Article

Procedural Pain Management During Tenotomy for Congenital Talipes Equinovarus

Clinical Pediatrics
1–6

DOI: 10.1177/00099228221131688
journals.sagepub.com/home/cpj
SAGE

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Abstract

The majority of infants with congenital talipes equinovarus (CTEV) require tenotomy of the tendoachilles. The pain response of this procedure in the awake infant has not been previously reported. In this observational study, multimodal pain management strategies, including oral sucrose, oral paracetamol, topical anesthetic, local anesthetic, a pacifier (dummy), and swaddling, were used. Physiological responses and pain were recorded. Pain was rated out of 10 at regular intervals, using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale. Ninety-one infants (65 men, mean age = 53 days, range = 19-217 days) were observed. At baseline, median FLACC, heart rate (HR), and oxygen saturation (Spo_2) were 1, 159, and 97% respectively. Peak median FLACC and HR were 9 and 200, respectively, and lowest median Spo_2 was 92%. The median (interquartile range) time for FLACC to return to 3 or less was 2 (2-5) minutes. Achilles tenotomy for CTEV in the awake infant is associated with high pain levels despite provision of multimodal pain relief measures.

Keywords

clubfoot, tenotomy, sucrose, talipes, pain, congenital talipes equinovarus

Introduction

The Ponseti method of treatment for congenital talipes equinovarus (CTEV) is currently the most practiced technique, with excellent long-term outcomes.[1] This technique involves a series of manipulations and casting to correct the midfoot and then a procedure to release the tendoachilles (TA) in up to 90% of cases to correct the remaining equinus deformity.[2] Dr Ignacio Ponseti[3] described the percutaneous tenotomy procedure being performed while the baby is relaxed with a bottle of milk with local anesthetic.

Despite the initial description by Dr Ponseti, there are varied environments and circumstances in which tenotomy occurs, depending on the treating surgeon and procedure location. This varies from the outpatient setting, using non-pharmacological and pharmacological pain relief, to operating theaters, performed under general anesthesia (GA).[4-6] Advantages of the procedure being performed in the outpatient setting include the infant being able to be fed if required, immediately prior to or following the procedure, the infant being able to be returned to the parent/carer immediately post procedure, and the infant not being exposed to the possible adverse effects of GA, including anaphylaxis, intraoperative or postoperative cardiac and respiratory complications, as well as the possible long-term effects on neurodevelopment.[7,8] In addition, there is a reduced cost to the health system in terms of surgical theater usage and associated implications of resource allocation. However, both infant safety during an invasive procedure and the experience of pain need to be considered.

If the procedure is to be performed in the outpatient setting on the awake infant, management of procedural pain is important not only for the immediate situation

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but also for the long-term pain experiences of these children . Infants experiencing painful procedures have been shown to have long-term effects on their perception of pain.[9] Neuroplasticity, particularly in infancy when neural pathways are still maturing, means that recurrent and poorly treated painful episodes can lead to both short- and long-term hypersensitivity to painful stimuli.[10] There is significant evidence that newborns experience measurable physiologic and emotional pain responses to painful procedures. If this procedural pain is left unmanaged, it can lead to short-term and long-term behavioral changes.[11]

For this reason, we must consider the best method to manage the experience and perception of pain during expected painful procedures. This approach should be multimodal, combining nonpharmacological with pharmacological techniques, to maximize analgesic efficacy and procedure tolerance while minimizing adverse side effects and potential psychological sequelaes.[10] A large prospective study by Carbajal et al[12] showed that only a small percentage of infants undergoing painful procedures were given adequate pain relief despite recommendations. Sucrose combined with other pharmacological and nonpharmacological comfort measures, such as non-nutritive sucking, positioning, and appropriate analgesia, has been shown to have optimal effect in a range of infant procedures, including heel prick, venipuncture, intramuscular injection,[13] and circumcision.[14]

The aim of this study was to establish the safety and tolerability of performing a percutaneous Achilles Tenotomy procedure for CTEV, using multimodal pain management, on awake infants in an outpatient setting.

Materials and Methods

Participants

This was a single-center observational study of current clinical practice performed at Sydney Children's Hospital Randwick between March 1, 2011, and July 30, 2014. The inclusion criterion was CTEV requiring percutaneous elongation of the TA (tenotomy). Participants were recruited from orthopedic clinics. The study was approved by the Human Research Ethics Committee, South Eastern Sydney and Illawarra Area Health Service, New South Wales. Ethics approval number is LNR/14/SCHN/109.

