Lidocaine - Epinephrine - Tetracaine Topical Anesthetic Solution for Simple Laceration Repair in Children

Gigi Wo, Monica Lancaster and James Shipley

ABSTRACT

This prospective, non-comparative study describes the efficacy, safety and patient/parent satisfaction of Lidocaine-Epinephrine-Tetracaine (LET) solution for topical anesthesia in children who require uncomplicated face or scalp laceration repair.

Children up to 13 years old with uncomplicated laceration of face or scalp were eligible for inclusion in the study. Patients were excluded from the study if their laceration involved a mucous membrane, the nares, pinnae, or significant injury to an underlying structure, or if they were allergic to any ingredient in the solution. LET, 3 mL, was applied to the laceration for at least 15 minutes. The attending emergency physician or nurse collected the following information for each participant: location and length of laceration; adequacy of anesthesia before and during suturing; number of sutures placed; and suturing time. A telephone survey was conducted with the child's parent/guardian to determine if any complications developed after discharge from the emergency department. Patient satisfaction with the LET method of anesthesia was also solicited.

Data were obtained from 55 children (1 to 13 years). Forty (73%) of the children experienced complete anesthesia with LET without the use of supplemental lidocaine injection. No side effects were attributed to LET. Forty-seven (93%) of the parents/guardians surveyed were satisfied with the LET method of anesthesia and recommended it for future use. The emergency staff also found LET suitable for use in an emergency department setting.

In conclusion, LET appears to be an effective and safe method of topical anesthesia for simple laceration repair of the face or scalp in children.

Key Words: Epinephrine, Lacerations, Lidocaine, Tetracaine, Topical Anesthesia

RÉSUMÉ

Cette étude prospective et non comparative décrit l'efficacité et l'innocuité de l'association LET (lidocaïne-épinéphrine-tétracaïne) en solution pour l'anesthésie locale, ainsi que le degré de satisfaction des patients et (ou) des parents à l'utilisation de celle-ci, chez des enfants ayant besoin d'une réfection des lacérations non compliquées du visage ou du cuir chevelu.

Les enfants âgés d'au plus 13 ans et ayant des lacérations non compliquées du visage ou du cuir chevelu étaient admissibles à l'étude. Étaient exclus de l'étude ceux dont la lacération intéressait une muqueuse, les narines, ou le pavillon de l'oreille, ou encore ceux présentant une blessure importante à une structure sous-jacente ou ayant une allergie à l'un des ingrédients de la solution LET. Trois mL de solution LET ont été appliqués sur la lacération et laissés ainsi pendant au moins 15 minutes. L'urgentiste en poste ou l'infirmière d'urgence a recueilli les renseignements suivants pour chaque patient : la localisation et l'étendue de la lacération; le degré d'anesthésie avant et pendant la suture; le nombre de points de suture; et le temps de suture. Un sondage téléphonique a été mené auprès des parents/tuteurs pour déterminer si aucune complication n'était survenue après la sortie du patient de l'urgence et quel était leur degré de satisfaction avec la méthode anesthésique LET.

Les données ont été issues de 55 enfants âgés de 1 à 13 ans. Quarante (73 %) des enfants ont eu une anesthésie locale complète avec la solution LET, sans qu'on ait eu besoin de recourir à une injection additionnelle de lidocaïne. Aucun effet indésirable n'a été attribué à la solution LET. Quarante-sept (93 %) parents/tuteurs sondés ont déclaré être satisfaits de la méthode d'anesthésie LET et l'ont recommandée. Le personnel de l'urgence a également trouvé que la solution LET convenait aux besoins du service d'urgence.

En conclusion, la solution LET semble constituer une méthode anesthésique locale sûre et efficace pour la réfection des lacérations mineures du visage et du cuir chevelu chez les enfants.

Mots clés : lidocaïne, épinéphrine, tétracaïne, anesthésie locale, lacérations

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INTRODUCTION

Local injection of lidocaine for anesthesia of laceration repair has some disadvantages. Lidocaine injection may increase a patient's apprehension and anxiety of needles, thus hindering the suturing procedure and further adding to the patient's discomfort. In cosmetic areas, injection of a local anesthetic agent can distort the tissue borders. Injection in a contaminated wound may also increase the chance of infection. Topical administration of anesthetic agents offers the advantage of painless application. Moreover, topical anesthesia can minimize the exposure of needles to health care workers.

