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Satisfaction of Trauma Patients in Their Pain Management in Rwandan Teaching Hospitals: A Cross-Sectional Study

By Dr. Joseph Niyitegeka, MD

Supervisors:

- **Dr. Theogene Twagirumugabe, MD, MMed, PhD**
- **Dr. Paulin Banguti Ruhato, MD, MMed**
- **Dr. Gaston Nyirigira, MD, MMed**

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DECLARATION

I hereby declare that this dissertation: "Satisfaction of Trauma Patients in Their Pain Management in Rwandan Teaching Hospitals: A Cross-Sectional Study" is my own work. This study in whole or in part has neither been submitted for publication anywhere nor has it been submitted for the award of a degree in other University.

Signed

Date 19/09/2019

Dr. Joseph Niyitegeka, MD

Supervisor: Dr. Theogene Twagirumugabe, MD, PhD.

I hereby declare that this dissertation has been submitted with my approval as the supervisor.

Signed

Date 19/09/2019

DEDICATION

To the Almighty God, to my wife Mukandera, to my Daughter Ishimwe and to my Son Mugisha for unlimited love and sacrifices and for everyone struggling to relieve pain from suffering population.

Dr. Joseph Niyitegeka, MD

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Dr. Joseph Niyitegeka, MD

ABSTRACT

Background
Postoperative pain management in Rwanda is well documented in trauma patients but few studies have investigated pain management in trauma patients in general and factors associated with patient's satisfaction in Rwanda.

Methods
We explored clinical aspects of trauma patients, pain management offered to them in particular, their satisfaction on this and associated factors in the four teaching and referral hospitals in Rwanda. We collected data on 375 patients and calculated the rate of satisfaction among them. Different variables associated with satisfaction were assessed using Chi-square. Of them, those achieving an important association ($p<0.25$) were used in a multivariate logistic regression to identify independent factors to satisfaction. The data analysis consisted of calculation of frequencies and percentage of patients' factors.

Results
The patients were having more mild and moderate injuries, surgery was already done in 71.94%. The pain grade trend was from severe (89.81%) to mild (68.28%) from admission to the interview. The majority of patients received medications in less than ten minutes when they ask for pain relief. Paracetamol (67.73%) was the most prescribed medication for pain followed tramadol (41.98%) and morphine (40.53%). The combination of Paracetamol, NSAIDs and opioid was common prescription (71.6%). The most severe side effect was dizziness. Almost every patient wanted to be treated for pain 77.03%. The satisfaction for pain management was very high (86%). Independent predictors for satisfaction for pain management in trauma patients were the mode of access to AED, pain intensity at interview and time waited for pain relief along the stay in the hospital.

Conclusion
The majority of patients admitted for trauma had their pain managed and were satisfied for their pain relief. delay to respond for pain relief, interrupted pain relief especially during contact with interviewers and patients admitted by their own means to the AED.

Keywords :
Pain management, trauma patients, patient satisfaction

Abbreviations:

AED: Accident and Emergency Department
CHUK: University Teaching Hospital of Kigali
CHUB: University Teaching Hospital of Butare
RMH: Rwanda Military Hospital
KFH: King Faisal Hospital, Kigali
AED: Accident and Emergency Department
UR: University of Rwanda
NSAIDs: non-steroid anti-inflammatory drugs
CHI: Community Health Insurance
MMI: Military Medical Insurance
RAMA: *La Rwandaise Assurance Maladie*
(Rwanda Public Servant Health Insurance)
Ubudehe: National Wealth Category
DH: District Hospital
HC: Health Center
PH: Provincial Hospital
RH: Referral Hospital
EMS: Emergency Medical Service
PMH: Past Medical History
ISS: Injury Severity Score
PNB: Peripheral Nerve Block

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Chapter I: GENERAL CONSIDERATION

I.1. Introduction

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage(1). In the United States of America, more than half of the population consulting hospitals experience pain (2)

In 2015 Nahin et al. showed that more than 55% of new patients as in-patients or outpatients in high income countries experience pain at least once in three months(3). Pain management does not have to be significantly limited by available resources as the low-cost medication can be used in management of pain (4). To treat the pain successfully, the health care provider has to take into consideration psychological and behavior component of the patients(5).

The multimodal approach for pain management is the most effective model and leads to the satisfaction of patients(6). The pain can be managed using medications, local regional anesthesia, non-pharmacological methods and psychological support (7). The benefit of pain management postoperatively includes patient comfort and satisfaction, early mobilization, reduced pulmonary and cardiovascular complications, faster recovery and reduced chances of developing chronic pain (8).

In a multisystemic review of problems and barriers for pain management at emergency department, Motov and Khan listed different barriers to pain management which include socio-economic, gender, age biases, lack of training in pain management, opiophobia and department culture (9).

Ufashingabire showed that working in different hospital and level of education was the main barrier for Intensive Care Unity nurse for pain management. Most of the patient managed for pain in hospital are satisfied (11).

The Management should include the component of patient psychology and behavior(12). Little investigation has focused on pain management in pre-operative period (7) and there is often a culture of waiting for diagnosis so that pain can be managed, although the evidence now shows that the pain management preoperatively improve patient outcome without altering the diagnosis (13).

In this study we collected data from trauma patients including their demography, clinical presentation, pain assessment, management and satisfaction.

I.2. Review of literature

Rwanda pain management guidelines define pain as an abnormal sensation from the body caused by injury or dysfunction to the nervous system. The pain can be central, peripheral or mixed(14). The pain management has to be multidisciplinary where everyone brings her or his expertise to the common goal of pain relief. Pain assessment offer different advantages namely pain management, diagnosing the disease and communication with health care providers. The pain can be rated according to the patient self-report or health care provider assessing using different tools for pain assessment(14). Rwanda national guidelines offer different methods for assessing pain; one is for numerical rating, verbal numeric rating, visual analogue scale. The pain management is not limited to medications but also non-pharmacological methods. Pharmacological methods include administration of non-steroid anti-inflammatory drugs (NSAIDs), weak and strong opioids. The world health Organization (WHO) offers pain management tailored to the severity of pain in a 3-level ladder(15).

