outcome measure was the patients' postoperative opioid consumption. The secondary outcome measures were postoperative pain scores, intraoperative fluid administration, first oral intake, and hospital length of stay.

MATERIAL AND METHODS

Trial Design

This study was an RCT. The trial protocol and statistical analysis plan were approved by the Thomas Jefferson University Hospital Institutional Review Board and registered at clinicaltrials.gov (NCT04110080) before any patient enrollment. Informed consent was obtained before enrollment for each patient. Safety of the participants and evaluation of the benefit–risk balance were overseen by an independent data and safety monitoring board. The trial was conducted in accordance with Good Clinical Practice guidelines, the principles of the Declaration of Helsinki and reported according to Consolidated Standards of Reporting Trials (COSNORT). This study was named ERASKT (Enhanced Recovery After Surgery in Kidney Transplantation) study.

A literature search and multidisciplinary collaboration were conducted to consider elements across the preoperative, intraoperative, and postoperative phases (**Appendix 1, SDC**, http://links.lww.com/TXD/A673). An evidence-based ERAS protocol was established specifically designed to expedite the postoperative recovery of living kidney donor patients. This optimization includes preoperative nutritional preparation, appropriate carbohydrate loading, preoperative counseling to promote a healthy lifestyle, smoking and alcohol cessation, regular exercise, proactive measures to prevent nausea and vomiting, the adoption of multimodal pain management strategies (ie, regional nerve blocks to reduce opioids), expedient removal of lines and tubes postoperatively, and the encouragement of early mobilization and oral nutrition.

Randomization, Allocation Concealment, Blinding

The patients were randomized to either the ERAS or control group. Computer randomization was performed with central randomization software and was conducted in a 1:1 ratio with a permuted block design including random block sizes of 4. Allocation concealment was performed to conceal the randomization sequence from all study personnel. An opaque envelope with the randomization was sealed and sequentially numbered by an independent, blinded research staff member. Another research staff member enrolled the patients. After enrollment, the envelope was opened by the principal investigator, and patients were assigned to each group as per randomization. Patients, anesthesiologist, and surgeons were blinded to the group assignment. Preoperative patient education was conducted by the nutritionist and kidney coordinator, without attributing specific components to the ERAS or control group. Carbohydrates were provided for patients in the ERAS group. Ketorolac was administered at the end of surgery by the anesthesia personnel in accordance with instructions from the designated research personnel. Postoperative care was administered by the surgical team, with postoperative assessment conducted by a designated research member.

The regional anesthesiologist performing the transversus abdominis plane (TAP) block was the only provider that was aware of the group assignment and this person was not involved in data collection.

Participants

Participants were recruited from the outpatient clinic at our institution. Inclusion criteria were patients 18–80 y of age with the American Society of Anesthesiologists (ASA) Physical Status 1–3 who were scheduled to undergo living donor nephrectomy. Exclusion criteria included patient refusal, and chronic opioid use.

Intervention

ERAS Group

The ERAS group received the ERAS pathway intervention. This included 15 preoperative, 17 intraoperative, and 19 postoperative elements (**Appendix 2, SDC**, http://links.lww.com/TXD/A673). Preoperative elements were patient education and counseling, risk assessment and optimization, carbohydrate loading, postoperative nausea and vomiting prophylaxis, deep vein thrombosis prophylaxis, and preemptive multimodal analgesia. For pain management intraoperatively a single-shot TAP block and rectus sheath block were performed at the end of surgery. Additionally, ketorolac 15 mg IV was given near the end of surgery. Postoperatively, multimodal analgesia included ketorolac 15 mg every 6 h, acetaminophen 1000 mg every 6 h, and pregabalin 75 mg twice daily for 48 h. For breakthrough pain, tramadol 50 mg PO every 6 h was available as needed and hydromorphone 0.2 mg IV every 2 h as needed was given as a one-time dose if the patient could not take oral medications. Intraoperative elements included goal-directed fluid management. Postoperative elements included early diet and ambulation, early invasive line removal, and discharge education.

