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Lidocaine/Prilocaine cream Decreases Narcotic Use following Gastrostomy Placement: A Novel Pain Management Strategy for Children

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Abstract

Background

Gastrostomy tube (gastrostomy) placement is an increasingly common procedure in children requiring alternative means of nutrition. Pediatric patients have been shown to tolerate percutaneous endoscopic gastrostomy (PEG) placement. Pain management is a chief concern in the care of children and often involves the use of opiates. Lidocaine/ Prilocaine cream (LPC) has demonstrated emerging effectiveness for pain management in a myriad of pediatric procedures with minimal side effects. Our study aims to determine whether LPC cream can decrease the need for narcotics during post-operative pain management following PEG pediatric patients.

Methods

This retrospective study involved the review of patient charts from January 2015 to May 2017 who underwent gastrostomy placement. Primary endpoints studied included demographic information, length of stay, medication reconciliation, complications, and hospital costs.

Results

59 patient records were reviewed for study inclusion (mean age 5.0±5.4 years, 57.6% male, and 15.0±12.1 kg). LPC was provided to 57% (n=34) subjects which was associated with decreased morphine milligram equivalent doses (MME), P=00.01, shorter hospitalization stay (mean days difference 13.74±5.62, median days difference=1), P=0.018 and decreased cost of hospitalization.

Conclusion

Our study is the first to characterize the effectiveness of LPC cream in the management of post-operative pain following gastrostomy placement in pediatric patients. Our team demonstrated that patients with LPC cream, regardless of gastrostomy technique employed, required fewer weight-based MME doses, a shorter hospital stay, and decreased hospital costs.

Keywords: LPC cream, gastrostomy, narcotics, pain, post-operative

Acronyms: gastrostomy tube (gastrostomy); weight-based morphine milligram equivalent doses (MME); Laparoscopically-assisted PEG (LAPEG); Lidocaine/ Prilocaine cream (LPC); Electronic Health Record (EHR); percutaneous endoscopic gastrostomy (PEG); length of stay (LOS); length of procedure (LOP); length of pain treatment (LOT); United States Dollars (USD), 95% Confidence interval (CI)

Introduction

Gastrostomy tube (Gastrostomy) placement has become a common procedure in the care of pediatric patients requiring enteral nutrition that cannot be acquired orally (1). Phalen et al recently estimated that 3-10% of children nationwide have feeding disorders leading to nutritional deficiencies. Furthermore, the American Academy of Pediatrics recommends enteral nutrition, such as gastrostomy tube feeds, when patients cannot consume (or safely consume) adequate calories to support growth (2). Fox previously demonstrated an increasing rate of gastrostomy placement in children from 1997 (16.6 procedures/ 100,000 children) to 2009 (18.5 procedures/ 100,000 children)(1).

Our review of the medical literature, a query of Pubmed on December 25, 2017, using the keywords "gastrostomy"+ "pain

management", did not reveal any studies describing the acute post-procedural pain management following gastrostomy placement in children. The post-operative pain management for many other pediatric procedures is well-documented (3-9). There is evidence to support the use of Lidocaine/ Prilocaine cream (LPC) for painful interventions. Bjerring achieved pain relief greater than skin thickness when LPC was applied for greater than 90 minutes, and Wahlgreen showed that longer LPC application times (4-6 hours) facilitated maximum skin punch biopsy (diameter= 4mm, depth=6mm) (10, 11). LPC has also shown decreased pain associated with: immunizations, venipuncture, lumbar puncture or splint removals, circumcision, or poxvirus curettage (12-17). Finally, Usmani et al demonstrated the decreased narcotic use when LPC was applied to the surgical site following inguinal herniotomy (18).

Our study aims to determine whether LPC cream decreases the need for narcotics in post-operative pain management following gastrostomy placement in children.

Methods

This is a retrospective analysis of patients admitted to our institution from January 2015 to May 2017 for the purposes of gastrostomy placement.

Patient records were first queried from our institution's inpatient Electronic Health Record (EHR), Meditech, with the primary purpose for describing care provided during admission for gastrostomy placement (19). Records were then cross referenced with outpatient
EHR, Athena for confirmation.

