PREVALENCE OF SECONDARY MEDICAL COMPLICATIONS AFTER TRAUMATIC SPINAL CORD INJURY DURING ACUTE CARE IN KENYATTA NATIONAL HOSPITAL

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DECLARATION

I hereby declare that this study is my original work and has not been presented as a dissertation at any other university.

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LIST OF ABBREVIATIONS

AD – Autonomic Dysreflexia

AIS – Asia Impairment Scale

ASIA – American Spinal Injury Association

DVT – Deep Vein Thrombosis

KNH/UoN – ERC – Kenyatta National Hospital, Ethics and Research Committee

LMICs – Low and middle income countries

MAS – Modified Ashworth Scale

MV – Mechanical Ventilation

NP – Neuropathic pain

PUs – Pressure Ulcers

ROM – Range of Motion

SCI – Spinal Cord injury

tSCI – Traumatic Spinal Cord Injury

UTI – Urinary Tract Infections

VOP – Plethysmography

VTE – Venous Thromboembolism

OPERATIONAL DEFINITIONS

Complication	Operational definition and diagnosis
Pulmonary complications	Atelectasis refers to the collapse of alveolar lung units and which could be lobar or diffuse, is radiographically diagnosed. Pneumonia refers to the lung tissue inflammation due to infectious aetiology. Pneumonia was confirmed radiographically combined with either sputum or blood tests and physical examination.
Pressure ulcer	Is a region of skin damage due to decreased tissue perfusion caused by pressure, shear or friction. Due to the subjects being of African origin, we excluded stage 1 PU's due to the difficulty of diagnosing darkly pigmented skin tones.
Urinary tract infection	This is mainly due to the neurogenic bladder associated with SCI. Infections are caused by lack of bladder emptying and the introduction of bacteria into the bladder via catheterization. Diagnosis of UTI was via lab analysis of the urine cultures identifying responsible bacteria.
Autonomic dysreflexia	This refers to imbalanced reflex sympathetic discharge that occurs in SCI above the autonomic sympathetic outflow. History and physical examination was used to diagnose the presence of autonomic dysreflexia.
Deep vein thrombosis	Clotting of blood is common after an SCI. Diagnosis was mainly be based on physical examination results on the basis of Well's criteria (Appendix III)
Pulmonary embolism	Persons with deep vein thrombosis were followed more closely. Blood tests were performed to measure levels of D-dimer protein. A diagnosis of pulmonary embolism was made if a person with high D-dimer levels developed acute respiratory distress.
Neuropathic pain	This is defined as pain originating from spinal cord ischaemia or trauma.
Spasticity	This is a feature of upper motor neuron lesion presenting with exaggerated stretch reflex due to hyper-excitability of spinal reflexes.

ABSTRACT

Background: There is paucity of data in low and middle income countries concerning the burden of traumatic spinal cord injury (tSCI). Despite advanced acute care and better awareness and identification of complications, many complications still occur during acute phase. These complications lengthen hospital stays and adversely affect rehabilitation. Attempt aimed at improving quality of care should be based on comprehensive and reliable data. This data is lacking in our local setting.

Study Design: Hospital based Prospective Cohort Study.

Objectives: To identify the prevalence of selected medical complications after tSCI during acute care and to identify predisposing factors for pressure ulcers.

Study Population: Patients with acute tSCI or traumatic cauda equina syndrome aged 18 years and above at admission.

Methods: Demographic, injury characteristics and neurological severity data were captured using International SCI Core Data Set. The predefined medical complications were screened for and recorded. Risk factors for pressure ulcers were assessed through logistic regression models.

Results: A sample of 63 (92.65%) patients was analyzed. Overall, the most common secondary medical complication was Urinary Tract Infection (UTI) (n= 46 (73.02%)), followed by pulmonary complications (n=38 (60.32)) and pressure ulcers (n=26 (41.27%)). Other complications were neuropathic pain, (n =22 (34.92%)), spasticity (n =18 (28.57%)), autonomic dysreflexia, (n =14 (22.22%)) and venous thromboembolism (n =9 (14.29%)).
Significant risk factors for development of pressure ulcers were development of urinary tract infections and pulmonary complications at risks of 3.5 and 11.7 times of developing PU, respectively (Odds Ratio (OR) =3.52; 95% CI: 1.15-10.75) (OR=11.75; 95% CI: 1.12-123.24). Additionally, those with more than one complication were 6.4 times more likely to develop PU, as compared to those with only one complication (95% CI: 1.05-39.33). Those aged between 46-60 years were 4.7 times more likely to develop PUs, compared with the younger (18-30) age group. This was only significant at 90% confidence interval. (OR = 4.7; 90% CI: 0.98–23.54).

Conclusion: Secondary medical complications are common in traumatic Spinal Cord injury in Kenyatta National Hospital during acute care. Individual risk factors for development of pressure ulcers were urinary tract infections, pulmonary complications and patients having more than 2 complications.

1.0 INTRODUCTION

Life expectancy for patients with tSCI has increased over the last few decades (1). This is due to medical advances that have led to improved health care (2). In this respect, it is noteworthy that tSCI not only results in paraplegia or tetraplegia but also adverse events (AEs) that have become frequent during acute care in patients with tSCI(3, 4). These complications lengthen hospital stays and affect the rehabilitation process. To prevent complications, more information about the number and nature of complications is needed (1).

Over half of tSCI patients will have at least 1 complication during hospital stay. 75% of these adverse events present within 2 weeks. These adverse events associated with tSCI carry a significant risk of morbidity and mortality. Prompt diagnosis and treatment is critical in care of the tSCI patients (5).

Most published and unpublished studies have reported the common secondary medical complications of traumatic spinal cord injuries to include, pulmonary complications, urinary tract infections, pressure ulcers, autonomic dysreflexia, deep vein thrombosis, pulmonary embolism, spasticity and neuropathic pain (1, 2, 6-9). Age, severity of neurological injury, associated traumatic brain injury, comorbid illnesses and mechanism of injury have all been shown to increase risk of complications (1, 5). There is limited local data regarding the prevalence of these secondary complications. One local study reported prevalence of 48.3% for neuropathic pain, 44.8% for pressure ulcers and 40.8% overall mortality within 3 months.(10) Above findings indicate that these complications are indeed a huge burden in management of traumatic spinal cord injuries in our local setting.

Pressure ulcers are serious and common complications in patients with tSCI. Though an ancient, pressure ulcers are still a problem today. Pressure ulcers commonly occur over bony prominences such as the sacrum, ischial tuberosities, heels, malleoli and greater trochanters. Previous reports have identified reduced activity, insensibility, moisture from urinary or fecal incontinence, atrophy, prolonged time since injury, depression, smoking and malnutrition as

the main predisposing factors. However, identification of pre disposing factors in the local settings is lacking. Pressure ulcers constitute a huge burden in the management and rehabilitation of tSCI patients especially in resource limited settings in developing countries (11, 12). As well as other complications, pressure ulcers are associated with longer hospital stay with dire financial implications (1, 13).