Control Group

The control group received conventional care (**Appendix 3, SDC**, http://links.lww.com/TXD/A673). Patients were instructed to consume a clear liquid diet 24 h before surgery with no food after midnight and no liquid 2 h before arrival. On the day of surgery, they received subcutaneous enoxaparin sodium. Intraoperatively, standard ASA monitors were utilized, and patients received general anesthesia. Fluid management and hemodynamics were treated as clinically indicated. All patients received ondansetron 4 mg IV for prevention of postoperative nausea and vomiting (PONV). Postoperatively, in postanesthesia care unit hydromorphone 0.2 mg IV every 30 min was available for postoperative pain, and promethazine 6.25 mg IV or ondansetron 4 mg IV q8 was administered as needed for PONV. On return to the floor, IV fluids were continued until the patient tolerated oral intake, and the diet was advanced first with clears and then with regular diet as per patient tolerance. IV hydromorphone 0.5 mg every 4 h was available as needed until the patient tolerated oral intake at which point oxycodone 5–10 mg every 4 h was available for pain as needed. Bowel regimen was administered as needed, ambulation was encouraged, and vital signs and urine output were monitored. Decisions regarding Foley catheter removal and diet initiation were made by the blinded rounding surgeon. All patients were discharged according to

the following criteria: independent ambulation, tolerating oral intake, baseline hemodynamics with urine output >0.5 mL/kg/h and adequate pain control with oral medications.

Statistics

The power analysis assumed that patients in the ERAS group would have at least a 35% reduction in opioid consumption based on a review of the literature. Using this assumption, with alpha set at 0.05, a sample size of 20 patients per treatment group would provide 80% power to detect a significant difference between the 2 treatment groups. The sample size was increased to total of 23 in each group to account for dropouts. A per-protocol analysis was performed. Continuous variables were compared with the Student *t* test and ANOVA for normally distributed data, and the Kruskal-Wallis test was used for data not fitting the normal distribution. The chi-square test was used to compare frequency data between groups. A *P* value of <0.05 was set for statistical significance, and all tests were 2-sided. Data analysis was performed using SPSS ver 29.0.1 and GraphPad Prism version 10.0.2.

RESULTS

Demographics

In total, 40 patients were enrolled, with 23 in the ERAS group and 17 in the control group (Figure 1).

The ERAS and standard of care groups were similar in age, sex, ASA classification, and body mass index (Table 1).

Primary Outcome

Postoperative opioid consumption calculated in intravenous morphine milligram equivalents was significantly less in the ERAS group until 48 h after surgery and for the total stay (Table 2; Figure 2).

Secondary Outcome

The ERAS group reported significantly lower pain scores postoperatively than the standard of care group. Postoperative pain scores were significantly lower in the ERAS group from 1 h postoperatively until 48 h of recovery

