Hand surgery: Wide Awake Local Anaesthesia with No Tourniquet Performed with Bupivacaine.

Alexandra Botha

Masters of Medicine Candidate (MMed)

Student number: 1893206

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Department of Plastic and Reconstructive Surgery

Supervisors:

Prof. E. Ndobe, Dr. M. Nel, Dr. S. Phiri

DECLARATION

I, Alexandra Botha, am submitting this research dissertation for the degree of Masters of Medicine at the University of the Witwatersrand, Johannesburg, I declare that this research report has not been submitted for examination to this or any other university before.

Alexandra Botha

5th Day of …August……..2022

DEDICATION AND ACKNOWLEDGEMENTS

- This work is dedicated to my husband, Morné Schroeder, for his support and unfailing love.
- I would like to thank my mom, Elisabeth Botha, who supported me through all my years of study with prayer and motivation. This work is dedicated to my late father, Dr Jacobus Botha. He shared with me a wealth of valuable medical knowledge through the years.
- This research is dedicated to my son, Kai Schroeder and my daughter, Milla Schroeder. They have always accepted my long working hours without complaining.
- A special word of thanks to my supervisors, Prof. Ndobe, Dr Nel and Dr Phiri. They have guided me in this whole process with kindness and patience.
- I would like to thank Prof. Ndobe especially for all his patience with me through many years of teaching. He is a special mentor to me.
- I would also like to express my gratitude to Dr Nel for her unconditional efforts to assist me with this project. She works extremely hard to help her students.
- Thank you to Dr Phiri in guiding me with the outlay of this research, this project was his brain child.
- I would also like to thank Elsabe Smit from the Statistical Department of the University of Johannesburg, who helped me with the statistical analysis of this work.
- Last, but not least, a special word of thanks to my Heavenly Father, without Him, I am but a lost soul.

ABSTRACT

Introduction

Wide awake anaesthesia with no tourniquet (WALANT) is a safe and acceptable method to perform hand surgery. Local anaesthesia used in WALANT is predominantly Lignocaine with adrenaline, however, although there is proof that Bupivacaine with adrenaline added to Lignocaine is just as safe and effective, the literature on this is limited.

Hand operations performed on adult patients in the Hand Unit in Charlotte Maxeke Johannesburg Academic Hospital are routinely performed with a regional anaesthetic block combined with tourniquet to achieve a bloodless operative field. Per unit protocol, the local anaesthetic used is Lignocaine, with longer acting Bupivacaine added for longer operations.

To incorporate the multiple advantages of WALANT in Charlotte Maxeke Johannesburg Academic Hospital's Hand Unit, the objective of this study was to evaluate four important factors in a group of patients operated under local anaesthesia with no tourniquet (WALANT) using Bupivacaine with adrenaline, compared to the control group of patients operated with regional block using Lignocaine and tourniquet namely:

1) Pain, 2) Haemostasis, 3) Time efficiency, 4) Toxicity of Bupivacaine with adrenaline (for which standard theatre procedures are in place, should it occur).

Methodology

A prospective study was performed at the Hand Unit of Plastic Surgery at CMJAH, of adult hand patients over the age of 18 years admitted for hand operations for elective and trauma surgery performed under local block.

Pain was evaluated by the patient's perception of pain during surgery. Patients graded their pain according to a Numeric Pain Grading Scale. Haemostasis was evaluated by excessive bleeding obscuring the operative field resulting in a need to swab excessive bleeding with swabs. Time efficiency was assessed by observing the waiting time spent prior to the first incision and total time was calculated by adding the time from first incision to the additional time spent on achieving a bloodless operative field. Toxicity of Bupivacaine with adrenaline combination was assessed by local anaesthetic related complications intra operatively. Standard theatre procedures are in place, should signs of toxicity occur. The sample of 72 was divided into two groups of 36 each, one half of the participants had trauma operations and the other half elective operations. The patients in each group were randomly assigned to the study group (WALANT with Bupivacaine and adrenaline) and the control group (local block with Lignocaine and tourniquet) The outcomes of the study results may lead to improvement in patient care in hand surgery by proving the safe use of Bupivacaine advantageous.

Results

Pain was found not to be more severe in either group. Bleeding was more severe in WALANT group compared to the control. Time to first incision for both groups was statistically similar. There was moderate evidence of a difference in total time between the two groups. There was no toxicity in either patient group.

Conclusion

To our knowledge, this is the first study reporting on Bupivacaine use exclusively in WALANT. In this local, prospective study carried out on 72 patients at the Hand Unit of

the Department of Plastic and Reconstructive Surgery at CMJAH, it was found that Bupivacaine can be used effectively and safely in WALANT. However, due to the relatively small study sample, a further larger study would be advisable to achieve results with a greater statistical significance.

LIST OF ABBREVIATIONS

CMJAH	**Charlotte Maxeke Johannesburg Academic Hospital**
CNS	**Central Nervous System**
CVS	**Cardiovascular System**
df	**Degrees of freedom**
N	**Sample size**
SE	**Standard error**
Sig	**Significance (p-value)**
StDev	**Standard deviation**
WALANT	**Wide Awake Local Anaesthesia with No Tourniquet**
WITS	**University of the Witwatersrand**

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TITLE

Hand surgery: Wide Awake Local Anaesthesia with No Tourniquet Performed with Bupivacaine.

