

Is WALANT Applicable in Distal Radius Fracture Osteosynthesis?

Study Protocol and Statistical Analysis Plan

October 2020

NCT (still not available)

ABSTRACT

Title → Is WALANT Applicable in Distal Radius Fracture Osteosynthesis?

Aims → To evaluate is Wide Awake Local Anaesthesia No Tourniquet (WALANT) is applicable to distal radius fracture (DRF) osteosynthesis and possible benefits of not using the ischemia cuff in distal radius osteosynthesis, by using the WALANT anaesthetic technique and compare it with patients who have undergone the current anaesthesia method (locoregional anaesthesia with or without sedation)

Material and methods → Randomized controlled study comparing patients operated on for distal radius fracture with osteosynthesis during a year (December 2020 to December 2021). The randomization will be done by 10 block in order to ensure similar numbers of patients in both groups of intervention. In the group A patients will be operated on with local anaesthesia (lidocaïne + adrenaline + bicarbonate) with or without sedation without the use of ischemia, while in group B patients will be given anaesthesia by proximal locoregional blockade with or without sedation and ischemia cuff. Immediate short-term results will be compared between both groups. Primary outcomes will be preoperative and postoperative pain, pre and postoperative swelling, and patient and surgeon satisfaction.

Results →

Conclusion →

1. INTRODUCTION

In recent years, the use of the WALANT (Wide Awake Local Anaesthesia No Tourniquet) anaesthesia technique is gaining weight, as multiple benefits of this type of anaesthesia have been found. The WALANT technique involves injecting local anaesthetic (lidocaine) at low doses and adrenaline to create a bloodless surgical field by avoiding the use of an ischemic tourniquet. In addition, there are many studies that support the safety of using this type of anaesthesia if it is administered according to the correct guidelines and dosage. (1), (2). Also, this technique has been shown to have high patient satisfaction rates. (3), (4)

Currently, and more so after Covid-19, which is causing unprecedented demand for an already saturated global health system, this anaesthesia technique is being implemented around the world in multiple centres and hospitals to perform some of the most common procedures in hand or foot surgery. Several studies can be found in the literature that demonstrate the benefits of applying circuits with anaesthesia type without the need for preoperative or admission compared to conventional Major Ambulatory Circuits (5), (6), (7).

The most commonly used drug for local anaesthesia is lidocaine, as it is the prototype short-acting anaesthetic and its physicochemical properties (solubility, relative potency, onset of action and duration) are those indicated to perform this type of procedure. The injection of lidocaine may or may not be associated with adrenaline, which produces vasoconstriction, decreasing local bleeding in the area, and at the same time prolongs the action of lidocaine. This combination of drugs can extend the duration of anaesthesia up to 3 hours. That is why in the WALANT technique these two drugs are administered together. Lidocaine is administered with a 1% (10mg / ml) solution, and if larger volumes or lower doses of anaesthesia are required, 0.5 of the solution may be used to avoid the maximum toxic doses, which in the combination of adrenaline + lidocaine, the maximum toxic dose is 7mg / kg with a maximum total dose of 500mg (50ml of 1% Lidocaine or 10cc of 5% Lidocaine). Concentrations above 1% lidocaine are not used, as they have not been shown to improve induction or duration of anaesthesia and may increase the risk of toxicity. In order to counteract the acidic pH of lidocaine, it is buffered with 8.4% (1M) sodium bicarbonate in a 10: 1 ratio, thus reducing pain during administration. This type of anaesthesia is performed according to the Lalonde's technique and is administered according to the Ahmad technique. (10) (22) (23) (24)

Our hypothesis is that the application of this anaesthetic technique, combined or not with sedation, causes less swelling and pain in the immediate postoperative period, without compromising patient satisfaction, altering short-term results or increasing the number of complications and without increasing the technical difficulty of the procedure to the surgeon.

2. OUTCOMES OF THE STUDY

The main objective of this study is to assess the applicability and benefits of LANT (Local Anaesthesia No Tourniquet) anaesthesia versus locoregional anaesthesia with proximal block and ischemia in osteosynthesis of distal radius fractures postoperatively immediately.

