CLINICAL DIAGNOSIS VERSUS AUTOPSY FINDINGS IN TRAUMA PATIENTS WITH MUSCULOSKELETAL INJURIES MANAGED AT THE KENYATTA NATIONAL HOSPITAL

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DEDICATION

This study is dedicated to the patients of Kenyatta National Hospital for whom the doctor is their voice and have entrusted their lives to the healthcare workers of the hospital.

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LIST OF ABBREVIATIONS

NTSA	National Transport and Safety Authority
KNH	Kenyatta National Hospital
WHO	World Health Organization
ISS	Injury Severity Score
RTS	Revised Trauma Score
NTSS	New Trauma Severity Score
TRISS	Trauma and Injury Severity Score
ICU	Intensive Care Unit
A and E	Accident and emergency
HDU	High Dependancy Unit
RR	Relative Risk

ABSTRACT

Background

Trauma is the leading cause for patients needing orthopaedic care in the accident and emergency department at The Kenyatta National Hospital and hence requiring admission. Globally, Trauma accounts for one tenth of the total burden of disease with the most catastrophic outcomes occurring in developing countries. The World Health Organization in its outline on trauma management and establishment of trauma centres emphasizes on the importance of understanding the trauma patterns as an effort to improve the care given to these patients and guide policy making.

To this date, no study has been done locally correlating the clinical diagnosis to autopsy findings of trauma patients. Subsequently, there is inadequate evidence based interventions that have been made towards improving the outcomes of trauma patients in Kenya at the Kenyatta National Hospital.

Aim: The aim of this study was to correlate the clinical diagnosis to the findings at autopsy for trauma patients with musculoskeletal injuries managed at The Kenyatta National Hospital.

Methodology

Prospective cross sectional study at the Kenyatta National Hospital where the clinical diagnosis of polytrauma patients with musculoskeletal injuries was be recorded, and mortalities followed to autopsy at the Kenyatta National hospital mortuary. Patients who presented with severe injuries and managed by the orthopaedic team but die in the accident and emergency department or in the Intensive care unit/High Dependency Unit were also be followed through and included in the study.

Statistical analysis

Data was collected using a data collection form which included the admission diagnosis and the autopsy findings. It was then exported to STATA 15 statistical software for further analyses. The descriptive statistics used to summarize the data included median, frequencies, proportions, and percentages. The inferential statistics used include Cramer's V test for correlation between categorical variables and logistic regression was used to produce relative risk (RR) ratios, confidence intervals and probability value (p-value). The hypothesis testing was done at 95% confidence interval.

Results

The study found that there was some discrepancy between clinical diagnosis and autopsy findings for patients with musculoskeletal injuries managed at The Kenyatta National Hospital. Head injury and femur fracture were the most prevalent injuries identified. A total number of 40 patients were investigated in the study 29 of which were males and 11 females.

Cramer's V correlation analysis showed that there was a strong positive statistically significant correlation ($p<0.05$) between diagnosis and autopsy results for patients with spinal injury; Essentially these patients succumbed to the injuries sustained.

A moderate statistically significant correlation ($p<0.05$) between diagnosis and autopsy results for pelvic fracture, head injury, and pulmonary embolism; and a low statistically significant correlation ($p<0.05$) between clinical diagnosis and autopsy results for blunt chest injury. However, there was no statistically significant correlation ($p>0.05$) between clinical diagnosis and autopsy results for rib fractures and humerus fractures. The study found that the most common causes of death among patients with musculoskeletal injuries was head injury (32%), pulmonary embolism (20)% and blunt chest injury (17%). . These are the patients who need further investigations to guide improvement of care to the injured patient. These findings were similar to other studies conducted in a similar setup((1).

CHAPTER 1: INTRODUCTION

1.1 Background

Trauma and polytrauma is the biggest indication for admission and emergent surgery at the Kenyatta National hospital. Kenya being a developing nation, has a poor public transport infrastructure with gross oversight on safety regulations. Despite this, the vast majority of the population depend on this informal and poorly managed and regulated transport system. This in turn exposes its populace to motor vehicle crashes causing mortality and morbidity which would otherwise have been avoided.

Statistics from the National Transport Safety Authority (NTSA), show that the number of accidents is on the rise (2). The number of patients admitted with multiple injuries some of whom succumb to their injuries is also on the rise and subsequently the burden of morbidity and mortality secondary to motor vehicle crashes is increasing at an alarming rate (2).

A significant number of patients sustain multiple injuries from other mechanisms of injury, largely in the domestic setup more so in the low-income dwellings. In this setup, patients present to hospital with injuries sustained after fall from a height, either accidentally, intentionally, or as a result of domestic violence. Negligence on the part of caregivers to children or construction building collapse due to lack of adherence to the building codes in the highly populous and low socioeconomic areas also contributes significantly to the morbidity and mortality associated with trauma.

Kenyatta National Hospital (KNH) is the largest National referral hospital in the region and handles a multitude of patients from different disciplines amongst them trauma and polytrauma. Patients who sustain any form of injury to the musculoskeletal system are admitted to the orthopaedic wards. KNH was chosen as it is centrally located in the greater Nairobi metropolis and receives patients through its Accident and Emergency department 24 hours a day. The hospital has 50 wards and 24 operating theatres with a total bed capacity of 1,804. It also serves as a general hospital for the more than four million inhabitants of Nairobi. In addition, being a publicly run institution, it is fairly affordable to the general populace and patients contributing to the National Health Insurance Fund are covered to receive full treatment and no extra costs.

1.2 Problem Statement

Kenyatta National Hospital is the apex hospital in Eastern and Central Africa, it is located centrally in the capital city of Kenya, and receives a vast majority of polytrauma patients most of whom have been in involved in motor vehicle crashes, falls from height, domestic violence and gunshot wounds (1).

Until now, there is no established trauma surveillance system in KNH and the country at large. Most of the trauma patients admitted with fractures, and are hosted in the orthopaedic wards some of whom have injuries to other systems and cor-morbidities. However, a significant number of patients who have sustained musculoskeletal injuries with concomitant head injury, blunt chest injury and blunt abdominal injury are also admitted to the orthopaedic wards. In other instances, patients with moderate to severe head injuries who would benefit from ICU/HDU, General Surgical or Neurosurgical ward care are admitted to the orthopaedic wards. This has been postulated to affect the clinical outcomes and affect the morbidity and mortality associated with trauma to these patients.

Much emphasis has been put on Advanced Cardiac Life Support training and is a requirement for employment at the KNH, however, Advanced Trauma Life Support training has taken a backseat in the hierarchy of qualifications prior to employment at the KNH. Perhaps this is beginning to take a toll on the management of trauma patients.

There has been no attempt to correlate the clinical diagnosis and the autopsy findings as an effort to improve care for the injured patient. The World Health organization advocates for creation of trauma surveillance systems of which the first step is to establish the causes of death for trauma patients. This study aims to do so. More so, some patients admitted in the orthopaedic wards would have benefitted from care in other wards prior to orthopaedic intervention. Other patients require a multidisciplinary approach which would have better been achieved in a different ward.

1.1Research Question and Objectives

1.1.1 Research Question

What is the correlation between the clinical diagnosis and autopsy findings in trauma patients presenting with musculoskeletal injuries and end up as mortalities in Kenyatta National Hospital.

1.1.2Study Objectives

Broad objective

To correlate clinical diagnosis at admission vs the autopsy findings of trauma patients with musculoskeletal injuries at the Kenyatta National Hospital.

Specific objectives

I. To describe the clinical diagnosis of trauma patients managed at the Kenyatta National Hospital (KNH).
II. To determine the causes of death in trauma patients with musculoskeletal injuries managed at KNH.
III. To document the autopsy findings in trauma patients managed at the KNH.
IV. To correlate the clinical diagnosis of trauma patients and the findings at autopsy.

1.2 Study Justification

Despite advances in trauma care, improvement in human resource of health care workers and facilities, trauma is still a leading cause of death. In the Kenyatta National hospital, the orthopaedic wards located on the sixth floor of the hospital host trauma patients most of whom have multiple injuries to other systems (3).

Currently the hospital lacks in protocols regarding anticoagulation of immobilized patients, and is still streamlining the admission protocols for multiple injured patients. Spinal cord injury is also a major cause of mortality, either due to thrombosis, multiple organ failure or sepsis as a result of decubitus ulcers. There has been no study correlating autopsy findings to the clinical diagnosis of patients in the orthopaedic wards at The Kenyatta National Hospital (3).