Procedure

After completion of the initial stage of casting series as described by Ponseti for the management of CTEV, the orthopedic consultant assessed each patient to determine the TA length and decide whether a tenotomy was required, based on the available dorsiflexion range of motion. It was generally considered that dorsiflexion of less than 15° required TA lengthening.[3] The procedure was explained to the parents/guardians and written informed consent for the procedure was obtained.

The order of procedural pain management for tenotomy was as follows:

Topical anesthetic, lignocaine/prilocaine topical (Emla) cream (5%) application—a sufficient quantity of cream (2 g) was applied to cleaned skin at the site of the procedure. Cream was covered with an occlusive dressing (Tegaderm, 3M) ensuring no leakage. This topical anesthetic was left in situ for approximately 60 minutes.

Oral paracetamol administration—the patient was weighed, and paracetamol dose was calculated appropriate to their weight according to the manufacturer's instructions. Parents self-administered the paracetamol to their child using the syringe or dropper supplied with the product. Paracetamol was administered 45 to 60 minutes prior to the procedure.

Comfort positioning—a "Spaghetti" wrap or other jersey wrap folded longways was used to secure the upper body only. The parents/carers were, in general, not present for the procedure and the comfort care or consoling was provided by the physiotherapist or physiotherapy aide.

Sucrose administration—25% sucrose was provided by the hospital pharmacy for administration. This amount was guided by corrected age according to hospital guidelines for sucrose administration and ranged from 0.05 to 2 mL for a single event. Patients were offered a pacifier and sucrose was placed on the pacifier to encourage non-nutritive sucking. The initial dose (0.5 mL) was given 2 minutes prior to the commencement of the procedure. Additional doses were administered during the procedure if the infant became unsettled up to the recommended maximum dose.

Local anesthetic—1% Xylocaine from a single-dose ampule was used for each procedure. The local anesthetic was drawn up by the doctor who administered it subcutaneously to the area close to the TA.

Tenotomy

The protocol used for tenotomy in the current procedure was derived from Dr Ignacio V. Ponseti.[3] Skin preparation of the leg and foot was done from all aspects after removal of the tegaderm covering the emla. Then, 1% Xylocaine was infiltrated around the tendon using a 25-gauge needle. The tendon was palpated 1 to 2 cm above its

Table 1. FLACC Behavioral Pain Assessment Tool.

	Scoring		
Categories	0	1	2
Face	No particular expression or smile	Occasional grimace or frown; withdrawn, disinterested	Frequent to constant frown, clenched jaw, and quivering chin
Legs	Normal position or relaxed	Uneasy, restless, and tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, and moves easily	Squirming, shifting back and forth, and tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, and frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to, and distractable	Difficult to console or comfort

Abbreviation: FLACC, Face, Legs, Activity, Cry, and Consolability Pain Assessment Tool.

calcaneal insertion and tenotomy was performed with a No. 15 blade (Swann-Morton retractable disposable scalpel). The blade was introduced through the skin on the medial aspect of the TA. The blade was introduced in front of the tendon that was severed from front to back. A "pop" is felt as the tendon is cut with an additional 10° to 15° of dorsiflexion achieved immediately after tenotomy. The wound was covered with adhesive strips (Steristrips 3M) and a small sterile pad and soft cotton roll (Webril), with a well-molded plaster of paris cast (Gypsona) and outer semirigid fiberglass cast (3M soft cast).

Outcomes

Observations were recorded by 1 of 3 independent, trained observers and included heart rate (HR), oxygen saturation (Spo_2), and perceived pain. The Face, Legs, Activity, Cry, and Consolability (FLACC) Pain Assessment Tool was used to measure pain (Table 1). Each of the 5 categories—Face (F), Legs (L), Activity (A), Cry (C), and Consolability (C)—is scored from 0 to 2, which results in a total score between 0 and 10. This tool has been validated and shown to be a sensitive measure in preverbal children undergoing surgery and painful procedures and as an objective measure for assessing response to treatments to relieve pain.[15-18]

Observations were recorded at baseline. Heart rate and Spo_2 were monitored throughout. The FLACC score was recorded every 2 minutes during the first 20 minutes, which included the period before, during, and after the tenotomy. The FLACC score was then recorded every 5 minutes until the entire procedure, including casting, was complete.

