UNIVERSITY of RWANDA

COLLEGE OF MEDICINE & HEALTH SCIENCES
SCHOOL OF MEDICINE & PHARMACY
DEPARTMENT OF SURGERY

EFFICACY OF BRUNER'S RULES IN DECREASING TOURNIQUET USE RELATED COMPLICATIONS: A PROSPECTIVE STUDY.

A dissertation submitted in partial fulfilment of the requirements for the award of the Degree of Master of Medicine in Orthopaedic Surgery of the University of Rwanda

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Kigali, 30th May 2019

DECLARATION

I hereby declare that this research is my original work and it has not been presented to any institution or University for the award of a degree.

Researcher: Signature: Date: 21/05/19

Dr Jean Thierry NIYOMUGABO

We, supervisors, hereby declare that this dissertation: **"Efficacy of Bruner's rules in decreasing tourniquet use related complications"** was submitted by Dr J.Thierry NIYOMUGABO with our approval.

Signature: Date: 30th May 2019

Prof Alex M. BUTERA

Signature: Date: 30/05/2019

Dr Emmanuel BUKARA

Dedication

This work is dedicated to Father the Almighty God, to whom I lean on throughout my life, for His inspiration and to my late parents although you have not been there with me during my studies. For your memory, I will strive for excellence. Dedication to my dear wife Olive Mutijima for your wholesome support and encouragement and to my family.

Acknowledgements

I owe my warm thanks to my supervisors and mentors, Professor Alex M. Butera and Dr Emmanuel Bukara, who provided me with valuable guidance, ideas and criticism to perform this work.

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My warmest thanks to my family and friends for their support, advices and many more which have been essential throughout my surgical training.

Finally, I thank the Ministry of health which financially supported my training.

Kigali, May 30th 2019 Jean Thierry NIYOMUGABO

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ABBREVIATIONS

ACL: anterior cruciate ligament

AORN: association of perioperative registered nurses

BCE: before current era; CE: current era

DVT: deep vein thrombosis

IMN: intramedullary nailing

IRB: institutional review board

KFH,K: King Faisal Hospital, Kigali

LA: local anesthetic

LL: lower limb

ORIF: open reduction and internal fixation

PE: pulmonary embolism

P- value: probability value, that the null hypothesis is true

PVD: peripheral vascular disease

RMH: Rwanda Military Hospital

SD: standard deviation (amount of variation or dispersion of data values)

UL: upper limb

ABSTRACT

Background: The pneumatic tourniquet is an efficient device used to achieve a surgical bloodless field, hence facilitating the surgeon during surgical procedures. However its use is not without risks as complications may occur. Studies have shown complication rate of 12.5% up to 60%. There are various recommendations and guidelines for its safe use to prevent the complications. Bruner's rules published in 1996 have been shown to be efficient in decreasing tourniquet complications but they are not commonly used in our settings.

Objectives: The aim of this study is to determine the efficacy of Bruner's rules in decreasing tourniquet related complications in Rwanda.

Patients and methods: This prospective descriptive study was conducted between October 2018 and March 2019 at KFH and RMH and included participants aged 12-75 years who underwent UL and LL surgery with use of pneumatic tourniquet. Bruner's rules were taught to surgeon/residents and used and we assessed the rate of tourniquet complications and functional recovery within 3 days post operation. We used multivariable analysis (Multiple logistic regressions) with the use of Chi-Square test.

Results: One hundred twenty six (126) patients were included in the study. Most patients were in the 26-45 years age group and were male. Complication rate was 3.1% (4 cases) and in 3 cases 2.38%) Bruner's rules were not respected and in 1 case (0.79%) there was no identifiable cause; 3 cases had tourniquet pain and 1 had case of unexpected bleeding. Mean duration of tourniquet time in tourniquet pain cases was 136.7 mins (SD: +/- 15.3). Surgeon awareness of Bruner's rules was 55%, surgeon satisfaction (bleeding control) was 99.2%. There was no case of sensory-motor deficit in postoperative. There was no correlation between complications and age, sex, site of surgery or type of surgery. There was strong correlation between complications and respect of Bruner's rules, respect of duration of tourniquet application and between respect of Bruner's rules and surgeon satisfaction.

Conclusion: Bruner's rules are efficient in decreasing tourniquet complications, which will have significant impact on postoperative functional recovery. We recommend all Bruner's rules to be applied and respected in all patients on whom the pneumatic tourniquet is used and need of education and teamwork of all theatre staff on Bruner's rules.
Keywords: Bruner's rules, tourniquet use, tourniquet complications.

1. INTRODUCTION

The pneumatic tourniquet is an efficient device to achieve a bloodless surgical field in surgery by blocking the arterial blood flow distal to its application site. It is a well-known method to provide such bloodless surgical field thus reducing the duration of surgery and facilitating the surgeon in his/her procedure. (1) It allows meticulous surgical dissection and causes less morbidity than an Esmarch bandage. (2)

Pneumatic tourniquet is widely used in upper and lower extremities surgery. Its history is closely linked with limiting blood loss during amputation, and nowadays its function remains primarily the same; to maintain a bloodless surgical field. (1,3,4) A recent survey reported that 95% of the members of the American Association of Hip and Knee surgeons used a tourniquet in TKA (total knee arthroplasty) to facilitate extensive soft tissue release and bone cuts (minimal blood loss). (3)

However, a number of disadvantages have been reported and their use is not without risk as complications may still occur. (4) Some studies reported complications associated with tourniquet use and include skin blistering or burning, muscle injury, post operative wound infection, nerve palsy, deep vein thrombosis (DVT), and pulmonary embolism (PE). Those complications might interfere with the postoperative functional recovery. (4,5)

In late 1950s Bruner first published reports evaluating the safety of tourniquets in surgery of the hand and they were later modified by Braithwaite and Klenerman in 1996 (ten rules) and are currently among the most common used guidelines for the safe use of tourniquet. (5) However, studies have shown that not all surgeons use them and improper use can have complication rate of 12.5% up to 60%, especially tourniquet pain (6)

The aim of this study was to determine the efficacy of Bruner’s rules in decreasing tourniquet related complications in Rwanda.

1. 1 PROBLEM STATEMENT AND RATIONALE

The tourniquet is commonly used by orthopedic and plastic surgeons for upper and lower extremities surgeries mainly for bloodless field to aid vision and hence safety and efficiency of the surgical procedure. Improper use can have complication rate of 12.5% up to 60%, especially tourniquet pain (6) and complications can cause significant morbidity including limb loss.

