MORPHOMETRIC AND MORPHOLOGICAL ANALYSIS OF THE CRANIOVERTEBRAL JUNCTION IN A KENYAN POPULATION

(A CROSS SECTIONAL, RETROSPECTIVE RADIOLOGICAL STUDY)

A thesis submitted in partial fulfillment of the requirements of Master of Science Degree in Human Anatomy, University of Nairobi.

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DECLARATION:

I hereby confirm that this thesis is my original work and has not been presented elsewhere for examination.

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DEDICATION

In heartfelt gratitude, I dedicate this work:

To my loving parents Mr and Mrs Wafula,

for their immense support throughout my academic odyssey...

My siblings;

Laura, Adeline, Sheila, Ian and Obrien

For being my anchors in the turbulence waters of life...

My son, Leon and partner Judy, for the joy and fulfillment they bring on board…

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LIST OF ABBREVIATIONS:

AOC	Area under Curve
APD	Anterior posterior Diameter of Foramen Magnum
BLR	Binary Logistic Regression Analysis
C1	The first Cervical Vertebrae/Atlas
C2	The second Cervical Vertebrae/Axis
CT	Computerized Tomography
CVJ	Cranioverterbral Junction
DFA	Discriminant Function Analysis
FM	Foramen Magnum
MRI	Magnetic Resonance Imaging
MOI	McRae – odontoid interval
N	Sample Size
OC	Occipital bone
ROC	Receiver Operating Characteristic
PACS	Picture Archiving and Communication System
PP	Posterior Ponticulus
TD	Transverse Diameter of the Foramen Magnum
3D	Three - Dimensional Ct scan formats

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Definition of Terms

Arthrodesis	:	A surgical procedure of fusing two or more bones
Myelopathy	:	Injury to the spinal cord
Neuroaxis	:	The brain and spinal cord as a continuum
Occipitalization	:	Fusion of the atlas to the occipital bone
Paedomorphic	:	Childlike features
Ponticulus	:	Latin for little bridge

SUMMARY

Background: The Craniovertebral junction (CVJ) is transition zone between the skull and cervical spine. It protects the neuroaxis, and is involved in moving the head on the neck.

The compact anatomy of the CVJ and inherent variations renders surgery a daunting task. It also gives rise to various vascular and neurogenic compression syndromes that may be difficult to diagnose. Craniometric indices that aid in diagnosis and surgical approach have been developed, and they have been shown to have gender and population differences.

Objective: To determine the morphometrical indices and morphology of the craniovertebral junction in a Kenyan population.

Study set up: Kenyatta National Hospital Radiology Department

Study design: Retrospective Cross-sectional study

Methods: CT scans of the CVJ of patients undergoing routine treatment at Kenyatta National Hospital were analyzed to derive craniometric indices. These craniometric parameters were then used to create sex prediction model. The presence of select atlantal variations was also assessed.

Data Management: SPSS software (Version 28.0, Chicago, Illinois) was used to analyze data. Descriptive and inferential statistics was generated, with gender-based comparison being done. Univariate discriminant analysis and logistic regression analysis was used to estimate the accuracy of predicting sex from the craniometric variables. Data was presented using photographs, tables and graphs.

Results: The mean age of the participants was 38 ± 12 years. The mean diameter of the anterior-posterior dimension of the foramen magnum was 35.7±2.88mm, while the transverse diameter was 30.2±2.88mm. The mean distance between the Odontoid peg and the anterior-posterior diameter was 6.3 ±2.3mm, indicating that none of the pegs protruded into the foramen. The mean area of the foramen was 847 ± 83.4mm2, while the foramen magnum index was 1.19 ± 0.1.

The difference in means between males and females was statistically significant for the anterior-posterior diameter, transverse diameter and the area ($p<0.001$). Rounded foramina dominated at 54.3. The prevalence of posterior ponticulus was 36.2%. A half of these ponticuli formed a complete arcuate foramen, and 76% of the total ponticuli were unilaterally placed.

Only midline posterior arch defects of the atlas were discovered in the study population, with a general prevalence of 6.9%. There were no cases of atlantal occipitalization reported. Discriminant functional analysis yielded an accuracy of 69% in sex prediction, while the binary logistic regression analysis correctly predicted 70.7% of skulls as males and 67.2% as females.

Conclusion: There are significant differences in craniometric indices of the foramen magnum within the Kenyan population. However, these differences have a relatively low sex prediction ability. rendering them only as secondary discriminators in sex determination forensically. Posterior ponticuli and arcuate foramens have high prevalence, necessitating low threshold of imaging the CVJ before surgical procedures.

CHAPTER ONE: INTRODUCTION

1.1 INTRODUCTION

The craniovertebral junction (CVJ) is an important anatomical entity that serves as a transition zone between the cranium and the vertebral column. It consists of the rim of bone around the foramen magnum, the first and second cervical vertebrae. Key neurovascular structures traverse the CVJ, including the neuroaxis, the vertebrobasilar circulation, the first and second cervical nerves and their derivatives (Martin, 2010; Lopez *et al.*, 2015a)

The key movements of the head and neck region are centered on the CVJ. Congenital and acquired pathologies of the CVJ make it an area of interest to neurosurgeons and orthopaedic surgeons. Its relation to other head and neck structures make it of interest to maxillofacial surgeons and otorhinolaryngologists as well (Steinmetz, 2010; Lopez *et al.*, 2015b).

Surgical approaches to the CVJ are challenging based on the complex anatomy that is packed in a tightly fitting space. A better understanding of its anatomy and physiology coupled with the advance in high-tech imaging modalities like Computed tomogram and magnetic resonance imaging has led to the development of several approaches that continue to be refined over time (Scholz *et al.*, 2010; Giammalva *et al.*, 2019).

Craniometric indices of the CVJ have been developed as part of these approaches. Dimensions of the foramen magnum like the transverse and sagittal diameter, shape, and size have been measured and used to develop formulas to predict sex in forensic anthropology, develop surgical implants, and define surgical access (Uthman, Al-rawi and Al-timimi, 2012; Kshettry *et al.*, 2016)

The relationship of the odontoid peg to the sagittal plane of the foramen magnum has been explored and used to define the diagnosis of congenital lesions like basilar invagination and basilar impression. Normally, the peg doesn’t protrude above this plane (Joaquim *et al.*, 2014; Pinter, Mcvige and Mechtler, 2016).

The anatomy of the CVJ is not standard textbook anatomy. Individual, sexual, ethnic and racial variations exist(Meral *et al.*, 2020) . The most prevalent variations exist on the posterior arch of the atlas. These include the presence of the posterior ponticulus and the arcuate foramen. From a clinical point of view, this variation is important as it complicates the insertion of screws in the C1 mass lateral screw fixation procedure in atlantooccipital instability (Pekela *et al.*, 2017; Sanchis-gimeno *et al.*, 2018).

The ponticulus gives an impression of a widened dorsal arch, yet underneath the bone lies the third segment of the vertebral artery and the sub occipital nerve, which are at risk of iatrogenic injuries. Furthermore, compression of the artery within the arcuate foramen can present with clinical manifestations that range from cervicogenic headaches, cerebrovascular accidents, muscle weakness, vertigo to sensory neuronal hearing loss (Elliott and Tanweer, 2014; Natsis *et al.*, 2019).

Other variations of clinical importance include defects in the development of the posterior arch of the atlas that can range from simple cleft defects to the entire absence of the arch. These defects can be clinically silent or interfere with the stability of the CVJ. They are commonly misdiagnosed as fractures, thus the need to be aware of their presence. The use of cross-sectional imaging modalities like CT ameliorates this problem (Currarino, Rollins and Diehl, 1994; Ouyang *et al.*, 2017).

Atlantal occipitalization manifests clinically as instability of the atlanto occipital joint. This is due to the elimination of the washer effect of the atlas. Key movements that occur at the atlantooccipital joint are compromised, leading to maladaptation (Kim, 2015).

In this study, we focused on the morphometric dimensions of the foramen magnum and sexual dimorphism and attempted to create a model that can predict sex based on these craniometric indices (Ukoha *et al.*, 2011; Toneva *et al.*, 2018).

The prevalence of the key morphological variations of the first cervical vertebrae within the Kenyan population was assessed and a comparison made with extant literature. The findings of this study will contribute to the database of knowledge of the craniovertebral junction, bearing in mind the high burden of the trauma of the base of the skull and cervical spine in the country(Saidi and Mutisto, 2013).

CHAPTER TWO: LITERATURE REVIEW

2.1 SEXUAL DIMORPHISM OF THE CRANIOVERTEBRAL JUNCTION INDICES

The craniovertebral junction (CVJ) is a composite anatomic structure intertwined between the base of the skull and the cranial end of the vertebral column. It is made up of the parts of the occipital bone that surrounds the foramen magnum, the first cervical vertebrae (the atlas) and the second cervical vertebrae (the axis). It incorporates several ligaments and membranes. These include the alar, apical, cruciform and tectorial ligaments, and the anterior and posterior atlanto –occipital membranes. (Debernardi*et al.*, 2011; Lopez *et al.*, 2015b; Pinter, Mcvige and Mechtler, 2016).

The osseous structure of the craniovertebral junction confers structural protection to the neural axis and associated vascular structures that traverse it. Key among them is the caudal aspect of the medulla, cervical spinal cord, the lower cranial nerves, the sinuvertebral nerve, and the vertebral-basilar circulation (Lopez *et al.*, 2015b; Giammalva *et al.*, 2019).

The CVJ is also involved in movements of the head around the neck. The atlantooccipital joint (OC/C1) and the atlantoaxial joint (C1/C2) are the key joints that play this role. (Martin, 2010; Debernardi *et al.*, 2011). Flexion and extension primary occurs at the OC/C1 articulation. Axial rotation is dominant at the C1/C2 joint (Steinmetz, 2010; Lopez *et al.*, 2015b).

Adult dimensions of the CVJ are acquired by the end of the first decade of life. Thus, developmental changes in puberty that affect other structures tend to have minimal impact on it (Scheuer, 2002).

Parameters of interest in the morphometric analysis of the foramen magnum include the sagittal diameter (anterior posterior diameter), the transverse diameter, the area of the foramen magnum, the foramen magnum index and the shape. (Ukoha *et al.*, 2011; Uthman, Al-rawi and Al-timimi, 2012).

Craniometric lines of clinical significance include the anterior-posterior diameter that has been defined in several ways depending on the point of reference on the anterior rim of the foramen. The eponymous name of the mid-sagittal diameter that transects the opisthion and the basion is the McRae’s line. Other alternative lines include the Chamberlain’s line, which is the distance between the posterior-most edge of the hard palate to the opisthion in the mid sagittal plane. McGregor's line, on the other hand, is the distance between the posterior-most edge of the hard palate to the mid occipital curve (Cirpan, Yonguc and Mas, 2016; Lashin, Eldeeb and Ghonem, 2019).

The transverse diameter is taken as the widest distance between the lateral curves of the foramen. All these lines can be measured with ease on radiology images and dried crania (Uthman, Al-rawi and Al-timimi, 2012; Pinter, Mcvige and Mechtler, 2016; Giammalva *et al.*, 2019).

The area of the foramen magnum is calculated based on its linear dimensions and shape (ellipsoid or circular). The most-reported formulas in literature are the Radinsky and Texeira's. The former considers the foramen to be oval in appearance and is shown in the parentheses: ($0.25\times\pi\times h\times w$). Texeira's formula, on the other hand, assumes that the foramen has a circular configuration and is stated as follows: ($\pi \times \{(h + w)/4\}2$). Both formulas give similar results (Govsa *et al.*, 2011; Cirpan, Yonguc and Mas, 2016).

The shape of the foramen magnum is directly influenced by the sagittal and transverse diameters. These, in turn, are a result of the developmental forces that influence the morphology of the occipital bone and its inherent synchondroses. While different shapes have been described by various authors, most agree that the dominant shape is either oval or circle. Of these two, variations exist with regard to geographical location and sex to some extent (Cirpan, Yonguc and Mas, 2016; Toneva *et al.*, 2018).

In order to determine the shape, the foramen magnum index is calculated first. It is taken as the ratio of the sagittal diameter to the transverse diameter. A ratio greater than or equal to 1.2 renders the foramen to be round, while a ratio less than 1.2 gives the foramen an oval configuration (Cirpan, Yonguc and Mas, 2016).

A practical application of these derived dimensions is in the planning of surgical access to the foramen magnum. It has been theorized that round-shaped foramina provide easier access compared to the other shapes, thus leading to lesser resection margins and resultant craniovertebral junction instabilities (Govsa *et al.*, 2011; Toneva *et al.*, 2018).

Males tend to have larger craniometric indices than females, with all other factors constant. This is due to the more robust nature of male skulls compared to females. This sexual dimorphism has been studied for different populations, with similar conclusions (Ukoha *et al.*, 2011; Babu and Kanchan, 2012; Uthman, Al-rawi and Al-timimi, 2012).