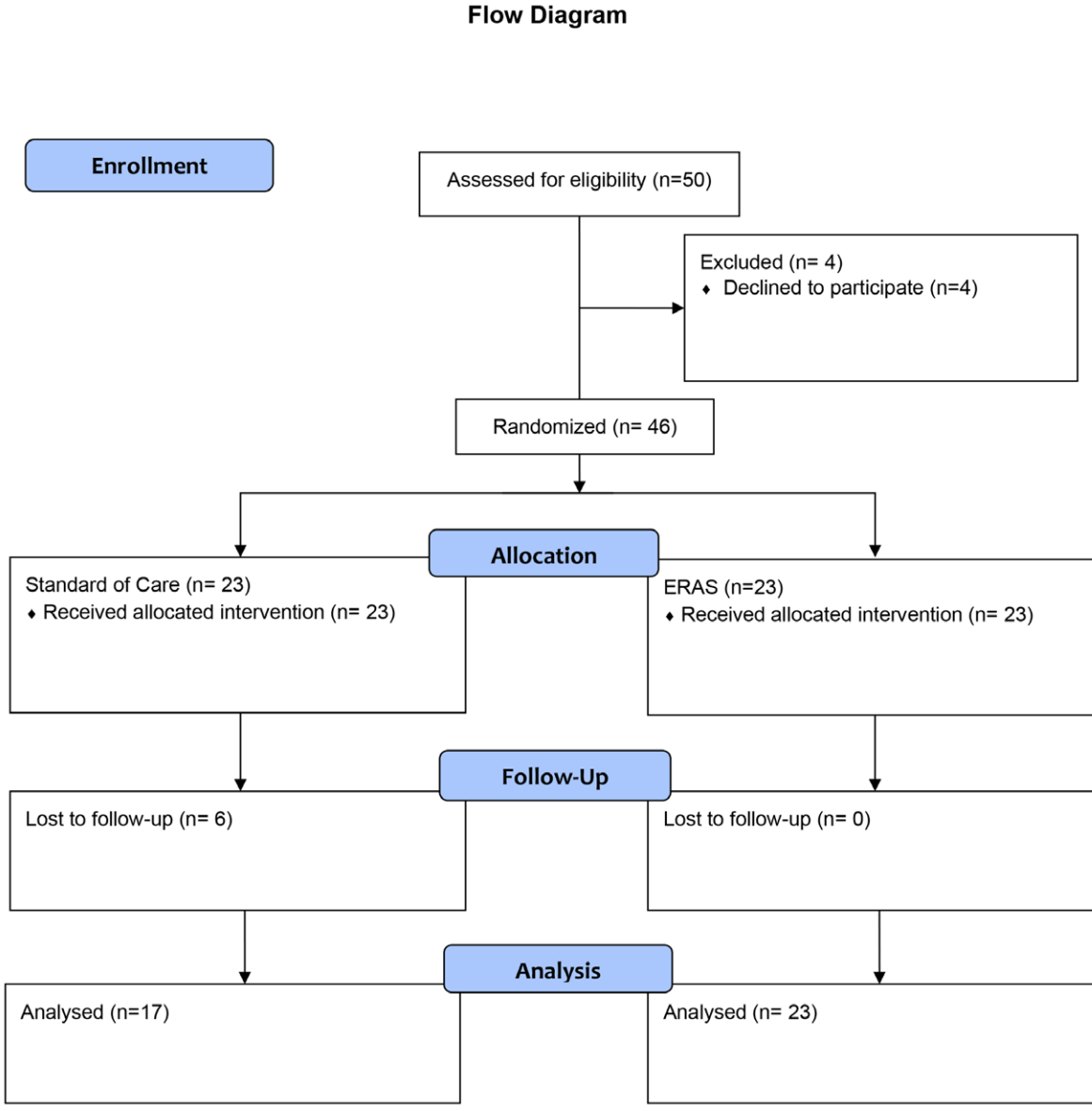

FIGURE 1. Enrollment flow diagram. ERAS, enhanced recovery after surgery.

TABLE 1.

Demographics of the ERAS and standard-of-care groups

	ERAS	Control	*P*
Age (y)	46 ± 15	42 ± 16	0.466
Sex (female %)	65.2	64.7	0.973
BMI (kg/m^2)	26.5 ± 3.5	26.9 ± 3.9	0.720
ASA, %			0.915
I	34.8	29.4	—
II	52.2	58.8	—
III	13.0	11.8	—

ASA, American Society of Anesthesiologists; ERAS, enhanced recovery after surgery.

TABLE 2.