To limit its complications Bruner's rules have been widely used and their efficacy has been studied (5). In our settings the pneumatic tourniquet is routinely used and there are no clear guidelines for its safe use. The survey among orthopedic surgeons and residents showed that the awareness (partial or all) of Bruner's rules was 55 %.

No such study has ever been done, in Rwanda and in our region; on tourniquet use and Bruner's rules efficacy.

1. 2 RESEARCH QUESTION

Are the Bruner's rules efficient in decreasing tourniquet use related complications in our settings?

1. 3 OBJECTIVES

1. 3. 1 General objective

To determine the efficacy of Bruner's rules in decreasing the tourniquet related complications

1. 3. 2 Specific objectives:

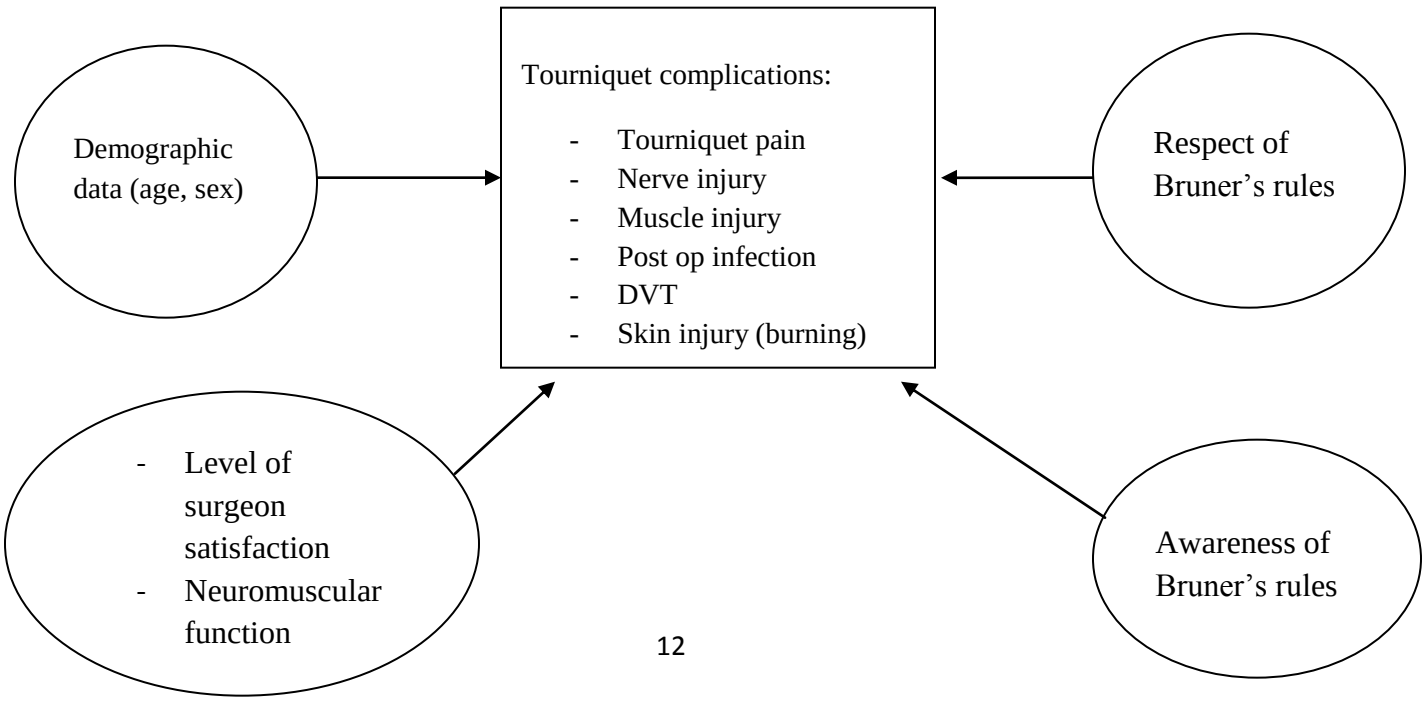
- To determine the rate of tourniquet complications in our settings with use of Bruner's rules
- Assess postoperative functional recovery after tourniquet use
- To raise the awareness of Bruner's rules among orthopedic surgeons and residents.

- To determine the satisfaction among surgeons with the use of Bruner's rules (bloodless field)

1. 4 VARIABLES

Specific objectives	Variables	Data collection method	Source of data
To determine the rate of tourniquet complications in our settings	Demographic data Clinical data (tourniquet complications)	Data collection form	Patients, Surgeon, Resident.
To raise the awareness	Yes or No	Data collection form	Surgeon or resident.
To assess postoperative functional outcome	Neuromuscular function outcome	Data collection form	Surgeon, resident.
To determine the satisfaction of surgeons	Level of satisfaction (Yes or No) (bleeding grade)	Data collection form	Surgeon or resident

1. 5 CONCEPTUAL FRAMEWORK

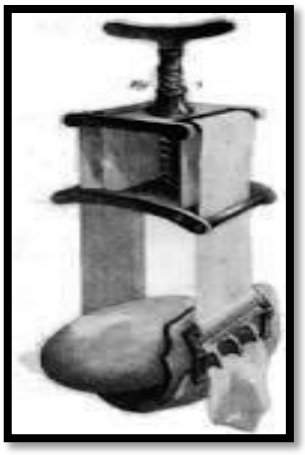


2. LITERATURE REVIEW

2.1 History of tourniquet use

The known earliest use of tourniquet dates back to 199 before CE–500 CE, when it was used by the Romans to control bleeding, especially during amputation. (5) The use of a pneumatic tourniquet is helpful during many orthopedic surgeries. However, a number of disadvantages have been reported and their use is not without risk as complications may still occur. The reported injuries are often pressure-related, but they can also be caused by excessive tourniquet time. (4)

Roman tourniquet (bronze coated with leather)



J.L. Petit screwing tourniquet in 1718

During roman times various constricting devices had been employed to help the control of hemorrhage during amputation. Archigenes and Heliodorus, two surgeons who practiced in Rome at the time of Celsus, used narrow bands of cloth placed directly above and below the line of incision, each passed two or three times about the limb and tied in a single knot. (7) This mainly controlled the venous bleeding. It was an advance on the practice of Hippocrates, who recommended cutting through the dead limb at a joint, care being taken not to wound any living part.