The task force on wait-times of the international association for the study of pain recommends that acute painful condition should be treated (16). The Royal College of Anaesthetists

recommends that(17). In one study done in Ethiopia for pain management at emergency found that the trauma patients receive pain medications more quickly than non-trauma patients with time gap of more than 35 minutes from admission (18).The pain should be assessed earlier to prevent complications including chronic pain (19).

There are factors associated with better pain management in postoperative periods and can be used in trauma patients: using intravenous route for medications, chronic user of pain medicines, early administration f pain medications, and using high potent medications in pain management (20).

While the presence of caregiver and the parts of the body namely the lower limbs and head influenced positively to receive pain medications quickly. The evaluation with physician favored to the patient to get pain medications(18). The young health care providers tend to give more opioids than others (21).

Pain assessment should be detailed showing natural progression of the pain, the effect to usual life and alleviating factors. Subjective and objective assessment is recommended for every patient. The history is given appropriately to the health care provider who builds good relationship with the patient and the family. Pain assessment should be done at the same time of patient full examination even though pain assessment may be not very reliable for different reasons like the anxiety, fear, decreased level of consciousness, etc. Furthermore, the extent of the injury like the wound size or blood loss does not correlate with the pain experienced by the patients.

Multimodal approach of pain management will reduce the need of using high dose of each medication. Intravenous and short acting medications are recommended for acute pain. The usage of regional techniques like regional anesthesia reduces opioid consumption and improves the patient recovery. The patients experiencing pain need psychological support. Non-pharmacological therapy reduces the use of medications for pain and their side effect (7).

The usage of pain assessment checklist, use opioids for moderate and severe pain, assesses pain at regular intervals and reassessment if pain persists is recommended in health facilities (22).

There are different guidelines at different level of health care systems in different countries, the persisting problem is that there is poor usage of guidelines (23). The pain needs follow up to improve the outcome (24).

The gap in knowledge of mechanism and management of pain, limited access to pain services, limited guidelines, lack and restriction of pain medications make pain management inadequate despite the declaration of pain management as human right (25)

I.3. Research question and objectives

Main Objective

-Evaluate the rate of satisfaction of trauma patients for their pain management.

Specific objectives

-To describe the demographic characteristics of trauma patients teaching hospitals in Rwanda.

-To describe the experience of trauma patients in the hospital.

-To list the pain medications used for trauma patients and their side effects.

-To assess patients' satisfaction for pain management.

-To assess the predictors of trauma patient satisfaction for their pain management.

CHAPTER II. METHODOLOGY

II. 1. Study site:

This study includes Kigali and Butare University Teaching hospitals, Rwanda Military Hospital and King Faisal Hospital. These hospitals are the teaching hospitals with University of Rwanda.

The University Teaching Hospital of Kigali receives mainly patients from West and North of the country, the University Teaching Hospital of Butare receives mainly the patients from South. The Rwanda Military Hospital receives patients from Kigali and the East Province. Rwanda Military Hospital is a teaching hospital located in Kigali City managed by Rwanda Ministry of Defense. This hospital receives mostly patients from Kigali City and most of the Eastern region. King Faisal Hospital is the private teaching hospital located in Kigali City. This hospital provides advanced medical treatment in country. The teaching hospitals receive the patients from all the parts of the country.

Trauma patients arrive in the hospitals and are received at emergency department where they receive basic and emergency treatment ~~a~~re followed by specialized treatment in the respective hospitals or referred to the facility where the treatment can be done.

II. 2. Study population:

This study included trauma patients managed in referral hospitals namely Kigali University Teaching Hospital (CHUK), Butare University Teaching Hospital (CHUB), Rwanda Military Hospital (RMH) and King Faisal Hospital (KFH).

a. Inclusion criteria:

This study included patient who had trauma and are admitted in the respective hospitals. We included 16 years old or more patients and full awake with Glasgow Coma Scale of 15/15.

b. Exclusion criteria:

We excluded the patients who were discharge less than 24 hours from admission.

II. 3. Sample size:

We have used the single population proportion formula $n_0=z^2pq/e^2$ where n= the sample size p= estimated proportion present in the population q= 1-p e= desired level of precision. In one study done in Nigeria Agodirin demonstrated that the incidence of pain in pre-operative period was 85% and z at 95CI (1.96). The minimum sample size was estimated to be 196 patients (13). Our study has been done on 375 patients.

II.3. Data collection

We collected data on adult trauma patients who were admitted to teaching hospitals in Rwanda from October 2018 to January 2019.The data were collected by trained medical students. We interviewed patients and used patient file. The data were collected on the questionnaire, hose data were entered in Excel spreadsheet. We put the data into Stata after cleaning.

The data we collected includes demographic characteristics of trauma patients, the pain they experienced in the first 24 hours of trauma, the pain the patient was experiencing at the time for interview using numeric rating scale, the longest time the patient waited for pain medications after requesting for them. We also reviewed the medications for pain the patient took, their side effects and the satisfaction rate for pain management.

We used Injury Severity Score (ISS) which predict the morbidity and mortality in trauma patient(26). The Injury Severity Score (ISS) (Table 1) is calculated from additions of squares Abbreviated Injury Score. Injury Severity has different levels from minor injury to critical injury (Table 2).

Table 1-The Abbreviated Injury Scale (AIS)

Injury	Abbreviated Injury Score (AIS)
Minor	1
Moderate	2
Serious	3
Severe	4
Critical	5
Survivable	6

Table 2- Injury Severity Score (ISS)

Injury Severity Score (ISS)	
1-8	Minor
9-15	Moderate
16-24	Serious
25-49	Severe
50-75	Critical

The Injury Severity Score (ISS) is calculated from additions of squares Abbreviated Injury Score. Injury Severity has different levels from minor injury to critical injury.

