



Enhanced Recovery After Cleft Lip Repair: Protocol Development and Implementation in Outreach Settings

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Abstract

Introduction: Clefts of the lip are of the most common congenital craniofacial anomalies. The development and implementation of an enhanced recovery after surgery (ERAS) protocol among patients undergoing cleft lip repair may decrease postoperative complications, accelerate recovery, and result in earlier postoperative discharge.

Methods: A modified ERAS program was developed and applied through Global Smile Foundation outreach craniofacial programs. The main components of this protocol include: (1) preoperative patient education, (2) nutrition screening, (3) smoking cessation when applicable, (4) use of topical anesthetic adjuncts, (5) facial nerve blocks, (6) postoperative analgesia, (7) preferential use of short-acting narcotics, (8) antibiotic administration, (9) use of elbow restraints, (10) early postoperative oral feeding and hydration, and (11) discharge planning.

Results: Between April 2019 and March 2020, GSF operated on 126 patients with cleft lip from different age groups and 58.8% of them were less than 1 year of age. Three patients (2.4%) had delayed wound healing and one (0.8%) had postoperative bleeding. There were no cases of mortality, length of hospital stay did not exceed 1 postoperative day, and patients were able to tolerate fluids intake at discharge.

Conclusion: The implementation of an ERAS protocol among patients undergoing cleft lip repair has shown to be highly effective in minimizing postoperative discomfort while reducing opioids use, decreasing the length of stay in hospital, and leading to early oral feeding resumption. The ERAS principles described carry increased relevance in the context of the ongoing COVID-19 pandemic and opioid crisis and can be safely applied in resource-constrained settings.

Keywords

cleft lip, cleft lip repair, enhanced recovery after surgery, outreach settings, opioids, opioids crisis, pain management, postoperative complications, length of hospital stay

Introduction

Clefts of the lip and/or palate (CLP) are the most common congenital craniofacial differences. In the United States, an estimated one in every 2800 livebirths suffers from congenital cleft lip (CL).¹ CL repair is best performed early during the first 12 months of life and has well-documented benefits to patients, their families, and communities at large.² However, patients with CL can also present during adolescence or adulthood, with an unrepaired primary CL or a secondary cleft deformity with scarring or functional sequelae from a previous repair. CL care can sometimes necessitate more than one surgery from birth to adulthood, and surgeons have historically relied on the use of opioids for pain control.³

Opioids typically play a prominent role in the management of postoperative pain, but can be associated with many adverse

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Table 1. Systematic Approach to Development and Implementation of ERAS Protocol for CL Repair

1. Preoperative patient education
2. Nutrition screening, weight assessment, and minimizing NPO time
3. Smoking cessation
4. Use of topical anesthetic adjuncts
5. Infraorbital nerve and external nasal nerve blocks
6. Preferential use of short-acting narcotics
7. Postoperative analgesia
8. Antibiotic administration
9. Elbow restraints
10. Early postoperative oral feeding and hydration
11. Discharge planning

Abbreviations: CL, cleft lift; ERAS, enhanced recovery after surgery; NPO, nil per Os.

events, particularly in younger patients.³ Opioid-induced nausea, vomiting, ileus, pruritus, urinary retention, and/or respiratory depression can contribute to prolonged recovery and hospital stay.⁴ Novel strategies in perioperative care lean on multimodal management to minimize the use of opioids, especially among infants.

Enhanced recovery after surgery (ERAS) is an evidence-based multidisciplinary evolution in perioperative care paradigms.⁵ ERAS protocols were first described by Kehlet in the mid-1990s.⁶ They include multiple elements that have been implemented for a wide variety of major surgical procedures for both adult and pediatric patients. These elements include preoperative assessment of nutritional status and organ function, early oral nutrition, and multimodal approach to pain management with reduced use of opioids.⁶ ERAS is associated with improved symptomatic control after surgery as well as reduction in postoperative complications, length of hospital stay, hospital readmission, and mortality.⁷ The efficacious execution of ERAS protocols requires meticulous work and resilient cooperation among members of a multidisciplinary team including surgeons, anesthesiologists, pediatricians, nurses, physical and occupational therapists, speech and language pathologists, and nutrition specialists.⁷ Adherence to ERAS by the entire team is crucial for maximal results.⁸