1. INTRODUCTION

Wide awake anaesthesia with no tourniquet (WALANT) is a safe and acceptable method to perform hand surgery. Local anaesthesia used in WALANT is predominantly Lignocaine with adrenaline, however, although there is proof that Bupivacaine with adrenaline added to Lignocaine is just as safe and effective, the literature on this is limited.

Hand operations performed on adult patients in the hand unit in Charlotte Maxeke Johannesburg Academic Hospital are routinely performed with a regional anaesthetic block combined with tourniquet to achieve a bloodless operative field. Per unit protocol, the local anaesthetic used is Lignocaine, with longer acting Bupivacaine added for longer operations.

To incorporate the multiple advantages of WALANT in Charlotte Maxeke Johannesburg Academic Hospital's Hand Unit, the objective of this study was to evaluate four important factors in a group of patients operated under local anaesthesia with no tourniquet (WALANT) using Bupivacaine with adrenaline, compared with the control group of patients operated with regional block using Lignocaine and tourniquet namely:

1) Pain, 2) Haemostasis, 3) Time efficiency, 4) Toxicity of Bupivacaine with adrenaline (for which standard theatre procedures are in place, should it occur).

The outcomes of the study results may lead to improvement in patient care in hand surgery by proving the safe use of Bupivacaine advantageous.

2. LITERATURE REVIEW

2.1 The adrenaline myth

In WALANT (Wide Awake Local Anaesthesia with No Tourniquet) the patient's hand is injected subcutaneously in a tumescent fashion with a combination of Lignocaine and adrenaline at the site where surgical dissection or fracture manipulation will be performed (Lalonde, 2014). Conventional hand surgery is performed with a tourniquet to provide a bloodless surgical field, however, the patient will require general anaesthesia or a regional block with sedation, to eliminate tourniquet pain (Klenerman, 1962). The use of a tourniquet is often poorly tolerated by the patients due to pain and paraesthesia (Hutchinson, 1993). Further reasoning to avoid tourniquet is that prolonged tourniquet use can lead to transient neurological damage (Flatt, 1972).

Tourniquet usage can be eliminated by other means of haemostasis for example adrenaline infiltration. The adrenaline causes vasoconstriction, minimizes bleeding and does not interfere with the quality of the surgery (Lalonde, 2014; Lalonde *et al.,* 2015).

It was previously believed that injecting adrenaline into fingers cause vasoconstriction and finger necrosis. However, it was proved that it is indeed safe to inject adrenaline into fingers, since it is Procaine which causes finger necrosis, and not adrenaline (Denkler, 2001). The Procaine used had expired and turned acidic to a pH of 1.0 which caused the finger necrosis (Thomson et al., 2007). Multiple recent publications have proven adrenaline injected into fingers as safe (Chowdry *et al.,* 2010; Mann and

Hammert, 2012; Muck *et al.,* 2010). In the event of adrenaline causing finger vasoconstriction, it can be successfully reversed with a phentolamine injection, 1mg phentolamine in 220 cc of saline subcutaneously injected where the adrenaline was injected (Nodwell and Lalonde, 2003). Adrenaline-induced cardiac ischaemia is rare, even at high doses (1:1000 adrenaline) (Cunnington *et al.,* 2013). Dentists routinely inject Lignocaine with adrenaline safely without monitoring patient's vital signs (Jeske, 1998). Furthermore, anaphylaxis to Lignocaine is very rare (Speca, 2010).

2.2 WALANT technique

In WALANT (Wide Awake Local Anaesthetic No Tourniquet) the only medications administered are subcutaneous Lignocaine and adrenaline (Lalonde 2014) Lalonde describes how adequate volumes of local anaesthetic needs to be injected to be visible and palpable under the skin, and that at least 1-2cm beyond the patient will have a painful stimulus (Lalonde, 2017). Lignocaine with adrenaline safe dosage is 7mg/kg. In liposuction, several studies have shown safe Lignocaine blood levels up to 35mg/kg (Burk *et al.,* 1996; Klein, 1990). Lalonde used 50ml of undiluted 1% Lignocaine with 1:100 000 adrenaline, as required. For procedures requiring tumescence volumes between 50 and 100ml, he added 50ml of saline to his standard 50ml 1% Lignocaine and adrenaline mix (Lalonde 2017). The optimal adrenaline vasoconstriction effect is about 30 minutes after injection of local anaesthetic with adrenaline, oppose to the traditionally taught seven minutes (Mckee, Lalonde *et al.*, 2015). Using Lalonde's tumescent combination of 1% Lignocaine and adrenaline as described, about 2.5 hours of reliable local anaesthesia is achieved (Lalonde 2017). The longer acting Bupivacaine was added in small doses to the 1% Lignocaine with adrenaline saline tumescent fluid,

in complex forearm tendon transfers or painful procedures such as trapeziectomy (Lalonde, 2017). Of interest, injection of top ups is considered a failure of the initial injection and is best avoided (Lalonde, 2014).

2.3 Advantages of WALANT

WALANT has multiple advantages besides no tourniquet use, including: no anesthesiologist is required, therefore saving time and cost to both patient and hospital, since no sedation or general anaesthesia is required, side effects such as nausea and vomiting are reduced, no overnight fasting is needed, which is especially relevant for diabetic patients, no pre-surgical special investigations are required to assess the patient's fitness for general anaesthesia, recovery is faster, patient comfort is improved and less postoperative analgesia is needed (Steiner and Calandruccio, 2018). Of particular value is that the patient is awake during the operation and can actively move the hand or wrist, and thus the functionality and stability of the repairs can be evaluated and adjustments can be made intraoperatively (Steiner and Calandruccio, 2018). Importantly, in a prospective study by Rhee and colleagues (2017), 71% of patients experienced less pain during WALANT procedures than during dental procedures.