Time until the infant's observations returned to an acceptable range was calculated. For FLACC, an acceptable range was determined as ≤ 3, as scores of ≤ 3 are categorized as indicating mild discomfort, and an FLACC of >3 is the threshold for the FLACC where analgesia administration is recommended.[17] For HR, return to the infant's baseline, measured pre-handling of the infant's limbs, was deemed acceptable. For Spo_2, a return to a normal value of $>95\%$ was deemed acceptable.[19]

Statistical Analyses

Descriptive statistics were performed in Microsoft Excel. Results are presented as median with interquartile range (IQR).

Results

A total of 91 patients (65 men, 26 women) (average age = 53 days, range = 19-217 days) were observed. Of these, 41 had unilateral CTEV and 50 had bilateral CTEV diagnosis. Eight of the feet treated were diagnosed as atypical, and all of the remainder were diagnosed as congenital idiopathic clubfeet.

The average duration of the entire procedure was 28 minutes. At baseline, the median (IQR) for FLACC score was 1 (0-2), HR was 158 (144-168), and Spo_2 was 97% (96%-98%).

The peak median (IQR) throughout the procedure for FLACC was 9 (6-10), which coincided with the tenotomy being performed. Peak median HR was 200 (180-207) and Spo_2 decreased to a median (IQR) of 92% (87%-95%) (Table 2).

There were 51 records of FLACC scores recorded at the moment of local anesthetic administration. The median (IQR) FLACC score during injection was 7 (4-10).

The median (IQR) for time to return to acceptable range was 2 minutes (2-5) for the FLACC, 2 minutes (2-7.5) for HR, and 2 minutes (0-4) for Spo_2 (Table 2).

Table 2. Median (Interquartile Range) for FLACC, Heart Rate, and Oxygen Saturation.

	Baseline	Peak (HR, FLACC); low (Spo_2)	Time to return to acceptable range (min)
FLACC	1 (0-2)	9 (6-10)	2 (2-5)
HR	159 (144-168)	200 (180-207)	4 (2-7.5)
SaO2	97 (96-98)	92 (87-95) low	2 (0-4)

Abbreviations: FLACC, Face, Legs, Activity, Cry, and Consolability Pain Assessment Tool; HR, heart rate; Spo_2, oxygen saturation.

There were no complications recorded during or after any of the procedures, with all infants going home on the day of the tenotomy.

Discussion

This observational study reports the pain and physiological response using sucrose combined with other pain relief and comfort measures in infants undergoing tenotomy as part of the Ponseti method for CTEV in the outpatient setting. The results of this study show that increases in pain and HR as well as reduction in Spo_2 occurred during the procedure, which persisted for an average of 2 to 4 minutes.

The role of different combinations of procedural pain relief during procedures in infants and young children, such as heel prick, venipuncture, and intramuscular injection, has previously been reported.[10,13] In a somewhat comparable procedure, routine infant male circumcision, Labban et al reviewed results comparing pain-relieving modalities, and although a multimodal approach is considered superior to any single modality, the optimal combination of pain-relieving interventions has not yet been identified. This study is unique in that it assessed the effectiveness of the combination of sucrose, non-nutritive sucking, injected local anesthetic, topical anesthetic, oral paracetamol, and swaddling during TA tenotomy for CTEV, which has not previously been reported.

The median peak pain response observed using the FLACC was 9/10, which coincided with the tenotomy. The FLACC during insertion of local anesthetic was 7/10. In comparison with FLACC scores during other procedures, similarly high FLACC scores have been reported during other invasive procedures, such as nasogastric tube insertion with topical anesthetic, where the average FLACC was 9.[20] Chest drain removal with intravenous administration of morphine or midazolam elicited an average FLACC of 7 in a group of postsurgical infants,[21] and bladder catheterization using an anesthetic lubricating gel elicited an average FLACC of 7.5.[22] While the pain response during tenotomy in this study is high, it is not dissimilar to the response during other invasive procedures performed on the awake infant. It is established that recurrent and poorly treated painful episodes can lead to both short-term and long-term hypersensitivity to painful stimuli, as well as neurodevelopmental changes.[10] Whereas this is well documented for repeated or long duration episodes of pain, it is not known whether a single event, short-duration episode, such as for the infants in this study, has the same effects.