The purpose of this manuscript is to describe an ERAS protocol for patients undergoing CL repair, developed, and implemented by Global Smile Foundation (GSF) in outreach settings through a standardized approach (Table 1). GSF is a non-governmental organization dedicated to providing safe, sustainable, and interdisciplinary cleft care in underserved settings, whose volunteers have been involved in outreach fieldwork for more than three decades. To our knowledge, this manuscript is the first description of the development and implementation of ERAS protocols for patients undergoing CL repair, particularly as it applies to resource-

constrained settings and to patients within a wide age spectrum of age ranging between 10 weeks and 60 years. We hypothesized that the implementation of such protocols would result in decreased postoperative complications, faster recovery, and early postoperative discharge. These elements are of paramount importance in the midst of the COVID-19 pandemic but also in the post-COVID-19 era, as extended hospital stays may put patients and healthcare workers at increased risk of contracting or spreading the virus and associated nosocomial infections, while increasing the utilization of scarce healthcare resources and equipment.

Methods

Since 2008, GSF has been developing and implementing an ERAS protocol for patients undergoing CL repair, based on collaboration between surgeons, anesthesiologists, pediatricians, and nurses. The protocol has been subjected to continuous modifications throughout the years to adapt to innovative perioperative approaches and maximize patient comfort and safety. The protocol focuses on minimizing intraoperative and postoperative opioid use and obviates the need for general anesthesia in appropriately selected patients aged 12 years or older. The protocol is designed for patients with primary or secondary CL deformities, with no difference in the perioperative management among them, and is applicable in resource-constrained outreach settings. Our ERAS protocol involves a multidisciplinary approach at every stage of the perioperative period. In the preoperative stage, we provide patient education, nutrition screening, and smoking cessation counseling. Intraoperative protocols focus on a multimodal pain control regimen that includes use of topical anesthetic adjuncts, facial nerve blocks and preferential use of short-acting narcotics. Postoperatively, appropriate analgesics and antibiotics are prescribed with emphasis on early oral feeding resumption.

Preoperative Patient Education

Preoperatively, all patients and their respective caregivers are thoroughly informed about the procedures and associated preoperative optimization and postoperative recovery. Instructions are provided orally and in writing in their native language and with illustrations to address illiteracy. GSF has also produced custom animated videos that we use to help explain the surgical procedure and the perioperative protocols to our patients and their families. This is critical to help reduce patient and caregiver anxiety while enhancing shared decision making and cooperation.

Nutrition Screening, Weight Assessment, and Minimizing Nil Per Os Time

The careful assessment of patients' nutritional status and weight is imperative. Patients who fall below the third

percentile for weight on World Health Organization growth charts do not qualify for CL repair. We follow the rule of 10 s for timing of CL repair, with surgical candidates having to be at least 10 pounds in weight and at least 10 weeks of age.⁹ Chow et al.¹⁰ questioned the validity of rule of 10 s for patients with CL but acknowledged that weight under 10 pounds is an independent predictor of overall complications among those patients. Secker and Jeejeebhoy¹¹ found that malnourished pediatric patients are more likely to have postoperative complications including infection and prolonged hospital stay. Additionally, GSF follows the Nil Per Os (NPO) time guidelines from the American Society of Anesthesiologists that focus on minimizing it to reduce the surgery-related state of catabolic stress and improve the ability of the body to cope with any associated complications.¹² Clear liquids may be ingested for up to 2 h before the procedure; breast milk for up to 4 h; infant formula, light meal, or nonhuman milk for up to 6 h, while heavy meals should be ingested up to 8 h before the procedure.

Smoking Cessation

Counseling for smoking cessation is provided prior to surgery for patients who present at an older age and report smoking cigarettes or any kind of tobacco containing products. Our local team members reach out to CL repair candidates 6 weeks prior to their surgery to reiterate the benefits of smoking cessation, emphasizing that if implemented at least 4 weeks preoperatively, it has been found to reduce the rate of wound infection and perioperative respiratory complications.¹³ Wong et al.¹⁴ showed that there was no significant difference between national estimates of smoking based on self-reports versus urinary cotinine concentration testing, which makes self-reporting for smoking status a valid tool to identify smokers and offer them smoking cessation counseling. In line with our belief of acting for the benefit of the patients, we would still provide adequate surgical care and keep enforcing the means and benefits of smoking cessation before surgery.