2.4 Disadvantages of WALANT

Some patients will not be ideal candidates for WALANT, these include patients with severe anxiety, post-traumatic stress disorder or those with cognitive impairments, who may not tolerate a wide-awake procedure (Lalonde, 2014). Certain patients will not tolerate multiple painful local anaesthetic injections. Some surgeons may not enjoy interactive discussions with patients that can occur during the operations (Lalonde,

2014). Preoperative preparation is more time consuming with WALANT compared with local anaesthesia with tourniquet (Gunasagaron, 2017). The surgery was delayed deliberately in Gunasagaron's study based on the recommendation to wait at least 26-30 minutes for the adrenaline to cause optimal vasoconstriction for haemostasis during surgery (Lalonde and Martin, 2014).

2.5 Bupivacaine safety

The Bupivacaine with adrenaline safe dose is 2mg/kg. Bupivacaine duration of action is longer than that of Lignocaine. Bupivacaine is preferred in operations lasting longer than 2.5 to 3 hours and for more painful operations (Steiner and Calandruccio, 2018). Importantly, Moore *et al*., (1978) showed that Bupivacaine is an extremely safe local anaesthetic drug. Indeed, in 11 080 blocks performed, systemic toxicity occurred from unrecognized intra-vascular injection in only 13 patients and from absorption in only two patients. Twelve of these 15 patients convulsed, while three had milder signs and symptoms (Moore *et al.,* 1978). All reactions were recognized immediately and treated rapidly and correctly and no untoward sequelae resulted (Moore, 1975).

From the published literature it is clear that Bupivacaine alone is not routinely used in WALANT, however Bupivacaine is occasionally added for longer operations due to the longer duration of action compared to Lignocaine (Lalonde, 2017).

3. MOTIVATION

3.1 Problem statement

From the published literature Bupivacaine alone is not routinely used in WALANT, however Bupivacaine with adrenaline is occasionally added for longer operations due to

the longer duration of action compared with Lignocaine (Lalonde, 2017). Lignocaine is preferred in WALANT due to its faster onset of action and is less cardiotoxic (severe ventricular arrhythmias) than Bupivacaine, however Bupivacaine is longer acting than Lignocaine. The literature review indicated that Bupivacaine with adrenaline added to Lignocaine is used in WALANT for longer operations (Lalonde 2017), but there is no published research on the sole use of Bupivacaine in WALANT. Therefore, there is a need for further research to verify the safety of Bupivacaine in WALANT hand surgery.

3.2 Aim

The aim of this study was to prove the use of Bupivacaine with adrenaline administered using WALANT, compared with a regional block with Lignocaine without adrenaline and tourniquet, advantageous, leading to improved patient care in hand surgery, performed in the Hand Unit of Plastic Surgery at CMJAH.

3.3 Study objectives

1. To assess the pain in patients operated with WALANT using Bupivacaine with adrenaline compared to patients operated with regional block and tourniquet.
2. To assess the haemostasis achieved in patients operated with WALANT using Bupivacaine and adrenaline compared with patients operated with regional block and tourniquet.
3. To assess time efficiency in patients operated with WALANT using Bupivacaine and adrenaline compared with patients operated with regional block and tourniquet.

4. To assess toxic effects of the combination of Bupivacaine with adrenaline in patients operated with WALANT compared with patients operated with a regional block performed with Lignocaine without adrenaline and tourniquet.

3.4 The null hypothesis

The null hypothesis stated that the variances between the two study groups are equal *versus* the alternate hypothesis which stated that the variances are different. The p-value was tested and the smaller the p-value, the stronger the evidence for the alternate hypothesis and against the null hypothesis.

4. RESEARCH METHODOLOGY

4.1 Setting

The study took place at the Hand Unit of Plastic Surgery at CMJAH.

4.2 Study design, study population and sampling procedures

4.2.1 The design: A prospective study

A prospective review of adult hand patients over the age of 18 years being admitted for hand operations for elective and trauma surgery performed under local block. This research fits the criteria for a pilot study, providing the groundwork for a future larger research project, if this is ever considered.

4.2.2 The study population

All adult patients over the age of 18 years requiring hand operations for traumatic injuries, for example tendon injuries or fractures presenting to the Emergency Department are managed by the Plastic Surgery Department at Charlotte Maxeke Johannesburg Academic Hospital. These patients with traumatic hand injuries are admitted daily. Adult patients requiring elective hand surgery, for example nerve

entrapment release are seen in the Plastic Surgery Hand Outpatient Department once a week and booked on the elective hand surgery list. All the adult patients requiring elective or trauma surgery of the hand fitting the study criteria were included in the study from the date of ethics approval.

4.2.3 The sample and sampling procedure

A sample size calculation was statistically performed. This was obtained by looking at a previously published study by Gunasagaron and colleagues (2017) with a similar objective with regards to pain. Patients assessed their perceived pain by a Visual Analogue Score (VAS) from 0 – 10 and statistical analysis for the mean VAS for two groups of patients were calculated. The mean (SD) came from the VAS estimates, assuming a power of 90% and a group ratio of 1:2. This calculated to the minimum estimated sample size N = 68 for my study. Data was collected over a two month period, between 10 May 2021 and 10 July 2021, which was long enough to collect 72 patients (18 patients in each of the four groups) as determined by the sample calculation in order to determine significance.

