

PATTERN OF PELVIC FRACTURES, ASSOCIATED INJURIES AND EARLY COMPLICATIONS AS SEEN IN ADULTS AT KENYATTA NATIONAL HOSPITAL

A dissertation submitted in part fulfillment for the requirements of the degree of Master of Medicine (M.MED) in Orthopedic Surgery of the University of Nairobi

By

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DECLARATION

This dissertation has been prepared as part fulfillment of the requirements for the degree award of Masters of Medicine in Orthopedics Surgery by the University of Nairobi, School of Medicine. I hereby declare that this study is my original work and has not been presented for dissertation at any other university.

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PATTERN OF PELVIC FRACTURES, ASSOCIATED INJURIES AND EARLY COMPLICATIONS AS SEEN IN ADULTS AT KENYATTA NATIONAL HOSPITAL

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CERTIFICATE OF AUTHENTICITY

This is to certify that this thesis is the original work of the author.

This research was carried out at Kenyatta National Hospital orthopedic wards, clinics and the Accident and Emergency Department.

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DEDICATION

This work is dedicated to my mother Mary Nduta and my son Joseck Wachira for their support and encouragement during the course of my studies.

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LIST OF ABBREVIATIONS

ATLS.....	Advanced Trauma Life Support
KNH.....	Kenyatta National Hospital
UoN.....	University of Nairobi
KNH/ERC.....	Kenyatta National Hospital ethical and research committee.
GCS.....	Glasgow Coma Scale
MCU.....	Micturiting Cystourethrogram
A & E.....	Accident and Emergency
AO.....	Association for the study of internal fixation
S.D.....	Standard Deviation
RTS.....	Revised Trauma Score
FAST.....	Focused Abdominal Sonography after Trauma
SOGC.....	Society of Obstetricians and Gynaecologists of Canada
CT Scan.....	Computed Tomography Scan
ARDS.....	Adult Respiratory Distress Syndrome

ABSTRACT

Objective: To determine the incidence, pattern, associated injuries and early complications of pelvic fractures in trauma patients presenting at A & E in KNH.

Design: Prospective longitudinal study.

Setting: Accident and Emergency department, Orthopedic wards and Orthopedic outpatient clinics at KNH.

Patient and methods: The study involved patients aged 18 years and above admitted in the orthopedic wards at KNH through A & E department with pelvic fractures and subsequent follow up in the clinics. They were recruited through convenient sampling as they were seen at Accident and Emergency. The patients were managed according to ATLS protocol, and after stabilization, were followed up in the orthopedic wards for 3 weeks. The ATLS protocol involved securing airway, ensuring normal rhythmic breathing, ensuring adequate blood circulation and assessing for disability. Patient demographics, fracture pattern and associated injuries were recorded after consenting for the study. The patient was then followed up for a period of 3 weeks documenting emerging and evolving complications. This was done on day 1, day 7, day 14 and day 21. Clear documentation of pelvic fracture pattern from the AP, inlet and outlet pelvic views, presence or absence of hemorrhagic shock, and all associated injuries. The data was analyzed using means, medians, and proportions for the baseline characteristics. The pelvic fracture pattern was correlated to the mechanism of injury, patient demographics, presence of early complications using the linear regression model as a statistical analytical tool.

Results: This study found that majority of patients with pelvic fractures were male with a mean age of 36 years. The average time before initiation of ATLS was 53 minutes. The main mechanism of injury was motor vehicle accidents. The main Tiles fracture type was type B.

This study also found out that 63 % of the pelvic fractures were associated with other injuries. Head injury followed by genito-urinary injuries were the most common associated injuries. This study also showed low incidences of hemorrhagic shock in patients with pelvic fractures.

Conclusion: The Tiles classification as originally intended did not predict mechanism of injury. Associated injuries remained a challenge to management of patients with pelvic fractures. Motor vehicle accidents were still the major cause of pelvic fractures. There were low incidences of hemorrhagic shock in those who arrived at the hospital.

CHAPTER ONE

Background: Pelvic fractures have presented a great challenge to orthopedic surgeons over the years. The mantra and philosophy of their management have evolved over time from conservative to operative management. Multiple classification systems exist to attempt to standardize care. However, no consensus exists. The incidence varies widely from one institution to another. In the advent of better road infrastructure and booming construction industry, there is an apparent increase in the incidence of pelvic fractures and a diversity of clinical presentation at A & E in Kenyatta National Hospital. Open pelvic fractures and hemorrhagic shock remain the greatest predictors of mortality. The impact of associated injuries on the mode of initial management also plays a critical role in the outcomes for these patients. KNH attends to an average of fifteen pelvic fracture patients a month. Some of these patients require intense multidisciplinary medical care that is both costly and prolonged. An earlier study at KNH showed that 87 per cent of pelvic fractures occurred from motor vehicle accidents(1). The common associated injuries included fractures of other bones (74%), urological injuries (24%), abdominal injuries (6%), head injury (3%), and thoracic injuries (1%). In literature, the contribution of associated injuries to the overall morbidity and mortality of patients with pelvic fractures is very high .The associated injuries that contribute most to mortality are head injury, chest injury and abdominal injury(2,3). In his study of 500 patients with pelvic fracture, Poole found an overall mortality of 8 per cent. In this category of mortality, only 14 per cent were associated directly with pelvic fracture. The other mortalities were due to associated injuries (4). The KNH study was done before the availability of FAST scans, CT Scans, and improved laboratory services. Therefore there was need to determine the incidence, pattern, associated injuries and early complications of pelvic fractures in the local set up. This will help in the

development of guidelines for initial and subsequent management of pelvic fracture patients who often present with polytrauma.

INTRODUCTION

The management of pelvic fractures has presented a long standing challenge to health care practitioners. This is often related to the fracture pattern and associated complications. Fractures of the pelvis have high morbidity and mortality despite modern care (5–11)

Faced with such a daunting challenge of Pelvic fractures, surgeons and other clinicians have sort ways to define the incidence and patterns and their most associated early complications in order to improve management and reduce morbidity and mortality. The Complications of pelvic fractures have been reported to be between 36.7 per cent and 50 per cent (15,16). The mortality of pelvic fractures ranges between 9 per cent and 30 per cent(12–14)

Open pelvic fractures have been associated with a high mortality of up to 50 per cent, this has been mostly attributed to fracture instability, rectal injury or perineal injury and delay in instituting diverting colostomy(17).

It is of note that almost 66 per cent of pelvic fractures are complicated by other fractures and other soft tissue injuries (18). Some specific examples include urethral injuries (19),

In the management of the poly traumatized patient with pelvic fractures, it is important to screen and be aware of the various possible complications and associated injuries. A relationship between the mechanism of injury and the associated injuries and complications has been shown (20,21)

The reported mean hospital stay varies between seventeen and twenty one days (3,15,20,22,23)

The use of ATLS in the initial evaluation of pelvic fractures has been shown to improve detection of associated injuries in a local study (24). This involves the trauma series radiographs of lateral cervical spine, chest x ray and the anteroposterior pelvis.

The management of pelvic fractures necessitates advanced trauma life support as from scene of accident to the hospital, and this may involve multidisciplinary teams due to associated injuries and complications of the fractures themselves.

There is no local data to inform the incidence, pattern, associated injuries and early complications of pelvic fractures. This would guide protocols on the evaluation of the pelvic fracture patient with better intuition, better pick up rates for complications and better patient outcomes.

CHAPTER TWO

LITERATURE REVIEW

The management of pelvic fractures has evolved over time as improvements take place in both radio-imaging and implant design. The surgical techniques have also changed over time (25,26). Early historical literature focused on visceral injuries and gave little focus to the musculoskeletal complications(27) . Holdsworth reported on 50 pelvic fractures in 1948. The main outcome was ability to return to work. He noted that severe complications included retroperitoneal bleeding, two burst bladder that were fatal and chronic sacroiliac pain in a sub-set of patients(28)

The pattern of pelvic fracture differs significantly based on the classification method used. In a study in Kenya, the Kane modification of the Key and Conwell system was used. The commonest fractures were type 2 which comprised 51 per cent followed by type 3 that comprised 27 per cent(1). In his paper, Tile noted that type A and type B fractures make up 70 to 80 per cent of all pelvic fractures. In Type A fractures the pelvic ring is stable and in type B fracture it's partially stable such as in "open book" and "bucket handle" fractures. The type C fractures have complete disruption of the posterior sacroiliac complex and are very unstable(29). In another study of 58 patients with pelvic fractures, Tile type B and Tile type C represented 46 per cent of all pelvic fractures. In this group of patients with unstable pelvic fractures 89 per cent had other associated injuries(30). There are many other classification systems and presently there is still no consensus on one system. One system favors the mechanism of injury as the key to relating the pattern of organ injury, the resuscitative requirements and eventual mortality incidence in these injuries. In this study, there is demonstrable correlation between the organ injuries and the four broad categories of lateral compression, anterior posterior compression,

vertical shear and the combined mechanical injury(20). Lateral compression injuries are associated with pelvic vascular injury, retroperitoneal hematoma and shock as the grade increases. The anteroposterior compression injuries are associated with injury to spleen, liver, bowel, pelvic vascular injury with retroperitoneal hemorrhage, shock, sepsis and ARDS.

