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Comparison of outcomes for pediatric paraphimosis reduction using topical anesthetic versus intravenous procedural sedation☆

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ABSTRACT

Background: Paraphimosis is an acute urologic emergency requiring urgent manual reduction, frequently necessitating procedural sedation (PS) in the pediatric population. The present study sought to compare outcomes among pediatric patients undergoing paraphimosis reduction using a novel topical anesthetic (TA) technique versus PS.

Methods: We performed a retrospective analysis of all patients <18 years old, presenting to a tertiary pediatric ED requiring analgesia for paraphimosis reduction between October 2013 and September 2016. The primary outcome was reduction first attempt success; secondary outcomes included Emergency Department length of stay (ED LOS), adverse events and return visits. Dichotomous outcomes were analyzed by Chi-square testing and multivariate linear regression was used to compare continuous variables.

Results: Forty-six patients were included; 35 underwent reduction using TA, 11 by PS. Patient age and duration of paraphimosis at ED presentation did not differ between groups. There was no difference in first attempt success between TA (32/35, 91.4%) and PS groups (9/11, 81.8%; $p = 0.37$). Mean ED LOS was 209 min shorter for TA patients (148 min vs. 357 min, $p = 0.001$) and remained significantly shorter after controlling for age and duration of paraphimosis (adjusted mean difference −198 min, $p = 0.003$). There were no return visits or major adverse events in either group, however, among successful reduction attempts, PS patients more frequently experienced minor adverse events (7/9 vs. 0/32, $p < 0.001$).

Conclusions: Paraphimosis reduction using TA was safe and effective. Compared to PS, TA was associated with a reduced ED LOS and fewer adverse events. TA could potentially allow more timely reduction with improved patient experience and resource utilization.

1. Introduction

Paraphimosis is an acute emergency affecting uncircumcised males in which the uncircumcised penile foreskin becomes retracted behind the coronal sulcus and results in incarceration of the glans. Without timely reduction, the retracted foreskin causes vascular engorgement, glans edema, and venous congestion, which in turn, may lead to necrosis and gangrene of the glans penis [1,2]. Paraphimosis is reported to occur in 0.7% of uncircumcised boys [3], and the overall incidence is likely to have increased in recent years with more boys now left uncircumcised worldwide [4]. While there are no universally endorsed guidelines, current practice is to attempt paraphimosis reduction by noninvasive manual compression before consideration of invasive procedures and surgical alternatives such as prepuce puncture [5], glans aspiration, dorsal slit or circumcision [1,2,4].

Manual reduction is a painful procedure and is particularly challenging in the anxious, and uncooperative pediatric patient. While several noninvasive manual reduction techniques have been described, few have been studied systematically and results are variable in the presence of significant pain and edema [1]. Consequently, manual reduction in children will usually require general anesthesia or procedural sedation (PS) [1,6]. While the safety of PS in the Pediatric Emergency Department (ED) is largely recognized, it requires a prolonged recovery period, and can be associated with adverse respiratory events, emesis, and emergence agitation [7,8]. PS requires a controlled setting and is thus rarely attempted by primary practitioners outside of the hospital setting, often further increasing time to presentation and prolonging reduction.

Technically simple, noninvasive techniques using topical anesthetic (TA) have recently been described as an analgesic alternative to PS. These techniques involve the application of TA to the edematous foreskin, followed by the use of a compressive dressing in order to facilitate

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manual reduction [2,4,9]. To our knowledge, no study has previously compared TA to PS for paraphimosis reduction. This study sought to compare outcomes among pediatric patients undergoing manual paraphimosis reduction in the ED by either TA or PS. We hypothesized that use of TA would result in a non-inferior rate of paraphimosis reduction compared to PS and would be associated with a shorter length of stay (LOS) and fewer adverse events.

2. Methods

2.1. Study design, setting and participants

We undertook a retrospective cohort study of all patients presenting to a single pediatric ED requiring analgesia for manual paraphimosis reduction. This ED is an urban tertiary pediatric referral center with a census of over 84,000 annual visits. At our institution, paraphimosis reductions are routinely performed by pediatric ED physicians, and selection of analgesia is at the discretion of the treating physician with consideration of patient/family preferences. The study population included all uncircumcised boys below 18 years of age with a paraphimosis reduced manually by an ED physician during the 36-month study period from October 2013 to September 2016. We excluded patients for whom the initial paraphimosis reduction attempt was made by the Urology service or by a health professional prior to ED presentation, patients with known allergies to either TA or PS agents, and patients with pre-existing genitourinary conditions. Study methodology and analysis were undertaken according to published recommendations [10]. This study was approved by the Research Ethics Board of the McGill University Health Center.