Postoperative morphine milligram equivalent opioid consumption and pain scores

Morphine milligram equivalents	ERAS (mg)	Control (mg)	*P*
POD 0	12 ± 7.6	21.4 ± 11	<0.01*
POD 1	7.7 ± 11.3	26.5 ± 15.6	<0.01*
POD 2	1.7 ± 5.1	14.1 ± 19.9	<0.01*
POD 3	2.9 ± 5.4	9.7 ± 11.2	0.071
Total	24.2 ± 20.2	71 ± 39.5	<0.01*
Pain scores, h			
1	4.9 ± 1.5	6.8 ± 2.2	<0.01*
1–2	4.0 ± 1.4	6.3 ± 2.3	<0.01*
2–4	3.5 ± 1.5	5.8 ± 1.9	<0.01*
4–6	3.2 ± 1.5	5.2 ± 2.1	<0.01*
6–12	2.8 ± 1.5	4.8 ± 1.6	<0.01*
12–18	3.0 ± 1.6	5.1 ± 1.4	<0.01*
POD 1 morning rounds, h	2.8 ± 1.3	4.4 ± 1.3	<0.01*
18–24	2.3 ± 1.2	4.6 ± 1.8	<0.01*
24–30	2.0 ± 1.6	4.2 ± 1.8	<0.01*
30–36	1.6 ± 1.7	3.8 ± 1.5	<0.01*
36–42	1.5 ± 1.9	3.6 ± 1.3	<0.01*
42–48	1.3 ± 1.6	3.4 ± 1.4	<0.01*

*$P < 0.05$.
Pain score: 0–10, 0 is no pain, and 10 is being the worst pain imaginable.
ERAS, enhanced recovery after surgery; POD, postoperative day.

(Figures 3 and 4). Post hoc analysis with Bonferroni correction showed significant ($p < 0.001$) differences at all time points.

Intraoperative and postoperative outcome measures are listed in Table 3. Intraoperatively, surgical time was 45 min shorter ($P = 0.037$) in the ERAS group. A total of 5 surgeons were involved in the study. The operating surgeon (n = 5, $P = 0.144$) was not a factor in the decreased surgical time between the 2 groups. There was no difference in the anesthesia intraoperative drug administration doses between the 2 groups except for phenylephrine. Patients in the control group received a statistically significantly higher amount of phenylephrine (phenylephrine 135 ± 257 versus 363 ± 376 μg, $P = 0.017$). Intraoperative PlasmaLyte administration was significantly lower in the ERAS group (PlasmaLyte: 1444 ± 907 versus 2168 ± 1347 mL, $P = 0.049$).

The Foley catheter was removed earlier in the ERAS group. There was no difference in the first clear diet administration. Patients in the ERAS group received a regular diet 2.2 h earlier than the standard of care group. ERAS group patients were discharged 10.1 h earlier.

DISCUSSION

In this study, we showed that patients who were given an evidence-based ERAS treatment protocol for living donor nephrectomy consumed fewer opioids, experienced improved pain control, and had a shorter hospital length of stay. These outcomes were the result of multiple preoperative, intraoperative, and postoperative interventions in the ERAS pathway. Two patients in the control group were administered standing pregabalin, and 1 patient received a standing acetaminophen order, both of which were components of the ERAS protocol. A review of those patients revealed higher immediate postoperative pain scores, likely resulting in the need for additional pain management. Similar to our study, the literature shows that ERAS pathways resulted in decreased opioid consumption in kidney transplantation and other surgeries.[6-8] In those studies, the ERAS pathway was a multifactorial perioperative strategy to reduce the patient's surgical stress response, improve pain management, optimize their physiologic function, and facilitate recovery. Especially in a retrospective analysis by Elsabbagh et al,[3] kidney transplant recipients were studied, comparing those managed with and without ERAS. The ERAS group exhibited significantly reduced postoperative pain, with morning after surgery pain scores of 2 compared with 5, peak pain scores of 4.5 versus 10, and lowest pain scores of 0 versus 2 ($P = 0.0001$). Additionally, earlier ambulation, advancement of oral nutrition, and shorter hospital stays were observed.[3]

