

# Patient satisfaction after distal upper limb surgery under WALANT versus axillary block: A propensity-matched comparative cohort study

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Patient satisfaction after distal upper limb surgery under WALANT versus axillary block:

a propensity-matched comparative cohort study

Satisfaction des patients opérés de la partie distale du membre supérieur sous WALANT

ou bloc axillaire : analyse comparative d'une cohorte avec score de propension

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Consent to publish:

Not applicable.

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France" but restrictions apply to the availability of these data, which were used under license for

the current study, and so are not publicly available. Data are however available from the authors

upon reasonable request and with permission.

**Authors' contributions:** 

All authors have read and approved the manuscript. YG: study design and statistical analysis;

VM: data acquisition and inclusion; OM and NS: inclusion and data collection ans analysis;

PK: data management and collection; PC: principal investigator, study design and writing the

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Universitaire, Nimes, Place du Professeur Debré, Number 2019-A0I12-03, Date :

3/December/2019)

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3 Distal upper limb surgery is performed under WALANT (Wide Awake Local Anesthesia No 4 Tourniquet) in many outpatient centers because the benefits are numerous: simple, low-cost 5 technique, with fast turnover and short length of stay. In view of a paucity of data concerning 6 patient satisfaction, this non-randomized cohort study was designed to compare EVAN-LR 7 anesthesia satisfaction questionnaire results (information, pain, expectation, attention, 8 discomfort: 0-100 points) between patients receiving WALANT or axillary nerve block (AxB). 9 After IRB approval, patients (>18 years, stable ASA 1-3) scheduled for outpatient distal upper 10 limb surgery were prospectively enrolled in the two groups. At discharge, patients in both 11 groups received standard information on postoperative recovery and care, with a multimodal 12 analgesic regime (acetaminophen and ketoprofen for 5 days). The primary endpoint was EVAN-13 LR score before discharge. Secondary endpoints were pain relief and side-effects over a 7-day 14 period. Results were recorded as median and 25-75% interguartile range. Propensity-score-15 matched analysis was performed. Over the study period, from October 2019 to November 2020, 16 183 patients were included; 48 WALANT patients were propensity-score matched to 48 AxB 17 patients. Pre-procedural APAIS anxiety score was lower in the WALANT than the AxB group: 9 18 (IQR, 6-12) vs 12 (IQR, 8-14) (p=0.01). EVAN-LR scores were similar between the WALANT 19 (78 [72-82]) and the AxB group (73[67-80]. Incidences of paresthesia and of pain (NRS pain 20 score, opioid rescue) were similar. WALANT patients had shorter length of stay: 135 (110-175) 21 min vs 170 (110-250) min (p=0.01). The present study demonstrated that WALANT was 22 associated with a high level of patient satisfaction. For clinical relevance and quality of care, 23 WALANT should be proposed in first line for distal limb surgery.

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#### Résumé

La chirurgie distale du membre supérieur sous WALANT s'est développée dans de nombreux centres ambulatoires en raison de nombreux avantages : simplicité technique, faible coût, rotation rapide, courte durée de séjour. Peu d'études rapportent la satisfaction des patients opérés sous WALANT. Cette étude de cohorte non randomisée a été conçue pour comparer les