Inclusion criteria for this study: patient age 0 to 17 years; patient required a non-oral method of receiving enteric nutrition. Patients were excluded if the gastrostomy was placed by a non-endoscopic technique such as an open gastrostomy, a laparoscopic technique [mini Open Stamm, Seldinger, modified Seldinger] or by interventional radiology. Informed consent was exclusively obtained via written consent from the patient's parent. At our institution, application of LPC in the post-operative period has become a standard operating procedure based on provider practices. When ordered by the on-service gastroenterologist, LPC was provided in a strict nursing protocol which includes a step by step process:

- Clean the gastrostomy site,
- Turn the gastrostomy device turned 360 degrees,
- Apply the LPC cream to the gastrostomy site,
- Leave the LPC on the site for 20 minutes and then wipe away.

Patients were not randomized in this retrospective analysis.All patients receiving gastrostomy were prophylactically treated with Ancef at the time of the procedure with 2 additional doses given during the first 24 hours post-surgery to reduce the risk of wound infection (20).

Data collected included demographic data (age, sex, weight, comorbid medical conditions), clinical characteristics for admission (length of stay, length of procedure (LOP), procedure type, length of pain treatment (LOT), pain medications and frequency of use), Face, Legs, Activity, Cry, Consolability scale (FLACC) pains cores (when available), additional clinical outcomes (major complications, minor complications). Primary endpoints of interest included: length of stay post procedure, narcotic pain medications used, and complication rates within 7 days of the procedure. Complications defined for this study were similar to those described by McSweeney et al, Major complications: (re-hospitalization following discharge, re-operation/surgical intervention, tract disruption, perforation, intraoperative complication); Minor complications (gastrostomy dislodgement, leaking, granulation tissue growth, bleeding, need for additional acute outpatient visit) (21).

Finally, a cost analysis of all admissions for the study participants was performed with the help of business operations colleagues within the Baylor College of Medicine. To account for variability in patient medication costs, laboratory investigations, etc, the cost of a medical/surgical hospital bed daily charge = $4106, was used as a normalizer. All total costs were adjusted for the length of stay.

Categorical data were summarized using descriptive methods including percentages and analyzed using Chi-Squared tests or Fisher's Exact test as appropriate. Means and standard deviations or medians and inter-quartile ranges were used as summary statistics for continuous variables and were analyzed using Student's t-test and ANOVA or Wilcoxon's Test. A 2-way ANOVA with a Tukey adjustment was performed to determine if the difference between the gastrostomy methods and pain management was associated with the subjects' aforementioned clinical outcomes. A p-value <0.05 was considered statistically significant.

This study was approved by the Institutional Review Boards of the Baylor College of Medicine (Protocol number: H-37260).

Results

Patient Demographics

A total of 59 patient charts were reviewed (mean age 5.0±5.4 years, 57.6% male, 15.0±12.1 kg).

Table 1: Patient Demographics, Pertinent Medical Histories Data Table.

	LPC	No LPC	P-value
Number subjects (n, %)	34, 57.6%	25, 42.0%	NS
Male (n, %)	21, 35.6%	13, 22%	NS
Age, years (mean ± SD)	4.6±5.6	5.5±5.1	NS
Weight, kg (mean±SD)	13.6±9.4	16.9±15.1	NS
LOS, days (mean ± SD)	4.3±5.2	18±32.3	0.018
Procedure length, minutes (mean ± SD)	13.2±5.3	18.3±13.6	NS

Length of pain treatment, days (mean ± SD)	3.4±2.4	3.0±2.0	NS
Neurologic Disease (n, %)	24, 64.8%	21, 77.8%	0.001
Prematurity (n, %)	3, 8.1%	4, 14.8%	NS
Genetic/ Metabolic Disease (n, %)	6, 16.2%	8, 29.6%	NS
Oncologic/ Immunologic Disease (n, %)	4, 10.8%	3, 11.1%	NS
Pulmonary Disease (n, %)	4, 10.8%	5, 18.5%	NS
Cardiac Disease (n, %)	5, 13.5%	6, 22.2%	NS
Chronic Kidney Disease (n, %)	0, 0%	0, 0%	NS

N=number; SD=standard deviation; NS=not significant

Table 1 outlines the frequency of pertinent past medical conditions for the study population. The most common finding was neurologic injury, 72.9% (n=43), most commonly associated with cerebral palsy, and oropharyngeal dysphagia.

