Extended Study Protocol

Title:

Lidocaine-Adrenaline-Tetracaine gel (LAT gel) vs lidocaine infiltration as local anesthesia for suturing a superficial wound: a comparative study in adults.

Investigators:

- Jonas Stiers
- Prof dr. Hubloue
- Dr. Clinckaert

Sponsor:

Vrije Universiteit Brussel

Introduction

UZ Brussel has a busy emergency department where patients are triaged upon arrival. Depending on the pathology, they are referred to urgent care (internal medicine pathology), trauma care (orthopedic and surgical emergencies), or pediatric care (pediatric emergencies). Patients presenting with wounds requiring suturing are frequently triaged to the trauma care unit.
At UZ Brussel, the standard local anesthesia for suturing a wound in adults is always an infiltration anesthetic (such as lidocaine). However, other (topical) treatments exist. For example, LAT gel is used in children at UZ Brussel.
Adult patients frequently complain about the additional pain caused by the lidocaine injection. Moreover, it has previously been described that the injection can make the technical procedure of suturing more difficult. Additionally, the increased risk of needle-stick injuries argues against lidocaine injection.
In children, LAT gel has been implemented precisely for these reasons. Studies also show that the additional pain caused by injections increases the risk of developing needle anxiety. Furthermore, the technical procedure of applying LAT gel in a restless and anxious child is much easier than administering a lidocaine injection.
LAT gel consists of lidocaine 4% (80 mg), adrenaline 0.1% (2 mg), tetracaine 0.5% (10 mg), and hypromellose gel. It is a gel that can be prepared magistrally and sterily by the pharmacy in a 2 mL syringe with a Luer cap. It should be stored in the refrigerator to maintain optimal consistency and to achieve a shelf life of three months. The gel is not classified as a narcotic, therefore a prescription for narcotic substances is not required.
Ernst et al. (1) already investigated the difference in pain experience between LAT gel and lidocaine injection in 1997. Vandamme et al. (2) wrote a similar article but with a retrospective study design. Adler et al. (3) also compared LAT gel with placebo. All three studies conclude that LAT gel is at least equivalent to lidocaine infiltration. The literature regarding the use of LAT gel in children is much more extensive and justifies its standard use in pediatric patients.

Objective

The objective of this study is to document and compare the pain experience of a patient requiring suturing between anesthesia with LAT gel and anesthesia with lidocaine infiltration.
This study could therefore provide an indication of which form of local anesthesia in adults is preferable in terms of pain experience, both during administration of the anesthetic and during suturing.
Hypothesis (H1):
LAT gel results in less severe pain during administration, during testing of the anesthesia, and during suturing compared with lidocaine infiltration.
Hypothesis (H2):

LAT gel results in more severe pain during administration, during testing of the anesthesia, and during suturing compared with lidocaine infiltration.
Null hypothesis (H0)
LAT gel results in a similar pain experience during administration, testing of anesthesia, and suturing compared with lidocaine infiltration.

Department Involved in the Study

Emergency Department, UZ Brussel
Laarbeeklaan 101
1090 Jette
Belgium
Prof. dr. Hubloue I: Supervisor en promotor.

Methods

Study design
Comparative prospective monocentric study.

Materials
- **Electronic Medical Record: Emergency report**
- **2 mL LAT gel (4% lidocaine, 1:1000 epinephrine, 0.5% tetracaine) per patient in the LAT gel group – treatment option**
- **Maximum 4.5 mg/kg 1% lidocaine per patient or maximum 7 mg/kg 1% lidocaine with epinephrine per patient – treatment option**
- **Suturing materials as described in the hospital protocol**
- **Linear Visual Analogue Scale (VAS)**
- **Ruler**
- **Physician data collection form**

Study Population
Inclusion Criteria:
- Adults
- Wounds ≤ 7 cm
- Wounds suitable for single-layer closure
- No mucosal involvement or wounds in the direct vicinity of mucosa

Exclusion Criteria:
- Age < 18 years
- Suspected nerve injury
- Suspected tendon injury
- Wounds located on the genitalia, nose, or ears
- Substance intoxication
- Substance abuse
- Additional sedation with nitrous oxide (NO)
- Pregnancy
- Glaucoma
- Allergy to the described anesthetic agents or preservatives
- Wounds older than 8 hours
- Contaminated wounds
- History of cardiac disease
- History of respiratory disease
- Altered mental status
- Inability to use or interpret the visual analogue scale
- Inability to experience or report pain

Target Population Size:
50–100 selected patients presenting to the Emergency Department of UZ Brussel. Patients will be selected according to the predefined inclusion and exclusion criteria. Study period: September 2020 – February 2022 (maximum). Based on estimates from 2018 data at UZ Brussel (approximately 1800 sutures per year), the required data could likely be collected within 1–2 months.