All other methods used thereafter still were associated with many complications as there was no measurable applied pressure and controlled timing. (8)

There is a lack of evidence to define a safe tourniquet time in lower limb surgery. (4) Recommendations suggest a time limit of two hours for healthy patients, but elderly, trauma patients and those with peripheral vascular disease are probably more susceptible. Most studies of tourniquet time are of the experimental animal type, and few clinical human studies use tourniquet times of more than two hours. In a retrospective study, it was found that tourniquet times over 120 minutes (2 hours) were associated with an increased risk of nerve injury in total knee arthroplasty (TKA). (2,7)

Other studies have shown an increased rate of re-operations, a higher incidence of nerve injuries, inferior knee mobility, and more surgical wound complications when longer tourniquet times have been used. In a review evaluating tourniquet use, it was concluded that the existing assumption of a two-hour safe time limit is mainly based on animal studies, and because the reported complications are mostly minor and of a short-term nature are therefore questionable. (4)

The early development of the tourniquet is linked up with amputation procedure. It was about a hundred years ago that the tourniquet was first used in other operations on the limbs. The introduction of the bloodless field is a landmark in the development of orthopaedic operative technique. (7)

2.2 Pneumatic tourniquet

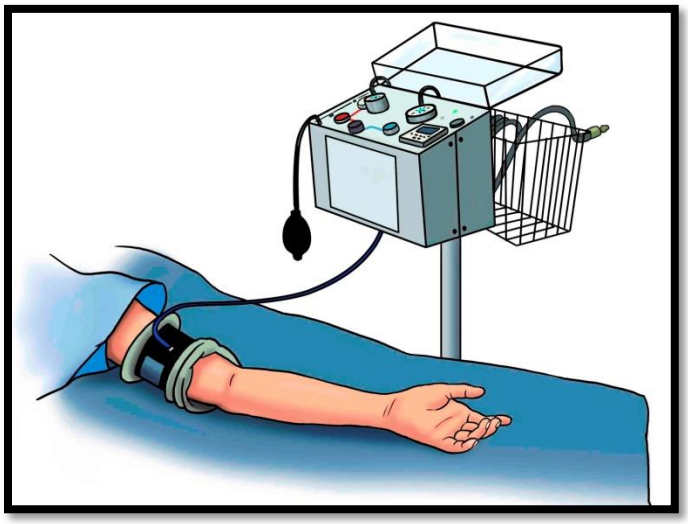
It was introduced by Harvey Cushing in 1904 after he abandoned the rubber band as it carries high risk of nerve palsy and was difficulty to remove rapidly and reapply during an operation, so he used an inflatable cuff that was connected to large bicycle pump and inserted a manometer to control the required pressure. (9)

The pneumatic tourniquet is widely used in orthopaedic surgery to create a bloodless field in limb surgery. It allows meticulous surgical dissection and causes less morbidity. Nonetheless, complications still occur, of which nerve damage causing paralysis is the most feared. (2,9)

2.3 The tourniquet use today

The pneumatic tourniquet is the instrument of choice for both upper and lower limbs surgeries and with it there is measurable control of pressure exerted on the vessel wall, usually 250- 300 mm Hg in adults. (10) There are several instructions of how to safely use the tourniquet including the site of cuff application, applied pressure and timing. In 1954, Bruner set up a number of rules that would be followed to limit or decrease the complications associated with tourniquet use and in many studies this has decreased the rate of complications down to less than 2%. (7,11)

Electric pneumatic tourniquet



Pneumatic tourniquet application (here on UL)

The tourniquet controls intraoperative blood loss, but cannot stop postoperative blood loss. In addition, the benefits of the tourniquet must be balanced against risks. (5,7)

2.4 Bruner's rules

It was not until nearly a century later that Bruner first published reports evaluating the safety of tourniquets in surgery of the hand. Since then, numerous publications, as well as proposed guidelines for safe tourniquet use, have studied the real and potential complications of prolonged ischemia. (8)

Application	Only to a healthy limb
Size of tourniquet	*Arm*: 10 cm; *leg*: 15 cm or wider in large limbs
Site of application	*Upper limb*: upper arm; *lower limb*: mid or upper thigh (enough muscle bulk)
Padding	At least 2 layers of orthopedic wool or padding
Skin protection/preparation	Occlude the skin to prevent padding or wool soakage with cleaning solution
Exsanguination	3 – 5 minutes limb elevation or Esmarch bandage
Pressure (cuff pressure)	**Upper limb**: 50-100 mm Hg above SBP or 200-200 mmHg; **Lower limb**: double the SPB or 250-350 mmHg
Time	Generally not to exceed 2 hours (absolute maximum: 3 hrs). If time> 2 hrs, deflate and re-inflate after 15-20 minutes
Temperature	Avoid heating (eg: hot lights), cool if feasible and keep tissues moist
Documentation and maintenance	Of duration and pressure; 3 monthly maintenance (calibration, manometer)

Bruner's ten rules for the safe use of tourniquet (Modified by Barithwaite and Klenerman in 1996) (5)

2.5 Tourniquet complications

Numerous publications, as well as proposed guidelines for safe tourniquet use, have studied the real and potential complications of prolonged ischemia. Tourniquet-related injury usually involves nerve and other soft tissues (e.g., skin, muscle, and vasculature) and is believed to be caused by the combined effects of direct compression by the tourniquet and ischemia. Studying these two factors more closely, some studies used animal models to demonstrate that irreversible nerve injury occurs after 8 h due to ischemia. (8)

Other complications related to tourniquet use have been reported in the literature and include nerve palsy, rhabdomyolysis, and subcutaneous thigh fat necrosis. The application of a tourniquet also tethers the quadriceps mechanism. (12)

Intraoperative bleeding may occur due to an under-pressurized cuff, insufficient exsanguination, improper cuff selection, loosely applied cuff, calcified vessels or too slow inflation or deflation. Compartment syndrome, pressure sores, chemical burns, digital necrosis, deep venous thrombosis leading to pulmonary or venous embolization, tourniquet pain, thermal damage to tissues, and rhabdomyolysis are the other potential complications. High pressures and forgotten digital tourniquets can lead to severe ischemic injuries of the digits. (5)

Tourniquet pain

The clinical presentation of tourniquet pain consists of several components and is not just due to the pain and pressure under the tourniquet. The smaller unmyelinated C-fibers are more resistant to local anesthetic (LA) induced conduction block as compared to the larger myelinated A-fibers. After intrathecal administration of an adequate dose of LA, conduction in both A- and C-fibers is blocked. But when the concentration of LA in the cerebrospinal fluid (CSF) decreases, the C-fibers start conducting impulses before the A-fibers, resulting in a dull tourniquet pain in the presence of an anesthetic, which when assessed by pin prick appears adequate. (5,13)

3. METHODOLOGY

3.1 Study description

In my study I enrolled patients who underwent upper and lower extremities surgeries in the orthopedic department. Patients were monitored during intra operative and post operative period (within 3 days) for tourniquet complications. Surgeons and residents were educated on Bruner's rules before data collection.

