

Referral for CT brain in adult patients with head injury: are Emergency Centre doctors adhering to the Western Cape Head Injury guidelines?

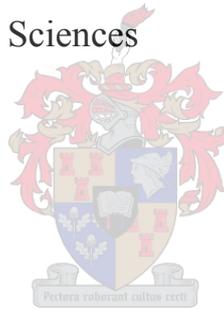
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This study is in partial fulfilment of the MMed (Emergency Medicine) degree

DECLARATION OF ORIGINAL WORK

I declare that this research report is my original work, and that all the sources have been duly acknowledged. I further declare that this work has not previously been submitted by me for a degree at the University of Stellenbosch or any other institution.

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Date : 20 August 2013

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GLOSSARY

CBD: Central business district

CHALICE: Children's Head injury Algorithm for the prediction of important Clinical Events

CHC: Community Health Centre

CHI: Closed head injury

CT: Computer tomography

DAI: Diffuse axonal injury

EC: Emergency centre

EMS: Emergency Medical service

EMSSA: Emergency Medicine Society of South Africa

EDH: Extradural haemorrhage

GCS: Glasgow coma scale

GFJ: GF Jooste

GSH: Groote Schuur hospital

ICP: Intracranial pressure

MVC: Motor vehicle collision

NEXUS: National emergency X-radiology Utilisation study

NHS: National health service

NICE: National Institute for Clinical Evidence

NSH: New Somerset hospital

SAMJ: South African Medical Journal

SDH: Subdural haemorrhage

SIGN: Scottish Intercollegiate Guidelines Network

SXR: Skull X-ray

TBH: Tygerberg hospital

TSSA: Trauma Society of South Africa

TBI: Traumatic brain injury

UK: United Kingdom

US: United States

WCHI: Western Cape head injury

WHO: World Health Organisation

PART A

RESEARCH PROTOCOL

PROTOCOL OUTLINE

Abstract

1. Introduction
 - 1.1 Background & Literature review
 - 1.2 Hypothesis
 - 1.3 Aim and Objectives
2. Methodology
 - 2.1 Study design
 - 2.2 Study population
 - 2.3 Sampling
 - 2.3.1 Inclusion criteria
 - 2.3.2 Exclusion criteria
 - 2.4 Data collection and management
 - 2.5 Timeline
 - 2.6 Data analysis
3. Ethical and legal considerations
4. Limitations and bias
5. Budget
6. References
7. Appendices

ABSTRACT

Head injuries constitute a large number of trauma cases due to high rates of interpersonal, motor vehicle accidents, falls and use of recreational substances. This puts a huge amount of pressure on Emergency Centres (EC) as these patients require prompt management, observation and careful assessment before referral and discharge. The Western Cape head injury guidelines have been developed to decide which patients with head injuries require computer tomography (CT). There are no documented local validation studies for the guideline or studies on the knowledge and adherence thereof.

OBJECTIVE: The aim of this study is to investigate whether Emergency Centre doctors in the Western Cape are using the local head injury guidelines when referring adult patients with head injury for CT head injury scans.

METHODOLOGY: An audit will be performed, using a data capture sheet, based on the local guidelines. A retrospective chart review will be performed over six months (January to July 2011) at the five local public hospitals with CT scanner facilities (Groote Schuur, Tygerberg, GF Jooste, New Somerset, Paarl hospitals). The first two hospitals are tertiary hospitals with 24-hour CT availability and the other three only have CT facilities during working hours, but are still able to refer to tertiary units if an urgent head scan is required. Data capture sheets will be used to record patient data to review the reasons doctors use to refer patients for CT head scans.

RESULTS: Summary statistics will be used to assess doctors' adherence to the head injury guidelines. Secondary analysis will be done to compare the amount of CT head scans performed during and after working hours. This will be analysed using methods appropriate for discrete data depending on normality.

1. INTRODUCTION

1.1. Background and literature review

Traumatic brain injury (TBI) is an important public health problem in South Africa, with high incidence of motor vehicle collisions (MVCs), falls and assault rates. The cost to society due to TBI is staggering, from both a socio-economic and a psychological standpoint. ^(1,2) Prompt diagnosis and intervention in patients with head injuries improves morbidity and mortality. ⁽¹⁾ It is therefore imperative for emergency centre (EC) doctors to be competent in the initial management of these patients.

The management of TBI has been revolutionised due to the advent of computer tomography. ^(1,3,4) CT scanning and use of intracranial pressure (ICP) monitoring devices has shown that cerebral compression may be present before it is clinically detectable. ⁽²⁾ Appropriate use can facilitate early surgical intervention, often with improved outcomes as a result of reductions in mortality and morbidity. ⁽¹⁾

During the past few years, several studies have concluded that aggressive treatment of trauma patients decreases mortality and morbidity ^(1,3,4). Prompt assessment and intervention are crucial for a favourable outcome. Early protection of the airway, treatment of hypotension and hypoxia, early transport to a hospital with neurosurgical facilities, quick detection and evacuation of intracranial haematomas and advanced neuro- intensive care are cornerstones in modern neurosurgical management. ⁽³⁾

A number of head injury patients are initially managed by community health centres and secondary level hospitals, and later referred to the nearest CT facility if indicated. This entails transferring very ill and potentially unstable patients to a tertiary unit. Clinical experience cannot be solely relied upon to identify these patients who present as a minor head injury but may shortly require emergency surgery for neurosurgical intervention. The goal of institutions that derive guidelines is to provide measures that safely allow low risk patients to be discharged, whilst identifying all patients at high risk as rapidly as possible. ^(1,2)

This has led to the development of the Western Cape Head Injury guidelines, ⁽¹⁵⁾ which are adapted from the National Institute for Clinical Excellence (NICE) ⁽¹⁶⁾ guideline. They have been slightly modified to suit the local burden of diseases. The departments of Surgery, Neurosurgery and Emergency Medicine at Groote Schuur and Tygerberg hospital and the surrounding referral hospitals appraised and approved these guidelines initially in 2008, with the aim to review them every two years.

Most hospitals in the Western Cape utilise these guidelines when referring head injury patients for CT head scans. From my experience working in different ECs, the Western Cape Head Injury Guidelines are visibly displayed in most EC units and therefore it is assumed that doctors are fully aware and are able to implement them. ⁽¹⁵⁾

Research post modification of the NICE guidelines in 2007 identified an increase in the number of requested CT scans, as well as a dramatic incline in the cost of head injury management. ^(1,3,7) This may be due to the NICE 2007 guidelines which suggests that CT head scan should be performed instead of skull x-rays and or observation/admission as the first investigation, when indicated. This led to a two- to five-fold increase in the rates of CT

head scans in most hospitals in the UK and US. ^(1,6) This, however, was based on efficient and prompt patient management, rather than cost-effectiveness. ⁽¹⁾

The many causes of injury, differing trauma care systems and facilities available in hospitals must be considered before applying these guidelines in a developing world setting. ⁽⁷⁾ It is therefore mentioned in the Western Cape head injury guidelines that this guideline may prompt request for more CT head scans, putting further strain on the radiology departments. It is further recommended that doctors use their own clinical acumen in conjunction with these guidelines to suit resource availability. The guideline clearly distinguishes between management of these patients at a district- versus tertiary- level hospitals.

1.2 Hypothesis

There is a propensity to over-investigate patients due to on-sight availability of resources and medico-legal reasons. ⁽⁵⁾ Doctors working at the trauma units in Groote Schuur and Tygerberg hospitals, which both have 24-hour CT facilities are likely to refer patients for CT head scans, whereas doctors working at regional and district hospitals (GF Jooste, Somerset, Paarl,) and community health centres are likely to refer only patients with high risks of TBI and follow local guidelines. Due to limited or complete lack of CT facilities at some district hospitals, doctors are more likely use this service sparingly and appropriately.

There is an increase in the number of head scans requested from referral hospitals since skull x-rays are no longer considered useful in the management of head injuries ^(5,15), as well as a lack of beds for neurological observation and monitoring. According to research, many cases of head injury in the Western Cape are alcohol and drug-related, which may lead to patients being over-investigated as the guideline strongly suggests scanning intoxicated patients due to fear of intracranial injury. ^(4,15)

The study reviewed whether EC doctors refer patients for CT head scans based on knowledge of local protocols or merely because of resource availability. The hypothesis is that even though GSH or TBH doctors may be aware of the guidelines, they may still refer patients for CT purely because it's standard practise to scan all trauma patients, in lieu of the existing guidelines.

1.3 Aims and objectives

- i. To determine if EC doctors are using the local guidelines when referring patients for CT head scans following head injury.
- ii. Secondly compare the amount of CT head scans requested during working hours (8am-4pm) and after-hours (After 4pm, weekends, holidays).