Tetracaine 0.5%, epinephrine 0.05%, cocaine 11.8% topical solution (TAC) is an effective local anesthesia and is better accepted than injected lidocaine for simple laceration repair in children.[1-3] However, serious adverse effects with TAC such as seizure and death secondary to systemic absorption of cocaine have been reported.[4-7] Moreover, the cocaine powder used to prepare TAC is expensive and requires strict narcotic control measures. These concerns led to the development of a non-narcotic topical anesthetic solution containing lidocaine 4%, epinephrine 1:1000, and tetracaine 0.5%.[10-12] Lidocaine provides a fast onset of anesthesia while tetracaine gives a long duration of anesthesia; epinephrine causes vasoconstriction to minimize bleeding from the wound and to limit the systemic absorption of lidocaine and tetracaine.

The Emergency Department of Oshawa General Hospital currently uses a local injection of buffered lidocaine for anesthesia of laceration repair. In striving for excellence in pain management in children we wanted to find a safe and effective but less painful alternative to buffered lidocaine injection to achieve local anesthesia for laceration repair. Due to the aforementioned concerns regarding TAC, we chose to trial the use of LET in our Emergency Department. The purpose of this report is to describe the efficacy, safety, and patient/parent satisfaction of LET for topical anesthesia in children who require simple laceration repair of the face or scalp.

METHODS

LET Preparation

Since LET is not available commercially, it was manufactured by the Pharmacy Department based on the work of Larson et al.[8] (Appendix A) In their study, Larson et al prepared LET using the injectable forms of lidocaine HCL, tetracaine HCL, and racemic epinephrine HCL. We used powdered ingredients because they are less expensive and the injectable forms were not commercially available at the time of this study. The resulting product is a clear and colourless solution with a final concentration of lidocaine 4%, epinephrine 1:1000, and tetracaine 0.5%. The solution was dispensed as a 3 mL unit dose in a capped, sterile syringe. The prepackaged LET syringes were stored protected from light in ultraviolet light inhibitant polybags at room temperature with a 4-week expiry. The expiry dating was extrapolated from the work of Larson et al.[8]

Sterility tests were performed on randomly chosen samples of LET. Each sample of solution was placed in a Bactec bottle containing a broth media and logged into the Bactec Analyzer. The culture was kept in the analyzer for 5 days in darkness at 35°C. During this time, if the culture was read as positive for growth by the analyzer, it was gram stained and cultured on an appropriate agar based media.

Patients

Patients were included into the study between April 4 and June 30, 1996, if they were 13 years or younger, and presented with a simple laceration to the face or scalp where the length of wound could be adequately covered by a sterile 2x2 inch gauze square. Patients were excluded if the laceration involved a mucous membrane, the nares, pinnae, or significant injury to an underlying structure (i.e., bone, cartilage, tendon, nerves, vessels, or parotid ducts) or if they were allergic to any ingredient in the solution. All patients were admitted to the Emergency Department of Oshawa General Hospital. After verbal and written information regarding LET was provided to the parent/guardian by the Emergency Department nursing staff and written consent was obtained from the parent/guardian, a 3 mL LET solution was applied to the laceration for at least 15 minutes according to method described in Table I.

Table I. Method of LET Application

1. Equipment
   - 3-mL unit dose LET solution in sterile, capped syringe
   - a sterile cotton ball or sterile 2 X 2 inch gauze pad
   - tape
   - 27 gauge needle
2. The nurse applies LET on a sterile 2 X 2 inch gauze pad or a cotton ball into and around the wound. This is held in place for 15 minutes by tape or by the parent's hand.
3. The physician probes the wound margin with a 27 gauge needle to test the effectiveness of anesthesia before suturing. If the patient is still sensitive to needle prick, the nurse/parent reapplies the LET saturated gauze/cotton ball. If the wound is still sensitive at 20 minutes, the nurse/parent reapplies for another 10 minutes to the 30 minute time limit.

   If at the 30 minute limit, anesthesia is not adequate then lidocaine injection can be used to achieve optimal anesthesia for suturing.
4. The physician sutures the wound within 30 minutes of the removal of LET saturated gauze/cotton ball from the wound.

Assessment of Efficacy

The emergency physicians and nurses were taught the methodology of the trial. The attending emergency physician or nurse recorded the following data for each participant: location and length of laceration; adequacy of anesthesia before suturing (adequate, inadequate, or unsure); duration of anesthesia during suturing (complete, partial, or incomplete); total number of sutures (superficial or subcutaneous) placed, and total suturing time (time from removal of drug to completion of suturing). The adequacy and duration of anesthesia were assessed by the attending physician who also performed the suturing. The categories used to determine adequacy of anesthesia before suturing and duration of anesthesia during suturing were derived from the literature[9,10] and are defined in Table II.