In addition, patients in ICU who sustained polytrauma more often than not are left to the ICU team or lost to follow up. Other patients with significant polytrauma die within the first two hours of presentation at the accident and emergency department despite emergent care. There has never been a study to correlate the clinical diagnosis to the autopsy findings of such patients.

Prof Saidi et al in his Thesis on Major injury cases in Nairobi: characterization of contexts, outcomes and injury documentation concluded that a trauma registry has proven to be accurate and served as a tool for uncovering trauma trends in trauma care and improving quality of trauma care (4). This study in part serves as a basis for the initial development of a trauma registry at the Kenyatta National Hospital and the first of its own in the country of Kenya.

In essence, this study will unravel the gaps in trauma care, and highlight the areas that need emphasis and improvement to better the outcomes and reduce mortality of trauma patients managed at Kenyatta National Hospital.

1.2.2 Expected intervention

In light of the above, the researcher planed to collect data, analyse this data, and came up with recommendations towards the improvement of trauma care to the patients managed at KNH. It was expected that the problems highlighted wouldl be resolved by the recommendations at the end of this study. These solutions included recommendations of study protocols, recommendations for increased investment in hospital equipment and human resource, and further training of personnel who handle trauma patients in ATLS protocols. It is also

recommended that autopsy findings should form an integral part of quarterly mortality and morbidity meetings done at KNH.

1.3 Way Forward

Considering the current trends across the globe and the evident benefits of autopsy for trauma patients, it is imperative that we first set our standards. WHO has already laid out the guidelines towards a trauma registry. The first step is documenting and critically analysing the cause of death for trauma patients in the pre-existing setup. With this information, retrospective analysis will lead to identification of gaps in the management of trauma patients which then can inform policy, budgeting and funding.

Identification of these gaps in patient management, will allow for clinicians to address the specific issues this leading to improvement of care for the injured patient. Thus, this study will form a foundation for further studies and development of trauma registries.

CHAPTER TWO: LITERATURE REVIEW

The musculoskeletal system consists of muscles, tendons, bones, ligaments, intervertebral discs and their respective arterial blood supply and venous drainage. The musculoskeletal system is the primary site of action for an orthopaedic surgeon (5). Injuries may be isolated musculoskeletal injuries, or may involve other systems in the body, which require a multidisciplinary team in management of the patient. However, musculoskeletal is primarily orthopaedics.

Polytrauma as defined by Buschman et al. is a trauma pattern with an injury severity score of greater than 16 points with injury to more than two systems amongst which at least one is life threatening (6). This has been associated with a mortality rate of 23% in the western world. Severe injury is the leading cause of death in children adolescents and young adults in the North Americas and Europe.

An autopsy is defined as a post-mortem dissection of a dead human body in order to determine the cause, seat, or nature of disease or injury and includes the retention of tissues customarily removed during the course for evidentiary, identification, diagnostic, scientific or therapeutic purposes (7). Very few studies have been done in the Kenyan setting with regard to polytrauma and subsequent autopsy findings. Prof Saidi et al., in a thesis on major injury cases in Nairobi: characterization of contexts, outcomes and injury documentation published in August 2016 reported that the few studies done in Kenya suggested an escalation problem associated with high injury and associated mortality rates (4).

Subsequent studies done by authors in Kenya and Sub-saharan Africa have depended largely on data from police traffic departments which often has been shown to over represent pedestrian casualties and lack proper clinical diagnosis or provide misleading clinical data as determined by Ogendi et al. in a paper published on the pattern of pedestrian injuries in the city of Nairobi in 2011 (8). Data from police departments is insufficient, as it labels injuries as fatal(immediate death),severe(needing hospitalization), and mild(not needing hospitalization) described by prof Saidi et al. (4). This broad and inadequate classification of injuries fails to give a clear picture of the burden on mortality and morbidity caused by trauma and is thought to have a profound impact on resource allocation at the policy making. In his paper, Ogendi et al. brought into the foreground the fact that there is very little published research work detailing the types of road crashes and providing details on the type of pedestrian injuries sustained. He

however did not determine the cause of death for fatalities involved in these accidents after autopsy.

Other attempts at defining the morbidity and mortality caused by trauma in Kenya were done in a private facility by Gichuhi et al. who conducted research at The Nairobi hospital on the pattern of injuries sustained by pedestrians involved in road traffic crashes. The site of the study was however limiting as the private facilities cater to a very small percentage of Kenyans who have access to private health insurance or are able to meet the high financial costs of private healthcare thus it was not a true representation of the trauma associated mortality and morbidity in Nairobi.

Buschman et al. declared that autopsy is the gold standard to define the cause of death in trauma fatalities depending on the patients' pre-existing condition, the mechanism of injury and need for cardiopulmonary resuscitation (6). In the same publication, Buschman et al. emphasized the need for autopsy as part of trauma registries as a quality assessment tool. In the recent times, many scoring systems and guidelines have been developed for improving the quality of treatment in polytrauma patients. A good example is the Advanced Trauma Life Support program which was developed as an effort to improve and standardize the quality of care given to trauma patients. As part of the trauma quality assurance system, autopsy reports are used and should be used to evaluate the quality of care given at any centre tasked with care of trauma patients (6).

Trauma registries provide data on all injuries and outcomes in a centre. Trauma registries provide information that is analysed, both for quality assurance of the trauma management protocols but also to detect areas where intervention is needed towards improving the outcomes of patients involved in trauma. No such registry exists in Kenya for routine trauma surveillance (4).

Hospital reports in towns and cities outside Nairobi have put road traffic incidents and interpersonal violence to be the highest causes of trauma in the country. In the western part of the country, at The Jaramogi Oginga Hospital in Nyanza, the leading cause of visits to the hospital was due to road traffic accidents(41%), followed by assault at 16%(4). Previous authors have analysed the available data and concluded that majority of the road traffic accidents involve the so called vulnerable road users who are pedestrians, cyclists and passengers of the largely informal public transportation system. This coupled with the poor

enforcement of road traffic rules puts these groups at increased risk of injury from road traffic crashes.

At the global level, although trauma has largely been labelled as a disease of the young, recent advances in the management of diabetes, cardiovascular disease and cancer have seen a healthier and more mobile elderly population making them susceptible to incidents of trauma and increasing their visits to the emergency department. Injuries and violence are a major public health problem and account for about 5 million deaths in the world yearly. It is quoted by The World Health Organization(WHO) that about 90%of these deaths occur in the middle and low income countries (9). In spite of this, data to systematically monitor management and case fatalities of these deaths is still scarce in majority of the low and middle income countries, worse in sub-Saharan Africa. In this regard, the World Health Organization published a manual primarily intended for professionals working in institutions responsible for the collection, compilation and use of mortality data for public health action (9). The manual is applicable to all countries but catered more so for low and middle income countries that lack a formal civil registration or only have a skeleton system of documentation that is insufficient in the quality and quantity of information captured (10). The WHO came up with a step by step surveillance system in this manual. The manual was designed to help low to middle income countries as well as developed nations monitor, improve and report deaths as a result of trauma in their countries. It is a vital tool in terms of quality assurance in management of trauma (11).

It must be noted however, that there is a significant difference between countries with regard to the obtainability and the quality of mortality data available. The largest source of national mortality data in Kenya is;

- Verbal autopsy
- Vital registration systems

Civil registration and vital statistics systems are registers used by governments to record events such as birth, marriages, deaths, divorces, and foetal deaths. The aim is to generate statistics on the dynamics of populations and indicators of health on a continuous basis at the national level for a country but also at administrative subdivisions (9). The statistics generated from these registers are used in policy formulation and division of resources to the populace. Verbal autopsy is used extensively in regions where there is no medical certification of deaths either due to lack of qualified human resource or places where it is too remote for routine access of medical personnel. In the middle and low income economies, mortality data is sometimes

collected through community based reporting systems (12). In these cases, the care givers give information on the deceased about the signs and symptoms prior to his/her death which is extrapolated to infer a cause of death.

