

A local anesthesia without tourniquet for distal fibula hardware removal after ORIF: the safe use of epinephrine in the foot. A randomized clinical study.

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ABSTRACT

Hardware removal after fractures surgical treatment fracture is one of the most common procedures in orthopaedic daily activity. A percentage from 14,5 to 21 of total removal involves the ankle joint. Trying to reduce the important socio-economic impact of this surgical procedure, we thought to perform it using the Wide Awake Local Anaesthesia Without Tourniquet (WALANT), a particular technique presented by D. Lalonde that associated a local anaesthetic drug with epinephrine in order to obtain an effective haemostatic effect despite the lack of a tourniquet. Nowadays, the WALANT efficiency and safety in hand surgery is widely demonstrated in literature but there are no data about its use in lower limb extremity surgeries. Then, authors performed a randomized study with 60 patients underwent distal fibula hardware removal between 2014 and 2016.; they were divided into two groups: Group A under loco-regional anaesthesia with tourniquet and Group B under WALANT. We didn't found significant differences in term of maximum pain level felt during the anaesthesiologic and the surgical procedure. Although, the WALANT use significantly reduced post-operative pain levels. The WALANT procedures also reduced the number of hospitalization days. No differences in term of post-operative complications rate were found. In conclusion, the WALANT can be considered as a suitable option for distal fibula hardware removal in selected patient; it shows important clinical and economical advantages compared with the traditional loco-regional anaesthesia with tourniquet. This study also lays the foundation for the use of the WALANT beyond the only field of the hand surgery.

Level of clinical evidence: II

KEYWORDS

Local anesthesia without tourniquet, WALANT, foot and ankle hardware removal, epinephrine.

INTRODUCTION

Hardware surgical removal after open reduction and internal fixation (ORIF) of bone fracture is one of the most common procedures in orthopaedic daily practice(1, 2), although the indications for this operation are not yet defined in literature(3-5). Most of these (from 15 to 21%) are performed after ORIF for distal tibia or distal fibula fractures(6, 7). Indications for hardware removal are, in order of frequency: hardware related pain or ankle stiffness, hardware infections, patient's insistence even if asymptomatic and implant failure (like screw breakages or peri-device fractures)(6-9). In a era of increasing interest in economic impact of medical procedures, the important socio-economic effect of this frequent surgical procedure must be taken into consideration(1). We thought that the introduction of the Wide Awake Local Anaesthesia without Tourniquet (WALANT) - that is already largely employed in hand surgery(10-12) – also for this kind of surgical procedures could reduce its significant economical impact. In our knowledge, literature presents only one article suggesting the use of local anaesthesia for ankle trauma surgery(13). In order to evaluate clinical results of the use of WALANT in hardware removal, Authors created a monocentric randomized study dividing a total of 60 patients underwent distal fibula plate removal between January 2014 and December 2016 into two groups: the former using a traditional loco-regional anaesthesia (group A) and the latter using the WALANT (group B). The primary outcome of this study is to highlight differences in pain scores between the two groups in pain scores measured before and during the surgical procedures but also throughout the five days after the surgery.

MATERIALS AND METHODS

From January 2014 and December 2016 Author evaluated 60 patients underwent lateral malleolus hardware removal. Inclusion criteria were: isolated distal fibula fracture (no other associated fractures or intra-operative demonstrated tibio-fibular syndesmosis imbalance), ORIF (open reduction and internal fixation) surgical procedure for the original distal fibula fracture performed under loco-regional anaesthesia (in particular, a “bi-block” anaesthesia), X-Ray confirmed fracture healing, hardware removal for local pain (also mild pain levels) or ankle stiffness, more of 12 month between the ORIF and the hardware removal surgical procedure. Exclusion criteria were: preference to have the procedure under intravenous sedation anaesthesia (IVSA) or general endotracheal anaesthesia (GETA), medical contraindication for the WALANT use (substantially history of peripheral vascular disorder due to occlusive peripheral arteries disease diabetes etc and history of allergic reaction to local anaesthetic drugs), clinical and X-Ray signs of

hardware infection, X-Ray documented hardware failure, delayed healing of the surgical scar or tardive distal fibula skin coverage suffering (clinically documented by an ulcer development) after ORIF procedure, and inability to sign the informed consent. Our local Ethics Committee approved this study.