Assessment of Safety and Patient/Parent Satisfaction

A follow-up telephone survey using a standard set of questions (Appendix B) was conducted with the child's parent/guardian to determine if any side effects occurred after drug application and if any wound infection developed after discharge from the Emergency Department. Patient satisfaction with the LET method of anesthesia was also solicited. The phone surveys were conducted in the last week of each month with the parent/guardian of the patients enrolled for that month. All telephone surveys were conducted by a single member of the pharmacy secretarial staff.

At the end of the 3-month trial, the Emergency Department medical staff were asked to evaluate their experience with LET.

Table II. Criteria for Assessment of LET Efficacy

Adequacy of Anesthesia Before Suturing	
Adequate	No painful response is noted when the wound margin is probed with suturing needle before suturing.
Inadequate	A painful response is noted when the wound margin is probed with suturing needle at 30 minutes time limit before suturing.
Unsure	Unable to assess adequately as patient is in too much distress.
Duration of Anesthesia During Suturing	
Complete	Suturing **finished without supplemental lidocaine injection** or Painful response requiring supplemental lidocaine injection **at least 30 minutes** after removal of LET from the wound.
Partial	Painful response requiring supplemental lidocaine injection **between 15 and 30 minutes** after removal of LET from the wound.
Incomplete	Painful response requiring supplemental lidocaine injection **within 15 minutes** after removal of LET from the wound.

Data Analysis

Demographic data are presented as the mean ± standard deviation.

RESULTS

LET Preparation

The samples of LET sent for sterility testing all were negative for growth (Table III).

Patients

Sixty-six children were enrolled into the trial between April 4 to June 30, 1996. Each had one laceration that required suturing. Eleven children were excluded atthe time of data analysis. Of the 11 patients, 7 did not fit the inclusion criteria: 4 were older than 13 years, 2 had lacerations of nares, 1 had lacerations of ear. In 2 of the remaining 4 excluded children, more than 1 hour elapsed between LET removal and suturing. No data on efficacy of LET solution were collected for the remaining 2 children; one of these children could not be assessed adequately as he was in too much distress. Data analysis was performed on the remaining 55 patients.

The mean patient age was 5.20 (± 3.07) years (range 1 to 13 years; median age 5 years). The male to female ratio was 2:1. The mean length of laceration was 1.75 (± 0.78) cm (range 0.5 to 4 cm; median length 1.75 cm). The most frequent location of laceration was on the forehead (38%)

Table III. LET Sterility Test Results
Syringes were manufactured in 3 batches: 2 batches of 60 syringes and a third of 65 syringes.

Time Elapsed After Manufacture (days)	Number of Samples* Tested	Lab Report
0	7	no growth
14	6	no growth
28	3	no growth
36	1	no growth
112	1	no growth
199	1	no growth

* One sample is the content of 3 x 3 mL syringes.

followed by chin(20%), eyebrow(18%), and scalp(11%). Patient demographic data are listed in Table IV.

Assessment of Efficacy

Most patients (80%) achieved adequate anesthesia with LET before suturing. Of these, 40 (73%) experienced complete anesthesia and suturing was completed without requiring supplemental lidocaine injection. Four patients (7%) experienced partial anesthesia during stuturing and required supplemental lidocaine injection between 15 to 30 minutes after removal of LET from the wound to complete the suturing. Eleven patients (20%) experienced inadequate anesthesia after 30 minutes application. Of these 44 patients who achieved adequate anesthesia with LET alone, 7 had LET applied for greater than 30 minutes, 15 for 30 minutes, 9 for 20 minutes, 5 for 25 minutes, 4 for 15 minutes, and the application time was not available for 4 patients.

Total suturing time (time from the removal of drug to completion of suturing) was recorded for 27 of the 40 patients who experienced complete anesthesia after LET application. The total suturing time for these 27 patients ranged from 1 to 20 minutes (mean = 3.3 min) (Table IV). LET provided effective anesthesia for up to 20 minutes in a 4-year old girl who presented with a 3.5 cm laceration on the chin. The laceration required placement of 8 superficial sutures.