We rated the side effects from zero to ten: zero for patient with no side effects and ten the patient with worst side effect then we categorized side effect score into three according to the severity: <4 Mild, 4-6 moderate and >6 Severe.

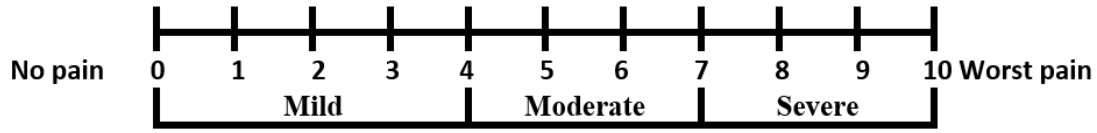

Figure 1- Pain Numeric Scale from 0 to 10

II.4. Statistical analysis

We collected data using data collection sheet, put those data Excel Spreadsheet after clean we exported them to the STATA 14th Edition (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP). We produced prevalence in different characteristics using percentages, we determined the factors associated with satisfaction using Chi-square. The factors with important association ($p<0.25$) were used in multivariate logistic regression analysis to identify independent factors associated with poor satisfaction. Their results were presented by Odd Ratios and their 95% Confidence Intervals and a p value <0.05 was considered as significant.

II. 5. Ethical considerations

The Institution Review Board of the College of Medicine and Health Sciences at the University of Rwanda gave approval for this study then we have got ethical approval in every hospital which participated in the present study: University Teaching Hospital of Kigali and Butare, Rwanda Military Hospital and King Faisal Hospital, Kigali.

CHAPTER III. RESULTS

III.1. Description of sample

In total, 375 trauma patients were included in this study from different four teaching hospitals across the country. Representation of patients from different hospitals is shown in figure 2. The University Teaching Hospital of Kigali had more patients admitted for trauma 200, followed by Butare University Teaching Hospital 91, Rwanda Military Hospital 70 and King Faisal Hospital 11 (Figure 2).

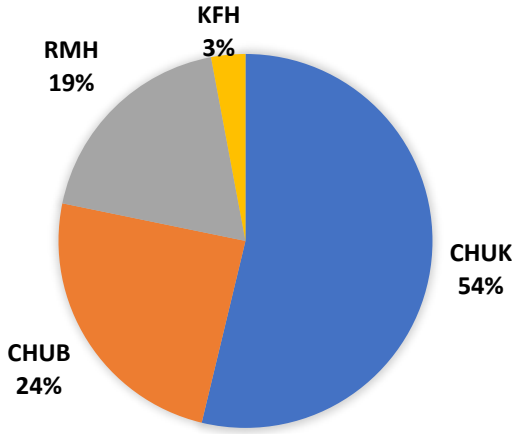

Figure 2- The distribution of trauma patients from different hospitals.

III. 2. Social demographic data

The patients involved in trauma were mainly male (72.7%) than female (27.3%) and most of the patients were between thirty and sixty years (51.8%.) Almost all patients had health insurance (93.3%) and the *Ubudehe* II (36.5%) and III (40.2%) Categories were mostly involved in trauma. The majority of admissions were done using ambulances (89.4%). The majority of patients were not having any chronic illnesses (89.1%). The main cause of trauma was road traffic accidents (55.0% (followed by falling (36.7%) and assaults (8.3%). We used Injury Severity Score (ISS) to grade the severity of injuries of patients who had trauma and found that many were having mild (33.2%) and moderate (43.9%) injuries. Surgery was done already in (71.9%) of all patients, no surgery or plan in (22.5%) and those who were waiting were (5.5%) (Table 3).

Table 3- Demography of patients involved in trauma.

Patient Characteristics	N=375	%
Age		
<30	93	27.7
30-60	174	51.8
>60	69	20.5
Sex		
Female	102	27.3
Male	272	72.7
Ubudehe		
I	57	15.2
II	137	36.5
III	151	40.3
None	30	8.0
Health Insurance		
No	25	6.7
Yes	350	93.3
Mode of admission		
Ambulance	332	89.5
Private transportation	39	10.5
Chronic illness		
No	328	89.1
Yes	40	10.9
Cause of trauma		
Assault	31	8.3
Falling	137	36.7
RTA [a]	205	55.0
Injury Severity Score (ISS)		
Minor	124	33.2
Moderate	164	43.9
Serious	66	17.7
Severe	20	5.4
Surgery done at the time of interview		
No	57	22.5
Waiting	14	5.5
Yes	182	71.9

[a] RTA: Road Traffic Accident

III. 3. Pain Experience in Trauma Patients.

The majority of patients were experiencing mild pain at the time of interview (68.3%), others were having moderate (21.0%) and severe pain (10.6%) (Table 2). The worst pain the first 24 hours from trauma was severe (89.8%) followed by mild (5.9%) and moderate pain (4.3%). The majority (58.5%) of patients waited less than ten minutes pain medications when they asked for pain medications, others received between 10 and 30 minutes (10.9%), 30 to 60 minutes (7.7%), above 60 minutes (9.7%), asked and never received (4.4%) and never asked nor received pain medications (8.8%) (Table 4).

Table 4- Pain Experience in Trauma Patients.

Pain Experienced	N=375	%
Pain grade at time of interview		
Mild	254	68.3
Moderate	78	21.0
Severe	40	10.8
Worst pain score during the first 24 hours		
Mild	22	5.9
Moderate	16	4.3
Severe	335	89.8
Longest time the waited after requesting pain medications		
<=30 minutes	236	76.1
>30 minutes	74	23.9

III. 4. Medications used for pain

Different medications were used for pain management: Paracetamol was the commonest medications to be used (67.7%), followed by tramadol (42.0%), morphine (40.5%), ibuprofen (24.8%) and diclofenac (2.9%). Multimodal analgesia combining opioids and non-opioids pain medications (71.6%), non-opioids alone (14.2%) the same as opioids alone (Table 5).