Table 1: Leading causes of death, 2004 versus 2030

2004		2030	
1	Ischaemic heart disease	1	Ischaemic heart disease
2	Cerebrovascular disease	2	Cerebrovascular disease
3	Lower respiratory infections	3	Chronic obstructive pulmonary disease
4	Chronic obstructive pulmonary disease	4	Lower respiratory infections
5	Diarrhoeal diseases	5	Road traffic crashes
6	HIV/AIDS	6	Trachea, bronchus, lung cancers
7	Tuberculosis	7	Diabetes mellitus
8	Trachea, bronchus, lung cancers	8	Hypertensive heart disease
9	Road traffic crashes	9	Stomach cancer
10	Prematurity and low birth weight	10	HIV/AIDS
11	Neonatal infections*	11	Nephritis and nephrosis
12	Diabetes mellitus	12	Suicide
13	Malaria	13	Liver cancer
14	Hypertensive heart disease	14	Colon and rectum cancer
15	Birth asphyxia and birth trauma	15	Oesophagus cancer
16	Suicide	16	Homicide
17	Stomach cancer	17	Alzheimer and other dementias
18	Cirrhosis of the liver	18	Cirrhosis of the liver
19	Nephritis and nephrosis	19	Breast cancer
20	Colon and rectum cancer	20	Tuberculosis
22	Homicide		

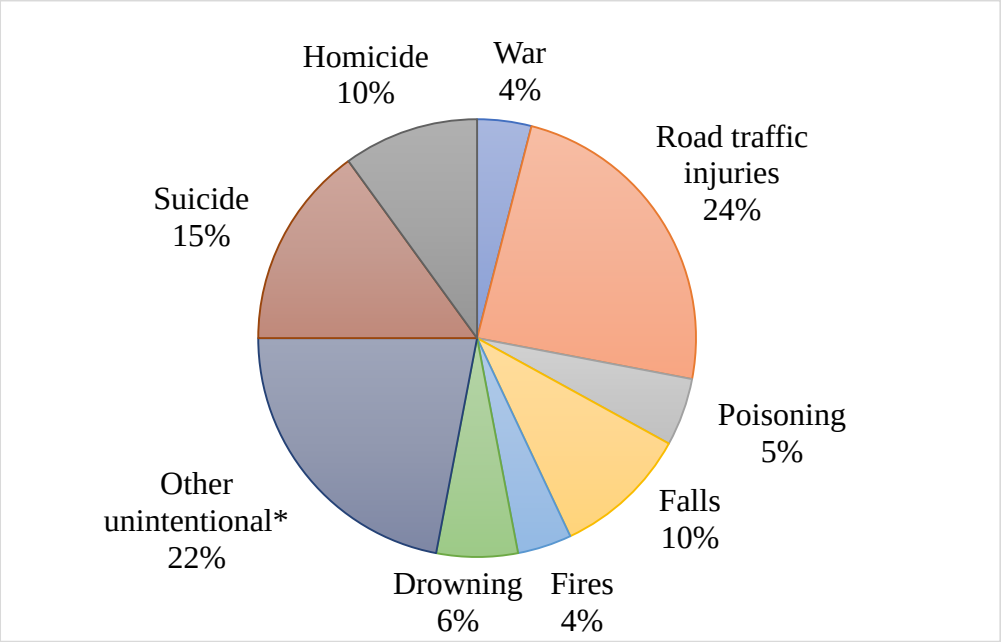
* Comprises severe neonatal infections and other, non-infectious causes arising during the perinatal period.

Furthermore, it has been noted by the WHO, that with increase in industrialization, economic growth and population, mortality caused by trauma is projected to rise from the 9th leading cause of death in 2004 to the 5th leading cause of death in 2030 after lower respiratory tract infections as presented in the table 1.1 above (10).

2.1 Fatality as a result of trauma

Injuries are classified into two broad categories, which are intentional and Unintentional. Intentional deaths include interpersonal violence, self-harm, civil insurrection, war or legal action for countries enforcing the death penalty. Unintentional deaths include burns, falls drowning, road traffic accidents or deaths of undetermined intent (9).

The pie chart that follows (figure 1.1) represents the percentage of deaths as a result of the different causes as defined by WHO (9).



* Other unintentional includes injury causes such as smothering, asphyxlation, choking, animal and venomous bites, hypothermia and hyperthermia as well as natural disasters

Figure 1: Proportion of world injury mortality by mechanism of injury, 2008

2.1.1 Timing of Death in Traumatology

The timing of death related to trauma as described by Baker and Trunkey et al. as having a trimodal distribution with three peaks defined by time. By this, the authors divided the timing of death as a result of trauma, whether intentional or unintentional as immediate, early or late deaths (13). Each is described as follows;

- Immediate deaths- Which is described as death occurring before the patient has been evacuated to a capable hospital e.g. death occurring instantly at the scene of a motor vehicle crash or within 1 hour of arriving at the hospital injury, or deaths occurring at

the emergency department. This formed the basis of the "golden hour" in emergent care.

- Early deaths- Which are described as those occurring within 24 hours of arriving at the hospital excluding immediate deaths. These are as a result of severe injuries but patients were treatable with prompt care.
- Late deaths - these are deaths occurring after the first 24 hours to weeks after the initial trauma

Backer and Trunkey et al. noted that over time the rates of late deaths were decreasing over time in contrast to the former death rates which remained fairly constant at 30% for early deaths and 50%-60% in the immediate deaths. This was in cognisance that the constant rates were despite all progress made in emergency medical services and trauma systems(14), prehospital care, injury prevention and automotive safety.

In a study done between 1991 and 1993 Mullins et al. reported an in-hospital mortality rate of less than 1 percent in Medicare hospital in the United States. In addition, he noted a 30 day mortality of trauma patients between 1.9% to 2.3% (15). A meta-analysis of studies within the same time frame at different centres, showed a higher risk of mortality in post-traumatic patients post discharge from hospital.

The table below were findings made by Backer and Trunkey et al. in the tri-modal model (15).

Table 2: Cause of Death by Timing Category

Immediate and early deaths	Late deaths	Postdischarge
Brain injury	Infection	Cardiovascular disease
Hemorrhage	Multiple-organ failure	Second major trauma
	Brain injury	Neurologic disease
	Hemorrhage	Malignancy

2.1.2 Injury Scoring Systems

The assessment of injury sustained from external trauma is vast and continuously evolving. Patients with fatal injuries needing intensive care treatment after major surgery to the head, chest or abdomen are classified as major injury. The American College of Surgeons developed a system of measuring the severity of injury caused by external factors (12).

The injury severity score (ISS) is a scoring system based on the anatomy of patients with multiple injuries. This scoring system has been widely used and has been in use for the longest time compared to the other injury scoring systems. It has been shown to have a good correlation to the length of hospital stay, morbidity and mortality(16).

The injury severity score is derived from the Abbreviated Injury Scale(AIS) which is also anatomical and divided the body into the following six body regions; head/neck, face, chest, abdomen, extremity, external/skin. Each injury is ranked on a scale of one to six(17). The injury severity score is obtained by summing the squares of the three highest AIS score from different regions. The range of the score is between 1 to 75. If any of the three scores is 6, then the ISS score is set at the maximum as a score of 6 is deemed not survivable(4).

An injury severity score of 1-9 is categorized as a minor injury, score between 10-15 are moderate injuries and scores greater than 25 are critical injuries(18). It has been noted that the mortality associated with trauma correlates with increase in the Injury Severity Score and a study by Boyd Tolson et al. done in the US reported that mortality increases by at least 10% for ISS above 15 (4).

The major setback of the ISS was that it only considered one injury per body region. This led to severe injuries being overlooked and attention being drawn to less severe injuries in other body regions being included in calculating the overall injury severity score.(19) Hence, to counter this, a modification to the ISS was done by Osler et al. in 1997. He developed the New Injury Severity Score (NISS). The NISS is calculated by summing the squares of the three most severe injuries regardless of the body region (12).

Other physiological injury severity scoring systems were developed which showed greater inter-observer reliability and greater accuracy when predicting morbidity and mortality. One such scoring system is the Revised Trauma Score (RTS), which consists of Glasgow Comma Scale, systolic blood pressure and respiratory rate. It was reported that the RTS showed greater reliability as a predictor of death is elderly trauma patients by Javali et al. (20).

2.2 Development of Trauma Registries

A trauma registry gathers data for a set population of persons with some inclusion criteria. The registry records clinical outcome data, demographics in regional cohorts and serves as a repository of data that can be plotted and extrapolated(21). The developed countries have been using formal trauma registries for the past four decades and have continued to use this rich source of information to influence their health policies in trauma in order to improve outcomes (22).