Table IV. Patient Data

		Level of Topical Anesthesia	
		Adequate (n = 44)	Inadequate (n = 11)
Age (years)	1 to 2	12	2
	3 to 5	14	6
	> 5 to 12	18	3
Gender	Male	29	8
	Female	15	3
Length of Laceration (cm)	< 1	4	0
	1 to 2	32	7
	> 2 to 4	8	4
Location of Laceration	Scalp	4	2
	Forehead and/or Eyebrow	23	8
	Cheek and/or Chin	12	0
	Bridge of Nose and/or Area above lip	5	1
Suturing Time (min)	1 to 2	16	3
	3 to 5	12	1
	10	1	0
	20	1	7
	not available	14	0
Total # of Superfacial Sutures Placed	< 5	33	4
	5 to 8	10	6
	not available	1	1

Assessment of Safety and Patient/Parent Satisfaction

Fifty-one (93%) parents/guardians were surveyed by telephone. None reported any side effects after LET application and/or during the suturing process. Most (84%) reported that his/her child did not develop any wound infection after suturing. The stitches were taken out or dissolved 4 to 10 days later. These parents were satisfied with the LET method of anesthesia and recommended it for future use in the Emergency Department.

Four (8%) parents/guardians reported that his/her child developed a wound infection after suturing which required oral or topical antibiotic treatment. These parents/guardians, nevertheless, were satisfied with LET as a topical anesthetic and recommended it for future use. The remaining 4 (8%) parents/guardians were not satisfied since LET did not provide adequate anesthesia for their children; no adverse complications occurred in these children.

There were 11 treatment failures. Of interest, the parents/guardians of 5 of the treatment failures stated they would recommend LET for future use in their children. Additional comments made by the parents regarding the LET solution were all positive.

In addition, no adverse effects after LET application and/or during the suturing process were documented by the attending physician for 33/55 participants. This information was not available for the remaining 22 participants.

DISCUSSION

The frequency of adequate anesthesia achieved after LET application in this study was similar to that achieved by Schilling et al (80 vs 74%).[10] Of the 11 patients who experienced inadequate anesthesia, inappropriate method of application was documented as the cause of failure in 2. The first case involved a 13-year old boy who presented to the Emergency Department with a 3.8 cm laceration on the left side of his scalp which required suturing. 3 mL of LET on a 4x4 inch gauze was applied to the laceration. A painful response was noted by the attending physician after application for 30 minutes. The attending nurse observed that the LET saturated gauze had not been held with constant pressure over the wound but was left lying on top of the wound. The child's long hair covering over the wound may have prevented maximum contact with LET.

The second case involved a 10 year-old boy who presented to Emergency Department with a 2.5 cm laceration on the scalp which required suturing. A solution of 3 mL LET on a 4 x 4 inch gauze was applied to the laceration for 20 minutes. The attending physician noted that only half of the wound was adequately anesthetized when probed with a suturing needle. The physician surmised that part of the gauze had slipped off the wound. The child's mother confirmed the hypothesis during the telephone survey.

For LET to work properly, the applicator (gauze or cotton ball) should be saturated with the solution but not dripping, and applied with constant pressure to the wound for the entire 15 minutes or longer application time. The thickness of the applicator used is also important since too thick a gauze or cotton ball can soak up too much of the drug solution. It was interesting to observe that the majority of treatment failures (7/11) involved lacerations to the forehead. The total number of cases with forehead lacerations was 21. Some of the treatment failures may have involved children who cried, not due to ineffectiveness of the LET solution, but because they were in too much situational distress.

At end of the trial, 8 Emergency Department staff (5 registered nurses and 3 physicians) chosen randomly were asked for feedback on the LET solution. All of them stated that LET application is feasible in the Emergency Department setting. A few found the minimum 15 minutes application requirement a hinderance at times; occasionally, the waiting period for simple laceration repair in our Emergency Department can be less than 15 minutes. Some of the staff would like to extend the use of LET to include laceration on other areas of body; others would like to remove the current age restriction of the present study. Some additional comments from the staff were that LET is an "excellent product" and "great for patient/family care."

The timing of LET application can be problematic. The present study specified that LET remain on the wound for a maximum of 30 minutes to minimize drug absorption. Of the patients who achieved adequate anesthesia before suturing, 7 had the drug solution applied for greater than 30 minutes before being tested for adequacy. The duration of application was in part influenced by how quickly the emergency physician could attend to the patient. Furthermore, if the attending physician is called away for longer than 30 minutes to attend to a more urgent case after the drug solution has been removed from the wound, the anesthetic effect will dissipate.