Pediatric pelvic injuries have also been studied. In one of the largest pediatric series of the pelvic fractures, it was found to have 60 % multi-systemic injuries and 50 % additional skeletal injuries. Mortality rate was at 3.6 %, and mostly associated with head and viscera injury. Urethral injury was not common like in adults, and anterior ring fractures predominated (31).

Classification of pediatric pelvic fractures can be associated with specific patterns of injury. In his study, Silber classified his as skeletally mature or skeletally immature based on the status of the triradiate cartilage(32). The immature group had a higher propensity to isolated pubic rami and iliac wing fractures while the mature group had a higher predilection to pubic Studies that relate the pattern of injury to complications were also done in the early literature. These showed a higher complication for the fractures of the posterior weight bearing sacroiliac region than the non weight bearing region (18). A large consecutive series study of those early times revealed associated injuries rate of 62 percent and that 82 percent were high energy injuries (21). There were two categories of stable fractures that included isolated pubic rami fracture, and isolated rim fractures. The other category includes unstable pelvic fractures including double vertical and crushed pelvis fractures.

In his study of 75 patients with pelvic fractures in South Africa, Froman found a mortality of 20 patients, 46 of the patients suffered urinary tract injuries. This included rupture of the urethra, bladder or ureters. 12 patients had laceration or perforation of the anorectum. 4 patients were pregnant with resultant loss of pregnancy. 4 patients had sciatic nerve palsy(33). In a study in Brazil, Parreira studied 103 patients with pelvic fractures. He found most frequent associated

injury being orthopedic (fractures of the spine, lower and upper extremities) at 48 per cent, followed by abdominal injuries in 42 per cent, closed head injury in 37 per cent and thoracic injuries in 25 per cent. In Kenya, Mutiso studied 101 patients with pelvic fractures. He found fractures of other bones in 74 per cent, urological injuries in 24 per cent, abdominal injuries in 6 per cent, severe head injuries in 3 per cent and thoracic injuries in 1 per cent. 4 per cent of the patients had open pelvic fractures. He also reported a mortality of 3 per cent(1).

There are some early complications that present after fracture pelvis. These are directly attributable to the pelvic fracture. In literature, hemorrhage is one of the common complications of pelvic fractures. In his study, Peltier reviewed 186 patients with pelvic fractures. 28 of them had retroperitoneal hematoma(18). In another study, posterior ring pelvic fractures were noted to require larger amounts of blood transfusion and subsequently higher mortality outcomes. This was also correlated to the blood pressure and the hemoglobin level at admission(13). In rare presentations this has evolved into retroperitoneal abscess with fatal outcomes due to missed early diagnosis(34). In a different study of urethral injuries as an early complication, pelvic fractures involving both pubic rami and those that involve the sacroiliac joint had the highest incidence of urethral tears(35). In literature, Morel Lavelle lesions which are internal degloving injuries, have also been documented in patients presenting with pelvic fractures. These often occur over the greater trochanter, flank or lumbardorsal region(36). They are a result of direct trauma to the pelvis. In a study of 236 patients with pelvic fractures from blunt trauma, 32 per cent developed complications. These were infections such as pneumonia, urinary tract infection, wound infection and sepsis from unknown sources. Pulmonary complications such as ARDS, significant atelectasis and fat emboli also occurred. The rates of wound infection are high where an aggressive approach to treatment is not used when there is an open pelvic fracture(37). In his study, Tile documented peripheral nerve injury in patients with pelvic fractures. This involved the L5 and S1 nerve roots(29).

The incidence of pelvic fractures has been reported in literature as ranging from 29:100000 for women and 20/100000 for men. The female to male ratio in those over 49 years was 1: 2.9 and 1: 0.5 for those younger than 49 years(23,38). These have been noted to be far less in pediatric patients, who also have fewer complications and associated injuries(39). In the local data, pediatric pelvic fractures have been few in those associated with fall from height(40). There has been increased association of severe pelvic fractures with motor vehicle collision especially side lateral collision. These correlate well with the poor outcome of this select category in terms of associated injuries and complications(41).

The utility of radiology in formulating classification systems has also been studied. In his paper Young, used plain radiographs to delineate four basic patterns of injury vertical shear, anterior posterior compression and lateral compression and combined mechanical injury(42). This has been corroborated by the work of Dalai(43). There are few studies to validate the myriad classification systems of the pelvis. One of them demonstrates moderate intraobserver and interobserver agreement in both the Tile and Young and Burgess systems(44). In this study the Tiles classification of pelvic fracture will be used. It has moderate inter and intraobserver variability, it has been adopted by the AO, and it is easy to use.

Its reported that soft tissue signs of trauma and the soft tissue planes between muscles and fat are useful in the interpretation of the plain x rays, the bladder, obturator internus, levator ani are frequently visible (45,46). The three views of the pelvis namely anteroposterior, inlet view and outlet view have been validated to accurately pick up pelvic fractures(47). The CT scan was shown to be superior to the plain radiograph in detecting pelvic fractures(42,48).The role of CT scan is affirmed as an effective tool for evaluating the pelvis. Its limitations arising from time

consumption and impracticality in certain select patients with severe injuries. It is also not available in certain localities.

In the evaluation of the associated injuries in patients presenting with pelvic fractures, various methods have been adopted. In the case of urologic injuries, the commonly associated injuries include urethra, corpora cavernosa, bladder and bladder neck(49,50). Reported cases of missed urologic injuries in pelvic fractures are described to be as high as 23 per cent(51). This is due to dependence on macroscopic hematuria instead of microscopic hematuria. Men are noted to have more incidences of genitourinary injuries than women. These injuries are also more likely to be associated with bowel injuries(52).

Abdominal injuries such as abdominal compartment syndrome are known to have a high mortality. In a series, up to 24 per cent of cases of pelvic fractures presented with this life threatening condition (53). Its earliest manifestation is cardiovascular dysfunction due to abdominal hypertension. The evaluation of blunt abdominal trauma (BAT) is a subject of great interest in traumatology. Clinical evaluation is key in detecting abdominal injuries. It is however confounded by altered levels of consciousness due to neurologic injury, drugs or alcohol. Tools for abdominal injury analysis include clinical examination, paracentesis, diagnostic peritoneal lavage, and CT scan. These are a validated surgeons armamentarium(53–57).

Hypovolemia and shock are known causes of most of the mortality from pelvic fractures. Early identification of patients at high risk of bleeding is imperative. Guidelines are that injuries that increase the bony volume of the pelvis (open book injuries) cause more bleeding than those that reduce the volume of the bony pelvis (lateral compression injuries)(58)

Predictors of major ongoing hemorrhage have been defined as duration of hypotension (systolic blood pressure < 100mmhg) , female gender, sacroiliac joint disruption, pubic symphysis diastasis, hematocrit of < 30, and a pulse rate greater than 130 (59,60). The pattern of the pelvis

fracture has been termed as stable or unstable. This has been shown to correlate with hemorrhagic shock in the patient(61).

Thorax injuries are commonly evaluated through a judicious clinical examination, and directed imaging in form of radiographs and CT scan. These could range from simple rib fractures to the grave pulmonary contusion. Thoracic injuries have been shown to have high morbidity rates of 36% and mortality rate of 15 %(3). The severity has been shown to be independent from the presence or absence of rib fractures or any other thoracic bony trauma.

Head injuries follow the guidelines of detection using the Glasgow coma scale, a validated tool. Those with moderate and severe head injury are evaluated using the CT scan head to expound on the injuries. Precise definitions have been elaborated to avoid confounding parameters (62–64). Peripheral nerve injuries occur especially with injuries to the posterior pelvic ring. This also includes sacro-iliac disruptions, and sacral fractures(65).

The revised trauma score (RTS) has been utilized since 1989. It has been used for triage of trauma patients and has been shown to predict outcome(66,67). This tool will be used in this study to show relationships of the score to the various parameters being studied. These are demographics, mechanism of injury, pelvic fracture pattern, associated injuries and early complications

STUDY QUESTION

What are the patterns of pelvic fractures, associated injuries and their early complications as seen at KNH?