questionnaires EVAN-LR (information, douleur, attente, attention, inconfort : 0-100 points) des patients opérés sous WALANT ou sous bloc nerveux axillaire (BAx). Après accord de l'IRB, les patients (>18 ans, ASA 1-3) prévus en ambulatoire pour une chirurgie distale du membre supérieur ont été prospectivement inscrits dans deux groupes: WALANT ou BAx. A leur sortie, les patients ont reçu les mêmes informations concernant leur rétablissement et des soins postopératoires dont leur analgésie orale multimodale (acétaminophène, kétoprofène pendant 5 jours). Le critère d'évaluation principal était le score EVAN-LR réalisé avant la sortie. Les critères d'évaluation secondaires étaient le soulagement de la douleur et les effets secondaires sur une période de 7 jours. Les résultats ont été enregistrés sous forme de médiane et d'interquartiles (25-75). Une analyse appariée par score de propension a été réalisée. Sur la période d'étude (octobre 2019-novembre 2020), 183 patients ont été inclus et 48 patients avec WALANT ont été appariés par score de propension à 48 patients avec BAx. Le score d'anxiété APAIS avant la procédure était plus faible dans le groupe WALANT par rapport au groupe Bax : 9 (6-12) vs. 12 (8-14) (p=0,01). Les scores EVAN-LR étaient similaires entre le groupe WALANT, 78 (72-82) et le groupe BAx, 73 (67-80). L'incidence de la paresthésie et le soulagement de la douleur (score de douleur, consommation d'antalgiques opiacés additionnels) étaient similaires. Les patients du groupe WALANT ont eu une durée totale de séjour plus courte dans le centre : 135 (110-175) min vs. 170 (110-250) min (p=0,01). La présente étude démontre que la WALANT est associé à un niveau élevé de satisfaction des patients. Pour la pertinence clinique et la qualité des soins, cette série souligne que la WALANT devrait être proposé en première intention pour la chirurgie distale des membres.

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Keywords: WALANT; Axillary block; Pain; Satisfaction; Paresthesia; EVAN score

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Mots-clés: WALANT; Bloc axillaire; Douleur; Satisfaction; Paresthésie; Score EVAN

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## 1. Introduction

Over the past 10 years, the Wide Awake Local Anesthesia No Tourniquet (WALANT) technique has been used in many centers [1-3]. As demonstrated by several authors, this technique enables more patients to be treated, more safely, and at lower cost. Stay is also shorter, as little to no recovery time is needed. Studies reported that there was no need for a tourniquet and no need to accelerate or change medication schedules, which is particularly helpful for many diseases (diabetes or cardiac or renal failure) [3-5]. In contrast, the same surgeries performed under general anesthesia or peripheral nerve block incurred higher costs, more adverse effects such as nausea and vomiting, or motor impairment (e.g., loss of grip strength) that can be harmful for the patients in the early postoperative period [6].

However, WALANT is not without risk, and some adverse events have been reported: intoxication by local anesthetics due to overdose, and digital necrosis with the use of procaine or cocaine. Currently, regional anesthesia with a pneumatic tourniquet on the arm is often preferred for hand surgery, using an axillary block (AxB). In this case, a pneumatic tourniquet minimizes intraoperative blood loss and improves the visibility of the operative field. However, it can be a source of discomfort, pain or transient neurological deficit [5-6].

To date, few studies comparing WALANT and AxB are available, and none evaluated patients' perioperative experience or the incidence of paresthesia in the short and long term.

In order to measure the perioperative satisfaction of patients undergoing hand surgery with AxB or WALANT, we conducted a prospective observational non-randomized study evaluating the EVAN-LR (*Evaluation du Vécu de l'Anesthésie LocoRégionale*: evaluation of experience of locoregional anesthesia) satisfaction score at discharge using propensity-score-matched analysis (Appendix 1) [7]. The endpoints were rates of postoperative adverse events (digital necrosis, paresthesia, local anesthetic intoxication, infection in the operated limb) and consumption of postoperative analgesia according to group.

## 2. Patients and methods

2.1. Institutional Review Board approval, consent, and setting

In line with French law, the present study was approved by the institutional review board (IRB,

87 Centre Hospitalier Universitaire, Place du Professeur Debré, Nimes; n° 2019-A0I12-03,

December 3<sup>rd</sup>, 2019) and was registered on ClinicalTrials.gov (NCT04855149). The STROBE

recommendations for reporting cohorts were followed.

All participants had given written informed consent before inclusion.