Use of Vapocoolant Before Performing Nerve Blocks for Cases Under Local Anesthesia

Vapocoolant is manufactured in a spray bottle. It is judiciously applied on the facial skin around the target areas within less than 1 min from performing the intended nerve blocks, providing fast topical anesthesia, and minimizing the discomfort of subsequent needle insertion.

Infraorbital and External Nasal Nerves Blocks

The infraorbital nerve (ION), a branch of the maxillary nerve (CN V2), provides sensation to the lower eyelid, cheek, nasal ala, and upper lip. The external nasal nerve (ENN), a branch of the ophthalmic nerve (CN V1), provides sensation

mainly to the nasal sidewall and tip. ION and ENN blocks are crucial components of our protocol, providing optimal patient comfort. For patients over the age of 12 years, we use equal volumes of lidocaine 1% with epinephrine 1:150 000 and bupivacaine 0.5% with epinephrine 1:150 000. For patients under the age of 12 years, we use equal volumes of lidocaine 0.5% with epinephrine 1:150 000 and bupivacaine 0.25% with epinephrine 1:150 000.

The ION block is performed at the midpoint of a virtual line extending from the oral commissure to the mid pupil. The needle is introduced 0.5 cm lateral to the alar rim and directed superolaterally along the vector described. In children, the vector is tilted more laterally, and it is safer to palpate the infraorbital rim while making the injections to avoid penetration of the infraorbital foramen and to protect the orbit.⁴ One milliliter is injected into each side for adolescents and adults, while 0.25 mL is used into each side for infants.

The ENN block is performed at the distal end of the nasal bone, above the upper lateral cartilage, around 7 mm lateral to the midline of the nasal dorsum.⁴ For adolescents and adults, we inject 0.5 mL into each side, while for children under 12 years of age we inject 0.25 mL into each side. Figure 1 illustrates the injection locations of ION and ENN blocks among pediatrics and adults.

In children, nerve blocks reduce perioperative pain as well as opioid use.⁴ For adolescents and adults who can remain still and tolerate awake surgery, this can permit safe execution of CL repair without the need for general anesthesia or intravenous sedation.

Smaller-Gauge Needles

In the senior author's (U.S.H.) experience, ION and ENN blocks can be accomplished using 27- or 30-gauge, 1-inch needles instead of the 25-gauge, 1.5-inch needles. Those have been found to be safer and better tolerated than large-gauge needles.¹⁵

Adequate Time Allowance

When performing CL repair under local anesthesia, nerve blocks are executed in the preoperative room 15–20 min prior to local lip infiltration. This helps the patient become more comfortable and tolerate local infiltration with ease. After local infiltration, 12 min are allowed to elapse prior to proceeding with surgical incisions in order to maximize the vasoconstrictive effect of epinephrine and minimize the need for electrocautery.

Anesthesia

Since 2006, GSF volunteer surgeons have been able to perform CL repair for adolescents over the age of 12 years and adults without general endotracheal anesthesia. These cases are performed under local anesthesia, with ION and ENN blocks, with or without sedation. GSF has been careful in selecting



Figure 1. Injection locations of the infraorbital nerve and external nasal nerve among adults (A and B) and pediatrics (C and D).

patients who can undergo their procedure under local anesthesia, bearing in mind some limiting factors, such as cognitive impairment, anxiety, or inability to fully understand the procedure. Between 2008 and 2009, GSF surgeons performed primary CL repair under local anesthesia on 22 patients aged 12 years or older abiding by the ERAS protocols described in this manuscript. All patients were discharged home on the day of surgery and were able to tolerate oral fluids at the time of discharge. There were no immediate postoperative complications, including infection, hematoma, wound dehiscence, ischemia, or adverse reaction to anesthetic agents.¹⁵ For CL repair under general anesthesia, our anesthesia team developed a protocol relying mainly on IV acetaminophen and short-acting narcotics, mainly fentanyl, with the occasional addition of intermediate-acting narcotics, such as morphine, in select synchronous premaxillary setback cases. This combination of short-acting narcotics with minimal use of intermediate-acting ones has helped in reducing postoperative nausea and vomiting, leading to sooner initiation of oral feeding during the postoperative period.¹⁶ Combining an