STUDY JUSTIFICATION

The incidence of pelvic fractures is thought to be rising in the recent years. This in Kenya is attributable to high speed motor vehicle accidents due to improved road networks. The increase in numbers of motorcycles popularly known as “boda boda” in local parlance has also contributed to road traffic accidents.

The approach to evaluation and management of these pelvic fractures has also evolved in the local set up. Specifically there are tools such as FAST, CT scan, and digital X-rays for evaluation of the pelvic fractures and associated injuries. The availability of competent first contact orthopedic residents in the Accident and Emergency set up has also improved pick up of primary and secondary injuries in the trauma patient.

The study institution tends to see approximately fifteen pelvic fractures per month on average. A study done by Mutiso revealed 3 per cent mortality from pelvic injuries. This study was conducted about three decades earlier when imaging modalities were still nascent, the roads in the country were not well developed, and more significantly before the advent of commercial motorcyclists and the construction boom. In recent years, the number of motorcyclists has increased, the road network has improved and the construction industry has also grown exponentially(68–70).In the new era, there is need to understand better the incidence, patterns, associated injuries and early complications of pelvic fractures. This will help inform policy on collaborative management in the patient with pelvic fractures and associated injuries.

STUDY OBJECTIVES

MAIN OBJECTIVE

To determine the pattern of pelvic fractures associated injuries and early complications in patients seen at KNH

SPECIFIC OBJECTIVES

1. To determine mechanism of injury of the pelvic fractures.
2. To describe the Tiles pattern of pelvic fractures.
3. To describe the associated injuries in pelvic fractures
4. To determine the early complications of pelvic fractures.

CHAPTER THREE

METHODOLOGY

STUDY DESIGN

Prospective cross-sectional study

STUDY SETTING

KNH Accident and Emergency department, orthopedic wards and outpatient orthopedic clinics.

KNH is the national referral and teaching hospital serving Nairobi, its environs and the country at large through the national referral system.

STUDY POPULATION

All the patients aged above 18 years presenting to Accident and Emergency Unit with pelvis fractures as determined at Accident and Emergency.

SAMPLE SIZE

It is estimated that fractures of the pelvis constitute 9.3 % of all trauma patients(71).

Using the Cochran formula to estimate sample size when the population size is infinite (72)

$$n_0 = \frac{Z^2 pq}{e^2}$$

Where n is the sample size, Z is the desired confidence level (95%), p is the estimated proportion of an attribute that is present in the population (0.093), q =1-p and e is the desired level of precision (0.05)

Substituting:

$$n_0 = \frac{1.96^2(0.093)(1-0.093)}{0.05^2} = 129.616$$

From KNH registry, 62 patients were admitted between April and July 2016, an average of 15 per month with pelvic fractures. Then the sample size will be

$$n = \frac{n_0}{1 + (n_0 - 1) / N}$$

Where N is the population size. Substituting

$$n = \frac{126.616}{1 + (129.616 - 1) / 62} = 41.8426 = 42$$

Adding 10 % for non-responsive participants gives a total of **46 participants**

INCLUSION CRITERIA

- Patients who have pelvis fractures as determined using three views of X- ray (AP, pelvic inlet and pelvic outlet views), and/or CT scan as appropriate
- Patients from another institution with AP, pelvic inlet and pelvic outlet views of pelvis
- Patients who are above 18 years of age.
- Patients who have given consent.

EXCLUSION CRITERIA

- Patients that refuse to give consent.
- Patients below 18 years of age.

METHODS

Sampling procedure

Patients were recruited into the study by the principal researcher and two assistants through convenient sampling method. The two assistants were senior clinical officers with 3 years'

experience in clinical practice. They hold a Diploma in Clinical Medicine and Surgery from the Kenya Medical Training College, Nairobi. They were trained on collecting data from five patients with pelvic fractures as a pilot sample. The accuracy and completeness of the questionnaire was assessed. In the actual study group, all subjects seen by the research assistants were reviewed by the principal investigator within twenty four hours. Patients were managed as per hospital protocol. The principal researcher and his assistants were notified that a patient with pelvic fracture has been seen at Accident and Emergency department.

The principal investigator and/or the research assistants would review the patients file for eligibility into the study. Those that met inclusion criteria were recruited into the study. Their file notes were reviewed in accordance to the designated data collection questionnaire. The data have demographics of the subjects, mechanism of injury, type of pelvic fracture pattern, associated injuries and early complications were recorded. The evaluation of the patient records by the principal researcher was systematic and exhaustive as delineated by the study protocol below. The patients were evaluated on day 1, day 7, day 14 and on day 21. There were consultative sessions between the principal researcher and the doctor managing the patient to address any missing documentation in the files.

Head injury assessment

This was assessed clinically through inspection for lacerations, and deformities of the head and face. The Glasgow Coma Scale (GCS) was also used. Those that have GCS of less than 12 undergo CT scan of head as deemed appropriate by the neurosurgeon on duty. This provided bony window and soft tissue windows as well. All injuries were accurately described and recorded in the questionnaire.

Cervical spine assessment

This was assessed clinically and lateral cervical spine X rays were done. Injuries of the thoracic, lumbar and sacral were also assessed clinically and through X rays where necessary. Neurological deficits were documented. Findings were recorded on the questionnaire as well.

Thoracic assessment

This was done using clinical examination. As appropriate, X-rays of the chest were done. Most often this will suffice. For severe chest injuries, the CT scan chest were done to delineate the injuries for documentation.

Abdominal assessment

This was done clinically and where signs of peritonitis, and /or organ injury, three tools were employed appropriately. Patients in coma were excluded from clinical abdominal examination. This included paracentesis, focused abdominal sonography after trauma (FAST) and CT scan. The decisions were made by the surgeon attending to the patient independent of the investigator. All findings were documented on the data collection sheet.

Genitourinary assessment

This was done clinically through inspection of the perineum, the urethral orifice, vulvovaginal vault for any injuries. Urine was observed for gross hematuria. If subtle signs of bladders injury such as tenderness are found, urine was analyzed for microscopic hematuria. If positive, appropriate urological tests were done such as micturating cystourethrogram (MCU), and ascending urethrogram. All findings were documented on the data sheet.

Appendicular skeleton assessment

This was done by clinical examination of both the upper and lower limbs. The bony injuries, soft tissue injuries, and neurovascular injuries were defined and documented. Simple terminologies

were used. These included articular fractures, extra-articular diaphyseal fractures, open fractures, and closed fractures.

Pelvic fracture assessment

The fracture was imaged using three views of x-rays. Anteroposterior and pelvic inlet and outlet views were used. For complex injuries, the CT scan was used. In this study Tiles Classification of pelvic fractures was used.

Hemorrhagic/ Hypovolemic shock Assessment

This was judiciously assessed using clinical assessment, physiological parameters measurement, inferences made from amounts of fluids used to maintain homeostasis, and the shock was graded using the SOGC criteria. A classification chart was used to aid in capturing and correctly classifying shock. (Appendix 3)

Duration of study

Patients were recruited and followed up for twenty one days from the date of the fracture. This was consistent with other models of study that show most patients averaging three weeks stay in hospital following pelvic fracture(3,15,22,23)

DATA COLLECTION AND MANAGEMENT

Data was collected using a standard data sheet. Data collected will include:

- Patient demographics
- Mechanism of injury
- Fracture classification
- Associated injuries
- Early complications

Data was coded, entered and managed in a Microsoft Access database and at the end of data collection exported to SPSS version 17.0 for analysis. The baseline characteristics were summarized and presented as means, medians and proportions.

The hospital based incidence of the pelvic fractures was determined. The pelvic fracture pattern was correlated to the mechanism of injury, the patient demographics, presence of early complications, and the revised trauma score using linear regression model.

All statistical tests were performed at 5% level of significance (95% confidence interval). The results of the study were presented in forms of tables, histograms and pie charts.

ETHICAL CONSIDERATIONS

Approval for the study was sought from the department of orthopedic Surgery, University of Nairobi and the KNH ethics and research committee (KNH/ERC). Patients were given a clear explanation of the study before they decide to consent or otherwise.

For those who did not consent, they received treatment as per the regular pelvic fracture management protocol in Accident and Emergency department and in the ward.

STUDY LIMITATIONS

- There were difficulties obtaining appropriate imaging as desired. This was due to inadequate pain control to allow positioning. These were mitigated by liaising with the team of radiologists and improving their awareness of the study and its requirements allowing adequate analgesia for the same.
- Lack of funds for pelvic CT scan by those without NHIF insurance.