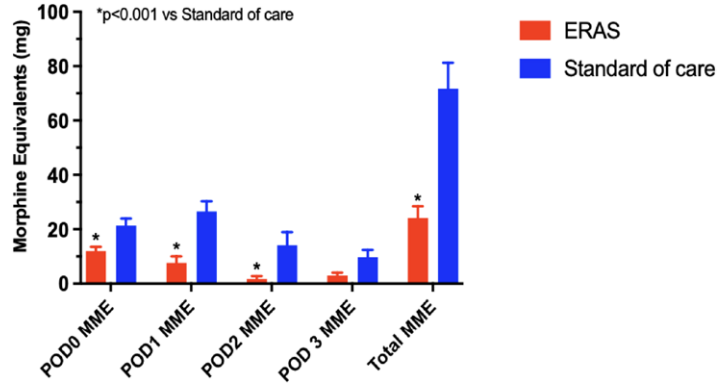

FIGURE 2. Postoperative morphine milligram equivalent opioid consumption. *$P < 0.001$ vs standard of care. ERAS, enhanced recovery after surgery; POD, postoperative day.

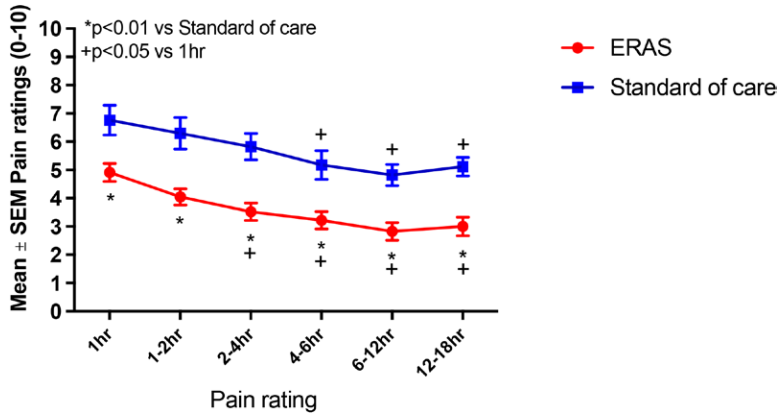

FIGURE 3. Pain scores 1–18 h postoperatively. ERAS, enhanced recovery after surgery. *$P < 0.001$ vs standard of care; +$P < 0.05$ vs 1 h.

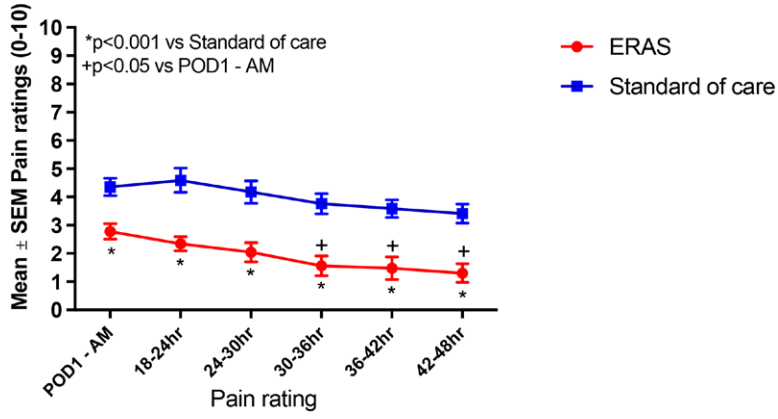

FIGURE 4. Pain scores postoperative day 1–48 h postoperatively. *$P < 0.001$ vs standard of care; +$P < 0.05$ vs POD1-AM. ERAS, enhanced recovery after surgery; POD, postoperative day.

TABLE 3.