Table 5- Medications used for pain.

Medications used for pain relief	N=375	%
Acetaminophen	254	67.7
Tramadol	157	42.0
Morphine	152	40.5
Ibuprofen	93	24.8
Diclofenac	11	2.9
Combination of pain medication		
Multimodal analgesia	237	71.6
Non-opioid alone	47	14.2
Opioid alone	47	14.2

III. 6. Patient attitudes towards pain medications

The majority of patients wanted to be relieved from their pain (77.0%), others the willing was depending on severity of pain (19.3%) and few were not willing to have their pain to be relieved (Table 6).

Table 6- Patient attitudes towards pain medications.

Patient willingness for pain relief	N=375	%
No	13	3.6
Depend on severity	69	19.3
Yes	275	77.0

III. 7. Patient satisfaction for pain management

The majority of patients admitted for trauma were satisfied for their pain management. The rate of satisfaction was more than (86%) versus (14%) who were not satisfied for pain relief (Figure 3).

Figure 3- Patient satisfaction for pain management in Trauma Patients

III. 8. Factors associated with pain management satisfaction

We run the bivariate analysis of patient characteristics against the patient satisfaction rate, we found statistically significant patients factors to be the sex of the patient($p=0.057$), the way the patient accessed the hospital ($p<0.001$), the presence of chronic illness($p=0.013$), the time the patient waited for pain medications ($p<0.001$), the pain grade at interview ($p=0.177$), and injury severity score($p=0.205$). Male patients seem more dissatisfied than female and the patients who used their means to reach the hospital are more dissatisfied than those who used ambulance. The patients with chronic illness were more dissatisfied. Those with grade intensity of pain tended to be more dissatisfied. The waiting time for pain medications for longer than thirty minutes was associated with patient dissatisfaction (Table 7).

Table 7- Significant factors for pain management satisfaction.

Significant factors for pain management satisfaction N=375					
Patient characteristics	Not satisfied	%	Satisfied	%	p value
Age					
<30	13	14.0	80	86.0	0.829
30-60	29	16.9	143	83.1	
>60	11	15.9	58	84.1	
Sex					
Female	9	8.8	93	91.2	0.057
Male	45	16.6	226	83.4	
Access to the hospital					
Ambulance	35	10.6	295	89.4	<0.001
Private	18	46.2	21	53.9	
Ubudehe					
None	4		25		
I	9	15.8	48	84.2	0.51
II	24	17.5	113	82.5	
III	17	11.3	133	88.7	
Chronic illness					
No	42	12.9	284	87.1	0.013
Yes	11	27.5	29	72.5	
Most important experienced pain in first 24 hours					
Mild	2	9.1	20	90.9	0.733
Moderate	2	12.5	14	87.5	
Severe	50	14.9	285	85.1	
Pain grade at the interview					
Mild	31	12.2	223	87.8	0.177
Moderate	15	19.2	63	80.8	
Severe	8	20	32	80	
The time the patient waited for medications after requesting for them (minutes)					
<=30	19	8.05	217	92.0	0.001
>30	21	28.4	53	71.6	
Injury Severity Score					
Minor	13	10.5	111	89.5	0.205
Moderate	28	17.2	135	82.8	
Serious	12	18.2	54	81.8	
Severe	1	5.3	18	94.7	

III. 7. Independent factors which lead the trauma patient satisfaction.

Independent predictors to the dissatisfaction on pain management in our trauma patients are the private mode of arrival to the AED compared to the public ambulance, presence of moderate to severe pain at interview and a longer waiting time for pain relief along the hospital stay (Table 8).

Table 8- Factors associated with satisfaction for trauma patients managed for pain.

Factors associated with dissatisfaction for trauma patients managed for pain					
Factors		Satisfied	Dissatisfied	OR [95% CI]	P value
Sex	Female	93	9	Ref	
	Male	226	45	1.95 [0.76-5.05]	0.17
Modality to arrive at AED	Ambulance	295	35	Ref	
	Private	21	18	11.21 [3.96-26.34]	<0.001
Chronic Illness	No	284	42	Ref	
	Yes	29	11	1.60[0.54-4.73]	0.40
Pain at interview	Mild	223	31	Ref	
	Moderate	63	15	2.46 [0.99-6.10]	0.05
	Severe	32	8	4.04 [1.30-12.56]	0.02
Waiting time	=<30 minutes	217	19	Ref	
	>30 minutes	53	21	6.00 [2.60-13.85]	<0.001
ISS	Mild	111	13	Ref	
	Moderate	135	28	1.09 [0.37-2.81]	0.87
	Serious	54	12	1.79 [0.52-5.10]	0.31
	Severe	18	1	0.48 [0.03-4.95]	0.56

Chapter IV. DISCUSSION

In this cross-sectional study we enrolled patients admitted in teaching hospitals for trauma and evaluated their mode of transportation to the hospital, their socioeconomic characteristics, characteristics of pain, modalities of pain relief in the hospital, rates of satisfaction for the pain management and associated factors.

The distribution of trauma patients is concentrated mainly in one hospital located in the capital. This hospital alone received more than half of trauma patients admitted in teaching hospitals (Figure 3).

More than half of the patients received pain medications in less than ten minutes from the time they requested for them. Fosnocht have done a study in United States of America explored factors associated with receiving pain medications and found that the patients were expecting pain medications in 23 minutes from admission, this time was far less than the actual time the patients get pain medications which was more than one hour. This delay in receiving medications leads to poor satisfaction of patients (27).