Data were collected using a data collection form, including demographic data and clinical data such as surgeon satisfaction (bloodless field) and tourniquet complications (tourniquet pain, neuropraxia, skin lesion, post tourniquet syndrome, DVT)

3.2 Study design and population

It is a prospective, correlational study, for six (6) months (October 2018 to March 2019), for patients aged 12 to 75 years who underwent upper and lower extremities surgery in orthopedic department at RMH (Rwanda military hospital) and KFH (King Faisal hospital), with use of pneumatic tourniquet, during the study period and who met the inclusion criteria.

The surgeon satisfaction with regards to intraoperative bleeding control was assessed with World health organization bleeding grading (14) and postoperative functional recovery was assessed by Motor power scale.

3.3 Study site and period

Period of study: six months from October 2018 to March 2019. The study was conducted at two referral hospitals located in Kigali: RMH (Rwanda Military Hospital) and KFH, K (King Faisal Hospital, Kigali); which are the two main orthopedic centers in the country and with modern pneumatic tourniquet.

RMH is a referral hospital located in Kicukiro district that provides healthcare to military and civilian population particularly from Eastern province of Rwanda and Kigali city with a bed capacity of 260. The commonly performed procedures in orthopedics are trauma and pediatrics.

KFH is a private tertiary hospital located in Gasabo district and was inaugurated in 1998; it has a bed capacity of 162 and common orthopedic procedures are joint replacements (hip and knee), trauma, spine and sport surgery (shoulder and knee arthroscopy, arthroscopic ACL reconstruction, meniscectomy and meniscal repair).

3.4 Selection criteria

- **Inclusion criteria**: - Patients aged 12 to 75 years
  - Surgery of upper or lower extremity with use of tourniquet

- **Exclusion criteria**:
    - Comorbidities like peripheral vascular disease and peripheral neuropathy
    - Patients with skin diseases
    - Patients with severe soft tissue and neurovascular injuries.
    - Refusal of consent

Patients less than twelve years were excluded for poor communication as far as the clinical examination is concerned and patients above seventy five years were excluded as more than 30% have PVD (calcified vessel walls that can't be compressed by tourniquet).

3.5 Sampling

The sample size for this study was calculated using the formula below (15):

$$\boldsymbol{n = Z^2 * P(1 - P)/D^2}$$

where **n** = sample size,

Z = confidence level at 5% of type I error,

P = proportion of patients whom the application of pneumatic

tourniquet surgical approach was safe among the study population

(0.5 was taken because P was unknown)

D=Precision of 6%

Z =

1. 64 for two sided test of hypothesis; stating that patients developped complications due to pneumatic tourniquet application.

This formula gives 114 patients that were to be recruited for this study.

3.6 Data collection and analysis

Data collection was done, by orthopedic residents, using a data collection form with information such as patient's demographic data, clinical data including the tourniquet complications, procedure duration, pressure used and satisfaction of the surgeon.

All data collected were entered and cleaned using SPSS version 23. The data were kept on my personal computer and both the folder and computer were secured with a password. The data analysis was performed using Stata version 13 by the principle investigator and the stastician. Descriptive measures such as frequency, percentages, mean and standard deviation were generated in addition to graphical illustrations before further analysis aiming at analyzing the efficacy of pneumatic tourniquet using Bruner's rules and its association with clinical and demographic variables. For this effect, bivariate and multivariable analysis (Multiple logistic regression) with the use of Chi-Square test of significance of a relationship was performed.
The resulting multiple logistic regression model is described below (16):

$$Logit\ (P(Y_i = 1)) = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \cdots + \beta_i X_i$$

Where:
Y_i represents safety of pneumatic tourniquet surgical approach for patient i, $Y_i = 1$ if there is safety, and $Y_{ij} = 0$ if the opproach resulted in any complication. β_0 Represents the model's constant;
β_1 Stands for parameter estimate for clinical variables
β_2 ,….,β_i represents parameters estimates for demographic variables

3.7 Ethical considerations

Participation in the study was voluntary, participants did not get any compensation and there was full explanation about the study. Confidentiality was assured by protection of participant identity with a code.

The risks to participants in our study were minimal. Participant and next of kin were asked questions, participants were assessed and managed as any patient according to normal medical management; there was no extra care charges.

We have written an informed consent and assent for participants <18 years in Kinyarwanda and English. This was done after full explanation to participant and to next of kin (for participants <18 years the parent or next of kin signed the assent). The participant had right to withdraw from our study at anytime and without any pursuit.

Ethical approval from IRB (institutional review board) of University of Rwanda was obtained *(Approval notice: No 334/CMHS IRB/2018)* as well as the approval of each hospital ethical committee (*RMH/IRB/022/2018 and KFH approval letter*).

4. RESULTS

4.1 OVERVIEW

Of the 126 participants on whom the pneumatic tourniquet was used during surgery of upper and lower extremities, we had four (4) complications, including three (3) cases of tourniquet pain and one case (1) of unexpected bleeding during surgery, which were all intraoperative complications. There were no postoperative complications identified (skin burning, neuropraxia, DVT, postop infection, compartment syndrome)

The majority of participants were in the age group 26 to 45 years and were males. The most common performed procedure was arthroscopic surgery, followed by open reduction and fixation of fractures. Most procedures were performed on the lower extremity.

I have found that there was strong association between respect of Bruner's rules and tourniquet complications with a p-value <0.001. The mean duration of tourniquet application was 136 minutes (SD +/- 15.3) in patients who had tourniquet pain. There was strong association between duration of tourniquet application and complications (p value <0.001).