2.1. PRIMARY OUTCOMES

1. Pain (Difference between preoperative and postoperative EVA (24 hours, 10-15 days after surgery, 1 month after surgery))
 - a. Analgesia intake
2. Swelling (difference with healthy limb and difference between preoperative and postoperative (24 hours, 10-15 days after surgery, 1 month after surgery))
3. Patient satisfaction (Scale 1-5 and questionnaire)

2.2. SECONDARY OUTCOMES

1. Evolution of the surgical wound (active bleeding and dressing condition at 24 hours and 10-15 days after surgery)
2. Postoperative mobility
 - a. Thumb mobility and opposition (Kapandji scale)
 - b. Finger mobility (capability of the patient to arrive at proximal and distal palm crease)
 - c. Wrist mobility (flexion, extension, pronation, supination, ulnar deviation, radial deviation)
3. Surgeon's technical difficulty.
 - a. Scale 1-5 (1 easy- 5 difficult)
 - b. Intraoperative stress /yes/no) and reason
4. Insufficient anaesthesia
 - a. Need of change to General Anaesthesia
 - b. Need of adding more anaesthesia
 - i. Type of anaesthesia used (sedation, local anaesthesia reinforcement, etc.)

- ii. Reason for change
- 5. Postoperative complications (total number and description)

3. MATERIAL AND METHODS

3.1. TYPE OF STUDY

This is a randomized prospective study comparing two groups of patients with distal radius fracture during a year

A → Local Anaesthesia (WA) LANT + NO ISCHEMIA +/- sedation.

B → Locoregional anaesthesia proximal block + ISCHEMIA +/- sedation.

3.2. INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria will be those patients ≥18 years of age who agree to participate.

Patients with any of the following conditions will be excluded from the study:

1. Do not sign informed consent.
2. They have associated fractures in which additional osteosynthesis is required: scaphoid fracture, ulnar fracture, bifocal radius fractures, etc.
3. Open fractures.
4. Polytrauma
5. Non-synthesized flying fractures with a single plate or other type of plate.
6. Patients in whom a different surgical technique than the one mentioned above has been required.
7. Contraindications to the use of ischemia (14)

- a. Peripheral vascular disease.
- b. Seriously injured or traumatized limb.
- c. Peripheral neuropathy or CNS disease
- d. Severe infection in the limb.
- e. Thromboembolic disease in the extremity.
- f. Poor skin condition of the limb.
- g. Arteriovenous fistula.
- h. Sickle cell hemoglobinopathy.

8. Contraindications for proximal blocking: (15)

- a. Existence of previous trauma or anatomical distortion of the area that prevents the abduction of the arm.

- b. Active presence of infection at the puncture site.
- c. Previous axillary lymphadenopathy.
- d. Previous history of local anaesthetic allergy.
- e. Severe coagulopathy.
- f. Severe pre-existing neurological diseases in the upper extremity.

9. Contraindications for WALANT anaesthetic technique

- a. Documented hypersensitivity to lidocaine.
- b. Compromised peripheral circulation.
- c. Patients with previous vascular pathology, a history of vasculitis, Buerger's disease, and scleroderma.
- d. Patients with infection of the area surrounding the injection.

3.3. VARIABLES

Independent variables:

These variables will be collected during the surgery and in the subsequent from patient anamnesis, clinic history and filling the Collection Data Guide Form:

- Age (years)
- Sex (male / female)
- Dominant hand (left / right / both)
- Injured hand (left / right / two)
- Fracture classification according to American Orthopaedic (AO) (16), (17)
- Number of days from injury to surgery (days)
- Preoperative pain (VAS scale (18))
- Preoperative swelling injured hand and healthy hand. The perimeter of the wrist will be measured at the height of the proximal palmar fold in cm.

Dependent variables:

These variables are the ones we want to study and will be collected during the surgery and afterwards from patient anamnesis, clinic history and filling the Collection Data Guide Form:

- Duration of admission (hours).
- Duration of surgery (minutes).
- Duration of ischemia in group B (minutes).