Procedure

All selected patients will be treated by the attending physician for their open wound. Based on the physician's treatment plan, the patient will be assigned to either the LAT gel group or the lidocaine group. Pain during administration of the anesthetic will be recorded by the treating physician using a Visual Analogue Scale (VAS). Immediately after patient contact, the physician will complete additional information regarding patient and wound characteristics on a data collection form prepared by the researchers. In the lidocaine group, lidocaine infiltration will be administered immediately before suturing. A VAS score will also be obtained and documented on the designated form. After 30 minutes (LAT gel group) or 5 minutes (lidocaine infiltration group), the effectiveness of the anesthesia will be assessed using a 25G needle prick, and documented by the treating physician using the VAS. If the anesthesia is insufficient, additional lidocaine infiltration will be administered and documented on the same form. If sufficient anesthesia is achieved, the treating physician will suture the wound according to the UZ Brussel hospital protocol. During suturing, pain experience will again be assessed using a VAS and recorded on the form together with the physician's observations regarding the characteristics of the suturing procedure. Further data analysis will be performed by the investigators.

Analysis

Primary analysis

The first analysis will determine whether LAT gel reduces pain experience compared with lidocaine infiltration, specifically during:

- Administration of the anesthetic
- Testing of the anesthesia
- Suturing

Sub-analyses:

The following aspects will also be analyzed:

- Wound Characteristics
  - Length and location (skull, face, fingers, toes, lower limb, upper limb, trunk)
- Suturing Characteristics
  - Number of sutures
  - Duration of suturing
  - Suturing technique (sutures, staples, glue, other)
- Patient Characteristics
  - Age
  - Seks
  - Weight
- Medication
  - Dose of LAT gel
  - Dose of lidocaine
  - (+ additional doses if required)

Statistical Analysis Plan*:*

Data entry will be performed in Excel.
Further statistical processing will be performed in SPSS using ANCOVA.

Publication Policy / Agreements:

- **Thesis:** Jonas Stiers, supervisor Prof. Hubloue, co-supervisor Carol Clinckaert
- **Poster and presentation:** Jonas Stiers, supervisor/Hubloue, co-supervisor Carol Clinckaert
- **Scientific article:** Jonas Stiers – Carol Clinckaert– Prof. Hubloue

Referenties

1. Ernst AA, Marvez-Valls E, Nick TG, Mills T, Minvielle L, Houry D. Topical lidocaine adrenaline tetracaine (LAT gel) versus injectable buffered lidocaine for local anesthesia in laceration repair. West J Med. 1997;167(2):79-81.
2. Vandamme E, Lemoyne S, van der Gucht A, de Cock P, van de Voorde P. LAT gel for laceration repair in the emergency department: not only for children? Eur J Emerg Med. 2017;24(1):55-9.
3. Adler AJ, Dubinisky I, Eisen J. Does the use of topical lidocaine, epinephrine, and tetracaine solution provide sufficient anesthesia for laceration repair? Acad Emerg Med. 1998;5(2):108-12.

Short Study Protocol

Title

Lidocaine-adrenaline-tetracaine gel (LAT gel) vs lidocaine infiltration as local anesthesia for suturing a superficial wound: a comparative study in adults.

Brief Description of the Proposed Content

Problem Statement

UZ Brussel has a busy emergency department where patients are triaged into urgent care, trauma care, and pediatric care. Trauma care frequently treats patients with wounds requiring suturing. At UZ Brussel, the standard local anesthesia for suturing wounds in adults is infiltration anesthesia with lidocaine. However, other (topical) treatments exist. In children at UZ Brussel, LAT gel is already used. Adult patients frequently complain about the additional pain caused by lidocaine injection. Moreover, the injection has been described as making the technical act of suturing more difficult. The increased risk of needle-stick injuries is another disadvantage. In children, LAT gel has been implemented precisely because of this pain complaint. Studies also show that injection pain increases the risk of needle phobia. Furthermore, applying LAT gel in an anxious or restless child is technically easier than administering a lidocaine injection.

Short Description:

The study could therefore provide an indication of which form of local anesthesia in adults is preferable with regard to pain experience during administration of the anesthetic and during suturing.

Method

All selected patients will be treated by the attending physician for their open wound. Based on the physician's treatment plan, the patient will be assigned to either the LAT gel group or the lidocaine group. Pain during anesthetic administration will be recorded by the physician using a Visual Analogue Scale (VAS). Immediately after patient contact, the physician will complete additional data regarding patient and wound characteristics on a form prepared by the investigators. In the lidocaine group, lidocaine infiltration will be administered just before suturing, and a VAS score will also be recorded. After 30 minutes (LAT gel group) or 5 minutes (lidocaine infiltration group), the effectiveness of anesthesia will be tested using a 25G needle prick and documented using a VAS. If anesthesia is insufficient, additional lidocaine infiltration will be administered and recorded. If anesthesia is adequate, the physician will suture the wound according to the hospital protocol. Pain during suturing will again be assessed using the VAS and recorded together with the physician's observations. Further analysis will be performed by the investigators.

Study population

At least 70 selected patients presenting to the Emergency Department of UZ Brussel. Patients will be selected using the predefined inclusion and exclusion criteria. Study period: September 2020 – February 2022. The number of patients was calculated based on internal data and a power calculation.

