



EVALUATING THE NEED FOR CT ANGIOGRAPHY IN DIAGNOSING VASCULAR INJURY IN PENETRATING NECK INJURIES IN THE PIETERMARTIZBURG METROPOLITAN TRAUMA SERVICE.

By

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Table of Contents

Supervisors' Declaration	iii
Student Declaration	iii
Acknowledgements.....	iv
Overview of the thesis	v
Part 1: The Review of Literature	1
Part 2: A submission ready manuscript.	11
Appendices.....	XIX
Appendix 1: The final Study Protocol.....	XIX
Appendix 2: The Guidelines for Authorship for the Journal selected for submission of the manuscript	XXVIII
Appendix 3: Ethical approvals.....	XXXV
Appendix 4: Data collection tools	XLIV

Supervisors' Declaration

As the candidate's supervisor I have approved this thesis for submission.



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Date: 25/08/2019

Student Declaration

I Bianca van den Berg declare that

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Overview of the thesis

Penetrating injuries to the neck are a very common occurrence in South-Africa. It encompasses a broad range of injuries including pathology of the aerodigestive and vascular systems. Before the advent of CT scans, conventional angiography was the first line of imaging the vascular system. Conventional angiograms are an invasive procedure and require arterial catheterization, which increases the risk of complications. With the advent of CT scans, imaging the vascular tree is now a relatively safe and quick procedure. CT scanning also has the added benefit of allowing the visualization of other structures in the neck.

Previously it was believed that all penetrating injuries in Zone 2 of the neck required surgical exploration. Following articles published in high volume centers, policies changed from mandatory exploration to clinical observation. With the advent of CT Angiography, practice has now changed to image all patients with penetrating neck injuries even in the absence of hard signs of vascular injury. If no injury is found on CT Angiogram, conservative management is instated with mandatory observation of the patient. This is leading to an increasing number of negative scans, cost and complications. The object of the present study is to evaluate the need for CT angiography when physical examination fails to reveal any hard signs and no other soft signs except proximity to major vascular structures as a soft sign.

Part 1: The Review of Literature

Trauma in South Africa is a significant disease burden on the public health care system and contributes about a quarter of the workload at public health care facilities. It requires specialized facilities and staff to investigate and manage these patients, which adds significant cost^[1]. Facilities needed to investigate and manage trauma patients includes pre-hospital emergency care providers to initially manage and stabilize trauma patients and transport them to the appropriate health care facility, Trauma Centres with specialized Multidisciplinary teams, Radiology Suites with access to specialized investigations e.g. Computer Tomography with angiogram capabilities, intensive care units, dedicated operating theatres with multidisciplinary surgical teams capable of performing General Surgical and Orthopedic surgeries, to name but a few.

According to a study published by the WHO, trauma in South Africa is a significant disease burden^[2]. Statistics have shown that of approximately 60 000 injury related deaths in South Africa in 2000, 46% of them were homicide related, 27% were road traffic incidents and 9% were self-inflicted injuries. Homicide rates were most common amongst young males aged 15 to 29 at a rate of 184:100 000, many times higher than the global rate. Injuries were responsible for 2,3 Million disabilities in South Africa in 2000, with the second most common cause interpersonal violence^[2]. Major contributing factors to the high rate of violence in South Africa are income inequality, poverty, gender based issues and inequalities, breakdown of family structure, gang-based violence, alcohol and drug abuse and easy access to firearms^[2].

A study conducted at Pietermaritzburg Metropolitan Trauma Service from 2010 to 2011 highlighted the trauma disease burden and divided it between blunt and penetrating trauma^[3]. Blunt trauma comprised 70 % and penetrating trauma contributed 30% of the disease burden. Of the penetrating group, 5% were firearm related penetrating injuries and 25% were stabs showing the significant number of penetrating injuries caused by stabs^[3]. Of these, 2,5% of all penetrating injuries were located in the neck region.

In another study conducted in Cape Town the statistics differed significantly, showing that the most common mechanism of injury is penetrating injuries at 20 % of the total injury burden, second road traffic injuries at 19% then blunt injuries at 17%. They also showed a higher incidence of firearm injuries at 8% and stabs at 35%^[4].

From the above statistics it is clear that the disease burden from injury is significant, even though there is different regional distribution. Due to the high numbers of interpersonal violence in South Africa the number of penetrating injuries are high.

The neck is a complex structure with multiple vital structures ranging from airway to major vascular structures. Penetrating neck injuries have a broad range of presentations ranging from stable asymptomatic patients to patients presenting with airway compromise or exsanguination from arterial bleeding. The management of penetrating neck injuries has evolved over many years with improvement in imaging technologies and surgical techniques.

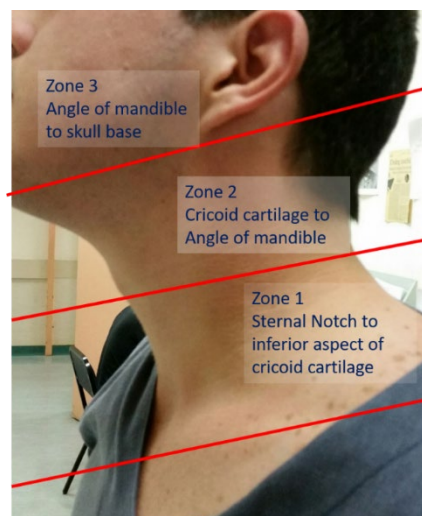
Before World War 2, all patients with a penetrating neck wound were treated conservatively with observation only due to the lack of modern imaging techniques. Mortality rates exceeded 35% [5], due to a high rate of missed injuries with catastrophic complications.

During World War 2 and the Korean War, mandatory exploration of all penetrating neck trauma that penetrated the platysma was necessary to exclude occult injury [6], significantly decreasing mortality rates, but also leading to a high rate of negative explorations with increased cost and post-operative complications.

In the 1970s and 1980s several authors questioned the necessity of surgical exploration of all patients with penetrating neck injuries. Professor Muckart (UKZN) was one of the first authors to publish a prospective study on selective surgical management in patients with penetrating neck injuries [7]. The study concluded *'that a selective policy for surgical intervention is safe and justifiable. A minimum mortality and morbidity can be obtained by adequate preoperative evaluation which includes the use of contrast radiography and angiography'* [7]. Management shifted to mandatory angiography and endoscopy.

Following this a Zonal approach was suggested to manage penetrating neck injuries. Injuries were classified into Zones depending on their location [8]. The neck is traditionally divided into three different Zones, see figure 1, and different structures are vulnerable in each of the different Zones, as can be seen from table 1.

Figure 1



Zone	Borders	Structures Vulnerable
1	Cricoid ring to sternoclavicular notch	<ul style="list-style-type: none"> • Trachea • Subclavian, innominate and jugular veins • Recurrent laryngeal and vagus nerves • Oesophagus • Proximal section of common carotids • Vertebral and subclavian arteries • Spinal cord and brachial plexus
2	The angle of mandible to the cricoid ring	<ul style="list-style-type: none"> • Larynx and pharynx • Vagus nerves • Vertebral arteries • Distal section of the common carotids • Proximal parts of the internal and external carotid artery • Jugular veins • Spinal cord
3	Base of skull to angle of mandible	<ul style="list-style-type: none"> • Extracranial internal carotid Arteries • Vertebral arteries. • External carotid artery • Jugular veins • Cranial nerves IX–XII • Spinal cord

Table 1

This approach states that any unstable patient receives immediate surgical exploration. The stable patient will be classified according to the location of the injury and be managed according to the zone involved. With easy access in zone 2, patients with hard or soft signs of vascular injury, see Table 2, may be explored without imaging. Patients with zone 1 and 3 penetrating wounds should have imaging done if stable to exclude an injury or to locate the exact position of the injury to aid in either intervention via endovascular means or for careful planning of the surgical approach at exploration^[8].

