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Responsibilities include providing clinical and consultative service; teaching Fellows, Residents, and Medical Students; and maintaining an active research program. These non-tenure track appointments will be made at a rank (Instructor/Assistant/Associate/Full Professor) and salary commensurate with experience.

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Application Procedure: Complete the online faculty application at http://www.gwu.jobs/postings/56800 and upload a CV and cover letter. Review of applications will be ongoing beginning November 30, 2018 and will continue until positions are filled. Only complete applications will be considered. Employment offers are contingent on the satisfactory outcome of a standard background screening. Questions about these positions may be directed to Department Chair, Robert Shesser M.D., at rshesser@mfa.gwu.edu.

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A Randomized Double Blind Trial of Needle-free Injected Lidocaine Versus Topical Anesthesia for Infant Lumbar Puncture

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ABSTRACT

Objectives: Lumbar punctures (LPs) are commonly performed in febrile infants to evaluate for meningitis, and local anesthesia increases the likelihood of LP success. Traditional methods of local anesthesia require injection that may be painful or topical application that is not effective immediately. Recent advances in needle-free jet injection may offer a rapid alternative to these modalities. We compared a needle-free jet-injection system (J-Tip) with 1% buffered lidocaine to topical anesthetic (TA) cream for local anesthesia in infant LPs.

Methods: This was a single-center randomized double-blind trial of J-Tip versus TA for infant LPs in an urban tertiary care children’s hospital emergency department. A computer randomization model was used to allocate patients to either intervention. Patients aged 0 to 4 months were randomized to J-Tip syringe containing 1% lidocaine and a placebo TA cream or J-Tip syringe containing saline and TA. The primary outcome was the difference between the Neonatal Faces Coding Scale (NFCS) before the procedure and during LP needle insertion. Secondary outcomes included changes in heart rate (HR) and NFCS throughout the procedure, difficulty with LP, number of LP attempts, provider impression of pain control, additional use of lidocaine, skin changes at LP site, and LP success.

Results: We enrolled 66 subjects; 32 were randomized to J-Tip with lidocaine and 34 to EMLA. Six participants were excluded from the final analysis due to age greater than 4 months, and the remaining 58 were analyzed in their respective groups (32 J-Tip, 34 TA). There was no difference detected in NFCS between the two treatment groups before the procedure and during needle insertion for the LP (p = 0.58, p = 0.37). Neither HR nor NCFS differed among the groups throughout the procedure. Median perception of pain control by the provider and the need for additional lidocaine were comparable across groups. LPs performed with a J-Tip were twice as likely to be successful compared to those performed using TA (relative risk = 2.0; 95% confidence interval = 1.01–3.93; p = 0.04) with no difference in level of training or number of prior LPs performed by providers.
Conclusions: In a randomized controlled trial of two modalities for local anesthesia in infant LPs, J-Tip was not superior to TA cream as measured by pain control or physiologic changes. Infant LPs performed with J-Tip were twice as likely to be successful.

The American Academy of Pediatrics recommends the use of pain control during lumbar punctures (LPs) in infants to reduce both the pain to the patient and the stress for the family. Several studies have demonstrated greater LP success with the use of local anesthesia in infants. Despite this recommendation and evidence supporting its use, only 24% to 33% of infants receive any type of local anesthesia. Common reasoning for providers to forgo pain management include the time for topical anesthetics (TAs) to be effective, the pain associated with injectable lidocaine, and loss of anatomic landmarks with injectable lidocaine.

A recent development in pain management for pediatric procedures is the use of needle-free jet injection of lidocaine. One such device is the J-Tip (National Medical Products), which uses a compressed CO2 cartridge to deliver medication to the subcutaneous tissues to a depth of 5 to 8 mm in 0.2 seconds. Multiple studies have shown it to be effective in reducing pain associated with peripheral IV placement in children. One study compared the J-Tip with lidocaine to J-Tip with saline solution during infant LPs and found superior pain control and reduced time of crying in the lidocaine group. A recent study of LPs in adults demonstrated superior pain control using the J-Tip compared to local needle infiltration of lidocaine.

No study to date, however, has compared the J-Tip with TA cream. TA has the advantage of painless application, but takes a significant amount of time to be effective. The objective of this study was to evaluate the effectiveness of pain control with the J-Tip compared to TA during LPs in infants 0 to 4 months of age. We hypothesized that the J-Tip with lidocaine would provide superior pain control compared to TA during infant LPs.