Surgeon satisfaction with the efficacy of tourniquet use was 99.2 % and there was no motor and sensory deficits identified in early postoperative period. The predictors of intraoperative complications were tourniquet application of more than two (2) hours, use of inappropriate cuff size and low exsanguination time (<3 minutes).

The results have shown that Bruner's rules, if all respected, are efficient in preventing the complications of tourniquet use during surgery.

4.2 PRESENTATION OF RESULTS IN FIGURES AND TABLES

4.2.1 SAMPLE CHARACTERISTICS

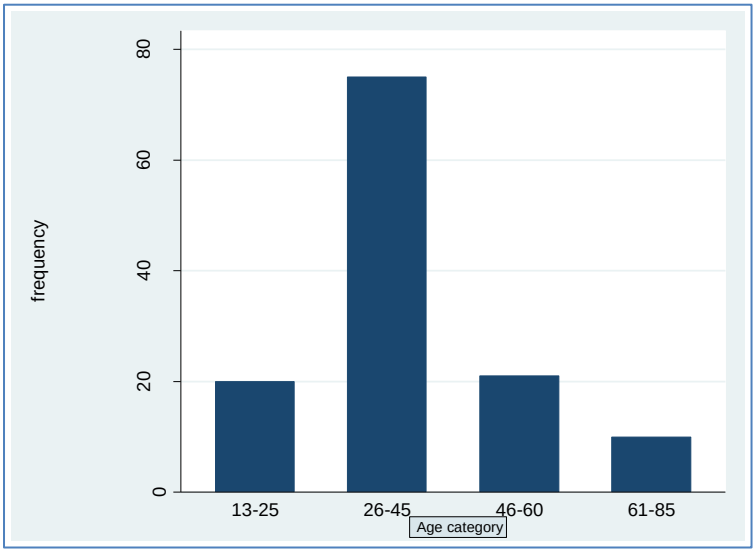


Figure 1. Age of participants (the majority were in the age group 26-45 years)

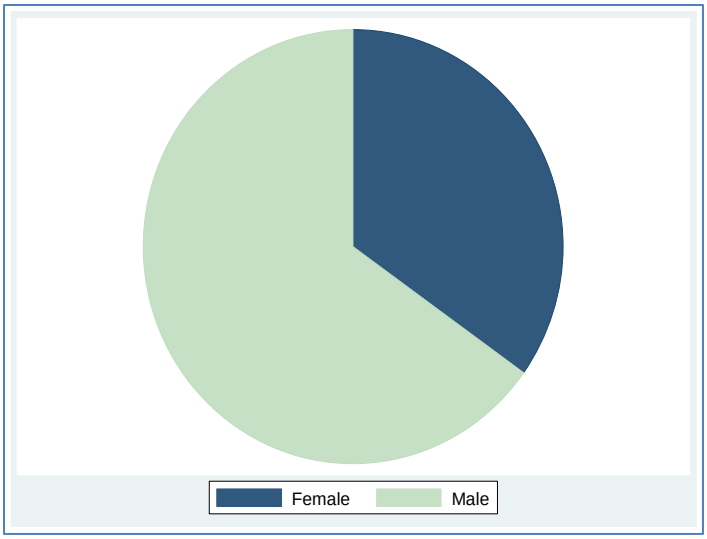


Figure 2. Gender of participants (the majority were males)

4.2.2 CLINICAL DATA

1. Site of surgery

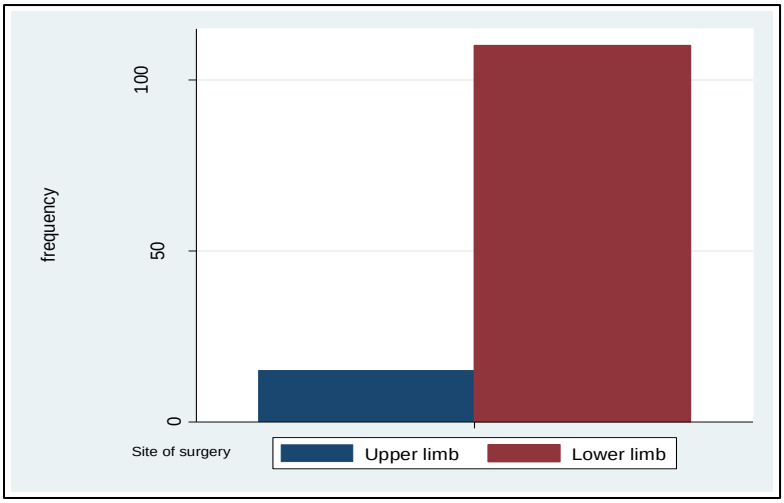


Figure 3. Most surgeries were performed on lower extremity

2. Type of surgery

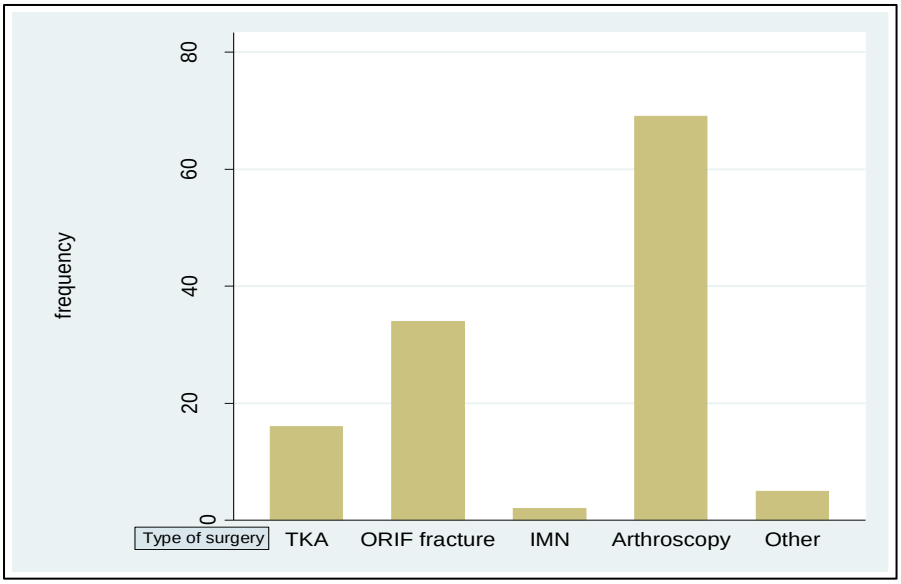


Figure 4. Arthroscopic surgery was the common procedure followed by ORIF of fractures.