Discriminant function analysis and binary logistic regression have been applied to exploit these sex differences in a bid to come up with models that can accurately predict sex given a set of craniometric dimensions. The reported accuracy is variable, but most hover around the seventy per cent mark, which is way much below the ideal ninety-five per cent. Thus, it has been suggested that the foramen magnum can be used as a secondary aid in sex identification (Gapert, Black and Last, 2009; Toneva *et al.*, 2018).

To the best of our knowledge, only one study has been done in Kenya to look at the dimensions of the foramen magnum. Loyal and her colleagues did an osteological study of the foramen magnum, focusing on craniometric indices and whether the indices could be used to predict sex. Their conclusion was that the shape of the foramen magnum could not be used to determine sex on its own. They didn’t find sexual dimorphism in the dry crania that they looked at (Loyal et al., 2010).

2.3 THE ATLAS: GENERAL ANATOMY AND VARIATIONS.

Named after the Titan who was condemned to hold the celestial realm for eternity as punishment for waging war against Zeus, the atlas is the first cervical vertebrae. It is an osseous ring made up of two lateral masses with anterior and posterior arches that act as a washer between the cranium and the spine (Forseen and Borden, 2018).

It is an atypical vertebra that lacks a centrum and a spinous process. The lateral masses are ovoid in shape, with long axes that are directed anteriorly and medially. The cranial aspect of the lateral masses bears a kidney-shaped facet that articulates with the respective occipital condyle. The inferior surface has an articular facet that accommodates the axis. The medial aspect of the lateral masses has a rough tubercle for the attachment of the transverse ligament. This ligament restrains the odontoid process within the anterior third of the C1 vertebral canal.(Debernardi *et al.*, 2011; Lopez *et al.*, 2015a).

The ventral arch has a convex configuration anteriorly. Its middle portion hosts a tubercle that the anterior longitudinal ligament attaches to. The anterior atlanto - occipital membrane is attached to the superior and inferior borders of the arch. The posterior surface of the arch restrains the odontoid peg within a circular facet (Wysocki *et al.*, 2003; Rajani, 2014).

The dorsal arch is more prominent than its counterpart. Its superior aspect bears grooves that host the third segment of the vertebral artery and the posterior ramus of the first cervical nerve. The posterior atlanto occipital membrane is attached to the superior edge of the arch, while the inferior margin hosts the ligamentum flavum. The ligamentum nuchae is attached at the posterior median tubercle (Steinmetz, 2010; Debernardi *et al.*, 2011).

The atlas has a prominent transverse process that is adapted for muscle attachment. It has a foramen (foramen transversarium) that hosts the vertebral artery. The artery forms an arcade that supplies the bone and the apical part of the odontoid process. This vascular ring is further accentuated by branches from the occipital artery (Donnell *et al.*, 2014; Pruthi *et al.*, 2018).

Variations in the morphology of the atlas have been described in the literature. The variations may be clinically silent or present with morbidity of varying extents.(Kanodia *et al.*, 2012; Toneva *et al.*, 2018). The key variations are featured in the succeeding text.

Atlantal Occipitalization

Occipitalization of the atlas is one of the commonest anomalies of the craniovertebral junction. It describes a bony fusion of the atlas and the occipital bone. The fusion may involve the superior articular facet, the arches, or the entire ring. it occurs as a result of failure of segmentation between the fourth occipital sclerotome and the first cervical sclerotome during atlantal development (Mudaliar *et al.*, 2013; Kim, 2015).

Mudalier proposed a classification system for atlantal occipitalization. He based his classification on the regional aspect of C1 that is involved. Zone I fusion involves the anterior arch. Zone II fusion involves the lateral processes. Involvement of the posterior arch is described as zone III while a combination of several regions is zone IV (Mudaliar *et al.*, 2013; Kim, 2015).

Occipitalization causes a compensatory shift of mobility to the C1-C2 junction. The resultant stress on this joint and the restricted range of movement leads to a gradual weakening of the supporting ligaments, thus leading to atlanto axial instability and subluxation (Rajani, 2014).

Compression of neurovascular structures at the CVJ may occur, with clinical presentation that range from transient headaches, neck pain, dizziness, limb weakness, ataxia, and sensory deficits associated with the long ascending tracts (Guenkel *et al.*, 2013; Rajani, 2014).

Ponticulus posticus and the arcuate foramen

The posterior ponticulus or the ponticulus posticus is a normal variant of the first cervical vertebrae. Ponticulus is Latin for bridge, in this sense, a spicule of bone that runs from the posterior arch of the atlas to its lateral mass. This bone spans over the groove that houses the third part of the vertebral artery, its accompanying periarterial venous plexus, and the posterior ramus of the first cervical nerve (Pekela *et al.*, 2017; Sanchis-gimeno *et al.*, 2018).

The ponticulus can either be a complete bridge, or be incomplete with only a bony spur projecting across either end. It has been known by different names in literature, with the eponymous Kimmerle anomaly being among them after the person who first described it. Other names include the pons posticus, posterior glenoid process, posterior glenoid speculum, canalis arterie vertebralis amongst other names (Elliott and Tanweer, 2014; Sanchis-gimeno *et al.*, 2016).

When complete, the ponticulus forms a foramen between it and the posterior arch of the atlas that has been named the arcuate foramen. These variants of the atlas can either occur unilaterally or bilaterally (Kim, 2015).

The origin of the posterior ponticulus is debatable. Some authors speculate it could be a remnant of the pro atlas, others think it is an ossified lateral part of the posterior atlanto occipital membrane or an accessory transverse foramen of C1(Cossu *et al.*, 2019).

The significance of the ponticulus and its associated foramen is varied. Different symptoms associated with compression of the underlying neurovascular structures have been described. These range from cervicogenic headaches, sensory neuronal hearing loss, posterior cerebral circulation strokes, vertebral artery dissection and stroke, migraines without auras, vertigo amongst others (Kim, 2015; Pekela *et al.*, 2017).

Of interest to neurosurgeons and spinal surgeons, this variant anatomy complicates surgeries designed to fix occipital atlantal instability. In the C1 lateral mass fixation screw technique as first described by Goel and Laheri in 1994, the screw is anchored through the posterior arch before being driven through the lateral mass. The presence of the posterior ponticulus gives the impression of a widened dorsal arch that may tempt the surgeon to use larger screw sizes. This places the vertebral artery and its venous plexus at risk of iatrogenic injury with disastrous consequences that range from exsanguination to stroke.

The rise in popularity of the C1 lateral mass screw fixation has raised awareness on the need to appreciate this increasingly common variant anatomy of the atlas (Elliott and Tanweer, 2014; Pekela *et al.*, 2017).

Since its description by Kimmerle at the turn of the nineteenth century, the posterior ponticulus has been researched widely worldwide. Its prevalence has been stated to range between 1.3% to 45%. Historically the methods of study have included cadaveric dissections (considered the gold standard), plain radiographs and lateral cephalograms (Karau *et al.*, 2010; Sharma, Chaudhary and Mitra, 2010).

Increasingly, the superior techniques offered by computed tomography have been employed to study the variant anatomy with greater accuracy. These modalities allow 3D reconstruction of the atlas and addition of angiography techniques allow the anatomy of the vertebral artery to be appreciated in detail (Cho, 2009; Hyun *et al.*, 2017).

Sexual and geographical variations in prevalence of the arcuate foramen have been reported in literature. A meta-analysis by Pekela et al that involved 55985 subjects showed that the North American region led in prevalence for complete posterior ponticuli at 11.3% while the African region led in incomplete bridges at 30.2%. Regional studies done by several workers have echoed the trends described by the Pekela group (Simsek *et al.*, 2008; Cho, 2009; Sharma, Chaudhary and Mitra, 2010; Pekela *et al.*, 2017).

Within South Korea, Yong Jae Cho et al did a study on the posterior ponticulus using CT images, and found a prevalence of 15.5%. Male and female prevalence stood at 14% to 17%. Using plain radiographs, the overall prevalence dropped to 6.5%, pointing out the low sensitivity of the latter as an imaging modality. The latter prevalence closely mirrors what Sharma et al got in an Indian study using lateral cephalograms at 4.3%. In this particular study, there was a slight male predominance at 5.33% compared to 3.76% for females (Cho, 2009; Sharma, Chaudhary and Mitra, 2010).

Within the Kenyan context, Karau and his colleagues investigated the prevalence of atlantal bridges on osseous samples belonging to the National Museum of Kenya. They found complete posterior bridges with their respective arcuate foramens at a prevalence of 14.7% and 13.7% on the right and left sides. Furthermore, the female to male prevalence stood at 11.2% to 3.2% respectively (Karau *et al.*, 2010). This current study provides an opportunity to corroborate their findings and compare how radiological data differs from osteological sources.

Posterior Arch defects

Congenital defects may involve the anterior arch, the posterior arch, or both. They result from local mesenchymal defects that lead to lack of chondrification. The normal development of the atlas starts with three primary ossification centres that give rise to the lateral masses and the anterior arch. The posterior arch develops from extension of the lateral masses posteromedially at the end of the seventh week of gestation. Posterior arch defects are more common compared to anterior ones, in addition, their relative location to the neuroaxis and the vertebral artery have given them more prominence in research (Gaunt *et al.*, 2018; Choy *et al.*, 2020).

Currarino classified the posterior arch defects into five types. He described Type A as a small fissure due to failure of fusion of the posterior hemi arches at the mid line. Type B is a cleft or absence of either one or both arms of the arch. Type C is a bilateral defect. Type D is absence of posterior arch with a persistent posterior tubercle. Type E is absent of posterior arch and tubercle (Currarino, Rollins and Diehl, 1994).

The clinical picture resulting from posterior arch defect varies from asymptomatic individuals to those that present with neck pain, occipital headache and cervical myelopathy. The latter condition is due to the impingement of the spinal cord by free floating segments of the arch. Presence of these arch defects may be mistaken for vertebral fractures especially in patients presenting with trauma, thus need for keenness during interpretation of radiological images. Furthermore, arch defects put the cervical spinal dura mater at risk of being breached during surgical procedures if not identified early (Guenkel et al., 2013; Natsis et al., 2019).

2.4 BASILAR INVAGINATION

The relationship of the odontoid peg to the sagittal plane of the foramen magnum is important clinically. Normally, the tip of the odontoid process doesn’t cross this plane. On average, it is found 5mm below McRae’s line. Protrusion above this line is indicative of basilar invagination (Pinter, Mcvige and Mechtler, 2016).

Basilar invagination is a congenital anomaly that can occur either in isolation or as a complex of developmental disorders. It can manifest clinically in various ways, as a result of impingement of adjacent neuroaxis and nerves, blood vessels and dura mater by the odontoid peg. Associated anomalies include the Chiari malformation and atlanto axial instability (Botelho, Ferreira and Zandonadi Ferreira, 2018).

The Goel group has classified it into two broad categories, i.e Group A and Group B. The former has an unstable pattern and is characterized by an abnormal increase in the atlanto dental interval. The latter is stable, and the atlanto dental interval lies along the normal range (Goel, Jain and Shah, 2018).

Mwang’ombe and Kirongo investigated craniovertebral junction anomalies in Kenyatta National Hospital in patients seen between 1988 and 1994. Out of 38 patients with various anomalies, 12 had been diagnosed with basilar impression reflecting a relatively high prevalence of the condition (Mwang’ombe and Kirongo, 2000). This study provided an opportunity to compare the prevalence then and now.

2.4 STUDY JUSTIFICATION

The craniovertebral junction presents with a complex anatomy that plays a vital role in supporting movements of the head and neck, and provides mechanical protection of the neural axis and associated vasculature. (Lopez *et al.*, 2015b; Visocchi, 2019).

This intricate anatomy necessitates the need to have a thorough knowledge to guide iatrogenic interventions and define pathology. The proximity of vital neurovascular structures limits the sites available for arthrodesis to the surgeon. Presence of variant anatomy complicates interventions further (Steinmetz, 2010; Kshettry *et al.*, 2016).

Ethnic variations and sexual dimorphism of the CVJ has been reported by various authors (Rajani, 2014; Premnarayan *et al.*, 2020) In the Kenyan context, there is paucity of data regarding morphology and morphometric indices of the CVJ in literature. This is despite the high incidence of trauma patients with injuries of the cervical spine and base of skull. Furthermore, prediction scores in sex determination are population specific and thus need to have comparable local data.

This study sought to define the normal baselines of craniometric indices and morphological variants of the CVJ as pertains to the Kenyan population, and find out how these baselines compare with other populations, and whether there are any statistically significant sexual differences.