Hard Signs	Soft Signs
<ul style="list-style-type: none"> • Pulsatile bleeding • Absent distal Pulse • Arterial thrill • Audible bruit • Expanding hematoma 	<ul style="list-style-type: none"> • Stable hematoma • Nerve injury • History of significant hemorrhage • Proximity to major vascular structure • BP difference of more than 10mmHg between upper limbs

Table 2

Most recently a ‘No-Zones’ approach to the management of penetrating neck injuries has been suggested. All stable patients presenting with either hard or soft signs of penetrating neck injuries undergo imaging irrespective of the location of the injury^[9,10].

Already in the late 1980s the necessity of routine Angiography was questioned^[6]. Although the practice of non-surgical management of penetrating neck injuries is generally accepted, it has not been clearly demonstrated that angiography can be abandoned in stable clinically asymptomatic patients, as the absence of overt clinical signs or symptoms does not mean that no injury is present^[11].

The current management algorithm published by the Trauma Society of South Africa ^[12] still advocates imaging in the form of CT Angiogram in stable patients with soft signs of vascular injury including proximity in patients presenting with penetrating neck injuries.

Imaging investigations of penetrating neck injuries has also seen a major shift from conventional catheter directed angiogram to CT Angiogram as the gold standard. With the rise in the use of CT angiograms to investigate penetrating neck injuries, so the cost and complications will rise as well due to the larger numbers of patients having these procedures.

CT Angiogram has well documented complications associated with it, either from the contrast medium, procedural related, or due to radiation exposure. Complications due to the contrast medium include minor allergic reactions to anaphylaxis with circulatory collapse, contrast induced nephropathy either transient or requiring dialysis (although this is disputed in recent literature). Procedural due to injection site complications, bleeding, sepsis or hematoma formation. Radiation exposure increases risk of cancer in the long term^[13].

Recent research has questioned the validity of previous research done in relation to contrast-induced nephropathy. Iodated contrast mediums have been used for more than a hundred years in diagnostic radiology. Initially contrast mediums were used with little consideration of the potential side-effects, e.g. nephrotoxicity. Only in the 1960’s did the first report appear of renal dysfunction following contrast administration appear, and papers started being published supporting this^[14]. Contrast induced nephropathy was rated as the third most common cause of iatrogenic Nephropathy^[15].

Contrast mediums used have also undergone a major shift from the historically used high-osmolar contrast medium to the newer modern iso or low-osmolar contrast mediums. Most of the historic studies were done using high-osmolar contrast mediums, where the gold standard of radiological investigation were catheter directed angiograms. Traditional Catheter directed angiograms delivers the contrast medium directly into the arterial system of the body with a subsequent high contrast dose delivered directly to the renal system^[14]. These early studies also had no control groups to verify the results. In view of this, recent studies have challenged the traditionally understood complication of contrast induced nephropathy. Recent studies have found that contrast induced nephropathy is an uncommon complication following CT Angiograms and that the renal dysfunction is most like due to the underlying condition, rather than the contrast administration^[14,15].

To minimize the cost of CT Angiogram investigations and to decrease associated complications, the use of CT Angiograms needs to be limited to decrease the number of negative investigations.

A major driver of ordering costly and unnecessary investigation is the practice of defensive medicine. Doctors are trained to make clinical and investigative decisions, taking the risk of malpractice lawsuits into consideration. Due to this fear, unnecessary investigations are undertaken to minimize the risk of being sued by the patient or patient's family for malpractice^[16].

Defensive Medicine has been around for many years but has been steadily on the increase in recent years. Defensive Medicine leads to increased hospitalizations, unnecessary investigations and prescribing of drugs including antibiotics and redundant costly referrals to specialist. It has steady caused an increase in healthcare cost and even contributed to the spread of antibiotic resistance^[16].

A study undertaken in the US to estimate the cost of defensive medicine in unnecessary investigations due to fear of litigation is estimated at \$46 billion annually^[17]. It is estimated that 27% of CT scans orders are unnecessary and not indicated and only ordered for fear of litigation^[17].

As with other countries, defensive medicine is also practiced in South Africa. Unnecessary costly investigations are performed in fear of misdiagnosis and malpractice litigation. So too are costly CT Angiogram investigations ordered in stable patients with no signs of vascular injury, to avoid a missed injury, increasing the rate of negative scans and increasing to rate of complications and putting further strain of the already fragile health care budget.

Numerous studies were published with conflicting evidence regarding mandatory angiography and the reliability of physical examination in detecting a vascular injury in a patient presenting with a penetrating neck injury.

Studies Highlighting Absence of Physical Signs in Clinically Significant Vascular Injury.

Fogelman and Stewart^[18] found that 43% of patients with a clinically significant cervical vascular injury were hemodynamically stable on presentation. Their study also concluded that 70% of patients did not exhibit clinical evidence of active bleeding at time of presentation.

In another study done by Apffelstaedt and Muller^[19] on 393 patients with penetrating neck injuries, they concluded that 30% of patients with clinically significant vascular injury had absent Physical signs. Another study done by Bishara^[20] found that 23% of patients presenting with penetrating neck injuries had negative physical exams.

At the 2012 SRS conference, a paper was presented which evaluated the need for mandatory CT Angiography in penetrating neck injuries. The study concluded that screening of all patients with CT angiography with penetrating neck injuries seems valid, even if there are no hard signs of vascular injury on physical exam^[21].

Studies Highlighting the High Sensitivity and Specificity of Physical Examination in Diagnosing Vascular Injury.

On the other side of the debate, Atteberry^[11] et al. found that if patients did not have physical examination findings of arterial injury (active bleeding, expanding hematoma or hematoma larger than 10 cm, a bruit or thrill, or a neurologic deficit) no vascular injuries were present based on angiography, duplex ultrasound, or clinical follow-up. They observed patients for at least 23 hours^[11].

Jarvik^[22] et al. concluded that clinical examination has excellent sensitivity at showing clinical significant vascular injury in patients with penetrating neck injuries. Moreover, the cost of performing screening angiography in patients who have no clinical evidence of vascular injury adds significant cost to hospitalization.

Azuaje^[23] et al. conducted a study on a total of 216 patients with penetrating neck injury. Of 63 patients with negative physical examination of vascular injury, only 3 patients had a positive angiogram and none of these injuries required operative repair. In this study the sensitivity and negative predictive value for detecting vascular injuries requiring operative intervention were both 100%.

Conclusion

As has been shown, the high rate of violent crimes in South Africa and particularly the rate of penetrating neck injuries, will translate to a high rate of CT angiograms being ordered. With the rise in practice of defensive medicine more CT angiograms will be ordered out of fear of litigation and not good clinical practice.

Current practice for management of penetrating neck injuries according to the 'No Zones' approach^[9,10] as reinforced by the Trauma Society of South Africa^[12], advocates for CT angiograms to be performed on stable patients with penetrating neck injuries who display either hard or soft signs of vascular injury including proximity to major vascular pathways.

The purpose of this prospective observational study is to evaluate the need for CT Angiography in patients with penetrating neck injuries who have no hard signs of vascular injury and only proximity to major vascular structures presenting to Pietermaritzburg Metropolitan Hospitals from October to December 2018.

Due to the conflicting evidence in the literature, further study is needed to evaluate the need for CT Angiography in stable patients with no hard signs of vascular injury and only proximity as an indication to perform a CT Angiogram. The research question is: Is proximity alone a good enough indication to perform a costly CT angiogram and expose the patient to risk of angiogram related complications?

This study will only focus on the investigation of possible vascular injury as previous studies have shown that contrast swallow is simple and cost effective in excluding aerodigestive injuries with minimal complications, in patients presenting with penetrating neck injuries. These patients should have a contrast swallow during the admission to exclude occult injuries as a missed injury could be catastrophic^[24].

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Part 2: A submission ready manuscript.

Rational use of Proximity as an indication for CT Angiography in patients with Penetrating Neck Injuries.

Abstract

Background: Penetrating neck injuries are a common occurrence in South Africa. Management has significantly changed from initial conservative management with high mortality rates to mandatory exploration with high number of negative explorations. With improvements in radiological techniques, investigations have also shifted from conventional angiograms to less invasive CT Angiogram. Current practices of the 'No Zones' approach to management of penetrating injury advocates that all patients with penetrating neck injuries be subjected to a CT angiogram, even in the absence of hard signs of vascular injury, leading to an increase in negative studies.