ENN and ION block for all CL repair cases achieves optimal pain control and diminishes the need for perioperative opioid analgesia.⁴ Rajamani et al.¹⁷ demonstrated that the use of bilateral ION block is superior to fentanyl in terms of shorter time to awakening, enhanced postoperative pain control and earlier time to feeding. Doyle and Hudson¹⁸ reported a 4% incidence rate of oxygen desaturation among CL repair patients following consistent use of opiates postoperatively while keeping their use to minimum intraoperatively. Van Boven et al.¹⁹ stated that up to 31% of the CL repair patients received intraoperative fentanyl or alfentanil, with the majority (87%) having a unilateral cleft lip, and documented three cases of oxygen desaturation. IV acetaminophen is emerging as an adjunctive medication to provide a multimodal approach to pain control upon extubating patients. Data has shown that IV acetaminophen use can result in reduced stays duration and less sedation in PACU, minimize opioid utilization, and lesser opioid-related side effects.²⁰⁻²⁰ Rectal route for acetaminophen administration can be used as a substitute to the IV one, especially in resource-restricted sites where it is

more cost-effective. Mireskandari and Makarem²³ showed that rectal acetaminophen administered in the operating room at the end of surgery for patient undergoing palatoplasty is more effective in pain control than rectal placebo, and both were equals in regard to postoperative nausea and vomiting. Yung et al.²⁴ demonstrated that there is no clinical difference or advantage with the use of rectal versus IV acetaminophen regarding postoperative pain intensity, need for supplementary analgesic medications, stays in the PACU, or discharge time from the hospital.

Analgesic Agents

In concordance with efforts to reduce postoperative pain while minimizing opioids use, a multimodal pain management strategy using acetaminophen and/or ibuprofen is employed. We recommend prescribing appropriate doses of acetaminophen, as needed postoperatively, for patients undergoing CL repair. Appropriate doses of ibuprofen can be prescribed, as alternative to acetaminophen, for patients older than 6 months of age.

Antibiotics

Prophylactic antibiotics are administered intravenously prior to the incision, and usually consist of one dose of first or second generation cephalosporins. Postoperatively, patients are discharged with a prescription of the appropriate dose of the same class of antibiotics, to be given orally for a total course of 5 days following surgery. Topical antibiotics are recommended in case of crusting around the nostrils and/or the vermillion border. If Dermabond® is used, topical antibiotics should be avoided during the first week after surgery. The potential risk of postoperative complications caused by wound infection support the need to use antibiotics after CL repair.²⁵

Elbow Restraints

To prevent unwanted manipulation of the wound, young pediatric patients are still required to wear elbow restraints postoperatively. Before being discharged, the nurses show parents how to properly place the restraints around their infant's elbow and communicate with the surgeon the appropriate duration for that. Petersen²⁶ reported that 95% of respondents to a survey lead by the Cleft Palate teams support the use of postoperative arm restraints. Katzel et al.²⁷ stated that 85% of cleft care surgeons advocate the use of elbow restraints after surgery. However, Huth et al.⁴⁰ showed in their study that there was no significant difference in the incidence of postoperative complications among patients without elbow restraints following cleft lip and palate surgery.

Oral Feeding and Hydration Resumption

Oral feeding is resumed on postoperative day 0 or 1, starting with a full liquid diet and progressing to a soft/pureed diet

on postoperative day 2. Patients can typically progress to a regular diet 2 weeks later. For patients who are bottle fed, detailed oral and written instructions are provided to the caregiver for proper guidance, to minimize stress and local tension at the level of the surgical wound. In outreach settings, where many of the primary CL repair patients are older children, adolescents, and adults, an emphasis on specifying the different diet types and how to progress with each, is required and usually done by our nutrition and feeding specialists (Figure 2).

Discharge Planning

Detailed instructions are provided, in the patient and/or caregiver's native language, detailing antibiotics and pain medication administration, wound care, and feeding, with a full description of potential complications (Figure 2).

Patient Follow-up

Strong collaboration between on-site volunteers and coordinators and US-based team members and surgeons has helped smoothen and streamline the follow-up process. Additionally, GSF's diagonal model of care delivery has led to the development of comprehensive cleft centers in Ecuador and Lebanon, allowing year-round on-site presence, care, and support for our patients. Patients are scheduled to have regular face-to-face and phone meetings with local surgeons who are always in contact with their US-based colleagues for continuation of care and exchange of expertise and experience. Most patients are also seen again during the team's upcoming outreach trips to the same site.