2. Methodology

2.1 Study Design

A retrospective chart review will be performed using a data capture sheet based on the Western Cape head injury guidelines.

2.2 Study population

Only head injury patients who were referred for CT head scans will be included in the study. It will be performed at five public hospitals with CT scanner facilities in the Western Cape,

namely Groote Schuur hospital, Tygerberg hospital, GF Jooste, Paarl and New Somerset hospitals. GSH and TBH have 24-hour CT facilities while the other district and regional hospitals have access to CT only during working hours. Central referrals are also made if urgent scans are required after working hours.

2.3 Sampling

All patients who presented to the five mentioned hospitals (GSH, GFJ, TBH, Paarl, NSH) with acute head injury requiring CT head scan between 1 January 2011 and 30 June 2011 will be recruited into the study. Radiology records will be used to identify patients who had CT head scans. The patient folder will then be traced to find out the reason for the CT request. This will be done by reviewing patient records, radiology records, trauma registry and admission records. This will be done on a 2-weekly basis over a period of six months

Head injury will be operationally defined and referred to throughout the study defined as any injury involving the head, face and neck. *Acute* will be defined as any injury over the past 24 hours. This is to make provision for patients who might have been admitted in the hospital awaiting CT head scan the next day, when resources are available.

2.3.1 Inclusion criteria

- i. All patients >16 yrs presenting with acute head injury referred for CT head scan.
- ii. All patients presenting within 24 hours of the head injury.

2.3.2 Exclusion criteria

- i. Children <16 yrs presenting with head injury.
- ii. Any inpatients with subsequent head injury requiring CT head scans.
- iii. Indications other than acute head injury.
- iv. Head injury patients presenting after 24 hours.
- v. Patients returning to ECs after discharge with head injury sheet.

2.4 Data collection and management

A descriptive audit will be performed using a data capture sheet based on the head injury guidelines. The study will be conducted by reviewing medical records, CT request forms and reports of patients presenting with head injury. A trauma registry and radiology records at the five afore-mentioned hospitals will be used to identify these patients. The researcher will visit the hospitals on a 2-weekly basis to review all the notes of the identified patients and record information using a provided data sheet (*see appendix 4*).

The data sheet comprises details such as:-

- Name of hospital where CT scan was performed
- Patient demographics (Age, sex)
- Whether patient self-presented to hospital or referred from another hospital or by a general practitioner.
- CT request (Date and Time)
- A tick box extrapolated from the Western Cape Head Injury guidelines is provided for indication(s) for CT head scans
- CT results

- Patient disposition

The information will then be recorded electronically on a weekly basis using Microsoft Office Excel spread sheet. Data will be stored in a password-locked computer to which only the researcher has access.

2.5 Timeline

All head injury patients referred for CT head scans from 1 January 2011 to 30 June 2011 will be included in the study. The chart review will be conducted over 6 months from August 2011 (2 months undergoing ethics approval, 2 months of data collection and 2 months of analysing results and writing up).

2.6. Results and Reporting

MS Excel will be used to capture the data and STATISTICA version 9 (StatSoft Inc. (2009) STATISTICA (data analysis software system, www.statsoft.com.) will be used to analyse the data.

The primary objective of the study is to describe the current referral practices at tertiary or central, district and regional hospitals. Patients have to fulfil at least one head injury criteria to qualify as appropriate referral for CT head. The primary analysis will be comparison between appropriate and inappropriate referrals, and secondarily compare the difference between scans requested during working hours and after-hours. Summary statistics will be used to describe the variables. A significance level of 5% will be applied.

The following general analysis guidelines will be adhered to:

Relationships between two continuous variables will be analysed with regression analysis and the strength of the relationship measured with the Pearson correlation, or Spearman correlation, if the continuous variables are not normally distributed. If one continuous response variable is to be related to several other continuous input variables, multiple regression analysis will be used and the strength of the relationship measured with multiple correlation.

The relationships between continuous response variables and nominal input variables will be analysed using appropriate analysis of variance (ANOVA). When ordinal response variables are compared versus a nominal input variable, non-parametric ANOVA methods will be used. A p-value of $p < 0.05$ will represent statistical significance in hypothesis testing and 95% confidence intervals will be used to describe the estimation of unknown parameters.

3. Ethical and legal considerations

No patients will be harmed or put at risk as a result of the study. A waiver of consent is attached in Appendix 6. Ethics approval will be obtained from the Ethics committee at Stellenbosch University and WC DOH research committee.

4. Limitations and bias

The study will be conducted by only looking at patient records and charts. The information provided in the notes will be entered in the data capture sheets as it is. Any missing or unrecorded information involving patient management will not be considered, i.e. no follow-up with attending or referring doctors will be done. This will pose a major difficulty as some EC notes are inadequate and/or incomplete and may not be a true reflection of the doctors' thoughts at the time of CT request.

All records will be reviewed (day hospital referral letters, CT records, nurses; records, doctors' notes) to try and overcome this limitation. Inadequate or missing notes might skew the results and give the impression that CT scans were not indicated even though this might not have been the case. There is also a possibility that some patients will be missed if they are not entered into trauma registries or if their notes are missing (especially patients referred from other hospitals). This will be overcome by tracking all trauma patients recorded captured by radiology department. The PACs system will help with tracking of these patients as well as results of CT head scans.

5 Budget

The study costs will be funded by the researcher. No sponsors or bursaries at the time of research proposal. The following is the proposed budget:-

RESOURCES	COST
A4 paper x 200 (Data capture sheet)	
Printing (Estimated 50c/page)	
Transport (144c/km)	
Assistants	
TOTAL	

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PART B

LITERATURE REVIEW

Introduction

Objective of literature review

Literature search strategy: Inclusion and exclusion criteria

Quality criteria: Trauma in the Western Cape:

Public health service in the Western Cape

Trauma Care Systems in the Western Cape

South African trauma guidelines

Western Cape Head Injury Guidelines

International literature

Doctors, Protocols and Adherence

African relevance

Summary of literature

Gaps and needs for further research

INTRODUCTION

Traumatic brain injury (TBI) is one of the most common presentations to accident and emergency (A&E) centres.^(4,5) Prompt and efficient management of these patients is pivotal in combating morbidity and mortality rates related to head injury.^(4,6,7) Mild head injury management often poses a challenge to emergency centre doctors as these patients may not necessarily show any obvious signs of brain injury on initial presentation.^(1,2) If not detected and treated early, the complications can lead to life-long disability and morbidity, or even worse, death.

Studies have already demonstrated that clinicians cannot solely rely on experience, current patient condition and or history to determine whether a patient has sustained a traumatic brain injury requiring CT scan and neurosurgical intervention.⁽⁶⁾ Therefore guidelines, together with clinical acumen, are important in deciding which patients need a CT brain scan. The Western Cape Head injury guidelines were adopted from the NICE 2007 guidelines in order to assist emergency centre doctors with acute management of head injury patients.

OBJECTIVE

The primary aim of the literature review was to identify research that has previously been done on the topic, i.e. *whether emergency centre doctors adhere to head injury guidelines when referring patients for CT head scans following acute head injury*. It also seeks to review trauma care systems and protocols in the Western Cape. Quality research, both locally and internationally, was identified in order to extract and review what we already know about neuroimaging and TBI in adults. More research was reviewed on factors that influence doctors 'adherence to guidelines and protocols.

SEARCH STRATEGY

Medline, OVID, EMBASE, via the Stellenbosch university library were used as the primary source of published research. Cochrane, Trip database, as well as other world-renowned emergency medicine and trauma journals were also used. The search was narrowed down to articles containing adult head trauma or injury, CT brain scans, neuroimaging, head injury guidelines or protocols or rules as well doctors 'adherence to guidelines.

Inclusion criteria

- Articles on acute head injury/ traumatic brain injury and CT scans
- Articles on doctors' adherence to institutional guidelines, e.g. NICE, Canadian, New Orleans head CT rules, etc.
- Articles on trauma care systems and protocols
- Articles on adult patients with TBI > 16 years
- Articles published over the past 10 years
- Articles published in English

Exclusion criteria

- Articles on head injury in paediatric patients
- Non-English articles
- Articles older than 10 years

TRAUMA IN THE WESTERN CAPE

Trauma is the second leading cause of death among young South Africans, after HIV/AIDS.^(30,31,32) it accounts for 145 deaths per 100 000 in Cape Town. According to the Western Cape burden of disease reduction project, violence is the major contributor to injury in the Western Cape.^(30,32) Domestic violence and community-related violence account for 12.9% of deaths related to trauma, followed by motor vehicle collisions (MVC), which account for 6.9 %.⁽³⁰⁾ The Violence and Injury Surveillance Consortium, an organisation comprising of the South African Medical Research Council, University of South Africa and Council for Scientific and Industrial research regularly review trauma statistics and patterns in South Africa.⁽³²⁾ Recent results showed progressively increasing rates of injury-related diseases, e.g. homicide, suicide, MVCs and interpersonal violence.⁽³²⁾ This is more pronounced in rapidly growing cities such as Cape Town.