It has been noted by the World Health Organization that countries with well-established trauma registries have shown steady decline in trauma associated mortality(23). Between 2000 and 2020, road traffic deaths have been projected to decline a further 30% in high income countries where trauma registries are part of trauma management systems (4).

The development and retention of data from trauma patients impacts on the care of the injured patient in many ways including

- Detecting defects in care of the injured patient
- Measuring improvement in care delivery
- Monitoring the process of treating the injured patient
- Health resource budgeting and allocation
- Research in trauma and re-evaluating systems

The development of trauma scoring systems including the Revised Trauma Score(RTS), the Injury Severity score(ISS) and the Trauma and Injury Severity score(TRISS) were based on trauma registries that have been developed and retained in the high income countries (4).

2.2.1 Developing countries and Trauma

Injury surveillance is largely non-existent in low and middle income countries including Kenya. According to WHO, developing countries must make efforts to develop trauma registries as part of their trauma systems towards improving the care of the injured patient (24).

In Africa, Uganda and South Africa have made some efforts towards developing trauma registries. In Uganda, the Kampala Trauma Score is calculated from the patients age, number of injuries, systolic blood pressure, respiratory rate and neurologic status, Kobusingye et al(8). In South Africa a digital registry has been developed in the Martizberg region which is used in several hospitals but not most as an effort to create a trauma registry (4).

2.3 Autopsy and clinical diagnosis

In a study conducted by Sandritter et al., out of 1096 deaths at an autopsy rate of 63.5 percent, the accuracy of clinical diagnoses with recorded autopsy findings, 81.3% of the cases had the correct primary diagnosis(25). The findings of this study however, improved the clinical outcomes as demonstrated by a follow up study done by Drexler et al., after implementation of the recommendations done by Sandritter et al(25).

Chaido et al. in a study done in Greece, where 252 cases were analysed reported a much lower rate of 29% where the correct primary diagnosis was made(26). In this study, it was concluded that pulmonary embolism and coronary disease were often misdiagnosed clinically both in surgical and non-surgical patients. He concluded in this study that autopsies repeatedly disclose findings which were not expected but are crucial in the management of the patient. Chaido et al. also concluded based on the data he collected that autopsy is necessary to improve the quality of patient's care(26).

Rossi et al. at the University of Ferrara-Arcispedale established that autopsy is a valid tool to improve clinical outcomes despite the availability of advanced diagnostic techniques in medicine. This was after he looked at the autopsy findings of 110 cases, chosen randomly and correlating the autopsy findings to the clinical diagnoses. For his study, he found that 81% of diagnoses made clinically were correct at autopsy with the most conflicting results being those for malignancy. Trauma was found to have a correlation between clinical diagnosis and autopsy findings but it was concluded that clinical outcomes could be significantly improved as there were gaps in management(27).

At the university of Malay Medical centre, Wong et al., carried out a study to investigate the autopsy cause of death in comparison to the clinical cause of death. Of importance is that Wong et al. found a correlation rate of 86%. More so, he noted that in almost 4.5% of the cases an incorrect initial diagnosis was made which worsened the prognosis of the deceased(28). Furthermore, Wong et al. noted that the length of patient survival was directly correlated to the correct clinical diagnosis for the first 28 days. (28)

Hodgson et al. at the London health sciences centre looked at 108 deaths due to trauma. He found that out of his sample size, injuries were missed in 29% of in-hospital deaths and 100% of emergency department deaths, out of which the most commonly missed injuries were abdominal and head injuries. He concluded that the inaccurate findings which were recorded

as the clinical diagnosis had a negative and misleading impact on development of trauma care (21).

The need for a coordinated national trauma system to optimize trauma care was emphasised by Stinner et al. in his article on the surgical management of musculoskeletal trauma(29). The correlation of autopsy findings and clinical diagnosis is just but the first step in pursuit of a trauma system. The role of the orthopaedic surgeon was also emphasized in the paper, especially when it comes to prevention of secondary and tertiary deaths.

In addition, the previous studies, have raised the debate which has been perpetual with orthopaedic surgeons between early appropriate care, or Damage control orthopaedics(30). Both with their own advantages and disadvantages, but perhaps the researcher will collect data relevant to the local setup which would tilt the argument.

1.5 Conceptual Framework

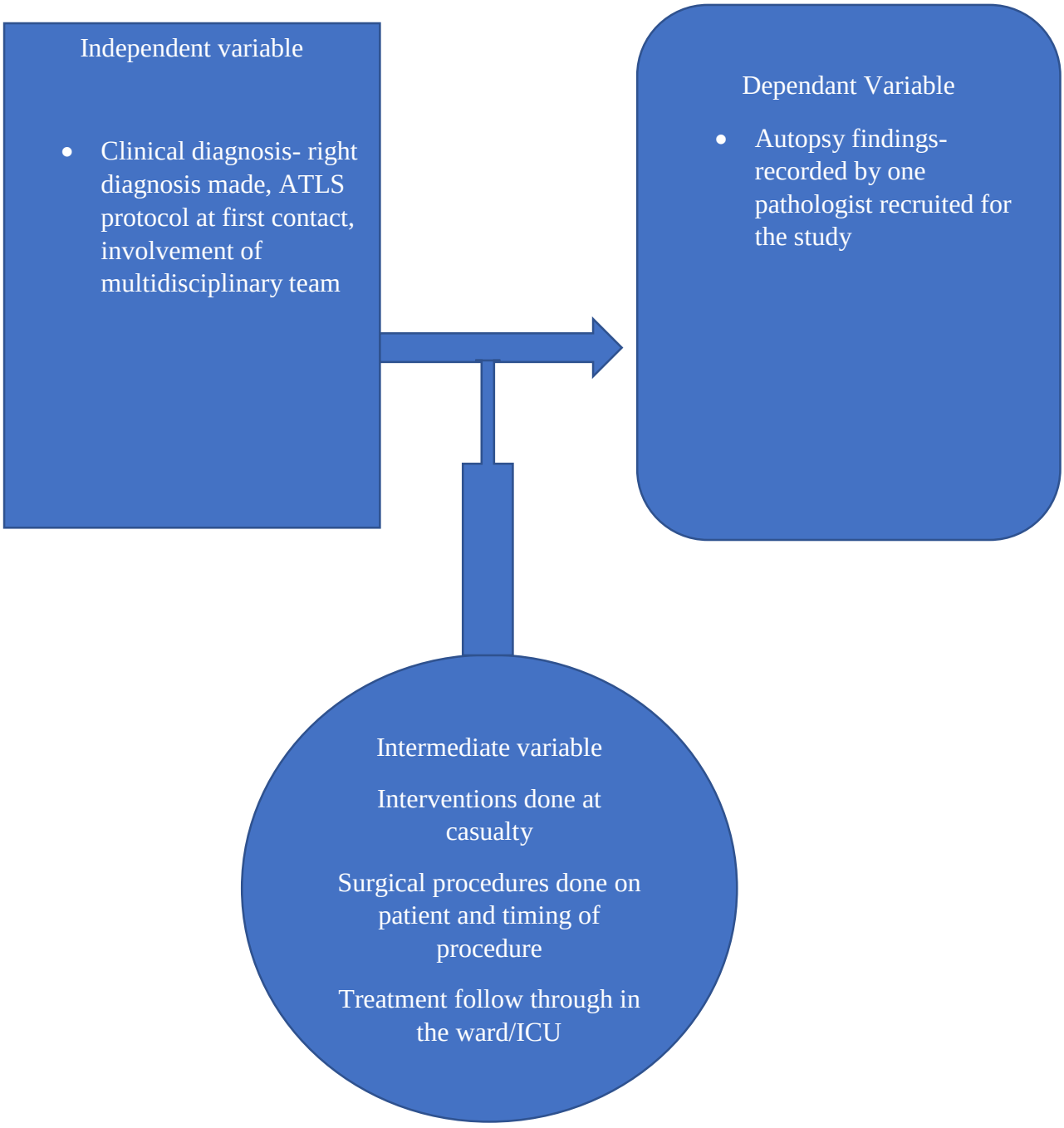


Figure 2: Conceptual Framework

CHAPTER 3: METHODOLOGY

4.1 Study Design

A prospective cross sectional descriptive study of patients with musculoskeletal injuries at the KNH

4.2 Study Duration

Over a period of 4 months from January 2021 to April 2021

4.3 Study Setting

Kenyatta National Hospital orthopaedic wards, ICU/HDU Accident and Emergency department and Kenyatta National Hospital Mortuary (Farewell home).