Improvement Pathway

If the hypothesis is confirmed, lidocaine infiltration could potentially be replaced by LAT gel application for specific indications (based on the study's inclusion and exclusion criteria).

Lidocaine infiltration could then serve as an alternative or additional local anesthetic, with the aim of reducing patient pain experience.

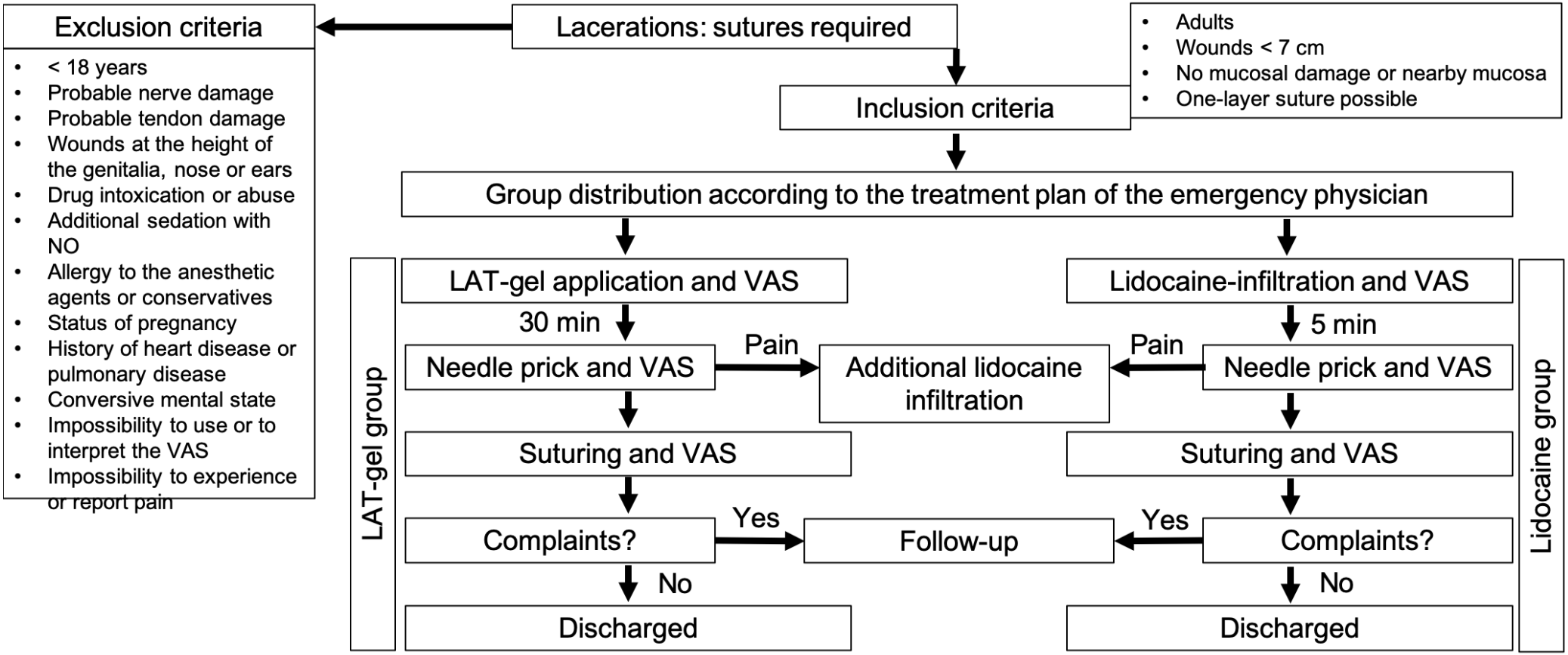
Intended objective

Hypothesis (H1): LAT gel results in less severe pain during administration, testing of anesthesia, and suturing compared with lidocaine infiltration.

Sub-analysis:

- Wound characteristics
- Suturing characteristics
- Patient characteristics
- Need for additional lidocaine administration

Flow chart


Exclusion criteria
< 18 years
Probable nerve damage
Probable tendon damage
Wounds at the height of the genitalia, nose or ears
Drug intoxication or abuse
Additional sedation with NO
Allergy to the anesthetic agents or conservatives
Status of pregnancy
History of heart disease or pulmonary disease
Conversive mental state
Impossibility to use or to interpret the VAS
Impossibility to experience or report pain
Lacerations: sutures required
Inclusion criteria
Adults
Wounds < 7 cm
No mucosal damage or nearby mucosa
One-layer suture possible
Group distribution according to the treatment plan of the emergency physician
LAT-gel group
LAT-gel application and VAS
30 min
Needle prick and VAS
Pain
Additional lidocaine infiltration
Suturing and VAS
Complaints?
Yes
Follow-up
No
Discharged
Lidocaine group
Lidocaine-infiltration and VAS
5 min
Pain
Needle prick and VAS
Suturing and VAS
Yes
Complaints?
No
Discharged