LPC was provided to 57.6% (n=34) of the subjects. **Table 2** demonstrates the clinical characteristics and complications when comparing patients with LPC use to those without LPC use. This study did not find any differences between the groups in regard to patient age, weight, sex, or the gastrostomy technique employed. Initially, LPC use was associated with a shorter hospitalization stay (mean days difference 13.74±5.62, median days difference=1), p=0.02. When evaluating children admitted for ≤7 days, there was no significant difference in length of hospital stay between the groups. In addition, Table 2 demonstrates the vital signs charted above the expected age-based norms for the subjects (22), separated by LPC use, which revealed no significant differences between the two groups. Finally, Table 2 demonstrates there were no significant differences in complications rates when comparing subjects provided LPC following gastrostomy compared to those without LPC.

Table 2: Patient Vital Signs and Complication Rates Data Table.

	LPC	No LPC	P-value
Number subjects with Heart rate, >2 SDs mean for age	9, 45%	3, 43%	NS
Number subjects with Respiratory rate, >2 SDs mean for age	4, 20%	2, 29%	NS
Number subjects with Mean Arterial Pressure, >2 SDs mean for age	18, 90%	6, 86%	NS
Leakage (n, %)	8, 23.5%	5, 20.0%	NS
Extreme pain, (n, %)	2, 5.9%	2, 8.0%	NS
Granulation, (n, %)	10, 29.4%	8, 32.0%	NS
Bleeding, (n, %)	2, 5.9%	2, 8.0%	NS
ED visit, (n, %)	7, 20.6%	9, 36.0%	NS
Dislodged, (n, %)	4, 11.8%	6, 24.0%	NS
Malfunction, (n, %)	4, 11.8%	5, 20.0%	NS
Feeding intolerance, (n, %)	4, 11.8%	5, 20.0%	NS
Cellulitis, (n, %)	0, 0%	0, 0%	NS
Re-admission, (n, %)	0, 0%	0, 0%	NS
Ileus, (n, %)	0, 0%	0, 0%	NS
Candidiasis, (n, %)	1, 2.9%	0, 0%	NS

N=number; SD=standard deviation; NS=not significant

Patient Pain Management with LPC, Sub analysis

Patients who received narcotics without LPC tended to have longer procedures (n=22.3±16.5 minutes), p=0.047. Further analysis reviewed that the mean weight-based morphine milligram equivalents per patient was smaller for subjects who received LPC without narcotics, n=34, (mean MME=1.0) compared to the sub-population who received no LPC, n=25, (mean MME=1.5), p=0.001 (23). Furthermore, the MME for subjects who received both narcotics and LPC, n=17, (mean MME=1.7) was significantly decreased compared to subjects who received narcotics without LPC, n=12, (mean MME=2.6), P=0.001. Additionally, subjects who received LPC with narcotics demonstrated both greater rates of Ibuprofen use (n=7, 41.2%) and number of doses (5.7±2.4 doses) compared to the group provided narcotics without LPC (n=0, 0%), p=0.02 and p=0.02.When adjusted for similar drug classes and frequency of use, all other medication usage was similar between the groups.

From a medical resource management perspective, our cost analysis demonstrated that the average hospital charge for stay of patients following gastrostomy who had LPC was 54449 ± 70164 (95% confidence interval (CI) 18942-89956) United States Dollars (USD). By comparison similar patients discharged following gastrostomy, without LPC use post-operatively, had an associated, average hospital charged stay of 70564 ± 90901 (CI 20887-180241) USD, p<0.05.

Discussion

Our study is the first to characterize the effectiveness of LPC cream in the post-operative care of gastrostomy placement in

children. Specifically, we have demonstrated that children across the age spectrum tolerate LPC cream placement immediately post-operatively, have a decreased use of narcotics, and generally similar complication rates as compared to the rest of the cohort