DISSEMINATION OF THE STUDY FINDINGS

Findings of the study have been disseminated in a three tier fashion. One copy of the published dissertation will be kept at the department of orthopedic, University of Nairobi. Another one is at the university library. The highest level of sharing of the findings will be through publication in a peer reviewed journal.

CHAPTER FOUR: STUDY FINDINGS

4.1 Patient Demographics

The study sample included 46 patients. Majority (82.6%) patients were male. The mean age of patients was 36.6 (SD 10.7) years within the range of 20 to 67 years (Figure 4.1).

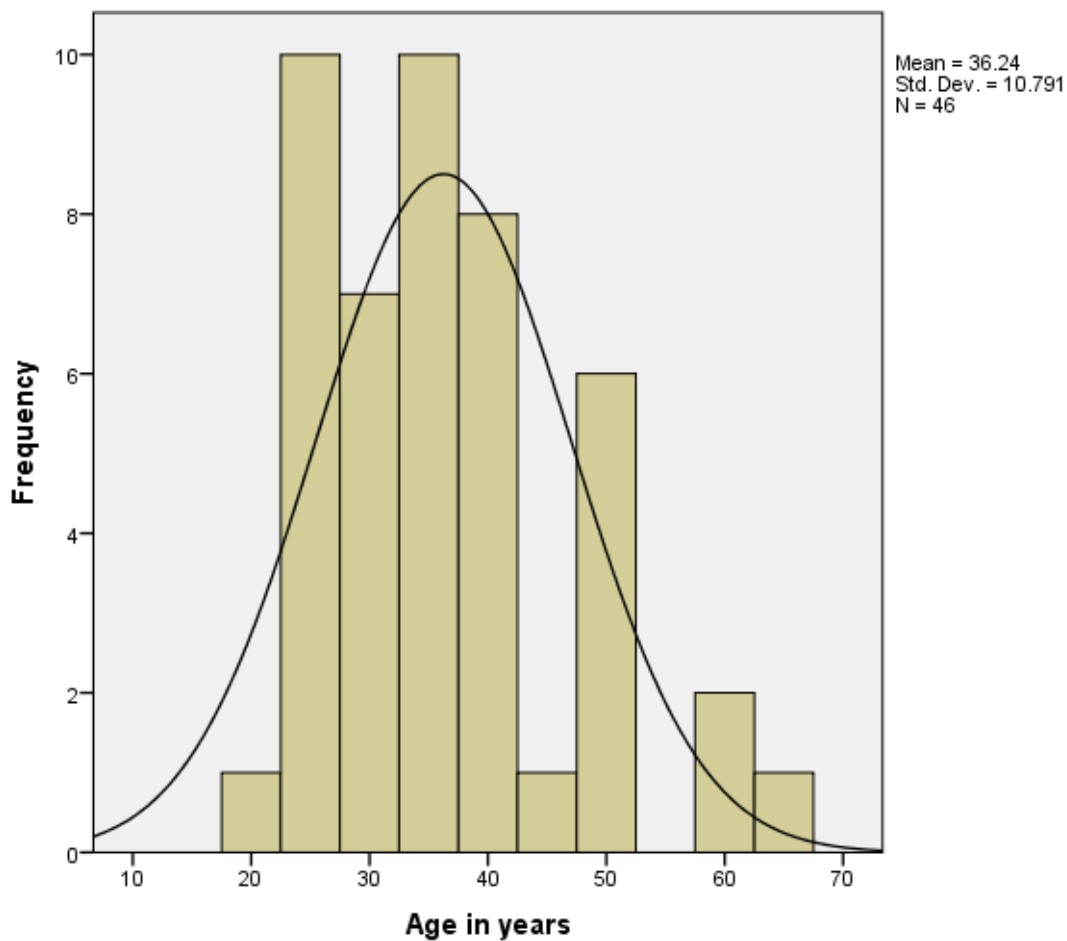


Figure 4.1: Age in years

The average time before ATLS protocol was 53.6 (SD 106.6) minutes within the range of 15 and 720 minutes. Mean blood pressure was 109.7/70.6; pulse rate 89.9; respiratory rate 18.1; Sapo2 (%) 98.7; and two types of fluids were given (Table 4.1).

Table 4.1: Physiological vital parameters

Variable	Frequency	Minimum	Maximum	Mean	Std. Deviation
Time Before ATLS Protocol (Minutes)	42	15	720	53.57	106.572
Systolic Blood Pressure	46	80	151	109.65	15.782
Diastolic Blood Pressure	46	32	105	70.61	12.263
Pulse Rate	46	70	123	89.89	14.369
Respiratory Rate	44	10	26	18.05	3.199
Sapo2 (%)	43	81	100	98.7	3.136
Amount of Fluids Given (Litres)	23	0	2	1.478	0.648

4.2 Mechanism of injury of the pelvic fractures

The main (60.9%) mechanism of injury of the pelvic fractures was motor vehicle hitting pedestrians. Mechanisms of injury are as listed in Table 4.2.

Table 4.2: Mechanisms of injury

Mechanism of Injury	Frequency	Percent
Motorcycle(Rider)	2	4.3
Motorcycle(Passenger)	4	8.7
Motor Vehicle(Driver)	4	8.7
Motor Vehicle(Passenger)	2	4.3
Motor Vehicle (Pedestrian)	28	60.9
Fall (Less than 4 metres)	3	6.5
Fall (More than 4 metres)	2	4.3
Assault	1	2.2

4.3 Pattern of pelvic fractures

The main (67.5%) pelvic fractures were B. Acetabular fractures were reported in 26.1% cases. There was no significant relationship between acetabular fracture and pattern of pelvic fractures (p value= 0.950) (Table 4.3).

Table 4.3: Tiles Pattern of pelvic fractures and frequency of acetabular fractures

Pelvic fractures	Interpretation	Frequency	Percent	Acetabular Fracture (Frequency)
None	None	2	4.3%	2
A	A2	4	8.7%	0
B	B1	9	19.6%	1
	B2-1	16	34.8%	5
	B2-2	1	2.2%	0
	B3	5	10.9%	2
C	C1-1	5	10.9%	1
	C1-2	1	2.2%	1
	C2	3	6.5%	0

There was no significant relationship between mechanisms of injury and pattern of pelvic fractures (likelihood p value= 0.289). See Table 4.4 for cross tabulation.

Table 4.4: Mechanisms of injury and pattern of pelvic fractures

Pattern of pelvic fractures	Mechanisms of Injury							
	Motorcycle (Rider)	Motorcycle (Passenger)	Motor Vehicle (Driver)	Motor Vehicle (Passenger)	Motor Vehicle (Pedestrian)	Fall (Less than 4 metres)	Fall (More than 4 metres)	Assault
None	0	1	1	0	0	0	0	0
A2	0	0	1	0	1	2	0	0
B1	1	1	0	0	7	0	0	0
B2-1	0	2	1	1	9	1	1	1
B2-2	0	0	0	0	1	0	0	0
B3	0	0	0	1	4	0	0	0
C1-1	1	0	1	0	3	0	0	0
C1-2	0	0	0	0	0	0	1	0
C2	0	0	0	0	3	0	0	0

4.4 Associated injuries in pelvic fractures

Head injuries were the most common. Head injuries were reported in 23.9% patients and were in most cases mild. Genitourinary injuries were reported in 21.7% patients and included 10.9% urethral, 2.1% bladder contusion, and 8.7% perineal lacerations. Urethral injuries were identified using gross blood at urethral orifice (2.1%); microscopic haematuria (2.1%); and macroscopic haematuria (6.5%).

Blunt thoracic injuries were reported in 13.0% patients and were mainly (10.9%) identified through chest X-Rays and the rest through clinical assessment. Thoracic injuries included lung contusion (10.9%); haemothorax (4.3%); pneumothorax (4.3%); and rib fractures (4.3%).

Blunt abdominal injuries were reported in 6.5% patients and were identified through chest X-Ray, FAST and clinical assessment. Abdominal injuries included bowel perforation (2.1%); haemoperitoneum (2.1%); and upper GI bleed (2.1%).

Contusion in bladder was identified using CT scan. Perineal injuries identified included vulvovaginal (2.1%); penile scrotal (2.1%); abrasions (2.1%); and degloving (2.1%). There were no C-spine; thoracolumbar spine, and peripheral nerve injuries reported (Table 4.5).