## 2.2. Study design, patients, and group allocation

This was a prospective non-randomized controlled trial. All patients >18 years with American Society of Anesthesiologists (ASA) physical status score 1-3, scheduled for outpatient distal upper limb surgery (elbow, wrist, hand, finger) under WALANT or AxB were eligible and approached by the surgeon or the investigators. Non-inclusion criteria were: ASA status 4 or unstable 3; refusal to participate; age >80 years; weight <50 kg; emergency or bilateral surgery; any contraindication to regional anesthesia; psychiatric disorder (delirium, dementia); pregnancy; alcohol or drug abuse; uncontrolled epilepsy; patient unlikely to be fully cooperative; and participation in another study within the previous 30 days. Patients reporting any allergy for or contraindication to the study drugs were not included.

This was a non-randomized study: group allocation was proposed to the patient, who could freely choose to be operated under WALANT or AxB. For WALANT, only one experienced surgeon performed the anesthesia; AxB was performed by experienced anesthesiologists.

#### 2.3. Study groups

In both groups, patients were admitted in the outpatient center in the morning; no premedication was given. WALANT and AxB injections were performed in the preoperative room. For AxB, patients were monitored and intravenous (IV) access was secured. No sedation was performed in either group.

#### 2.3.1. WALANT group

After the skin was prepared with povidone iodine, anesthesia was performed with a 25G needle, according to the technique described by Lalonde [6]. Local anesthetic was injected into

the planned area of incision and dissection. The solution of lidocaine 10 mg.mL<sup>-1</sup> and epinephrine 5µg was diluted 1:1 with an isotonic solution of sodium chloride to obtain a solution of lidocaine 5 mg.mL<sup>-1</sup> + epinephrine 2.5µg.mL<sup>-1</sup>.

#### 2.3.2. AxB group

AxB was performed under ultrasound guidance. Briefly, using an ultrasound approach (LogiqE 7, GE, USA), the median, ulnar, musculocutaneous and radial nerves were identified and located around the axillary artery. Then, a 100 mm needle (Stimuplex, B Braun, Germany) was inserted in the axillary area in the plane of the probe and approached to the four nerves. Five mL mepivacaine 15 mg.mL<sup>-1</sup> was injected around each nerve.

## 2.4. Surgery and standard postoperative care

For all patients, surgery was performed in the operating room by same experienced surgeon (>5 years of practice, >500 procedures). In case of pain during surgery, additional local anesthesia (lidocaine 5 mg.mL<sup>-1</sup>) could be injected.

At the end of surgery, patients were transferred to the post-anesthesia care unit (PACU). At the PACU, patients with pain >3/10 on a numeric rating scale (NRS, 0-10: 0, no pain; 10, worst imaginable pain) were registered and received acetaminophen and ketoprofen if needed.

Both groups were then managed similarly in a standardized manner, with rapid rehabilitation (early oral intake, walking and eating as early as possible and at least before discharge); IV ondansetron (4mg) was injected in case of nausea or vomiting. Patients were discharged from the outpatient unit when their Chung score was 9-10/10 [8].

At discharge, patients received standard information regarding postoperative recovery and care at home (analgesia, dressing change, etc.). A 24-hour telephone helpline was available if they had any questions or concerns out of office hours, and they were advised to contact the local hospital's emergency department if in need of acute care. After discharge, both groups systematically received standard oral analgesic drugs: acetaminophen (1g every 6 hours) combined with ketoprofen (100 mg every 12 hours) for 5 days.

## 2.5. Clinical assessment

In our study, the Amsterdam Preoperative Anxiety and Information Scale (APAIS) was self-administered on the day of surgery at arrival [9]. Pain intensity at rest and maximum pain were rated on an NRS (0 = no pain and 10 = worst imaginable pain) in the PACU, at discharge, and on Day 1 and Day 7 [8]. Any adverse events arising from the analgesic protocol were systematically assessed: nausea, vomiting, urinary retention, drowsiness, dizziness, headache, sweating, pruritus, confusion/hallucination, sedation, and sore throat. On Days 1 and 7, nurses from the outpatient center telephoned the patients and recorded any adverse events, quality of sleep, comfort and anxiety using a 0-10 NRS. Rescue doses of study drugs, additional drugs or discontinuation of study drugs were also recorded.