Objectives: The objective of the present study is to evaluate the rationale of only proximity to vascular structures, as an indication for CT Angiography.

Methods: All patients presenting with penetrating neck injuries to Greys and Edendale Hospitals, over a 3-month period, were included in the study. Data collected included hemodynamic status, site of penetration, blood pressure readings in both upper limbs and presence of any hard or soft signs of vascular injury. CT angiogram findings will be recorded including indications for CT Angiogram.

Results: Forty patients were included in the study. Five patients were stabbed by a broken bottle, two sustained gunshot wounds, one was stabbed by a screwdriver, six patients have an unknown weapon and 26 were stabbed with a knife. Eighteen patients had Zone 1 injuries, nineteen patients had Zone 2 injuries and three patients had Zone 3 stabs. Six patients had vascular injury, 3 arterial and 3 venous. Of these, three arterial injuries were in Zone 1 and three venous injuries were in Zone 2. Thirteen patients presented with only proximity, 26 presented with 2 signs and one patient presented with 3 signs of vascular injury. Of the patients presenting with two signs, three patients had a subsequent hard sign and all 3 patients had an injury to the vascular system. The patient with three positive signs had a venous injury. Of the 13 patients with only proximity to major vascular structure, none had any significant blood pressure differences between the upper limbs or an arterial injury present.

Conclusions: Proximity alone is not a reliable indication to subject a patient to a CT Angiogram. Patients need to have at least 2 soft signs of vascular injury, or a significant difference in blood pressures in the upper limbs.

Introduction

Penetrating injuries to the neck are a very common occurrence in South-Africa constituting 5 to 10 % of all trauma to adult patients^[1]. This encompasses a broad range of injuries including aerodigestive and vascular injuries of varying severity. The neck is traditionally divided into different Zones, see figure 1, and different structures are vulnerable in different Zones, as can be seen from table 1.

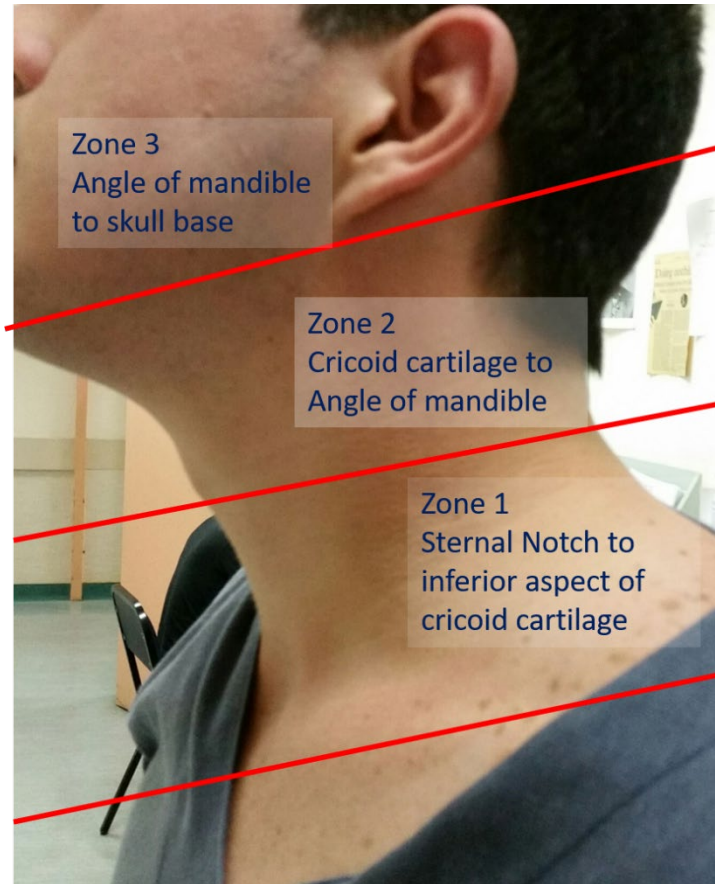


Figure 2

Zone	Borders	Structures Vulnerable
1	Cricoid ring to sternoclavicular notch	<ul style="list-style-type: none">• Trachea• Subclavian, innominate and jugular veins

		<ul style="list-style-type: none"> • Recurrent laryngeal and vagus nerves • Oesophagus • Proximal section of common carotids • Vertebral and subclavian arteries • Spinal cord and brachial plexus
2	The angle of mandible to the cricoid ring	<ul style="list-style-type: none"> • Larynx and pharynx • Vagus nerves • Vertebral arteries • Distal section of the common carotids • Proximal parts of the internal and external carotid artery • Jugular veins • Spinal cord
3	Base of skull to angle of mandible	<ul style="list-style-type: none"> • Extracranial internal carotid Arteries • Vertebral arteries. • External carotid artery • Jugular veins • Cranial nerves IX–XII • Spinal cord

Table 2

Before the advent of CT scans, conventional catheter-directed angiography was the ‘gold standard’ of imaging the vascular system. Conventional angiograms are an invasive procedure and require arterial catheterization, which increases the risk of complications^[2]. With the advent of CT scans, imaging the vascular tree is now a relatively safe and quick procedure. CT scanning also has the added benefit of allowing the visualization of other structures in the neck.

Previously it was believed that all penetrating injuries in Zone 2 of the neck required surgical exploration^[3,4]. Following research published from high volume centers, policies changed from mandatory exploration to clinical observation^[5]. With the advent of CT Angiography, a new practice has emerged, to image all patients with penetrating neck injuries even in the absence of hard signs of vascular injury, as depicted in table 2^[6,7], also known as the “No Zone approach^[8]”. This is leading to an increasing number of negative scans, cost and complications. The objective of the present study is to evaluate the rationale of only proximity to vascular structures, a soft sign of vascular injury, as an indication for CT Angiography even if physical examination fails to reveal any hard signs.

Soft Signs of Vascular Injury	Hard Signs of Vascular Injury
<ul style="list-style-type: none"> • Stable hematoma • Nerve injury • History of significant hemorrhage • Proximity to major vascular structure 	<ul style="list-style-type: none"> • Pulsatile bleeding • Absent distal Pulse • Arterial thrill • Audible bruit • Expanding hematoma

Table 3

It has been well documented in previous studies that imaging of the aerodigestive system following penetrating neck trauma, using water-soluble contrast alone is simple, cost effective and accurate with minimal complications^[9], thus the main aim of this study will be directed towards vascular injuries and their investigation.

Methods

All patients presenting with penetrating neck injuries to Greys and Edendale Hospitals, over a 3-month period, were included in the study. Grey's Hospital is a Secondary Hospital serving the greater Pietermaritzburg and surrounding areas. Edendale hospital is a regional and district hospital serving Edendale and the surrounding rural area.

The criteria for patients to be included in the study was an age above 18, those who presented with a penetrating injury to the neck, who had no neurological deficit, with a GCS of 15 and who were investigated with a CT angiogram.

The exclusion criteria were polytrauma patients i.e. with stabs in multiple regions. Patients who were clinically confused were also excluded, as they were unable to give consent to participate in the study.

The patients were consented, and a standardised data-proforma completed. Data collected included initial hemodynamic status, site of penetration, blood pressure readings in both upper limbs and presence of any hard or soft signs of vascular injury. CT angiogram findings were recorded. Information was captured on a Microsoft Office® (Microsoft Corp, Redmond USA) spread sheet on a password protected computer. Specific attention was paid to the indications for CT Angiogram. Ethical approval was obtained from the Biomedical Ethics Research Committee (BE292/16).

As the main aim of the study was the observation of vascular injuries following penetrating injuries and not aerodigestive injuries, it will only be noted if any injury was found during observation or with additional investigations.

The methodological limitations of this study were that not all 3 hospitals in the Metropole were included as Northdale Hospital does not have a CT scanner and all their referrals for Imaging would be sent to Greys Hospital.