The most prescribed medications were the combination opioid and NSAIDs or paracetamol (Table 5). The management of acute pain requires more non-steroid anti-inflammatory drugs (NSAIDs) than opioid or acetaminophen (28). In one randomized controlled study done in Netherlands in 2018 showed no big difference in using either acetaminophen, diclofenac or the combination of both in trauma patients (29).

The multimodal approach for pain management was mostly used in trauma patients. The use of multimodal approach for pain control help in reduction of opioids use, improves pain control but also increases patient satisfaction for their pain management (30,31). In our study, the multimodal approach for pain management was not a predictor for patient satisfaction. The multimodal approach for pain control should not be limited to the combination of medications but also should include other techniques like regional anesthesia or peripheral nerve blocks which improve the patient satisfaction (32). The lack of different techniques may be the reason in our study there were no association between pain medications combination and patient satisfaction. In a multicenter cohort study done in Germany found that the combination of different techniques for pain relief lead to better satisfaction of patients undergoing knee arthroplasty(33).

The majority of trauma patients admitted in hospital were satisfied for pain management. This satisfaction is high compared to other studies conducted in high income settings which tried to quantify satisfaction for pain management post trauma (34). The satisfaction may not only be associated with medications but the level of customer care, the health system organization, and availability and affordability of healthcare services and uninterrupted pain relief.

The pain grade at the time for interview was a predictor of dissatisfaction whereas the pain grade in the first 24 hours post trauma was not. These findings were different from those found in one done on surgical patients which showed powerful predictor pain satisfaction to be associated with the worst pain in the first 24 hours post-surgery.

The patients who used the private transport to reach hospitals were more likely to be dissatisfied for their pain relief. One study done in Pakistan compared the use of private and public transport to reach hospitals, the same study found that the patients who used private means to reach the hospital experience more delay (35). One study done in Arizona University in 2002 showed that the reduction in the waiting time leads to improve to patient satisfaction (36). Using private transport to reach the hospital don't necessary means that the patient is rich but

sometimes this may lead to delayed access health facility, the patient without category used less the ambulance to reach the hospital.

This study has different limitations: we sampled patients admitted in teaching hospitals but other patient may have been admitted in other hospitals be public or private and this may have impact on the overall outcome of our study

Chapter V. CONCLUSION AND RECOMMENDATIONS

V.1. Conclusion

Patients with trauma go to hospital or directly to hospitals use their means. There are mild and moderate injuries. The more prescribed was acetaminophen and multimodal approach was commonly used for pain relief. Almost all patients wanted to be relieved from their pain. The pain grade, the use of private means to reach the hospital and the time the patient has to wait for pain relief is significant predictor of patients' dissatisfaction. We need more exploration and interventions to increase the awareness about pain management and establishment of guidelines.

V.2. Recommendations

- **To the patients:**
  - the patients have to know that the pain relief is their right and can request the relief any time they feel pain.
- **To the healthcare providers:**
  - to increase knowledge and skills to provide pain relief for their patients,
  - to document clinical presentation of the patient with pain,
  - to provide different types of pain relief used and their outcomes.
- **To the University:**
  - to teach students about pain, the pathophysiology of pain, the pain relief methods and their complication of poor pain relief,
  - to collaborate with different institutions towards pain free population,
  - to organize of pain medicine education.
- **To the hospitals**
  - to ensure uninterrupted pain relief for every patient reaching the hospital,
  - to put in place a standardized mechanism of assessing and reporting pain,
  - to conduct quality improvement project in pain management
- **To the ministry of health**
  - to put in place and update guidelines about pain management,
  - to avail medications staff, equipment and infrastructure for pain management at every level of healthcare system,
  - to collaborate with different institutions to reduce in accessing pain relief centers.

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Appendices

Appendix 1: IRB Approval

UNIVERSITY OF RWANDA — COLLEGE OF MEDICINE AND HEALTH SCIENCES

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 3rd /04/2018

Dr NIYITEGEKA Joseph
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 082 /CMHS IRB/2018

Your Project Title ***"Pain Management in Trauma Patients in Rwanda: A Prospective Descriptive Study in Rwanda Teaching Hospitals from April 2018 to May 2018"*** has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	No (Reason)	
			Absent	Withdrawn from the proceeding
Prof Kato J. Njunwa	UR-CMHS		X	
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS	X		
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS	X		
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met on 23rd March 2018, **Approval has been granted to your study.**

EMAIL: researchcenter@ur.ac.rw P.O. Box: 3286, Kigali, Rwanda WEBSITE: http://cmhs.ur.ac.rw/ www.ur.ac.rw

Please note that approval of the protocol and consent form is valid for **12 months**.

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 3rd April 2018

Expiration date: The 3rd April 2019

Professor Kato J. NJUNWA
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:
- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

EMAIL: *researchcenter@ur.ac.rw* P.O. Box: 3286. Kigali. Rwanda WEBSITE: http://cmhs.ur.ac.rw/ *www.ur.ac.rw*

Appendix 2: CHUK Approval

CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Quality Health Care
Training & Research

Ethics Committee / Comité d'éthique

August 20th, 2018 **Ref.: EC/CHUK/648/2018**

Review Approval Notice

Dear Dr.Joseph Niyitegeka,

Your research project: ***"Pain management in trauma patients in Rwanda:a prospective descriptive study in Rwanda university teaching Hospitals"***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 20th August 2018 to evaluate your protocol of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your protocol.

You are required to present the results of your study to CHUK Ethics Committee before publication.

PS: Please note that the present approval is valid for 12 months.