All the patients included in the study met the following criteria:

Inclusion criteria:

- Adults over 18 years
- Inpatients and/or day patients presenting to the Hand Unit of the Department of Plastic and Reconstructive Surgery at CMJAH.

Exclusion criteria:

- Patients requiring general anaesthesia

- Poly trauma patients
- Severe medical comorbidities like ischaemic heart disease.
- Patients using any anticoagulants such as Warfarin or Aspirin.
- Patients refusing to participate in the study.

How patients rated their pain:

Intra-operatively the patients graded their pain according to a Numeric Pain Grading Scale from 0-10, where 0 equals no pain and 10 is the worst pain possible. To apply the score clinically, if a patient graded their pain between 3 and 8 a top-up local anaesthetic injection was offered to the patient. Pain graded less than 3 required no further interventions and the procedure could continue. Pain above 8 equals abandoning the procedure and making alternative arrangements like converting to a general anaesthetic. If the pain was caused due to the tourniquet in the control group, the tourniquet was deflated. The patient's comfort was of the utmost importance.

How excessive bleeding was assessed:

Excessive bleeding was any bleeding obscuring the operative field, thus requiring the use of a vascular swab to remove the blood. The amount of vascular swabs used was recorded.

4.3 Data collection

4.3.1 Participant identification

The sample of 72 was divided equally into 36 each, one half trauma operations and the other half elective operations.

For the trauma operations: Over the study time period a total of 36 patients admitted from the emergency department requiring trauma operations were included in the sample. In the trauma group, 18 patients were randomly allocated to each group, namely the experimental group (WALANT) and the control group (Lignocaine and tourniquet). The trauma patients (fitting the inclusion criteria) were given a study number from 1 to 36, number 1 to 18 were randomly assigned to the experimental group and number 19 to 36 were randomly assigned to the control group.

For the elective operations:

Over the study time period a total of 36 patients admitted from the hand clinic requiring elective hand operations were included in the sample. The same method as described above applied to assign participants in the elective operations group.

4.3.2 Participant consent

Patients signed a hospital routine informed consent for their hand operation which includes the technique of local anaesthetic injection and its risks. Separate consent was obtained for participation in the study, after an explanation and reading of the information sheet which explains the purpose of the study.

4.3.3 Data capturing

Data was collected from each patient's operation and recorded on the data sheet (Tables 1 and 2 in Appendix A). The data was captured into an MS Excel spreadsheet. (Microsoft Office version 2010).

4.4 Data analysis

The data was analysed using SPSS (version 27) and MS Excel software (Microsoft Office version 2010).

Numeric (continuous) variables, such as time to first incision was reported as means and standard deviations. The age variable was grouped into age categories and represented as frequencies. Bar graphs and box-and-whisker plots were used to represent data visually.

Categorical variables were tested with the Pearson Chi-square test to assess relationship between the two groups. The Independent samples t-test was used to test if variances between the two groups are equal or not and then differences in means were then tested. A p-value of less than 0.05 was significant if tested at the 5% level of significance and supported strong evidence for the alternative hypothesis. A p-value of less than 0.01 was significant if tested at the 1% level of significance.

4.5 Ethics

Ethical approval for conducting this research was obtained from the WITS Human Research Ethics Committee (HREC) (medical), clearance certificate number M210205 is attached in the Appendix. Furthermore, medical approval was obtained from the CEO of CMJAH.

Patients were not identified in any way since no identifier was be recorded on the data sheets. Each patient was assigned a study number for data collection purposes. Patients signed informed consent for their hand surgery, as well as a separate consent form for participation in the study. There is no patient financial gain for participating in this study as it is purely for academic purposes.

5. RESULTS

The number of patients admitted for elective and trauma hand surgery, performed under local blocks at the Hand Unit of Plastic Surgery at CMJAH, over an approximately 2-month period, was 72. Of the total of 72 patients, 36 were in the WALANT group (Group A) and 36 were in the regional anaesthesia group operated with tourniquet (Group B).

5.1 Patient characteristics

In terms of gender, as shown in Table 5.1, most of the patients in group A and Group B were males, being 26 and 31 patients respectively. Looking at elective *versus* trauma surgery performed, the genders were slightly more equally distributed in the elective group with 13 patients being female and 23 male, interestingly in the trauma patients 34 were male and only two females. Figure 5.1 shows the frequency distribution by gender and type of surgery.

Table 5.1: Patient characteristics by gender and type of surgery as percentage.

Characteristic		Group		Type of surgery	
		Group A (n=36)	Group B (n=36)	Elective (n=36)	Trauma (n=36)
Gender	Female	27.8 (n=10)	13.9 (n=5)	36.1 (n=13)	5.6 (n=2)
	Male	72.2 (n=26)	86.1 (n=31)	63.9 (n=23)	94.4 (n=34)
	Total	100%	100%	100%	100%

The frequency distribution of patients in terms of age categories is shown in Figure 5.2. Pertaining to age of patients operated, in group A: the largest group of patients (25%) were between 20 and 29 years *versus* Group B where almost 39% of patients were between 30 and 39 years. Looking at the types of operations, in the elective group 25% of patients were elderly in the category of 50-59 years and most patients in the trauma group were younger with 33% being 20 to 29 years old, 44% were 30 to 39 years old and 0% were in the 50-59 age category. Data are shown in Table 5.2.