2.0 LITERATURE REVIEW

There is paucity of data in low and middle income countries (LMICs) concerning the burden of tSCI. The incidence of tSCI in LMICs is estimated to be 25.5 million per year. This causes a major impact on patients and their caregivers due to the social structure and limited resources. Traumatic spinal cord injury is likely to be fatal within a year (14). One local study reported overall mortality of 40.8% within 3 months of follow up (10).

Spinal cord injury often occurs following high-energy mechanisms, or lower-energy mechanisms (weakened skeletal system). Comprehensive neurologic assessment at initial evaluation guides subsequent diagnostic procedures and early supportive measures to help prevent further associated complications (4).

2.1 Pressure Ulcers

Pressure ulcers are a frequent complication following traumatic spinal cord injury (SCI). Advanced age, more severe ASIA grade, and cervical lesions as well as increased Charlson Comorbidity Index are also significantly associated with occurrence of pressure ulcers (15, 16).

Occurrence of pressure ulcers decrease significantly when there is motor sparing. Cauda equina syndromes are a lower risk, not dependent on ASIA grading and are statistically equivalent to motor sparing at cord levels. Motor sparing at cord levels or any cauda equina level is most predictive neurologically for pressure ulcers (17).

Pressure ulcers occur in bony prominences that are under pressure when the patient is recumbent. These areas are vulnerable to compression due to immobility and because they lie closely under the skin with no muscle layer cushioning in between (18).

Two major processes that cause pressure ulcer are ischemic damage and deformation damage. Ischemic damage takes several hours to initiate while deformation damage occurs at high strains and is evident within minutes (19).

Pressure ulcers increase length of hospital stay, cost of care of spinal cord injury patients, may be a portal of systemic infections. One study demonstrated meningitis with pneumocephalus originating from a sacral pressure ulcer. Strategies to prevent occurrence of pressure ulcers include; use of ripple mattresses, 2- 4 hourly turning in bed, crease free bed spreads, good nutrition, proper skin care, sphincter control and management of muscle spasms (20).

2.2 Pulmonary complications

Respiratory complications have been shown to be the most frequent cause of morbidity and mortality in acute spinal cord injury (SCI), at a prevalence of 36% - 83%. One study showed 80% mortality in cervical SCI patients due to pulmonary complications, with pneumonia causing half of the cases (21-24).

This risk of developing pulmonary complications has important implications in the management of tetraplegic patients. Atelectasis refers to the collapse of alveolar lung units and which could be lobar or diffuse, and is radiographically diagnosed. Pneumonia refers to the lung tissue inflammation due to infectious aetiology. Pneumonia is confirmed radiographically combined with either sputum or blood tests and physical examination. (25).

Patients injured at cervical level often need prolonged mechanical ventilation due to risk of respiratory failure as a result paralysis of respiratory muscles, impairment of clearance of tracheal and bronchial secretions and high incidence of respiratory complications. Patients injured at thoracic level may need mechanical ventilation due to associated injuries. Due to these reasons, tracheostomy is often performed in cervical spinal cord injuries (26).

Prevention of pneumonia and atelectasis is important to reduce mechanical ventilation in tetraplegic patients. Prolonged mechanical ventilation is linked with poor neurologic status (27).

2.3 Urinary tract infections

After an acute SCI the majority of the patients require bladder evacuation.

Spinal cord lesions can contribute to urinary tract infections. In one particular study, urinary tract infections was 65.7% in a spontaneous voiding group, 20% in a clean intermittent catheterization group, 78.9% in an in dwelling urethral catheterization group and 87.5% in a suprapubic Foley catheterization group (28, 29). Other comparative studies have shown lower infection rates to be associated with indwelling suprapubic catheters compared to in dwelling urethral catheters (30, 31). Intermittent catheterization as a form of evacuation in neurogenic bladder has resulted in low rate of urinary tract infections (32, 33).

Intermittent catheterization is widely accepted throughout the world as the best initial form of treatment. Other strategies to prevent and control urinary tract infections include; increased fluid intake, sterilization of urine, acidifying urine, change of catheter and crede's manouvre (34).

2.4 Autonomic dysreflexia

Autonomic dysreflexia has been shown to be present in about 90% of patients with T6 or above level spinal cord injury and can be as frequent as 40 times per day.

Autonomic dysreflexia refers to transient and uncontrolled rise in systolic blood pressure of more than 20 mm Hg, which may or may not be accompanied by bradycardia (35).

Autonomic dysreflexia is common in chronic phase of spinal cord injury. In acute phase (1 month) after SCI, it is rarely reported. In one study, the prevalence of early autonomic dysreflexia was 5.2%, whereas the adjusted prevalence for the population at risk (SCI at T6 or above) was 5.7%. The triggers for autonomic dysreflexia were somatic pain, fecal impaction, and abdominal distention (36). Other documented triggers include pressure ulcers, ejaculation and anal fissures (37).

A noxious stimulus triggers a rise in blood pressure causing vasodilation. In autonomic dysreflexia, patients are unable to vasodilate below the level of injury due to disruption of

the autonomic outflow below the injury. This results in persistently high blood pressure that present with autonomic responses such as headache, flushing, sweating, and hypertensive crisis (38).

Autonomic dysreflexia is a dangerous complication in chronic SCI at T6 or above and can be fatal. (39) In one clinical review, 22% mortality was noted to occur to be directly linked to complications following autonomic dysreflexia (40).

2.5 Venous thromboembolism

Venous thromboembolism (VTE) encompasses both deep vein thrombosis and pulmonary embolism (41).

The Virchow triad includes hypercoagulability, stasis/ turbulence, and endothelial damage. Stasis and hypercoagulability are the major factors that predispose to venous thromboembolism in SCI patients.

Prevalence of VTE following SCI in western countries has been well documented. However, studies on the prevalence of DVT and PE following SCI in African populations are scanty (42).The diagnosis of DVT is based up on clinical examination, doppler ultrasound examination, impedence plethysmography, venous occlusion plethysmography (VOP), venography, D-dimer measurement or by fibrinogen scanning. There is no particular “gold standard” examination for DVT(43).

Well’s criteria is the most commonly used clinical prediction rule in diagnosis of DVT. Prevalence of DVT based on pretest probability of low, intermediate and high (as estimated by Wells Criteria) is 5%, 15% and 70% respectively. Therefore well’s criteria was used to predict DVT in this study (44).

