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REVIEW ARTICLE

Implementation of enhanced recovery protocols reduces opioid use in pediatric laparoscopic cholecystectomy surgery

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Abstract

Purpose Enhanced recovery protocols [ERPs] standardize care and have been demonstrated to improve surgical quality in adults. We retrospectively compared outcomes before and after implementation of ERPs in children undergoing elective laparoscopic cholecystectomy [ELC] surgery.

Methods A pediatric-specific ERP was implemented for children undergoing ELC at one [C1] of the two Pediatric Surgical Centers in July 2016. We retrospectively reviewed 606 patients undergoing ELC between July 2014 and December 2019. Of these, 206 patients underwent ELC prior to ERP implementation [Pre-ERP] were compared to 400 patients undergoing ELC managed in the post-ERP implementation period (between January 2017 and December 2019), 21 of which were managed by enhanced recovery protocol. Primary Outcomes included immediate peri-operative and post-operative narcotic use in mean morphine equivalents [MME], narcotics at discharge, complications, nurse calls and returns to system [RTS].

Results There was a significant decrease in opioid use both post-operatively and at time of discharge in the ERP managed cohort. The MME use during the post-operative period was 0.85 in the in ERP-compliant patients compared to 6.40 in the non-compliant group ($p < 0.027$). Eighty-six percent of ERP-compliant patients in the study required no narcotics at discharge, which was statistically significant when compared to ERP non-compliant cohort ($p < 0.0001$). There was also no change in RTS, nurse calls or complications. In addition, in the post-ERP period (2017–2019), a dominant proportion of patients at C1 partially complied with the ERP, resulting in a statistically significantly decrease of opioid use between sites in the post-op period (6.54 vs 10.57 MME) post-ERP ($p < 0.001$). Similar effects were noted in discharge narcotics.

Conclusion The use of pediatric-specific ERP in children undergoing ELC is safe, effective, and provides compassionate pain control while leading to a reduction in opioid use peri-operatively and at discharge. This improvement occurred without changes in RTS, nursing calls or complications.

Level of evidence Level III; Retrospective study.

Keywords ERAS · Cholecystectomy · Opiates · ERPs · Fast-track

Abbreviations

ELC	Elective laparoscopic cholecystectomy
ERPs	Enhanced recovery protocols
RTS	Returns to system
MME	Mean morphine equivalents

Background

Enhanced recovery protocols [ERPs] have gained significant traction across multiple surgical disciplines [1–5]. These fast-tract or enhanced recovery after surgery [ERAS] protocols have been shown to improve surgical quality, reduce length of stay [LOS], reduce cost, and decreased opiate use/

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prescriptions, with similar complication rates and returns to system [RTS]. Protocols including standardized peri-operative counseling, limited pre-operative fasting and peri-operative narcotics, goal-directed intra-operative fluids, early enteral intake, and ambulation have been demonstrated to maintain physiological homeostasis, decrease inflammation, and minimize stress leading to early return to baseline [6–8]. Despite significant data in the adult realm, literature examining ERPs in pediatric surgery lags and the literature regarding the benefits of ERP's tend to focus on decreased LOS without an increase in RTS. However, recent data in pediatric surgery have been consistent with adult literature demonstrating safety and effectiveness using ERPs in the pediatric population [6, 9–11].