At discharge, patients filled out the self-administered EVAN-LR questionnaire [7] (Appendix 1). All medical or surgical complications (including readmission) throughout the study period were recorded. The 19-item questionnaire comprises 5 components: attention, information, discomfort, expectation and pain [7]. Based on their expectations, patients score from 1 (much worse than I expected) to 5 (much better than I expected). The total score is thus out of 95 points.

#### 2.6. Endpoints and sample-size calculation

The primary endpoint was the total EVAN-LR score at discharge, ranging between 5 and 95. A difference of more than 5 points between groups was considered clinically relevant (confidence interval CI: 10 points). A minimum 45 subjects per group was estimated to be necessary to demonstrate a difference between the two groups (alpha risk at 5% and beta risk error 80%). Secondary endpoints were paresthesia and pain relief following surgery during the first 7 postoperative days.

## 2.7. Statistical analysis

Statistical analysis used SAS software, version 9.4 (SAS Inc., Cary, NC). An initial analysis was performed for both groups as a whole (Table 1), followed by a propensity-matched analysis. Matching used a 1:1, greedy, nearest neighbor strategy, with a caliper set to 0.1,

which resulted in the matching of 48 WALANT patients to 48 AxB patients. The Shapiro-Wilk test was used to test for normal distribution of continuous variables. Statistical results were expressed as mean (SD) or median [25–75 IQR], according to distribution. Numbers and percentages were given for categorical variables. Comparison of continuous variables between groups used Student's t-test or Wilcoxon-Mann-Whitney test, according to distribution.

Categorical variables were compared between groups by chi² or Fisher's exact test. All statistical tests were two-sided, with the significance threshold set at p<0.05.

## 3. Results

## 3.1. Study population

Between October 2019 and November 2020, 202 patients were approached to participate in the study. Nineteen were not included, for the following reasons: age <18 years (n=4), other surgical site (n=8), incomplete records (n=4), or duplicate records (n=3). A total of 183 patients were analyzed: 106 in the WALANT group and 77 in the AxB group (Table 1). After matching, 48 patients in each group were again analyzed (Table 2). Demographic, anesthesia and surgery data are shown in Table 1. After matching, baseline patient characteristics and type of surgery were similar between groups (Table 2).

## 3.2. Primary endpoint

Total EVAN-LR score was 73 (IQR, 67-80) in the AxB group and 78 (IQR, 72-82) in the WALANT group (p=0.20) (Fig. 1). Data for each EVAN-LR component (information, pain, expectation, attention, discomfort) were similar between the groups (Fig. 1). Removing the 3 regional anesthesia information items, the EVAN-LR score was 65 (59-70) in the AxB group and 66 (60-70) in the WALANT group (p=0.68).

## 3.3. Secondary endpoints

Pre- and post-operative pain scores did not differ at any time point (D0, D1, and D7) (Table 3). Anxiety on APAIS score was lower in the WALANT group (Table 1). The rate of

surgical complications, including paresthesia, was similar between the two groups at D1 and D7 (Table 3).

The times spent for each step are shown in Table 2. Total hospital stay was shorter in the WALANT group than in the AxB group (Table 1).

## 4. Discussion

In this prospective matching observational study after upper limb surgery, the WALANT group presented similar satisfaction scores and outcomes, in terms of pain relief and analgesic rescue, to the axillary block group, but with a lower level of anxiety at admission and faster discharge.

Perioperative experience and patient satisfaction are increasingly preponderant quality indicators in the evaluation of health establishments and the management of care. The originality of the present results lies in the use of a robust and validated quality instrument, the EVAN-LR score, and in the large cohort evaluated. The study demonstrated that the satisfaction scores of patients operated under WALANT were similar to those of patients operated on with the conventional technique (axillary block) [10]. These results confirm previous findings in 31 patients with bilateral carpal tunnel syndrome, who underwent surgery under WALANT without sedation for one side and under sedation for the other side. The authors found no significant difference in satisfaction between the two anesthetic techniques 6 weeks after surgery [11].