Table 5.2: Patient characteristics by age and type of surgery as percentage.

Characteristic		Group		Type of operation	
		Group A (n=36)	Group B (n=36)	Elective (n=36)	Trauma (n=36)
Age category	20-29	25.0 (n=9)	25.0 (n=9)	16.7 (n=6)	33.3 (n=12)
	30-39	22.2 (n=8)	38.9 (n=14)	16.7 (n=6)	44.4 (n=16)
	40-49	22.2 (n=8)	13.9 (n=5)	22.2 (n=8)	13.9 (n=5)
	50-59	13.9 (n=5)	11.1 (n=4)	25.0 (n=9)	0.0 (n=0)
	60+	16.7 (n=6)	11.1 (n=4)	19.4 (n=7)	8.3 (n=3)
	Total	100%	100%	100%	100%

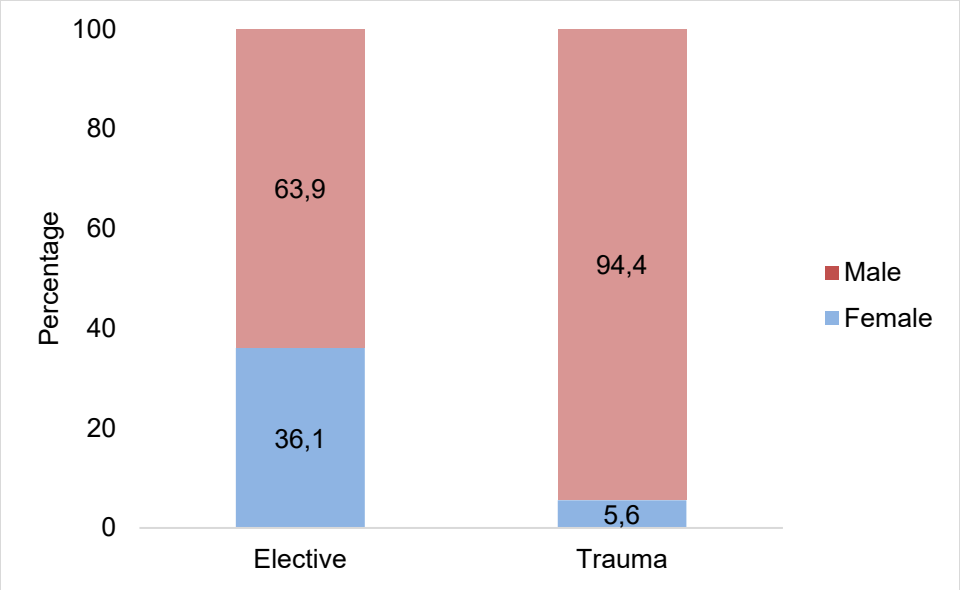

Figure 5.1: Frequency distribution by gender and type of surgery depicted as percentages.

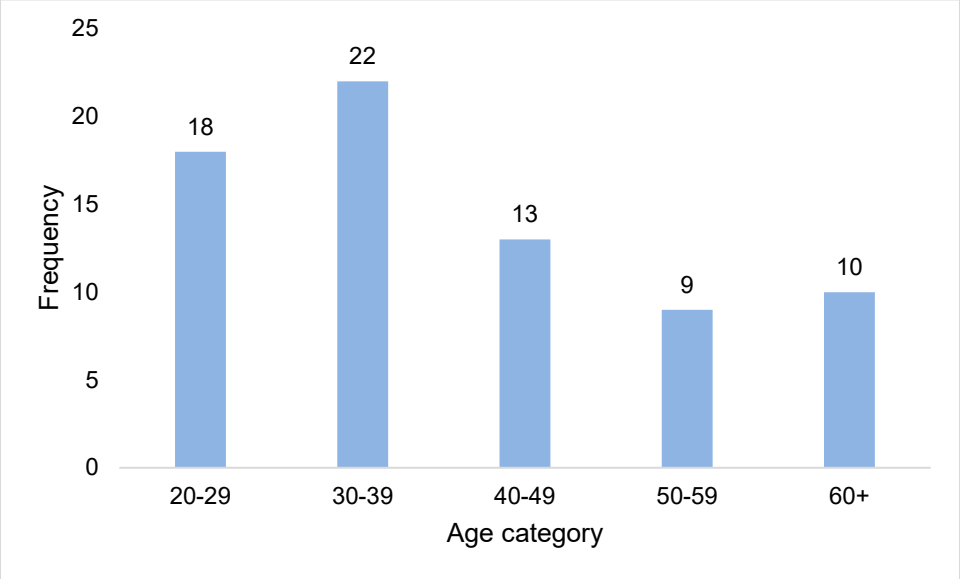

Figure 5.2: Frequency distribution by patient's age.

5.2 Study objectives

5.2.1 Objective 1: Pain

In terms of quantifying pain, if a patient scored 0 on the Numeric Pain Grading Scale they were categorized into the "none" pain grading category, if a patient scored from 1-5, they were categorized into "little to average" pain category and lastly, a score of 6-10 placed the patient in the "above average" pain category. The data captured are depicted in Table 5.3.

Table 5.3: Pain grading categorized in groups.