Yours sincerely,

ETHICS COMMITTEE CHUK

Dr. Rusingiza Emmanuel
The President, Ethics Committee,

University Teaching Hospital of Kigali<<***University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations***>

B.P. :655 Kigali- RWANDA www.chk.rw Tél. Fax : 00 (250) 576638 E-mail :chuk.hospital@chukigali.rw

Appendix 3: CHUB Approval

CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

CENTRE HOSPITALIER UNIVERSITAIRE DE BUTARE (CHUB)
OFFICE OF DIRECTOR GENERAL

Huye, 04/10/2018

N° Ref: CHUB/DG/SA/09/1731../2018

Joseph Niyitegeka
School of Medicine and Health Sciences

Dear Niyitegeka,

Re: Your request for data collection

Reference made to your letter requesting for permission to collect the data within University Teaching Hospital of Butare for your research proposal entitled **"Pain management in trauma patient in Rwanda: a prospective descriptive study in Rwanda University Teaching Haspitals"**, and based to the different approvals: **No. 082/CMHS IRB/2018** from Institution Review Board of University of Rwanda and **No: RC/UTHB/040/2018** from our Research and Ethics committee, we are pleased to inform you that your request was accepted. Please note that your final document will be submitted in our Research Office.

Sincerely,

Dr. Augustin SENDEGEYA
Director General of CHUB

Cc:

- Director of Education and Research
- HoCSD
- Chairperson of Research Committee
- Research officer

CHUB

E-mail : info@chub.rw
Website: www.chub.rw
B.P : 254 BUTARE
Hotline: 2030

Appendix 4: RMH Approval

REPUBLIC OF RWANDA
RWANDA MILITARY HOSPITAL
Website: www.rwandamilitaryhospital.rw
P.O. Box: 3377 Kigali, Tel: (+250)252586420, Hotline: 4060
Email: info@rmh.rw

September 28, 2018 **Ref.: RMH/IRB/017/2018**

REVIEW APPROVAL NOTICE

Dear **Dr. Joseph NIYITEGEKA**
Department of Anesthesiology
School of Medicine and Pharmacy, CMHS, UR

Your Research Project: **"Pain Management in Trauma Patients in Rwanda: A Prospective Descriptive Study in Rwanda Teaching Hospitals from April 2018 to May 2018".**

With respect to your application for ethical approval to conduct the above stated study at Rwanda Military Hospital, I am pleased to confirm that the RMH/Institutional Review Board (IRB) has approved your study. This approval lasts for a period of **12 months** from the date of this notice, and after which, you will be required to seek another approval if the study is not yet completed.

You are welcome to seek other support or report any other study related matter to the Research office at Rwanda Military Hospital during the period of approval.

You will be required to **submit the progress report** and any major changes made in the proposal during the implementation stage. In addition, you are required to **present the results** of your study to the RMH/IRB before publication.

Sincerely,

Prof. Alex M. Buteera
Colonel
Chairperson Institutional Review Board, RMH

Appendix 5: KFH Approval

KING FAISAL HOSPITAL KIGALI

KING FAISAL HOSPITAL, KIGALI

Patient Centered Care

November 12th, 2018

DR. JOSEPH NIYITEGEKA
Post graduate student
Dept of Anaesthesiology, Critical Care and Emergency Medicine
School of Medicin and Pharmacy
College of Medicine & Health Science (CMHS)
University of Rwanda
Phone: 0788761667
Email: joeniyitegeka@gmail.com

We acknowledge receipt of your study protocol: **"Pain management in trauma patients in Rwanda: A prospective cross-sectional study in Rwanda University teaching hospitals."**

After a thorough review, the reviewers of KFH Ethics Research Committee consider the study important but it needs to be improved to give a true picture of post trauma pain management.

Therefore; it is recommended to the full committee that the researcher should only be permitted to commence work at KFH after responding to the issues raised by the reviewers and depositing the response to the Office of Continuous Quality Improvement.

N.B. It is a requirement that you deposit a final copy of your research in the office of Continuous Quality Improvement in King Faisal Hospital, Kigali for our records.

Best Regards

King Faisal Hospital by OSHEN Healthcare I Rwanda

Prof. Samuel Lutalo
Clinical Professor of Medicine;
Chief Consultant Physician and
Chairperson KFH, K Ethics Research Committee

CC:
- Chief Executive Officer, Oshen- KFH
- All KFH, K Ethics-Research Committee Members.

Appendix 6: Questionnaire

Pain management in trauma patients in Rwanda teaching hospitals

Data collection Sheet Study ID: _____/_____/_____

Date and time (DD/MM/YYYY): ____/___/_____ ____hh___mm

Date of admission (DD/MM/YYYY): ____/___/_____ ____hh___mm

Hospital: CHUK CHUB RMH KFH

I. Sociodemographic characteristics

- Distance travelled to Hospital:
  - Kilometers:____
  - Hours_____
- Date and time of your injury
  - dd/mm/yyyy __/__/___ hh__mm
- Origin (select all that apply):
  - □Home
  - □SAMU
  - □Road
  - □Health Center
  - □District Hospital
  - □Provincial Hospital
  - □Referral Hospital
  - □Other (specify)
- Refereeing health facility name:_____
- Gender: Male__Female__
- Birth date (dd/mm/yyyy)___/__/____
- Marital status:
  - □Single
  - □Married
  - □Divorced
  - □Widow
  - □Living together
  - □Separated
  - □numbers of children
    - Ages of children__ __ __
- Education status
  - □No formal education
  - □Primary school
  - □Secondary school
  - □High institutions(University, College…)

- Ubudehe Category:

- occupational status
  - □Unemployed
  - □Employed
  - □Self-employed
  - □Financially dependent eg:student,…
- health insurance coverage
  - □Self-payer
  - □Private insurance coverage
  - □RSSB (Former RAMA)
  - □RSSB (Former MUSA)
- Degree of the condition of the disease
  - □Emergency (Managed Now)
  - □Urgency(can wait 24 hours)
- Department or service
  - □Emergency
  - □Surgery
  - □Internal medicine
  - □Intensive Care Unit
  - □Ear Nose and Throat (ENT)
  - □Ophtalmology
  - □Somatology
  - □Others (specify)

Traumatized by

□Bicycle

□Car

□Motorcycle

□Falling from height

□Assault

□Burn: electrical, fire, others (specify)

□Other….