During the COVID-19 pandemic, lockdowns and restricted face-to-face consultations necessitated strict implementation of telehealth for adequate and efficient follow-up. Video calls and photographic documentation contributed to maintaining follow-up and monitoring progress throughout the crisis.

Results

GSF has recently internally developed an integrated Electronic Medical Record (EMR) system allowing standardized, consistent, and centralized documentation of patient outcomes, and accumulation of longitudinal patient data for prospective outcome evaluation. Since April 2019, 95 primary CL repairs and 29 CL revisions have been performed, with 20 (16.1%) procedures done in Beirut, Lebanon, 25 (20.1%) in Trujillo, Peru, 68 (54.8%) in Guayaquil, Ecuador, and 11 (8.8%) in El Salvador. Most of our patients were males (66.1%), with a male-to-female ratio of 2:1. Most patients were less than 1 year of age (58.8%) (Table 2). In total, 96% of primary CL repair patients are under the age of 12 years while 56% of secondary CL repair patients are above the age of 12 years (Figure 3). Average fentanyl used intraoperatively is 30 µg per patient, whereas the average morphine used is 1 mg during select surgical cases. No patient received or was prescribed opioids during the postoperative period. All patients

Global Smile Foundation

How to Care for Your Child

Name of Patient: _____ Allergies: _____

Give your child the antibiotic colored: _____

_____ in the morning  and _____ in the evening 

for _____ days.

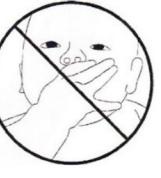
If pain medication is needed, use _____ every 4 hours (only if there is pain).



Lip Care

- Keep lips clean and dry for 3 weeks.
- Use water to wipe your child's nose and lips
- Do not use pacifiers or bottles for 3 weeks (unless it is a specialty bottle provided by Global Smile)
- Do not allow your child to suck on anything for 3 weeks
- In 6 weeks, _____, begin circular massage on the scar of the lip 5-6 times a day for 5-6 months



Hands

- Do not allow your child to touch his mouth or nose for 3 weeks
- Use the braced immobilizers constantly during most of the day and night
- Allow your child to move his or her arm 3 times a day for 20 minutes. Watch your child carefully and do not allow your child to touch the mouth or nose during this time






Do Not Eat Solid Food for Two Weeks

- First day: milk, juice, soup
- For 3 weeks: milk, juice, soup, purees, creams, shakes, smoothies, yogurt.
- For expecting mothers, avoid exposure to smoking and take multivitamins containing folic acid

Return to the hospital on _____ for the first post op check on _____ and on _____ for the second check with Dr. _____.

**** When to call for emergency ****

- Heavy bleeding / bright red blood
- Difficulty breathing
- Unable to take food orally

Emergency Contact: _____

Parent/Guardian Signature: _____

Date: _____

Figure 2. Postoperative care instructions for patients undergoing cleft lip repair.

Table 2. Cleft Lip Repair Patients Demographics Between April 2019 and March 2020

Mission site	Date	Procedure		Age (in years)				Sex	
		CL repair	CL revision	<1 year	1-3 years	3-12 years	>12 years	F	M
BEY	Apr-19	7	13	3	5	5	7	7	13
TRU	May-19	20	5	14	2	6	3	10	15
GYE	Jul-19	25	0	20	2	2	1	8	17
GYE	Sep-19	14	4	11	2	2	3	3	15
SAL	Jan-20	9	2	8	1	1	1	3	8
GYE	Mar-20	20	5	17	2	2	4	11	14
Total		95	29	73	14	18	19	42	82

Abbreviations: BEY, Beirut; CL, cleft lip; F, female; GYE, Guayaquil; M, male; SAL, El Salvador; TRU, Trujillo.

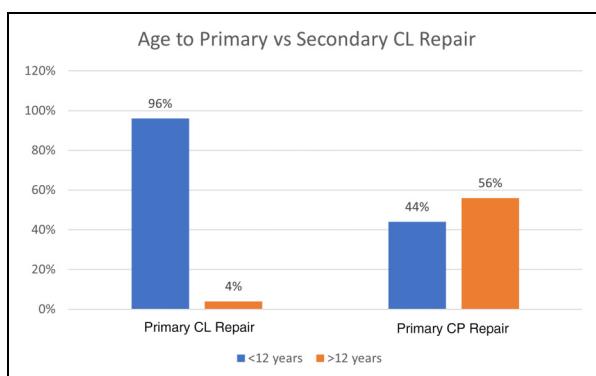


Figure 3. Age correlation analysis of patient age to primary versus secondary cleft lip repair during Global Smile Foundation outreach programs between April 2019 and march 2020.

were discharged home either on postoperative day 0 or day 1 and were able to tolerate oral fluids at the time of discharge. Three patients (2.4%) had delayed wound healing and one patient (0.8%) had postoperative bleeding. There were no cases of mortality following CL repair.