1.5 STUDY SIGNIFICANCE

Findings of this study will provide data on variant anatomy and morphological indices of the CVJ within the Kenyan context. Availability of baseline values can be useful in designing of surgical implants, optimize pre operative surgical planning, and help in diagnosing of neurogenic and vascular compression syndromes of the craniovertebral junction.

2.6 STUDY QUESTION

What are the morphometric indices and anatomical variants of the craniovertebral junction in a select Kenyan population?

2.7 OBJECTIVES

2.7.1 Broad Objective

To evaluate the morphometry and morphological variations of the craniovertebral junction in a Kenyan population from radiological data.

2.7.2 SPECIFIC OBJECTIVES

1. To determine the sex differences in craniometric indices of the craniovertebral junction with respect to the transverse diameter, anterior posterior diameter (McRae's line), shape, foramen magnum index and use the variables in sex prediction.

2. To investigate the prevalence of the ponticulus posticus and the arcuate foramen, posterior arch defects, and atlantal occipitalization and ascertain their sexual dimorphism.

3. To evaluate prevalence of basilar invagination by means of McRae's line.

CHAPTER THREE: MATERIALS, AND METHODS

3.1 STUDY DESIGN

A cross-sectional, retrospective radiological study. The study period was between the months of August 2021 to October 2021.

3.2 STUDY SETTING

The study was done at the Radiology Department of Kenyatta National Hospital (KNH). KNH is a Level Six National Referral Hospital with a bed capacity of 1800. It receives a diverse group of patients from the whole of Kenya.

It has a busy radiology unit as such, with more than 600 CT scans being done in a month. It has a total of 12 Consultant Radiologists.

The technical specifications of the CT scan used to carry out imaging is a multi-detector CT scan with a 128 slice capability (Neusoft).

3.3 STUDY POPULATION

The study population are the patients who undergo routine diagnostic imaging of the head and neck region at the radiology department, Kenyatta National Hospital

The radiology department conducts an average of two hundred head and neck Ct scans in a month. This reflects to a population of about 800 scans for the study duration.

3.4 SAMPLE SIZE

In order to determine the number of computed tomography (CT) scans that were used for the study the following formula was used:

$$n^1 = \frac{4\sigma^2(Z\beta+Z\frac{\alpha}{2})^2}{\Delta A^2}$$

n1 - the desired sample size for each group

σ - the standard deviation in the population, acquired from a previous study.

Zβ -the power of the test. For 80% power the value is 0.84.

Zα2 -the critical value. Using a confidence interval of 95%, this value is 1.96.

ΔA - the difference in the means expected to be clinically significant.

Using a power of 80%, a statistical significance of 0.05, standard deviation of 2.61 and the difference in mean expected to be clinically significant being 1.2 (Marathe et al., 2019)

Substituting into the formula;

$$n^1 = \frac{4 \times 2.61^2 (0.84+1.96)^2}{1.2^2} = 116$$

Hence a sample size of 116.

This sample size falls within the accepted range basing on the study population estimate of approximately 1000 head Ct scans over the study period. It mirrors previous studies done on the subject matter (Patil *et al.*, 2020)

3.5 SAMPLING TECHNIQUE

Systematic random sampling was used to select the scans for the study. Every 5th scan that met the selection criteria was chosen and stored in a special folder for later data analysis.

3.6 SELECTION CRITERIA

CT scan images of head and neck region of patients undergoing routine scanning was analyzed from the Picture Archives and Communication System (PACS).

3.6.1 The inclusion criteria

Axial images of the craniovertebral junction of an adult patient (above 18 years) of either gender. Furthermore, the patient had to be a Kenyan of African origin as confirmed by their surnames and a copy of National ID that is part of the patient's database.

3.6.2 The exclusion criteria

Patients with pathologies of the craniovertebral region. A Consultant Radiologist was at hand to guide on the presence or absence of pathology in doubtful cases.

3.7 IMAGING AND EXPOSURE TECHNIQUES USED

The CT scans had been done on patients undergoing routine diagnostic imaging for other pathologies of either the head and neck and stored in the PACS system. All the scans had been taken as 1mm slice axial images with the patients lying supine. Reformats into coronal, sagittal and 3D images is done automatically by the PACS software depending on the need of the requesting clinical teams.

3.8 DATA COLLECTION PROCEDURE AND STUDY VARIABLES

Images of patients that met the selection criteria were stored in a computer folder and accessed through the PACS system.

Bone window images were analyzed on the sagittal and axial sections. On axial sections, the anterior posterior (McRae’s line) dimension of the foramen magnum in millimeters was measured using the PACS software. The transverse diameter of the foramen magnum was measured as the widest distance between the lateral curves of the foramen magnum.

The perpendicular distance from McRae’s line to the tip of the odontoid peg was also measured to determine prevalence of basilar invagination on mid sagittal reformats.

The area of the foramen magnum was a derived variable which is a multiple of the anterior posterior diameter and the transverse diameter based on Radisnky’s formula (**FM area =** $\mathbf{(0.25\times\pi\times h\times w)}$**)**

The shape of the foramen magnum was determined by the foramen magnum index. This index was determined by dividing the anterior posterior diameter with the transverse diameter. An index greater than or equal to 1.2 denoted an oval foramen, while an index less than 1.2 denoted a round foramen (Cirpan, Yonguc and Mas, 2016).

Bone window 3D multiplanar reconstruction images were obtained to determine the variant morphology of the atlas, with particular attention to presence of posterior arch defects, arcuate foramens and atlantal occipitalization.

The following figures illustrate the lines of measurement.

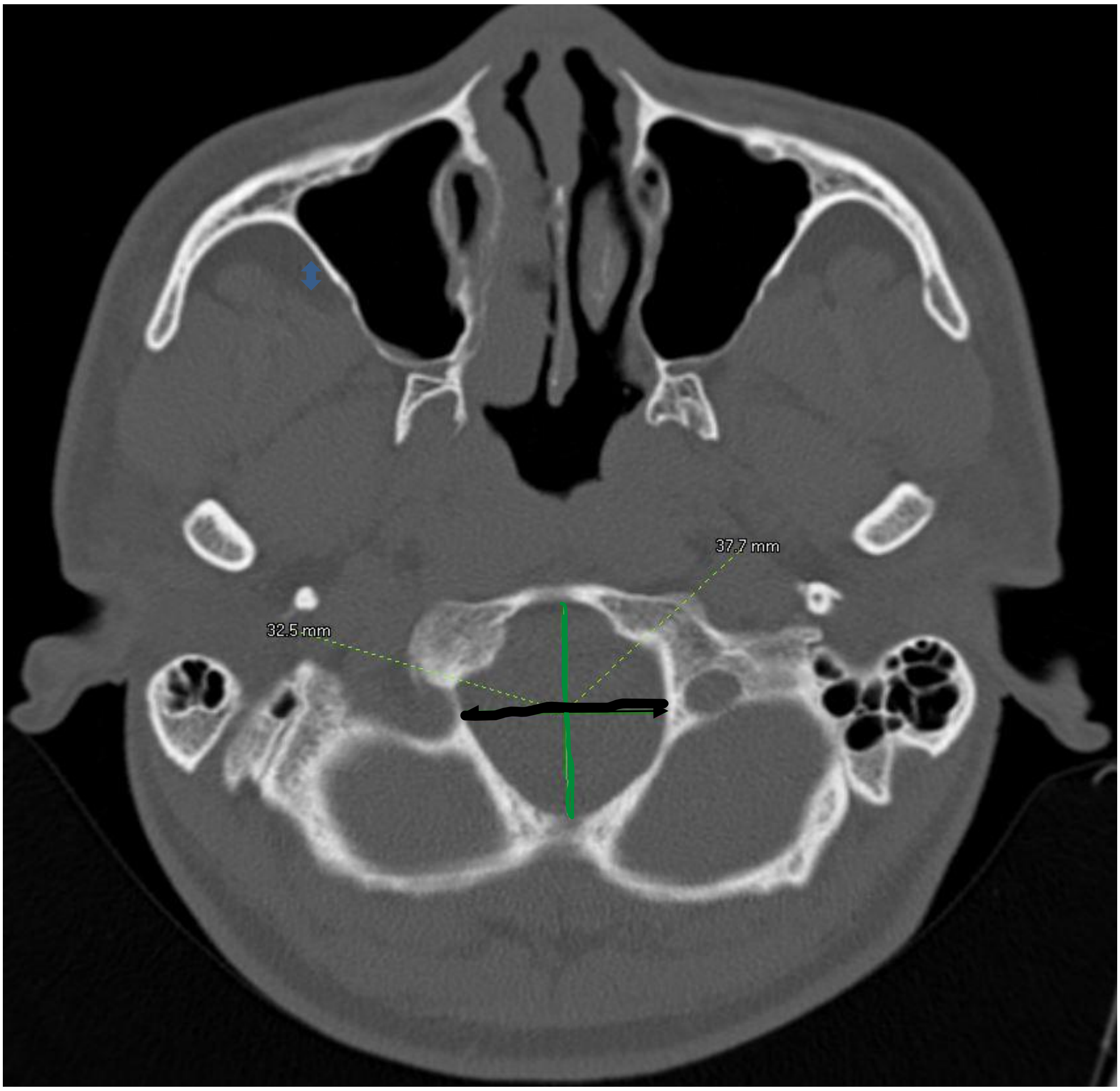

***Figure 1: Axial bone window CT scan of the skull base showing foramen magnum dimensions*.**

Green line: The sagittal diameter of the foramen magnum

Black Arrow: The transverse diameter of the foramen magnum

Figure 2: Sagittal bone window CT scan of the head showing the anteroposterior diameter of the foramen magnum (McRae's line)in green and the distance between the McRae's line to the tip of the odontoid process (McRae-odontoid interval) in orange.

Study Variables

1. Transverse and Anterior Posterior diameter of the foramen magnum (in millimetres)
2. Mean distance of the odontoid tip from the anterior posterior diameter of foramen magnum (in millimetres)
3. Presence of posterior ponticulus and arcuate foramen, posterior arch defects and atlantal occipitalization.
4. Foramen magnum index, area and shape – derived variables from transverse and anterior posterior diameter.

3.10 INTER/INTRA OBSERVER REVIEW

The PACS system is able to automatically calculate measurements once selected by the user thus minimizing user error. The measurement points were defined by two investigators, and where discrepancy arose, especially in the transverse diameter, a radiologist was asked to review the particular image and give directions.

3.10 DATA ANALYSIS AND PRESENTATION

Morphometric measurements were tabulated and analyzed using SPSS software (Version 28.0, Chicago Illinois). Data was presented in terms of frequencies, means and standard deviation.

Kolmogorov-Smirnoff test of normality was used to indicate the normal distribution of variables while Levene's test for equality of variances confirmed the homogeneity of variances in male and females. Thus, independent t-test was used to compare the means. At a confidence interval of 95%, a p-value of <0.05 was considered significant. Univariant discriminant function analysis, binary logistic regression and receiver operating characteristic were used to determine the predictive ability of the measured variables in sex estimation. The data was illustrated using representative photographs, tables and graphs.

3.11 ETHICAL CONSIDERATION

Ethical approval for the study was sought from the Ethics and Research Committee at the Kenyatta National Hospital- University of Nairobi. The study was approved on 5th July 2021 with the unique identifier of P221/04/2021.

Data collection and processing was done as per the ethical guidelines laid out by the Ethics and Research Committee.

The identifying biodata was annulled on the PACS system and only information of interest was left. The folder used to store the films had a secure access with password encryption.

CHAPTER FOUR : RESULTS

The study recruited computer tomography (CT) scans from 116 patients, all adults between the ages of 19 and 68 (mean=38±12 years). The patients were equal parts male and female, i.e., 50/50%, with the ages of the males (median 36, IQR 16 years) and females (median 40, IQR 23 years) not differing in any statistically significant way. The general statistics, including means and standard deviations for each dimension related to the foramen magnum (FM), are presented in Table 1.

Variable	Mean	SD
APD (mm)	35.7	2.88
TD (mm)	30.2	2.88
MOI (mm)	6.3	2.3
AREA (mm^2)	847	83.4
FMI	1.19	0.1

Table 1. General statistics – means, standard deviation for each dimension related to the Foramen Magnum (APD (anterior-posterior diameter of the foramen magnum), TD (transverse diameter of the foramen magnum), MOI (Mc-Rae's odontoid interval), AREA (area of the foramen magnum as calculated using Radinsky's formula), FMI (foramen magnum index)

Kolmogorov-Smirnoff test of normality indicated the normal distribution of variables in both groups, while Levene's test for equality of variances confirmed the homogeneity of variances in the two groups; hence independent t-test was used to compare their means. The difference in means between the males and females was significant for the anteroposterior diameter (p<0.001), transverse diameter (p<0.001) and area of the foramen magnum (p<0.001). The means for the Mc Rae's-Odontoid index (MOI) and Foramen Magnum Index (FMI) did not differ significantly between the sexes. Comparative statistics, including the maximum and minimum values, of the males versus the females are presented in Table 2.