Table 4.5: Associated injuries in pelvic fractures

Body part	Injury	Category	Investigation	Frequency	Percent
Head (GCS)	Head injuries (GCS)	Normal		35	76.1
		Mild(12-14)		5	10.9
		Moderate (8-11)		4	8.7
		Severe (<7)		2	4.3
Thoracic	Blunt Thoracic injuries	Normal		40	87.0
		Clinical Assessment		1	2.2
		Chest X-Rays		4	8.7
		Clinical assessment Chest X- ray		1	2.2
Abdominal	Abdominal injuries	Normal		43	93.5
		Blunt	Clinical Assessment	1	2.2
			FAST	1	2.2
			Clinical assessment and FAST	1	2.2
Genitourinary	Urethral injuries	Normal		41	89.1
		Gross Blood at urethral orifice		1	2.2
		Microscopic haematuria		1	2.2
		Macroscopic haematuria		3	6.5
	Bladder injuries	Normal		45	97.8
		Contusion	CT Scan	1	2.2
	Perineal injuries	Normal		42	91.3
		Vulvovaginal (Females)		1	2.2
		Penile Scrotal (Male)		1	2.2
		Abrasions		1	2.2
		Degloving Perineal injury		1	2.2

Additional Injuries included right femur fracture, and right tibia/fibula fracture among others.

See table 4.6 for more injuries.

Table 4.6: Additional injuries

Additional injuries	Frequency	%
Right femur fracture	3	6.5%
Right tibia/fibula fracture	3	6.5%
Avulsed teeth	1	2.2%
Transverse Femur	1	2.2%
Distal radius fracture	1	2.2%
Left subtrochanteric femur fracture	1	2.2%
Left posterior hip dislocation	1	2.2%
Right humerus fracture	1	2.2%
Upper G.I bleeding	1	2.2%
Left femur fracture	1	2.2%
Right distal ulna fracture	1	2.2%
Open Pelvic fracture	1	2.2%
Deep cuts on pinna and upper lip	1	2.2%
Distal tibia fracture	1	2.2%
Urethrocutaneous fistula	1	2.2%
Left humerus fracture	1	2.2%
TOTAL	20	43.8

There was no significant relationship between associated injuries and pattern of pelvic fractures (p value= 0.289) (Table 4.3).

5.0 DISCUSSION

This study showed that majority of the patients who presented with pelvic fractures were male (86.2 %). This is similar to a study by Mutiso et al at Kenyatta National Hospital that showed 71.3 percent of pelvic fracture patients were male (1). However other studies showed a variation in gender depending on the age of the patient. The incidence was shown to be higher in males than females in patients below 49 years and higher in female than males in those above 49 years (23, 38). This has been attributed to the higher incidence of osteoporotic fractures in elderly females (73)

The mean age of the patients was 36.1 years which is a relatively young population. This results are comparable to a study by Mutiso et al which had a mean age of 30.5 years. However Mutiso study had 3 pediatric patients which could have affected the slightly lower average age (1). Other studies in German and Netherlands reveal a higher average mean age than local data (73, 74). The age of the patients has been shown to be a risk factor to acute cardiac events in the outcome of these patients (75). However in this study this was not noted within the three week follow-up.

The average time after accident and before ATLS protocol initiation was 53 minutes.

In this study most of the patients were hemodynamically stable (93.4%) The Mean blood pressure was 109.7/70.6; pulse rate 89.9; respiratory rate 18.1; and Sapo2 (%) 98.7. The mean amount of fluid given was 2 litres of normal saline and this was done in half of the patients (23). This fluid administration shows a different pattern than the massive fluid resuscitation seen in other studies in both the prehospital and the in hospital setting (76) It is possible that patients with hemodynamic instability died before arrival at hospital.

The overwhelming majority of patients were hit by motor vehicles (60.7%). This is higher than Mutiso et al study which showed pedestrians involved in motorcycle accidents were 46.5 %. In his study Mutiso also had a higher proportion of passenger and drivers involved in motor vehicle

accidents at 37.5 %. This is higher than this study which shows 13 % of the same category of patients. Motorcycle accidents contributed 13 % of pelvic fractures patients as compared to Mutiso et al 3 %, a fourfold rise. This is attributable to the increase in motorcycle use in the country as a form of transport .Injury from falls are 10.8% and this compares with the 10 % found in his study. One unusual case of assault was also recorded in this study. The major cause of the pelvic fractures which is motor vehicle accident is similar to other studies done in other countries (77).

The commonest type of pelvic fracture pattern in this study is the tiles B2-1. This is a rotationally unstable but vertically stable injury. In this study B2-1 represent 34.7 %. This is similar to Tiles et al research and also the Young Burgess research of an earlier time (7, 42). Open book injuries also represented 19.6% in this study. Stable fractures of type A2 formed 8.7 %. Notably 21.7 % of the pelvic fractures were associated with acetabular fractures. This concomitant presentation has been shown to adversely affect outcome of management (78) the rotationally and vertically unstable fractures type C accounted for 19.6 %. In this category the highest types were C1-1. At 10.9 %. The most severe forms of C2 which accounted for 6.5 % also included the 3 cases of hemorrhagic shock in this study. In a comparative classification system-the Kane modification of the key and Conwell system used in Mutiso et al study, he found 51.5 % type 2 fractures. This corresponds to the Tiles classification B1 and B2 used in this study which represents 56.6%. The Kane type 1 represented 6% and in this study the equivalent tile type A represent 8.7 %

There was no statistical significant relationship between mechanisms of injury and pattern of pelvic fractures (likelihood p value= 0.289) as shown in table 4.4. There was a challenge in documenting the exact mechanism of injury due to a higher number of patients who were intoxicated at the time of the injury. Thus in this study a general guideline in etiology identification was adopted.

In this study, the highest number of associated injuries was head injuries at 23.9%, however most of these fell in the mild head injury category at 45%. In a local study by Mutiso et al, 47% of pelvic fracture patients had head injury, with only 3 % presenting with severe head injury(1). In this study 4.3% of the patients presented with severe head injury. In other studies internationally, there lacks a clear constant in the highest incidence of an associated injury. In Mutiso et al study this was represented by skeletal trauma and fractures other than pelvic bone in 74%, in South Africa, Froman et al found urinary tract injuries at 46% (3), and in Brazil Pereira found orthopedic fractures of the spine, lower and upper extremity as the commonest at 48 % (33)

Blunt abdominal injury was 6.5 % in this study. In a local study by Mutiso et al it was at 5%. However in other studies internationally, this has been shown to be as high as 24% (53). In this study the abdominal injuries involved the bowel perforation, haemoperitoneum and upper GI bleed. This is in contrast to Mutiso et al which noted solid organ injuries of the spleen, the liver, the pancreas and a retroperitoneal hematoma.

Urologic injuries accounted for 21.7% and were mostly clinically diagnosed. Microscopic hematuria was found in one case. These injuries included urethral injuries, bladder contusion and perineal injuries. In the study by Mutiso et al 24 % of the patients had a urological injury. Froman, in South Africa found 61 % urologic injuries in patients with pelvic fractures. In this study one man had a penile scrotal laceration, another had a degloving injury of the perineum, and a lady patient had a vulvovaginal tear.

In this study, there were 13.1 % thoracic injuries, in a study by Mutiso et al, he found 16.3 % of thoracic injuries. This study found mainly blunt thoracic injuries evaluated using plain radiographs and CT scan.

Other associated injuries that were found in this study included fractures of various bone other than the pelvic 34.7%. This composed mainly of tibia and femur fractures. This contrasts sharply with Mutiso et al who found 74% of associated skeletal system fractures (1). However it compares with Pereira et al study that found 48 % associated skeletal fractures (3). The incidence of open pelvic fractures was 2.2%, and this contrasts with Mutiso et al who found open pelvic fracture in 4 %. In a large study in the US, the open pelvic fracture were found to be at 7.6 %

Hemorrhagic shock was found in 6.5 % of patients, all of whom had Tiles type C2. They were resuscitated and pelvic binding was done with modified bed sheets sling. In Mutiso's study no patient suffered hemorrhagic shock. Exsanguination due to isolated pelvic fracture is low at 0.8 to 1.4 %. The major cause of mortality is associated injuries (79).

One patient had cancer of the cervix with a pathological fracture of the pelvic Tiles Type B2-1 and a concomitant ipsilateral intertrochanteric fracture. In the study by Mutiso, 2 cases of follicular thyroid carcinoma and neurofibrosarcoma were found (1). However this patterns of fracture were due to lytic bone lesions and not comparable to traumatic bone loading.

In this study, the number of pelvic fractures associated with other injuries is 63.3 %. Other studies have shown comparable values at 66 % (18)

6.0 Conclusion

This study shows that the mechanistic classification systems by Tiles do not correlate to specific associated injuries as described in some studies. It also highlights the high prevalence of associated injuries in patients with pelvic fractures. The study also show the common cause of pelvic fractures remain motor vehicle accidents, more so the pedestrians .The study shows relatively low incidences of hemorrhagic shock, and co-relates incidence of hemorrhagic shock with the vertically and rotationally unstable pelvis.