Eligible patients were detailed informed about the differences between the general, loco-regional and the WALANT anaesthesia and all of them signed a written informed consent to be admitted into our study. Then, they were randomly divided into two groups of 30 patients: group A performed the hardware removal under loco-regional anaesthesia (in particular, a “bi-block” anaesthesia) and group B performed the same surgical procedure under WALANT. Both groups underwent the surgical procedures into the main operative room.

For each patient, we collected demographic data such as: age, gender, distal fibula fracture AO/OTA classification, type of hardware for ORIF, hardware removal indication, time between ORIF and hardware removal procedure. We registered also the number of hospitalization days; we considered 2 days of hospitalization if patient had to stay into the hospital for the night after surgery. Then, we collected data about maximum felt pain using the numeric pain rating scale (NRS). The bi-block anaesthesia was performed by an anaesthesiologist using 1% mepivacaine; a tourniquet was placed at the middle third of the thigh(14). He used an electric bipolar signal in order to locate the femoral and the sciatic nerve; then he injected the local anaesthetic around this two nerve to reach a complete lower limb sensitive and motor block(14). The WALANT was instead performed by the same surgeon using a mixture of 0,5% ropivacaine (40 ml) and 1:1000 epinephrine (0,2 ml). The first 30 ml was injected into subcutaneous tissues of the middle point of the before-created surgical scar and the last 10 ml was injected with the contact of the needle with the distal fibula bone (Figure 1 and Figure 2). We injected the mixture not only near the lateral fibula surface but also near its anterior and posterior surface in order to reach also the medial surface by periosteal membrane diffusion phenomena as described by D. Lalonde(11). In order to reduce the pain related to the local anaesthetic injection, we warmed the mixture(15) and we added 1 ml of 8,4% bicarbonate(16). We waited 20-30 minutes from the injection before starting surgical procedure(11, 17). All patients received an antibiotics prophylaxis with 2 g of sodic cefazoline administered 30 minutes before the surgical incision. An equipe of three surgeons performed all the hardware removal procedures.

For each patient we fixed a medical examination five days after the surgery in order to control the wound conditions and the post-operative maximum pain score. We planned also another examination at 15 days after surgery to remove stitches and point out possible cases of delayed wound healing.

Statistical analysis was performed using the Statistical Package for Social Sciences, Version 13 (SPSS Inc., Chicago, Illinois). Continuous variables were showed as mean±standard deviation and discrete variables were expressed as frequency percentages. The non-parametric Mann-Whitney test was used to analyse variables differences between the two groups of patients. We used a 5% level of confidence for the test.

RESULTS

Patients mean age at the time of hardware removal was 32 years (from 21 to 59 years old). They were 49 males (81,6%) and 11 female (18,4%). The mean time between the ORIF and the hardware removal procedure was 15 month (with a range between 12 and 21 month). Using the AO/OTA classification, 51 fractures (85%) were 44-B1.1/2 and 9 (5%) fractures were 44-B1.3. ORIF procedure was performed using Syntes LCP Lateral Distal Fibula Plates in 43 (71.6%) cases and Intrauma O'Neil Kite Plates in 17 (28.4%) cases. Data about type of hardware removal indications showed that 43 (71.6%) patients reported distal fibula local pain (with a mean NRS of 2.7 and a range from 1 to 7) instead 17 patients (28.4%) suffered both for pain and ankle stiffness related to the hardware presence.

Our study definitive differences in demographic and clinical data between two groups are shown in table 1. No differences in term of mean age, gender ratio and time between ORIF and hardware removal procedures were found.