Parameters	Males (n = 58)			Females (n = 58)			
	Max.	Min.	Mean ± SD	Max.	Min.	Mean ± SD	P-value
APD (mm)	42.7	31.3	36.7 ± 2.81	42.1	28.7	34.8 ± 2.63	<**0.001**
TD (mm)	36.1	26.1	31.4 ± 2.69	35.3	23.4	28.9 ± 2.55	<**0.001**
MOI (mm)	-1.5	-13.5	-6.6 ± 1.89	-1.5	-10.4	-5.8 ± 2.65	0.094
AREA (mm^2)	1128	691	906.9 ± 123.7	1037	559	792.8 ± 110.8	<**0.001**
FMI	1.37	0.94	1.17 ± 0.1	1.51	1.02	1.20 ± 0.1	0.093

Table 2. Maximum, minimum, means, standard deviations and P values for foramen magnum related parameters - gender comparative results.

Using the Foramen Magnum Index (FMI) to estimate the shape of the foramen, it was noted that a rounded shape was more common in the study population (54.3%), especially for the males, with 58.6% of them having rounded foramina. A posterior ponticulus was more likely to be found unilaterally (54.8%) than bilaterally, with a total prevalence of 36.2%.

Almost half of the present posterior ponticuli formed an arcuate foramen (prevalence 15.5%), especially on the left side (6.9%). Only midline posterior arch defects of the atlas were discovered in the study population, with a prevalence of 6.9%. There was no single case of occipitalization of the atlas. None of the scans had the Odontoid process protruding above McRae's line.

The frequency of various categorical variables related to the foramen magnum and the craniovertebral junction is indicated both generally and when sex is factored in Table 3.

		Frequency (Percentage) - N (%)		
Variable	**Factor**	**Total (n=116)**	**Male (n=58)**	**Females (n=58)**
Shape	Oval	53(45.7)	24(41.4)	29(50)
	Round	63(54.3)	34(58.6)	29(50)
Posterior ponticulus		42(36.2)	20(34.5)	22(37.9)
	Both sides	19(16.4)	10(17.2)	9(15.5)
	Only Left side	11(9.5)	5(8.6)	6(10.3)
	Only Right side	12(10.3)	5(8.6)	7(12.1)
Arcuate foramina		18(15.5)	8(13.8)	10(17.2)
	Both sides	6(5.2)	4(6.9)	2(3.4)
	Only Left side	8(6.9)	4(6.9)	4(6.9)
	Only Right side	4(3.4)	0(0)	4(6.9)
Posterior arch defect	Midline	8(6.9)	5(8.6)	3(5.2)
Atlantal assimilation		0	0	0
Basilar Invagination		0	0	0

Table 3. Frequency distribution of various categorical variables related to the foramen magnum and atlantal variations.

From Table 4, to obtain a discriminant function score from each measurement of the variables, the unstandardized coefficient was multiplied by the magnitude of the measurement (in millimeters) with the corresponding constant added. For example, the discriminant function score (D) for APD would be:

D= 0.368 × APD (in mm) + (-13.139).

A skull would then be classified as male if the discriminant function score was greater than 0.000 (grouping point) and as female if the score was less than or equal to 0.000. Adding all FM measurements to the regression model gave an overall classification accuracy for gender of 69.0 % (accuracy rate 70.7% in females and 67.7% in males). The equation provided for calculating D was as follows:

D= (-0.120 × APD) + (-0.004 × TD) + (0.011 × AREA) + (-4.752)

The further the discriminant function score is from the sectioning point, the greater the reliability in correctly assigning sex. Accuracies were higher in the female group compared with male for most of the functions in the univariate analysis.

Variable	**Wilk's Lambda***	**Unstandardized Coefficient**	**Constant**	**Centroid (mean)**	**Grouping point***	**Accuracy (%)**	
						By Sex	**Average**
APD	0.887	0.368	-13.139	M= 0.354 F= -0.354	0.000	M= 70.7 F= 69.0	69.8
TD	0.819	0.382	-11.508	M= 0.465 F= -0.465	0.000	M= 63.8 F= 67.2	65.5
AREA	0.806	0.009	-7.239	M= 0.486 F= -0.486	0.000	M= 69.0 F= 69.0	69.0

***Table 4**: Univariate discriminant function analysis using FM measurements to discriminate sex.*

Discriminant function score equation (DFS)= unstandardized coefficient x variable (in mm) + constant

*DFS greater than 0.000 (grouping point) is male and less than is female.

*All (Wilk's Lambda) were significant with $p < 0.001$

AREA- FM area; APD- FM anteroposterior diameter; TD- FM transverse diameter; M- male; F- female.

A logistic regression was also performed to ascertain the utility of the Anteroposterior diameter (APD), Transverse diameter (TD) and Areas of the foramen magnum via Radinsky's formula (AREA) on predicting whether a study subject is either male or female. A value greater than 0.5 was predictive of male, while a value less than 0.5 was predictive of female. The logistic regression model was statistically significant, $\chi 2(4) = 25.211$, $p < 0.0001$. The model explained 26.0% (Nagelkerke R^2) of the variance in sex and correctly classified 69.0% of cases.

Increasing APD, and TD was associated with an increased likelihood of being male, but increasing AREA was associated with an increased likelihood of being female in this model. The three variables combined to form the binary logistical regression model below which accurately predicted 70.7% of females and 67.2% of males; having an overall accuracy of 69.0%

$Y= 3.597 + (0.145*APD) + (0.034*TD) + (-0.012*AREA)$

*Cut-off for Y for the equation is 0.500

				Classification accuracy (%)		
Logistic regression models	**Nagelkerke R^2**	**Wald**	**p-value**	**Males**	**Females**	**Overall**
Anteroposterior diameter						
(-0.261× **APD**) + 9.333	0.150	11.879	0.001	70.7	69.0	**69.8**
Transverse diameter						
(-0.352× **TD**) + 10.596	0.237	17.745	<0.001	63.8	67.2	**65.5**
Area of FM						
(-0.008× **AREA)** + 6.871	0.254	18.945	<0.001	70.7	67.2	**69.0**

*Cut-off = 0.500

Table 5: Logistic regression model.

Receiver Operating Characteristics (ROC) curves of the predicted probabilities of each univariate binary logistic regression model are also shown below

The area under the curve (AUC), i.e., the area under the ROC curve, was a measure of discrimination. The closer to 1 the AUC value was, the more strongly the discrimination.

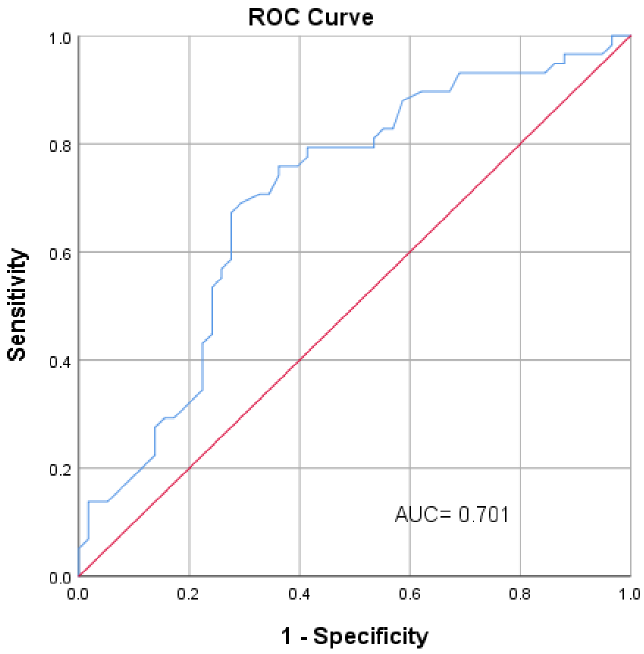

Figure 3: ROC of predicted probabilities of Anteroposterior diameter of foramen magnum (APD)

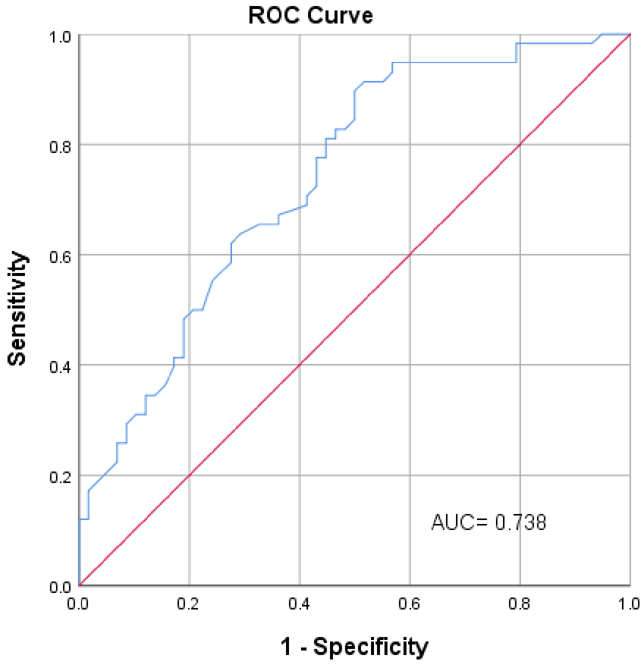

Figure 4: ROC of predicted probabilities of Transverse diameter of foramen magnum (TD)

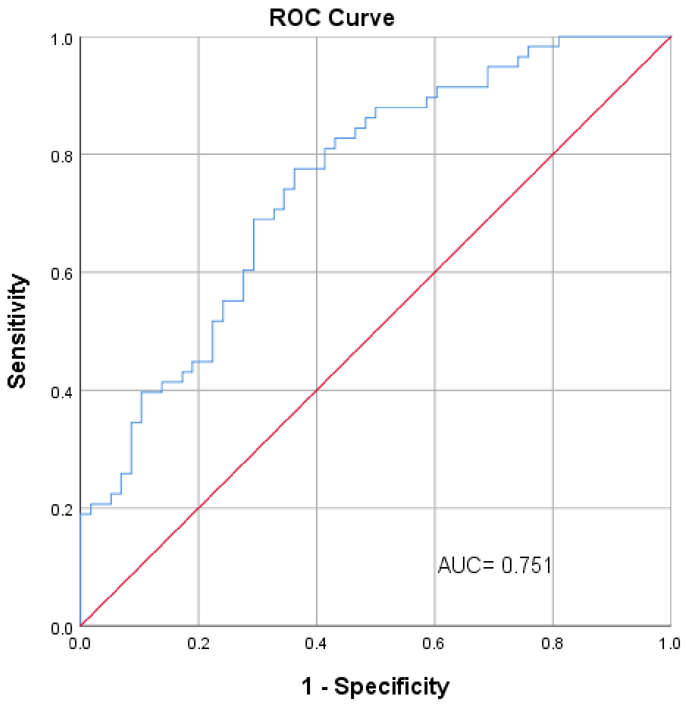

Figure 5: ROC of predicted probabilities of Area of foramen magnum by Radinsky's formula (AREA)