Pain grading	Group A	Group B	Total
None	29	29	58
Little to average pain	2	3	5
Above average pain	5	4	9
Total	36	36	72

Table 5.4: Results for Pearson Chi-Square test: p-value

Pearson Chi-Square test	Value	Df	**p-value**
Pearson Chi-Square	0.311	2	0.856
N of Valid Cases	72		

As seen in Table 5.4, the Pearson Chi-square test was performed on the data and a p-value of 0.856 was calculated. If assuming a 1% significance level, the null-hypothesis

was accepted and this indicated that the variables are not related and thus group A patients did not necessarily have more pain than Group B patients and *vice versa*.

5.2.2 Objective 2: Haemostasis

Table 5.5: Observed frequencies of excessive bleeding for Group A and B.

Observed frequencies		Group		
		Group A	Group B	Total
Excessive bleeding	Yes	9	2	11
	No	27	34	61
	Total	36	36	72

Table 5.6: Expected frequencies of excessive bleeding for the two groups.

Expected frequencies		Group		
		Group A	Group B	Total
Excessive bleeding	Yes	6	6	11
	No	31	31	61
	Total	36	36	72

Table 5.7: Results for Pearson Chi-Square test: p-value

Chi-Square Test	Value	Df	p-value
Pearson Chi-Square	5.28	1	0.022
N of valid cases	72		

As seen in Table 5.7, the Pearson Chi-square test was performed on the data. Although the sample size was relatively small, the criteria for the Pearson Chi-square test were met because 0 of the cells in the table have a count of less than 5, as the minimum expected count is 5.5, and the p-value of 0.022 proved that there is a relationship between excessive bleeding and the group of patients (A or B). By calculating proportions, 9/36 patients translate to 25% of group A who experienced excessive bleeding, and 2/36 patients equal 5.5% of patients in Group B who experienced excessive bleeding. Group A patients were more likely to have excessive bleeding compared with group B.

Table 5.8: Excessive bleeding incidence and number of swabs used.

		Excessive bleeding		
		Yes	No	Total
Number of swabs used	1	0	61	61
	1.5	1	0	1
	2	5	0	5
	3	4	0	4
	6	1	0	1
	Total	11	61	72

Table 5.9: Total amount of swabs used for each group.

		Group		
		Group A	Group B	Total
Number of swabs used	1	27	34	61
	1.5	0	1	1
	2	4	1	5
	3	4	0	4
	6	1	0	1
	Total	36	36	72

As seen in Table 5.8, 11 patients from the total sample size experienced excessive bleeding with 61 experiencing the contrary. Of the 11 patients, 5 required the use of 2 swabs and only 1 patient required the use of 6 swabs. It is suspected that the patient requiring 6 swabs might have had an undiagnosed bleeding tendency or the patient omitted to disclose the use of an anticoagulant such as aspirin and this could have skewed the data.

Table 5.9 depicts clearly that both groups of patients required the use of swabs, however the tourniquet group of patients required the least number of multiple swabs overall, compared to the WALANT group of patients requiring a slightly larger number of multiple swabs.

5.2.3. Objective 3: Time efficiency

Time to first incision

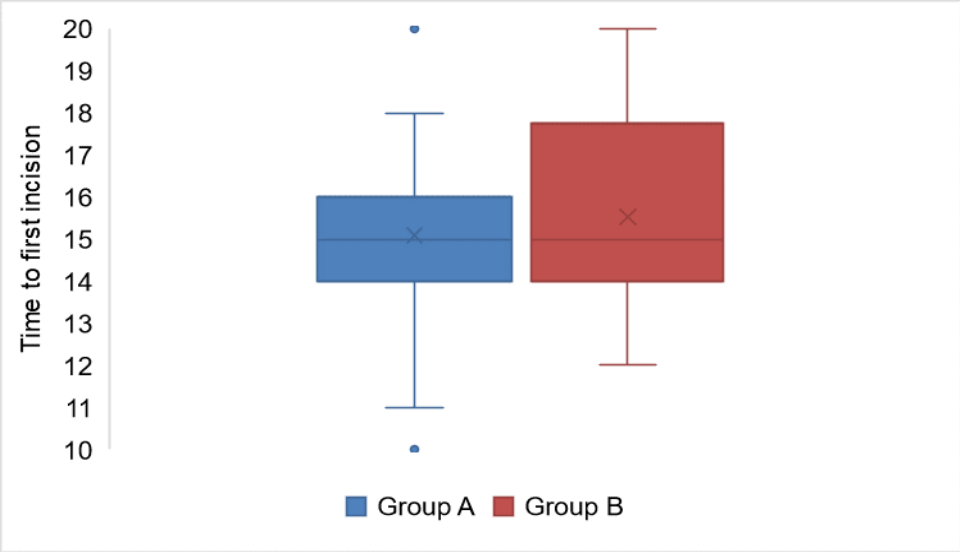

Figure 5.3: Box and whisker plot for distribution of time to first incision for Group A and Group B.

As seen in Figure 5.3, the plot shows the distribution for the variable, time to first incision, for each group of patients. The box depicts the distribution for the middle 50% of observations, the whiskers / lines extending beyond the box show variability in the scale and outliers are depicted by the dots. The line in the box depicts the median value and the x depicts the mean (average). Figure 5.3 shows that the results are very similar for both groups of patients with regard to mean and times to first incision, which varies only by about two minutes.

Table 5.10: Time to first incision descriptive data.

Summary statistics	N	Mean	StDev	SE
Group A	36	15.08	2.442	0.407
Group B	36	15.53	2.678	0.446

Table 5.11: Time to first incision independent samples t-test data.