2.2. TA paraphimosis reductions

TA-assisted manual reductions were performed using LET gel (LET: Lidocaine 4%, Epinephrine 0.1%, Tetracaine 0.5%) for 33/35 patients, or Lidocaine hydrochloride 2% jelly for 2/35 patients. TA gel (3–10 cm^3) was applied topically to the affected penile prepuce which was then wrapped in an occlusive dressing for 30 min prior to attempting manual reduction. Adjunctive analgesic or sedative agents were used at the discretion of the treating physician in 4/35 TA patients. Manual reduction was by standard non-invasive compressive technique, and was only attempted if pre-procedural analgesia was achieved prior to attempting reduction. Standardized pain scores were not recorded, however TA reductions limited by pain were discontinued and considered unsuccessful. There was no pre-defined observation duration following successful manual reduction. Unsuccessful reduction patients were prepared for PS and Urology service consulted urgently.

2.3. PS paraphimosis reductions

PS administration followed a standardized protocol. Patients were not eligible for PS if they presented with one of the following contraindications: American Society of Anaesthesiologists (ASA) class > 2, seizure disorder, acute respiratory illness, anticipated potentially difficult airway, uncontrolled hypertension or glaucoma. In accordance with recently published guidelines [11], PS was undertaken once adequate personnel were available and immediately following intravenous access, without delay to achieve a pre-procedural fasting state. Patients were given ketamine at a starting dose of 1–2 mg/kg and subsequent doses of ketamine were administered as needed. Adjunctive analgesia was used at the discretion of the treating physician in 1/11 patient prior to PS. Manual reduction under PS was attempted using standard non-invasive compressive technique. Throughout the procedure, patient vital signs were monitored and recorded on standardized forms. Standardized sedation and pain scores were not recorded. Following successful reduction, patients were observed until emergence from sedation and discharged upon return to a pre-sedation level of alertness, as determined by the treating physician, with no pre-defined observation duration. For unsuccessful reductions, patients were maintained under PS and Urology service consulted on an urgent basis.

2.4. Outcome definitions

All outcomes were defined a priori before data abstraction. The primary outcome measure was successful first reduction attempt, with a pre-specified non-inferiority margin of 10%. An attempt was analyzed as unsuccessful if a first TA reduction was limited by patient discomfort, or if the paraphimotic ring could not be reduced by the ED physician using either TA or PS. Secondary outcome measures included total ED LOS, adverse events and return visits. Total ED LOS was defined as ED registration to discharge (DC), and was further subdivided into 1) time from first physician assessment to DC, and 2) time from reduction start to DC. Adverse events were defined for PS according to consensus-based guidelines [12]. For both PS and TA groups, major adverse events included seizure, hemodynamic instability, respiratory event requiring intubation, anaphylaxis, penile tissue necrosis or significant bleeding. Minor adverse events of PS included, but were not limited to, oxygen desaturation, laryngospasm, vomiting, multiple intravenous access attempts, and unpleasant recovery reactions requiring pharmacological intervention. Minor adverse events of TA included anxiety requiring pharmacological intervention, pain during procedure or residual pain and localized skin reaction. Return visits were defined as unscheduled ED or Urology clinic visits during the 7-day period following reduction for paraphimosis recurrence or procedure-related complications.

2.5. Data collection and analysis

Eligible patients were identified from the ED patient registration database using International Classification of Diseases (ICD-10) coding of discharge diagnosis for both “phimosis” and “paraphimosis” to ensure no missed cases for inclusion (Fig. 1). Electronic medical records for all identified patients were reviewed by a single un-blinded abstractor (BB). A total of 167 patient charts were reviewed and 76 paraphimosis cases were identified. Thirty patients were excluded; 10 cases reduced spontaneously or prior to ED registration, 18 cases reduced in the ED with no analgesia and 2 cases reduced in the ED by the Urology service a priori. Forty-six cases were included in the final analysis. Data extracted included patient demographic information, exposure (TA or PS), adjuvant medication use, and the pre-defined outcomes of interest including duration of paraphimosis prior to ED presentation. There was no missing data for the variables of interest. Dichotomous outcomes are expressed as proportions and were analyzed by Chi-square testing while continuous variables are expressed as mean ± SD and were analyzed using an unadjusted Student's *t*-test. Logistic regression models were used to explore the relationship of potential confounders (age and paraphimosis duration) with reduction success. Additionally, multivariate logistic and linear regression models were fit to analyze

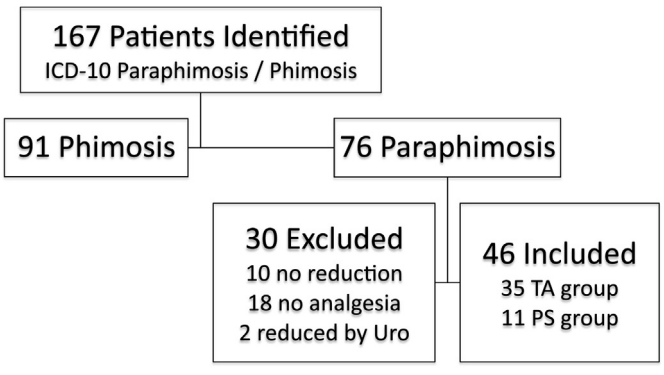

Fig. 1. Eligible patient identification.

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