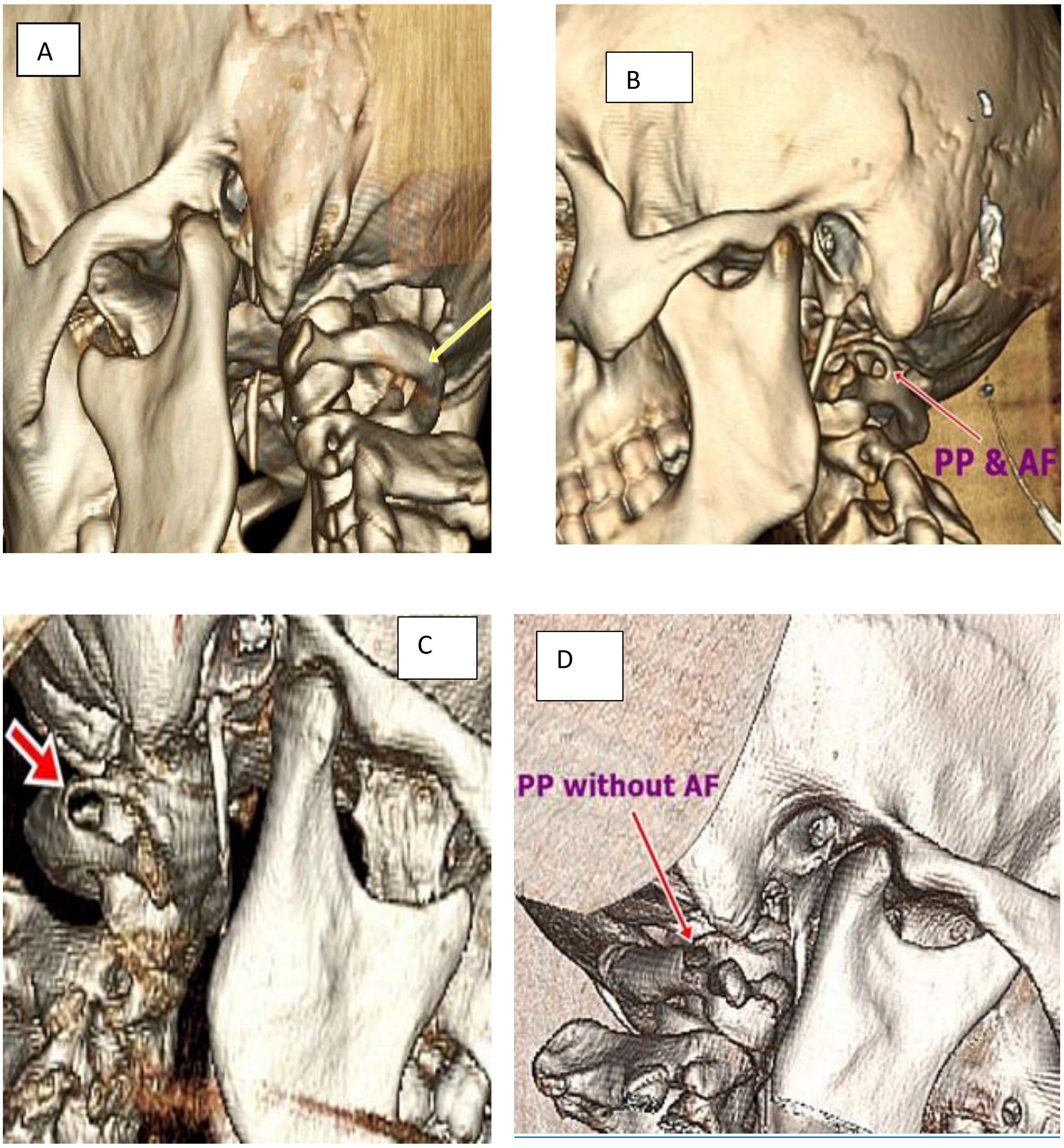

Figure 6- Representative Photos Showing Atlantal Variations in the Study Population.

A : 3D reconstructed CT scan of the skull showing a normal atlas and craniovertebral junction. The arrow points at the posterior arch of C1.

B: atlas with a posterior ponticulus forming an arcuate foramen on the left side (red arrow)

C: atlas with a posterior ponticulus forming an arcuate foramen on the right side (red arrow)

D- atlas with an incomplete right-sided posterior ponticulus (red arrow)

CHAPTER FIVE : DISCUSSION

Observations of this study have shown that there are statistically significant sex related differences in the craniometric dimensions of the craniovertebral junction. The differences are seen in the anterior posterior diameter, the transverse diameter and the area of the foramen magnum. However, the sexual dimorphism is inadequate to correctly predict sex of a skeletal remain in the absence of other parameters. There are atlantal variations within a subset of the population with respect to presence of the posterior ponticulus and arcuate foramen. This study didn’t show any case of atlantal occipitalization and basilar invagination.

5.1 SEXUAL DIMORPHISM OF THE FORAMEN MAGNUM

The four cardinal biological identifiers are sex, age, stature and ethnicity. The determination of sex is an important aspect in medico legal investigations particularly in unidentified remains. The accuracy of prediction depends on the wholesomeness of the sample available to the investigator. The whole skeleton gives an accuracy of 100%. The skull and the pelvis give an accuracy of 98% while the skull and long bones give an accuracy of about 90%. In some forensic cases, it is impossible to get whole bone specimens and the investigators have to rely on fragmented pieces (Scheuer, 2002; Tambawala *et al.*, 2016).

The foramen magnum has been found to survive inhumation and taphonomical processes. This is attributed to the relatively deep location of the foramen at the base of skull, surrounded by protective muscle bulk. Furthermore, the relatively robust bones that form the foramen are not easily broken (Singh and Talwar, 2013; Tambawala *et al.*, 2016). All these attributes make it a natural candidate for sex prediction from a forensic aspect.

Men tend to have bigger dimensions of the craniometric indices than women in general irrespective of ethnicity, race, or geographical location (Govsa *et al.*, 2011; Ukoha *et al.*, 2011; Kamath *et al.*, 2015; Toneva *et al.*, 2018; González-Colmenares *et al.*, 2019). This trend has been replicated in the current study and it agrees with published literature as shown in the following table:

Author	Year	Population	Male		Female	
			APD	**TD**	**APD**	**TD**
Govsa	2011	Turkey	35.68±1.77	28.91±1.62	32.57±2.08	28.91±1.61
Ukoha	2011	Nigeria	36.26±2.39	30.09±2.58	34.39±8.85	30.09±2.58
Kamath	2015	India	33.21±3.25	26.92±2.52	30.99±3.49	25.45±2.31
Samara	2017	Iraq	35.80±3.00	3030±2.30	34. ±3.10	28.30±2.30
Toneva	2018	Bulgaria	36.63±2.93	31.47±2.35	35.19±2.33	29.25±2.11
Colmenares	2019	Colombia	40.98±2.19	35.45±1.86	36.88±2.09	33.63±2.19
Loyal	2013	Kenya	40.00	38	34	28
This Study	2021	Kenya	36.7±2.81	31.4±2.69	34.8±2.63	28.9±2.55

Table 6: Craniometric indices comparison (measurement in millimeters)

An analysis of the preceding table shows similarity in the dimensions listed irrespective of population studied, including the one in the current study. We can conclude that craniometric indices on their own are a poor tool to discriminate between different populations on that basis alone (González-Colmenares *et al.*, 2019).

Loyal's osteological study on the foramen magnum at the National Museum of Kenya collection deserves a mention. This is because the geographic set up of her study is similar to this study. She didn't find statistically significant sexual differences with respect to the mean sagittal diameter and mean transverse diameter. The differences between her study and this one can possibly be attributed to the aging effect on the specimens or the technique employed. i.e osteology specimens versus CT scan image analysis (Loyal, 2013).

Our results showed statistically significant differences between males and females for the anterior posterior diameter, the transverse diameter and area. This is in agreement with the studies done by Gapert in the St Bride's cranial collection in Britain, Ukoha in Nigeria, and Uthman in Baghdad. In all cases, men generally had greater dimensions than females (Gapert, Black and Last, 2009; Ukoha *et al.*, 2011; Uthman, Al-rawi and Al-timimi, 2012).

The foramen magnum index and the McRae - Odontoid interval didn’t cut the threshold for significance. This is comparable to what Lashin got when he studied the craniometric indices in an Egyptian Population with a sample size of 200 using CT scan data. It can be deduced that the insignificance springs from the fact that the foramen magnum dimensions are acquired by the end of the first decade of life and remain relatively unchanged afterwards, thus paedomorphic characteristics are maintained that could have been altered by sexual differences brought by puberty as seen in other body parts. This is supported by the positive correlation between the anterior posterior diameter and the transverse diameter in this study (Gapert, Black and Last, 2009; Lashin, Eldeeb and Ghonem, 2019).

The craniometric indices of the foramen magnum have been used to predict sexual identity through use of discriminant function analysis and logistic regression models for different populations. The application of this is important in sexing archaeological remains or remains of forensic interest. A higher level of accuracy is needed for the latter category because the legal consequences of such an exercise bear more significance(Scheuer, 2002; Ukoha *et al.*, 2011; Toneva *et al.,* 2018).

Sexing parameters that give an accuracy of more than ninety five percent have been deemed to be primary discriminators while those ones that give a yield below that have been considered to be secondary discriminators. Given the rarity of the primary ones, the latter have found use as adjunct aids in sex determination and more so in an archaeological context (Babu and Kanchan, 2012; Toneva *et al.*, 2018).

Discriminant function analysis and binary logistic regression models have been employed in literature to come up with predictive scores for sex determination in the foramen magnum. In the current study, discriminant function analysis gave predictive score of 69.8% for the anterior posterior diameter, 65.5% for the transverse diameter and 69% for area. The three variables when combined predicted 70.7% of females and 67.2% of males with an overall accuracy of 69.0% (tables 4 and 5). The receiver Operating characteristic analysis augmented this discriminating ability marginally (figures 3, 4 and 5).

The anterior posterior diameter was a better discriminator for sex at 69.8% compared to area and transverse diameter (Table 4). This is in agreement with a Colombian study done by the Gretel Gonz’ales group.

However, they had higher than average score of 86.4% predictability for the anterior posterior diameter despite similar sample size and analysis (González-Colmenares *et al.*, 2019). Gapert argues that discriminant functions can only apply to the population they were derived from and are not exportable. This could explain the differences between their scores and ours (Gapert, Black and Last, 2009).

The Toneva group found the transverse diameter was the best predictor using discriminant function analysis and binary logistic regression at 67.9% each in a Bulgarian population while Uthman found the anterior posterior diameter and the area of the foramen magnum to be better predictors at 69.3% each. Despite the differences in the best predictors, the scores are similar to ours and the dissimilarities can be explained by population wise differences (Uthman, Al-rawi and Al-timimi, 2012; Toneva *et al.*, 2018).

An Indian study by Babu found the anterior posterior diameter to be most reliable when binary logistic regression and receiver operating characteristic was used, with area of the foramen magnum closely coming second at 0.8605 and 0.816 respectively. An Egyptian study found the area of the foramen magnum to be best predictor at 67%, while a Swiss study found the anterior posterior diameter and the transverse diameter to equally predict sex at 63.6% (Halas, Hunt and Eberhardt, 1986; Babu and Kanchan, 2012; Edwards *et al.*, 2013; Lashin, Eldeeb and Ghonem, 2019).

The differences in the predictive scores between this study and others can be explained by differences in measurement of the variables. For instance, the area of the foramen magnum can be calculated using the Radinsky formula, the Texeira formula or automated programming software like Fiji which all give slightly different results. Given that the transverse diameter is chosen as the widest diameter on the lateral rims of the foramen magnum, its measurement can have significant variance because of lack of standardized landmarks. (Seifert *et al.*, 2016; Toneva *et al.*, 2018).

It can be inferred that ethnic (and in extension genetic) differences between different populations will lead to variations in scores as well.

A further comparison of our results to what has been published in extant literature is shown in the following table (Gapert, Black and Last, 2009; Kamath *et al.*, 2015; Toneva *et al.*, 2018; González-Colmenares *et al.*, 2019).

	Author	Year	Population	Analysis	Predictive Score (%)		
					APD	TD	FMA
1	Gapert	2009	British	DFA	-	-	68
2	Toneva	2018	Bulgaria	DFA	60.7	67.9	64.3
3	Kamath	2015	Indian	BLR	69.6	66.4	70.3
4	Gretel	2019	Colombian	DFA	87.2	85.7	-
5	Uthman	2022	Iraqi	DFA	69.3	68.2	69.3
6	Tambawala	2016	Indian	DFA	62.45	61.1	65
7	Current study	2021	Kenyan	DFA	69.8	65.5	69

Table 7: Sex Predictive Scores of the Foramen Magnum. (DFA- Discriminant function Analysis, BLR – Binary Logistic Regression)

Based on the rationale by Lewis and Scheur on the cut off point for predictive discrimination of 95%, we can argue that our results are at best secondary predictive discriminators. This appear to be the case across for the above selected studies (Scheuer, 2002; Toneva *et al.*, 2018). Thus, these indices have to be combined with other methods of sexing specimens like DNA analysis for better accuracy.

With respect to the shape of the foramen magnum based on the foramen magnum index, rounded foramina were more common than the oval ones (63% to 53%). This is agreeable with what Cirpan and colleagues found in their study. Fifty eight percent of their study subjects had round foramen while forty two percent had oval foramens. A similar study by Chethan in an Indian Population came to the same conclusion (Cirpan, Yonguc and Mas, 2016). In terms of gender differences there was no statistically significant differences between the sexes hence, in agreement with Loyal's conclusion, the shape of the foramen magnum cannot be used to ascertain gender with accuracy (Loyal, 2013).

Rounded foramina are said to enable easier surgical access, reduce resection margins, therefore resulting in lesser cases of subsequent CVJ instability (Guenkel *et al.*, 2013; Rajani, 2014).

5.2 VARIANT ANATOMY OF THE ATLAS

5.2.1 Posterior ponticulus and the arcuate foramen

The posterior ponticulus (little bridge) is a normal variant of the first cervical vertebrae. It is a bony spicule on the posterior arch of the atlas that spans over the groove that hosts the third segment of the vertebral artery and its venous plexus and the posterior ramus of the first cervical nerve (sub occipital nerve). The foramen formed as a result is called the arcuate foramen or the retroarticular foramen (figure 6) (Pekela *et al.*, 2017).