4.4 Study Population

Patients who presented to the accident and emergency department at the KNH with musculoskeletal injuries as a result of trauma and end up as mortalities.

4.5 Inclusion and Exclusion Criteria

4.5.1 Inclusion Criteria

- All trauma patients seen by the orthopaedic registrar/consultant at accident and emergency who ended up as a mortality prior to admission.
- All patients admitted to the orthopaedic wards following musculoskeletal trauma but ended up as mortalities.
- All trauma patients admitted in the orthopaedic wards with co-morbidities including Diabetes, Hypertension and other chronic illness but end up as mortalities.
- All patients admitted to ICU with musculoskeletal injuries but ended up as mortalities.
- All age groups of the above criteria.

4.5.2 Exclusion criteria

- Patients with no signs of life on arrival to hospital
- All trauma patients managed as outpatient and discharged

- Admissions due to burns

4.6 Sample size determination

The sample size calculation was done using a finite population. Previous studies on autopsy findings have had an average of 35 cases, hence for analytical purposes the minimum sample size was 35 (20) mortalities from trauma patients.

$$n^1 = \frac{NZ^2\mathrm{P}(1-P)}{d^2(N-1)+Z^2\mathrm{P}(1-P)}$$

Where

n' = sample size with finite population correction,

N = size of the target population = 58 (The estimated number of mortalities in patients admitted in orthopaedic wards of KNH, ICU and seen at A and E by the orthopaedic team for over a period of 3 months).

Z = statistic for 95% level of confidence = 1.96

P = estimated proportion of patients expected to die from polytrauma 9.6% from literature reviews.

D=margin of error 5%

The sample size was thus calculated using the above formula as shown below

$$n^1 = \frac{58 * 3.8416 * 0.096(1-0.096)}{0.0025 * (58-1) + 3.8416 * 0.096\ (1-0.096)}$$

Thus n^1 (sample size) = 40

Case definition: Trauma patient in this study was a patient who presented with musculoskeletal injuries and ended up as a mortality. The sample size of 40 was the number of autopsies targeted by the principal researcher to correlate the clinical diagnosis and findings at autopsy. These patients who ended up as mortalities were then followed to autopsy where the principal researcher witnessed the autopsy under supervision of the Pathologist Dr. Walong who was also a supervisor in this study. The autopsies were therefore done prospectively as they were witnessed by the principal researcher.

4.7 Sampling Procedure

Consecutive sampling of all patients who met the criteria until the sample size was achieved.

All patients who ended up as a mortality were be summarised on the day of death. The autopsies were done within 48hours and were witnessed by the principal researcher and findings thereof documented in the data collection form.

Patients were recruited at mortality and followed to autopsy where the principal researcher will witness the autopsy being conducted under supervision of Dr. Walong (Consultant Pathologist and lecturer UoN).

The autopsy findings were then recorded and correlated to the clinical diagnosis.

The primary researcher took deliberate steps to attend the autopsy examinations in order to improve the quality of data collected. In addition, a consultant pathologist was a supervisor in this study and was involved in the conduction of autopsies to prevent inter-observer discrepancies as autopsies are qualitative and may be subjective.

4.8 Data Collection and Analysis

Data collection was done using a simple data collection form. The form included patient demographics, clinical diagnosis at admission to the ward/A and E, and the autopsy findings. The data collection form also included a unique patient identifier, patient names were used for reasons of confidentiality.

All autopsies were coordinated and conducted or supervised by Dr. Walong, a Pathologist at the Kenyatta National Hospital and also a lecturer at the Department of Pathology at the University of Nairobi to reduce inter-observer differences.

All regulations and guidelines from the Ministry of Health were followed to ensure safe handling of the bodies during the COVID 19 pandemic (31).

Data was analysed using STATA software and any statistical association was tested at a 95% confidence interval. The descriptive statistics used include median, frequencies, proportions, and percentage. The inferential statistics used include logistic regression to produce relative risk ratios, confidence intervals and probability value (p-value).

4.9 Ethical Considerations

Ethical approval was sought from the Department of Orthopaedic Surgery University of Nairobi and the Ethics and Research committee Kenyatta National Hospital before the study was conducted. In addition, the study was registered in the clinical research division of Kenyatta National hospital.

All relevant certificates of approval have been attached to this thesis.

4.10 Dissemination of Results and Utility

The results of the study were be presented to the Orthopaedic Department University of Nairobi and shared with the Department of Orthopaedics Kenyatta National Hospital. The premise of the results should take further the steps towards establishing Kenyatta National Hospital as a trauma centre in continuation with the work published by Prof Saidi et al.

Furthermore, the results of this study will set a basis for further research in traumatology at The Kenyatta National Hospital.

4.11 Study Limitations

Decline of autopsy by next of kin

4.12 Study Delimitations

Patients whose next of kin declined autopsy were excluded from the study.

Patients admitted to the orthopaedic wards are seen by the consultant orthopaedic surgeon on call for that week in the post admission ward round. This increases the clinical accuracy in the management of the patient.

CHAPTER 4: RESULTS

The purpose of this study was to correlate clinical diagnosis versus autopsy findings in trauma patients admitted at the Kenyatta National Hospital. The study included a sample of 40 patients admitted with musculoskeletal injuries as a result of trauma but ended up as mortalities.

The data collected was collected primarily by the primary researcher. There were no major challenges faced during data collection and no problems encountered in terms of answering the questions posed in the introduction.

4.1 Background data

There were 29 male patients (72.5%) and 11 female patients (27.5%). The median age of the sample was 35(IQR: 24.25-42) years. The minimum age was 11 years and the maximum age was 61 years. The results show that there were differences in the number of fractures identified at admission and after autopsy with 18 patients (45%) identified with one fracture during admission compared to 20 patients (50%) after the autopsy. Seventeen patients (42.5%) had two fractures during admission but autopsy results show only 14 patients (35%) had two fractures and those that had three fractures were five patients (12.5%) at admission compared to six patients (15%) identified after the autopsy. However, results from Wilcoxon signed-rank test show that the difference in the number of fractures from clinical and autopsy results are not statistically different ($Z = -0.209$, $p = 0.835$). The summary of the findings is presented in table 1 below.

Table 1: Background Information of the Patients Admitted to the Orthopaedic wards at the KNH

		n		%	
Gender	Male	29		72.5	
	Female	11		27.5	
Age in years	<20	5		12.5	
	20-29	9		22.5	
	30-39	13		32.5	
	40-49	6		15.0	
	>=50	7		17.5	
Fractures	Number of fractures identified	At admission		After autopsy	
		n	%	n	%
	1	18	45.0	20	50.0
	2	17	42.5	14	35.0
	3	5	12.5	6	15.0

4.2 Cause of Death for Trauma Patients with Musculoskeletal Injuries Managed at KNH

On the cause of death for trauma patients with musculoskeletal injuries, the study found that 32% died of head injury, 20% died of pulmonary embolism, 17% died of blunt chest injury, 10% died of pelvic haemorrhage, 10% died of blunt abdominal injury, 8% died of spinal injury and 3% died of sepsis. The summary of the results is presented in figure 2.