Pediatric gallbladder disease is increasing in the United States, likely in relation to increasing prevalence of childhood obesity [12]. There is a well-documented relationship between obesity and gallbladder disease in adults [13]. Since 1959, the prevalence of cholelithiasis in children younger than 16 has increased from 0.15% to estimates of up to 4.0% [12]. With this increase in prevalence, there has been an increase in cholecystectomies performed in the pediatric population, and it is now a relatively common pediatric procedure [8]. Recently, studies have emerged investigating ERP implementation in laparoscopic cholecystectomy. A study published by Yeh et al. supported the findings seen in pediatric colorectal surgery following implementation of enhanced recovery protocols in pediatric laparoscopic cholecystectomy [6, 9]. The investigators demonstrated dramatically improved rates of same day discharge [SDD] as well as reduced peri-operative opioid use. Gould et al. also demonstrated the use of clinical pathways to increase same day discharge rates [14]. However, long-term data examining compliance to such protocols have not yet been substantially addressed. In addition, in our current era of opioid stewardship, little data exist addressing ERAS as it relates to rates of opioid prescription use in children of this population [11]. Our hypothesis is that compliance with ERPs in laparoscopic pediatric cholecystectomy surgeries will lead to decreased peri-operative as well as post-operative opiate use without affecting rates of complications and returns to the system.

Methods

Study design

A retrospective review of children aged 1–18 undergoing elective laparoscopic cholecystectomy between January 2014 and December 2019 was conducted. A pediatric-specific ERP was implemented in children undergoing laparoscopic cholecystectomy at one [C1] of two pediatric surgical centers within the Children's Healthcare of Atlanta [CHOA] system starting in January 2017. ERPs have been previously integrated at C1 for other procedures (elective colorectal, foregut and thyroid surgery) dating back to January of 2012. C2 (ERP non-compliant surgical center) was naïve to formal enhanced recovery protocols. A review of 206 patients who underwent laparoscopic cholecystectomies between the periods of January 2014–December 2016 was performed as a control. This cohort was compared to 400 patients managed post-ERP implementation between January 2017 and December 2019, of which 21 patients were managed with the enhanced recovery protocol. C1 and C2 were staffed by separate attending surgeon groups that did not cross between centers. 2/6 surgeons at C1 incorporated ERPs and were responsible for the 21 patients managed on the Enhanced recovery pathway. For patients managed without ERP, both pre- and post-ERP implementation, diet advancement, pain management, length of stay, etc. was at the discretion of each individual surgeon. Typical post-operative pain management regimens included acetaminophen, ibuprofen, ketorolac, and/or gabapentin. Patients managed with ERP were identified retrospectively by documented pre-operative (either in clinic or while inpatient) ERP specific counseling as well as pre-operative chart/H&P labeling of "ERAS" pathways. In the ERP cohort 8 elements were measured including: pre-operative visit with expectant counseling, clear liquids up to 2 h prior to OR start time, pre-operative carbohydrate load, placement of sequential compression devices, loading dose of analgesia, use of regional/local anesthetic, antibiotic prophylaxis, and goal-directed intra-operative fluid administration. These elements were selected based on previously produced research on ERAS from our institution. The protocol also included scheduled multimodal analgesia, maintenance of normothermia, no bowel preparation, and early diet advancement.

All patients aged 1–18 years old were included in the data collection. Additional comparison was only limited to those patients undergoing elective laparoscopic cholecystectomy. Exclusion criteria included patients with sickle cell, those undergoing additional procedures in tandem (splenectomy or gastrostomy tube placement) and patient with complex medical comorbidities that necessitated additional post-operative surveillance. Primary outcomes of interest included opioid use, both peri-operative (intra-op and PACU), post-operative and narcotic use at discharge in MME. Secondary outcomes investigated included protocol compliance (defined by chart documentation demonstrating adherence to the eight elements of the protocol), length of stay [LOS], complications (surgical site infections, non-healing wounds, post-operative bleeding, etc.), nurse calls (documented as separate electronic chart encounters/episode), 30-day readmissions (all cause) and 30-day returns to system (all cause). The study was approved by the Institutional Review Board at Children's Healthcare of Atlanta.

Protocol implementation

The elements of the ERP were implemented for pediatric cholecystectomy surgery at C1 in January of 2017 through extensive multi-disciplinary coordination. This team included surgical staff, pre-operative and recovery unit nursing staff, anesthesiologist and pain specialist including respective department chiefs, surgical floor nurses, ancillary staff, residents, and fellows. An order-set was developed and used during patient admission. The program was designed such that each patient who received counseling had a specific dictation in the pre-operative H&P as well as header, "ERAS", in the electronic medical record signifying their inclusion in the protocol. OR staff were alerted of ERAS status on the OR schedule and post-operative nursing staff were alerted with a hard copy of the protocol in the patient's chart. The compliance of these indicators of ERAS status were difficult to retrospectively analyse, however can be extrapolated from the definitive compliance with the protocol.