Interest in the posterior ponticulus waxed with the increasing adoption of the C1 lateral mass crew insertion that was developed by Goel and Laheri for atlantal axial instability fixation. In this procedure, the posterior arch is used as fixation point. It is known in literature by several names i.e., the Kimerly anomaly, pons posticus, posterior glenoid process, posterior glenoid speculum, atlantal bridge amongst others. The arcuate foramen that results if the ponticulus is complete is also known as canalis arterie vertebralis, foramen atlandoideum or retroarticluar ring (Simsek *et al.*, 2008; Elliott and Tanweer, 2014).

The presence of the posterior ponticulus has been associated with various clinical symptoms that range from neck pain, shoulder and arm pain, cervicogenic headaches, symptoms associated with occlusion or stenosis of the vertebral artery like vertebra basilar insufficiency, vertebral artery dissection and sensory neuronal hearing loss type. The increasing adoption of the C1 lateral mass screw fixation that uses the posterior arch of the atlas as an anchorage point has thrown the posterior arch and its variations into contemporary discourse because of the inadvertent risk of injury to the vertebral artery when it courses through an arcuate foramen (Sanchis-Gimeno *et al.*, 2018).

There is no consensus on the origin of this bridge, with several theories postulated. Some workers believe it is as a result of the ossification of the oblique atlanto occipital ligament, while others think it is a remnant of the pro atlas or even a remnant of an atlantal degenerative process (Karau *et al.*, 2010; Kim, 2015). There is speculation that the foramen may develop to protect the underlying vertebral artery (Afsharpour *et al.*, 2016). If this was an evolutionary advantage, then it would be a trait that would be found in most atlases.

In this study, the prevalence of the posterior ponticulus was 36.2% with a similar distribution between males and females (20 and 22 respectively). Unilateral bridges were more common than bilateral ones (23 to 19). In 42.9% of the cases, of the ponticulus were complete, forming an arcuate foramen. Furthermore, there was negligible difference in sidedness of the ponticuli. We also found more left sided arcuate foramina than right ones (Table 3). The bias towards unilaterality could be explained by the differences in mechanical strains on the neural arch as a result of unequal load bearing (Karau *et al*. 2010).

The prevalence we got in this study is on the higher end of the spectrum of reported literature that ranges from 1.3% to 45.9%. It is comparable to a Turkish study done by Kavakli et al who studied the morphology and prevalence of the posterior ponticulus involving 698 cervical 3D cone beam computed tomography scans. They found a prevalence of 36.8%, with bilateral bridges comprising 22.5% of the total. There was a higher male predominance at 41.2% compared to females at 33.2% (Kavakli *et al.*, 2004).

Yong Jae Cho's group did a similar study on prevalence of the ponticulus on a segment of the South Korean population. The prevalence of the posterior ponticulus was 15.5% in a sample size of 200. In a parallel study using plain radiographs, the prevalence gotten was 6.5% thus pointing towards the superior sensitivity of computed tomograms in evaluating the anatomical variations of the first cervical vertebrae. In terms of gender distribution, there was no significant difference in prevalence, with 14% of the males having the variation compared to 17% of the females. In terms of laterality of the ponticulus, the differences were not statistically significant (p=0.65). These findings closely mirror our results (Cho, 2009)

Eliot and Tanweer did a meta-analysis on the posterior ponticulus and its importance in the Goel – Hams procedure. This procedure is a technique that involves use of screws to reduce the lateral mass of the atlas through the posterior arch. Out of 21789 subjects, 16.7% had the posterior ponticulus, with CT scan studies showing a prevalence of 17.2%, cadaveric studies at 18.8% and radiographic studies at 16.6%. This is lower than our figures but within the global average (Elliott and Tanweer, 2014).

On the other hand, Pekala et al did a meta-analysis involving 55,985 subjects. They got an overall pooled prevalence of complete ponticuli at 9.1% that is much lower than our results. In terms of geographical distribution, the North American studies had a pooled prevalence of 11.3%, European ones had 11.2% and Asian studies were the lowest at 7.5%. In terms of data sources, CT imaging led in prevalence at 10.8%, Cadaveric dissection followed closely at 9.7% while plain radiographs had the least prevalence at 7.9%. This demonstrates the superior sensitivity of CT scans compared to plain radiographs in assessing craniovertebral junction anomalies. In terms of sexual dimorphism, this meta-analysis showed a male predominance at 10.4% compared to females at 7.3%.

The same meta-analysis also assessed the prevalence of incomplete posterior ponticuli. A total of 43995 subjects were involved (95 studies). The overall poled presence of the incomplete ponticulus was 13.6%, slightly higher than for the complete ones. Interestingly, the geographical distribution showed the incomplete arcuate foramen was more common amongst Africans at 30.2% and least among Indians at 14.7%. Females had a greater prevalence of the incomplete posterior ponticulus compared to males (18.5% and 16.7% respectively) (Pekela *et al.*, 2017).

This current study and the ones discussed above seem to suggest that the prevalence of these atlantal variations seem to be higher in our set up compared to other parts of the globe. While population differences due to genetic make up seem to be the predominant reason, there could be other factors at play including differences in techniques and the sample sizes involved. There is a postulation that load bearing on the head, which is common in Kenya, may have an impact on development of the ponticulus. This is inferred from the theory that the ponticulus may be a result of ossification of the posterior atlanto occipital membrane due to the resultant mechanical stresses (Karau *et al.*, 2010).

In an osteological study done on documented osseous remains at the National Museum of Kenya by Karau and others, the prevalence of complete posterior ponticulus was found in 14.2% of the cases, with a female predominance at 11.2% versus 3% for males. This significantly differs with the findings of the current study and various factors could explain the disparities. These include the source of data, i.e., radiological verse osteological. It is also possible that there could be sedentary changes in the prevalence of the ponticulus over time, as societies are not static (Karau *et al.*, 2010). Bilaterally placed bridges may present with more sinister neurological deficits due to involvement of both vertebral arteries than unilaterally sided ones. In terms of left or right sidedness, the clinical difference is negligible.(Simsek *et al.*, 2008; Elgafy *et al.*, 2014).

The following table summarizes some of the extant literature on the prevalence of the posterior ponticulus.

Author	**Year**	**Population**	**N**	**Prevalence (%)**	**Complete PP**	**Incomplete PP**
Cho	2009	Korea	2008	15.5	-	-
Simsek	2008	Turkey	158	7.59	5.6%	3.8%
Kavakli	2014	Anatolia	86	22%	12.8	9.3
Vanek	2016	Czech	511	14.3%	-	-
Sharma	2009	India	858	4.3%	-	-
Sekerci	2015	Turkey	257	36.8%	-	-
Chen	2015	Taiwan	500	7%	66%	34%
Karau	2010	Kenya	108	52.9%	26.8%	37%
This Study	2021	Kenya	116	36.2%	15.5%	20.6%

Table 8: Comparison of Posterior ponticuli.

5.2.2 Posterior arch defects

Posterior arch defects result from incomplete fusion of the inter neural synchondrosis. Their clinical importance lies in the fact that they can easily be confused for fractures of the neural arch (Park *et al.*, 2014). This is especially applicable to the Kenyan setting due to the high trauma burden (Saidi and Mutisto, 2013). They may also lead to compressive syndromes of the craniovertebral region.

Zhi –Yuan Ouyang reported a case study of a 16 year old girl who presented with features of a posterior circulation stroke secondary to vertebral artery dissection that was related to the presence of a posterior arch anomaly and atlantoaxial joint instability (Ouyang *et al.*, 2017).

Jong Kyu Kwon did a retrospective review of 1,153 cervical spine computed tomography to identify patients with arch defects of the first cervical vertebrae in South Korea. 0.95% of the patients had atlantal arch defects with nine patients having type A and two patients having type B. The other types were not observed. None of the patients with atlantal arch defects presented with any neurological deficits (Kwon, Kim and Lee, 2009).

This current study showed a prevalence of 6.9% of posterior arch defects. Five were found in males, and three in females (Table 3). All these defects were midline defects, corresponding to Type A arch defects according to the Currarino classification. Currarino classified the posterior arch defects into five types. Type A is a small fissure due to failure of fusion of the posterior hemi arches at the mid line. Type B is a cleft or absence of either one or both arms of the arch. Type C is a bilateral defect. Type D is absence of posterior arch with only a posterior tubercle present. Type E is absent of both the arch and tubercle. (Wysocki et al., 2003; Kim, 2015).

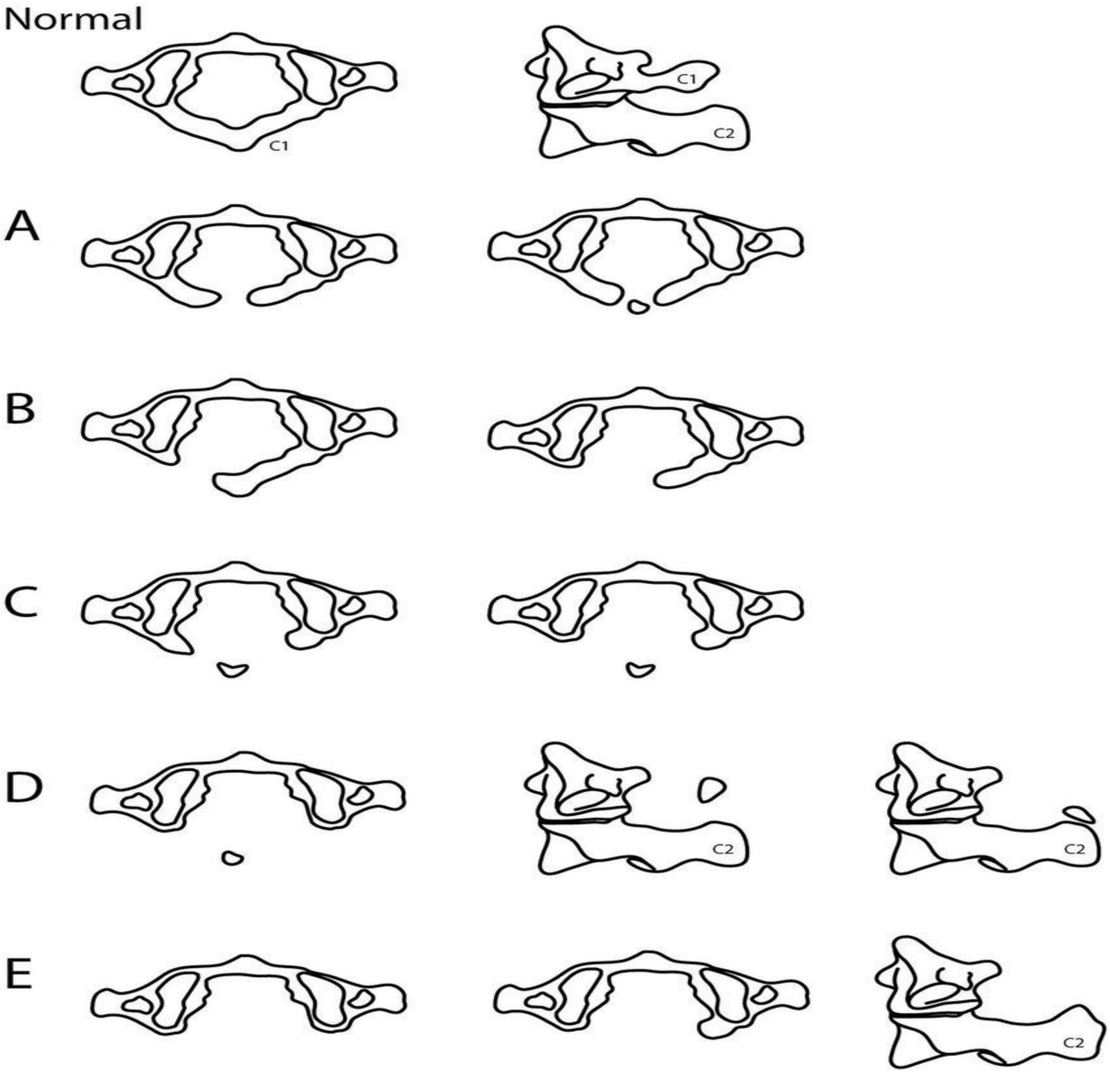

Figure 7 : Currarino classification of Posterior Arch defects. (Choy et al., 2020)

According to published literature, type A arch defects are the most common, representing more than 80% of cases. In this study, all the posterior arch defects were type A. Gina Hyun et al looked at the prevalence of posterior arch defects in a single institution in the United States. 5.16% of 3273 subjects had isolated posterior arch defects. With regard to the Currarino classification, 81.6% of these patients had type A defects (Hyun *et al.*, 2017).