- Preoperative and postoperative pain (VAS scale): Pain at baseline, 24 hours post-intervention, at the visit of the first treatment 10-15 days post-intervention and pain 1 month after the intervention.
- Intraoperative pain (VAS scale): Assessable only if it has not required sedation.
- Time (minutes) of anaesthesia administration
- Time (minutes) from the end of administration to the beginning of IQ
- Need for anaesthetic reinforcement:
 - Sedations (yes/no) and reason
 - In the case of WALANT: Taking into account the reference technique used (10), if any extra doses are needed and location within the wrist
- Postoperative analgesia during admission and discharge (drugs used, dose and frequency of use)
- Postoperative swelling injured hand and healthy hand (cm).
- Stained dressing and the presence of active bleeding due to the wound within 24 hours and during the first outpatient clinic 10 or 15 days after surgery.
- Patient satisfaction during the first outpatient clinic 10 or 15 days after surgery. → Assess satisfaction (1-5) / Would you repeat the anaesthesia type? / Would you recommend the technique?
- Description of the complications of anaesthesia.
- Description of postoperative complications.
- Mobility 24 hours post-intervention, first aid and one month later. (The mobility of the fingers, intrinsic and extrinsic muscles, Kapandji exercises 1-10 and wrist mobility will be assessed by measuring flexion-extension and prone-supination with a goniometer).
- Surgeon's experience
 - a. Technical difficulty due to lack of visualization in the surgical field (Scale 1-5. 1 no difficulties, 5 very difficult))
 - b. Added stress to the surgery (yes/no) and reason.

3.4. DATA COLLECTION AND INSTRUMENTS

A sample of patients with a distal radius fracture operated in our Hospital will be obtained. Those who meet the inclusion criteria will be asked to participate and will be told what the study is about. Those who accept must sign the specific informed consent of this study.

Prior to surgery, an external observer will collect the personal data of the patients, assign them a code (P1, P2, P3...) and perform the anamnesis following the Data Collection Guide Form

Patients' recruitment will be done during a year, from December 2020 to December 2021. They will be separated into two groups. The external observer will do this process with 10-block randomization using Study Randomizer (2017), a web based randomization service (19)

The first (Group A) in which WALANT technique will be performed and the second (Group B) in which locoregional anaesthesia (either axillary or supraclavicular block) with axillary ischemia will be applied. Because it is considered a long-term intervention, all patients will be offered the option of sedation or not, and this variable may change depending on the criteria of anaesthesia or the patient himself in order to facilitate their well-being. All patients participating in the study will receive the same antibiotic prophylaxis following our protocol (Cefazolin 1g iv in <80Kg or 2g 80-160Kg and in patients with normal renal function, to pass in 5 minutes. In those with FG The dose should be adjusted, and a second dose of 2g iv should be given if the surgery lasts 3 hours or more. In patients with penicillin allergy, Teicoplanin 600mg iv will be administered in 10 minutes, without repeating the dose. in no case) (20)

Group A (WALANT Anaesthesia +/- sedation + NO ischemia)

In WALANT technique, the doses are followed according to Lalonde's (21). 1% lidocaine with 1: 100,000 adrenaline is generally used to counteract the acidic pH of lidocaine, which is buffered with 8.4% (1M) sodium bicarbonate in a 10: 1 ratio to decrease pain during administration. If more volume is required, Lidocaine is diluted to 0.5% so as not to exceed the maximum toxic dose of 7mg / kg with a maximum total dose of 500mg (50ml of 1% Lidocaine or 10cc of 5% Lidocaine) (22)

In this case, the preparation will be made by the nurse with 100cc of SF, from which 15cc will be extracted and 10cc of 5% Lidocaine + 1cc Adrenaline + 4cc of 1M Bicarbonate will be added.

Anaesthesia will be administered in the operating room, monitoring the patient's HR, BP, and SatO2. It will take 20-30 minutes before starting the surgery, as the peak of vasoconstrictor action of the adrenaline is reached after this time.