A literature review by Goosen J et al on provision of trauma care in South Africa revealed that initial management of trauma is challenging because of unique problems related to South Africa such as poverty, high unemployment rates, rapid urbanisation and inequality.⁽³²⁾ The review also highlighted the vast inequalities between private and public health care facilities. Within the province, one could move from the most developed and privileged community to poverty-stricken and under-serviced communities.^(30,32) The Western Cape province is further affected by escalating use of alcohol and recreational drugs such as “tik”, a methamphetamine. This leads to high rates of interpersonal violence, road traffic accidents and domestic violence.

PUBLIC HEALTH SYSTEM IN THE WESTERN CAPE

The Western Cape is one of the nine provinces in South Africa, with a population of about 5,8 million people, according to the Census 2011.⁽³¹⁾ Although it is considered the second richest province in South Africa after Gauteng, poverty, high unemployment rates, rapid urbanisation and inequality remain high threats to health care and economy.^(30,31) The Western Cape boasts one of the most organised public health services in the country with 34 district hospitals, 8 regional hospitals, 3 central hospitals, 50 ambulance stations and more than 250 primary health care centres.⁽³¹⁾

The five hospitals included in this study are mostly situated in and around the Cape Town Metropole, and provide health care services to the most urbanised population of the Western Cape. GSH and TBH are the two central and academic hospitals, with different drainage areas, according to patients' residential addresses. Paarl regional hospital is 45 kilometres from Cape Town, and refers trauma patients to TBH if they need an urgent CT brain. NSH and GFJ service the metro east and west regions of Cape Town; and often refer patients to GSH for neuroimaging and or neurosurgical services. Some patients are transferred directly to central hospitals.

Tygerberg hospital is a central academic hospital servicing the northern sub-division of the Western Cape. It is a 1400-bed multidisciplinary teaching hospital with a high turn-over of patients.⁽³³⁾ The TBH trauma unit manages 22 000 patients a year, presenting with multitudes of trauma patterns ranging from polytrauma, burns, head injuries, etc.⁽³³⁾ About 1500 of these patients are major trauma and mostly transferred intubated and ventilated from the accident scenes or other hospitals.⁽³³⁾

Groote Schuur hospital, popularly known as the home of the first heart transplant, boasts a world-renowned trauma centre with multiple subspecialties, including neurosurgery and trauma surgery. It serves about 50% of Cape Town's population. It is the referral centre for most of the metropole's southern sub-district, CBD and the western sub-district.

GF Jooste hospital is a district-level hospital in Manenberg, 25 km outside Cape town CBD. It provides a health care service to a population of 1,1 million people.⁽³⁴⁾ This 224-bed hospital admits over 12000 patients annually, 20% of which are trauma-related.⁽³⁴⁾ This hospital also serves a poverty-stricken and under-resourced population with severe budget constraints. The EC is led by emergency physicians who strive to provide the best possible care with the limited resources. There are surgical and medical wards with full anaesthetic and theatre support. Critically ill and polytrauma patients are regularly referred to GSH for further management.

New Somerset hospital is a regional hospital located in Greenpoint, Cape Town, about 10 km from GSH. It provides medical services to about half a million people in the metro west sub-district of the Cape metropole, This 330-bed hospital has an emergency centre and subspecialties such as internal medicine, general surgery, paediatrics, obstetrics and gynaecology, anaesthesiology and radiology. The radiology services are only available during working hours. Any abnormal CT head findings or polytrauma patients are referred to GSH for further management.

Paarl hospital is 60 km from Cape Town and it services a semi-rural community in the south-western part of the Western Cape. It is a district hospital with a 24-hour emergency centre, several subspecialty departments, i.e. internal medicine, paediatrics, general surgery, obstetrics and gynaecology, anaesthesiology and radiology. Like the other smaller hospitals, the radiology services are only available during working hours. The trauma referral centre for Paarl hospital is TBH.

TRAUMA SYSTEMS IN THE WESTERN CAPE

The majority of trauma patients present to primary health care centres, general practitioners and community health care centres.⁽³⁰⁾ These service centres are managed and serviced by nursing sisters, medical officers and community service doctors. Most of these community health centres have an emergency unit with basic medical equipment and no theatre or imaging facilities. There are no specialists on site or facilities to monitor critically ill patients. The paramedics and prehospital staff also play a vital role in stabilisation, initial management and transport of trauma patients. The patients seen at CHCs are stabilised, triaged and often referred to regional or district hospitals for further management or admission.

Some patients are transferred directly to central hospitals, bypassing the district and regional hospitals, according to protocols stipulated by the South African Trauma Society.⁽³⁸⁾ The WCHI guidelines make clearly outline initial management, care and transfer of patients with head injury presenting to different levels of health care. Emergency care systems Western Cape comprise of a chain of multiple actions taken to improve the injured patient until they are referred to appropriate facilities. This ranges from the initial first aider, prehospital EMS personnel, community health centre doctors and to allied surgical specialties. These systems have to work together and constantly communicate in order to better trauma care in the Western Cape. This has improved dramatically since Emergency Medicine in the Western Cape was classified as a general specialist service in 2008⁽³⁸⁾. This has served as a bridge

between prehospital and in-hospital patient care and has greatly improved trauma care in the province.

A literature review by Hardcastle et al identified windows of opportunity to improve trauma care in South Africa. This entailed reviewing existing trauma guidelines by different bodies⁽³⁵⁾, i.e. Trauma Society of South Africa, Critical Care Society of Southern Africa, and liaising with new fields such as Emergency Medicine Society of Southern Africa to compile up to date WHO-approved protocols. There was also a move towards reclassification of trauma and emergency centres into easily recognisable and manageable facilities. The suggested trauma centre description were Level I (major trauma centre), II (urban trauma centre), III (community hospital) and IV (primary health care centre). This will help with planning towards staffing, resources, equipment education and training of health care providers at these facilities. The board also encourages alliance between private and public trauma centres in order to improve health care at large.⁽³⁵⁾

TRAUMA PROTOCOLS IN SOUTH AFRICA

The Trauma Society of South Africa (TSSA)⁽³⁶⁾ has historically been at the forefront of trauma management, education and prevention of injury. It is affiliated with the South African Medical Association, Association of Surgeons in South Africa and EMSSA. The trauma guidelines, including head injury guidelines, are reviewed and updated regularly. The guidelines range from basic ATLS principles, emergency management and disposition of common trauma and orthopaedic presentations. The guidelines are straightforward, user-friendly and relevant to EC management in South Africa.

The Critical Care Society of Southern Africa,⁽³⁹⁾ founded in 1970, serves to augment continued care of critically ill trauma and medical patients while awaiting transfer or referral to intensive care units. This takes cognisance of the constant shortage of beds in most ICUs, leaving the EC staff to take care of critically ill patients over prolonged periods. The Emergency Medicine guidelines for the Western Cape were first published in 2011 and reviewed and expanded in 2013.⁽³⁶⁾ These are currently widely accepted practise guidelines for ECs, CHC and other health practitioners in the Western Cape. The guidelines were formulated with the help of multiple subspecialties and medical disciplines. A considerably large portion is dedicated to trauma guidelines, among which, the WCHI guidelines are contained.

WESTERN CAPE HEAD INJURY GUIDELINES⁽¹⁵⁾

The Western Cape head injury guidelines were adopted from the NICE 2007 head injury guidelines. They were initially modified and reviewed by the division of emergency medicine, department of neurosurgery and surgery departments at tertiary hospitals in the Western Cape (Groote Schuur and Tygerberg hospitals) in 2008, with the aim to review them every two years in order to keep up to date. The guidelines were circulated throughout the Western Cape hospitals and community health centres to aid with the management of head injury in the province.

The guideline outlines initial management of head injury patients, referral criteria to appropriate health centres, and a rough guideline of time intervals, should CT be indicated. There are different protocol paths and schematic pathways for different levels of care, e.g.

community health care centres, pre-hospital environment and secondary/tertiary trauma centres. It also outlines management of these patients apart from CT brain scans, e.g. indications for neurological observations, discharging criteria, etc. This is very important to point out because CT scans only play a limited role in the management of head injury patients.⁽¹⁵⁾

The guideline states that other protocols may have to be used in the management of head injury in children. A small section of these protocols also addresses indications for neuro-imaging in patients presenting with C-spine injury. There is currently no published research on the effect of implementation of local head injury guidelines or if doctors are adhering to them.