Results

A total of 42 patients were included in the study. On analysis of the data, two patients were excluded for incomplete data on data collection sheets. Of these, 38 were male patients and 2 were females. The ages ranged from 17 to 40 years.

Examining mechanism of injury revealed five were stabbed by broken bottles, two were gunshot wounds, one screwdriver, six had an unknown weapon (Table 1). The vast majority, namely 26, were stabbed with knives. One patient stabbed with a bottle had an Arterial injury and required operative intervention. Four patients stabbed with knives had positive CT Angiogram Findings, two venous injuries and two arterial injuries, all requiring operative intervention. One patient with an unknown weapon had a venous injury that required exploration to tie off the vessel.

Weapons Used	
Number	Weapon
5	Broken Bottle
2	GSW
1	Screwdriver
6	Unknown
26	Knife

Table 1

Eighteen patients had stabs in Zone 1 of the neck, one patient had a stab extending from Zone 1 into Zone 2, nineteen patients had isolated Zone 2 stabs and only 3 patients had Zone 3 wounds. Equal amounts of wounds were present on the left and on the right side of the neck. Of the patients with Zone 1 stabs, 3 (16%) had arterial injury requiring intervention. Three of the patients with Zone 2 stabs (16%) had only a venous injury that required intervention (Table 2).

Location of Stabs		
Zone	Total	Vascular Injury
1	18	3 X Arterial Injuries
1 and 2	1	
2	19	3 X Venous Injuries
3	3	No Vascular injuries
L=R		

Table 2

Of the 40 patients included, only three patients (7.5%) demonstrated an arterial injury on CT Angiogram. All three required operative intervention. The first patient presented with a penetrating injury in Zone 1 of the neck with an associated pneumothorax requiring an intercostal drain to be placed. The patient also displayed a hard sign of vascular injury, an absent pulse on the affected upper limb. No blood pressure was able to be recorded on the affected limb. The patient had a surgical exploration and primary repair of a subclavian artery injury and had an uneventful recovery.

The second patient with an arterial injury also presented with a Zone 1 penetrating wound with a pneumothorax necessitating intercostal drain placement. A hard sign of vascular injury was present in the form of a pulsatile hematoma. He also had a history of a significant bleed. Blood

pressures in both upper limbs measured the same. He had a later neck exploration to repair a pseudo-aneurysm of the Common Carotid Artery.

The last patient with an arterial injury presented with a Zone 1 injury. He had no hard sign of arterial injury but had two soft signs present. He had a significant history of bleeding at the scene and proximity to major vascular structures. There was also a more than 20mmhg difference in both the systolic and diastolic blood pressures on the upper limbs, with the effected side being much lower. He has surgical exploration and primary repair of an injury to the subclavian artery.

Three patients presented with venous injury all in penetrating injuries of Zone 2. The first patient had two soft signs of vascular injury present, with a history of significant bleeding and proximity. The second patient with venous injury had a hard sign of vascular injury present, an expanding hematoma. There was also a more than 20 mmHg difference in blood pressures again of both the systolic and diastolic. He required operative intervention. The last patient with venous injury had no significant difference in blood pressures of the upper limbs but had 3 signs of vascular injury present. He presented with an expanding hematoma at the site and had a history of a significant bleed.

On analysis of the number of signs present per patient, thirteen patients presented with only proximity, 26 presented with 2 signs and one patient presented with 3 signs. Interestingly the patient with three signs only had a venous injury. Of the patients presenting with two signs, three patients had a subsequent hard sign and all 3 patients had an injury to the vascular system. Five patients had an associated stable hematoma, one had a nerve injury and 17 had a stable hematoma. Of the 13 patients with only proximity to major vascular structure, none of these had any significant blood pressure differences between the upper limbs, even though 2 patients had intercostal drains placed for pneumothoraxes and no vascular injury was identified (Table 3).

Signs of Vascular injury		
Number of Signs	Number of Patients	Vascular injury
Proximity Only	13	No vascular injury
2 Signs	26	5 Vascular injuries
>2 Signs	1	1 Vascular Injury

Table 3

All patients had a contrast swallow to exclude aerodigestive injuries, with all studies performed being negative for any injury. All patient was observed for at least 24 hours.

Discussion

This study, over a three-month period in two busy trauma centers identified 40 patients with isolated penetrating neck injury and evaluated whether proximity alone predicted the need for CT-angiography in addition to contrast swallow (the latter done routinely). The injury rate was 16% for zone 1 and 16% for zone 2, but no injury in zone 3 was found. For those with only proximity no injury was noted and those with presence of an injury had at least one **additional** soft sign, or hard vascular signs present.

Increasing financial constraints on the healthcare budget has forced healthcare practitioners to implement more efficient and cost-effective strategies to improve patient outcome. This is even more apparent in Lower-and-Middle-Income-Countries, where trauma is endemic^[10,11].

Comparing the international literature with the results of the current study, the sensitivity of adequate physical examination is again confirmed. It is clear that all patients with a vascular injury had a hard sign of vascular injury, or at least two soft signs on presentation. None of the patients with only proximity had a vascular injury, but all of them were subjected to a costly examination placing even more strain on the fragile healthcare budget. Adequate physical examination and observation with frequent re-examinations, to exclude any change in condition of patient presenting with penetrating neck injury, can significantly decrease the need for costly investigations.

Reviewing the history of management of penetrating neck injuries, prior to World War 2, all patients with a penetrating injury of the neck were treated non-operatively by observation with extremely high mortality rates, exceeding 35%^[12]. During World War 2 and the Korean War, opinions dramatically shifted to compulsory exploration of all penetrating neck injuries to exclude non apparent injury^[3,4], significantly decreasing mortality rates. During the 1970s to 1990s several researchers questioned the necessity of surgical exploration of all patients with penetrating neck injuries^[4]. Professor Muckart and the team from UKZN was one of the first groups to publish a prospective study on selective surgical management in patients with penetrating neck injuries^[5]. The study concluded “*that a selective policy for surgical intervention is safe and justifiable. A minimum mortality and morbidity can be obtained by adequate preoperative evaluation which includes the use of Contrast Radiography and Angiography*”^[5]. Management shifted to mandatory angiography and endoscopy. Only in the late 1980s was the necessity of routine angiography questioned^[3]. Since then conservative management of penetrating neck injuries has been accepted practice, but the usefulness of routine angiography in a clinically stable patient, with only proximity injury, has not been clearly demonstrated. Also, the absence of overt clinical signs or symptoms of vascular injury, does not mean that one is not present^[13].

Numerous studies were published highlighting the high sensitivity and specificity of physical examination alone in diagnosing vascular injury. Atteberry^[13] et al found that if patients did not have physical examination findings of arterial injury (active bleeding, expanding hematoma or hematoma larger than 10 cm, a bruit or thrill, or a neurologic deficit) no vascular injuries were present based on angiography, duplex ultrasound, or clinical follow-up. They observed patients for at least 23 hours^[13]. Jarvik^[4] et al concluded that clinical examination has excellent sensitivity at showing clinical significant vascular injury in patients with penetrating neck injuries. Moreover, the cost of performing screening angiography in patients who have no clinical evidence of vascular injury adds significant cost to hospitalization.

Azuaje^[14] et al. conducted a study on a total of 216 patients with penetrating neck injury. Of 63 patients with negative physical examination of vascular injury, only 3 patients had a positive Angiogram and none of these injuries required operative repair. In this study the sensitivity and negative predictive value for detecting vascular injuries requiring operative intervention were both 100%.

Most recently a local paper was published advocating for selective imaging of patients with penetrating neck injury, stating that only patients with hard or soft signs should be investigated with a CT angiogram^[15]. Interestingly their list of soft signs of vascular injury did not include proximity to major vascular structures, so it was not regarded as an indication for imaging.

With so many studies showing the sensitivity of physical examination and mandatory observation of patients presenting with penetrating neck injuries to exclude vascular injury, should the management not shift to observation of these patient that present only with proximity to major vascular structures as the only sign of vascular injury, provided an aerodigestive injury can be easily excluded. As previous studies have shown that contrast swallow is simple and cost effective in excluding aerodigestive injuries with minimal complications, patients presenting with penetrating neck injuries should have a contrast swallow during the admission to exclude occult injuries, since a missed injury could be catastrophic^[9].