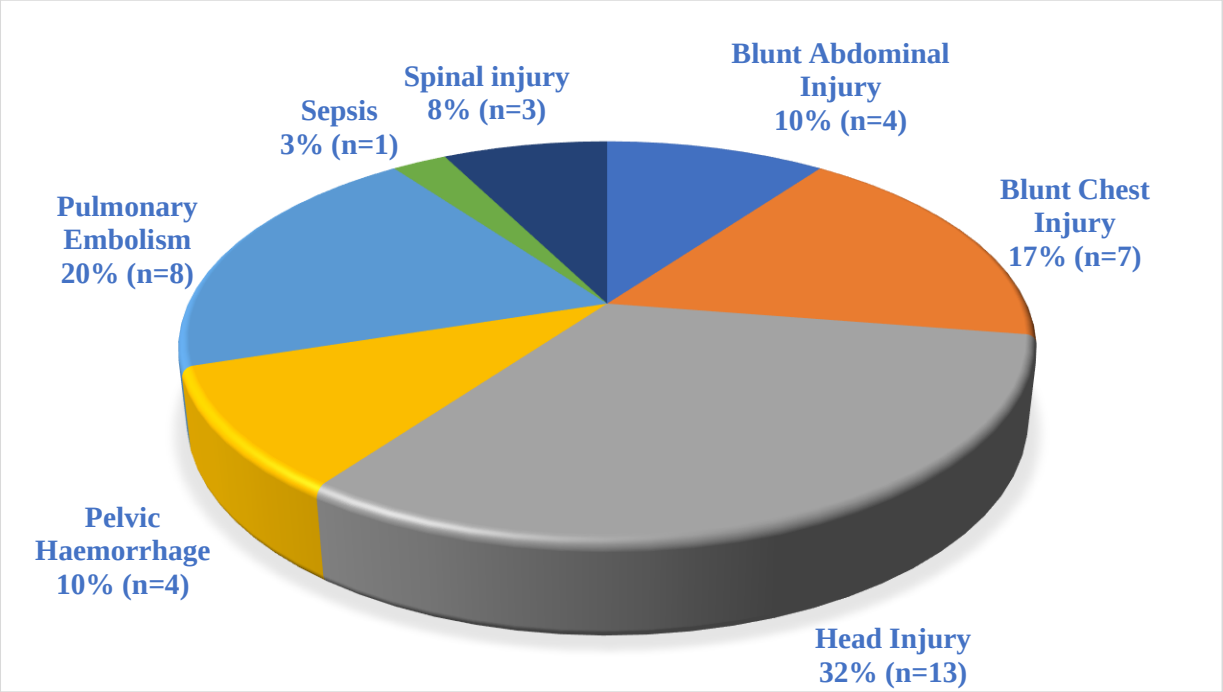


Figure 3: Cause of Death for Trauma Patients with Musculoskeletal Injuries Managed at KNH

4.3 The Clinical Diagnosis of Patients Managed at the KNH

The results from clinical diagnosis 16 patients (40%) were diagnosed with a head injury, 12 patients (32.5%) were diagnosed with femur fracture, 10 patients (25%) were diagnosed with pelvic fracture, 10 patients (25%) were diagnosed with spinal injury, 9 patients (22.5%) with blunt chest injury, 3 patients (7.5%) had Tibia fracture, 2 patients (5%) had humerus fracture, 2 patients (5%) had rib fracture and 4 patients had either limb fractures, sepsis, pre-eclampsia or pulmonary embolism. The summary of the results are presented in figure 3.

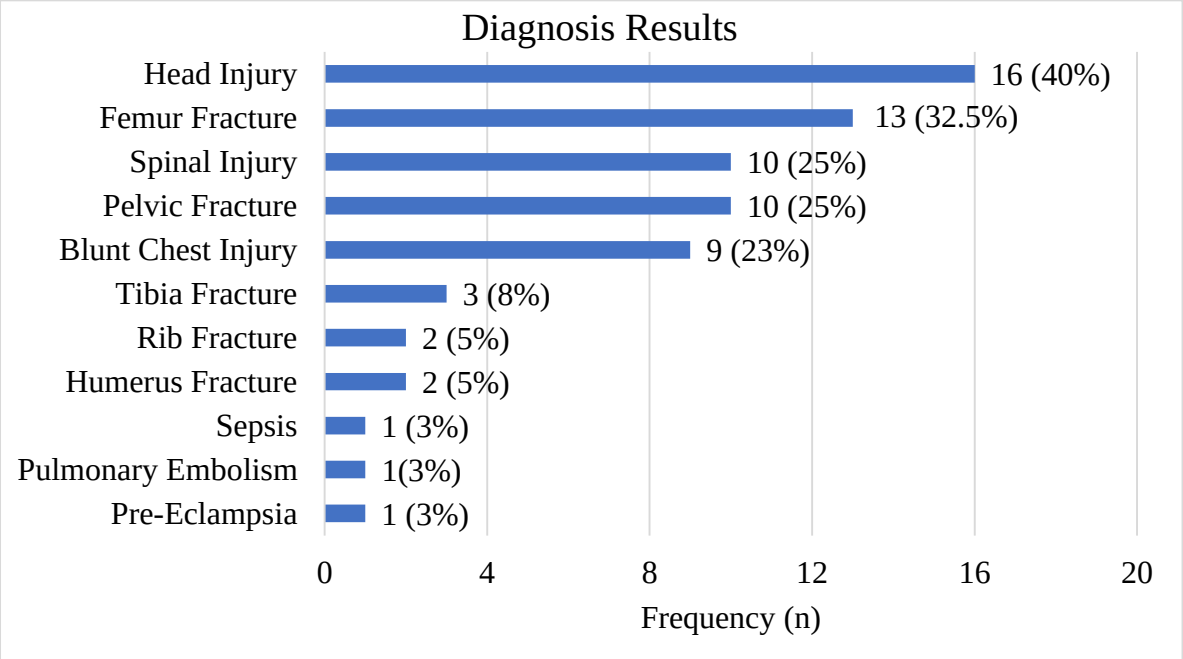


Figure 4: The Clinical Diagnosis of Trauma Patients Managed at the KNH

4.4 The Autopsy Findings of Trauma Patients Managed at the KNH

The autopsy results showed that 14 patients (35%) were diagnosed with head injury, 11 patients (27.5%) were diagnosed with spinal injury, 13 patients (30.0%) were diagnosed with femur fracture, 9 patients (22.5%) were diagnosed with rib fracture, 9 patients (22.5%) with pelvic fracture, 4 patients (10%) had blunt abdominal injury, 4 patients (10%) had pulmonary embolism, 3 patients (7.5%) had tibia/fibula fracture and 2 patients had either humerus fracture or blunt chest injury. The summary of the results are presented in figure 4.

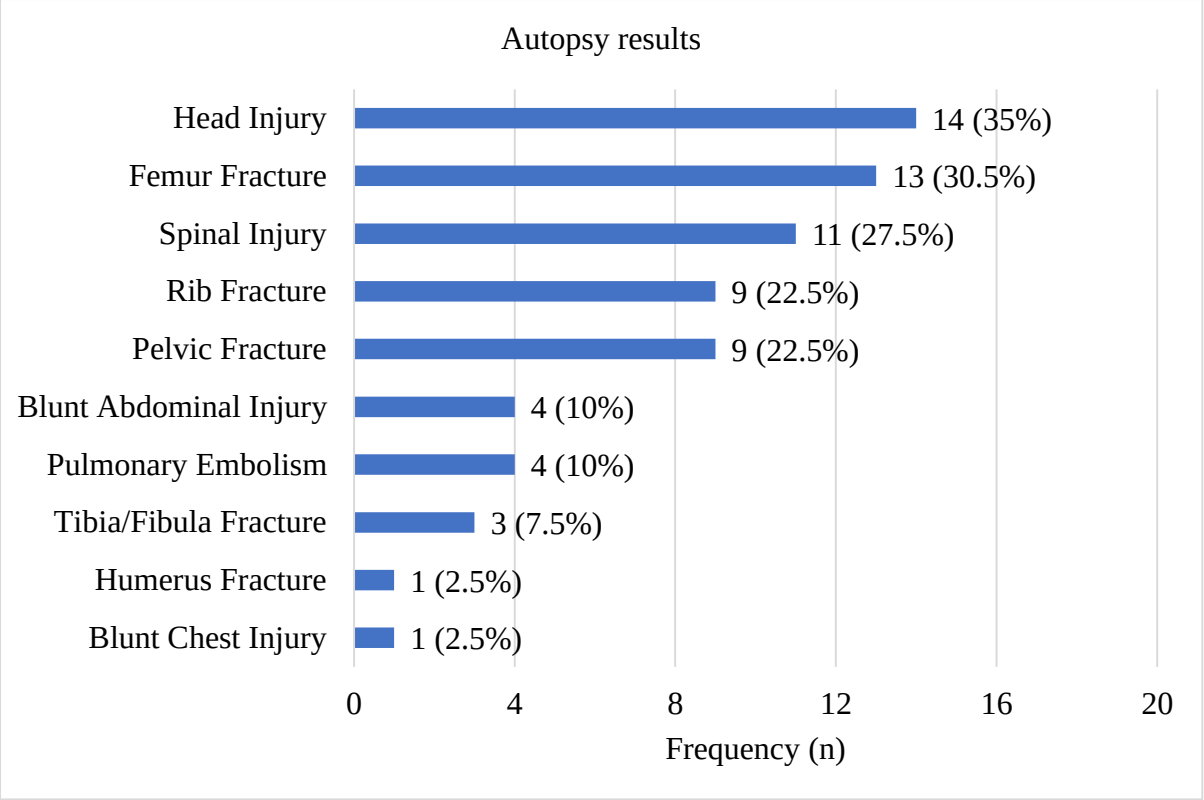


Figure 5: The Autopsy Findings of Trauma Patients Managed at the KNH

4.5 Correlation of Clinical Diagnosis of Trauma Patients versus the Autopsy Findings at KNH

The study also wanted to compare the clinical diagnosis versus autopsy findings of trauma patients admitted at KNH. The correlation was done using Cramer's V that is used to test strength of association between two categorical variables. The results presented in table 4 show that there was a strong positive statistically significant correlation ($p<0.05$) between diagnosis and autopsy results for spinal Injury (Cramer's V = 0.928, p 0<0.001) and Tibia Fractures (Cramer's V = 0.806, p <0.001). There was a moderate statistically significant correlation ($p<0.05$) between diagnosis and autopsy results for Femur Fractures (Cramer's V = 0.658, p <0.001), pelvic fractures (Cramer's V = 0.657, p <0.001); head injury (Cramer's V = 0.535, p 0.001); and pulmonary embolism (Cramer's V = 0.48, p 0.002). A low and significant