Intraoperative and postoperative outcome measures

	ERAS, N = 23	Control, N = 17	*P*
Length of stay (h)	51.8 ± 10	62.9 ± 14	0.010*
OR time (min)	315 ± 42	350 ± 51	0.037*
PONV	2 ± 0.1	2.4 ± 0.6	0.090
Intraoperative medications			
Fentanyl induction dose, (μg)	98 ± 12	94 ± 17	0.705
Toradol 15 mg (%)	91.3	23.5	<0.001*
Additional fentanyl (μg)	70 ± 59	107 ± 56	0.062
Phenylephrine (μg)	135 ± 257	363 ± 376	0.017*
Ephedrine (mg)	9 ± 12.9	13.8 ± 19	0.588
Furosemide (mg)	4.8 ± 5.1	5.9 ± 10	0.850
Heparin (mg)	2477 ± 1115	2324 ± 1131	0.726
Protamine (mg)	24 ± 16	21 ± 12	0.566
Lactated Ringer's (mL)	1024 ± 650	862 ± 533	0.705
PlasmaLyte (mL)	1444 ± 907	2168 ± 1347	0.049*
Dexamethasone (mg)	1.1 ± 0.6	0.7 ± 1	0.085
Postoperative			
Time until postoperative Foley catheter removal (h)	15.3 ± 3.6	21.5 ± 55	<0.001*
Time until initiation of clear diet (h)	2.3 ± 1.6	3.94 ± 4.1	0.190
Time until tolerance of regular diet (h)	10.6 ± 5.1	14.8 ± 4.8	0.008*

*$P < 0.05$ is considered statistically significant.
ERAS, enhanced recovery after surgery; OR, operating room; PONV, postoperative nausea and vomiting.

Multimodal pain management and regional anesthesia have exhibited considerable benefits across various studies, especially TAP blocks. After considering the effectiveness of pain relief, patient discomfort, operator experience, time, availability, regional anesthesia training level of physicians, and institutional resources, we concluded that the TAP block was the best option. A 2010 Cochrane review found evidence that TAP blocks for abdominal surgery reduced morphine requirements over the first 48 h postoperatively.[9] A meta-analysis of 51 RCTs showed that TAP blocks reduced the pain score and 24-h morphine consumption after gynecological, appendectomy, inguinal, bariatric, and urological surgery.[10]

The ERAS group had a strict protocolized fluid management plan resulting in significantly less intraoperative fluid administration. Optimal perioperative fluid management is an important component of an ERAS pathway. The goals of preoperative fluid management are for the patient to arrive in the operating room in a hydrated and euvolemic state. The goals of intraoperative fluid management are to maintain central euvolemia and to avoid excess salt and water.[11] The higher dose of phenylephrine in the control group could be the result of hypovolemia when patients arrived in the operating room. Control group patients were nil per os as per ASA guidelines compared with ERAS patients who had carbohydrate loading of 10 oz within 1 h of scheduled arrival time.

The decreased length of stay in the ERAS group may be due to the optimized pain management strategy and early initiation of oral intake and discharge protocols. Compared

with the literature, our study results show a below average hospital stay of 51–63 h. An ERAS study in kidney transplant recipients reported that the median length of stay for patients on the ERAS protocol was 5 d (range 3–16 d). This was 2 d shorter than the median length of stay for patients in the control group (7 d; range 5–14 d).[12]

Similar to our findings Rege et al[13] retrospectively evaluated 40 laparoscopic living donor nephrectomy patients in an ERAS group compared with 40 controls. The ERAS group was associated with a decrease in median length of stay from 2.0 to 1.0 d ($P = 0.001$). The ERAS group demonstrated significantly lower overall pain scores, with peak pain scores of 6.0 versus 8.0 ($P < 0.001$), morning after surgery pain scores of 3.0 versus 7.0 ($P = 0.001$), and lowest pain scores of 0.0 versus 2.0 ($P = 0.016$). Moreover, the ERAS group had shorter average durations of surgery (248 versus 304 min, $P < 0.001$) and significantly lower average intraoperative fluid usage (2500 versus mL, $P < 0.001$), without adverse effects on donor renal function. The surgical technique utilized in our study was a hand-assisted intraperitoneal approach in 84% (31/37) and intraperitoneal laparoscopic in 16%. Subanalysis showed that 5 of 6 intraperitoneal laparoscopic techniques were performed in the ERAS group. The shorter surgical time in the ERAS group is a significant finding, but its lack of scientific explanation and correlation requires further investigation. A larger sample size is needed to evaluate this finding and address disproportionate distribution. Drain placement was performed only on an as-needed basis. An analysis showed that no patient received a surgical drain.