Discussion

For the past two decades, multiple variations of ERAS protocols have been implemented for a diversity of surgical procedures. Most of these protocols have traditionally targeted the adult patient population and focused on major abdominal surgery. ERAS protocols have been found to be highly effective among adults, resulting in improved postoperative outcomes. Greco et al.²⁸ showed that strict implementation of ERAS protocols for major colorectal surgery helps reduce the recovery time and length of hospital stay to 2 to 3 days and decreases non-surgical complications by 60%, with no increase in readmission rates. Following the development of a modified ERAS protocol for pediatric patients undergoing cleft palate repair, Hush et al.²⁹ reported that implementation of such practice along with shifting away from the traditional perioperative narcotic pain regimens is efficient and safe.

Their results showed effective pain control, faster oral feeding resumption, and a shorter duration of hospital stay.

In this manuscript, we describe our protocol and ongoing experience applying ERAS principles to CL repair. After 2008, our perioperative management approach was revised and included key changes and additions. These include executing CL repair for patients aged 12 years and more under local anesthesia without the use of opioids, changes in the local anesthetics mixture and the nerve blocks techniques. Moreover, adapting to ongoing perioperative advances encouraged adjusting some of the elements of the protocol. This includes using topical vapocoolant spray within 45 s before executing facial nerve blocks as opposed to the traditional use of local anesthetics mixture, EMLA, within 60 min of performing nerve blocks. This protocol aims mainly at controlling pain and minimizing perioperative patient discomfort, speeding up functional recovery, and encouraging adequate nutrition and hydration while maintaining airway safety. Our protocol relies on a systematic approach including: (1) preoperative patient education, (2) nutrition screening, weight assessment, and minimizing NPO time, (3) smoking cessation, (4) use of topical anesthetic adjuncts, (5) ION and ENN blocks, (6) preferential use of short-acting narcotics, (7) postoperative analgesia, (8) antibiotic administration, (9) use of elbow restraints, (10) early postoperative oral feeding and hydration, and (11) discharge planning. The components of the ERAS pathway can help mitigate the metabolic and hemodynamic stress caused by surgery and promote a faster and smoother come back to homeostasis (Ljungqvist, 2014).

Between April 2019 and March 2020, a very low postoperative complication rate of 3.2% was encountered, length of hospital stay was no longer than 1 day postoperatively, and patients were able to tolerate oral fluids at discharge. Schönmeyr et al.³⁰ reported an overall complication rate of 4.4% following 2062 CL repair procedures, mainly including skin dehiscence and wound infection. Abdurrazaq et al.³¹ described a rate of postoperative complications of 5.4% following 92 CL repair procedures consisting mainly of hypertrophic scars. In their study, Adesina et al.³² reported that 30 complications have been documented following 90 CL repairs. Lees and Pigott³³ advocated that CL repair patients

should remain in hospital for 3 days following surgery as they found that respiratory and hemorrhagic complications occur mainly within the first 48 h postoperatively. Preidl et al.³⁴ conducted a survey in 70 international plastic and maxillofacial departments and reported that the average postoperative inpatient stay for CL repair patients is 4.1 ± 2.6 days. Longer hospital stays are associated with increased risk of complications and resource utilization, with the additional newfound risk of potential exposure to COVID-19. Efunkoya et al.³⁵ reported that patients remain in the hospital for 7 days after cleft lip and palate repair for monitoring in a Nigerian teaching hospital. Hush et al.²⁹ found that the length of hospital stay after cleft palate repair has reduced from 1.83 to 1.16 days following implementation of ERAS protocol. Comparing our results to the literature shows that adherence to the above-mentioned protocols may result in reduced rate of postoperative complications for patients undergoing CL repair and shorten the length of hospital stay.