2.6 Neuropathic pain

Following spinal cord injury, neuropathic pain (NP) can occur from damage to the neural tissues and nociceptive pain can result from damage to non-neural tissues. The prevalence of NP among persons with SCI is high, ranging from 15-38% in acute care and up to 59% in the community. NP symptoms include burning sensation, painful cold, electrical shocks, tingling, pins & needles, numbness and itching (45).

Treatment of neuropathic pain is often challenging and can be a frustrating encounter in patients with tSCI. (46).

2.7 Spasticity

Spasticity is a frequent problem in about a third of patients with spinal cord injury up to 5 years post injury. One in every 5 patients have functional limitations due to spasticity, highlighting the importance of close community follow-up and the need for more evidence on spasticity management strategies (47).

The Modified Ashworth Scale (MAS) is the most popular clinical measure of spasticity. (48).

2.8 STUDY JUSTIFICATION

Spinal cord injury (SCI) is one of the most disabling consequences of trauma in terms of economic, social, and personal burden.

Attempts aimed at improving quality of care should be based on comprehensive and reliable data. This data is inadequate in our local setting.

Few studies have sought to assess complications of spinal cord injury in Kenyatta National Hospital. Therefore, there is paucity of data concerning the prevalence of complications in Kenyatta National Hospital (KNH).

This knowledge gap hinders resource allocation to address complications that negatively impact the individuals.

This study has availed comprehensive data on medical complications and predisposing factors for pressure ulcers in SCI in Kenyatta National Hospital thus offer recommendations for practice and future research. This should necessitate establishment of acute tSCI unit in Kenyatta National Hospital to offer focused care to traumatic spinal cord injury patients.

2.9 OBJECTIVES

1. To identify the prevalence of selected secondary medical complications during acute care of tSCI patients.
2. To identify factors that pre dispose to occurrence of PUs during acute care of tSCI patients.

3.0 MATERIALS AND METHODS

3.1 Setting

This study was carried out amongst patients admitted in the orthopedic wards at Kenyatta National Hospital (KNH). KNH is a national referral hospital in Nairobi – Kenya. Geographically, Nairobi is centrally located; therefore, the hospital draws its patients from all over the country.

Acute care starts from admission to discharge to different levels of care. This includes up to 1 month of primary hospital stay.

Participants intermediately managed at another hospital before referral to KNH were assessed for only newly developed complications during their acute care.

3.1.1 Inclusion criteria

1. Patients with tSCI or traumatic cauda equina syndrome; aged 18 years or above at admission.
2. Survival of at least 1 week post injury.

3.1.2 Exclusion criteria

1. Patients with ASIA E after 1 week following injury.
2. All patients with pressure ulcers from casts and plasters.
3. Patients with diabetes as a premorbid medical condition predisposing to foot ulcers.
4. Patients with severe head injury
5. Patients with injuries older than 1 month on admission.

3.2 Sample Size

Kenyatta National Hospital has three wards that admit approximately 6 patients per week from review of medical records. This study envisaged a recruitment period of twelve weeks which would result in a study population of 72 patients. The sample size was calculated using Fischer's formula as follows;

$$n_0 = \frac{Z^2(1-\infty/2) \times P(1-P)}{d^2}$$

Where;

n_0 = sample size to be determined

Z^2 (1-∞/2) =is the standard error of the mean corresponding to a 95% confidence interval and the corresponding value from a t-table is 1.96.

P =is the expected prevalence of the event to occur. Value of P was 0.5. This is best average estimate for the predetermined secondary complications.

d = is the target margin of error which will be 5 %(0.05) to increase precision.

$$n_0 = \frac{1.96^2 \times 0.5 \,(\, 1 - 0.5)}{0.05^2}$$

Hence n_0 = 384.

However, given the small population, we modified Fischer's formula by including the finite population correction factor (fpc) as;

$$n = \frac{n_0 N}{n_0 + (N - 1)} \quad \textbf{(8.14)}$$

Where;

n= The sample from the finite population

N= Total population and n_0 retains its earlier definition

Therefore;

$$n = \frac{(384)(72)}{384 + (72 - 1)} = 60.8$$

$n \approx$ **61.**

From literature, similar work that this study sought to emulate reported success rates of between 92% and 97% (1, 2). An attrition rate of 5% was hence proposed to mitigate for anticipated loss to follow up. That resulted in an upping of the sample size to 65.

This study utilized purposive sampling based on the defined inclusion criteria until the appropriate sample of 65 was reached.

3.3 Data collection

Demographic, injury characteristics and neurological severity data were captured using International SCI Core Data Set (49). The neurological evaluation, done by the lead researcher and research assistants (level 6 medical students), was carried out as per the international standards (50). To ensure the validity and reproducibility of findings, the research assistants underwent one week training on the use of the data collection tools. The lead researcher selected one patient per week at random and re-administered the questionnaire to ensure standardization.

The list of variables included pressure ulcers, pulmonary complications, UTI, DVT, autonomic dysreflexia, pulmonary embolism, spasticity and neuropathic pain. The diagnosis of complications was based on pre - determined definitions as used by the hospital and indicated in the definition of terms.

The pre selected expected medical complications were screened on admission and on a weekly basis by the lead researcher and research assistants for the duration of up to 1 month of hospitalization. To improve pooling of secondary medical complications, a standardized listing was developed with response options for the presence of complications, severity and method of diagnosis.

3.4 Data analysis

Demographic, characteristics of injury and prevalence of selected complications were descriptively analyzed. Factors predisposing to pressure ulcers were assessed using logistic regression models. ASIA Impairment Scale classification was dichotomized into motor complete and motor incomplete lesions. Entries of predisposing factors for PUs were made in univariate logistic regression models. Significant predictors were then set at alpha level equal to 0.10 for further inclusion in the multivarite analyses. Finally, predictors were entered into a multivariate logistic regression model where confounders were added if they caused a change in B (unstandardized regression coefficient) of the independent variables that exceeded 10%. The statistical significance level was set at $P \leqslant 0.05$.

3.5 Ethical approval

All regulations on use of human participants were strictly adhered to. Permissions were sought from the Department of Orthopedic Surgery, University of Nairobi as well as Kenyatta National Hospital, Ethics and Research Committee (KNH/UoN-ERC).

All participants were provided with written informed consents. (Appendix IV)

3.6 LIMITATIONS OF STUDY

The study population was skewed as most of cervical level of injury patients did not meet the inclusion criteria as death occurred within one week due to ventilation failure.

It was impossible to ascertain diagnosis of pulmonary embolism through autopsy.

Deep venous thrombosis was evaluated using a clinical well's criteria which has lower sensitivity and specificity compared to Doppler ultra – sound and CT scan.

The study population included only motor complete injuries, therefore it was impossible to determine this entity as a predisposing factor for occurrence of pressure ulcers.

4.0 RESULTS

Table 1: Participant's characteristics

Characteristics		
Total (N, %)	63	100
Gender		
Male	56	88.89
Female	7	11.11
Age at Injury (Mean and S.D)	39.22	11.02
Age at Injury (Median and range)	38	22-70
Age Category		
18-30	16	25.40
31-45	31	49.21
46-60	13	20.63
>61	3	4.76
Injury Aetiology		
Assault	5	7.94
Transport (including pedestrians)	42	66.67
Fall	16	25.40
Vertebral Injury		
No	8	12.70
Yes	55	87.30
Associated Injury		
No	40	63.49
Yes	23	36.51
Spinal Surgery		
No	26	41.27
Yes	37	58.73
Level of education		
Primary	9	14.29
Secondary	34	53.97
Tertiary	20	31.75

A total of 68 participants were recruited in this study. Five percent of (7.35%) participants were lost to follow up during the study duration. 63 participants with tSCI had complete data collection for analysis. Majority of participants were of male gender (n = 56 (88.89%)). The mean injury age was 39.22 with a range of 22 to 70 years.

The main cause of injury was transport through motor vehicle and motorcycle accidents (n = 42 (66.67%)), followed by fall then assault. Participants who had associated injuries were 23 (36.51%).

Most of the patients in this cohort had secondary level of education (53.97%) followed by tertiary and primary levels respectively (31.75%, 14.29%).

Table 2: Prevalence of Medical Complications

Complications	***N (%)***					
	Week 0	Week 1	Week 2	Week 3	Week 4	Overall Burden
Pressure Ulcers	2 (3.17)	2 (3.17)	13 (20.63)	15 (23.81)	26 (41.27)	26 (41.27)
Pulmonary complications	4 (6.35)	7 (11.11)	19 (30.16)	31 (49.21)	25 (39.68)	38 (60.32)
UTI	3 (4.76)	10 (15.87)	24 (38.10)	38 (60.32)	30 (47.62)	46 (73.02)
Autonomic Dysreflexia	13 (20.63)	13 (20.63)	7 (11.11)	4 (6.35)	4 (6.35)	14 (22.22)
Venous thromboembolism	1 (1.59)	3 (4.76)	6 (9.52)	7 (11.11)	7 (11.11)	9 (14.29)
Neuropathic pain	5 (7.94)	8 (12.70)	16 (25.40)	20 (31.75)	17 (26.98)	22 (34.92)
Spasticity	6 (9.52)	9 (14.29)	14 (22.22)	17 (26.98)	16 (25.40)	18 (28.57)

As indicated in table 2, the most common secondary medical complication was UTI (n= 46 (73.02%)), followed by pulmonary complications (n=38 (60.32)) and pressure ulcers (n=26 (41.27%)). Other complications were neuropathic pain, (n =22 (34.92%)), spasticity (n =18 (28.57%)), autonomic dysreflexia, (n =14 (22.22%)) and venous thromboembolism (n =9 (14.29%)).

Table 3: Complications in reference to Neurological Level

Complications	*Cervical*	*Thoracic*	*Lumbar*	*Total*
	2 (3.17)	*35 (55.56)*	*26 (41.27)*	*63(100)*
	N (%)	*N (%)*	*N (%)*	*N (%)*
Pressure Ulcers	2 (100.00)	18 (51.43)	6 (23.08)	26 (100.00)
Pulmonary complications	2(100.00)	17 (28.57)	19 (53.85)	38 (100.00)
UTI	2 (100.00)	23 (42.86)	21 (22.58)	46 (100.00)
Autonomic Dysreflexia	2 (100.00)	12 (5.71)	0 (0.00)	14 (100.00)
Venous thromboembolism	1 (50.00)	6 (14.29)	2 (3.85)	9 (100.00)
Neuropathic pain	1 (50.00)	9 (17.14)	12 (30.56)	22 (100.00)

Overall, most of the complications were seen in patients with injuries at thoracic level (n= 35 (55.56)), followed by lumbar level (n =26 (41.27)). Only 2 (3.17%) patients had injuries at cervical level as the population distribution was skewed owing to cervical injury patients not surviving for more than 1 week.(n = 2 (3.17)). This was attributed to early deaths as a result of ventilation failure within week 1 of recruitment.

4.1 Analyses of risk factors for PUs

Table 4: Univariate Logistic regression for PUs

Variables	**Odds Ratio (95% CI)**	**P-value**
Age Category		
18-30	1.00 (Reference)	
31-45	1.894736 (.4948006-7.255498)	0.351
46-60	**4.799998(.9785778 -23.54435)**	**0.053**
>61	5.999997(.4222977- 85.24784)	0.186
Injury Aetiology		
Assault		
Transport	.5 (.0754842-3.311953)	0.472
Fall	.3030303 (.0379275-2.421127)	0.260
Vertebral Injury		
No	1.00 Reference	
Yes	1.197917(.2598209-5.523053)	0.817

Variables	**Odds Ratio (95% CI)**	**P-value**
Associated Injury		
No	1.00 Reference	
Yes	2.025974(.7127032-5.759159)	0.185
UTI		
No	1.00 Reference	
Yes	**3.518519(1.151356-10.75252)**	**0.027**
Spinal Surgery		
No	1.00 Reference	
Yes	.9297521 (.3359836-2.57286)	0.888
Pulmonary Complications		
No	1.00 Reference	
Yes	**11.74998 (1.120277-123.2391)**	**0.040**
Patient Complications		
1 complication	1.00 Reference	
2 complications	1.22449	0.785
Above 2 complications	**6.428571 (1.050789-39.32903)**	**0.044**
Neuropathic Pain		
No	1.00 Reference	
Yes	.7090909 (.2238634-2.246056)	0.559
Education Level		
Primary	1.00 Reference	
Secondary	.3826087 (.0855169-1.711819)	0.209
Tertiary	.8 (.1647515-3.884639)	0.782
Level of injury		
Thoracic		
No	1.00 Reference	
Yes	**2.865079 (.9728968-8.437358)**	**0.056**
Lumbar		
No	1.00 Reference	
Yes	**.255 (.0833518- .7801274)**	**0.017**

OR, odds ratio

Bold figures indicate significant association with PUs at 95% CI.

Table 5: Multivariate Logistic regression for PUs

Variables	Odds Ratio (95% CI)	P-value
Patient Complications		
1 complication	1.00 Reference	
2 complications	4.916999 (.3990011-60.5935)	0.214
Above 2 complications	**77.84921 (1.398402-4333.876)**	**0.034**
Neuropathic pain		
No	1.00 Reference	
Yes	.081936 (.0044967-1.49297)	0.091

Notes: Controlled for age categories, education level, pulmonary complications, UTI, injury aetiology, vertebral injury and associated injury. Abbreviations: OR, odds ratio; UTI, Urinary Tract Infection. Bold values indicate significant association with PUs at the 5% level.

Univariate logistic regression results (Table 4) indicated that those aged between 46-60 years were 4.7 times more likely to develop PUs, compared with the younger (18-30) age group (odds ratio (OR)= 4.7; 90% (CI): 0.98–23.54). Development of UTI and pulmonary complications were associated with risks of 3.5 and 11.7 times of developing PU, respectively (OR=3.52; 95% CI: 1.15-10.75) (OR=11.75; 95% CI: 1.12-123.24). Additionally, it was observed that those with more than one complication were 6.4 times more likely to develop PU, as compared to those with only one complication (95% CI: 1.05-39.33).

Those with lumbar levels of injury were close to three (**OR=2.87; 95% CI: .97-8.44) times more likely** for PU development and although not significant at the 5% level, those with thoracic level of injury were **0.74 (OR=.255 (0.083- 0.78)** times less likely (**P=0.056)** to develop PU as compared with those without such additions. These findings are not clinically significant.

In this cohort, surgery was demonstrated to be protective to development of pressure but these findings were not significant at 90% or 95% confidence interval. **(OR =0. 9297521 (.3359836-2.57286)) (P =0.888).**

For the multivariable logistic regression model, after controlling for confounders, it showed that developing more than two complications was the major independent risk factors for developing PUs, with an exposure risk level (OR=78; 95% CI: 1.40-4333.88) of close to 78 times as compared to those with only one complication. Although not significant at the 5% level, those with two complications were, independently, 4.92 (OR=4.92; 95% CI: 0.40-60.59) times more likely to develop PUs (P=0.21) (Table 5)

5.0 DISCUSSION

The purpose of this study was to determine the prevalence of selected secondary medical complications and to identify the pre disposing factors for Pressure Ulcers during early care phase in traumatic spinal cord injury.

The results obtained indicate that the selected secondary medical complications were common during acute care. UTI was the commonest acute medical complication (73.02%), followed by pulmonary complications (60.32%) and pressure ulcers (41.27%). Other complications were neuropathic pain (34.92%, spasticity (28.57%), autonomic dysreflexia (22.22%) and venous thromboembolism (14.29%) (Table 2). These findings are higher compared to results in a similar study done in Cape Town. The study reported prevalence of pressure ulcers at 42%, pulmonary complications at 33% and urinary tract infections at 24%. From their results, pressure ulcers we the most common complication, followed by pulmonary and urinary tract infections respectively (2). These differences could be attributed to lack of specialized traumatic spinal cord injury units in our setting as these patients require specialized care compared to other trauma patients. The comparative study done in Cape Town was also community based therefore risks predisposing to development of complications could have been less prevalent.

Urinary Tract Infection was the most common complication in this study (73.02%). Similar study in Cape Town reported UTI as the third most common complication at a prevalence of (17.0%) (2). It was unclear which method was used for bladder evacuation in that study. High prevalence of UTI could be attributed to use of in dwelling catheter as a means of voiding amongst the participants in this study. Zhang Z et al demonstrated a prevalence of 78.9% of UTI when indwelling catheters was used. Suprapubic catheterization had higher UTI rate when compared to in- dwelling urethral catheters (87.5%)(28). Other comparative studies have showed lower infection rates with indwelling suprapubic bladder catheterization compared to indwelling urethral catheterization (30, 31). Urethral catheterization exposes a larger surface area of the urinary system to a foreign material(s) which acts as a portal for inoculation of

infection. This explains the higher infection rate as demonstrated by the comparative studies (51).

The UTIs are as a result of neurogenic bladder following tSCI. In our study, most of the patients recruited had complete spinal cord injury hence the predisposition to development of UTI was higher (2). All of our study participants were had indwelling catheters.
It was unclear how frequently the in dwelling catheters were changed in this study population. Longer duration of in dwelling catheters beyond to 2 weeks is associated with higher infection rate(52). There is evidence to suggest low prevalence of urinary tract infection when less invasive methods are used (intermittent catheterisation) to evacuate neurogenic bladder, compared with the use of indwelling catheters. One reason for this is that the latter method is known for inoculating organisms into the urinary system (2, 53, 54).

As is evident from the results obtained that the urinary tract infection rate is significantly high (Table 2), other bladder drainage methods should be considered in these patients. Studies evaluating benefits of alternative strategies to prevent and control urinary tract infections like increased fluid intake, sterilization of urine, acidifying urine, regular change of catheter and credes manouvre are recommended (34).

Pulmonary complications were the second most common complication in this cohort (60.32%) (Table 2). In the study done by Joseph and his colleagues in Cape Town, pulmonary complications were the most prevalent at 23.4% (2). Overall, this study had higher prevalence of medical complications compared to results from the Cape Town study. This study being hospital based may offer an explanation to higher complication rates compared to community based study in Cape Town. Breathing is controlled by the diaphragm, the cervical accessory respiratory muscles, intercostals and abdominal muscles. Therefore, patients with higher levels of injury may present with hypoventilation, decreased tidal volume with pulmonary hypoventilation, deterioration of gas exchange, and incompetent insufficient coughing, rendering these patients susceptible to atelectasis and pulmonary infections. Accessory

muscles are innervated by C1- C7, intercostals muscles by T1 – T11, abdominal muscles by T6 – T12, and the diaphragm is innervated by C3- C5 nerve roots thus susceptible to incompetence in higher spinal cord injuries (55-57).

Most of the patients in this cohort had thoracic level of spinal cord injury. The results showed prevalence of pulmonary complications to be 73.08% (n= 19), at lumbar level, followed by cervical level at 50% (n= 1) and thoracic level at 48.57% (n =17) (Table 3). These findings are not comparable results reported by Joseph et al. Their findings showed cervical level of injury to have the highest prevalence 23 (31%), followed by thoracic level at 9 (17%) and lumbar level at 1 (8%). The difference can be speculated to be as a result of a smaller sample size in our study. Joseph et al had a sample size of 141 participants and therefore had a better sample distribution for analysis (2).

In the Cape Town; South Africa study; PUs (32%) was second only to prevalence of pulmonary complications (28%) during the acute phase (2). These finding were lower compared to our study which had pressure ulcers and pulmonary complications at 41.27% and 60.32% respectively. We speculate that amongst other factors, the prevalence of pressure ulcers was higher in this study as all participants had complete motor deficit.

In our study population, only 2 participants (3.17%) with cervical lesions were included in the study. Majority of the lesions were at thoracic level 35 (55.56%), followed by lumbar level 26 (41.27%) (Table3). Most of cervical lesion patients died due to ventilation related complications within one week and therefore were dropped out of the study as they did not meet the inclusion criteria. We recommend strategic establishment of ventilation support system for patients with cervical injuries to improve survival.

Although only 2 patients with cervical injury met the inclusion criteria due to early mortalities, they had the highest prevalence of complications. If survival of patients in this cohort is

improved by creating adequate ventilation support system; pattern of complications can be well studied at this injury level.

All patients recruited had motor complete injury, therefore it was impossible to do logistic regression of motor completeness as a risk factor for developing pressure ulcers.

On the basis of univariate logistic regression models, significant risk factors for PUs included urinary tract infections, pulmonary complications and patients having more than 2 complications. These findings are comparable to the results of Joseph et al in a study done in Cape Town (2). We can speculate that pulmonary complications and urinary tract infections are associated pressure ulcers due to bacteremia that result in inoculation of infectious organisms in the vulnerable skin areas. Urinary tract infections may also exacerbate pressure ulcers through direct spread of infections due to proximity to trochanteric and sacral regions.

Motor completeness, level of vertebral injuries and surgery could not be evaluated as the data were skewed. Almost all the participants recruited had motor complete and vertebral injuries therefore logistic regression of these potential risk factors could not be evaluated.

In this cohort, surgery was demonstrated to be protective to development of pressure but these findings were not significant at 90% or 95% confidence interval. A larger sample size study should be done to provide robust conclusions on effects of surgery in our setting.

The fitted multivariate logistic regression model retained only more than two complication as a risk factor for development of pressure ulcers. Joseph et al report completeness of motor injury and vertebral injury as the only significant risk factors for development of pressure ulcers upon multivariate regression. However, they did not analyze the effects of more than one complication on the development of pressure ulcers (2).

Neuropathic pain was at a prevalence of 34.92%. This was more than fourfold the result reported by Joseph et al in Cape Town (2). When compared to a study previously done at Kenyatta hospital, this prevalence is lower (10).

Similarly autonomic dysreflexia in this cohort was 22.22% which is higher than the findings of Joseph et al (1.4%) (2). Pre injury hypertension status was unknown in this cohort hence there is a likelihood of pre-existing hypertension confounding the results.

Deep vein thrombosis was found to be at a prevalence of 14.29%. We suspect that the findings could be higher than what was reported as only clinical evaluation was used for diagnosis. In the study by Joseph et al, deep venous thrombosis had a prevalence of 5.7% (n= 8) and only 1 participant had pulmonary embolism (0.7%). These findings we lower compared to this study. None of the study participants in our setting received prophylactic anticoagulation. It is unclear on whether the participants studied by Joseph et al were routinely anti – coagulated.Despite the high incidence of venous thromboembolism in SCI patients, there are currently no good quality studies that have assessed the efficacy and safety of antithrombotic prophylaxis. There is weak evidence to recommend routine use of antithrombotic prophylaxis in spinal cord injury and therefore individual patient factors should be considered. (58-60). Studies using other diagnostic modalities with higher sensitivity and specificity should be done to give more robust findings.

Although not exhaustive, this study showed more selected secondary medical complications in patients with traumatic spinal cord lesions in acute phase of injury and care in Kenyatta National Hospital as compared to previous studies done in Kenyatta National Hospital (10).

In contrast to the potential pitfalls of retrospective studies and limitation of studying exposures, this study was prospective in design, which enabled the inclusion of relevant covariates for studying risk factors for PUs.

The study had some tangible limitations. The study population was skewed in terms of vertebral level of injury and ASIA severity score. Thus, a knowledge gap persists regarding the level of vertebral injury and severity of spinal cord injury as risk factors for development of pressure ulcers and other medical complications in our setting. Therefore, these results should be interpreted with caution.

This study was limited to include only the complications that were easily assessed at Kenyatta National Hospital, therefore some other noteworthy complications, such as hyponatremia, labile blood pressure, paralytic ileus and bowel dysfunctions and depression were not investigated.

5.1 CONCLUSION

Urinary tract infections, pulmonary complications, pressure ulcers, neuropathic pain, spasticity, autonomic dysreflexia and venous thromboembolism are common complications during acute care of spinal cord injury patients in Kenyatta National Hospital. The highest complications of the selected medical complications were urinary tract infections, pulmonary complications and pressure ulcers.

Individual risk factors for development of pressure ulcers were presence of urinary tract infections, pulmonary complications and patients having more than 2 complications.

5.2 RECOMMENDATION FOR CLINICAL PRACTICE

1. High vigilance in making diagnosis and initiating appropriate treatment of secondary medical complications in traumatic spinal cord injury as the prevalence is relatively high causing a high morbidity.
2. Early diagnosis and treatment of urinary tract infections, pulmonary complications as they were found to be significantly associated with development of pressure ulcers in traumatic spinal cord injury patients.

3. Prompt treatment of complications as multiple complications predispose to high risk of pressure ulcers development.

5.3 RECOMMENDATION FOR FUTURE RESEARCH

1. Future studies with large sample sizes to be done to reinforce the findings of this study and even provide further analyses that could not be possible in this study.
2. Further research that will systematically evaluate severity of spinal cord injury as potential risk factors for PU development.
3. Further research to determine the risk factors for development of other secondary medical complications in traumatic spinal cord injury.

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APPENDICES

APPENDIX I: QUESTIONNAIRE

Serial Number: _____

1.0 SECTION A: BIODATA

- Birth date __ __ __ __/ __ __/ __ __
- Injury date __ __ __ __/ __ __/ __ __
- Date of Acute Admission __ __ __ __/ __ __/ __
- Date of Discharge __ __ __ __/ __ __/ __ __
- Date of Death __ __ __ __/ __ __/ __ __

- Gender: □ Male □ Female
- Level of Education: □Primary □ Secondary □Tertiary
- Pre – Injury Employment: □ No □ Yes □ Unknown

2.0 SECTION B

- Injury aetiology

  □ Sports; □ Assault; □ Transport; □Fall;

  □Other traumatic cause

- Vertebral Injury: □ No □ Yes □ Unknown

- Associated Injury: □ No □ Yes □ Unknown
- If Yes, Specify_____
- Is the patient continent for stool and urine? □ No □ Yes
- If No, specify (Catheterized patients will be considered continent)

  □Incontinent urine

  □Incontinent faeces

  □Doubly incontinent (urine &faeces)

- Is the patient fully mobile? □ No □ Yes
- If No, specify

  □Restless/fidgety

  □Apathetic (sedated/depressed/reluctant to move)

  □Restricted (restricted by severe pain)

  □Bedbound (unconscious/unable to change position/traction)

  □Chair bound (unable to leave chair without assistance)

- Spinal Surgery: □ No □ Yes □ Unknown
- If Yes, what is the time to spine surgery in hours/days from time of injury_____

- Ventilatory Assistance:

  □ No □ Yes

3.0 Section C: Neurological Data

- Week number:

- Date of Examination

  __ __ __ __/ __ __/ __ __

- Sensory level

  Left Right

  ___ ___ ___ ___ ___ ___

- Motor level

  Left Right

  ___ ___ ___ ___ ___ ___

- ASIA Impairment Scale

  ____

4.0 Section D: Medical complications **Week**

- Pressure ulcers □ No □ Yes □ Unknown
- Degree of severity

  Stage 1□

  Stage 2□

Stage 3□

Stage 4□

- Pulmonary complications □ No □ Yes □ Unknown

- If Yes, specify

  Atelectasis□

  Pneumonia□

- Urinary tract infections □ No □ Yes □ Unknown
- Autonomic dysreflexia □ No □ Yes □ Unknown
- Venous thromboembolism □ No □ Yes □ Unknown
- If Yes, Specify

  Pulmonary embolism □

  Deep venous thrombosis □

- Neuropathic pain □ No □ Yes □ Unknown

- Spasticity □ No □ Yes □ Unknown

- Scoring (taken from Bohannon and Smith, 1987):

  0 □ No increase in muscle tone

  1 □ Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension

  1+ □ Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM

2 □ More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved

3 □ Considerable increase in muscle tone, passive movement difficult

4 □ Affected part(s) rigid in flexion or extension

- Average number of nurses per shift
- Total number of patients in the ward

APPENDIX II: DVT PROBABILITY: WELLS SCORE SYSTEM

Select Criteria:

<table>
<tr><td colspan="3">Clinical Findings</td></tr>
<tr><td></td><td></td><td>Paralysis, paresis or recent orthopedic casting of lower extremity (1 point)</td></tr>
<tr><td></td><td></td><td>Recently bedridden (more than 3 days) or major surgery within past 4 weeks (1 point)</td></tr>
<tr><td></td><td></td><td>Localized tenderness in deep vein system (1 point)</td></tr>
<tr><td></td><td></td><td>Swelling of entire leg (1 point)</td></tr>
<tr><td></td><td></td><td>Calf swelling 3 cm greater than other leg (measured 10 cm below the tibial tuberosity) (1 point)</td></tr>
<tr><td></td><td></td><td>Pitting edema greater in the symptomatic leg (1 point)</td></tr>
<tr><td></td><td></td><td>Collateral non varicose superficial veins (1 point)</td></tr>
<tr><td></td><td></td><td>Active cancer or cancer treated within 6 months (1 point)</td></tr>
<tr><td></td><td></td><td>Alternative diagnosis more likely than DVT (Baker's cyst, cellulitis, muscle damage, superficial venous thrombosis, post phlebitic syndrome, inguinal lymphadenopathy, external venous compression) (-2 points)

<table><tr><td>3-8 Points:</td><td>High probability of DVT</td></tr><tr><td>1-2 Points:</td><td>Moderate probability</td></tr><tr><td>-2-0 Points:</td><td>Low Probability</td></tr></table></td></tr>
</table>

APPENDIX III: THE EUROPEAN PRESSURE ULCER ADVISORY PANEL CLASSIFICATION

Stage I: Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area. Further description: The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Stage I may be difficult to detect in individuals with dark skin tones. May indicate “at risk” persons (a heralding sign of risk).

Stage II: Partial-thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum filled blister. Further description: Presents as a shiny or dry shallow ulcer without slough or bruising. This stage should not be used to describe skin tears, tape burns, perineal dermatitis, maceration, or denudement. Bruising indicating suspected deep tissue injury.

Stage III: Full-thickness tissue loss. Subcutaneous fat may be visible but bone, tendon, or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling. Further description: The depth of a Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous tissue and Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Stage III pressure ulcers. Bone/tendon is not visible or directly palpable.

Stage IV: Full-thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.

APPENDIX IV: CONSENT FORM

APPENDIX IV (a): CONSENT FORM

Study Title: **PREVALENCE OF SECONDARY MEDICAL COMPLICATIONS AFTER TRAUMATIC SPINAL CORD INJURY DURING ACUTE CARE IN KENYATTA NATIONAL HOSPITAL**

Serial number:

Investigator: **Dr. Amos Omondi Salim MBChB**

Orthopedic Resident, University of Nairobi

Tel Number: - 0724-671250

- **Supervisors:**

  DR. E. M GAKUYA

  CONSULTANT ORTHOPAEDIC AND TRAUMA SURGEON,

  LECTURER, DEPARTMENT OF ORTHOPAEDIC SURGERY,

  UNIVERSITY OF NAIROBI.

- **DR. G. K MUSEVE**

  CONSULTANT ORTHOPAEDIC AND TRAUMA SURGEON,

  SENIOR LECTURER, DEPARTMENT OF ORTHOPAEDIC SURGERY,

  UNIVERSITY OF NAIROBI

Introduction

In low- and middle-income countries (LMICs), the burden of traumatic spinal cord injury (TSCI) is largely unknown. Despite improved acute care and greater awareness and recognition of complications, many complications still occur during acute phase. These complications may prolong hospital stays and adversely affect the rehabilitation process. To improve acute phase care and prevent complications, more information about the number and nature of complications is needed. Any attempt aimed at improving quality of care should be based on comprehensive and reliable data. This data is lacking in our local setting.

Purpose of the Research

This study will avail data on the prevalence of medical complications and risk factors of pressure ulcers in spinal cord injuries in Kenyatta National Hospital thus influence resource allocation to reduce morbidity and mortality.

Participant selection

Patients with confirmed acute tSCI or traumatic caudaequina lesion; age⩾18 years at the time of admission are invited to participate in the study

Voluntary Participation and Right to Refuse

Your participation in this research is entirely voluntary as such no remuneration or compensation will be offered to the participants of the study. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive will continue and nothing will change. If you choose not to participate in this research project, you will still be offered the treatment that is routinely offered in this hospital.

Duration

The research takes place over 28 days during that time we will require only 15 minutes of your time to gather information from you.

Procedures

This study will be conducted through use of a pre-tested questionnaire for the participants.

Safeguarding Privacy and Confidentiality

The interviewer will keep all information about you secure. Your name will be removed from all records involved in the study. A number will be assigned to the survey questionnaire instead. Only project staff will have access to the study data. We will not use your name when we report results of the study.

Risks and Benefits

Clinical evaluation and assessment may cause some discomfort. The research assistants have been trained to be gentle during clinical evaluation and assessment.

This study will avail data on the prevalence of medical complications and risk factors of pressure ulcers in spinal cord injuries in Kenyatta National Hospital thus influence resource allocation to reduce morbidity and mortality.

Problems or questions

If you have any questions about this research or about the use of the results, you can contact the principal investigator, Dr. Salim Omondi Amos by calling 254-724-671250.

If you have any questions on your rights as a research participant you can contact Professor Chindia M.L, secretary, KNH/UoN- ERC by calling Tel. 2726300, ext. 44102, Nairobi.