Independent Samples Test	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	T	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% CI of the Difference	
								Lower	Upper
Equal variances assumed	1.544	0.218	-0.736	70	0.464	-0.444	0.604	-1.649	0.760
Equal variances not assumed			-0.736	69.414	0.464	-0.444	0.604	-1.649	0.760

Looking at the data in table 5.10; the standard deviation (measure of variability) is again very similar. The independent sample's t-test was used to determine if there is a difference between the two patient groups on average, with respect to the time from first incision. In Table 5.11 the p-value of the independent sample's t-test is given as 0.464, which implies that the null hypothesis of equal means cannot be rejected at the 5% level of significance. Therefore, it can be assumed that the time to first incision for both groups are similar.

Total time

Total time was calculated by adding the time from first incision to the additional time spent on achieving a bloodless operative field.

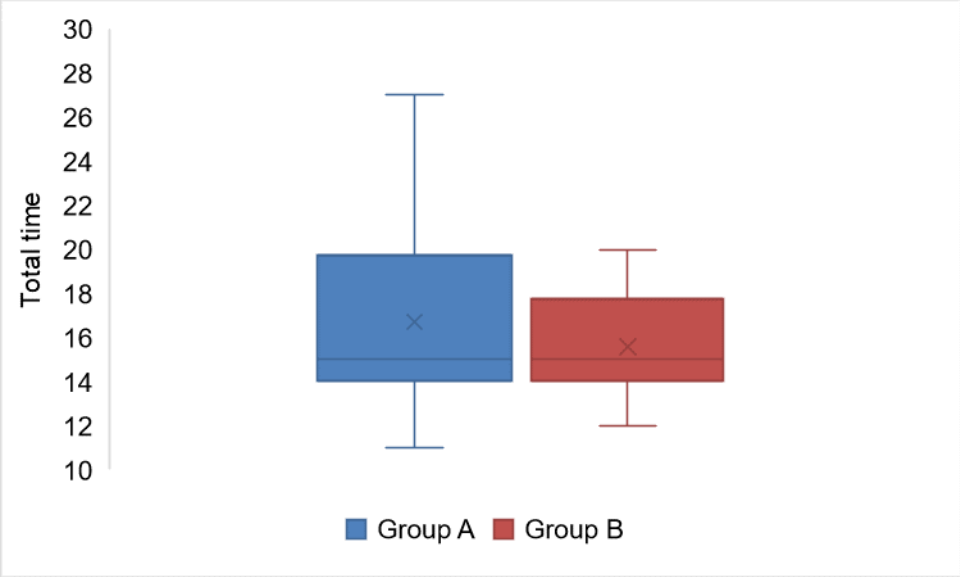

Figure 5.4: Box and whisker plot of total time for Group A and Group B.

Table 5.12: Total time descriptive data.

Summary statistics	N	Mean	StDev	SE
Group A	36	16.72	3.614	0.602
Group B	36	15.58	2.666	0.444

Table 5.13: Total time independent samples t-test data.

Independent Samples Test	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	T	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% CI of the Difference	
								Lower	Upper
Equal variances assumed	3.086	0.083	1.522	70	0.133	1.139	0.749	-0.354	2.632
Equal variances not assumed			1.522	64.386	0.133	1.139	0.749	-0.356	2.634

From Figure 5.4 and Table 5.12, it is clear that there was a longer duration of total time from the first incision with additional time spent to achieve a bloodless operative field for the patients in group A.

When referring to Table 5.13, the independent sample's t-test resulted in a p-value of 0.133, therefore there is insufficient evidence to show that there is a difference between the groups with respect to the total time.

5.2.4 Objective 4: Toxicity

Table 5.14: Frequency of CNS symptoms.

CNS symptoms	Frequency	Percent
No	72	100.0

Table 5.15: Frequency of CVS symptoms.

CVS symptoms	Frequency	Percent
No	72	100.0

Table 5.16: Frequency of anaphylaxis.

Anaphylaxis	Frequency	Percent
No	72	100.0

By looking at the data in Tables 5.14 - 5.16, no patients experienced any symptoms of toxicity in either group.

6. DISCUSSION

This prospective local study, with a relatively small sample size of 72 patients, shows the safe and effective advantageous profile of Bupivacaine in WALANT surgery, compared to the use of block and tourniquet in hand surgery. Importantly, this data adds to the armamentarium available to the hand surgeon

By assessing the two groups of patients' pain according to the numeric pain grading scale, the study data showed statistically significant evidence that the amount of pain between the two groups of patients was not different. In the study by Gunasagaran *et al.,* (2017) the results depicted the level of comfort during the surgery for the patients receiving WALANT to be higher compared to the group of patients operated with local anaesthetic block and tourniquet and the discomfort in most patients was due to the tourniquet. A study comparing patients operated with WALANT *versus* brachial plexus block with tourniquet found significantly higher pain averages in the WALANT group (Torre *et al*., 2021). However, Torre *et al*., also found patients had a higher pain score even before surgery and this can influence these patients overall pain perception (Torre *et al*., 2021).