Methods

Study Design
We performed a randomized, double-blind, controlled trial of J-Tip–injected lidocaine versus TA in a convenience sample of infants undergoing LPs in an urban tertiary care children’s hospital emergency department (ED) with over 70,000 visits annually. The study was approved by the local institutional review board. Written informed consent was obtained from the parent or guardian of all patients enrolled in the study.

Study Population and Setting
Study subjects were recruited from patients between 0 and 4 months of age who were undergoing a LP as part of their ED evaluation. After the parent/guardian consented to the LP, they were approached to participate in the study by a professional research assistant (PRA) trained in consent procedures. Patients were excluded for the following conditions: allergy to lidocaine, planned sedation for the procedure, or the administration of any preprocedural analgesia other than acetaminophen. Patients were also excluded if they were deemed to be critically ill or required immediate resuscitation or at the attending provider’s discretion. The original intent of this study was to examine two populations of patients undergoing LP: 0 to 4 months of age and 4 to 18 years of age. After initiation of the study, we chose to stop enrollment of the older population given resource constraints. Data from this population were excluded from this analysis.

Study Protocol
After enrollment, a computer model randomized patients to receive either a placebo topical cream followed by J-Tip–injected 1% buffered lidocaine or TA (EMLA, a eutectic mixture of 2.5% lidocaine and 2.5% prilocaine) in a ratio of 1:1 followed by J-Tip–injected sterile saline. The ED pharmacist compounded and distributed both cream (TA or placebo cream) and J-Tip (saline or lidocaine) ensuring allocation concealment. Both active and placebo creams were identical appearance, and J-Tips with saline and lidocaine were identical in appearance. The provider marked the spot for cream placement, which was then placed by the bedside nurse. Both placebo cream and EMLA were applied for a minimum of 30 minutes. Just prior to the start of the LP, the provider marked the LP site, and the J-Tip was administered by the nurse trained in J-Tip administration. The providers, nurses, and PRAs were blinded to the study drug assignment.
The PRA video-recorded the patient throughout the procedure and verbalized the heart rate (HR) during five points in time: before the procedure, at J-Tip application, at needle insertion, while needle was in place, and after the procedure. PRAs were individually trained to obtain accurate images of the infant’s face using a handheld camera while the infant was in a flexed position. The infant was allowed to calm and reach a steady state after positioning and after each intervention. The HR was then verbalized at a single point when it was most reflective of the infant’s steady state for the preprocedure, needle-in-place, and postprocedure time points. For infants who remained fussy during these times, the HR most reflective of this fussy state was verbalized. After the LP, the provider performing the procedure completed a questionnaire regarding the number of attempts needed, any difficulties encountered, the use of any additional lidocaine, and the provider’s perception of pain control during the procedure.

Videos were saved on a password-protected hard drive and on secure digital cards maintained in the custody of research personnel. Pain was assessed via video review by two blinded investigators using the Neonatal Facial Coding System (NFCS). The NFCS is a validated, reviewed by two blinded investigators using the Neonatal Tody of research personnel. Pain was assessed via video drive and on secure digital cards maintained in the cust- the procedure.

For normally distributed continuous variables, mean and standard deviation (SD) were reported; for non-parametric variables, median and interquartile range (IQR) were reported. For LP success, we calculated relative risk (RR) with 95% confidence intervals (CIs). For our sample size calculations, we set alpha at 0.05 and power at 80%. A p-value of ≤0.05 was considered statistically significant. Assuming a SD of 1.3, a total of 27 patients were required per group to detect a one-point difference on the NFCS at needle insertion.13 Two investigators assessed 30% of the videos to evaluate inter-rater reliability of the NCFS. Kappa was 0.81 (95% CI = 0.72–0.9) indicating excellent inter-rater reliability.20 Analysis was performed using SPSS 24.0 (2016, IBM SPSS Statistics). Given the blinding of the providers and nurses, randomization was not broken until the time of data analysis and all analyses were performed on an intention-to-treat basis.