Even though the sample size was small, it was a typical representation of the epidemiology of penetrating neck injuries, with all the patients being young adults and the majority being male.

Conclusion

Proximity alone is not a reliable indication to subject a patient to a costly investigation with inherent risks. Patients need to have at least 2 soft signs of vascular injury, or a significant difference in blood pressure readings in the upper limbs, to justify subjecting a patient to a CT Angiogram.

Previous studies have shown that contrast swallow is simple and cost effective and all patients presenting with penetrating neck injuries should have a contrast swallow during their admission.

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Appendices

Appendix 1: The final Study Protocol (the final protocol which was given full approval by BREC and/or the Postgraduate office)

Evaluating the need for CT Angiography in
Diagnosing Vascular Injury in Penetrating Neck
Injuries in the Pietermaritzburg Metropolitan
Trauma Service.

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Executive Summary

Penetrating injuries to the neck are a very common occurrence in South Africa, with devastating complications if injuries are not timeously diagnosed. Diagnosis of vascular injuries typically involves performing a thorough physical examination of the patient, looking for any hard or soft signs of vascular injury(See Below). Imaging modalities include a catheter directed Angiogram or a CT Angiogram, both of which has its own complications and cost involved.

Hard Signs

- Pulsatile bleeding
- Absent distal Pulse
- Arterial thrill
- Audible bruit
- Expanding hematoma

Soft Signs

- Stable hematoma
- Nerve injury
- History of significant hemorrhage
- Proximity to major vascular structure

This study aims to determine the need for CT Angiography in patients presenting with a stab neck but no signs of vascular injury apart from proximity. All patients with penetrating injuries to the neck, presenting to Edendale or Greys Hospital, will be included in the study. Data collection sheets will record initial physical examination, including the presence of hard or soft signs of vascular injury. CT Angiogram results will be reviewed and all collected data will be interpreted.

This study will place emphasis on the importance of thorough physical examinations in penetrating neck injuries and could decrease the need for CT Angiogram imaging in patients with no hard or soft signs of vascular injuries.

Table of Content

1. Defining the research problem	4
2 Literature overview and motivation	4
3.Aim and objectives	6
4. Methods	6
4.1 Study design	6
4.2 Setting	6
4.3 Patient/research object selection	6
4.4 Measurements	7
4.5 Data analysis	7
4.5.1 Sample size	7
5. Ethical considerations	7
6. Budget	7
7. Timelines and project management	8
8. Contributors and authorship	8
9. References	8
10. Appendices	9

Defining the research problem

Penetrating injuries to the neck are a very common occurrence in South-Africa. It encompasses a broad range of injuries including aerodigestive and vascular. Before the advent of CT scans, conventional angiography was the first line of imaging the vascular system. Conventional angiograms are an invasive procedure and require arterial catheterization, which increases the risk of complications. With the advent of CT scans, imaging the vascular tree is now a relatively safe and quick procedure. CT scanning also has the added benefit of allowing the visualization of other structures in the neck.

Previously it was believed that all penetrating injuries in Zone 2 of the neck required surgical exploration. Following articles published in high volume centres policies changed from mandatory exploration to clinical observation. With the advent of CT Angiography, practice has now changed to image all patients with penetrating neck injuries even in the absence of hard signs of vascular injury. If no injury is found on CT Angiogram, conservative management is instated with mandatory observation of the patient. This is leading to an increasing number of negative scans, cost and complications.

In the absence of a hard sign of a vascular injury in the neck or the root of the neck patients are admitted for observation. In our unit we practice selective conservatism. Only patients with signs of vascular injury are subjected to CT Angiography. Other units advocated a policy of routine investigation of all these patients. This policy originated at a time when imaging consisted of a catheter directed angiogram which was invasive and in itself associated with a small but significant risk of complications.

Since most of these studies were published CT angiography has become widespread. This is not catheter directed but the computer reconstructed images. The ease of CT angiography has meant that frequently patients who previously in our unit would not have been investigated are now being subjected to a CT angiogram, with its complications. The yield of this policy of de facto routine imaging has not been reviewed.

This study would like to re-emphasize the accuracy of physical examination and evaluate the need for CT Angiography in penetrating neck trauma in which the physical examination of the patient fails to reveal any hard or soft signs of vascular injury. Is mandatory angiography needed even if physical examination fails to reveal any hard or soft signs?

Literature overview

Increasing financial constraint on the health care budget has forced health care practitioners to implement more efficient and cost-effective strategies to improve patient outcome.

Before World War 2, all patients with a penetrating neck wound were treated conservatively and mortality rates exceeded 35%¹. During World War 2 and the Korean War, mandatory exploration of all penetrating neck trauma was necessary to exclude occult injury,² significantly decreasing mortality rates. In the 1970s and 1980s several authors questioned the necessity of surgical exploration of all patients with penetrating neck injuries. Professor Muckart was one of the first authors to publish a prospective study on selective surgical management in patients with penetrating neck injuries. The study concluded that a selective policy for surgical intervention is safe and justifiable. A minimum mortality and morbidity can be obtained by adequate preoperative evaluation which includes the use of contrast radiography and angiography³. Management shifted to mandatory angiography and endoscopy. Only in the late 1980s was the necessity of routine Angiography questioned². Although the practice of non-surgical management of penetrating neck injuries is generally accepted, it has not been clearly demonstrated that angiography can be abandoned in stable clinically asymptomatic patients⁴ as the absence of overt clinical signs or symptoms, does not mean that one is not present.

Following this study, numerous studies were published with conflicting evidence regarding mandatory Angiography and the reliability of physical examination in detecting a vascular injury in a patient with a penetrating neck injury.

Studies Highlighting Absence of Physical Signs in Clinically Significant Vascular Injury.

Fogelman and Stewart⁵ found that 43% of patients with a clinically significant cervical vascular injury were hemodynamically stable on presentation. Their study also concluded that 70% of patients did not exhibit clinical evidence of active bleeding at time of presentation.

In another study done by Apffelstaedt and Muller⁶ on 393 patients with penetrating neck injuries, concluded that 30% of patients with clinically significant vascular injury had absent Physical signs. Another study done by Bishara⁷ Found that 23% of patients presenting with penetrating neck injuries had negative physical exams.

Most recently at the 2012 SRS conference, a paper was presented which evaluated the need for mandatory CT Angiography in penetrating neck injuries. The study concluded that screening of all patients with CT angiography with penetrating neck injuries seems valid, even if there are no hard signs of vascular injury on physical exam⁸.

Studies Highlighting the High Sensitivity and Specificity of Physical Examination in Diagnosing Vascular Injury.

On the other side of the debate, Atteberry⁴ et al found that if patients did not have physical examination findings of arterial injury (active bleeding, expanding hematoma or hematoma larger than 10 cm, a bruit or thrill, or a neurologic deficit) no vascular injuries were present based on angiography, duplex ultrasound, or clinical follow-up. They observed patients for at least 23 hours⁴.

Jarvik⁹ et al concluded that clinical examination has excellent sensitivity at showing clinically significant vascular injury in patients with penetrating neck injuries. Moreover, the cost of performing screening angiography in patients who have no clinical evidence of vascular injury adds significant cost to hospitalization.

Azuaje¹⁰ et al conducted a study on a total of 216 patients with penetrating neck injury. Of 63 patients with negative physical examination of vascular injury, only 3 patients had a positive Angiogram and none of these injuries required operative repair. In this study the sensitivity and negative predictive value for detecting vascular injuries requiring operative intervention were both 100%.

Conclusion

In view of the conflicting literature, a further study is needed to evaluate the role of CT Angiogram in Penetrating neck injuries in patients with no hard or soft signs of vascular injury on physical examination.

Aims and Objectives

Aims:

- Establish the need of CT Angiography in patients presenting with a stab neck and does not have any signs of vascular injury

Objectives:

- Determine the number of patients who had a vascular injury on CT Angiogram but had no hard or soft signs of vascular injury on physical examination apart from proximity.