Clinical presentation

- Chief Complaint:
- History of the present illness(3lines)
- Past medical histor

Medications the patient is taking

Name	Dosage	Frequency	Route	Start time*	End Time*	**Adverse Effects	***Prescribed

**For starting and end time precise the date and hour and min of start and anticipated ending*
*** For side effect: State the side effect, the date and time, measure taken if any*
*** Yes or not if prescribed by medical doctor*

- Have you had any of the following **side effects**? Please circle "0" if no; if yes, please circle the one number that best shows the severity of each:

a. Nausea
0 1 2 3 4 5 6 7 8 9 10
None Severe

b. vomiting
0 1 2 3 4 5 6 7 8 9 10
None Severe

c. Drowsiness (sleepy)
0 1 2 3 4 5 6 7 8 9 10
None Severe

d. Itching
0 1 2 3 4 5 6 7 8 9 10
None Severe

d. Dizziness
0 1 2 3 4 5 6 7 8 9 10
None Severe

Investigation	Order date	Examination date	Results

I**nvestigations**

- Summary of clinical assessment
- Summary of investigations done and finding
- Differential diagnosis
- Definitive diagnosis
- Management done
- Management anticipated
- Surgery done or planned: Yes__No__Date and time: ___/___/___ ___hh__mm
- Type of anesthesia: General__ Spinal__ Regional__ Local__None___ others(specify)_____

II. **Pain assessment**

- When your pain started? Date&Time__/_/__ __/__

- Describe how your pain started
- What are you believing is causing pain?
- What can you do if you pain reduced by half?
- How pain is affecting your life?
- Describe your pain (cicle):
  - Aching, throbbing, sharp, hot, cold, etc
- describe your pain : Brief constant__comes and goes___ continuous___
- What do you do to ease your pain?
- What makes your pain worse?
- What is the treatment you believe can alleviate your pain?
- Describe the activities you can't perform because of pain?
- Does the pain irradiate somewhere else except primary site

  □Yes, specify

  □No

Pain intensity rating

- On this scale, please indicate the least pain you had in the first 24 hours since trauma

0 1 2 3 4 5 6 7 8 9 10
No pain Worst Pain Possible

- on this scale, indicate the worst pain you had in the first 24 hours since trauma

0 1 2 3 4 5 6 7 8 9 10
No pain Worst Pain Possible

- How often were you in **severe** pain in the first 24 hours? Please circle your best estimate of the percentage of time you experienced severe pain:

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
Never In severe pain always in severe pain

- Circle the one number below that best describes how much pain interfered or prevented you from:

A. doing activities in bed such as turning, sitting up, repositioning,…

0 1 2 3 4 5 6 7 8 9 10
Doesn't interfere Completely Interfere

B. Doing activities out of bed such as walking, sitting in chair, sitting on bed or going to toilet

0 1 2 3 4 5 6 7 8 9 10
Doesn't interfere Completely interfere

C. Falling asleep

0 1 2 3 4 5 6 7 8 9 10
Doesn't interfere Completely interfere

D. Staying asleep

0 1 2 3 4 5 6 7 8 9 10
Doesn't interfere Completely interfere

- Pain can affect our mood and emotions. On this scale, please circle the one number that best shows how much the pain caused you to feel:

a. anxious

0 1 2 3 4 5 6 7 8 9 10
not at all Extremely

b. depressed

0 1 2 3 4 5 6 7 8 9 10
not at all Extremely

c. frightened

0 1 2 3 4 5 6 7 8 9 10
Not at all Extremely

d. helpless

0 1 2 3 4 5 6 7 8 9 10
Not at all Extremely
At all

III. Patient attitude towards pain management

- Identified barriers to administration of medication for pain management
  - □ fear of adverse effects
  - □ Fear of addiction potential
  - □ Fear of additional dose
  - □ Fear of intolerance
  - □ Fear of injections
  - □ Others (specify)
- Generally, when you're in pain would you like to be treated
  - □ Yes
  - □ No
  - □ Depend on severity
- Was your pain assessed before start of pain medications?
  - □ Yes
  - □ No
- Did a healthcare provider discussed with you pain management?
  - □ yes
  - □ Yes, but not sufficient
  - □ No though I wanted to know
  - □ No and I don't want to know
- Did health care provider asked you to report when you have pain?
  - □ yes
  - □ Yes, but not sufficient
  - □ No though I wanted to know
  - □ No and I don't want to know
- Were you informed when your pain medicine where about to be administered
  - □ yes
  - □ No
  - □ Not consistent

- What was the longest time you had to wait to get a pain medication after asking for it
  - □ < 10 min
  - □ 10-30 min
  - □ 30-60 min
  - □ >60 min
  - □ Asked but never received medication

Appendix 7: Consent form in English

University of Rwanda
College of Medicine and Health Sciences
School of Medicine and Pharmacy
Department of Anesthesiology, Critical Care Medicine
and Emergency Medicine

Informed Consent form for participation in study called: pain management in trauma patients in teaching hospitals in Rwanda

This consent form is for adult trauma patients presenting at the following teaching hospitals: Kigali University Teaching Hospital, Butare University Teaching Hospital, Rwanda Military Hospital and King Faisal Hospital, Kigali

PI: Joseph Niyitegeka Anesthesiology Resident in University of Rwanda
Supervisor: Dr. Paulin Ruhato Banguti

Introduction

I am Joseph Niyitegeka, anesthesiology resident in department of Anesthesiology, Critical Care and Emergency Medicine, school of medicine and pharmacy, college of medicine and health sciences, University of Rwanda. I am conducting this study under supervision of Dr. Paulin Ruhato Banguti.