RESULTS

Between October 2012 and March 2015, a total of 195 patients were screened, of whom 66 were consented and randomized to J-Tip versus TA (Figure 1). Two patients (one J-Tip and one TA) did not receive the allocated treatment due to provider concerns that the TA cream would result in a delay in performing the LP. An additional six patients were excluded from the analysis as they were older than 4 months of age resulting in a total of 58 patients in the study; 29 receiving J-Tip and 29 receiving TA. Table 1 shows that there was no difference between groups based on sex, median age in days, race, or ethnicity. In addition, providers performing the LP were similar with regard to level of training and number of prior LPs performed (Table 1).

For our primary outcome, we found no difference between the two groups in the NFCS between needle insertion and before the procedure (J-Tip median difference = 2, IQR = 2–5; TA median difference = 5, IQR = 2–5; p = 0.18). In addition, neither HR or NCFS differed between the two groups throughout the procedure (Table 2).

Median number of minutes of cream application, median number of LPs attempts, perceived difficulty with LP, median perception of pain control by provider, and the need for additional lidocaine were the same for both groups. There was no difference between groups related to physiologic skin changes including bleeding, redness, bruising, or petechiae at the LP site. LPs

Outcome Measures

The primary outcome measure in this study was the difference in pain scores between needle insertion and before the procedure. Secondary outcomes included a comparison of HR and NCFS throughout the procedure, number of LP attempts, difficulty with LP (open-ended question), provider impression of pain control (on a scale of 1 to 5), additional use of lidocaine, skin changes at the LP site, and LP success. LP success was defined as obtaining cerebrospinal fluid (CSF) on the first attempt with < 1 × 10^9 red blood cells/L.

Data Analysis
Categorical variables were analyzed with either a chi-square test or a Fisher’s exact test. Continuous variables were analyzed with either a Student’s t-test or a Mann-Whitney U-test depending on their distribution.
performed with the J-Tip were twice as likely to be successful compared to those performed using TA (RR = 2.0; 95% CI = 1.01–3.93; p = 0.04; Table 3) with no difference in provider type or number of LPs performed previously (p = 0.51 and p = 0.39; Table 1).

**DISCUSSION**

Lumbar puncture is a common and necessary procedure performed in the evaluation of febrile infants in the pediatric ED. It is routinely recommended in febrile infants less than 30 days of age to rule out meningitis and commonly performed in those less than 3 months. While necessary to perform, they are painful for the patient and stressful for the family. In our study comparing J-Tip to TA cream, we found that the J-Tip was not superior to TA cream as measured by pain control or physiologic changes suggesting lidocaine administered via J-Tip is an option for pain control during LPs.

In our study, NFCS scores were similar at all points in time between the two groups, and there were no detectable differences in HR. Despite the infants receiving local anesthesia in both groups, we still saw the maximum median score of 5 in both groups during needle insertion. This suggests that there remains an element of pain during needle insertion even with local anesthesia. This finding is consistent with prior studies comparing intervention to a placebo. It may be impossible to remove all the stress associated
with LP in infants, as it has been shown that simple handling and immobilization of neonates increases their pain response. In addition to local anesthesia, providers should consider other adjuncts to improve comfort such as oral sucrose.

**Table 1**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>J-Tip (n = 29)</th>
<th>TA (n = 29)</th>
<th>p-value</th>
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<tbody>
<tr>
<td>HR</td>
<td>Before the procedure</td>
<td>156 (±28)</td>
<td>154 (±40)</td>
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<tr>
<td></td>
<td>J-Tip application</td>
<td>167 (±29)</td>
<td>160 (±37)</td>
</tr>
<tr>
<td></td>
<td>Needle insertion</td>
<td>169 (±35)</td>
<td>170 (±49)</td>
</tr>
<tr>
<td></td>
<td>Needle in place</td>
<td>178 (±40)</td>
<td>172 (±54)</td>
</tr>
<tr>
<td></td>
<td>After the procedure</td>
<td>159 (±28)</td>
<td>157 (±30)</td>
</tr>
</tbody>
</table>

Data are reported as mean (±SD) or median (IQR). HR = heart rate; IQR = interquartile range; NFCS = Neonatal Facial Coding System; TA = topical anesthetic.

As more difficult (54% vs. 35%) despite blinding to the type of anesthesia provided.