The present study evaluated the patients using the EVAN-LR score, a composite score enabling more detailed assessment of patient satisfaction, which is ultimately multi-factorial. Analysis of the 5 components of the score did not show any predominance in favor of the WALANT group. On the other hand, the level of preoperative anxiety was clearly lower in the WALANT group (Table 1). Similar results were reported in a retrospective study of 31 patients undergoing foot and ankle surgery under WALANT, with low preoperative anxiety on VAS-A score [12]. This lower anxiety has several reasons. The first is undoubtedly the absence of anesthetic pathway (stress linked to the performance of the block by an unknown anesthetist); the second is that local anesthesia, performed by a surgeon whom the patient knows, is not considered invasive, unlike regional anesthesia. These hypotheses need be evaluated. Scores

for evaluating anesthesia techniques lack evidence base, and the EVAN score is considered the most robust. Scores evaluating the quality of anesthesia mainly assess quality of care, in particular the EQ5D and QOR 40 scores, which focus more on care than on the technique [13].

Regarding postoperative pain, 30 patients used tramadol or opioids postoperatively: 12 in the WALANT group and 18 in the AxB group. Four of these patients in the WALANT group had undergone trapeziometacarpal arthroplasty. This leads us to raise the question of a pain rebound effect in WALANT for major procedures: pain rebound after regional anesthesia is well known, and there seems to be a similar problem for WALANT for major surgery. Larsen et al. discussed adding a long-acting local anesthetic to limit this rebound effect [14].

Regarding complications, 2 patients in the WALANT group presented a vagal symptom under local anesthesia, without loss of consciousness. This complication is classic with local injections and encourages the use of the supine position to limit the risk of falling. International guidelines do not mandate monitoring for low doses of local anesthetic. To reduce the risk of systemic toxicity, surgical teams should pay attention to the maximum dose. In our study, we did not find any significant difference in occurrence of postoperative paresthesia between the two techniques. This result will have to be analyzed in a larger cohort, because the advocates of WALANT put forward this argument of fewer complications (paresthesia) than with regional anesthesia to promote their technique.

In our study, stay in the outpatient center was shorter in the WALANT than in the AxB group, due to rapid passage into the postoperative care unit. In the logic of enhanced recovery after surgery, WALANT seems more appropriate and clearly more beneficial than regional anesthesia (Table 1) [15]. In addition, this shorter stay reduces the cost of surgery (not analyzed in the present study). Recently, an American study of 352,779 patients undergoing hand surgery (de Quervain's tendonitis, carpal tunnel syndrome) found that, over 5 years, a saving of \$133 million could have been made by the absence of an anesthetist if these procedures had been performed under WALANT [16]. Many studies today support this, showing cost saving when WALANT is used instead of general anesthesia or regional block for distal upper limb surgery [16-19].

There are many limitations to the present study. The first is the absence of randomization between groups, leading to a selection bias, with potentially easier or more difficult surgeries in one group and different patient profiles in surgical terms, as shown in Table 1. Also, the surgeries in the WALANT group were predominantly soft tissue procedures(carpal tunnel, trigger finger release), whereas they were bone-and-joint procedures (osteosynthesis) in the AxB group before matching, and similar after matching. A second limitation was that the operators performing the axillary block were several, unlike for WALANT in which there was only one operator, who moreover knew and followed the patients, which probably created a bias in the satisfaction analysis because the caregiver-patient relation was not the same as in the AxB group.

## 5. Conclusion

This non-randomized matching study showed high satisfaction in patients undergoing upper limb surgery under WALANT, with similar adverse events in terms of pain and paresthesia over the first 7 postoperative days compared to axillary block. A randomized study could confirm these findings.

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#### Competing interests:

The authors declare that they have no competing interests.

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## **Ethics approval and consent:**

In accordance with current French law and Declaration of Helsinki, this study was approved by local institutional review board (IRB, Centre Hospitalier Universitaire, Nimes, Place du Professeur Debré; n° 2019-A0I12-03, December 3, 2019) and was registered at ClinicalTrials.gov prior to launch (ClinicalTrials.gov: NCT04855149). Written informed consent was obtained from all participants before inclusion.