INTERNATIONAL LITERATURE: HEAD INJURY PROTOCOLS

The topic of TBI has been well researched in many developing countries. Head injuries constitute about 10-20% of patients presenting with trauma, and the majority of them are minor head injuries.^(1,3,4,5) Head injury guidelines such as NICE head injury, Canadian CT rules, SIGN, New Orleans, CHALICE guidelines have been used over many years.^(1,2,4,5,15) Despite developed management protocols and established health care facilities, acute head trauma is still a challenge to most emergency centre doctors, due to balancing patient safety and care while trying to avoid medico-legal proceedings, which is major concern to many practicing physicians. It is therefore imperative for doctors to keep up with current practise by accessing journals, attending training courses and practicing evidence based medicine. The United Kingdom, for example, follows the NICE head injury guidelines, recognised by the NHS as standard of care. These guidelines are reviewed regularly based on current research.

Several studies showed that a major modification to the NICE head injury guidelines in 2007 led to a 20% increase of CT head scans following head injury.^(7,9,12) The reason for this was mostly because skull X-rays were not regarded useful in the management of these patients, as they could not rule out intracranial brain injury. Another addition to the guideline was the time limits to head scan investigations for different patients. This obviously had a lot of financial implications for the NHS. The management cost of TBI in trauma centres was balanced out by reduction on the number of admission for neuro-observations. Interestingly, this did not improve patient waiting times as patients would still have to wait for CT investigations, interpretation, etc. in A&E departments.

A Canadian-based study, published by Wallace et al, showed that early diagnosis of an intracranial haematoma and prompt surgical intervention reduced the morbidity and mortality resulting from head trauma.⁽²²⁾ The reason and indication for any diagnostic test or procedure exists only when the risk, cost and inconvenience are outweighed by the potential value of the results.⁽²²⁾ It has been previously shown that clinical experience and signs cannot accurately predict or determine the extent of head injury. Therefore a combination of patients' expectations, medico legal aspects and availability of objective guidelines exert pressure on physicians to subject a large number of patients to CT radiography.⁽¹⁾

A study by Sultan et al demonstrated that it is often difficult to strictly follow head injury guidelines in a department or hospital where CT availability is deficient.⁽⁹⁾ Radiology departments are getting many more referrals over the past decade, and the case loads vary from hospital to hospital.^(5,9,10) Doctors may be influenced to veer away from guidelines in

order to avoid the EC being overloaded by patients awaiting CT scans as well as strict radiology gatekeepers. One way suggested in most UK trauma departments is for emergency physicians to be adequately trained to interpret CT head scans.^(8,9)

Sultan et al also reviewed the impact of Canadian CT rules on the management of mild head injury (MHI) in Scotland. Prior to 2002, Scotland followed the Royal College Galasko guidelines. Thereafter Canadian rules were implemented. When using a 'before and after' study to assess the effects, a significant 20% increase in CT head scans was noted. Admission rates for neurological observation increased from 34 to 45% and the rate of skull x-rays fell from 33% to 1.9% without any adverse effects.⁽⁹⁾ Of the 0.5-1% of patients presenting with TBI in the UK, the majority are minor i.e. GCS 13-15. This group of patients seems challenging to manage and varies in different hospitals and countries.⁽¹²⁾

A review by Kerr et al in 2005 showed that implementation of SIGN guidelines in Scotland did not lead to any significant difference in management of TBI. Therefore, despite guidelines and protocols, management of head injury is still largely influenced and determined by local policy and availability of resources.⁽¹²⁾

Despite the fear that constantly evolving CT head guidelines will dramatically increase CT rates, Mooney et al demonstrated that they are more likely to increase the rate of guideline – compliant imaging; this is even more pronounced when the guidelines are implemented properly and reviewed regularly.

DOCTORS, GUIDELINES AND ADHERENCE

Most clinical departments increasingly recognise practise guidelines as an efficient way of promoting and practising evidence-based medicine. This is particularly important for a field such as Emergency medicine, a constantly developing and evolving field. The training system for registrars, medical officers and community service doctors in this department typically involves rotating through different departments and or hospitals every 3 or 4 months. The emergency centre always has different doctors with different levels of clinical knowledge, experience and expertise.

It is therefore important to standardise care and practise by developing and effectively implementing protocols and guidelines, especially for junior or inexperienced doctors. Although there is great emphasis among doctors to formulate guidelines for their departments, there is a great lack at implementation, especially in busy and resource-impooverished hospitals. This results in doctors not adhering to these protocols and just using their clinical acumen or previous experiences regardless of well-formualted guidelines.

An audit by Perry & Stiell on the impact of clinical decision rules in an emergency centre in Canada yielded good results.⁽²¹⁾ They reviewed the impact of Ottawa ankle and knee rules, Canadian C-spine and head injury protocols in emergency centres. The findings were that, with proper implementation, studies, follow-through and regular reviews, health care can be standardised without compromising patient safety and costs.

Specifically looking at doctors' adherence to head injury guidelines, a Scandanavian study was conducted by Heskestad et al, reviewing practise at several teaching hospitals. Outcome measures reviewed were emergency doctors' decisions to refer for CT head scan, admit for neurological observation, referral to specialist, as well as initial triage.⁽²⁴⁾ The retrospective

audit of emergency charts revealed a physician compliance rate of only 51 %. Most patients with mild head injury were initially overtriaged (69%), 27 % referred for unindicated CT scans, while 18 % were hospitalised for observation despite no clinical or guideline indications. Among those who were overtriaged and those who received unnecessary CT scans, 40% had normal scans. Doctors were more guideline-compliant when managing moderate to severe head injury patients. There was a major problem with initial management of mild head injury patients. The author did not speculate or study reasons for this.

This raises an important point when it comes to doctors' adherence to guidelines- the role of patient age, gender, race, socio-economic status as well as the type of hospital setting, physician experience and years of practise. Social and behavioural sciences suggest that these non-medical factors significantly influence doctors when making decisions, sometimes more than the patient's symptoms and signs.

Studies show that hospitals in teaching facilities and large trauma centres in the UK and Canada experienced a 2-to-5 fold increase in the number of requested CT head scans following TBI after the implementation of new updated head injury guidelines (NICE, SIGN, Canadian) in 2008.^(9,11,12) There was not great change in most peripheral or rural hospitals despite implementation of these guidelines. This is an indication of how practise is somewhat driven by the population it provides health care to.

Whereas there is a lot of literature on addressing patient barriers to compliance to treatment, there is very little written on barriers in clinical practise to physician adherence to recommendations. Some of the recognised reasons for this are inadequate professional training, inability to address complex medical problems, too many guidelines on one topic, e.g. other doctors using NEXUS while the current best evidence is Canadian C-spine rules and lack of system support, i.e. electronic medical facilities and lack of participation in decision-making.

Leentjies et al made a few recommendations on implementation of guidelines.⁽²⁰⁾ Protocols should not be viewed as lone entities leading to big changes, they should be part of a quality circle in which implementation and evaluation also play an important role.⁽²⁰⁾ The degree of adherence is therefore markedly influenced by a few factors, viz. Doctors' involvement in implementation, efforts made by the institution or department in implementation, the patients involved as well as the morale of the physicians. A good relationship with staff almost guarantees good compliance.

AFRICAN RELEVANCE

According to protocols and standards in developed countries, head injury patients are initially managed by emergency centre doctors at all levels of health care. Access to emergency care still remains one of the greatest challenges in Africa. Emergency Medicine in the western Cape, being the oldest and most developed programme in Africa, has taken the lead by formulating and compiling emergency medicine guidelines for the province, within which the head injury guidelines are contained.⁽³⁶⁾

There is, however, limited research in Africa on acute management of traumatic brain injury. Most of the published research on trauma in South Africa is on specialist management of these patients, e.g. neurosurgical care, rehabilitation and management of delayed presentations. In a country riddled with crime, motor vehicle collisions and interpersonal

violence, there is a great burden on emergency centres to deal with alarming numbers of head injury patients. This research aims to address adequate and timeous management of these patients in high turnover, resource-limited health care facilities in comparison to most developed countries.

Rabie et al published a study on CT scans performed at Bloemfontein hospital, an academic hospital attached to University of Free state in South Africa.⁽²⁵⁾ The objective of this study was to determine whether CT brain scans were indicated in the following group of patients: those with clinically-suspected skull fractures, those with GCS scores of 13-15 and those with no clinical neurological deficit. They performed a retrospective descriptive analysis based on CT results. The findings proved that neuroimaging is warranted in these patients, even though they may appear well on initial presentation. This was, however, a small study, only consisting of 130 patients, 56% of whom were found to have significantly abnormal scans and the majority of them were referred to neurosurgery for further management and or follow up.

A few studies performed in Nigeria were also reviewed. One was by Shehu BB et al on the practical management of head injury.⁽²⁸⁾ The study outlines that head injury in Nigeria is the leading cause of trauma-related injury and death, especially among young males, accounting for 50% of trauma deaths.⁽²⁸⁾ The importance of understanding the pathophysiology of head injury was stressed, in order to adequately manage them. Their initial management seems to be lagging far behind compared to their peers in the developed world in terms of investigation modalities, e.g. the authors still used SXR as an imaging modality in TBI and CT scan seems to be reserved for only severely injured patients. This was the finding from another Nigerian-based study by Adeyekun et al.⁽²⁹⁾ This may serve as a reflection of resource limitation and poor guideline compliance in most hospitals in Africa.

SUMMARY

The literature review outlines the different trauma care systems and trauma guidelines locally and internationally. Extensive research has been done on the effect of implementation of updated head injury guidelines in the US and most of Europe. There are very few studies on TBI in South Africa, as well as in Africa at large. Even fewer studies are available on implementation and effects of trauma guidelines in South Africa.

SUGGESTIONS FOR FUTURE RESEARCH

There is an enormous gap in published research on head injuries from South Africa, even Africa at large. As mentioned earlier, most of the available research is by specialists' department reviewing follow up management of TBI. Most of these studies are audits, case reviews and retrospective chart reviews, which are not highly ranked in the hierarchy of evidence. There is scarcity of published research on the practise of emergency medicine in Africa, let alone doctors adhering to guidelines and effecting change in practise.

Most of the research used for these literature reviews is based on studies in developed countries. The emergency care system in those is well developed and well-supported by other departments and national health boards. There is a lot of emphasis on practising evidence based medicine: and protocols and guidelines are well implemented and received.

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PART C

ARTICLE ACCORDING TO SAMJ CRITERIA

Referral for CT brain in adult patients with head injury: are Emergency Centre doctors adhering to the Western Cape Head Injury guidelines?

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Declaration of conflict of interest

None

Ethics approval

Approval for this research was obtained at University of Stellenbosch Health Research Ethics Committee on 28 September 2011. Ref no. N11/09/279. Further permission to access patient records was obtained at allied heads of departments at different hospitals.

ABSTRACT

BACKGROUND: Head injuries constitute a large number of trauma cases due to high rates of interpersonal, motor vehicle accidents, falls and use of recreational substances.^(3,4,6) The Western Cape head injury guidelines were developed to guide EC doctors with the management of acute head trauma.

OBJECTIVE: To investigate whether emergency centre doctors in the Western Cape are guideline-compliant when referring adult patients with head injury for CT head scans. Secondly, we reviewed the difference in CT head referral rates during working hours and after-hours.

METHODOLOGY: A retrospective chart review was performed over six months (January to July 2011) at the five local public hospitals with CT scan facilities (Groote Schuur, Tygerberg, GF Jooste, New Somerset, Paarl). Trauma and emergency centre admission records, radiology and electronic records were used to locate suitable subjects.

RESULTS: 882 charts were reviewed, 77 % males and 23% females. The average age was 24 years for both genders. Results showed that NSH, GFJ & Paarl were more likely to adhere to WCHI guidelines than central hospitals during working hours (81% and 59% respectively). Guideline compliance after-hours at TBH and GSH was 73%, almost similar to rates at NSH,GFJ & Paarl. The after-/working hours ratio of CT head scan at GSH and TBH was 1.05 and 1.18 respectively.

CONCLUSION: Doctors working at GFJ, NSH and Paarl hospitals are adhering to the WCHI guidelines more stringently than those working at GSH and TBH. Compliance rates are higher at central hospitals after-hours, during which time a lot more scans are performed.

INTRODUCTION

Traumatic brain injury (TBI) is an important public health problem in South Africa, with high incidence of motor vehicle collisions (MVCs), falls and assault rates.^(1,2) The cost to society of TBI is staggering, from both a socio-economic and a psychological standpoint.^(1,2) Prompt diagnosis and intervention in patients with head injuries improves morbidity and mortality.⁽¹⁾ It is therefore imperative for emergency centre (EC) doctors to be competent in the initial management of these patients. Trauma is the second leading cause of death among young South Africans, after HIV/AIDS^(1,4). It accounts for 145 deaths per 100 000 in Cape Town. According to the Western Cape burden of disease reduction project, violence is the major contributor to injury in the Western Cape.^(4,5,6) Domestic violence and community-related violence account for 12.9% of deaths related to trauma, followed by motor vehicle collisions (MVC), which account for 6.9 %.⁽³⁾

Studies have already demonstrated that clinicians cannot solely rely on experience, current patient condition and or history to determine whether a patient has sustained a traumatic brain injury requiring CT scan and neurosurgical intervention.^(7,8) Therefore guidelines, together with clinical acumen, are important in deciding which patients need a CT brain scan. The Western Cape Head injury guidelines⁽⁴⁾ were adopted from the NICE 2007 guidelines⁽⁷⁾ in order to assist emergency centre doctors with acute management of head injury patients. Research post-modification of the NICE guidelines in 2007 identified an increase in the number of requested CT scans, as well as a dramatic incline in the cost of head injury management in the US, Canada and most of Europe.^(7,8,9) This may be due to the NICE 2007 guidelines which suggests that CT head scan should be performed instead of skull x-rays and or observation/admission as the first investigation, when indicated. This led to a two- to five-fold increase in the rates of CT head scans in most hospitals in the UK and US.^(8,9)

The many causes of injury, differing trauma care systems and facilities available in hospitals must be considered before applying these guidelines in a developing world setting.⁽⁷⁾ It is therefore mentioned in the Western Cape head injury guidelines that this guideline may prompt request for more CT head scans, putting further strain on the radiology departments. It Studies have already demonstrated that clinicians cannot solely rely on experience, current patient condition and or history to determine whether a patient has sustained a traumatic brain injury requiring CT scan and neurosurgical intervention.⁽⁶⁾ Therefore guidelines, together with clinical acumen, are important in deciding which patients need a CT brain scan.

AIMS AND OBJECTIVES

- i. To determine if EC doctors are using the local guidelines when referring patients for CT head scans following head injury.
- ii. Secondly compare the amount of CT head scans requested during working hours (8am-4pm) and after-hours (After 4pm, weekends, holidays).

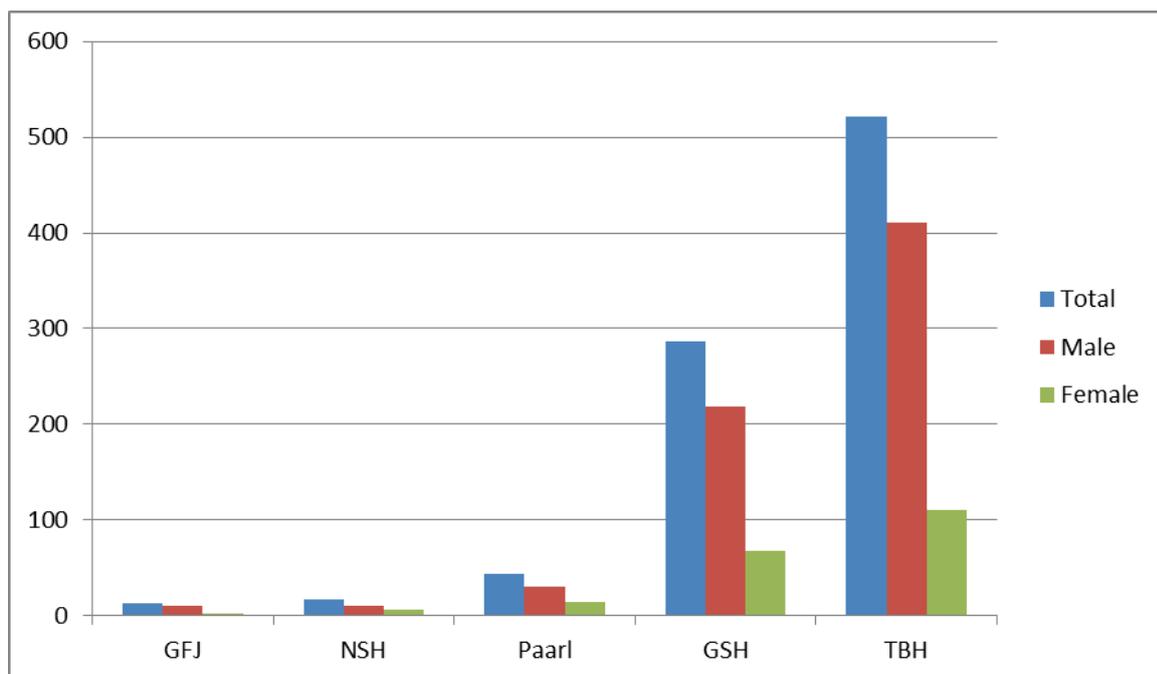
METHODOLOGY

Five emergency centers were evaluated, viz. Groote Schuur, Tygerberg, GF Jooste, New Somerset and Paarl hospitals. The first two hospitals are central/academic hospitals with 24-hour CT facilities and well-organized trauma and neurosurgical facilities. New Somerset and Paarl hospitals are regional hospitals and GF Jooste is a district hospital. The last 3 hospitals only have CT scan facilities during working hours, i.e. 8 am to 4 pm. Patients from district

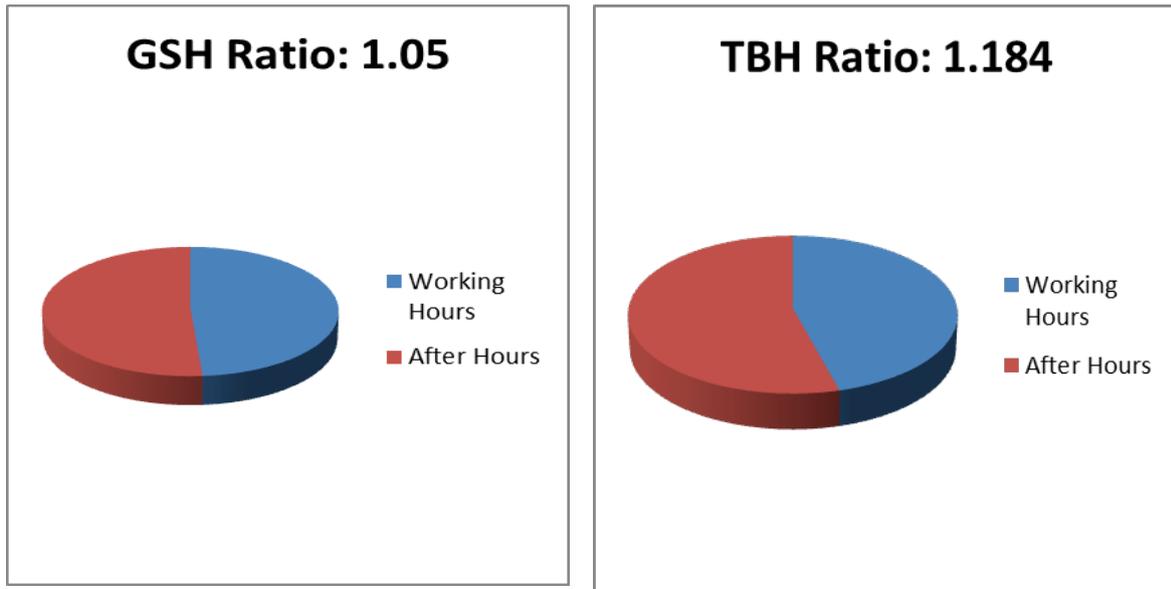
and regional hospitals are regularly referred to either GSH or TBH after-hours if there is an indication for an urgent CT head scan or neurosurgery referral after hours. A retrospective chart review was performed at the afore-mentioned hospitals. A data capture sheet was used to capture essential information such as demographics, hospital presenting to, indication for CT brain scan (as per WCHI guidelines), time scan was requested, results and disposition). Records of head injury patients who presented to these centers between January and June 2011 were evaluated to identify reasons for CT head referral, and secondarily compare CT scans during working hours and after hours. Data was later captured using Microsoft excel and basic statistical analysis was carried out.

RESULTS

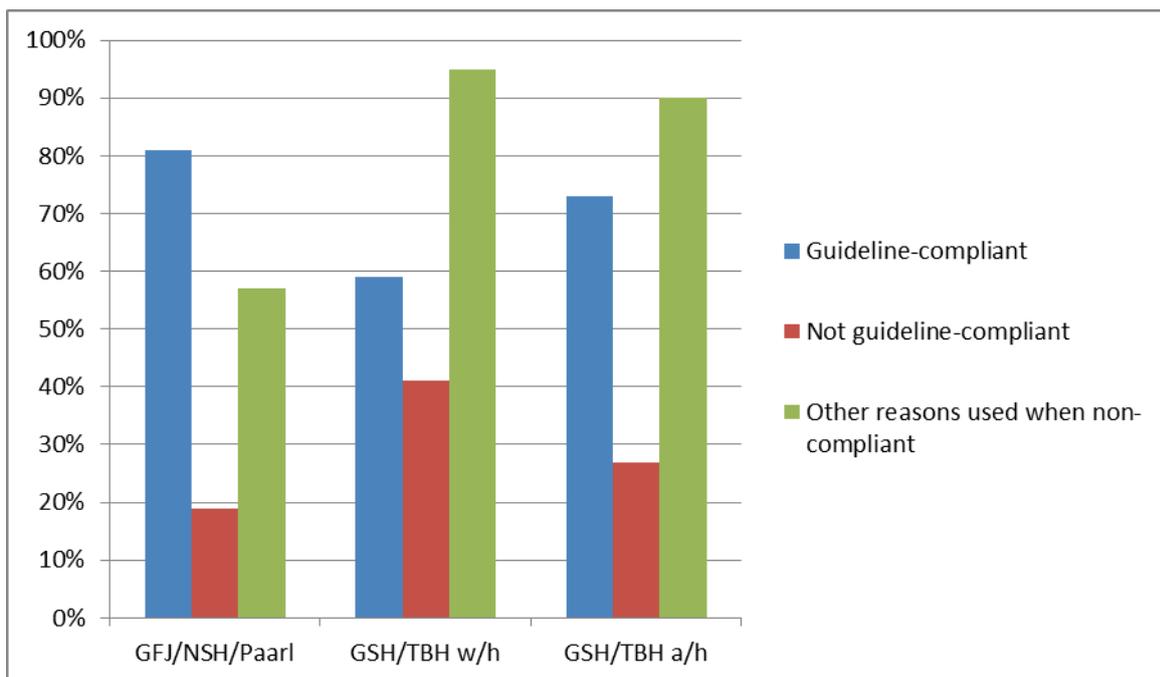
A total of 882 charts were analyzed, the majority being from the two tertiary hospitals. Notably, there is a big percentage of males presenting with TBI to all the hospitals. The study population comprised of 680 males (77%) and 202 females (23%). The average age was 24 years for both men and women, with an age distribution of 17- 85 years. GFJ and NSH had the smallest number of subjects compared to Paarl hospital. A considerably higher amount of CT head scans were performed after hours at both GSH and TBH, i.e. at a ratio of afterhours to working hours was 1.05 and 1.2 respectively.



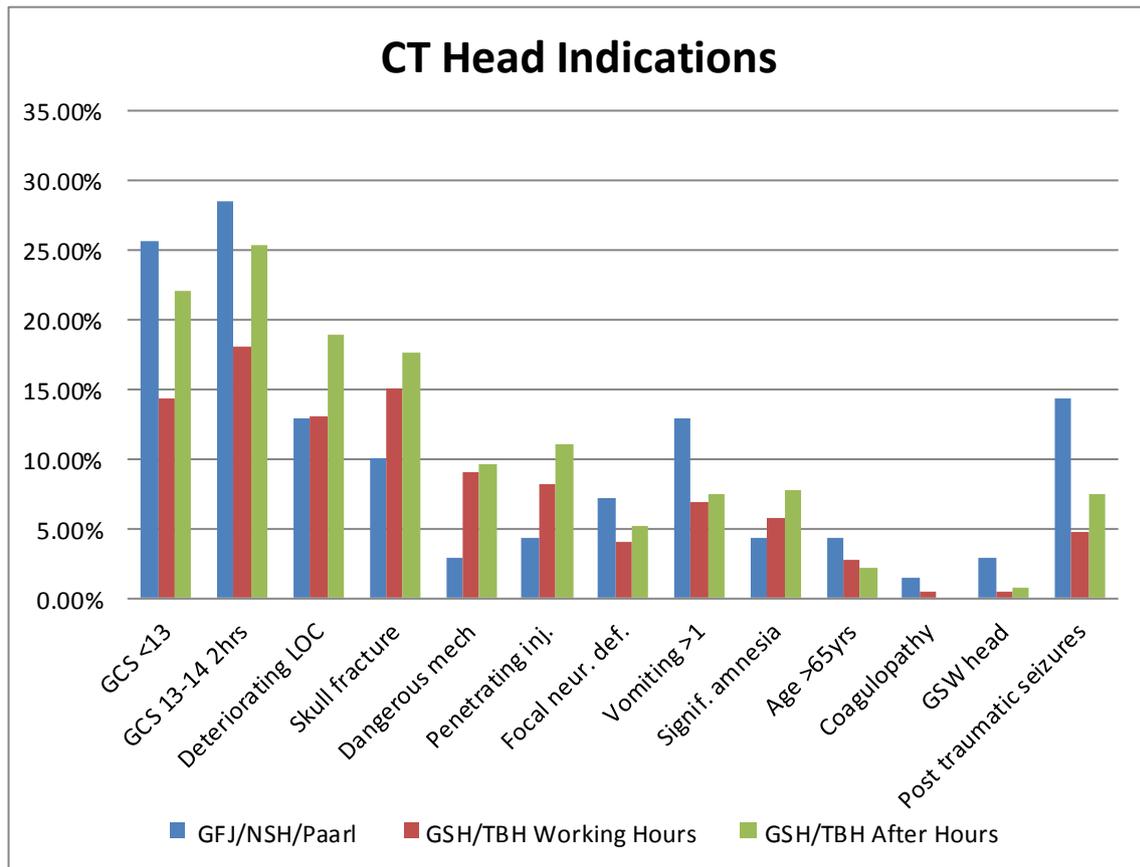
Graph 1. Study population at different hospitals