Statistical analysis

Primary outcomes included peri-operative [peri-op] and post-operative [post-op] narcotic use in mean morphine equivalents [MME], narcotics at discharge, length of stay and intra-operative fluid use were compared between cohorts (Pre-ERP, Post-ERP, and ERP compliant) at C1 and C2 using *T*-test analysis. Specifically, we compared these outcomes for pre-implementation C1 vs C2, post implementation C1 vs C2, ERP (only at C1) vs post implementation non-ERP compliant at C1 and ERP vs post implementation C2 (all non-compliant). Complications, nurse calls and returns to system [RTS] were measured as categorical variables and analyzed by chi-square test for the same subgroups. The null hypothesis was rejected at an alpha of $p < 0.05$.

Results

A total 606 pediatric patients undergoing elective laparoscopic cholecystectomy between January 2014 and December 2019 were included in the study. Of these, 206 (34.3%) patients were in the pre-ERP implementation period and 400 (65.6%) in the post-ERP implementation period, 21 (3.4%) of which participated in the ERP pathway. The median age for both cohorts was 15, with an average age of 13 and 14, pre- and post-ERP cohort, respectively. Average BMI was 27.1 and 27.5 in the pre-ERP and post-ERP cohort, respectively. Average BMI was 31 in the ERP compliant patients. There was no significant difference in patient age or BMI amongst cohorts (Table 1). There was a higher Black/African American predominance in the ERP cohort. There was no statistically significant difference in 30-day return to system, readmissions, nursing calls, or complications amongst the cohorts (Table 2). Indications for surgery are included in Table 3.

A total of 590 (97%) patients underwent traditional 4 port site Laparoscopic cholecystectomy, with 15 (2%) undergoing robotic and 1 requiring conversion to open. When comparing surgical centers, a total of 234 (38%) (81 pre- and 132 post-ERP) patients were treated at the ERP-integrated facility (C1) vs 372 (61%) (125 pre- and 247 post-ERP implementation) at the ERP non-integrated site (C2). There was no significant difference in baseline patient characteristics between centers (Table 1). Seventeen (8%) patients in the pre-ERP cohort were discharged on the same day compared to 94 (23%) patients in the post-ERP cohort. Most patients, 425 (70%), were discharged post-operative day 1. All 21 ERP protocol patients were discharged on POD1. The average LOS was 1.23 vs 1.14 for pre-ERP and post-ERP groups respectively (95% CI 0.02 to 0.17).

Table 1 Patient demongraphics

	Pre-ERP ($n=206$)			Post-ERP ($n=379$)			ERP ($n=21$)	
	C1 ($n=81$)	C2 ($n=125$)	p value	C1 ($n=132$)	C2 ($n=247$)	p value	C1	p value
Age (mean)	13.8	13.8	0.99	14.4	14.4	0.96	14.25	0.09
BMI (mean)	28.1	26.5	0.23	28.6	27	0.16	31.4	0.08
Gender (% Female)	81.10%	78.95%	0.68	77.80%	80.00%	0.73	76%	0.99
Ethnicity								
White (n)	49 (60%)	86 (68%)	0.23	61 (46%)	137 (55%)	0.08	6 (28%)	0.04* (vs post)
Black	20 (24%)	22 (18%)		37 (28%)	65 (26%)		12 (57%)	
Hispanic	11 (13%)	16 (13%)		31 (23%)	41 (16%)		1 (4.7%)	
Other	1 (1.2%)	1 (1.2%)		3 (2.3%)	4 (1.6%)		2 (9.5%)	
Operation								
Laparoscopic	201 (97%)			368 (97%)			21 (100%)	
Robotic	4 (1.9%)			11 (2.9%)			0 (0%)	
ERP elements received	2.96 (3, 3)			2.85 (3, 3)			6.47 (6, 6)	