Methods

Study Design

- Prospective cohort study

Setting

The study will be done at Grey's and Edendale hospital, Pietermaritzburg, South Africa. Grey's Hospital is a Secondary Hospital serving the greater Pietermaritzburg and surrounding areas. Edendale hospital is a regional and district hospital serving Edendale and the surrounding rural area.

Patient selection

All patients presenting to the above-mentioned hospitals in the study period will be eligible for the study.

Inclusion Criteria

- Age above 18
- Penetrating injury to the neck
- Hemodynamically stable
- No neurological deficit
- Investigated by CT Angiogram

Exclusion Criteria

- Polytrauma patients
- Simultaneous penetrating injuries to thorax or upper limbs
- Confusion
- Hard signs of vascular injury

Measurements

The primary investigator will personally examine all patients with penetrating neck injury within 24 hrs of admission. Data will be collected on a data collection sheet.

CT Angiograms will be reviewed with a radiology consultant and only final reports will be included in the study.

Data Analysis

Data Analysis will be done at the end of every month. All information will be captured on a Microsoft Office® Spread Sheet including CT Angiogram results. CT Angiogram report will be collected and interpreted.

Sample Size

Data will be collected over a fixed period of time. I anticipate that 50 patients will be enrolled in the study.

Ethical Considerations

All patients who volunteer to participate in the study will be asked to provide written informed consent as a prerequisite for inclusion. The study will only commence after it has been approved by the University of KZN's ethics committee. Patient data will be entered into a data base on a password protected computer, with each patient allocated a study number. No patient names or hospital numbers will be entered. Principles of Helsinki and Good Clinical Practice will be adhered to. Since only a questionnaire is used, and no interventions are applied, the risk of the study is negligible. The Informed consent document can be found as Appendix 2.

Budget

Expense Subcategories	Specific Cost	Justification	Rands
Material and supplies	Paper	For data collection sheets	R100
	Printing	Of data collection sheets	R300
Travel	Local	Researchers travel between hospitals	R1000
Total			R1400

Timeline

The project will run over three months.

Contributors and Authorship

Name	Department	Contribution	Acknowledgement
Dr Van den Berg	Surgery		Author
Mr S van Wyk	Surgery	Moderator	

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Appendix 2: The Guidelines for Authorship for the Journal selected for submission of the manuscript

SAMJ Author Guidelines

Publication Fees

All articles published in the *South African Medical Journal* are open access and freely available online upon publication. This is made possible by applying a business model to offset the costs of peer review management, copyediting, design and production, by charging a publication fee of R5 250 (ex vat) for each research article published. The charge applies only to **Research** articles submitted after 1 March 2017. The publication fee is standard and does not vary based on length, colour, figures, or other elements.

Authorship

Named authors must consent to publication. Authorship should be based on: (i) substantial contribution to conceptualisation, design, analysis and interpretation of data; (ii) drafting or critical revision of important scientific content; or (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)

Conflicts of interest

Conflicts of interest can derive from any kind of relationship or association that may influence authors' or reviewers' opinions about the subject matter of a paper. The existence of a conflict – whether actual, perceived or potential – does not preclude publication of an article. However, we aim to ensure that, in such cases, readers have all the information they need to enable them to make an informed assessment about a publication's message and conclusions. We require that both authors and reviewers declare all sources of support for their research, any personal or financial relationships (including honoraria, speaking fees, gifts received, etc) with relevant individuals or organisations connected to the topic of the paper, and any association with a product or subject that may constitute a real, perceived or potential conflict of interest. If you are unsure whether a specific relationship constitutes a conflict, please contact the editorial team for advice. If a conflict remains undisclosed and is later brought to the attention of the editorial team, it will be considered a serious issue prompting an investigation with the possibility of retraction.

Research ethics committee approval

Authors must provide evidence of Research Ethics Committee approval of the research where relevant. Ensure the correct, full ethics committee name and reference number is included in the manuscript.

Other individuals

Any individual who is identifiable in an image must provide written agreement that the image may be used in that context in the *SAMJ*.

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Manuscript preparation

Preparing an article for anonymous review

To ensure a fair and unbiased review process, all submissions are to include an anonymised version of the manuscript. The exceptions to this are Correspondence, Book reviews and Obituary submissions.

Submitting a manuscript that needs additional blinding can slow down your review process, so please be sure to follow these simple guidelines as much as possible:

- An anonymous version should not contain any author, affiliation or particular institutional details that will enable identification.
- Please remove title page, acknowledgements, contact details, funding grants to a named person, and any running headers of author names.
- Mask self-citations by referring to your own work in third person.

General article format/layout

General:

- Manuscripts must be written in UK English.
- The manuscript must be in Microsoft Word format. Text must be single-spaced, in 12-point **Times New Roman** font, and contain no unnecessary formatting (such as text in boxes).
- Please make your article concise, even if it is below the word limit.
- Qualifications, **full** affiliation (department, school/faculty, institution, city, country) 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)'.
- Include sections on Acknowledgements, Conflict of Interest, Author Contributions and Funding sources. If none is applicable, please state 'none'.

- Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dL).
- Litres is denoted with an uppercase L e.g. 'mL' for millilitres).
- Units should be preceded by a space (except for % and °C), e.g. '40 kg' and '20 cm' but '50%' and '19°C'.
- Please be sure to insert proper symbols e.g. μ not u for micro, α not a for alpha, β not B for beta, etc.
- 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: '...'
- Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.
- If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the *only* exception. Please DO NOT use fill, format lines and so on.

Preparation notes by article type

Research

Guideline word limit: 4 000 words

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important clinical question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

Select figures and tables for your paper carefully and sparingly. Use only those figures that provided added value to the paper, over and above what is written in the text.

Do not replicate data in tables and in text .

Structured abstract

- This should be 250-400 words, with the following recommended headings:
 - **Background:** why the study is being done and how it relates to other published work.
 - **Objectives:** what the study intends to find out
 - **Methods:** must include study design, number of participants, description of the intervention, primary and secondary outcomes, any specific analyses that were done on the data.
 - **Results:** first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
 - **Conclusion:** must be supported by the data, include recommendations for further study/actions.
- Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors.
- Do not include any references in the abstracts.

Illustrations/photos/scans

- If illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.
- Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Fig. 1)'. Each figure must have a caption/legend: Fig. 1. Description (any abbreviations in full).
- All images must be of high enough resolution/quality for print.
- All illustrations (graphs, diagrams, charts, etc.) must be in PDF or jpeg form.
- Ensure all graph axes are labelled appropriately, with a heading/description and units (as necessary) indicated. Do not include decimal places if not necessary e.g. 0; 1.0; 2.0; 3.0; 4.0 etc.
- Scans/photos showing a specific feature e.g. *Intermediate magnification micrograph of a low malignant potential (LMP) mucinous ovarian tumour. (H&E stain)*. –include an arrow to show the tumour.
- Each image must be attached individually as a 'supplementary file' upon submission (not solely embedded in the accompanying manuscript) and named Fig. 1, Fig. 2, etc.

Tables

- Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged.
- Large tables will generally not be accepted for publication in their entirety. Please consider shortening and using the text to highlight specific important sections, or offer a large table as an addendum to the publication, but available in full on request from the author
- Embed/include each table in the manuscript Word file - do not provide separately as supplementary files.
- Number each table in Arabic numerals (Table 1, Table 2, etc.) and refer to consecutively in the text.
- Tables must be cell-based (i.e. not constructed with text boxes or tabs) and editable.
- Ensure each table has a concise title and column headings, and include units where necessary.
- Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.

References

NB: Only complete, correctly formatted reference lists in Vancouver style will be accepted. Reference lists must be generated manually and **not with the use of reference manager software**. Endnotes must **not** be used.

- Authors must verify references from original sources.
- 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.**
- Volume and issue numbers should be given.
- First and last page, in full, should be given e.g.: 121-1217 **not** 1215-17.
- **Wherever possible, references must be accompanied by a digital object identifier (DOI) link). Authors are encouraged to use the DOI lookup service offered by CrossRef:**
 - On the Crossref homepage, paste the article title into the 'Metadata search' box.