Despite the evidence that local anesthesia is associated with LP success rates, analgesia is infrequently used, with only 24% to 33% of infants receiving any type of local anesthesia prior to LP. In a survey of five academic Midwestern EDs, Hoyle et al. found that 78% of respondents agreed that taking the time to treat the pain of a brief procedure, such as a LP, is worthwhile. However, in that same study, many respondents indicated that they never used sucrose (53%), lidocaine (41%), or anesthetic cream (49%).

**Table 2**

<table>
<thead>
<tr>
<th>Experience by Randomization Groups</th>
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<tr>
<td><strong>Patient demographics</strong></td>
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<tr>
<td>Race*</td>
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<tr>
<td>Ethnicity</td>
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<td>Provider training and experience</td>
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<td>Level of training</td>
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<td>Attending</td>
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<td>Number of prior LPs performed</td>
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</table>

Data are reported as mean (±SD), median (IQR), or n (%). IQR = interquartile range; LP = lumbar puncture; TA = topical anesthetic.

*Caregivers were allowed to choose more than one race and could choose either a race or an ethnicity or both.
†Included Asian, Pacific Islander, Indian.
‡Questionnaire not completed by one provider.

Perhaps the biggest advantage provided by the administration of lidocaine through the J-Tip device is its immediate effect. As described above, there are notable differences between J-Tip and TA with regard to the time needed to achieve a similar depth of anesthesia. Prompt initiation of parenteral antibiotics in young febrile infants with concern for serious bacterial infection is critical and has been identified as a potentially important quality metric in pediatric emergency care. The needle-free injection system allows for the ability to quickly obtain CSF without the delay of
waiting for TA cream to take effect. The association of the needle-free injection system with increased success in infant LPs combined with its immediate efficacy makes its use potentially superior to TA cream in this clinical situation.

The same maximum pain score (median NCFS = 5) was noted during J-Tip administration and LP needle insertion. The J-Tip device makes a loud popping noise immediately prior to the infusion. Ferayorni et al.\textsuperscript{13} noted that this noise startled almost every infant followed by crying in their study resulting in the maximum pain score at J-Tip administration, an observation we also made during video review. Unfortunately, it is impossible to distinguish between a startle reaction and pain in infants with the NCFS. Ferayorni et al.\textsuperscript{13} also noted a decreased length of cry in the lidocaine arm of their study compared to the saline group, suggesting that pain was ultimately better controlled in the lidocaine group. Our study design did not allow us to control for the potential confounder of the noise made by the J-Tip device immediately prior to infusion as all infants in our study received either lidocaine or saline via the J-Tip device. However, we felt that ensuring blinding of all providers and investigators to the study arm was crucial. Future studies should consider a comparison of lidocaine infused with a needle-free injection system to topical anesthesia without needle-free injection of saline.

**LIMITATIONS**

There are limitations to our study. Our convenience sample could have resulted in selection bias as we only enrolled patients during the hours when both an ED pharmacist and a research associate were available. In addition, providers who were less comfortable performing LPs on infants may have been reluctant for their patients to be enrolled. Given our small sample size, we were unable to control for potential confounders (e.g., level of training) for our outcome of LP success. We did not observe a difference in HR or NCFS between the two study groups, which may represent a type 2 error. We performed our sample size calculations using the difference seen in a prior study, but our sample size still may have been too small to detect a clinically significant difference and was not powered adequately to serve as a noninferiority trial.\textsuperscript{21} We did not track length of cry of the infants, which might have helped distinguish the pain response between the two study groups. It is also difficult to distinguish between pain and anxiety in infants, although we felt that allowing infants to calm while in the flexed position prior to performing the LP reduced the distress prior to obtaining the NFCS during the procedure. We did not use oral sucrose for additional pain control as a pacifier would obscure the facial expressions for the NFCS, and we had concerns that administration of oral sucrose would vary and potentially confound the results of our study. As oral sucrose is a common form of pain control in infants, this limits the generalizability of our study to real-world practice.

**CONCLUSIONS**

In conclusion, in a randomized controlled trial of two modalities for local anesthesia in infant lumbar punctures, J-Tip is not superior to topical anesthetic cream as measured by pain control or physiologic changes. Advantages to the needle-free injection system are its quick onset of action and the increased success rate seen in this study, suggesting that lidocaine administered via the J-Tip device may be an alternative to topical anesthesia.

**References**