Statistically significant differences were instead found in term of days of hospitalization. After the surgical operation under WALANT, no patients had to remain into the hospital for the night against the 10 patients after the bi-block anaesthesia. Patients remained into the hospital after the bi-block anaesthesia fundamentally because they had a persistence of the lower limb motor nerve block (and then an inability in free deambulation) beyond the term of the surgical block closure (8 pm); this was the reason why surgeon preferred not to dismiss them before the following day starting of his elective surgical activity (8 am). No difference in mean maximum NRS evaluated during the anaesthetic procedure was found (table 1). Patients from Group A referred they felt the worst pain during the anaesthetic infiltration around the sciatic nerve; less pain was instead reported during the infiltration around the femoral nerve. Patients from Group B instead referred the worst pain during the infiltration of the first 10-20 ml of local anaesthetic and epinephrine mixture; local pain decreased after almost 2 minutes so the surgeon could deeply infiltrate the mixture also near the periosteal membrane without further patient suffering. We didn't found difference also in term of local pain felt during the surgical procedure of hardware removal. Some patients from Group B (26%) referred only the persistence of a tactile perception during the surgery that they described as "strange" but not painful. Patient from Group A didn't referred any particular perception during the surgical operation. We highlighted a significant difference in term of maximum NRS score during the 5 days after surgery. Patients from Group B reported a lower NRS than patients from the group A during our first clinical examination. We didn't found any case of peripheral ischemic infarction. Moreover, we didn't found any case of delayed wound healing at our second clinical examination (fixed 15 days after surgery) in both two groups of patients.

DISCUSSION

Hardware surgical removal after open reduction and internal fixation (ORIF) of bone fractures represents a significant part of elective orthopaedic surgery. Different authors reported variable percentage from 15 to 30% of total planned orthopaedic surgeries(1, 18). Three different reviews show that the ankle joint is the most frequent involved anatomic district with percentage from 14,5 to 21 of total hardware removals (6-8). Although, there are little information regarding the incidence and indications for implant removal after ORIF for ankle fractures. Previous reports indicate that hardware-related complaints represent the most common indication(19, 20). Removal due to infection varies from 1.3 to 4.8% and hardware failure from 0,8 to 1.2%(21, 22). Also the patient's personal preference is a recurring indication but it is frequently hid under a mild hardware-related pain or ankle stiffness. However, the indications and the clinical need for routine hardware removal after ORIF are disputed (23); surgeons express different viewpoint on this argument with some advocating and many opposite the routine removal(24). This frequent surgical procedure obviously represents an important item of expenditure for the national health system. In a era of increasing attention for socio-economic impact of medical procedure, we thought to perform distal fibula hardware surgical removal under the Wide Awake Local Anaesthesia without Tourniquet (WALANT), a particular anaesthesiologic technique presented by D. Lalonde that is actually largely employed in hand surgery(10, 11, 25). Nowadays, there are lot of articles in literature showing that the WALANT offers a wide range of clinical and economical advantages in hand surgery comparing with a traditional loco-regional anaesthesia with tourniquet; in particular, main advantages are: no need for tourniquet (because of the haemostatic effect of the epinephrine), the anaesthesiologist presence is not essential for its use (because of it is "only" a particular application of a local anaesthesia), the possibility for an intraoperative motoric check (because it blocks only sensitive nervous fibres) and a more rapid patient's discharge after the surgical operation(10, 11, 25). Lot of articles also highlighted the WALANT substantial safety; also the widely-mentioned risk of peripheral ischemic infarction due to the epinephrine injection into upper limb extremities is already disproven(11, 26). Moreover, an antidote (phentolamine) is largely available if this rare side effect appears after the injection. Obviously, literature reports that the use of this particular kind of local anaesthesia also has some contraindications like the history of peripheral vascular disorder (due to occlusive peripheral arteries disease, diabetes etc) or the history of allergic reaction to local anaesthetic drugs. Despite the large number of articles about the use of the WALANT in hand surgery, literature presents no data about its application in lower limb extremity surgeries such as ankle hardware removal.

Then, Authors planned a single centre randomized clinical study including 60 patients underwent distal fibula hardware removal from January 2014 to December 2016 that were divided into two groups: Group A performed the surgery under a traditional loco-regional anaesthesia with tourniquet and Group B performed the surgery under the WALANT technique. The two groups showed no significant differences in term of demographic and trauma-features data. We excluded from our study patients that preferred another kind of anaesthesia (like IVSA or GETA) and patients that were

not able to sign the informed consent. We didn't include also patients with with history of allergic reaction to local anaesthetic drugs, history of peripheral vascular disorder due to occlusive peripheral arteries disease, diabetes, vasculitis etc and patients that – after the ORIF procedure - developed a delayed wound healing or tardive distal fibula skin coverage suffering; indeed, this facts clearly reveal a local microcirculation impairment that could make worse with the use of epinephrine (11, 25). Finally, we excluded also patients with clinical and radiographic signs of hardware infection and/or failure because the removal procedure could be more invasive requiring a more extended anaesthetized area.