- Look for the correct, matching article in the list of results.
- Click Actions > Cite
- Alongside 'url =' copy the URL between { }.
- Provide as follows, e.g.: <https://doi.org/10.7196/07294.937.98x>

Some examples:

- *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>
- *Book references:* Jeffcoate N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975:96-101.
- *Chapter/section in a book:* Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974:457-472.
- *Internet references:* World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: WHO, 2002. <http://www.who.int/whr/2002> (accessed 16 January 2010).
- Legal references
 - Government Gazettes:
National Department of Health, South Africa. National Policy for Health Act, 1990 (Act No. 116 of 1990). Free primary health care services. Government Gazette No. 17507:1514. 1996.
In this example, 17507 is the Gazette Number. This is followed by :1514 - this is the notice number in this Gazette.
- Cited manuscripts that have been accepted but not yet published can be included as references followed by '(in press)'.
- Unpublished observations and personal communications in the text must **not** appear in the reference list. The full name of the source person must be provided for personal communications e.g. '...(Prof. Michael Jones, personal communication)'.

From submission to acceptance

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To submit an article:

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- All submissions should be submitted via [Editorial Manager](#)
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 - **Author Agreement form**
 - Manuscript
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- AJOL
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- Scielo

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1. Named authors consent to publication and meet the requirements of authorship as set out by the journal.

2. The submission has not been previously published, nor is it before another journal for consideration. All research already published as 'Conference proceedings' needs to be substantially re-written, with a new title, a new abstract and new and important results to back up any study before it will be considered for a new publication.
3. The text complies with the stylistic and bibliographic requirements in **Author Guidelines**.
4. The manuscript is in Microsoft Word document format. The text is single-spaced, in 12-point Times New Roman font, and contains no unnecessary formatting.
5. Illustrations/figures are high resolution/quality (not compressed) and in an acceptable format (PDF or jpeg). These must be submitted individually as 'supplementary files' (not solely embedded in the manuscript).
6. For illustrations/figures or tables that have been published elsewhere, the author has obtained written consent to republication from the copyright holder.
7. Where possible, references are accompanied by a digital object identifier (DOI).
8. An abstract has been included where applicable.
9. The research was approved by a Research Ethics Committee (if applicable)
10. Any conflict of interest (or competing interests) is indicated by the author(s).

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Appendix 3: Ethical approvals



30 September 2019

Dr D van den Berg (202500281)
Discipline of Surgery
School of Clinical Medicine
Vdbergb22@yahoo.com

Dear Dr van den Berg

Protocol: Evaluating the need of CT angiography in diagnosing vascular injuries in penetrating neck injuries in Pietermaritzburg metropolitan. Degree: MMed
BREC reference number: BE292/16

EXPEDITED APPLICATION: APPROVAL LETTER

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 09 May 2016.

The study was provisionally approved pending appropriate responses to queries raised. Your response received on 25 September 2019 to BREC letter dated 27 July 2016 has been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have been met and the study is given full ethics approval and may begin as from 30 September 2019. Please ensure that outstanding site permissions are obtained and forwarded to BREC for approval before commencing research at a site.

This approval is valid for one year from 30 September 2019. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be noted by a full Committee at its next meeting taking place on 12 November 2019.

Yours sincerely

Prof V Rambiritch
Chair: Biomedical Research Ethics Committee

cc supervisor: steynvanwyk@lantic.net

postgraduate administration: jantjies@ukzn.ac.za

Biomedical Research Ethics Committee

Professor V Rambiritch (Chair)

Westville Campus, Govan Mbeki Building

Postal Address: Private Bag X54001, Durban 4000

Telephone: +27 (0) 31 260 2486 Facsimile: +27 (0) 31 260 4609 Email: brec@ukzn.ac.za

Website: <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>



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DIRECTORATE:

Physical Address: 330 Langaibalele Street, Pietermaritzburg
Postal Address: Private Bag X9051
Tel: 033 395 2805/ 3189/ 3123 Fax: 033 394 3782
Email: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

Health Research & Knowledge
Management

NHRD Ref: KZ_201909_025

Dear Dr B. van den Berg

Approval of research

1. The research proposal titled 'Evaluating the need for CT Angiography in Diagnosing Vascular Injury in Penetrating Neck Injuries in the Pietermaritzburg Metropolitan Trauma Service.' was reviewed by the KwaZulu-Natal Department of Health.

The proposal is hereby **approved** for research to be undertaken at Edendale Hospital.

2. You are requested to take note of the following:
 - a. Kindly liaise with the facility manager BEFORE your research begins in order to ensure that conditions in the facility are conducive to the conduct of your research. These include, but are not limited to, an assurance that the numbers of patients attending the facility are sufficient to support your sample size requirements, and that the space and physical infrastructure of the facility can accommodate the research team and any additional equipment required for the research.
 - b. Please ensure that you provide your letter of ethics re-certification to this unit, when the current approval expires.
 - c. Provide an interim progress report and final report (electronic and hard copies) when your research is complete to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Mr X. Xaba on 033-395 2805.

Yours Sincerely

Dr E Lutge

Chairperson, Health Research Committee

Date: 25/09/19

13 Baker Rd

Prestbury

Pietermaritzburg

26 September 2018

To Medical Manager

Greys Hospital

RE: Request to conduct research study

I would like to request permission to conduct my research study at greys hospital from October 2018. I have obtained BREC approval.

Please find attached the following document:

- Research Protocol
- Data collection sheet
- Consent form
- BREC approval form

I look forward to your response. I can be contacted on email: vdbergb22@yahoo.com

Kind regards,

Dr Bianca van den Berg



To: Dr. B. van den Berg Department of Surgery – Grey's Hospital
From: Dr. K. B. Bilenge CEO - Greys Hospital
Date: 26 September 2018
Re: Request for permission to conduct research at Grey's Hospital: <i>Evaluating the need of CT angiography in diagnosing vascular injuries in penetrating neck injuries in Pietermaritzburg metropolitan</i>

Dear Dr. van den Berg

Your request to conduct research at Grey's Hospital refers.

Permission to conduct the above study is hereby granted under the following conditions:

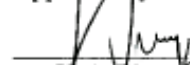
- Final ethics approval is a prerequisite for conducting your study at our hospital. Once obtained, please submit a copy of the full and final ethics approval;
- You are also required to obtain approval for your study from the Provincial Department of Health KZN Health Research Unit prior to commencement. You will find more information at: <http://www.kznhealth.gov.za/hrkm.htm>
- Confidentiality of hospital information, including staff and patient medical and/or contact information, must be kept at all times; **Patient/staff records are not to be removed from the hospital premises nor are you allowed to photocopy/ photograph them.**
- **You are to ensure that your data collection process will not interfere with the routine services at the hospital.**
- You are to ensure that hospital resources are not used to manage your data collection, e.g. hospital staff collecting and/or collating data; photocopying; telephone; facsimile, etc.;
- Informed consent is to be obtained from all participants in your study, if applicable;
- Policies, guidelines and protocols of the Department of Health and Grey's Hospital must be adhered to at all times;
- Professional attitude and behaviour whilst dealing with research participants must be exhibited;
- The Department of Health, hospital and its staff will not be held responsible for any negative incidents and/or consequences, including injuries and illnesses that may be contracted on site, litigation matters, etc. that may arise as a result of your study or your presence on site;
- You are required to submit to this office a summary of study findings upon completion of your research.
- You are requested to make contact with the HOD of Surgery, **Prof. D. Clarke**, at Grey's Hospital, once you are ready to commence data collection.

Recommended by:



Dr L. Naidoo
Senior Manager: Medical Services

Approved by:



Dr. K. B. Bilenge
Hospital CEO

13 Baker Rd

Prestbury

Pietermaritzburg

26 September 2018

To Medical Manager

Edendale Hospital

RE: Request to conduct research study

I would like to request permission to conduct my research study at greys hospital from October 2018. I have obtained BREC approval.

