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Comparing foot anesthesia achieved using two injection sites in the ankle in patients undergoing foot surgery

Submission date
27/07/2019

Recruitment status
No longer recruiting

Registration date
20/08/2019

Overall study status
Completed

Last Edited
06/12/2021

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Anesthesia is used to block pain and uncomfortable sensations during surgery. It uses drugs that block nerve function temporarily so that pain signals are not transmitted to the brain. How well the anesthesia works can affect the patient's satisfaction with the surgery and their willingness to undergo surgery. Surgery on the foot involves an anesthetic procedure called ankle blocking, which targets the 5 nerves that connect the foot with the spinal cord. It is a safe technique, with a high success rate and a low risk of complications, and is very well accepted by both surgeons and patients. Of the 5 nerves, the tibial nerve is the most difficult to anesthetise and also the most important for successful blocking of pain. This study aims to compare injecting the anesthetic drug into the tibial nerve at two different sites - behind the ankle bone and above the ankle bone - to understand which produces the most effective anesthesia.

Who can participate?
Adults aged 18-75 who need surgery involving a tibial nerve block and who are otherwise healthy or have a mild systemic illness (an illness that affects several organs or tissues). Those with ankle swelling or other conditions that made it difficult to locate the nerve were excluded.

What does the study involve?
Participants were randomly assigned to one of two groups. Both groups received the same anesthetic procedure except for whether the tibial nerve injection was behind or above the ankle bone. They were assessed on how well the anesthetic blocked pain and temperature sensitivity in several places on the foot, how long the anesthetic took to block pain and sensation completely, how long the anesthesia lasted, their reported level of pain and whether they needed top-up anesthesia.

What are the possible benefits and risks of participating?
If one of the injection sites was more effective, the participants in that group might benefit from better pain control and fewer injections of additional anesthetic. The risks of the two anesthetic

techniques being studied are the same as for other foot anesthesia techniques and are very infrequent. The most frequent side effects, although still rare, are temporary alterations in sensitivity because of nerve damage from the injection.

Where is the study run from?
The University of Valencia (Spain)

When is the study starting and how long is it expected to run for?
July 2016 to January 2018

Who is funding the study?
The University of Valencia (Spain)

Who is the main contact?
Dr Maria Benimeli-Fenollar, Maria.Benimeli@uv.es

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
mb072019

Study information

Scientific Title
Supramalleolar anesthetic approach does not improve tibial nerve block success rates: a randomized trial in 110 participants.

Study objectives
Of the five nerves that innervate the foot, the one in which anesthetic blocking presents the greatest difficulty is the tibial nerve. Firstly, this nerve follows a deeper pathway. Secondly, the morphological features of the patient's foot (which may be edematous or deformed or have peripheral vascular disorders) can make it difficult to identify the anatomical structures that serve as reference points for tibial nerve blocking. Lastly, effective blocking of the tibial nerve necessitates blocking all three of its terminal branches: the calcaneal nerve, the medial plantar nerve and the lateral plantar nerve.
Several studies have agreed in locating the bifurcation of the tibial nerve at the tarsal tunnel level in a great number of cases. However, a number of publications note that the branching point of the calcaneal nerve shows considerable anatomical variation between individuals, which can contribute to a high rate of incomplete or failed blocks.
The particular interest in effective blocking of the tibial nerve is because a successful ankle block almost always depends on achieving satisfactory anesthetic blocking of this nerve. Moreover, in the majority of incomplete ankle block cases the sensitivity is located in the region innervated by the tibial nerve.
The study hypothesis of the present trial is that a supramalleolar tibial nerve block using a conventional technique could achieve a higher effective blocking rate, as the tibial nerve is less likely to have divided into its terminal branches. The objective was to compare the anesthetic efficiency of a retromalleolar tibial nerve block at the level of the most prominent point of the medial malleolus with that of a supramalleolar tibial nerve block injected 4 cm proximally from the lower edge of the medial malleolus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/11/2016, Research in Humans Ethics Committee of the Experimental Research Ethics Commission of the University of Valencia (Av Blasco Ibanez 13, Valencia 46010; +34 9638 64109; vicerec.investigacio@uv.es), ref: H1477566491165.