4.2.3 COMPLICATIONS AND COVARIATES

Table 1. Tourniquet complications

Variable	**Frequency**	**%**
Intraoperative complications		
Tourniquet pain	3	2.38
Unexpected bleeding	1	0.79
None	122	96.83
Postoperative complications		
None	126	100

Table 2. Complications and other covariates (correlations)

Variable	Tourniquet pain (%)	Unexpected bleeding (%)	None (%)	P-value
Gender				**0.391**
Female	1(0.8)	1(0.8)	42(33.3)	
Male	2(1.6)	0	80(63.5)	
site of Surgery				**0.754**
Upper limb	0	0	15(12)	
Lower limb	3(2.4)	1(0.8)	106(84.8)	
Type of Surgery				**0.78**
TKA	1(0.8)	0	15(11.9)	
ORIF fracture	0	1(0.8)	33(26.2)	
IMN	0	0	2(1.6)	
Arthroscopy	2(1.6)	0	67(53.2)	
Other	0	0	5(4.0)	
All Bruner's rules respected				**P<0.001**
Yes	1(0.8)	0	113(89.7)	
No	2(1.6)	1(0.8)	9(7.1)	

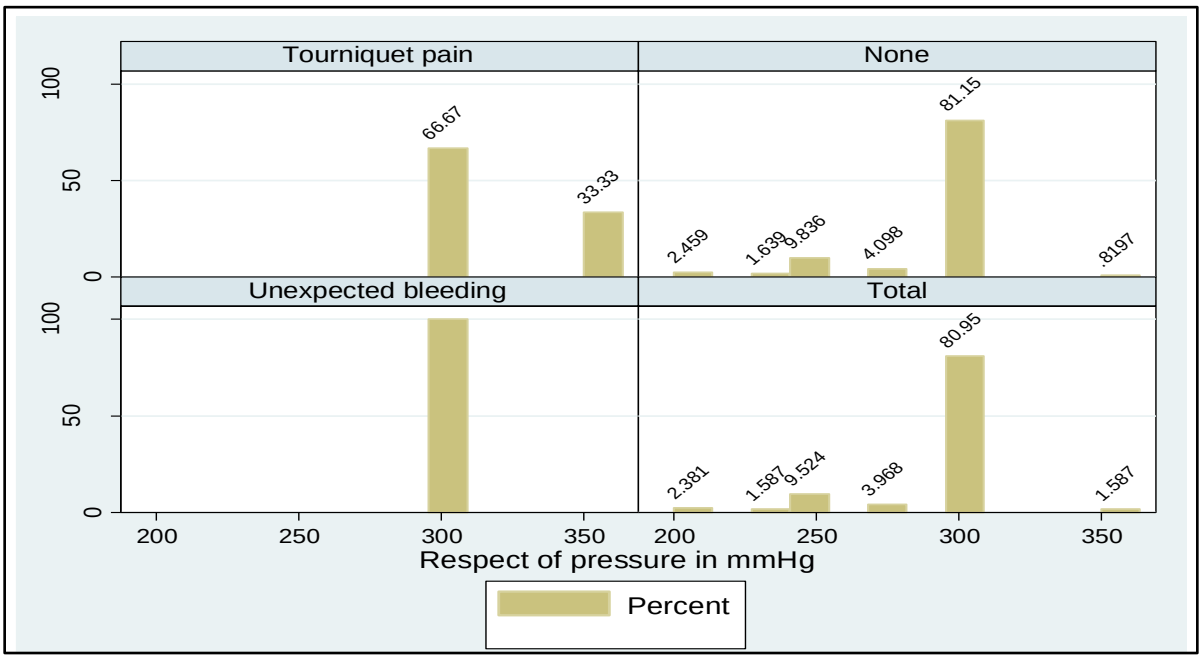


Figure 5. Intraoperative complications and pressure used

Table 3. Duration of tourniquet application (minutes).

Complications	Patients	Mean	STD	Min	Max
Tourniquet pain	3.0	136.7	15.3	120.0	150.0
Unexpected bleeding	1.0	40.0	.	40.0	40.0
None	122.0	77.0	29.0	20.0	130.0

Table 4. Duration of tourniquet application, age groups and intraoperative complications

Variable	Complications (%)	No complications (%)	P-value
Age category			**0.724**
13-25	0	20(100)	
26-45	3(4)	72(96)	
46-60	1(4.8)	20(95.2)	
61-85	0	10(100)	
Respect of tourniquet application duration			**P<0.001**
Not respected	2(28.6)	5(71.4)	
Respected	2(1.7)	117(98.3)	

Table 5. Bruner's rules and surgeon satisfaction measures

All Bruner's rules respected	**Surgeon satisfaction**		**P-value**
	Yes	No	0.002
Yes	114(90.5)	0	
No	11(8.7)	1(0.8)	
	Muscle power		P<0.001
	Some resistance	Full strength	
Yes	0	114(90.5)	
No	2(1.6)	10(7.9)	
	Sensory deficit		NA
	Yes	No	
Yes	0	114(90.5)	
No	0	12(9.5)	
	Motor deficit		NA
	Yes	No	
Yes	0	114(90.5)	
No	0	12(9.5)	

5. DISCUSSION

This study was conducted at KFH and RMH and 126 participants were recruited and included patients on whom the pneumatic tourniquet was used during upper and lower extremity surgery. Data were collected over a period of six months (October 2018 to March 2019) at the two centers with respectively ninety-one (91) and thirty five (35) participants from each hospital and we collected all the required information for all participants.

The involved team (surgeons, residents) was educated on Bruner's rules and tourniquet sizes used were 10 cm cuff size for upper limb and 15 cm cuff for lower limb; 300 mmHg pressure was used for LL in adults and 250 mmHg in <18 years group, 250 mmHg pressure was used for UL in adults; exsanguination time was between 3 and 5 minutes;

All above guidelines were used according to Bruner's rules, AORN recommendations of pneumatic tourniquet use (17), standard practice for safe use of pneumatic tourniquet (11), A. Odinsson et al (2) and M.Yalcinkaya, Sokucu, Erdogan et al (6). During our study, our findings were enough directed to respond to our objectives.