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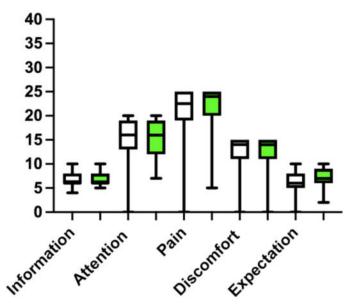
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342	Table titles
343	Table 1. Demographics and surgery (before matching)
344	Table 2. Demographics and surgery (after matching)
345	Table 3. Side-effects and pain relief
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347	Figure legends
348	Fig. 1. EVAN-LR score for each component.



**Table 1.** Demographics and surgery (before matching)

	WALANT	Axillary block	р
N Age (years) Gender (male) Weight (kg) Height (cm)	106 60 (49-72) 48 (45) 75 (65-85) 169 (161-176)	77 58 (38-67) 42 (54)* 72 (62-83) 169 (162-176)	0.05 0.01 0.61 0.36
ASA status score	1 (1-2)	2 (1-2)*	0.04
APAIS anxiety score	10 (7-12)	12 (8-14)*	0.03
Carpal and ulnar tunnel Trigger finger Hardware removal Trapeziometacarpal arthroplasty Osteosynthesis Tendon transfer Tenotomy Dupuytren disease Synovial ganglion Lacertus fibrosus release Arthroscopy: wrist Flap Other Time for each step	35 19 12 9 8 6 4 3 3 2 1 0 4	16 0 5 6 17 3 0 10 4 1 8 3	
Preoperative area (min) Time to perform anesthesia (min) Surgery (min) PACU time (min) Time from entrance to discharge (min)	44 (25-93) 5 (5-7) 13 (8-20) 53 (32-76)* 140 (109-184)	60 (27-135) 15 (10-25)* 25 (16-39)* 32 (21-57) 182 (112-262)*	0.19 0.001 0.001 0.002 0.01

Values are number (percentage) or median (interquartile range) \*p< 0.05 vs WALANT group PACU: post-anesthesia care unit

**Table 2.** Demographics and surgery (after matching)

	WALANT	Axillary block	p
N Age (years) Gender (male) Weight (kg) Height (cm)	48 60 (49-71) 25 (52) 78 (65-85) 170 (162-178)	48 58 (45-65) 24 (50) 73 (60-84) 169 (162-176)	0.26 0.90 0.28 0.45
ASA status score	2 (1-2)	2 (1-2)	0.04
APAIS anxiety score	9 (6-12)	13 (8-14)	0.01
Surgery Carpal and ulnar tunnel nerve Hardware removal Trapeziometacarpal arthroplasty Osteosynthesis Tendon transfer Dupuytren disease Synovial ganglion Other Time for each step	16 4 6 6 4 3 3	16 4 6 6 3 3 4 6	
Preoperative area (min) Time to perform anesthesia (min) Surgery (min) PACU time (min) Time from entrance to discharge (min)	44 (25-93) 7 (5-8) 13 (8-25) 50 (35-80) 135 (110-175)	60 (27-135) 15 (10-26) 23 (13-34) 31 (19-49) 170 (110-250)	0.19 0.001 0.01 0.01 0.01

Values are number (percentage) or median (interquartile range) \*p< 0.05 vs WALANT group PACU: post-anesthesia care unit

Table 3. Side-effects and pain relief

Paresthesia	WALANT	Axillary block	р
Day 1 Day 7	16 (21) 13 (27)	11 (22) 7 (15)	0.25 0.07
Systemic complications	0	0	1
Local complications - Infection - Necrosis	1 0	0 0	0.8
Pain score at rest Before surgery In PACU Day 1 Day 7	0 (0-3) 0 3 (0-5) 0 (0-3)	0 (0-1) 0 3 (1-6) 0 (0-6)	0.31 1 0.44 0.9

Values are number (percentage) or median (interquartile range) \*p< 0.05 vs WALANT group PACU: post-anesthesia care unit