7.0 Recommendations

1. Improve on the Accident and Emergency service delivery time at Kenyatta national hospital.
2. Relevant authorities should institute robust road safety campaigns especially among the pedestrians.
3. To encourage multidisciplinary assessment and management of patients with pelvic fractures in order to improve their outcomes and reduce number of missed injuries.
4. To equip the Accident and Emergency Center at Kenyatta national hospital to manage pelvic hemorrhagic shock such as purchase of pelvic binders, and avail adequate equipment for resuscitation such as large bore cannulas and appropriate fluids including blood.

IMPLEMENTATION TIMETABLE

- **Proposal writing and submission for ethical approval**
-January 2016 – October 2016
- **Data collection and analysis**
-November 2016 –February 2017
- **Dissertation writing**
- March 2017
- **Presentation of results**
- April 2017

BUDGET ESTIMATES

ITEM	COST (SHS)
Research fees (KNH/ERC)	1,500
Stationery, printing and binding @ 200/patient	9,200
Statistician fee and Assistants	45,000
Contingencies	15,000
Supplementary tests as required	40000
Total	110,700

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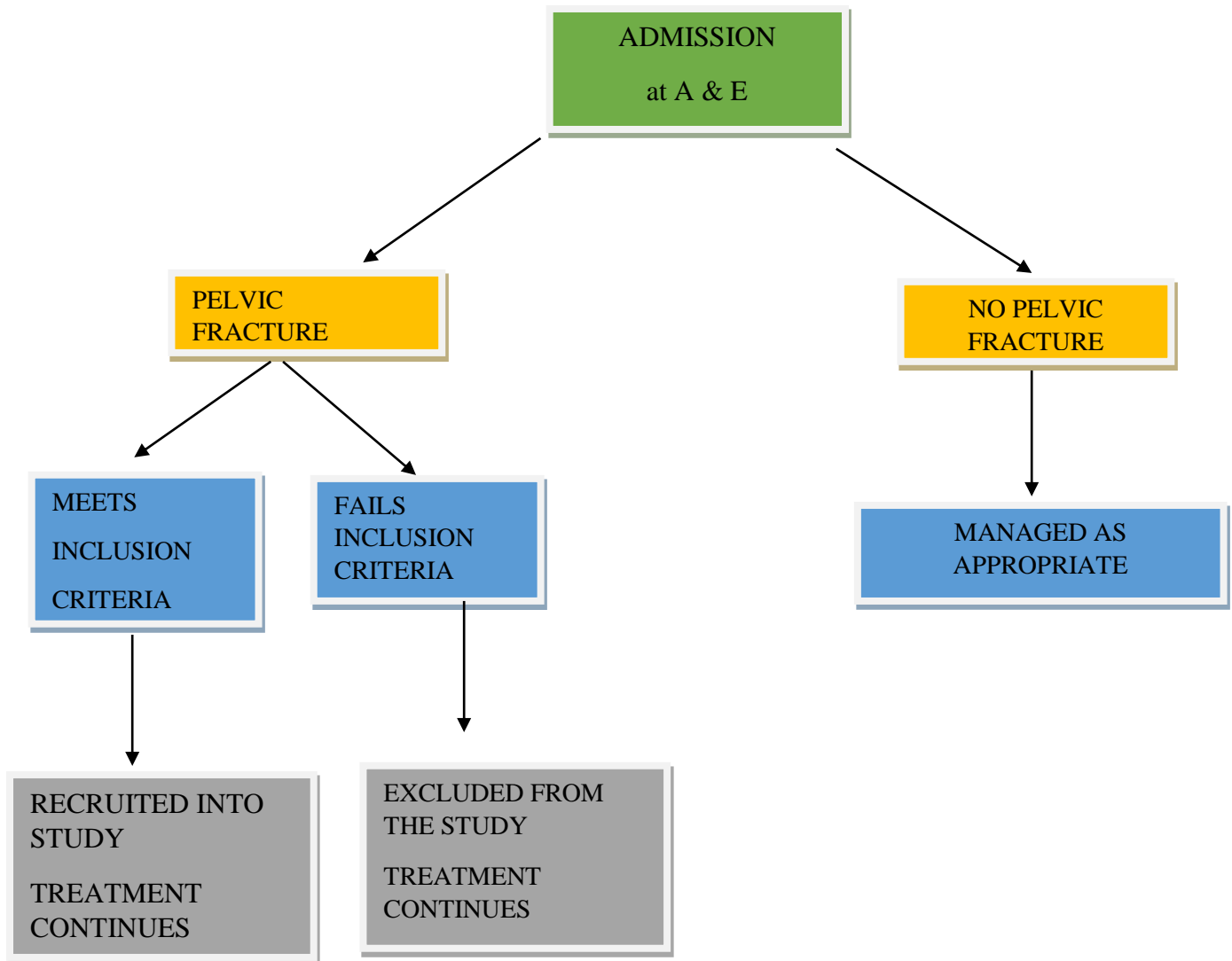
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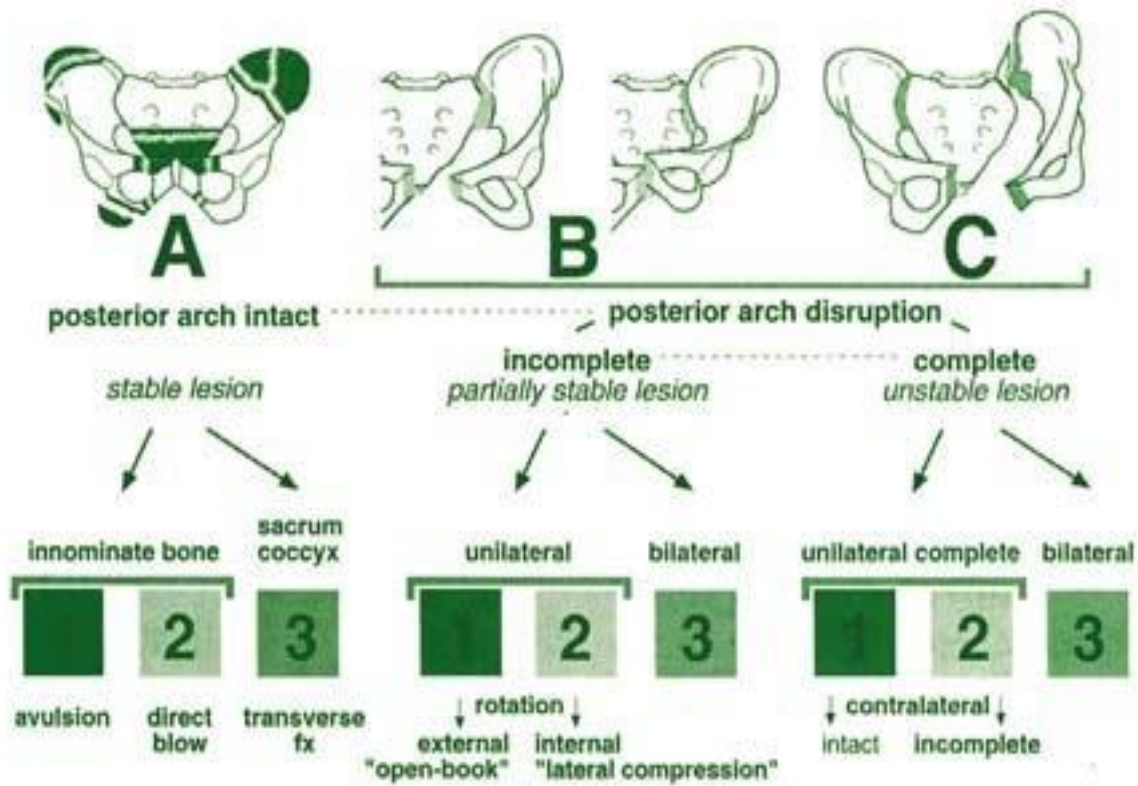
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APPENDIX I: Patient flow diagram



APPENDIX II



INTERPRETATION

- **A: stable**
 - A1: fracture not involving the ring (avulsion or iliac wing fracture)
 - A2: stable or minimally displaced fracture of the ring
 - A3: transverse sacral fracture (Denis zone III sacral fracture)
- **B - rotationally unstable, vertically stable**
 - B1: open book injury (external rotation)
 - B2: lateral compression injury (internal rotation)
 - B2-1: with anterior ring rotation/displacement through ipsilateral rami
 - B2-2: with anterior ring rotation/displacement through contralateral rami (bucket-handle injury)
 - B3: bilateral
- **C - rotationally and vertically unstable**
 - C1: unilateral
 - C1-1: iliac fracture
 - C1-2: sacroiliac fracture-dislocation
 - C1-3: sacral fracture
 - C2: bilateral with one side type B and one side type C
 - C3: bilateral with both sides type C

APPENDIX III

TABLE 3

CLASSIFICATION OF HEMORRHAGIC SHOCK^{1,5,16}

	Compensated	Mild	Moderate	Severe
Blood Loss (mL)	≤1000	1000–1500	1500–2000	>2000
Heart rate (bpm)	<100	>100	>120	>140
Blood pressure	Normal	Orthostatic change	Marked fall	Profound fall
Capillary refill	Normal	May be delayed	Usually delayed	Always delayed
Respiration	Normal	Mild increase	Moderate tachypnea	Marked tachypnea: respiratory collapse
Urinary output (mL/h)	>30	20–30	5–20	Anuria
Mental status	Normal or agitated	Agitated	Confused	Lethargic, obtunded

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APPENDIX IV

DATA COLLECTION SHEET

Study number.....