Senoglu et al reviewed craniocervical CT scans of 1104 patients, 166 dried C1 vertebrae and 84 cadaveric specimens focusing on the incidence of congenital defects of the posterior arch of the atlas. They had an incidence of 2.95% in total. Of these, type A arch defect comprised of 2.6%, type B at 0.54% and type E at 0.1%. There was no type C or D anomalies. In the cadaveric specimens, 3 type A posterior arch defects were reported (Senoglu, 2007).

The Senoglu results are comparable to a study done by Guenkel et al in Switzerland that focused on the congenital anomalies of the atlas vertebrae in a Caucasian population in Switzerland. The prevalence of type A dorsal arch defects was 3.2%. (n = 1069) (Guenkel *et al.*, 2013).

Given the rarity of defects other than type A, it is possible our modest sample size was inadequate to capture these atlantal variations.

These cases illustrate that even though dorsal arch defects may be rare, it is imperative that knowledge of the craniovertebral junction variant anatomy is known, and the need for routine preoperative imaging evaluation.

5.2.3 Atlantal Assimilation and Basilar Invagination

We didn’t get any single case of atlantal occipitalization in this study. This could be attributed to the relatively small sample size for such a rare anomaly (Table 3).

Kim was only able to get one case of atlantal occipitalization out of 1029 cervical CT scans in South Korea, reflecting the rarity of this anomaly (Kim, 2015). Its incidence has been reported to be between 0.08 to 3% of the population (Mudaliar *et al.*, 2013).

None of our CT scan images revealed the odontoid process going above the plane of McRae’s line, thus zero incidence of basilar invagination. This differs with the earlier study done by Mwang’ombe at the same institution in the early 90s. He was able to get 12 patients out of a total of 38 who had this condition. This can be explained that his cohort of patients were more likely referral cases for neurosurgery conditions unlike our cohort which came from general patient population.

It can also be reasoned out that with improvement in overall nutrition status and antenatal care has resulted in this congenital defects being rare. (Mwang'ombe and Kirongo, 2000).

5.3 LIMITATIONS OF THE STUDY

Most of the Kenyatta National Hospital patient population comes from Nairobi and its environs, especially for trauma cases. Thus, the study population cannot be said to be strictly representative of the Kenyan Population as whole. This is delimited with the fact that Nairobi is domiciled by Kenyans of different ethnic extractions.

The study population was young (ages between 19 and 58 years). Hence a significant chunk of the older age group was cut off, which may have altered the results if included. However, this is delimited by the fact that on average, the Kenyan Population Pyramid is a young one, and the CVJ retains its childhood dimensions in adulthood.

5.7 CONCLUSION

This study has shown that there are significant sexual differences in craniometric indices of the foramen magnum within the Kenyan population. However, these differences have a relatively low sex discriminating ability at about 69%, rendering them as adjunctive aids if one was to rely on them to predict sex in a forensic context.

With regard to morphological variations of the atlas, the posterior ponticulus and arcuate has a high prevalence in the study population (36%). There is need therefore, to have high caliber imaging modalities before conducting operations on the posterior half of the atlas to avoid iatrogenic injuries.

Type A posterior arch defects predominate within the study population, with a prevalence of 6.9%. Given the high load of cervical trauma in our set up, there is a high risk of misdiagnosis of these arch defects as fractures, thus cautioning clinicians to have a high index of suspicion. 3D reconstruction CT imaging is a useful modality in such a case to aid in diagnosis.

Atlantal occipitalization and Basilar invagination cases seem to be rare in the Kenyan population, however more research needs to be done on this with a bigger sample size.

This study has shed light on the craniovertebral junction in Kenya. It emphasizes the crucial role of high-resolution imaging in diagnostic formulation and peri operative planning, thus need for a low threshold.

5.8 Suggestions for further studies

1. Correlate neurological manifestations of craniovertebral junction anomalies within the Kenyan context.
2. Outcomes of surgical treatment interventions of the craniovertebral junction related syndromes.

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APPENDIX 1: Data collection sheet – Foramen Magnum

CT Scan Code		Date Acquired		Remarks
Age (years)		Sex		
Transverse Diameter (mm)				
Anterior-Posterior Diameter (mm)				
Occipitalization (Yes/No)				
Data collected by				Date
Data Reviewed by				Date

a: Radinsky’s formula for area of foramen magnum

FM area = $(0.25\times\pi\times h\times w)$

Where:

- **i. $\pi = 3.142$**
- **ii. h = anterior posterior diameter**
- **iii. w = transverse diameter**

APPENDIX 2: Data collection sheet – C1/C2

CT scan Code		Date acquired	Remarks
Age (years)		Sex	
Posterior Ponticulus (Yes/No)		Side (r)(l)(B)	
Arcuate Foramen (Yes/No) (Fissure/synostosis)		Side (r)(l)(B)	
Posterior Arch defect (Yes/No)		Side (r)(l)(B)	
Occipitalization (Yes/No)		Side (r)(l)(B)	
McRae’s/odontal interval (cm) (+ve if above McRae’s line) (-ve if below McRae’s line)			
Data Collected by			Date
Data Reviewed by			Date

Appendix 3: PARTICIPANT INFORMATION AND CONSENT FORM

TITLE OF STUDY:

Morphometric analysis of the craniovertebral junction in a Kenyan population: a cross sectional, retrospective radiological study

Principal investigator and institution affiliation**:** Dr Daniel Wafula Barasa- University of Nairobi

Co-investigators and institution affiliation:

Prof Moses Obimbo (University of Nairobi),Dr Paul Odula (University of Nairobi) and Dr Beda Otieno (University of Nairobi),

Introduction

I would like to inform you about this study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide if you will be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form.

Aim of the study (what is this study about?)

This study is about the radiological study of the base of the skull. It is applicable for all adults who undergo a CT scan of the head. Although this procedure is frequently done in our setup, morphometry of the base of the skull is unknown. This information would be useful in the surgical management of head and neck injuries.

This study has been authorized by the KNH/UoN Ethics and Research Committee for the period extending from ______________________ to __________________

Objectives of the study

To find out the baseline morphometry of the base of the skull at Kenyatta National Hospital

Benefits of the study

Head CT scans are done frequently at KNH. Regional and international data on its relevance in planning base of skull surgery is promising. However local data on the baseline skull morphometry is unclear. This study will inform on the baseline morphometry and help reduce the incidence of inadvertent injury during base of skull surgery in the future.

What will happen if you decide to be in this research study?

If you agree to participate in this study, your CT scans of the head and neck will be analyzed to look at the appearance of certain anatomical features that include the shape and size of the foramen magnum, the appearance of your first two cervical vertebrae and how they relate to each other. No data on your specific diagnosis that took you to hospital will be analyzed. No information that will identify you directly from the images will be revealed.

Are there any risks, harms or discomfort associated with this study?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort will always be put in place to minimize these risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all our paper records in a locked file cabinet.

Will being in this study cost you anything?

Absolutely NO. The data we are interested in already exists as part of your medical records.

Reimbursement to participants

There will be no reimbursement as you will not be needed at any point during the study period. Only your existing medical record at the hospital will be accessed.

The lead researcher (Dr Barasa Wafula) can be reached on telephone number **0700043665.** Besides, if you have any complaints pertaining this study, the chairperson of the KNH-UoN Ethics and Research Committee that authorizes this study can be reached on the number 020-2726300 ext. 44102.

Denial of consent will be duly respected and will not in any way affect your treatment at KNH.

Confidentiality

Your identity will be confidential and no information will appear on either the data sheets or the final report.

CONSENT FORM (Participant's statement)

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

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

Signature/thumbprint…………………….. Date…………………..

I, the principal investigator, having explained in detail the purpose of this study, hereby submit that, confidentiality of the data collected will be maintained and only details relevant to the study will be revealed.

Signature___ ___________ Date ________17/06/2021

Lead researcher: Dr Barasa Wafula- 0700043665

P.O. Box 30197-00100,Department of Anatomy, University of Nairobi,

Email: barassawafula@gmail.com

Co-investigators:

1. Sign: __ _ Date: 17/06/2021____

   Prof. Obimbo Moses Madadi, MBChB, Dip FELASA C, MSc, MMED (ObGyn), PhD.

   Associate Professor, Department of Human Anatomy, University of Nairobi

   Cell: 0721585906

   Email: obimbomad@gmail.com

   P.O. Box 30197-00100,

   Nairobi,

2. Sign: Date: 17/06/2021

   Dr Paul Odula, BSc, MBChB, MMED (Surg), PhD.

   Senior Lecture, Department of Human Anatomy, University of Nairobi.

   Cell: 0722773025

   Email: odula@uonbi.ac.ke

   P.O. Box 30197-00100,

   Nairobi,

3. Sign Date:17/06/2021

   Dr Beda Olabu,BscAnat(Hons), MBChB, MSc, MMED (Radiology)

   Lecturer, Department of Human Anatomy, University of Nairobi.

   Cell: 0720915805

   Email: otienobeda@gmail.com

   P.O. Box 30197-00100,

   Nairobi,

KNH-UoN Ethics and Research Committee Telephone number: 2726300 ext. 44102,

Email:uonknh_erc@uonbi.ac.ke**; P.O BOX 00202 (19676/20723)**

APPENDIX 4: CHETI CHA RIDHAA

KICHWA: Uchambuzi wa picha vya kichwa katika WaKenya

Mtafiti Mkuu: Dr Barasa Wafula- University of Nairobi

Wasaidizi: Prof Obimbo Moses , Dr Paul Odula, Dr Beda Otieno (University of Nairobi)

Kianzilishi

Ningependa kukujulisha kuhusu huu utafiti unaofanywa na watafiti walioandikwa hapo juu. Kiini cha barua hii ni kukupatia taarifa ambayo itakuwezesha uweze kufanya uamuzi wa kujiunga na huu utafiti au la. Kuwa huru kuuliza swali lolote kuhusu utafiti huu, nini litakalofanyika pindi unapoamua kujiunga na utafiti huu, madhara au maafa yatakayotokea, haki zako kama mhudhuriaji au jambo lengine lolote. Pindi tumeyajibu maswali yako yote na umeridhika, uamuzi wa kujiunga na utafiti huu ni wako. Pindi umefahamu na kuridhia kujiunga na utafiti huu nitakuomba usahihishe jina lako katika barua hii.

Lengo kuu la uchunguzi

Picha ya kichwa ni moja katika utafiti wa magonjwa ya kichwa yanayowakumba wakenya wengi. Baadhi ya wanaougua ugonjwa huu wanahitaji oparesheni. Ni muhimu kujua matokeo ya oparesheni kwa wale wanaoathirika ugonjwa huu kwa sababu baadhi yao wana majukumu muhimu sana katika familia zao. Kwa hivyo elimu ya vipimo vya kichwa kabla ya oparesheni katika kikundi hiki kitasaidia kutoa mwanga juu ya ugonjwa huu. Elimu hii pia itatusaidia kutambua namna ya kuwatibu wagonjwa wengine katika siku zijazo.

Uchunguzi huu umeruhusiwa na tume yamaadili inayoidhinisha utafiti (KNH-UoN Ethics and Research Committee) kuanzia tarehe _______________ hadi tarehe _______________

Malengo hususan

Katika uchunguzi huu, mtafiti mkuu ataweza kumuuliza maswali kadhaa mgonjwa kuhusu njia yake ya mkojo na namna inavyomuathiri maisha yake.

Manufaa

Elimu ya vipimo vya kichwa kitasaidia kutoa mwanga juu ya jinsi vipimo vya kichwa vitasaidia operesheni ya magonjwa haya. Elimu hii pia itatusaidia kutambua namna ya kuwatibu wagonjwa wengine katika siku zijazo.

Uchunguzi huu utafaidi maelezo kuhusu vipimo vya kichwa na hivyo kuchangia katika kutengeza matibabu yenye manufaa kwa wanaougua ugonjwa huu.

Hakuna manufaa ya papo hapo kwa mgonjwa au jamaa zake.

Kuna madhara yoyote kwa kujiunga na utafiti huu?

Hakuna madhara yoyote yatatokana na utafiti huu kwa sababu picha ambazo zitatumiwa ni zile ambazo ulipigwa wakati wa matibabu yako na ziko katika rekodi ya hospitali ya Kenyatta.

Kujiunga na utafiti huu utakugharimu nini?

Hakuna gharama yoyote utakuwa nayo kwa sababu ni rekodi zako za hospitali pekee ambazo zitatumika kwa utafiti huu.

Kulipwa kwa wagonjwa wanaojiunga na utafiti huu

Hakuna malipo au marupurupu ambayo utalipwa kwa sababu ni rekodi ya picha zilizo hospitalini ndio zitakozo tumika.

Ombi

Ili kutekeleza uchunguzi huu, tutahitaji ruhusa yako ya kuweza kujiunga na utafiti huu. Iwapo haujaelewa maagizo haya unahiari ya kumuuliza mtafiti maswali yoyote kuhusu matumizi hayo.