Table 2 Complications

	Pre		Post		ERP $n=21$	p value (pre vs post)
	C1 ($n=81$)	C2 ($n=125$)	C1 ($n=132$)	C2 ($n=247$)		
Return to ER (30 days)	4 (4.9%)	11 (8.8%)	7 (5.3%)	17 (6.9%)	0	0.4895
Readmission (30 days)	2 (2.4%)	3 (2.4%)	3 (2.3%)	2 (0.8%)	0	0.3336
Complications	1 (1.2%)	1 (0.8%)	4 (3.0%)	6 (2.4%)	0	0.2301

Table 3 Indications for surgery

Symptomatic cholelithiasis	419 (69%)
Biliary dyskinesia	111 (18%)
Acute cholecystitis	33 (5%)
Choledocholithiasis without ERCP	21 (3%)
Choledocholithiasis with ERCP	10 (2%)
Gallbladder polyp	12 (2%)

Outcomes

ERP patients required less peri-op and post-op opiates when compared to non-ERP patients at both C1 and C2 in the pre- and post-ERP implementation period (Table 4). Eight out of 21 (40%) of ERP patients required no narcotics during the admission compared with 1 out of 207 non-ERP patients in the pre-ERP cohort (C1 and C2). Furthermore, ERP patients were statistically more likely to be discharged without opiate pain medication when compared to patients treated at C2 (85.7% vs 9.71%; $p=0.0001$) in the post-ERP period and patients treated at C1 during the pre-ERP period (85.7% vs 12.3%; $p=0.0001$). This difference was not definitively produced in patients treated at C1 during the post-ERP period (85.7% vs 65%; $p=0.079$), suggesting on-going implementation and culture change strategies. ERP patients received significantly lower intra-operative fluids 557 cc vs 719 cc at C1 and 557 cc vs 993.8 cc at C2 ($p=0.02$) in the post-ERP period.

Regarding trends in opiate use, prior to ERP implementation, there was a statistically significant difference in peri-op (3.72 vs 5.24 MME; $p=0.011$) and percentage of patients discharged without opiates (12.35% vs 3.20%; $p=0.019$) between C1 and C2. In the post-ERP period, there was a statistically significant difference found in post-op narcotic use (6.5 vs 10.5 MME; $p=0.011$) and patients discharged without narcotics (65.15% vs 9.76%; $p=0.0001$) between sites. In addition, there was a statistically significant decrease in post-op narcotic use (14.8 vs 6.5 MME; $p=0.0001$) and patients discharged without narcotics (12.50% vs 65.65% $p=0.0001$) in non-ERP patients at C1 when comparing the pre- vs post-ERP period. This trend of decreased opiate use was also found at C2 for post-op opiate use (14.1 vs 10.6 MME; $p=0.017$) as well as patients discharged without narcotics (3.15% vs 9.72% $p=0.022$) when comparing the pre- and post-ERP period. In the pre-ERP period, 15 (7%) patients who returned to the ED (all cause), 5 (2%) readmissions (all cause) and 2 (1%) complications (wound site infections). There were 24 (6%) returns to ED, 5 (1.2%) readmission, 10 (2.6%) complications in the post-ERP. There was no significant difference when comparing these outcomes. There were no complications, returns to ER or readmissions in the 21 ERP patients.

In terms of protocol compliance, 3 out of 21 ERP identified patients (14%) were fully (8 out of 8 interventions) compliant with the protocol, with 76% mostly compliant (6–7 out of 8) and the remaining partially compliant (5 out of 8). The most missed elements were "Pre-op Carbohydrate Load" (3 out of 21 compliant) and SCDs (15 out of 21 compliant). There was found to be statistically higher rates of compliance in 6/8 elements for ERP patients when compared to C1 non-ERP patients in the post-operative period (Table 5). Most (86%) of non-ERP patients at in the post-ERP only completed 2–3 out of 8 elements of the protocol.