correlation ($p<0.05$) was established between diagnosis and autopsy results for blunt chest injury (Cramer's V = 0.339, *p* 0.032). There was no statistically significant correlation ($p>0.05$) between clinical diagnosis and autopsy results for rib Fractures (Cramer's V = 0.151, *p* 0.339); humerus fractures (Cramer's V = 0.037, *p* 0.816); and limb fracture (Cramer's V = -0.037, *p* 0.816). This is shown on table 5 below.

Table 5: Correlate of Clinical Diagnosis of Trauma Patients and the Autopsy Findings at KNH

	Clinical Diagnosis	Autopsy results	Bivariate Association	
	Freq (n)	Freq (n)	Cramer's V	p-value
Spinal Injury	10	11	0.928	<0.001
Tibia Fracture	3	3	0.806	<0.001
Femur Fracture	13	13	0.658	<0.001
Pelvic Fracture	10	9	0.657	<0.001
Head Injury	16	14	0.535	0.001
Pulmonary Embolism	1	4	0.48	0.002
Blunt Chest Injury	9	4	0.339	0.032
Rib Fracture	2	9	0.151	0.339
Humerus Fracture	2	1	0.037	0.816

The results presented in the pie-chart presented as figure 6 revealed that 18 patients (45%) had different autopsy results from the clinical diagnosis results and 22 patients (55%) had similar autopsy results in comparison to the clinical diagnosis.

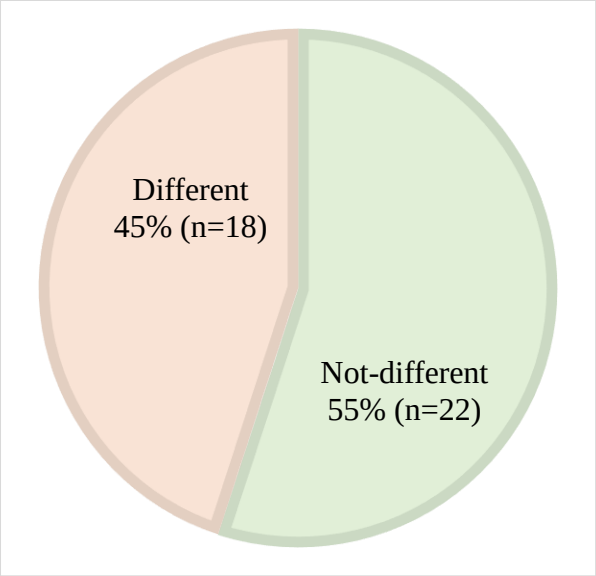


Figure 6: Comparison between autopsy results from clinical diagnosis results

CHAPTER 5.0 : DISCUSSION CONCLUSION AND RECOMMENDATIONS

5.1: Summary of findings and implications

This study primarily aimed at correlating the clinical diagnosis to the autopsy findings in an effort towards finding gaps in management which can be corrected and thus improve clinical management and thus clinical outcomes of trauma patients. The patients recruited to the study included patients with isolated musculoskeletal injuries, as well as patients with comorbidities, and multisystemic injuries managed at The Kenyatta National Hospital.

It was found that majority of the mortalities were as a result of head injury at 32% followed by pulmonary embolism 20% and blunt chest injury 17%. The percentage of males was found at 72% and females at 28% of the total number of patients. This is in keeping with statistics from studies done at KNH by Okemwa et al.(1). These findings are also in keeping with previous studies done in KNH and the Nairobi city mortuary by Prof Saidi et al. (4).

There was a strong statistically significant correlation between the clinical diagnosis and post-mortem findings for patients who had a clinical diagnosis of spinal injury, followed by death as a result of exsanguination from patients with fractures of the femur and tibia. Pelvic injuries showed a moderate statistically significant correlation between clinical diagnosis and autopsy as evident from the Cramer's V value as shown in Table 4. These patients essentially died of pelvic haemorrhage. There was no statistically significant correlation between clinical diagnosis and autopsy findings for patients with upper limb fractures. These patients were found to have multiple rib fractures and lung contusion some of which were not diagnosed at admission. This results were also in keeping with previous studies done in Kenya by Okemwa et al.(1) and Buschman et al. (6).

The findings thus imply that a significant number of patients with musculoskeletal injuries are admitted to the wrong unit. They also imply that a significant number of patients had missed or incorrect diagnosis at admission which affected the type and quality of care they receive.

In addition, these findings also implied that majority of patients admitted with musculoskeletal injuries at the Kenyatta National Hospital are correctly diagnosed at admission.

In the broader context, these findings are similar to previous studies done in the local setup as Rogena and Okemwa et al. found that 75% of the patients in their study at patterns on road traffic mortalities found(1) a paper which was published in the Annals of African surgery. In the same paper, the leading cause of mortality was head injury in multiply injured patients with other fractured bones, as is similar to the findings hereof. Femur fractures were the most common long bone injured and rib fractures were present in 17% of the patients which is consistent with the findings of Rogena and Okemwa et al(1) where 13% of their patients had concomitant rib fractures. Pulmonary embolism was found to be the second leading cause of death moreso in patients with spine injury and long bone fractures in the previous study and this is consistent with the findings of this study.

From and international perspective, Buschman et al in Germany(6), found a 17% discrepancy rate in the clinical diagnosis versus the autopsy findings for polytrauma patients managed at a level 1 trauma centre in berlin. This is in contrast to the findings of this study in which the discrepancy rate is at 45%. In the same study done in Berlin Germany, majority of the deaths were categorised as immediate deaths, which occur at the site of injury or within 1 hour of arrival to hospital, implying that these were fatally injured patients(6).

The results also showed the most common clinical diagnosis was head injury with femur fractures attributing to 40% of the trauma patients. Spinal injury formed 25% with pelvic fractures also at 25%. Blunt chest injury with concomitant Tibia/femur fractures formed 23% of the patients who ended up as mortalities. These values are similar but not the same as studies done in the European countries as investigated by Schmidt et al.(20) in Germany. In the study conducted by Schmidt et al. majority of trauma patients who ended up as mortalities died of haemorrhage and were categorised as early deaths, which are deaths within the first hour of injury. Schmidt et al. also reported a lower rate of mortalities in patients with spinal injury at less than 6% (20).

5.2 Conclusion and Recommendations

5.2.1 Conclusion

Conclusions based on the data analysis above are ultimately catered towards improving care to the injured patient at the Kenyatta National hospital. For a start, it is evident that there are still a significant number of patients (45)% who are admitted with incorrect or incomplete diagnosis from the initial assessment of the patient. This has a bearing on which ward the patient is admitted to and the type of care they receive.

The high rate of discrepancy between clinical diagnosis and autopsy findings raises gaps in management of patients when looked at retrospectively from autopsy findings. Considering the identified leading causes of death from this study are consistent with other studies puts emphasis of the need for improved hospital care as the injuries are showing a similar pattern of distribution.

From the analysis, the most common cause of death was head injury despite other musculoskeletal trauma. This essentially puts an emphasis on management of head trauma

Finally, it can be concluded that autopsy is a powerful tool in improving the management of trauma patients. It has been used in other centres, and forms part of routine care to enhance and inform policies in trauma management.