We know that the pain is most common cause of consultation in hospitals, this project will focus on trauma patients in teaching hospital in Rwanda. We will look specifically how pain is assessed in trauma patients, how it is managed and the perception of the patients from the management. The data will be collected from interviews and from the patient records after the later consented to participate in this study. During our data collection we will keep anonymous the data so that none will link the provided data to the patients. This study will give us the baseline and recommendations for management of trauma patients.

Your participation in this research is entirely voluntary, you can participate or refuse to participate without any consequence to you and it will not affect how you are treated. You may also withdraw from the study at any stage of this study.

This study will take from you about fifteen minutes and will not interfere with the treatment you are receiving. This study doesn't have any risks as there no special interventions planned to be done on you.

This study have been presented and accepted at the college of Medicine and and Health Sciences Institution Review Board (IRB), in case you fill that you are right are abused or need further clarifications you are allowed to contact the principle investigator (Dr. Jospeh Niyitegeka 0788761667), the supervisor of the study and head of department (Dr. Paulin Ruhato Banguti 0788772114) or the Chair of IRB Committee at the College of Medicine and Health Sciences.

Certificate of Consent

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 to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____
Date _____
Day/month/year

If the patient cannot sign consent him/herself a caretaker can approve the consent as below

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.
Print name of witness_____
Signature of witness _____
Date _____
Day/month/year

Statement by the researcher/person taking consent

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.
Print Name of Data collector_____

Signature of Data Collector _____
Date _____
Day/month/year

Appendix 8: Consent form in Kinyarwanda

University of Rwanda
College of Medicine and Health Sciences
School of Medicine and Pharmacy
Department of Anesthesiology, Critical Care Medicine
and Emergency Medicine

Amasezerano yo kwemera kuba mu bushakashatsi: Pain managment in trauma patients in teaching hospitals in Rwanda

Uru rupapuro rugaragaza amasezerano areba abantu barwaye bivuriza kubitaro bikurikira: Ibitaro bya Kaminuza bya Kigali, Ibitaro bya Kaminuza bya Butare, Ibitaro by' Igisirikari cy' u Rwanda, Ibitaro byitiriwe Umwami Faisal, Kigali

Umushakashatsi Mukuru: Joseph Niyitegeka, umunyeshuri mukinya murk Kaminuza y' u Rwanda
Uhagarariye Ubushakashatsi: Dr. Paulin Ruhato Banguti

Intangiriro
Nitwa Joseph Niyitegeka, Umunyeshuri mu Kinya muri Kaminuza y u Rwanda, ubu bushakashatsi ndikubukora nyobowe na Dr. Paulin Ruhato Banguti

Tuzi ko ububabare aribwo buza kumwanya wambere mugutma abarwayi bagana ibitaro, tuzareba abarwayi baba bakomeretse. Tuzareba ahanini abarwayi bakomeretse uburyo basuzumwa n' uburyo bavurwa. Tuzareba kandi uburyo abarwayi bakira imivurire y ububabare. Tuzavugana n' abarwayi turebe no muri dosiye zabo. Ntamazina tuzatangaza mubushakashatsi cyangwa icyatuma hamenyekana uwatanze amakuru muri ubu bushakashatsi. Ubu bushakashatsi buzatuma tuvugurura ubujyo tuvura ububabare.

Kuba muri ubu bushakashatsi ni kubushake, ushoboza kububamo cyangwa ukabureka kandi ntangaruka kumivurirwe yawe. Ushobora kandi kuva muri ubu bushakashatsi igihe burimo bukorwa igihe icyaricyo cyose ubishatse.

Gusubiza ibibazo biri muri ubu bushakashatsi bizatwara iminota cumi n'itanu kandi nibuzagongana no kwivuza kwawe. Ntangaruka ziteganijwe cyangwa ibizakorwa bidasanzwe kuri wowe binyuze muri ubu bushakashatsi.

Ubu bushakashatsi bwerekanwe kandi bwemezwa n ishami rishinzwe kwemerera ubushakashatsi mu ishuri ry' ubiganga n' ubuvuzi muri Kaminuza y' u Rwanda.

Ugize ikibazo, ushaka ubusobanruro cyangwa wumva uburenganzira bwawe buhungabanyijwe wakwiyambaza umushakashatsi mu kuru (Dr. Jospeh Niyitegeka 0788761667), Uhagarariye ubushakashatsi (Dr. Paulin Ruhato Banguti 0788772114) cyangwa uhagarariye komite yemerera gukora ubushakashatsi mu ishuri ry' ubuganga n' ubuvuzi muri Kaminuza y' u Rwanda.

Amasezerano

Nasomye cyangwa nasomye amakuru ari muri ubu bushakashatsi. Nahawe umwanye wo kubazag ibibazo no kubisubiza Kandis nanyuzwe.

Nemeye kubushake kuba muri ubu bushakashatsi

Amazina_____
Umukono_____
Itariki _____
Umunsi/Ukwezi/Umwaka

Igihe umrwayi atabasha kwisinyira muri ubu bushakashatsi umurwazawe azabimushamo mubujyo bukurikira

Nakurikiranye isomwa ry' aya masezerano kandi Umurwayi wanjye yabajije ibibazo arasubizwa kandi yemera kububamo.

Amazing y' umurwaza_____
Umukono _____
Itariki_____
Umunsi/ukwezi/Umwaka

Umushakashatsi

Nemeje ko Umurwayi cyangwa umurwaza yahawe umwanya wo kubaza ibibazo kuri ubu bushakashatsi kandi byasubijwe.
Ntategeko cyangwa agahato byakoreshejwe mukwemera kuba muri ubu bushakashatsi. Umurwayi yemeye kuba mubushakashatsi kubushake.
Umushakashatsi_____
Umukono _____
Itariki_____
Umunsi/Ukwezi/Umwaka