This study serves as the first investigation to describe the post-procedural pain management following gastrostomy placement in children. One of the central tenets of this investigation was to determine whether LPC might decrease opiate use in post-operative periods for children with gastrostomy placements. The patients who received LPC demonstrated a smaller MME compared to subjects who did not receive LPC. This would indicate to investigators that pain was more adequately controlled with the advent of topical analgesia. Furthermore, this superior analgesic effect appears to be compounded for subjects suffering from severe pain who required a combination of narcotics and LPC. When comparing this combination group to subjects who received narcotics in the absence of LPC, LPC conferred a significantly smaller MME indicating that significantly fewer narcotics were required to maintain adequate pain control for the child. When sub-stratified for comparison, the group who received LPC and narcotics used more Ibuprofen compared to patients not receiving LPC. However, this analysis is likely skewed due to the fact that patients provided narcotics without LPC had heavy use of Acetaminophen without any uses of ibuprofen catalogued. When comparing the patients receiving LPC and narcotics to those using LPC without narcotics, there was no difference in ibuprofen use or number of mean ibuprofen doses provided. Furthermore, the age-based, physiologic scoring of heart rate, respiratory rate, and blood pressures revealed no significant difference when patients were compared based on LPC use. Thus, in the absence of other medication use differences, this allowed investigators to theorize that the LPC cream, when used in concert with other either non-opiate medications such as nonsteroidal anti-inflammatory drugs or narcotic medications, confers optimal pain control following gastrostomy placement. Furthermore, investigators would submit that optimal pain control can likely be achieved with LPC and non-opiate medications alone without narcotics. This supposition for pain management has been supported previously by Krauss and Argoff et al (25-27). In addition, Bjerring et al, showed that LPC application for 90 minutes or greater was associated with optimal pain control compared to shorter application durations as in our cohort (10). As a result, we have considered that a protocoled application of LPC for longer periods, such as 60 minutes, compared to the 20 minutes in our study, could possibly lead to more definitive, optimal pain control and decrease the need for opiates (25). This technique may play an emerging role in the acute pain management of children given the current national shortage of medical grade narcotics as well as the growing national epidemic of narcotic addiction and abuse (28-30). Furthermore, by decreasing the use of opiates in the post-procedural pain management of gastrostomy placement in lieu of LPC, complications including: chronic opiate abuse, respiratory depression, sedation, constipation, urinary retention or development of drug tolerance which are often associated with opiates, can potentially be avoided (31).

With respect to post procedure complications, no significant differences were noted comparing LPC usage in hospital or up to 1 week post-operatively. Given the heterogeneity of the study subjects as detailed in Table 1, the relative safety profile exhibited with LPC in this study would indicate that LPC is a safe addition to the pain management protocol of children undergoing gastrostomy placement at other facilities and may serve as a useful alternative to narcotics.

Finally, the opiate abuse epidemic is a well-known phenomenon that has begun to surface within the pediatric population. A call for alternative pain management therapies to decrease the use of narcotics given the habituation potential has been made, and, as gastroenterologists, our team seeks to lead the charge within the field. While this approach seems to serve the appropriate moral and medically ethical solution for post-operative pain management in children, we concede that institutional change can be difficult and is oftentimes weighed against the cost of culture change. As evidence by our study, not only can LPC confer superior pain management compared to narcotics, the shorter length of stay can verifiably reduce the cost of hospitalizations even when adjusting for similar length of stay, as previously evidenced by Uchiyama et al (24). This indicates that patients requiring LPC required less cost compared to those without. In the future, this could serve as the lead point for introducing LPC into the care plan of new post-operative patients in other facilities for other indications.

Limitations

Although the greatest strength of a retrospective study design is the ability to establish associative relationships among identified variables, we are unable to attribute direct cause-and-effect linkages without prospective studies that validate these observations. Human errors during chart review and data collection are unavoidable and may distort data analysis. However, our use of random chart review audits should have minimized this effect. The use of patient driven pain assessment, scoring or surveys using Likert scales may provide an additional, clinically relevant end point for future studies to elucidate the true effect of LPC cream on pain management for gastrostomy procedures. Additionally, it is possible that patient complexity or severity of disease may have prolonged hospital stays which cannot be objectively quantified in this study. These variables may have affected data extrapolation, thus interpretations of cost should be made with caution. Finally, the relatively small study size may limit the generalizability of our results.

Conclusion

Our study is the first to characterize the effectiveness of LPC cream in the management of post-operative pain following PEG or GP in pediatric patients. Our team demonstrated that patients with LPC cream, regardless of gastrostomy technique employed required fewer morphine doses and a shorter hospital stay. Future prospective investigations will confirm the safety profile of LPC on gastrostomy sites in the post-operative period and will aid in the determination of whether LPC applications for longer periods can improve pain control.

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