Graph 2 & 3. After-hours: Working-hours ratio of CT head scans requested at GSH and TBH, respectively



Graph 3. Comparison of guideline-compliant and non-guideline compliant CT head scans performed at GFJ,NSH & Paarl hospitals vs. GSH & TBH during working hours and afterhours. Also shown in the graph are the rates doctors used 'other reasons' when CT was unindicated (i.e. other than indications as per WCHI guidelines)



Graph 4. The following graph shows a relationship between guideline-compliant and non-compliant CT scans requested at different hospitals, as well as usage of other reasons when CT is not indicated. a/h = after hours. w/h = working hours

ANALYSIS

According to these results, during working hours, GSH and TBH are less likely to use the CT test criteria than GFJ, NSH and Paarl. After hours they use them at almost similar rates as GFJ, NSH and Paarl do during work hours. To test this, tertiary and secondary level hospitals were compared via t-tests for independent samples. As represented in *Graph 3*, GFJ/ NSH/ Paarl utilized the following CT test criteria significantly more often than did GSH & TBH (at the 5% CI level): GCS < 13, GCS 13-14 2 hours after injury, post traumatic seizures, average number of criteria used. There were no significant differences on any of the other criteria.

Graphs 2 and 3 shows that there were slightly more scans performed at tertiary centers after hours. When comparing the working hours versus after hours utilization of CT test criteria at GSH and TBH, via t-tests for independent samples, the following CT test criteria were utilized significantly more often after hours than during working hours (at the 5% CI level): GCS <13, GCS 13-14 two hrs. after injury, deteriorating LOC, post traumatic seizures, average number of criteria used and use of any of the criteria. Males were also referred for CT scans significantly more often – relative to females – after hours than during working hours. There were no significant differences on any of the other criteria. As shown in *Graph 4* the frequency with which GSH and TBH used any of the criteria to refer patients for CT scans after hours did not differ significantly from the frequency with which GFJ, NSH and Paarl rely on them during working hours (73% and 81% respectively). Guideline-compliant scans were as low as 59 % during working hours at

GSH/TBH. Results also indicate that GSH and TBH are more likely to give other reasons e.g. headaches, accident, assault, etc. for CT scan referrals than GFJ, NSH and Paarl, both in the absence and presence of the use of CT test criteria (*Graph 4*). This observation was tested using t-tests for independent samples too. When no CT test criteria have been used GSH and TBH supplied other reasons significantly more often than did GFJ, NSH and Paarl (at the 0.0003% level), viz. 93% versus 57% respectively.

Notably, when any CT test criteria were used GSH and TBH supplied other reasons significantly more often than did GFJ, NSH and Paarl (at the 0.0008% level) i.e. 35.2% versus 6.8% respectively. When referring patients for CT because at all hospitals these ‘other reasons’ are used decidedly more frequently when CT test referral criteria are not used than when they are, so they are probably substituted to some degree. The general picture then is that CT test referral criteria are being used more reliably in secondary level hospitals; as well as after hours at tertiary hospitals than they are during normal working hours.

DISCUSSION

The results of this research confirm that some emergency doctors are adhering to the Western Cape head injury guidelines. As suggested in the hypothesis, secondary level doctors are more likely to follow guidelines than doctors working in tertiary trauma centers. The reason for this is multifactorial – secondary hospitals tend to have a smaller team of experienced doctors, interns and community service doctors with only one or two EC consultants, which makes it easier to implement and follow guidelines. Secondary level doctors have to be mindful when referring these patients to tertiary trauma centers, as the gatekeepers, i.e. receiving doctors have to agree with the indication for CT radiography prior to referral.

Tertiary trauma centers are staffed by a wide array of doctors from different departments with different levels of experience, e.g. general surgery, neurosurgery, emergency medicine, medical officers. There are usually also a lot more consultants and a constant flow of nursing staff. It is a bit more challenging to keep up to date with doctors’ adherence to protocols or accountability to patients. It seems that 24-hour availability of CT resources seems to play a role in unnecessary CT referral. As indicated in the results, it is more likely to happen after-hours, when there are no consultants available in both emergency centers and radiology departments. Referral for CT head scan following TBI at TBH and GSH is as easy as filling a request form or picking up a phone to call radiology suites.

GSH and TBH also manage more complex patients, e.g. polytrauma, severe head injury, gunshots, etc. These patients are likely to be referred for head CT for many other reasons other than the ones indicated by guidelines. It may be because certain consultants or departments require CT head before admission to respective units or use the investigation to ‘rule out’ head injury as differential diagnosis to an acutely ill and confused trauma patient. It is noted that a very small number of CT scans for head injury patients were done at secondary level hospitals. The explanation for this might be because patients needing CT head are most likely to be referred to a trauma center, as per Western Cape trauma referral guidelines. It is also because they might need review by neurosurgeons, a service that is unavailable at secondary level hospitals. The majority of patients at GSH and TBH are referred by community health centers and secondary hospitals. Only a small percentage presented to these trauma centers.

LIMITATIONS AND BIAS

Although all the charts were tracked using trauma and radiology records, there were a considerable number of patients that were missed. During data collection, some folders were not found, either because the patients presented again to hospital and needed their file, folders were kept separate for outpatients follow-up, patients demised or files lost. This was not a big problem at TBH as the radiology department computerizes all their notes, CT scan and the trauma CT request form. This might add to bias. To overcome this, the number of CT scan and patient records is considerably high, and hospitals were visited in multiple days to look for 'missing records'.

As mentioned in the protocol, only patients presenting within 24 hours of sustaining head trauma were reviewed. A considerable number of delayed presentations or referrals from secondary might have been missed. According to the direct tertiary trauma center guidelines, any polytrauma patient presenting to a secondary level hospital or community health center must be taken directly to a tertiary hospital. The majority of patients presenting directly to trauma centers actually bypass their local hospitals, hence a large number of severe head injuries at tertiary hospitals. Instead of analyzing one hospital, the different centers were grouped into secondary and tertiary hospitals and reviewed as such to look at a more general view.

CONCLUSION

It is clear that secondary level doctors are adhering to CT head protocols. GSH and TBH doctors are more compliant after-hours during working hours. There is higher amount of scans requested and performed after-hours at GSH and TBH. There is a considerable amount of non-guideline-compliant CT head scans at tertiary level hospitals - the majority of which yield negative results. This may be an indication that consultant cover is needed in tertiary centers, especially after-hours, in order to keep a uniform and standard level of medical care. Further local research is needed on initial management, presentation and cost-effectiveness in the management of head injuries in South Africa. More rigorous measures need to be put in place when referring patients for CT head scans, especially in tertiary hospitals.

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PART D

SUPPORTING DOCUMENTS



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03 October 2011

MAILED

Dr D Moiloa

Dear Dr Moiloa

Referral for CT brain in adult patients with head injury: are Emergency Centre doctors adhering to the Western Cape Head Injury guidelines?

ETHICS REFERENCE NO: N11/09/279

RE : APPROVAL

It is a pleasure to inform you that a review panel of the Health Research Ethics Committee has approved the above-mentioned project on 28 September 2011, including the ethical aspects involved, for a period of one year from this date.

This project is therefore now registered and you can proceed with the work. Please quote the above-mentioned project number in ALL future correspondence. You may start with the project. Notwithstanding this approval, the Committee can request that work on this project be halted temporarily in anticipation of more information that they might deem necessary.

Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly and subjected to an external audit.