We didn't found difference in term of perceived mean maximum NRS during the anaesthesiology procedures. Indeed, the pain that patients from group A referred during the peri-sciatic nerve injection was statistically comparable with the one that patients from group B experienced during the infiltration of the first 10-20 ml of local anaesthetic and epinephrine mixture. No differences were highlighted also in term of intraoperative maximum pain. Despite the use of a local anaesthesia, patients from group B didn't denounced particular pain neither during the initial unscrewing from the medial fibula cortical bone. This fact is probably due to the periosteal diffusion of the local anaesthetic drugs we injected at least 30 minutes before starting surgical procedures. For this reason, in our experience, it is important to insert the needle very close to the periosteal membrane in order to permit its medial diffusion. Mean maximum post-operative NRS referred at the 5 days follow-up instead showed a statistically significant difference. This fact is probably linked with the difference in local anaesthetic drugs pharmacokinetics. Indeed, the mepivacaine used for loco-regional anaesthesia generally allow an almost 10 hours of sensitive block instead the ropivacaine used for WALANT an almost 24 hours block with a valid post-operative analgesic effect(27). It is important to underline that, despite its limits in sensitive nerve block duration, we chose mepivacaine for the loco-regional anaesthesia because it is one of the local anaesthetic drugs with the shorter and the more stable period of motor nerve block (that is almost 3-4 hours)(27). Nevertheless, the use of mepivacaine didn't prevent the presence of a significant difference in number of hospitalization days between the two groups. This difference represents an important economical advantage in the use of WALANT that permit a more rapid patient dismissing standing the lack of peripheral motor nerve block.

Finally, authors didn't found significant difference even in term of wound healing delay. This is an important evidence against WALANT's detractors that says the local swelling due to the injection of epinephrine and local anaesthetic could cause difficulties in surgical suture and then increase the risk of wound healing complications. We highlighted also no cases of peripheral ischemic infarction confirming the WALANT substantial safety in upper and lower limb extremity surgical procedures despite the use of epinephrine.

In conclusion, the WALANT can be considered as a viable solution for distal fibula hardware removal procedures in carefully selected patients. This particular anaesthesiologic setting can offer important clinical and economical

advantages comparing with the traditional loco-regional anaesthesia with a significant reduction in term of post-operative pain and recovery duration without increasing in pre- and intra-operative pain levels and in post-surgical complications rate. Moreover, this study lays the foundations for the WALANT use not only for hand but also for and other kinds of extremities' surgical procedures. Furthermore, we propose ourselves to increase the clinical relevance of this study enlarging the number of enrolled patients and to improve the efficacy in post-operative pain control using the new bupivacaine liposomal formulation(13).

Table 1 Differences in demographic and clinical data between the two groups of patients.

Figure 1 Details of the technique we used for the injection of the mixture of ropivacaine and epinephrine.

Figure 2 The surgical site aspect after the injection of the mixture of ropivacaine and epinephrine.

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Table 1

	GROUP A	GROUP B	p value
Number of patients	30	30	
Mean age (years)	31 ± 0,8	32 ± 1,3	> 0,05
Gender Ratio (M/F)	25:5	24:6	> 0,05
Time between ORIF and hardware removal	15 ± 0,9	13 ± 1.4	> 0,05
1 day hospitalization	20 (66%)	30 (100%)	< 0,05

2 days hospitalization	10 (33%)	0 (0%)	< 0,05
Mean maximum NRS during anaesthetic procedure	6,23 ± 1,36 (range 4-9)	6,07 ± 1,34 (range 3-9)	> 0,05
Mean maximum NRS during surgical procedure	0,63 ± 0,67 (range 0-2)	0,67 ± 0,72 (range 0-2)	> 0,05
Mean maximum NRS after surgery	4,51 ± 1,04 (range 2-6)	3,30 ± 1,09 (range 1-6)	< 0,05
Delayed wound healing	0	0	> 0,05

Figure 1



Figure 2