Systemic toxicity can occur when local anesthetic agents are injected or systemically absorbed. There were concerns that LET may be accidentally injected intravenously or intramuscularly since it was dispensed in a syringe. Each syringe of solution was thus labeled with a red sticker "NOT FOR INJECTION"; there have been no occurrences of accidental injection of LET solution to date. Applying local anesthetic agents to large areas of mucous membranes can readily lead to their systemic absorption and toxicity. As such, the LET solution should only be applied topically to nonmucous membranes. The vasoconstrictor epinephrine in the LET solution also helps to limit the systemic absorption of lidocaine and tetracaine. No adverse effects were reported but blood levels were not measured to substantiate the absorption of lidocaine, the main ingredient. However, a pilot study conducted by Schilling et al[10] showed serum lidocaine concentration at 10, 20, and 40 minutes after LET application to be less than 0.1 μg/mL indicating minimal or no absorption of lidocaine. Since LET solution contains epinephrine, the solution should not be used on lacerations of extremities such as fingers or toes where circulation can be blocked by epinephrine.

The drug acquisition cost of LET ($0.09/3 mL dose) in our pharmacy is less than that of TAC ($3.52/3 mL). LET solution is comparable in drug cost to that of buffered lidocaine injection ($0.08/mL dose). However, LET preparation is more labour-intensive. About 2.5 hours of a pharmacist technician's time is required to manufacture and package a batch of 200 mL LET solution. In contrast, it takes only about half an hour to manufacture and label a batch of 200 mL (10 x of 20 mL vials) buffered lidocaine injection in our pharmacy.

A limitation of this trial included a small sample size. Another potential limitation involved using more than one physician to suture lacerations. The study may have also been limited by subjective method of pain assessment and the lack of standardization of the applicator. As well, due to staff constraints, it was possible only to conduct the telephone surveys collectively at end of each month. In some cases, there was a delay of 1 month between LET application and the telephone survey. This time delay may have contributed to the possibility of inaccurate recall.

In conclusion, this trial in 55 children has shown LET to be a safe and effective topical anesthetic for simple laceration repair of the face or scalp. LET allowed sutures to be placed in 73% of the participants without the use of supplemental lidocaine injection. No side effects were reported after LET application. The LET method of anesthesia was well-accepted by the parents/patients and the Emergency Department staff. Further study is needed to define other areas of injury where the LET solution can be used effectively and safely.

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Appendix A. Preparation of LET

Ingredients	Manufacturer	Quantity
1. Lidocaine HCl Powder USP	Wiler	8 g
2. Epinephrine Bitartrate Powder USP	Sel-WinChemicals Ltd	0.36 g
3. Tetracaine HCl Powder USP	Wiler	1 g
4. Sodium Metabisulfite Powder	Wiler	0.15 g
5. Sterile Water for Injection USP	Astra	QS ad 200 mL

Equipment and Supplies:

1. Sterile glass beaker
2. Sterlie glass (200 mL) volumetric flask
3. Syringes: 35 mL X 4
   3 mL X 65
4. 0.22 Micron Disk Filter X 2
5. Sterile syringe caps X 65
6. Needles 20 G
7. Alcohol swabs
8. Weighing paper
9. Electronic balance
10. UVLI bags X 4 (Ultra Violet Light Inhibitant polybag)

Procedure

Use aseptic technique in laminar air flow hood

1. Weigh out the tetracaine powder, lidocaine powder, epinephrine powder and sodium metabisulfite powder on electronic balance outside laminar air flow hood.
2. Transfer powdered ingredients into a sterile volumetric flask inside the laminar air flow hood and qs with SWI to 200 mL. Swirl flask well to dissolve powder.
3. Transfer solution into a sterile beaker.
4. Withdraw solution into a 35 mL syringe.
5. Attach the disc filter and a 20 G needle to syringe and wet filter. Dispense 3 mL of solution into 3 mL sterile syringes and cap.
6. Continue to fill syringes with 3 mL solution in same manner until all the solution is used up. Change the 0.22 micron filter after the first 100 mL of solution.
7. Label each syringe with "LET" canned label and "NOT FOR INJECTION" sticker. Place a brown UVLI bag over syringes to protect them from light until they have been checked.
8. Once checked, place 15 syringes into each UVLI bag. Label the UVLI bags with the "LET" canned label and "Not for Injection" sticker.

Storage and Stability: Room Temperature, Protect From Light.
4 Week Expiry

Appendix B. Standardized Questions used to Conduct Telephone Survey

1. Did the Emergency Department staff provide you with information about the LET solution?
2. How long was the LET solution applied to the wound (Approx. minutes)?
3. How well did the solution work?
   Was any additional freezing injection needed?
4. Were there any side effects after application or during suturing?
   If yes, describe:
5. When were the stitches removed?
6. Did the wound heal well?
   Was there any sign of infection?
   If yes, describe:
7. Are you/your child satisfied with this anesthetic method?
   If no, explain:
8. Would you recommend the same method for future use?