The traditional belief that surgery patients should be placed NPO from midnight was originally established to reduce the risk of aspiration during anesthesia induction. However, Brady et al.³⁶ stated that there is no evidence to support that a reduced state of fluid fasting can result in an increased risk of aspiration, regurgitation, or related morbidity. In addition to that, Ljungqvist¹⁶ mentioned that overnight fasting results in a greater metabolic stress which reduces the body's ability to cope with any complication potentially causing a prolonged recovery, which defies the rationale behind implementing ERAS protocols.

The specificity of our ERAS protocol and its efficacious implementation are the result of strong cooperation among surgeons, nurses, anesthesiologists, pediatricians, nutrition specialists, and volunteer coordinators. GSF has shed light on and given aggressive attention to safety protocols over the years, benefiting from the experience of highly qualified cleft team members. Eighty percent of team members return to the same location during subsequent outreach trips, adding an extra layer of safety to our protocols through increased team cohesion and familiarity with relevant procedures, workflows, and guidelines. The modified ERAS protocol has been gradually refined to be adaptable to all age groups, with a focus on faster and smoother recovery, reduced postoperative complications, and early hospital discharge. The implementation of ERAS protocols for CL repair carries renewed significance and uniqueness in outreach settings where multiple uncontrollable factors can complicate the postoperative course and follow-up. These factors include, but are not limited to, the distance traveled by our patients, which can sometimes exceed 24 h, the level of education of the patients and their families, and/or the unavailability of skilled surgeons in the areas where our patients reside to tackle postoperative complications. Due to these considerations, GSF had to implement certain steps out of an abundance of caution, to reduce potential complications, such as prescribing antibiotics for 5 days after surgery, progressing to regular diet over a 2-week period, using elbow restraints for younger patients or avoiding the use of

pacifiers/sucking on anything or breastfeeding for 3 weeks. Alternatively, breastfeeding mothers are offered hand pumps that allow them to express their breast milk. In addition to that, strict implementation of telehealth has promoted efficient communication with our patients while ensuring patients and providers' safety. The overall success of our ERAS protocol in outreach settings is a testament to its cost-effectiveness, ease of implementation, and versatility in resource-limited conditions.

ERAS protocols are also increasingly relevant in the context of the opioid crisis. One study found that 66.4% of drug overdose deaths were caused by opioids, including prescription opioid analgesics and illicit opioids.³⁷ Surgical services are thought to contribute to around 90% of controlled substance prescriptions for pediatric patients.³⁷ Traditionally, patients undergoing cleft repair received an average of 0.47 mg/kg of morphine equivalents during hospitalization with additional 6.8 doses of opioids after discharge.³⁸ In their study, Bennett et al.³⁹ found that the incidence of new persistent opioid use among patients following common cleft procedures is 4.4%. Hush et al.²⁹ reported a significant decrease in opioids use among patients enrolled in the ERAS group for cleft palate repair when compared to controls. Amid an exacerbating crisis of opioids abuse and misuse it is invariable for healthcare professionals to admit their contribution to the worsening of the problem. The implementation of our modified ERAS protocol for CL repair demonstrates that adopting a conservative approach of using opioids intraoperatively and transitioning to non-narcotic pain regimens post CL repair for pain control is feasible, safe, and applicable in outreach settings. The implementation of ERAS protocols can help reduce opioid-related complications among pediatrics and contribute to enhancing the impact of the opioid crisis among patients with clefts.

Conclusion

ERAS protocols have been shown to be highly effective among adults, reducing postoperative complications and promoting early hospital discharge. Limited experience exists for ERAS development and implementation in the outreach surgical settings and the pediatric surgical patient population.²⁹ In this manuscript, we describe the development and implementation of ERAS protocols by GSF for patients undergoing CL repair in outreach settings. Our experience and results demonstrate that this protocol is safe, effective, and well received through the spectrum of patient age ranging from 10 weeks of age to 60 years or older. Our ERAS protocol has proven to be a noteworthy alternative to routinely used pain control regimens, especially those relying on opioids. We hope other organizations involved with global craniofacial surgical outreach can build upon our experience and adopt our ERAS protocols for CL repair to abolish the discrepancies in the perioperative management of patients undergoing craniofacial reconstruction surgeries. The ERAS principles described carry increased relevance in the context of the ongoing COVID-19 pandemic and opioid crisis, particularly in resource-constrained settings.

Declaration of Conflicting Interests

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