Nambari ya simu ya mtafiti huyu ni **0700043665**.

Pia, iwapo una malalamishi yoyote kuhusu utafiti huu, mwenyekiti watume yamaadili inayoidhinisha utafiti huu (KNH-UoN Ethics and Research Committee), anaweza kupatikana kupitia nambari **020 7263009**.

Kukubali kujiunga katika uchunguzi huu silazima na hauna gharama yoyote.

Usiri

Hatutafichua wala kuchapisha mambo yoyote kukuhusu ila yale tu yanayohusiana na uchunguzi huu.

Uamuzi wa mgonjwa

Nimesoma na kuyaelewa yaliyomo katika barua hii. Nimepata fursa ya kujadiliana yaliyomo katika barua hii na mtafiti mkuu. Maswali yangu yamejibiwa kwa lugha ninayoifahamu. Naelewa kuwa kujiunga kwangu na utafiti huu ni kwa hiari yangu na naweza kujiondoa katika utafiti huu wakati wowote. Kwa hivyo nimeridhia kujiunga na utafiti huu kwa hiari yangu. Ningependa mambo yangu yawekwe siri katika utafiti huu.

Nimekubali kujiunga na utafiti huu: Yes No

Nimekubali kutoa nambari yangu ya rununu : Yes No

Sahihi…………………….. Tarehe…………………..

Nathibitisha nimeyafahamu aliyonieleza mtafiti na nimekubali kwa hiari yangu mwenyewe kushiriki katika uchunguzi huu.

Sahihi/kidole cha gumba………………… Tarehe ________________

Mimi, mtafiti nimemweleza mgonjwa kuhusu uchunguzi huu ipasavyo.

Sahihi ya mtafiti ____ ____________ Tarehe _17/06/2021

Dr Barasa Wafula - **0700043665**

S.L.P. 30197-00100, Department of Anatomy, University of Nairobi.

Kipepesi: barassawafula@gmail.com

<u>Watafiti wasaidizi:</u>

(1) Prof Obimbo Moses

S.L.P 30197-00100, Department of Anatomy, University of Nairobi,

Kipepesi: obimbomad@gmail.com

Simu: 0721585906

(2) Dr Paul Odula

S.L.P 30197-00100, Department of Anatomy, University of Nairobi,

Kipepesi: odula@uonbi.ac.ke

Simu: 0722773025

(3) Dr Beda Otieno

S.L.P 30197-00100, Department of Anatomy, University of Nairobi,

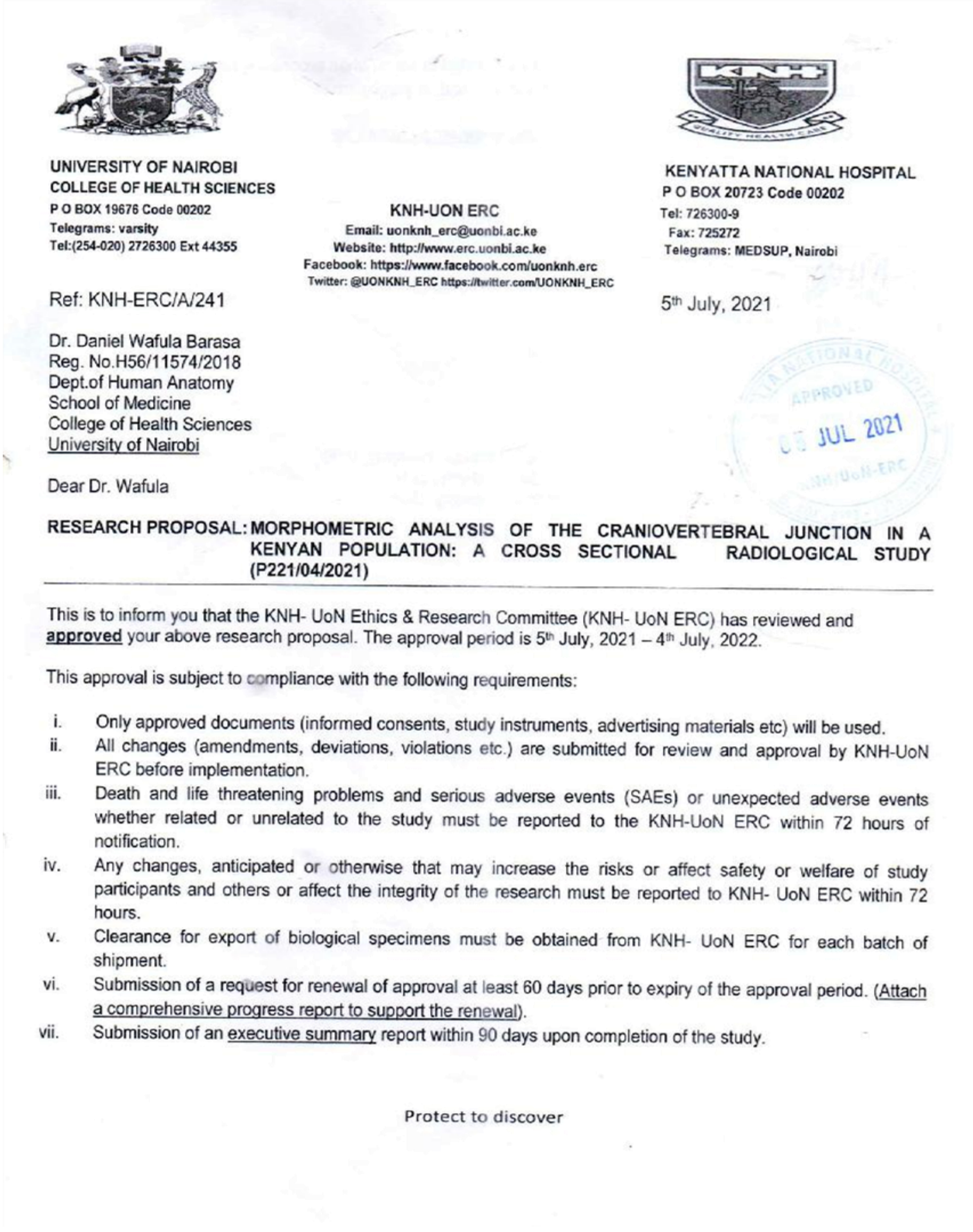
Kipepesi: otienobeda@gmail.com

Simu: 0720915805

KNH-UoN Ethics and Research Committee Telephone number: 2726300 ext. 44102,

Email: uonknh_erc@uonbi.ac.ke**; P.O BOX 00202 (19676/20723)**

Appendix 5 : Approval Letter



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Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/241

5th July, 2021

APPROVED
05 JUL 2021
KNH/UoN-ERC

Dr. Daniel Wafula Barasa
Reg. No.H56/11574/2018
Dept.of Human Anatomy
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Wafula

RESEARCH PROPOSAL: MORPHOMETRIC ANALYSIS OF THE CRANIOVERTEBRAL JUNCTION IN A KENYAN POPULATION: A CROSS SECTIONAL RADIOLOGICAL STUDY (P221/04/2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 5th July, 2021 – 4th July, 2022.

This approval is subject to compliance with the following requirements:

i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
ii. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
iii. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
vii. Submission of an executive summary report within 90 days upon completion of the study.

Protect to discover

This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

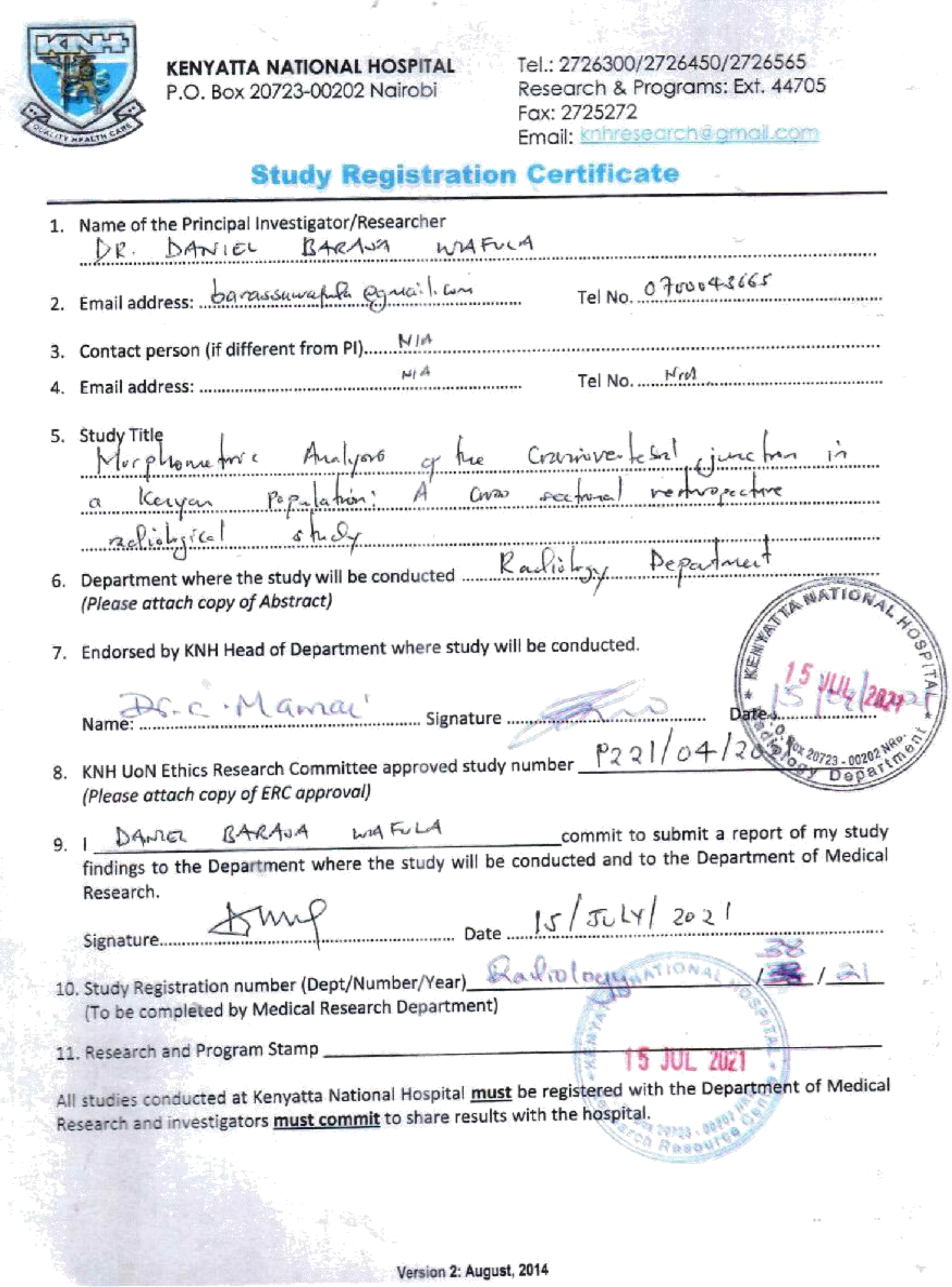
For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M.L CHINDIA
SECRETARY, KNH- UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chair, KNH- UoN ERC
The Dean, School of Medicine,UoN
The Chair, Dept. of Human Anatomy, UoN
Supervisors: Prof. Obimbo Moses Madadi, Dept.of Human Anatomy, UoN
Dr. Paul Odula, Dept.of Human Anatomy, UoN
Dr.Beda Olabu, Dept.of Human Anatomy, UoN

Appendix 6: Study Registration Certificate



KNH/R&P/FORM/01

KENYATTA NATIONAL HOSPITAL
P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
DR. DANIEL BARAWA WAFULA

2. Email address: barassuwafula@gmail.com Tel No. 0700043665

3. Contact person (if different from PI) N/A

4. Email address: N/A Tel No. N/A

5. Study Title
Morphometric Analysis of the Craniovertebral junction in a Kenyan population: A cross sectional retrospective radiological study

6. Department where the study will be conducted Radiology Department
(Please attach copy of Abstract)

7. Endorsed by KNH Head of Department where study will be conducted.

Name: Dr. C. Mamai' Signature .... Date 15 JUL 2021

8. KNH UoN Ethics Research Committee approved study number P221/04/20
(Please attach copy of ERC approval)

9. I DANIEL BARAWA WAFULA commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Medical Research.

Signature .... Date 15/JULY/2021

10. Study Registration number (Dept/Number/Year) Radiology/38/21
(To be completed by Medical Research Department)

11. Research and Program Stamp 15 JUL 2021

All studies conducted at Kenyatta National Hospital **must** be registered with the Department of Medical Research and investigators **must commit** to share results with the hospital.

Version 2: August, 2014