Duration of increase in pain scores using longitudinal FLACC measurements has not been reported in studies which used the FLACC for pain assessment; therefore, direct comparison of pain duration during tenotomy and other procedures is not possible. Previous literature using the FLACC to assess effectiveness of pain control modalities has also recorded crying time as a surrogate for duration of pain/distress. Sucrose administration during venipuncture was associated with an FLACC of 5 and crying time of 2 to 3 minutes,[23] and sucrose during vaccinations resulted in an average FLACC of 3 with crying time of 60 seconds.[24]

In the Ponseti management of CTEV, one other study has investigated procedural pain management. In a double-blinded randomized controlled trial, Milbrandt et al compared the use of sucrose, milk, and water during manipulation and casting stage of management, not tenotomy. The study found sucrose and milk were both effective in reducing the pain response, with sucrose having a more prolonged effect.[25]

There are limitations in this study that need to be discussed. There were several surgeons performing the tenotomies and this may have led to small variations in tenotomy technique, which may have contributed to variations in pain response. Another limitation of this study is that 1 of the 5 criteria for FLACC score was assessing leg position and movement, and these movements were restricted by the therapist to allow for the tenotomy to be performed, including keeping the contralateral limb clear of the procedure. To score the legs component of the FLACC, the therapist holding the legs commented on the attempted movements of the infants' legs during the procedure, which is not a validated method, but was considered the best available alternative, given the requirements of the procedure.

An additional limitation is that parents were generally asked to leave the room during the procedure as it

had been previously found too stressful an environment for caregivers, and therefore they did not engage in consoling behavior, which may have been more effective in reducing pain and physiological responses in the infant. It is acknowledged that while Dr Ponseti described the tenotomy being performed on the parent's lap, this was not the practice at our institution, secondary to health and safety concerns, as there were multiple episodes of parents fainting during previous procedures.

The FLACC score was taken only every 2 minutes; therefore, some detail regarding the pain response, particularly return to acceptable limits, was limited. That is, the first recording of FLACC was 2 minutes after the procedure, which means the FLACC may have lowered prior to this time. However, the IQR of 2 to 5 minutes indicated that 25% of infants were still displaying heightened FLACC scores at 5 minutes. In addition, FLACC scores may also have been influenced by other factors such as the removal of the tegaderm dressing, the skin preparation, and the foot/toes being held for the procedure. The infant may have been upset due to the environment, lights, sounds, people, and the absence of parent/carer, and for this reason, the score may not have purely related to the tenotomy.

A final limitation of the study is that there were multiple procedural pain relief measures, all provided simultaneously during the procedure; therefore, the contribution of each individual pain relief measure could not be evaluated. The aim of the study was not to review the effectiveness of the pain relief measures in isolation; rather, this study was an observational study of the current practice in our institution. The combination of all these pain relief measures was deemed necessary, given the invasive nature of the procedure being performed. A different combination of pharmacological and nonpharmacological pain-relieving techniques may need to be considered, in addition to assessment and education of parents and caregivers regarding their suitability to remain with and comfort their child during the procedure.

Conclusion

This study has shown that despite multimodal pain management strategies being in place, high levels of pain and physiological changes are recorded during the tenotomy procedure in the outpatient setting. Therefore, clinicians are encouraged to consider the current selection of multimodal pain management strategies that are available for use during TA tenotomy, in addition to assessing the infant's response to the procedure. Continued exploration of multimodal pain management options during awake tenotomy is recommended. The presence of pain and physiological responses that persist for between 2 and 4 minutes on average, and the potential impact on infants in the longer term which are not as yet fully understood, needs to be balanced against the alternative of the essential procedure being performed under general anesthetic, which is also not without risk.

Acknowledgments

We acknowledge the support of the Sydney Children's Hospital Orthopaedic Department, Physiotherapy Department, Pain Management Department, and Pain Research Team for participant recruitment and facilitation of testing and statistical analysis.

Author Contributions

KM: conceptualisation, methodology, data collection, data analysis and interpretation, drafting of article and approval of final version. PH: KM: conceptualisation, methodology, data collection, critical revision of article, approval of final version. MM: KM: Methodology, data analysis and interpretation, critical revision of article, approval of final version. MD: data analysis and interpretation, critical revision of the article and approval of final version.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Ethics Approval

The study was approved by the Human Research Ethics Committee, South Eastern Sydney and Illawarra Area Health Service, New South Wales. Ethics approval number is LNR/14/SCHN/109.

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