5.2.2 Recommendations

- In light of the findings and analysis of the data from this study, trauma patients should be thoroughly investigated including all relevant imaging prior to admission to the wards.
- Protocols e.g anticoagulation of spinal injury patients, or patients with long bone fractures should be streamlined and adhered to from point of initial contact and emphasis of continuous care of the injured patient.
- Regular follow up of autopsies for patients by the clinicians involved in the care and inclusion of the autopsy results in the quarterly mortality and morbidity meetings.
- Finally, but importantly, with the available data and conclusions made, further study is recommended to scrutinize the gaps which have been identified. There is room to duplicate the study using a wider sample size. Develop a trauma register initially at Kenyatta National hospital which eventually can be rolled out nationally in other centres. Countries with trauma registries have been shown to have lower mortality rates as a result of trauma, as discussed by Buschman et al in Berlin(6).

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BUDGET

Item	Cost(shillings)
Stationary and printing	5000
Statistician	40000
Ethics committee	2500
Autopsy	Funded by Government of Kenya
contingency	10000
total	57500

All mortalities as a result of trauma, or are unexpected undergo statutory autopsy as a pre-requisite to issuance of the death certificate according to section 18 of the Kenya Laws. The state this bears the cost of autopsies done at the Kenyatta National Hospital.

APPENDIX I: DATA COLLECTION FORM

Biodata

Initials: Sex:

Age:

Date of admission: Date of death:

Mechanism of injury

- Motor vehicle crash
  - Specify: Pedestrian Rider of motorbike passenger driver
- Fall from height
- Domestic violence
- Other mechanism of Injury-Specify

Autopsy findings(Summary)

Autopsy findings	Clinical diagnosis
Summary of autopsy findings:	
Autopsy diagnosis:	

APPENDIX II: CONSENT FORM ENGLISH

Title of the study: Clinical Diagnosis Versus Autopsy Findings in Trauma Patients With Musculoskeletal Injuries managed At The Kenyatta National Hospital.

Principle Researcher: Dr. Nelson Natalie Okedi (Registrar Department of Orthopaedics University of Nairobi)

The informed consent contains 3 parts

1. Information sheet
2. Certification of consent
3. Statement by the researcher

PART 1: INFORMATION SHEET

Investigator's Statement

I am **Dr. Nelson Natalie Okedi** I am conducting a study to find out the correlation between autopsy findings and clinical diagnosis of trauma patients with musculoskeletal injuries at The Kenyatta National Hospital. I am requesting you to participate in this study and the purpose of this form is for you to decide whether to participate or not.

Kindly read through the form carefully and feel free to address any queries or concerns regarding the study to me.

This study has been approved by the KNH/UON Ethics and Research Committee protocol number …….

I, the investigator will be available for any clarifications while filling the form and thereafter.

BRIEF DESCRIPTION OF THE STUDY

The study is meant to establish whether there is a correlation between the clinical diagnosis and the autopsy findings of the diseased. The findings of this study will be used to improve the medical care given to patients who have sustained trauma.

PARTICIPATION

If you chose to participate in this study, the details of the autopsy findings of your next of kin will be collected, kept anonymous and stored securely.

RISKS INVOLVED IN THE STUDY

There are no risks involved in the study, no personal identification information will be collected and data will remain anonymous and cannot be traced back to you or the deceased.

BENEFITS OF PARTICIPATING IN THE STUDY

The information gathered will provide new insight on how to improve care given to trauma patients at The Kenyatta National Hospital.

FUNDING OF THE STUDY

You will not be charged at any point during the study. The autopsy will be funded by the state.

QUESTIONS AND CHOICES

You are free to address and questions to the principal investigator via the contact information provided at the end of this document. Your participation is wholly voluntary and you may choose to decline to participate in the study of withdraw your participation at any stage without any repercussions.

PART 2: CERTIFICATE OF CONSENT

PARTICIPANT'S STATEMENT

I have fully read this consent form or had the contents read to me. My questions, if any have been answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in the study is completely voluntary and I may choose to withdraw at any time without repercussions. I freely choose to take part in this study.

Signed/thumb print…….

Date……

PART 3: RESEARCHERS STATEMENT

I, the undersigned have fully explained the relevant details of this research study to the participant and believe the participant has understood and has freely and willingly given his/her consent.

Researchers name……

Signature……Date……..

For more information, contact

- **Principal Researcher**

  Dr. Nelson Natalie Okedi

  Senior House officer –MMEd orthopaedics , Department of Surgery

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APPENDIX III: (CONSENT FORM IN KISWAHILI)

FOMU YA MAKUBALIANO KUSHIRIKI KATIKA UTAFITI

Sehemu ya Kwanza: Faharasa/Dibaji

Utangulizi

Majiraha ya kuumia haswaa kwenye viungo and mgongo ni shida kubwa katika mataaifa yanayoendelea kama yetu hii ya Kenya. Kuna uhusiano katika sababu la kifo na ile ugonjwa ambayo daktari alitangulia kutibu mwanzoni. Tunakuomba ushiriki katika utafiti huu wa kufumbua matokeo kulinganisha , uchunguzi wa maiti and utambuzi wa kliniki mfiwa alipoonekana mara ya kwanza na daktari

Tunakuomba usome fomu hii na uulize maswali yoyote ambayo unaweza kuwa nayo kabla ya kukubali kushiriki katika utafiti huu.

Sababu za utafiti

Kusudi la utafiti huu ni kufumbua matokeo ya kulinganisha sababu ya kifo na utambuzi wa kliniki ambao daktari aliaanza kutibu mwanzoni. Hii itatengeneza dimbwi la data litakalo tumiwa kwa uundaji wa sera ambazo zitasaidia katika matibabu ya wagonjwa walioumia majeraha kwa viungo na kwingineo mwilini.

Maelezo ya Utafiti

Mara baada ya kukubali kushiriki katika somo hili, utaruhusiwa kuuliza maswali yoyote kuhusu utafiti na kuongeza matatizo yoyote ambayo unaweza kuwa nayo. Mara baada ya kuridhika na majibu uliyopokea, utahitaji kusaini fomu ya idhini. Mtafiti mkuu atakupa dodoso litakalochukua historia ya kidemografia na historia ya majeraha.

Hatari zinazohusika

Utafiti huu hautakuathiri vibaya kwa namna yoyote na hakuna mashtaka yaliyofichika katika ushiriki wako. Matibabu hayaondolewi ikiwa hushiriki.

Faida

Taarifa tunayopata itatusaidia kuongeza maarifa kuhusa huu ugonjwa pamoja na kutengeneza dimbwi la data liatakalo tumika kwa uundaji wa sera.

Malipo

Hakuna malipo yeyote utakayo hitajika kulipa. Utafiti was mwili baada ya kifo italipiwa na serikali ya Kenya, ilhali, ni sharti kulingana na sharia ya Kenya.

Siri

Jina lako halitaonekana kwenye nyaraka yoyote na namba ya usajili tu itatumika kama alama ya kutambua.

Matumizi ya Data

Kama habari zote za kisayansi tunatafuta kushiriki matokeo yetu na watu wengine wanaofanya masomo kama hayo. Kwa hiyo, matokeo yatatolewa katika mikutano ya kisayansi na kuchapishwa katika majarida ya kisayansi.

Uhuru

Unaweza kujiondoa kwa hiari wakati wowote bila adhabu yoyote.

Tamko la Mtaalamu Mkuu

Mimi kama mchunguzi mkuu natangaza kuwa hakuna malipo ya kifedha niliopokea wala wasimamizi au hospitali ya Taifa ya Kenyatta kutoka kwa kampuni yoyote ya dawa au robo nyingine yoyote ili kujifunza utafiti huu.

Tafadhali jisikie huru kutafuta maelezo ya ziada kupitia anwani zilizopewa chini;

Mchunguzi mkuu

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Sehemu ya Pili: Fomu ya Makubaliano

Nimeelezwa utafiti huu kwa kina. Nimekubali kushiriki utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nimeelewa kuwa ninapo maswali zaidi, ninaweza kumuuliza mtafiti mkuu au watafiti waliotajwa hapo awali.

Jina la Mshiriki…….

Sahihi ya Mshiriki…….

Tarehe……

APPENDIX IV: TIMELINE OF THE STUDY

	Aug-Dec 2020	Dec-Jan 2021	Feb-April 2021	May 2021
Proposal development				
Ethical clearance				
Data collection				
Data analysis				
Results presentation and dissemination