CERTIFICATE OF CONSENT

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

Name of Participant_____ **Researcher's Name: Dr. Salim Omondi Amos**

Signature of Participant _____ **Researchers Signature_____**

Date _____ **Date _____**

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: I understand that if I have questions about this survey or my rights in taking it, I may contact Dr. Salim Omondi Amos on 0724671250 or Professor Chindia M.L, Secretary, KNH/UoN- ERC, Tel. 2726300,ext. 44102, Nairobi.

APPENDIX IV (b): FOMU YA IDHINI

Kichwa: KUENEA KWA MATATIZO YANAYOTOKANA NA KUUMIA KWA UTI WA MGONGO KATIKA HOSPITALI YA KITAIFA YA KENYATTA

Nambari ya utafiti:

Mtafiti Mkuu: Dk Amos Omondi Salim MBChB
Mwanafuziwa Orthopedic, Chuo Kikuu cha Nairobi
Nambari ya simu: - 0724-671250

1. Wasimamizi:
DR. E. M GAKUYA
CHUO KIKUU CHA NAIROBI

2. DR. G. K MUSEVE
CHUO KIKUU CHA NAIROBI

Utangulizi

Katika nchi za kipato cha chini na katikati ,mzigowa kuumia kwauti wa mgongo haujulikani sana. Lichayakuboreshwakwauangalizimkubwanaufahamuzaidinakutambuamatatizo, matatizo mengi bado yanatokea wakati wa awamu ya papo hapo.

Matatizohayayanawezakuongezamudawakukaahospitalinakuathirimchakatowaukarabati. Ili kuboresha huduma ya awamu ya papo hapo na kuzuia matatizo, habari Zaidi juu ya namba na asili ya matatizo huhitajika.

Jaribio lolote linalo lenga kuboresha ubora wa huduma linapaswa kuwa msingiwa data kamili na ya kuaminika. Data hii haipo katika mipangilio yetu ya ndani.

Kusudi la Utafiti

Utafiti huu utatumia data juu ya kuenea kwa matatizo wakati wa matibabu na sababu za hatarizavidondavyashinikizokatikamajerahayautiwamgongokatikaHospitaliyaTaifaya Kenyatta hivyo huathiri ugawaji wa rasilimali, kupunguza maradhi na vifo.

Uchaguzi wa washiriki

Wagonjwa wenye majeraha ya uti wa mgongo; umri wa miaka 18 au Zaidi wanaalikwa kushiriki katika utafiti huu.

Kushiriki kwa hiari na Haki ya Kukanusha

Ushiriki wako katika utafitihuu ni kwa hiari na hakuna malipo au fidia itatolewa kwa washiriki wa utafiti. Ni uchaguzi wako kushiriki au la. Ikiwa unachagua kushiriki au la, huduma zote unazozipata zitaendelea na hakuna chochote kitabadilika.

Ikiwa unachagua kushiriki katika mradi huu wa utafiti, badoutatolewamatibabuambayohutolewamarakwamarakatikahospitalihii.

Muda

Utafiti unafanyika kwa kipindi cha mwezi mmoja. Wakati huo tunahitaji dakika 15 tu ya muda wako kukusanya bari kutoka kwako.

Taratibu

Utafiti huu utafanyika kwa kutumia dodoso la awali la washiriki.

Kuhifadhi faragha nasiri

Msaidizi ataweka habari zote kuhusu we wesalama. Jina lako litatolewa kwenye kumbukumbu zote zinazohusika katika utafiti. Nambari itatumiwa kwenye dodoso la utafiti badala yake. Wafanyakazi wa mraditu watapata upatikanajiwa data ya utafiti. Hutatumia jina lako tunaporipoti matokeo ya utafiti.

HatarinaFaida

Tathmini ya kliniki inaweza kusababisha usumbufu.

Wasaidizi wa utafiti wamefundishwa kuwa wapole wakati wa tathmini ya kliniki.

Utafiti huu utatumia data juu yakuenea kwa matatizo ya matibabu na sababu za hatari za vidonda vya shinikizo katika majera haya uti wa mgongo katika Hospitali ya Taifa ya Kenyatta hivyo huathiri ugawaji wa rasilimali kupunguza maradhi na vifo.

Matatizo au maswali

Ikiwa una maswali yoyote kuhusu utafiti huu au kuhusu matumizi ya matokeo, unaweza kuwasiliana na mchunguzi mkuu, Dr. Salim Omondi Amos kwa wito 254-724-671250.

Ikiwaunamaswaliyoyotejuuyahakizakokamamshirikiwautafitiunawezakuwasilianana Profesa Chindia M.L, katibu, KNH / UoN- ERC kwa kupiga simu Tel. 2726300, ext. 44102, Nairobi.

HATI YA RUHUSA

Nimesoma taarifa iliyotangulia, au imesomewa.

Nimekuwanafursayakuulizamaswalikuhusuhilonamaswaliyoyoteniliyokuwanayoyamejibiwakwa kuridhikakwangu. Mimi _____najitoleakwahiarikushirikikamakatikautafitihuu.

Jina la Mshiriki _____ Jina la Mtafiti: Dr. Salim Omondi Amos
Saini ya Mshiriki _____ Watafiti Saini _____
Tarehe _____ Tarehe _____

Nani wa Kuwasiliana

Ikiwa una maswali yoyote unaweza kuwauliza sasa au baadaye, hata baadaya utafiti kuanza. Ikiwa unatakakuuliza maswali baadaye, unaweza kuwasiliana na yoyote yafuatayo: Ninaelewa kwamba ikiwa ninamaswali kuhusu utafiti huu au haki zangu katika kuitumia, nitawasiliana na Dr. Salim Omondi Amos kwenye 0724671250 au Profesa Chindia ML, Katibu, KNH / UoN- ERC, Simu. 2726300, ext. 44102, Nairobi.

APPENDIX V: TIMEFRAME

ACTIVITY	Mar 2017-Feb 2018	Feb 2018	May 2018	May –Jul 2018	Jul 2018	Jul 2018	Aug 2018
Proposal development and presentation							
Submission of proposal for ethical approval							
Pretesting the data collection tool							
Data collection							
Data analysis							
Thesis writing							
Thesis submission and preparation of manuscript							

APPENDIX VI: BUDGET

ITEM	QUANTITY	UNIT PRICE	TOTAL
Operating Costs:			
Internet:	3	5000/-	15000/-
Stationary:			
Pens (Box)	1	400/-	400/-
Writing pads	5	200/-	1000/-
Printing paper (rim)	1	1200/-	1200/-
Printing Cartridges	4	1200/-	4800/-
Binding Fees	5	100/-	500/-
Approval:			
Ethical Review Fee	1	2000/-	2000/-
Consultation:			
Statistician	1	25000/-	25000/-
Research Assistants	3	15000/-	45000/-
TOTAL			94,900/-