Please find attached the following document:

- Research Protocol
- Data collection sheet
- Consent form
- BREC approval form

I look forward to your response. I can be contacted on email: vdbergb22@yahoo.com

Kind regards,

Dr Bianca van den Berg



health
Department:
Health
PROVINCE OF KWAZULU-NATAL

DIRECTORATE: CHIEF EXECUTIVE OFFICER

Physical Address: No 89 Selby Maimang Road, Pietermaritzburg, 3216
Postal Address: P/Bag X 509, PLESSISLAER, 3216
Tel. 033 395 4040 Fax. 033 395 4087 Email: Fortunate.Mbele@kznhealth.gov.za

EDENDALE HOSPITAL

Enquiries: Ms.N.F Mbele
Ext: 4042
Date: 10 October 2018

Dr D Van den Berg
Discipline of Surgery
College of Health Sciences

Dear Dr Van den Berg

RE: EVALUATING THE NEED OF CT ANGIOGRAPHY IN DIAGNOSING VASCULAR INJURIES IN PENETRATING NECK INJURIES IN PIETERMARITZBURG METROPOLITAN


Your request dated 30 July 2018 is acknowledged and refers.

I have pleasure in informing you that permission has been granted by Edendale Hospital to conduct research.

Please note the following:

1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. This research will only commence once this office has received confirmation from the Provincial Health Research Committee in the KZN Department of Health.
3. Please ensure this office is informed before you commence your research.
4. The Hospital will not provide any resources for this research.
5. You will be expected to provide feedback on your findings to Edendale Hospital.

Yours Sincerely



Dr EK Mthembu
Senior Manager- Medical Services
Edendale Hospital

INFORMATION DOCUMENT HANDOUT TO PATIENT

Study title: Evaluating the need for CT Angiography in Diagnosing Vascular Injury in Penetrating Neck Injuries in Pietermaritzburg Metropolitan.

Introduction:

We, the doctors from Greys and Edendale hospital, are doing research on the management of stab neck patients. Research is just the process to learn the answer to a question. In this study we want to learn how to best investigate a patient who had a stab neck. Can we just observe a patient who shows no sign of injury or must we investigate all patients with a CT scan. We are asking you to participate in a research study.

All that your involvement will entail is recording of some information from when u presented to the hospital. This will include the site of the stab, your initial blood pressure and pulse rate, any signs or symptoms of a vascular injury and the blood pressure in both arms. If u had a CT scan the results of the scan will be collected. All personal information will be kept confidential. All the participants in the study will come from Greys and Edendale hospital and the study will run over 3 months. There is no risk of being involved in the study.

If you decide to participate in the study it will potentially improve how we investigate patients with stab neck in the future.

Your participation in the study is entirely voluntary and there is no penalty for not wanting to participate in the study. Your management will not at all be affected if u decide to participate or not participate in the study.

Every effort will be made to keep personal information confidential. Absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Biomedical Research Ethics Committee, Data Safety Monitoring Committee and the Medicines Control Council.

Contact details of researcher
Dr Bianca van den Berg
Cell 0827276426
Email: vdbergb22@yahoo.com

Contact details of BREC Administrator or Chair - for reporting of complaints/ problems:

Biomedical Research Ethics, Research Office, UKZN, Private Bag X54001, Durban 4000

Telephone: +27 (0) 31 260 4769 / 260 1074

Fax: +27 (0) 31 260 4609

Administrator: Ms D Ramnarain

Email: BREC@ukzn.ac.za

INFORMED CONSENT

Consent to Participate in Research

We, the doctors from Greys and Edendale hospital, are doing research on the management of stab neck patients. Research is just the process to learn the answer to a question. In this study we want to learn how to best investigate a patient who had a stab neck. Can we just observe a patient who shows no sign of injury or must we investigate all patients with a CT scan.

You have been asked to participate in a research study on the investigations of patients who sustained a stab neck.

You may contact Dr Van den Berg, the researcher, at 0827276426 any time if you have questions about the research or if you are injured as a result of the research.

You may contact the **Biomedical Research Ethics Office** on **031-260 4769 or 260 1074** or Email BREC@ukzn.ac.za if you have questions about your rights as a research participant.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop at any time.

If you agree to participate, you will be given a signed copy of this document and the participant information sheet which is a written summary of the research.

The research study, including the above information, has been described to me orally. I understand what my involvement in the study means and I voluntarily agree to participate. I have been given an opportunity to ask any questions that I might have about participation in the study.

Signature of Participant

Date

Signature of Witness

Date

Signature of Translator

Date

Appendix 4: Data collection tools (for example)

Stab Neck Data Collection Sheet

Age

Name: _____

Sex M F

Hospital No: _____

Date of Injury: ____ / ____ /20 ____

Time Of Injury: ____ : ____

Date of Presentation: ____ / ____ /20 ____

Time of Presentation: ____ : ____

Initial Examination

BP ____ / ____ On Arrival

P On Arrival

GCS M ____ V ____ E ____

Sats% FIO2

Airway Intervention

Supplemental O2 _____

Weapon: _____

Intubation _____

BP Left Arm: _____

ICD _____

BP Right Arm: _____

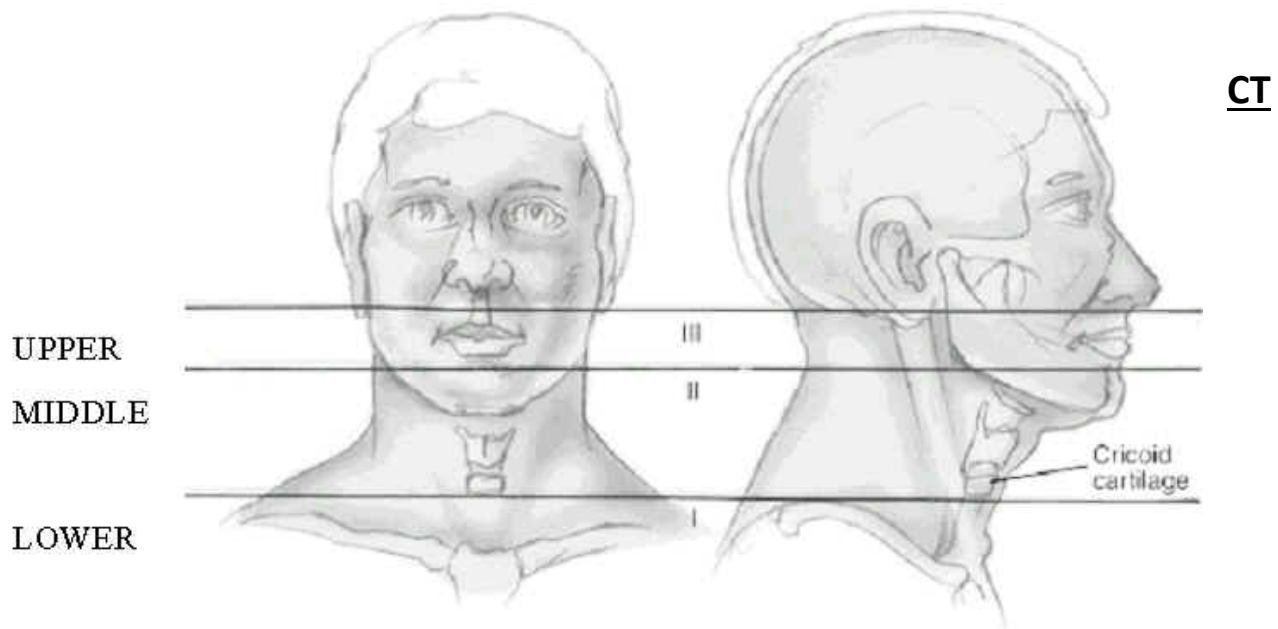
Hard Signs

- Pulsatile bleeding
- Absent distal Pulse
- Arterial thrill
- Audible bruit
- Expanding hematoma

Soft Signs

- Stable hematoma
- Nerve injury
- History of significant hemorrhage
- Proximity to major vascular structure

Indicate Position of stab on diagram



Angiogram Findings

Management