Table 4 Opiate requirements

Outcomes	Pre		Post		ERP	Pre C1 vs pre C2	Post C1 vs pre C1	ERP vs C1 post	Post C1 vs C2
	C1 (81)	C2 (125)	C1 (132)	C2 (247)	C1 (21)	p value	p value	p value	p value
Peri-op pain (MME)	3.72	5.24	3.88	4.301	1.206	0.0113	0.7822	0.0008	0.4818
Post-op pain (MME)	14.81	14.08	6.539	10.57	0.8533	0.6214	<0.0001	0.0273	0.0011
No narcotics at discharge (n)	10 (12%)	4 (3%)	86 (65%)	24 (10%)	18 (85%)	0.0201	<0.0001	0.0791	<0.0001

Table 5 Distribution of ERP requirements

ERP elements	Pre		Post		ERP	ERP Vs C1 post
	C1 (81)	C2 (125)	C1 (132)	C2 (247)	C1 (21)	*p* value
Pre-op clinic visit/counseling	58 (71%)	109 (87%)	84(63%)	200 (80%)	21 (100%)	< 0.001
Sequential compression device	7 (8%)	1 (1%)	1 (1%)	0	20 (95%)	< 0.001
Clear liquid diet until 2 h	11 (13%)	34 (27%)	28 (21%)	33 (13%)	16 (76%)	< 0.001
Pre-op carb load	0	0	1	0	3 (14%)	0.0083
Loading dose analgesia	0	0	0	0	18 (85%)	< 0.001
Antibiotic prophylaxis	79 (97%)	118 (94%)	130 (98%)	243 (98%)	21 (100%)	> 0.99
Regional anesthesia	78 (96%)	123 (98%)	130 (98%)	241 (97%)	21 (100%)	> 0.99
Intraoperative fluids (ccs)	767.18	981.95	719	993.77	557.47	0.0224

Discussion

The goal of our study was to retrospectively review the impact of implementing an ERP that standardized perioperative care of patients undergoing pediatric laparoscopic cholecystectomy. Following implementation of our protocol, there was a substantial decrease in opioid use both during hospitalization and at discharge. These quality improvements were obtained with no increase in either readmission, phone calls from parents to clinic nursing staff or ER visits. Site C1 was previously exposed to enhanced recovery principles in other surgical procedures (including colorectal, foregut and thyroid surgery) which we believed contributed to the pre-existing difference in opiate use between sites in the pre-ERP period. This difference persisted in the post-ERP period despite a statistically significant decrease in opiate use at C2. However, despite this general trend of decreased opiate use, patients who underwent the protocol were found to have significantly less opiate use when compared to otherwise similar patients treated at C1 and C2 in the post-ERP period. The ability to demonstrate such differences in opiate use between campuses and over time suggest the quality improvement is related to elements of the protocol, rather than site-specific surgeon habit or institutional culture, temporal changes in practice standards or influences of prior enhanced recovery protocols. The lower rates of post-operative opiate use observed at C1 suggests a halo effect attributed to previous use/exposure of enhanced recovery principles in various surgical cohorts, including those being treated for pediatric colorectal, thyroid or inflammatory bowel disease [IBD]. This 'Halo Effect' (or associated improved outcomes in patient that are not specifically on enhanced recovery pathway at a facility that has integrated enhanced recovery principles) may be due to previous ERP experience in the implementation, commitment of anesthesia staff, nursing and clinical support, staff education as well as surgeon familiarity. This 'Halo Effect' could also be related increased awareness of state or national efforts encouraging improved opioid stewardship. Further research is required to determine the relative contribution of either explanation to this finding.