Other use of an ERAS pathway in donor nephrectomy was reported previously, but the results were limited. Ricotta et al[12] implemented an ERAS protocol for laparoscopic living donor nephrectomy and reported that its use reduced the length of stay only among older individuals 61–72 y of age (3.5 versus 4.5 d) and resulted in no significant differences in the rate of postoperative complications and hospital readmissions.[14] A systematic review of living donor nephrectomy showed that with laparoscopic procedures duration of stay was significantly reduced by 0.98 d in the ERAS group. Opiate requirement was reduced by 32.4 mg.[15] A meta-analysis showed that ERAS protocols result in reduced perioperative morbidity, shorter length of hospital stay and improved quality of life after living donor nephrectomy.[16] A study reviewed ERAS in kidney transplant recipients and was targeting a discharge home within 5 d of surgery. Of 454 patients, 212 (46.7%) recipients were discharged within the ERAS target ≤5 d. Delayed graft failure (heart rate: 2.16) and in-hospital dialysis (heart rate: 3.68) were the only predictive factors for late discharge.[17]

The authors reported that no preoperative PONV prophylaxis or screening occurred, and limited information about the development of the protocol is available, making it difficult to interpret. All patients received epidural analgesia, ketorolac, and paracetamol, and intraoperative fluid was restricted (normal saline 0.9%; rate: 1.0 mL/kg/h).

Campsen et al[5] also described an ERAS pathway with ketorolac and pregabalin versus standard of care plus placebo during live donor nephrectomy for kidney transplant; however, this study only focused on pain management. No other components of an ERAS pathway were implemented in this study. Kruszyna et al[4] conducted a study using an ERAS protocol in kidney transplant recipients. The primary outcomes were length of hospital stay and mortality and morbidity rates. Preoperative intervention was limited to consent, counseling, and hemodialysis. Pain management was limited to early narcotic withdrawal on postoperative day 1 and only acetaminophen as needed as an adjunct.

LIMITATIONS

The sample size was calculated based on the primary outcome. Given the multifaceted nature of the ERAS protocol, we concentrated on the most relevant outcome measures, notably opioid reduction. The sample size presents challenges in achieving sufficient statistical power for analyzing secondary outcome measures, necessitating caution in their interpretation. Furthermore, the loss to follow-up further diminish the reliability of the secondary outcome data, emphasizing the need for careful consideration when drawing conclusions from these findings.

An unexpected higher drop out in the control group was noticed but the study followed the originally implied per protocol analysis to mitigate bias from noncompliance or partial compliance. Some patients declined to participate after enrollment and some in the control group received a TAP block due to violation of the study protocol. Those patients were excluded from analysis. Blinding challenges, and a higher rate of loss to follow-up in the control group could potentially skew results, narrowing the observed differences between groups and consequently underestimating the true effect of ERAS. Most likely, care providers consciously or unconsciously recognized the benefits of ERAS despite blinding measures. Implementing a more rigorous approach to patient follow-up, including documenting adherence rates to each element of the intervention, can be instrumental in minimizing loss to follow-up and mitigating biases.

The generalizability of our protocol may be limited because the ERAS protocol development process considered institutional resource availability and logistical challenges. Providing preoperative counseling from each department, patient education, and intra- and postoperative follow-up requires a multidisciplinary team approach and communication. Furthermore, elements of an ERAS protocol may vary based on the primary outcome measure of a study.

Another generalizability limitation is the choice of regional anesthesia. The laparoscopic approach can differ depending on the patient kidney anatomy and surgeon's approach. Consequently, the location and intensity of pain vary, and a more individualized regional anesthesia technique could be considered in the future. Newer techniques, such as serratus anterior block or erector spinae block, have been described. However, these techniques require more time and are usually performed preoperatively, which may result in additional discomfort and anxiety for the patient. Further research is essential for optimizing perioperative care in kidney transplantation recipients, given their higher ASA scores, multiple comorbidities, and limited physiological reserve, compared with live donors, which increase their risk of complications.

CONCLUSION

The ERAS group led to significantly reduced opioid consumption, pain scores, and length of hospital stay compared with the control group.

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