The technique according to Ahmad (10) is to infiltrate 40ml of local anaesthetic preparation, distributing 10ml to the subcutaneous tissue along the approach, from proximal to distal. Subsequently, 30ml is administered in deeper planes divided into

3 points, from proximal to distal, distributed in 4ml around the flying periosteum, 2ml radially and 4ml in the dorsal periosteum, through a lateral entrance, introducing the 'needle from the radial side avoiding puncturing through the radial artery. An additional 10ml will be added for the intra-articular region, using conventional 3-4 and 6R arthroscopy radiocarpal approaches. In some cases it may be increased if the surgeon considers that it requires more volume, as long as we do not exceed the toxic doses (23).

In patients with a history of cardiac pathology, it is possible to assess the possible dissolution of adrenaline at 1: 400000, this group will include those patients with ischemic heart disease and / or severe hypertension (irregular hypertension with the use of 3 different antihypertensive drugs).

Group B (Locoregional anaesthesia proximal block +/- sedation + ischemia)

The anaesthesiologist in charge of the operating room will perform the locoregional block. The same ischemia sleeve (size, brand, manufacturer and country of origin) will be used on all patients and the same ischemia pressure (250mmHg) will be applied.

In all of them, intraoperative monitoring will be performed, which will be the same in both groups, the FC, FR, TA, ECG, SatO2 and duration of the intervention must be recorded.

The surgical procedure will be the same for all patients. If the surgeon considers it necessary, arthroscopic assistance will be used with conventional dorsal radiocarpal portals (2-4R and 6R). Surgeons from the surgeons of our Upper Extremity Unit will perform all operations.

As for the postoperative period, the participants in both groups will require 24-48 hours of admission and will perform the first treatment on the floor before hospital discharge. They will receive a sheet with the guideline of rehabilitation exercises to be performed at home, with plaster and without (Appendix 5) so we make sure that everyone receives the same instructions to avoid swelling and promote mobility.

A first check-up will be performed at 10-15 days for treatment and a second check-up will be performed one month after the operation.

3.5 LIMITATIONS OF THE STUDY

- The sample size (N) may be small.
- VAS scale is a subjective measure and therefore makes it difficult to compare different patients. However, to date, there are no objective pain assessment scales that meet this purpose.

- The doses of anaesthesia used in the proximal block will not be the same in all patients and depend on the anaestheologist in charge of the operating room in that moment.

- Heterogeneity of fractures may vary the results of the study, as more complex fractures can cause more pain.

3.6 STATISTICAL PLAN

Quantitative values will be described as mean and standard deviation in case of normal distribution, or with median and interquartile range otherwise. Qualitative variables will be described with absolute and relative frequencies. The Student's t test for normal quantitative variables and the non-parametric Mann-Whitney U test will be used to compare the two experimental groups. Pearson's chi-square test for expected frequencies above 5 and Fisher's exact test would be used to compare the distribution of qualitative variables between groups. Statistical program R [ref] will be used, applying a statistical significance level of 5%.

3.5. SCHEDULE FOR THE STUDY

TASKS	CALENDAR
Drafting protocol	October 2020
Protocol presentation to the Ethical Scientific Committee	October 2020
Data collection	December 2020-December 2021
Data analysis	February 2022
Drafting results and conclusions	March 2022

3.7. PLACE AND TIME OF STUDY

The centre where the study will be carried out is the Arnau University Hospital of Vilanova de Lleida (HUV), belonging to the Catalan Institute of Health, is the reference centre for acute patients in the health regions of Lleida and the High Pyrenees and Aran.

3.8. CONFIDENTIALITY OF DATA

In order to maintain the confidentiality of the study participants, dissociated tables will be used, in this way the data of the participants will be hidden from the researchers.

3.9. ETHICS

This is a study to which the provisions of Law 14/2007, of 3 July, on Biomedical Research¹² and Royal Decree 1716/2011, of 18 November, which establishes the basic requirements for authorization and operation of biobanks for biomedical research purposes and the treatment of biological samples of human origin, and regulates the operation and organization of the National Register of Biobanks for biomedical research¹

3.10. CONFLICTS OF INTEREST

The authors and contributors have no conflict of interest for the present study.

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