Recently published pediatric ERAS research in cholecystectomies has focused on LOS as the primary outcome/benefit of application of ERP principles [9, 15]. Our investigation also noted a significant difference in average LOS for the pre- vs post-ERP cohorts with 1.23 vs 1.14, respectively ($p = 0.014$) and all ERP compliant patient discharged on POD1. However, the long-term implications of decreased opiate use are likely farther reaching than those of decreased hospital LOS. Our retrospective review identified patients as far back as 2014 discharged on the same day of procedure who adhered with very few ERAS principles and showed no difference in outcomes when compared to the traditional overnight stay cholecystectomy patients. In the above-referenced trials, patients were discharged with a standard opiate prescription. All ERP patients in our study adhered with the traditional overnight admission; however, 85% were discharged with no opiates and again with no increased returns to system or complications. A future prospective analysis applying ERP principles to same day discharge laparoscopic cholecystectomy to evaluate opiate requirement would be beneficial.

Only 3 out of 21 patients (14%) were fully compliant with the 8 elements of the protocol, with 76% mostly compliant (6–7 out of 8) and the remaining partially compliant (5 out of 8). Though non-ERP patients did use some elements of the protocol in their care (such as use of regional/local anesthetic and antibiotic prophylaxis was nearly universal for all patients), ERP element implementation was higher in the 21 ERP patients when compared to non-ERP patients. The low compliance was difficult to explain retrospectively but may be due to limitations in consistent documentation (i.e., SCD use or pre-operative carbohydrate loading). However, these relatively low rates of compliance leave room for additional investigation regarding the most efficacious elements of the protocol, as well as strategies for efficient implementation and improved protocol documentation and compliance.

This study supports recent literature demonstrating the positive impacts of ERPs on opiate use in pediatric laparoscopic cholecystectomies [6, 9]. These findings are consistent with ERAS literature for adult cholecystectomies as well [16]. The small population ($N=21$) in the intervention arm (ERP patients) is a significant limitation in this study when comparing to the total 606 patients studied during the time period. However, despite pre-existing trends towards decreased opiate use (demonstrated by the change seen at C2 between pre- and post-ERP), the results showing decreased post-operative and peri-operative narcotic use (compared to non-ERP patients treated at C1 in the post-ERP period) is significant and adds credence to the authors final conclusion. Additional limitations include the retrospective nature of the study, which can lead to confounding by selection bias. We acknowledge that the lack of patient satisfaction data (as an adjunct measure of relative pain control) is a potential weakness, along with evolving resolution of implementation barriers at C1, limitations of electronic medical records, limited review regarding the 'cost' of implementing such protocol, and early and incomplete implementation efforts at C1. Variations in use of non-opioid post-operative pain regimen (acetaminophen, ibuprofen, ketorolac, and/or gabapentin) as well as further differentiation regarding regional vs pre-operative analgesia was not discussed in this paper. Specific retrospective data demonstrating impacts of non-opiate pain medication regimen is warranted. Further prospective clinical data implementing ERP for all outpatient cholecystectomy patients and observing outcomes and complications would be beneficial to affirm these manuscripts results. Additionally, there are no data on the application of ERP to more complex pediatric patients, those with longer expected length of stays, sickle cell patients and those also undergoing tandem laparoscopic splenectomy surgery. Moving forward, further evaluation would need to be in conjunction with a cost–benefit analysis to parse out which components of the protocol may not be as necessary. A prospective trial that incorporated evaluation of compliance as well as a component of patient satisfaction would provide a true measure of quality improvement to the field.

Conclusion

In conclusion, this review demonstrated the use of pediatric-specific ERP in children undergoing elective laparoscopic cholecystectomy surgery is safe, effective, and provides compassionate pain control, while leading to a reduction in opioid use peri-operatively and at discharge. This improvement occurred without differences in return to system, nursing calls or complications.

Author contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by GD, OK, MM, OT and GD. The first draft of the manuscript was written by GoD and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Declarations

Conflict of interest The authors declare no conflict of interest.

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