Translations of the consent document in the languages applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Please note that for research at primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms _____ at Western Cape Department of Health _____) and Dr _____ at City Health _____. Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

03 October 2011 08:17

Page 1 of 2



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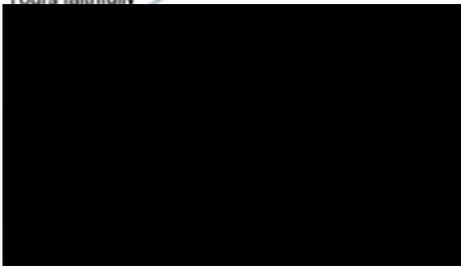


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Approval Date: 28 September 2011

Expiry Date: 28 September 2012

Yours faithfully



Enquiries: [REDACTED]
E-mail: [REDACTED]

Dr D. Moiloa

[REDACTED]
[REDACTED]
[REDACTED]

E-mail: [REDACTED]

Dear Dr Moiloa

RESEARCH: REFERRAL FOR CT BRAIN IN ADULT PATIENTS WITH HEAD INJURIES: ARE EMERGENCY CENTRE DOCTORS ADHERING TO THE WESTERN CAPE HEAD INJURY GUIDELINE?

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research.

Please note the following:

- a) Your research may not interfere with normal patient care
- b) Hospital staff may not be asked to assist with the research.
- c) No hospital consumables and stationary may be used.
- d) **No patient folders may be removed from the premises or be inaccessible. Please contact Mr Noel Weeder on ext. 4058 or 4066 in this regard.**
- e) Please introduce yourself to the person in charge of an area before commencing.
- f) Confidentiality must be maintained at all times.

I would like to wish you every success with the project.

Yours sincerely

[REDACTED]
[REDACTED]

Date: 8th October 2012

[REDACTED]

[REDACTED]
[REDACTED]

TYGERBERG HOSPITAL APPROVAL LETTER

RESEARCH ON CLINICAL INDICATIONS FOR CT HEAD SCANS

From : [REDACTED]

To : [REDACTED]

CC : [REDACTED]

Greetings Dr Moilola

Thank you for the opportunity to meet on Monday 17 September 2012.

I have had an opportunity to review your Research Proposal. I congratulate you on an ambitious and interesting project.

You have permission to proceed with data collection at Tygerberg Hospital in accordance with your Ethics Committee approval.

Regards

[REDACTED]

Head, Division of Radiodiagnosis
Tygerberg Hospital and Stellenbosch University

HEAD INJURY/ CT HEAD REFERRAL DATA CAPTURE SHEET

PATIENT STICKER				Patient referral	
				Presented to CT facility	Referred to CT facility
Hospital	GSH	TBH	GFJ	NSH	Paarl
INDICATION (S) FOR CT HEAD REFERRAL (Please tick)					
GCS<13 at time of injury					
GCS 13-14 at 2 hours after injury					
Deteriorating LOC					
Focal neurological deficit					
Significant amnesia					
Penetrating head injury					
Suspected open/depressed skull fracture					
GSW head					
Post-traumatic seizure					
Vomiting >1					
Age >65yr					
Coagulopathy					
Dangerous mechanism of injury Mode of injury :					
Other : e.g. Missing/ inadequate notes (specify)					
Time of CT scan		Working hours		After hours	
CT results :		Normal		Abnormal	
				DAI	EDH
Disposition :	Discharge	Refer to neurosurgery	to	Admit for neuro-obs	Other

WAIVER OF INFORMED CONSENT

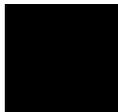
1. Protocol Title: Referral for CT brain in adult patients with head injury: are Emergency Centre doctors adhering to the Western Cape Head Injury guidelines?

2. Principal Investigator: Dr Dineo N. Moiloa
University of Stellenbosch 

3. Reasons for waiver of consent

There will be no contact between the researcher and patients at any point during the study. It will be an anonymous questionnaire-based study using patient folders and admission records. The only demographic information needed from patients will be gender and age. The referring doctors will not be contacted at any time during the study. The study is a prospective observational study and is merely an audit of current practise in the emergency centres. Anonymity will be retained throughout the duration of the study and afterward. The results will not affect the rights and welfare of subjects. No additional pertinent information is expected to arise during the study.

By signing this request for waiver of informed consent, I certify the information included in it.



Principal Investigator's Signature

12/07/2011
Date

WESTERN CAPE HEAD INJURY GUIDELINES (CT HEAD SCANS)**CT SCANNING INDICATIONS**

Note: For children these indications should be read in conjunction with the Head CT guidelines for children. The radiation risk of a Head CT is higher for children than for adults.

CT-scan within 1 hour for exclusion of head injury if:

- DECREASED LEVEL OF CONSCIOUSNESS
 - o Adults GCS less than 13 at any point since the injury
 - o Adult GCS equal to 13 or 14 at 2 hours after the injury
 - o Only children under 10yrs with GCS<8 should have within 1hr to avoid potential risks associated with irradiation.
- DETERIORATING LEVEL OF CONSCIOUSNESS
- Focal neurological deficit
- Loss of consciousness (any for adults; >5 minutes for children)
- Amnesia (antegrade & retrograde) lasting more than 5 min in children
- Any penetrating head injury (may be subtle in children)
- Penetrating orbital injury
- Suspected open or depressed skull or base of skull fracture, or tense fontanelle in children.
- Tangential gunshot wound of the head even if no bullet penetration is suspected
- Post-traumatic seizure
- More than one episode of vomiting for adults
- Clinical judgement should be used regarding the cause of vomiting in those aged less than 12, and whether imaging is required. The NICE guideline for children is 3 or more discrete episodes
- Age greater than or equal to 65 years
- Coagulopathy

CT-scan within 8 hours if:

- Amnesia for events occurring \geq 30 min before the injury.
- Dangerous mechanism of injury:
 - o High-speed MVA
 - o Fall from a height (>1m)

(Copyright: Western Cape Head Injury Guidelines 2008)

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Accepted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction, and will delay publication.

AUTHORSHIP

Named authors must consent to publication. Authorship should be based on substantial contribution to: (i) conception, design, analysis and interpretation of data; (ii) drafting or critical revision for important intellectual content; and (iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to www.icmje.org).

CONFLICT OF INTEREST

Authors must declare all sources of support for the research and any association with a product or subject that may constitute conflict of interest.

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Provide evidence of Research Ethics Committee approval of the research where relevant.

PROTECTION OF PATIENT'S RIGHTS TO PRIVACY

Identifying information should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives informed written consent for publication. The patient should be shown the manuscript to be published. Refer to www.icmje.org.

ETHNIC CLASSIFICATION

References to ethnic classification must indicate the rationale for this.

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Shorter items are more likely to be accepted for publication, owing to space constraints and reader preferences.

Research articles (previously 'Original articles') not exceeding 3 000 words, with up to 6 tables or illustrations, are usually observations or research of relevance to clinical medicine and related fields. References should preferably be limited to no more than 15. Please provide a structured abstract not exceeding 250 words, with the following recommended headings: Background, Objectives, Methods, Results, and Conclusion.

Scientific letters will, in future, be incorporated as shorter Research articles.

Editorials, Opinions, etc. should be about 1000 words and are welcome, but unless invited, will be subjected to the SAMJ peer review process.

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Letters to the editor, for publication, should be about 400 words with only one illustration or

table, and must include a correspondence address.

Forum articles must be accompanied by a short description (50 words) of the affiliation details/interests of the author(s). Refer to recent forum articles for guidance. Please provide an accompanying abstract not exceeding 150 words.

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Refer to articles in recent issues for the presentation of headings and subheadings. If in doubt, refer to 'uniform requirements' - www.icmje.org.

Manuscripts must be provided in UK English.

Qualification, affiliation and contact details of ALL authors must be provided in the manuscript and in the online submission process.

Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.

Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dl). Litres is denoted with a lowercase 'l' e.g. 'ml' for millilitres). Units should be preceded by a space (except for %), e.g. '40 kg' and '20 cm' but '50%'. Greater/smaller than signs (> and <) should be placed immediately preceding the relevant number, i.e. 'women >40 years of age'. The same applies to \pm and $^{\circ}$, i.e. '35 \pm 6' and '19 $^{\circ}$ C'.

Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160...

Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'

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The manuscript must be in Microsoft Word or RTF document format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes, with the exception of Tables).

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If tables or illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.

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and column headings. Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.

Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Fig. 1)'. Figure legends: Fig. 1. 'Title...'

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REFERENCES

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Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization,[2] and others.[3,4-6]

All references should be listed at the end of the article in numerical order of appearance in the Vancouver style (not alphabetical order). Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus.

Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al. First and last page, volume and issue numbers should be given.

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Journal references:

Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. *Stat Med* 1998;289(1):350-355. [<http://dx.doi.org/10.1000/hgjr.182>] [PMID: 2764753]

Book references:

Jeffcoate N. *Principles of Gynaecology*. 4th ed. London: Butterworth, 1975:96-101.

Chapter/section in a book:

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Internet references:

World Health Organization. *The World Health Report 2002 - Reducing Risks, Promoting Healthy Life*. Geneva: World Health Organization, 2002. <http://www.who.int/whr/2002> (accessed 16 January 2010).

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