Study design
Single-center assessor-blinded randomized parallel-arm trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Foot anesthesia

Interventions
The study sample comprised 110 subjects, who were assigned at random to the two study groups. A simple randomized list (allocation sequence) with numeric sequential unique identifiers was produced by a software (Random Allocation Software 1.0) for a sample size of 110 patients divided into two groups of equal sizes (allocation ratio 1:1). The name of the group was introduced placed in a scaled opaque envelopes with and the sequential numbers assigned to it were written on the front face of the envelope. As the patients agreed to participate in the study, the auxiliary staff assigned them to the group of the intervention groups, following the sequence. There were no restrictions such as blocking or block size. The first group (RMB; n=55) received a retromalleolar tibial nerve block. The second group (SMB; n=55) received a supramalleolar tibial nerve block. All the anesthetic blocks were administered by the same person, the principal researcher. The variables were analyzed and tested by an external observer who did not know which type of anesthetic block the subject had received.
The reference point for the retromalleolar technique was the most prominent point of the medial malleolus. The supramalleolar technique was performed 4 cm proximally from the lower edge of the medial malleolus. For both techniques, anesthetic blocking of the tibial nerve was performed with the subject in a supine position, with the knee bent and the hip rotated outwards until the external edge of the foot was in contact with the treatment table. Anesthetic blocking was performed with the subject's foot at a 90° angle to the tibia, using a goniometer for this purpose. A 23G 0.60 x 25 ml BL/L Braun® needle and a conventional 5 ml syringe were used. The anesthetic solution administered was 3 ml of 2% mepivacaine without a vasoconstrictor (Scandinibsa®). Preanesthetic medication was not prescribed for any of the subjects. In the incomplete or failed tibial nerve block cases, high-volume distal infiltration of a second tibial nerve block was administered prior to commencing surgery.

All the anesthetic blocks were administered by the same person. The variables were analyzed and tested by an external observer who recorded the results achieved in an anesthetic process record sheet. The data obtained were reviewed and analyzed once the study sample was achieved, with IBM SPSSv22 software.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Extent of nerve blocking assessed using the number of areas with an absence of pain sensitivity (pin-prick test with 21G needle) and thermal sensitivity (swab soaked in alcohol). For this purpose, the tibial nerve dermatome was divided into three areas. A1 was the region innervated by the calcaneal nerve, A2 the region innervated by the medial plantar nerve and A3 the region innervated by the lateral plantar nerve. Both sensitivity tests were conducted at 5-min intervals, starting 5 min after injection of the local anesthetic and ending on reaching the absolute latency time or 30 min after the blocking injection. The tibial nerve blocking result, measured 30 min after initiating the block, was considered a failed block if the patient presented pain in the pin-prick test or sensitivity to cold in each of the three areas into which the

tibial nerve dermatome was divided; an incomplete block if the patient only felt pain or cold in one or two of the areas; or an effective block if pain on pin-pricking and sensation of coldness were absent from all three areas.

Secondary outcome measures
1. Presence of vascular and/or peri/intraneural puncture during the procedure.
2. Relative latency time (time in s from inserting the needle until the patient showed the first symptoms of anesthesia)
3. Absolute latency time (time in s between inserting the needle and a complete absence of pain and thermal sensitivity in the sole of the foot)
4. Anesthetic blocking duration (time in hours between attaining blocking and the first appearance of paresthesias in the sole of the foot)
5. Patient's level of pain during puncture assessed on a 10-point visual analog scale (VAS). VAS scores of 0–3 were considered low pain, 4–6 moderate pain and 7–10 intense pain.
6. Need for intraoperative anesthetic reinforcement measured by the number of patients who had attained effective blocking of the tibial nerve but required additional local anesthetic during surgery. It was classed as 1 when the patient needed an additional deposit of local anesthetic during the surgical procedure.

All secondary outcomes were measured starting once the anesthetic block was achieved until the anesthetic block was completed. All the anesthetic blocks were administered by the same person. The variables were analyzed and tested by an external observer who recorded the results achieved in an anesthetic process record sheet. The data obtained were reviewed and analyzed once the study sample was achieved, with IBM SPSSv22 software.

Overall study start date
01/07/2016

Completion date
30/01/2018

Eligibility

Key inclusion criteria
1. Aged 18-75 years
2. Classified as ASA I or II,
3. Require anesthetic blocking of the tibial nerve

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
110

Total final enrolment
110

Key exclusion criteria
1. Non-palpable peripheral pulses and/or an ankle edema, making it impossible to locate the anatomical reference points
2. Coagulation disorders and/or infections at the target injection sites
3. Record of allergies to amide-type local anesthetics
4. Pregnancy or lactation
5. Neurological or neuromuscular diseases
6. Chronic analgesic treatment with opiate derivatives
7. Cognitive impairment

Date of first enrolment
15/11/2016

Date of final enrolment
15/09/2017

Locations

Countries of recruitment
Spain

Study participating centre
Podiatric Clinic of the University of Valencia
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Sponsor type
University/education

Website
https://www.uv.es/uvweb/infermeria-podologia/es/facultat-infermeria-podologia-1285850234948.html

ROR
https://ror.org/043nxc105

Funder(s)

Funder type
University/education

Funder Name
Universitat de València

Alternative Name(s)
University of Valencia, 85|86

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Spain

Results and Publications

Publication and dissemination plan
We would like to publish the trial results in PLoS One.

Intention to publish date
23/10/2019

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/09/2019	No	Yes
Results article		29/05/2020	06/12/2021	Yes	No