PATIENT DATA

1. Participant assigned code:
Inpatient number.....
X-ray/CT scan/ultrasound number.....
2. Age in years
3. Sex : M
F
4. **Date of injury**
Time of injury.....
Time of arrival at hospital.....
Total time before ATLS Protocol.....
5. **Physiological vital parameters upon arrival**
(i) Blood pressure.....
(ii) Pulse rate.....
(iii) Respiratory rate.....
(iv) Sapo2.....
(v) Type of fluids given.....
Amounts of fluids given.....

Vitals taken by admitting team of doctors and nurses using clinical examination, digital automatic blood pressure machines, digital pulse oximeters and digital mercury thermometers.

PELVIC FRACTURE DATA

1. MECHANISM OF INJURY

- a. Trauma
 - (1) **Motorcycle**
 - (i) Rider
 - (ii) Passenger
 - (2) **Motor vehicle**
 - (i) Driver
 - (ii) Passenger
 - (iii) Pedestrian
-

(3) Fall

(i) Low heights

(ii) High heights

(4) Others

(i) Sports

(ii) Missiles

b. Pathological

(i) Metabolic

(ii) Tumors

PELVIC FRACTURE PATTERN (TILES CLASSIFICATION)

TYPE	SUBTYPES		
<input type="text" value="A"/>	1	2	3
<input type="text" value="B"/>	1	2	3
<input type="text" value="C"/>	1	2	3

1. ASSOCIATED INJURIES

a. Head injury (GCS)

(i) Mild (12-14)

(ii) Moderate (8-11)

(iii) Severe (< 7)

b. C-spine injuries

(i) Clinical features

(ii) X-ray features

c. Thoracic injuries

Method:

(a) Clinical assessment

(b) Radiological assessment 1. Chest X-rays

2. Chest CT scan

(i) Blunt

(ii) Penetrating

Specifications:

1. Lung contusion

2. Haemothorax

3. Pneumothorax

4. Cardiac contusion

5. Rib fractures

6. Others.....

d. Thoracolumbar spine injuries

Method: Clinical

X-ray

CT scan

Present

Absent

e. Abdominal injuries

Method: (a) clinical assessment

(b) Paracentesis

(c) FAST

(d) CT Scan

(i) Penetrating

(ii) Blunt

Organs involved

- 1. Liver
- 2. Spleen
- 3. Kidneys
- 4. Bowel
- 5. Retroperitoneal hemorrhage
- 6. Pneumoperitoneum
- 7. Haemoperitoneum
- Others.....

f. Genitourinary injuries

- (a) Urethral
 - (i) Gross blood at urethral orifice
 - (ii) Macroscopic haematuria
 - (iii) Microscopic haematuria
 - (iv) MCU

- (b) Bladder
 - (i) Ultrasound
 - (ii) CT Scan
 - rupture
 - contusion

(c) Perineal

Method: clinical examination

- Vulvovaginal (females)
- Penile scrotal (males)

Others.....

(g) Peripheral nerve injury

Method: clinical examination- Dermatomes

- Myotomes

- (i) Present
- (ii) Absent

APPENDIX V

Table 1 Coded Categories of Physiological Parameters used for Calculation of the Revised Trauma Score

GCS	SBP	RR	Coded Value
13–15	>89	10–29	4
9–12	76–89	>29	3
6–8	50–75	6–9	2
4–5	1–49	1–5	1
3	0	0	0

GCS, Glasgow Coma Score; SBP, Systolic blood pressure; RR, Respiratory rate.

1. [Champion HR, Sacco WJ, Copes WS, et al. A revision of the trauma score. *J Trauma*. 1990;29:623.](#)

APPENDIX VI a

KIBALI CHA RUHUSA TAARIFA YA WASHIRIKI NA FOMU IDHINI

IDHINI YA WATU WAZIMA

Ajili ya uandikishaji katika STUDY

Jina la Utafiti:

Mtindo wa kuvunjika kwa mfupa wa makalio, majeraha mengineyo husika na matatizo yanayojitokeza mapema katika kitengo cha watu wazima wanaopata huduma katika hospitali kuu ya kitaifa ya Kenyatta.

Mpelelezi Mkuu \ na uhusiano wa kitaasisi:

DR Wachira Victor Gioko
Chuo kikuu Cha Nairobi
Kitengo cha upasuaji wa mifupa

Wakaguzi wasaidizi na uhusiano wa kitaasisi:

Hamna

Utangulizi:

Napenda kukuambia kuhusu utafiti utakaofanywa na watafiti waliotajwa juu hapo. Madhumuni ya fomu hii ya idhini ni kukupa taarifa unayohitaji kukusaidia kuamua kama au sivyo kuwa mshiriki katika utafiti. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, kile kinachotokea kama wewe utashiriki katika utafiti, hatari na faida, haki zako kwa kujitolea, na kitu kingine chochote kuhusu utafiti au mambo yoyote yasiowazi. Wakati tutakapo kujibu maswali yako yote hadi ukaridhika, unaweza kuamua kuwa katika utafiti au la. Mchakato huu unaitwa 'ridhaa'. Mara baada ya kuelewa na kukubali kuwa katika utafiti huo, nami nitaomba wewe uweke ishara ya jina lako katika fomu hii. Unapaswa kuelewa kanuni za jumla ambayo yanahusu washiriki wote katika utafiti wa matibabu: i) Uamuzi wako wa kushiriki ni hiari kabisa ii) Unaweza kuondoa kutoka utafiti wakati wowote bila lazima kutoa sababu kwa ajili ya uondoaji wako iii) Kukataa kushiriki katika utafiti sio kuathiri uwezo wako au haki yako kupata huduma katika kituo hiki au chengine chochote. Tutakupa nakala ya fomu hii kwa ajili ya kumbukumbu yako.

Naomba kuendelea? NDIO LA

Utafiti huu umeidhinishwa na hospitali kuu ya Kenyatta -Chuo Kikuu cha Nairobi Maadili na Kamati ya Utafiti wa itifaki nambari.....

Watafiti waliotajwa hapo juu watakuhoji, na kukukagua kwa njia ya heshima watu ambao wako na shida ya kuvunjika kwa mfupa wa makalio. Madhumuni ya mahojiano na uchunguzi ni kutaka kujua mwelekeo wa wale wenye kuvunjika mfupa wa makalio, majeruhi yanayohusiana wakati wa kuvunjika, na matatizo yanayokidhiri mapema. Washiriki katika utafiti huu wataulizwa maswali kuhusu jinsi walijeruhiwa, sehemu ya miili yao iliojeruhiwa, na jinsi vile siha yao iko baada ya majeruhi.

Washiriki wanaweza pia kufanyiwa vipimo kama vile X-ray, CT scan au vipimo vya maabara kama vile uchambuzi wa mkojo.

Kutakuwa na takriban 46 washiriki katika utafiti huu nasibu waliochaguliwa. Sisi tunakuuliza utupe idhini yako ya kuzingatia na kushiriki katika utafiti huu.

NINI KITATOKEA KAMA UTAAMUA KUTOSHIRIKI?

Kama wewe utakubali kushiriki katika utafiti huu, mambo yafuatayo yatatokea:

Utakuwa na mahojiano na watafiti katika eneo binafsi ambapo utajisikia shwari kujibu maswali vizuri. Mahojiano yatachukua dakika thelathini. Mahojiano yatakuwa juu ya jinsi ulivyojeruhiwa, aina ya majeruhi yako, na vile unavyoendelea kupata siha hadi sasa.