The commonest age group was 26-45 years (60 %). There were more male participants (65.1 %) than females distribution, the male sex was the majority with of participants.

Pneumatic tourniquet was mostly used on lower limb surgeries and accounted for 88.1 % of cases and upper limb accounted for 11.9 % of cases. Knee arthroscopic procedures were the most common type of operation accounting for 54.8 % of procedures. These include diagnostic arthroscopy, meniscectomy and ACL reconstruction. ORIF of fractures were the second common performed procedures (26.2 %) using pneumatic tourniquet and total knee arthroplasty accounted for 12.7 % of procedures.

5.1 Rate of complications

In total we had four (4) complications (3.1 %) which include 3 cases of tourniquet pain and 1 case of unexpected bleeding (Table 1). All are intraoperative complications and no postoperative complication was observed. 2 cases of tourniquet pain were due to tourniquet use above recommended time (>2 hours) and the other case's cause was not known, with all Bruner's rules respected (0.79 %). One case of unexpected bleeding was due to inappropriate cuff size as the patient was obese with big thigh circumference. No other complications were identified. Compared to Lee O-Sung et al (1) with complication rate of 6.4 % and mainly skin blistering (no padding occlusive bandage used), our rate of 0.79 % is low. Odinsson, A et al (2) reported the complications rate of 0.05 % (low compared to our research results) and Drolet C. Brian et al (8) reported a complication rate of 0 % in 505 UL procedures.

For the *tourniquet pain* cases the mean duration of tourniquet application was 136.7 minutes (SD +/- 15.3) which is above the recommended time of 120 minutes (2 hours). A. Odinsson et al (2) reported that most complications were seen with tourniquet time > 130 minutes; M.Yalcinkaya,

Sokucu, Erdogan et al (6), concluded that the maximum time was 2 hours (120 minutes) to prevent the complications.

5.2. Awareness of Bruner's rules and surgeon satisfaction

In their survey M.Yalcinkaya et al (6) found that the awareness of tourniquet use rules was 70 % which is above our group (55 %). Surgeon satisfaction with tourniquet function and bloodless field was at 99.21 %. A. Odinsson et al (2) reported the surgeon satisfaction with tourniquet use of 99.85 % and M.Yalcinkaya, Sokucu, Erdogan et al (6) reported the satisfaction of 98.7 %; both findings which are comparable to our results.

5.3 Postoperative functional recovery

We assessed the muscle power scale and sensory function below the level of tourniquet application on the involved limb, within a period of two days postoperative and no case of motor or sensory deficit was identified. Therefore all participants had fully functional recovery of the neuromuscular function. D. Dennis, A. Kittelson et al (18) found that there was slight decrease in quadriceps strength after tourniquet use in TKA over 3 months.

5.4 Correlations between complications and other covariates

Correlation between complications and sex (p value: 0.391); site of surgery (p value: 0.754); type of surgery (p value: 0.78); complications and age (p value: 0.724) were statistically unsignificant (Table 2).

The correlation between complications and respect of Bruner's rules, p value is <0.001 that is statiscally highly significant, suggesting a strong association between respect of Bruner's rules and complications (Table 2); no respect of Bruner's rules most likely lead to complications. Therefore, Bruner's rules are efficient in decreasing tourniquet complications.

There was strong association between complications and respect of duration of tourniquet application, p value <0.001, which is statiscally highly significant. C. Olivecrona, L. Lapidus et al (4) found that tourniquet time above 100 minutes is associated with a high risk of tourniquet complications after TKA; A. Odinsson et al (2) showed that most complications were seen in tourniquet time more than 130 minutes. For respect of Bruner's rules and surgeon satisfaction, there was a strong association (p value: 0.002) (Table 5).

5.5 Study limitations

This study was limited by lack of previous studies on the topic or related topics in our country and region to serve as baseline; comparative study not possible as there were no other rules or guidelines to compare; non compliance on Bruner's rules application, in particular tourniquet time, that led to increased rate of complications.

6. CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

Previous research works focusing on safe use of tourniquet with respect to Bruner's rules have yielded results that are comparable to ours. This study explored the efficacy of Bruner's rules in preventing tourniquet use complications in our settings.

We found that the rate of complications (0.79 %) was comparable to most of the previous studies. There was significant correlation or association between complications and duration of tourniquet application, respect of Bruner's rules; between Bruner's rules and surgeon satisfaction. There was no correlation between complications and age, sex, site and type of surgery. This study results showed that Bruner's rules are efficient in decreasing tourniquet use related complications.

6.2. RECOMMENDATIONS

According to the results of this study, we found that Bruner's rules are efficient to prevent or decrease significantly the complications of tourniquet; therefore we would like to recommend:

- To apply and respect the Bruner's rules in all patients on whom the pneumatic tourniquet is used as there was cases of non compliance that led to increased rate of complications

- To educate the supporting staff about Bruner's rules as they are involved in tourniquet use (nursing and anesthesia teams) as they often involve in tourniquet application.
- To document of tourniquet use parameters as there were cases of incomplete documentation on the intraoperative record sheet.

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APPENDICES

Appendix I: CONSENT FORM

PART I: INFORMATION SHEET

*RESEARCH TOPIC**: "EFFICACY OF BRUNER'S RULES IN DECREASING TOURNIQUET USE RELATED COMPLICATIONS IN RWANDA"***

Principal investigator: Dr Jean Thierry NIYOMUGABO, Senior resident in orthopedic surgery.

I am carrying out the above mentioned research in two (2) referral hospitals (KFH, RMH) in Rwanda.
I warmly welcome you in my research, further explanation is going to be given and feel free to ask any question.

- Pneumatic tourniquet is commonly used device in surgery, by blocking the blood from going distal, of upper and lower extremities. However, it is associated with some complications; including tourniquet pain, skin blistering, infection, muscle injury and nerve injury. The purpose of this study is to evaluate the efficacy of Bruner's rules in decreasing tourniquet use related complications that affect the postoperative functional recovery.
- Your participation in this research is entirely voluntary. Whether you choose to participate or not, all the services you receive will continue and nothing will change.
- After arriving in Theater room, a doctor or nurse will ask you to give some important information containing in our data collection form and after the operation they will also ask you some questions concerning your postoperative health status. No further follow up will be needed after you are discharged from the hospital.
- Patients in this study will not be subject to any harmful intervention and the risk is minimal as the tourniquet will be use in a procedure that it is indicated.
- In this study, no reimbursements of any kind will be provided, participation is voluntary.
- The information that we collect from this research project will be kept confidential. Your identification code will be kept locked and only available to the principal investigator.
- The patient is free to refuse to participate in this study and refusal to participate will not affect his/her treatment.
- The results of this study will be published and policy makers informed for possible recommendations for the use of Bruner's rules as a guideline of safe tourniquet use.

PART II: CERTIFICATE OF CONSENT

I have read the foregoing information, or it has been read to me. I (or witness) have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant/Witness……....

Signature of Participant/Witness ……

Date ……../……./……..(Day/month/year)

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done: filling the data collection form.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher/person taking the consent……

Signature of Researcher /person taking the consent…….

Date……./……../…..... (Day/month/year)

Researcher contact:

Dr Jean Thierry NIYOMUGABO Tel: + 250 784956049; Email: fabon8@gmail.com

If you have questions about your rights in the study, contact

CMHS / UR Directorate of Research, Technology Transfer and Consultancy

Tel: + (250) 788563312

Chairperson – IRB CMHS / University of Rwanda

Prof Kato J. NJUNWA,Tel 0788490522

Appendix II: ASSENT FORM (Patients under 18 years of age)

PART I: INFORMATION SHEET

*RESEARCH TOPIC: **"EFFICACY OF BRUNER'S RULES IN DECREASING TOURNIQUET USE RELATED COMPLICATIONS IN RWANDA"***

Principal investigator: Dr Jean Thierry NIYOMUGABO, Senior resident in orthopedic surgery.

I am carrying out the above mentioned research in two (2) referral hospitals (KFH, RMH) in Rwanda.
I warmly welcome you in my research, further explanation is going to be given and feel free to ask any question.

- Pneumatic tourniquet is commonly used device in surgery, by blocking the blood from going distal, of upper and lower extremities. However, it is associated with some complications; including tourniquet pain, skin blistering, infection, muscle injury and nerve injury. The purpose of this study is to evaluate the efficacy of Bruner's rules in decreasing tourniquet use related complications that affect the postoperative functional recovery.
- The participation of your child/relative in this research is entirely voluntary. Whether you choose to participate or not, all the services he/she receive will continue and nothing will change.
- After arriving in Theater room, a doctor or nurse will ask you to give some important information containing in our data collection form and after the operation they will also ask you some questions concerning your postoperative health status of your child. No further follow up will be needed after he/she is discharged from the hospital.
- Your child/relative will not be subject to any harmful intervention and the risk is minimal as the tourniquet will be use in a procedure that it is indicated.
- In this study, no reimbursements of any kind will be provided, participation is voluntary.
- The information that we collect from this research project will be kept confidential. Your identification code will be kept locked and only available to the principal investigator.
- The parent/guardian is free to refuse his/her child to participate in this study and refusal to participate will not affect his/her treatment.
- The results of this study will be published and policy makers informed for possible recommendations for the use of Bruner's rules as a guideline of safe tourniquet use.

PART II: CERTIFICATE OF CONSENT by Parent/Guardian

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily that my child/relative will participate in this research.

Name of Parent/Guardian ……....

Signature of Parent/Guardian ……

Date ……../……./……..(Day/month/year)

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant's parent/guardian, and to the best of my ability made sure that the participant's parent/guardian understands that the following will be done: filling the data collection form.

I confirm that the participant's parent/guardian was given an opportunity to ask questions about the study, and all the questions asked have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving assent, and the it has been given freely and voluntarily.

Name of Researcher/person taking the consent……

Signature of Researcher /person taking the consent…….

Date……./……../…..... (Day/month/year)

Researcher contact:

Dr Jean Thierry NIYOMUGABO Tel: + 250 784956049; Email: fabon8@gmail.com

If you have questions about your rights in the study, contact

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Chairperson – IRB CMHS / University of Rwanda

Prof Kato J. NJUNWA,Tel 0788490522

Appendix III: DATA COLLECTION FORM

PATIENT CODE: ……

Collector: Orthopedic Surgeon ☐ Orthopedic resident ☐ Surgical resident ☐

Theater nurse ☐ Other: ……

DEMOGRAPHIC DATA

Age (years): …… **Sex**: Male ☐ Female ☐

CLINICAL DATA

Site of surgery: Upper limb ☐ Lower limb ☐

Type of surgery: Total knee arthroplasty ☐ ORIF (open reduction internal fixation) ☐

OREF (external fixation) ☐ IMN (intramedullary nailing) ☐ Arthroscopy ☐

Other: ……

Is the Surgeon/resident aware of Bruner's rules? YES ☐ NO ☐ If YES, what is missing ?: …….

Are all tourniquet related equipments available? YES ☐ NO ☐

Intermittent deflation: Y ☐ N ☐ If Yes re-inflation after how much time (Minutes): …….

INTRAOPERATIVE COMPLICATIONS:

Tourniquet pain ☐

Unexpected bleeding ☐

POST OPERATIVE COMPLICATIONS:

Skin burning or blistering ☐

Muscle injury ☐

Neuropraxia ☐

DVT (deep vein thrombosis) ☐

Postoperative infection ☐

Compartment syndrome ☐

Other: …….

ARE ALL BRUNER'S RULES RESPECTED?

Size of tourniquet: Arm (10 cm) ☐ Leg (15 cm) ☐ Other: ……

Site of application: Upper arm ☐ Mid/upper thigh ☐ Other: …….

Padding (*at least 2 layers of orthopedic wool*): Y ☐ N ☐ If No, what is the reason? ……..…..

Skin preparation (*occludes to prevent soakage of wool; use the Opsite*): Y ☐ N ☐

Exsanguination of limb (*no use of Esmarch bandage*): in minutes ……

Pressure used: ……..mmHg

Duration of tourniquet application (*in hours +/- minutes*): ……..hours

Documentation done? YES ☐ NO ☐

LEVEL OF SURGEON SATISFACTION: YES ☐ NO ☐

NEUROMUSCULAR FUNCTION ASSESSMENT:

- Muscle power (*out of 5*): **1 2 3 4 5**
- Neurological status: Sensory deficit: Y ☐ N ☐ Motor deficit: Y ☐ N ☐