Bleeding was found to be statistically more significant in the WALANT group of patients. This could be attributed to the tourniquet controlling bleeding more effectively in the tourniquet group of patients from the start of the surgery compared with the WALANT group where added time was required in some patients to wait for the adrenaline effect to be optimal. Gunasagaran *et al*., (2017) found the blood loss in the WALANT group not to be statistically significant compared to the tourniquet group. Another factor to

consider in this study, could be that the time spent waiting to the first incision in the WALANT group was on average 15.08 minutes. This is shorter than the recommended waiting period of 26-30 minutes required for the optimal vasoconstriction effect of adrenaline (Lalonde, 2014). It is suspected that the optimal vasoconstriction effect of adrenaline was not achieved and therefore the bleeding was more significant in the WALANT group. Interestingly Farzam and colleagues also found more bleeding in the WALANT group of their study comparing WALANT to Bier block and tourniquet (Farzam *et al.,* 2020).

Time efficiency as study objective has shown that time to first incision was statistically similar in both groups. Traditional WALANT teaching advocates waiting 26-30 minutes from injection to first incision for the optimal vasoconstrictive effect of adrenaline (Lalonde 2014). In the current study the waiting time for the WALANT group on average was about 15 minutes and the bleeding was more significant in the WALANT group. This finding confirms the published evidence that the longer recommended waiting time improves the haemostatic effect of the adrenaline. Gunasagaran and his colleagues used the 30 minutes waiting time from injection to first incision in their WALANT group of patients and found the blood loss in the WALANT group not significant compared with the control group of local anaesthetic and tourniquet (Gunasagaran *et al.,* 2017).

The current study concurs with Moore *et al.,* that Bupivacaine is an extremely safe local anaesthetic drug (Moore *et al.,* 1978). This study has also proven that Bupivacaine can be used effectively and safely in WALANT, with no patients experiencing any toxicity.

7. CONCLUSION

To our knowledge, this is the first study reporting on Bupivacaine use exclusively in WALANT. In this local, prospective study carried out on 72 patients at the Hand Unit of the Department of Plastic and Reconstructive Surgery at CMJAH, it was found that Bupivacaine can be used effectively and safely in WALANT. Referring to the study objectives specifically; both groups experienced similar amounts of pain, excessive bleeding is more likely to occur in the WALANT group, total time to achieve a bloodless operative field was longer in the WALANT group and no patients experienced toxicity in any of the patient groups. However, due to the relatively small sample of the study, a further larger study would be advisable to achieve results with a greater statistical significance.

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APPENDICES

<u>Appendix A:Table 1</u> Patient data: Group A (Abbreviations: CNS: Central nervous system. CVS: Cardiovascular system)

Age		
Sex		
Type of operation: Trauma	**Trauma**	**Elective**
Procedure name		
Top up	**Yes**	**No**
Amount		
Location		
Excessive bleeding	**Yes**	**No**
Time from injection to first incision	**Minutes**	
Added time to achieve bloodless field	**Minutes**	
Duration of surgery	**Minutes**	
Time to top up		
CNS symptoms/signs	**Yes**	**No**
List		
CVS symptoms/signs	**Yes**	**No**
List		
Anaphylaxis signs	**Yes**	**No**
Amount local injected		
Location of injection		

Table 2 Patient data: Group B (Abbreviations: CNS: Central nervous system. CVS: Cardiovascular system)

Age		
Sex		
Type of operation: Trauma	**Trauma**	**Elective**
Procedure name		
Top up	**Yes**	**No**
Amount		
Location		
Tourniquet pain	**Yes**	**No**
Deflated tourniquet	**Yes**	**No**
Excessive bleeding	**Yes**	**No**
Time from injection to inflating tourniquet	**Minutes**	
Duration of surgery	**Minutes**	
Time to top up		
CNS symptoms/signs	**Yes**	**No**
List		
CVS symptoms/signs	**Yes**	**No**
List		
Anaphylaxis signs	**Yes**	**No**
Amount local injected		
Location of injection		

Appendix B: Ethics Clearance Certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Alexandra Botha

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M210205 MED20-08-218

NAME: (Principal Investigator)	Dr Alexandra Botha
DEPARTMENT:	Plastic and Reconstructive Surgery Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	Hand surgery: Wide Awake Local Anaesthesia with No Tourniquet performed with Bupivacaine
DATE CONSIDERED:	26/02/2021
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof Elias Ndobe and Dr Marietha Nel
APPROVED BY:	BB Penny Dr C Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	07/05/2021

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 301, Third floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed February and will therefore be due in the month of February each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix C:

Permission to do research from CMJAH CEO and Clinical director

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL (CMJAH)
OFFICE OF THE SENIOR CLINICAL MANAGER

Enquiries: *Ms. TT Mahlangu*
Email: Thandi.Mahlangu4@gauteng.gov.za
Tel: *011 488 3365/*
Ref: *1/7/2*
Date: 08 July 2021

GP202105_053

To: Dr. A.R Botha

RE: FINAL APPROVAL OF STUDY

TITLE: HAND SURGERY: WIDE AWAKE LOCAL ANAESTHESIA WITH NO TOURNIQUET PERFORMED WITH BUPIVACAINE

Permission is granted for you to conduct the above-mentioned study as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic Hospital will not in any way incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall always be observed.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the HOD and Unit Manager or Sister in charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Supported/~~Not Supported~~
Signed by:Jayshina Punwasi
Signed at:2021-07-12 18:40:26 +02:00
Reason:Witnessing Jayshina Punwasi

Dr J. Punwasi
Clinical Director
Date: _____

☐ **Approved/~~Not Approved~~**
Signed by:Gladys Magugudi Bogoshi
Signed at:2021-07-12 20:58:06 +02:00
Reason:Witnessing Gladys Magugudi Bog

Ms. G Bogoshi
Chief Executive Officer
Date: _____