Baada ya mahojiano kumalizika, wewe utakaguliwa katika eneo binafsi. Kunaweza kuwa na vipimo vya maabara ambavyo vinahitajika. Kunaweza kuwa na aina spesheli za picha kama vile X ray au CT scan zitakazohitajika.

Tutakuomba namba ya simu ambayo tunaweza kuwasiliana na wewe iposa tutahitaji. Kama utakubali kutoa taarifa za mawasiliano yako, itatumika tu kwa watu wanaofanya kazi kwa ajili ya utafiti huu na haitakuwa kamwe kwa watu wengine. Sababu ya kuhitaji kuwasiliana na wewe ni pamoja na kujua jinsi unavyoendelea kiafya siku ya 7, 14 na siku ya 21 toka kuvunjika kwa mfupa wa makalio.

KUNA MADHARA YOYOTE KUSHIRIKI KATIKA UTAFITI HUU?

Utafiti wa matibabu unaweza kubadili kisaikolojia, kijamii, kihisia na kimwili vile vile. lazima tunaweka juhudi kupunguza hatari. Hatari moja ya utafiti ni ujumbe wako kutokea faraghani. Sisi kama watafiti tunaweka siri kabisa. Tunatumia kodi kwa komputa na vile vile makaratasi huwekwa ndani ya kabati. Lakini bado kuna uwezekano wa watu inje ya utafiti kujua habari kuhusu wewe.

Pia, kujibu maswali katika mahojiano kunaweza leta wasiwasi kwako. Kama kuna maswali yoyote hautaki kujibu, unaweza ruka hayo. Una haki ya kukataa mahojiano au maswali yoyote unayoulizwa wakati wa mahojiano.

Unaweza kuhisi aibu wakati wa uchunguzi wa kliniki. Tutafanya kila kitu tunaweza kuhakikisha kwamba ukaguzi utafanyika pahali binafsi. Aidha, wafanyakazi wote katika utafiti ni wataalamu na wana mafunzo maalum katika huu ukaguzi na mahojiano.

KUNA FAIDA YOYOTE KUWA KATIKA UTAFITI HUU?

Unaweza kufaidika kwa kupokea habari za afya kuhusu kuvunjika kwa mfupa wa makalio. Na pia jinsi unavyoweza kuadhirika sasa na siku zijazo.

Sisi tutakuelekeza kwa hospitali kwa ajili ya kupata huduma na msaada inapobidi. Pia, habari utakayotupatia itatusaidia kuelewa njisi kuvunjika kwa mfupa wamakalio unaadhiri watu. Habari hii ni mchango wa sayansi na itatusaidia kusimamia vizuri wagonjwa ambao huja na shida hii kubwa ya kuvunjika mfupa wa makalio.

UTAPATA GHARAMA YA JUU KWA SABABU YA KUSHIRIKI KATIKA UTAFITI?

Ushiriki wako katika utafiti huu hauna gharama yoyote ya ziada. Sisi tunafuatilia tu usimamizi wako na tathmini na kuchunguza majeruhi yote yanayohusishwa na kuvunjika kwa mfupa. Gharama yako ya hospitali itakuwa sawa kama wagonjwa wale ambao hawajashiriki katika utafiti huu.

UTARUDISHIWA FEDHA UTAKAZOTUMIA KATIKA UTAFITI HUU?

Kama nilivyosema hapo juu, huwezi pata gharama yoyote ya ziada kutokana na kushiriki katika utafiti huu. Ushiriki wako katika utafiti huu hauhitaji hela zaidi.

JE KAMA UTATAKA KUULIZA MASWALI BAADAYE?

Kama kuna maswali zaidi au jambo lolote kuhusu kushiriki katika utafiti huu, tafadhali piga simu au kutuma ujumbe wa maandishi kwa wafanyakazi wa utafiti katika idadi zinazotolewa chini ya ukurasa huu.

Kwa habari zaidi kuhusu haki zako kama mshiriki utafiti unaweza kuwasiliana na Katibu / Mwenyekiti, Kenyatta National Hospital-Chuo Kikuu cha Nairobi Maadili na Utafiti Kamati Namba Hakuna 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

wafanyakazi wa utafiti wanaweza kulipa gharama yako ya simu kutokana na kuwasiliana nao.

UKO NA HIARI?

Uamuzi wako wa kushiriki katika utafiti ni hiari. Wewe ni huru kutoshiriki katika utafiti na unaweza kuondoka kutoka utafiti wakati wowote bila dhuluma au kupoteza faida yoyote.

IDHINI FOMU (TAARIFA YA IDHINI)

Kauli mshiriki

Nimesoma fomu hii ya idhini au nimesomewa taarifa hii. Nimekuwa na nafasi ya kujadili utafiti huu na mshauri wa utafiti. Maswali yangu yamejibiwa kwa lugha ninayoelewa vyema. Hatari na faida wamenielezea. Naelewa kwamba ushiriki wangu katika utafiti huu ni wa hiari na naweza

kuchagua kujiondoa wakati wowote. Mimi kwa uhuru nakubali kushiriki katika utafiti huu .Naelewa kwamba juhudi zote zitafanywa kuweka habari kuhusu utambulisho wangu binafsi za siri.

Kwa kutia saini fomu hii ya idhini, mimi si wamekata yoyote ya haki za kisheria kwamba nina kama mshiriki katika utafiti.

Mimi nakubali kushiriki katika utafiti huu: **Ndiyo** **Hapana**

Nakubaliana na kutoa taarifa za mawasiliano kwa ajili ya kufuatilia: **Ndiyo** **Hapana**

Mshiriki kuchapishwa jina:

Mshiriki saini :

Thumb stempu _____ **Tarehe** _____

APPENDIX V b

CONSENT FORM

PARTICIPANT INFORMATION AND CONSENT FORM

ADULT CONSENT

FOR ENROLLMENT IN THE STUDY

Title of Study:

PATTERN OF PELVIC FRACTURES, ASSOCIATED INJURIES AND EARLY COMPLICATIONS AS SEEN IN ADULTS AT KENYATTA NATIONAL HOSPITAL

Principal Investigator\and institutional affiliation:

DR WACHIRA VICTOR GIOKO
UNIVERSITY OF NAIROBI DEPARTMENT OF ORTHOPEDICS

Co-Investigators and institutional affiliation:

NONE

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or in this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No.

The researchers listed above are interviewing and examining individuals who have suffered broken pelvic bones. The purpose of the interview and examination is to find out the patterns of these pelvic bone fractures, the associated injuries during the fractures, and the early complications associated with the fracture. Participants in this research study will be asked questions about how they got injured, which parts of their bodies were injured, and how they are doing after the injuries. Participants may also have to undergo tests such as x-ray, CT scan or laboratory tests such as urine analysis as deemed appropriate for their care.

There will be approximately 46 participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately thirty minutes. The interview will be about how you got injured, what the injuries are, what was done to you and how you are faring on so far.

After the interview has finished, you will be examined in a private area where you feel comfortable. There may be laboratory tests that will be needed, blood or urine may be drawn from you. There may be radiological imaging that is needed, you will be taken to the X ray or CT scan department.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include knowing how you are faring on the 7th, 14th and 21st day since you broke you pelvic bone.

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

It may be embarrassing for you to have clinical examination. We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You have the right to receiving health information regarding your broken pelvic bone and the way it affects you now and in the future. This information will be offered to you.

We will refer you to a hospital for care and support where necessary. Also, the information you provide will help us better understand the way the pelvic bone breaks, how it injures other structures, and how other parts of the body are injured at the same time. This information is a contribution to science and will help us to better manage the patients who come with broken pelvic broken and other injuries in a better way.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

Your involvement in this study will not cost you anything extra. We are simply following your management and evaluation and detecting all injuries that are associated with your broken pelvic bone. Your hospital bills will be the same as those patients who choose not to participate in this study.

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

As stated above, you will not incur any costs solely for this study. Your costs will be the regular costs paid by all patients receiving treatment in the hospital. Your involvement in this study will not cost you any money.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counsellor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: **Yes** **No**

I agree to provide contact information for follow-up: **Yes** **No**

Participant printed name: _____

Participant signature -----

Thumb stamp _____ **Date** _____

Researcher's statement

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

Researcher's Name:

Date:

Signature:

Role in the study:

For more information contact **DR WACHIRA VICTOR GIOKO** at **UNIVERSITY OF NAIROBI, DEPARTMENT OF ORTHOPEDICS** from **MONDAY** to **FRIDAY WEEKDAYS.**

Witness

Name:

Contact information:

Signature /Thumb stamp:

Date: