CSPINE

(Correlating Soft tissue Projections in Injured NEcks)

A descriptive study on measuring prevertebral soft tissue thickness as a ratio of vertebral body width in paediatric cervical spine trauma

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Dissertation

Contents

Declaration

I, ……*Jeannie Katharine McCaul…*, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Abstract

Background: In paediatric trauma, measured increase in prevertebral soft tissue thickness on a lateral cervical spine (C-spine) X-ray is interpreted as swelling, raising suspicion of C-spine injury[1,2]. Defining swelling in absolute measurements is cumbersome – children's sizes vary. Evidence for potentially more consistent tools measuring soft tissue thickness *as a ratio of vertebral body width* is lacking. Clinical decision rules should be based on best available evidence to minimize patient harms and improve health outcomes. This study determined whether consistent, measurable ratios exist for use as simple diagnostic tools in assessing paediatric soft tissue swelling and C-spine injury.

Methods: A pragmatic quantitative retrospective cross-sectional study randomly sampled C-spine trauma X-rays taken at a South African children's hospital. Seventy-one un-intubated X-rays from 85 controls were used to identify normal ratios. The authors measured vertebral bodies and soft tissue at each level, created all possible ratios, then chose the two least variable – one for the upper and one for the lower C-spine. Twenty cases aided in determining diagnostic accuracy for C-spine injury.

Results: Mean soft tissue at the second cervical vertebral level (c2) was 38% of the seventh vertebra (C7) (95%CI:34-41.9%, SE:2.0%, variance:2.5%). Mean c6 soft tissue was 65.6% of C7 vertebra (95%CI:61.9-69.3%, SE:1.9%, variance:2.3%). In diagnosing C-spine injury, a Receiver Operating Characteristic (ROC) curve calculation gave an empirical optimal cut-point of 53.9% and 74.4% respectively. Using practical cut-offs of 55% at c2 and 75% at c6 yield specificities of 93.8% (95%CI:84.8-98.3%) and 81.8% (95%CI:70.4-90.2%), with negative predictive values of 90.9% (95%CI:81.3-96.6%) and 91.5% (95%CI:81.3-97.2%) respectively.

Conclusions: Consistent and specific ratios exist in the upper and lower paediatric C-spine. Both ratios have extremely poor sensitivities and positive predictive values and so are poor screening tools, but can aid in ruling in injury in patients with clinical suspicion.

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For You created my inmost being … I praise You because I am fearfully and wonderfully made; Your works are wonderful, I know that full well. Ps 139:13-14

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Abbreviations

ADI: atlanto-dens interval

BD: basion-dens interval

c1: prevertebral soft tissue, anterior to the first cervical vertebra

c2: prevertebral soft tissue, anterior to the second cervical vertebra

c3: prevertebral soft tissue, anterior to the third cervical vertebra

c4: prevertebral soft tissue, anterior to the fourth cervical vertebra

c5: prevertebral soft tissue, anterior to the fifth cervical vertebra

c6: prevertebral soft tissue, anterior to the sixth cervical vertebra

c7: prevertebral soft tissue, anterior to the seventh cervical vertebra

C2: the body of the second cervical vertebra

C3: the body of the third cervical vertebra

C4: the body of the fourth cervical vertebra

C5: the body of the fifth cervical vertebra

C6: the body of the sixth cervical vertebra

C7: the body of the seventh cervical vertebra

CI, 95% CI: confidence interval, 95% confidence interval

C-spine: cervical spine

CSPINE: correlation of soft tissue projections in injured necks (study title)

CT: computerised tomography

mm: millimetres

MRI: magnetic resonance imaging

ROC: receiver operating characteristic

SE: standard error

SD: standard deviation

X-ray: roentgenograph

Chapter 1: Introduction: A Critical Review of the Literature

Introduction

Cervical spine (C-spine) injuries are rare in children and mostly occur after falls in younger age groups, sports injuries in older children and motor vehicle accidents in all age groups, while infants should be evaluated for non-accidental injury. The pattern of cervical injuries in children differs from adult patterns, with the upper C-spine being the location of injury in the majority of cases. A limited English-language systematic review found that this is especially true in children younger than eight or nine years[2]. Plain X-rays are the standard initial radiological investigation to evaluate suspected C-spine injury. Apart from the bony anatomy, the projection of the prevertebral soft tissue on the lateral C-spine is also considered to be of use in identifying injury, as an increase in width may be due to swelling or haemorrhage. The soft tissue may be falsely widened in views where the neck is flexed or during forced expiration (such as crying). [1,2]

Various measurements and ratios have been proposed to act as a guide in the interpretation of the soft tissue shadow in lateral C-spine X-rays. Some are absolute measurements in millimetres (mm), which may vary across age groups. Another method of measurement is to express the soft tissue thickness as a ratio of a cervical vertebral body width. However, a literature review performed in an attempt to identify the origins of these recommendations revealed that the guidelines used may not be entirely evidence-based or, even when they are, not entirely applicable to paediatric trauma. The value of apparent soft tissue swelling as a true indicator of C-spine injury is also unclear.

A critical review of published literature was performed. Google Scholar, Pubmed, Cochrane Libraries and Medscape were searched using combinations of the keywords “paediatric” or “pediatric”, “soft tissue”, “prevertebral”, “ratio”, “trauma”, “X-ray” and “cervical spine”. Modifications included adding “normal measurement” or “lateral” when required. Reference lists of relevant articles were also perused for further relevant publications. Citation trails were followed to identify the original author and evidence base of each recommendation. A proportion of the literature was specific to soft tissue infections, specifically retropharyngeal abscesses, rather than trauma. However, when the authors made recommendations regarding what normal soft tissue measurements should be, these recommendations were still included in the review. Whether the pathology that increases soft tissue thickness be due to trauma or infection, the baseline normal measurement should still be a valid reference standard.

This review focuses on four aspects around this topic: published normal values, methods of measurement and of taking X-rays, the diagnostic value of soft tissue swelling in C-spine injury, and selected other measurements on the lateral C-spine X-ray.

Part 1: Normal values

With regards to measuring soft tissue as a ratio of vertebral width, only one recommendation was found that was clearly based on a primary study where normal paediatric X-rays were measured. This is the recommendation by Hay[3], which was developed in 1930 (See Table 1a) after measurement of 25 paediatric X-rays. Another ratio mentioned by Yeoh[4] may be based on measurements of 9 paediatric X-rays, but the methodology in the publication is unclear as no examples of individual measurements are provided. Yeoh also specifies that their measurement is of use in differentiating retropharyngeal cellulitis from abscess so does *not* represent a normal value that can be applied in other settings. Despite this, Yeoh’s values have been quoted as a reference standard for normal. Duncan[5] published Yeoh’s recommendation in an otorhinolaryngology

textbook, which Reyes et al[6] uses as a normal value in assessing any pathology of the deep neck space.

Various other ratios have been published in textbooks or in introduction or discussion sections of articles but with no citation to indicate the origin of the mentioned ratio. These are labelled "no citation" in Table 1. In other cases, ratios are mentioned and cited but the publications they are referenced to do not support the quoted measurement. The cited publications sometimes provide different values altogether. These measurements are labelled as "incorrect citation" in Table 1.

With regards to measuring soft tissue in mm, Table 1a shows that a greater number of recommendations on absolute measurements are based on primary evidence. Some uncited measurements bear close similarity to the evidence-based measurements.

Table 1b provides a summary of ratios and absolute measurements that pertain to adults. Adult recommendations seem to form the bulk of published literature and care must be taken to avoid generalising these potentially more well-known measurements to the paediatric population, where they may not be valid. The publications were included in this review to contrast against the paediatric normal values and emphasize that they may not be applicable to paediatric trauma, and to examine their study methodology to better inform our study design and methods.

A lowercase measurement, e.g. c4, refers to the thickness of the soft tissue adjacent to the numbered cervical vertebra (in this case, fourth). An uppercase measurement, e.g. C5, refers to the width of the numbered cervical vertebra (in this case, fifth). See Part 2 for clarification of terms such as postpharyngeal.

Table 1a: Published normal values for prevertebral soft tissue in children.

Type of measurement	Recommendation	Source	Evidence base
Ratios in children	• **Postpharyngeal tissue (c4):** ○ **= 1.5 C5 (age 0-1)** ○ **= 0.5 C5 (age 1-3)** ○ **= 0.4 C5 (age 3-6)** ○ **= 0.3 C5 (age 6-14)** • **Postventricular soft tissue (c5):** ○ **= 2.0 C5 (age 0-1)** ○ **= 1.5 C5 (age 1-2)** ○ **= 1.2 C5 (age 2-14)**	Hay[3] (as re-drawn in Keats and Lusted[7]	Measurements of 25 paediatric ("normal infants" or "normal children under 14" years old) C-spine X-rays
	• **c2 = 0.3 C3** • **c6 = C6**	Hoffman and Dix-Peek[8,9]	No citation
	• **c1-4 = <0.5 adjacent vertebra** • **c5-7 = adjacent vertebra**	Di Mascio and Sivaraman[10]	No citation
	• **Below cricoid cartilage = < 0.75 adjacent vertebra**	Phelps[11]	No citation. Possibly also applied to adults
	• **c3 ≤ 0.33-0.5 C3** • **c5 is ≤ 1.25 C5 or C6**	Baren et al[12]	No citation
	• **Retropharyngeal tissue = < adjacent vertebra** • **Retropharyngeal abscess only when retropharyngeal tissue = 2 x adjacent vertebra.**	Yeoh et al[4]	First bullet point: incorrect citation. Second bullet point: possibly based on measurements in

			cases of retropharyngeal abscess in 9 paediatric (<6 years old) C-spine X-rays. No actual measurements quoted or analysed in the original text
	• **Retropharyngeal tissue = 0.5-0.66 adjacent vertebra**	Egloff et al[13]	Incorrect citation*
Absolute measurements in children	• **c2 upper limit = 7mm** • **c6 upper limit = 14mm**	Wholey et al[14]	Measurements of 120 normal paediatric (<15 years old) C-spine X-rays
	• **c3 < 6mm** • **c6 < 14mm**	Rockwood and Wilkins[1]	No citation
	• **c3 ≤ 5–7 mm** • **c5 ≤ 14 mm**	Baren et al[12]	No citation
	• **Mean retropharyngeal tissue = 6.2mm (infant)** • **Mean retrotracheal tissue = 9.2mm (preschool children)**	Haug et al[15]	Measurements of 86 normal paediatric and adult C-spine X-rays (results stratified to age groups)
	Soft tissue (rounded to nearest 0.1 mm) at c2, c5 and c6 for age groups (in years): • **Age 0-1: c2 = 4.5-10.5, c5 = 9.2-12.6, c6 = 7.7-13** • **Age 1-2: c2 = 4.1-12.2, c5 = 6.6-9.7, c6 = 4.7-9.6** • **Age 2-3: c2 = 3.7-4.3, c5 = 7.9-13.2, c6 = 9.2-10.6** • **Age 3-6: c2 = 3.7-6.6, c5 = 4.5-13.4, c6 = 3.8-10.2** • **Age 6-14: c2 = 3.7-7.7, c5 = 7.8-16, c6 = 6.1-14.8**	Reyes et al[6]	Measurements of 50 normal paediatric (0-14 years old) C-spine X-rays
	• **Mean c3 (similar at c2 and c4) = 3.7mm – 0.02 x age (years) + 0.01 X weight (pounds)**	Sistrom et al[16]	Measurements of 227 randomly selected normal paediatric and adult (age 8-97) C-spine X-rays. Formula based on stepwise regression model. Also applicable to adults
	• **Above cricoid cartilage = <4mm after the age of 2 or 3 years**	Phelps[11]	No citation, possibly also applied to adults

* One citation listed could not be accessed at time of submission

Table 1b: Published normal values for prevertebral soft tissue in adults

Ratios in adults	• **Postpharyngeal tissue = 0.3 C5** • **Postcricoid tissue = 0.7 C5 (males) or 0.6 C5 (females)**	Hay[3]	Measurements of 50 normal adult C-spine X-rays
	• **Retrocricoid tissue = 0.7 C5** • **Retrotracheal tissue (or c6) = C5**	Chen and Bohrer[17]	Measurements of 54 normal adult (>18 years old) C-spine X-rays
	• **Above c4 = 0.3 adjacent vertebra** • **below c4 = adjacent vertebra**	Patel et al[18]	Incorrect citation
	• **Soft tissue < adjacent vertebra**	Herdman et al[19]	Incorrect citation
	• **c2-3 = 0.5 adjacent vertebra** • **c5-7 = adjacent vertebra**	Miles and Finlay[20]	No citation
Absolute measurements in adults	• **7-10mm at c2-4 is possibly abnormal: consult regarding further imaging** • **>10mm at c2-4 is abnormal**	Templeton[21]	Measurements of 318 (260 normal, 58 cervical fractures/dislocations) adult C-spine X-rays
	• **Mean retropharyngeal tissue = 3.7mm** • **Mean retrotracheal tissue = 12.1mm**	Haug et al[15]	Measurements of 86 normal paediatric and adult C-spine X-rays (results stratified to age groups)
	• **c2 =< 5mm** • **c3-4 =< 7mm** • **c5-7 =< 2cm**	Penning[22]	Measurements of 50 normal adult (15-78 years old) C-spine X-rays
	• **c2 upper limit = 7mm** • **c6 upper limit = 22mm**	Wholey et al[14]	Measurements of 480 normal adult (>15 years old) C-spine X-rays
	• **c2 upper limit = 7mm** • **c7 upper limit = 20mm**	Patel et al[18]	Incorrect citation (misquoting Penning)
	• **Mean postpharyngeal tissue = 3.1mm (range 1.5-4.5mm)** • **Mean post-tracheal tissue = 12.4mm (range 8-17mm)**	Oon[23]	Measurements of 150 normal adult C-spine X-rays
	• **Mean c2 = 2.95mm (0.4-6mm)** • **Mean c6 = 13.57mm (range 8.8-23.2mm)**	Chi et al[24]	Measurements of 171 normal adult (17-80 years old) C-spine X-rays

	• **Mean c3 (similar at c2 and c4) = 3.7mm – 0.02 x age (years) + 0.01 X weight (pounds)**	Sistrom et al[16]	Measurements of 227 randomly selected normal paediatric and adult (age 8-97) C-spine X-rays. Formula based on stepwise regression model. Also applicable to children
	• **c1: 5.26+-0.17mm** • **c2: 4.67+-0.13mm** • **c3 4.95+-0.14mm**	Harris[25]	Unclear population or methodology

Part 2: Methodology of soft tissue measurement and X-rays

Due to the inherent anatomy of the soft tissue anterior to the C-spine, most authors have different measurements for the upper and lower C-spine. The glottis area lies in the mid-C-spine, around c4, but its position is variable. The soft tissue shadow below it is much wider than above due to the presence of the collapsed oesophagus behind the larynx and trachea. Some authors quote measurements only by numbering the level according to the adjacent vertebral body, some refer to the supraglottic area as postpharyngeal or retropharyngeal soft tissue and to the infraglottic area as postventricular or, more often, retrotracheal soft tissue. Some authors measure the postcricoid (retrocricoid) distance in adults who have a visible calcified cricoid cartilage.

The exact levels and the lines along which measurements are taken also vary slightly between authors:

Penning[22] measures soft tissue along a line perpendicular to the soft tissue shadow, up to the anterosuperior or anteroinferior edge of the vertebral bodies of C2-C7, or the anterior arch of C1.

Chen and Bohrer[17] also measure retrocricoid soft tissue along a line that is perpendicular to the soft tissue shadow. Their retrotracheal soft tissue thickness was measured at C5, or upper or mid C6 if retrotracheal tissue started below C5.

Reyes et al[6] measure from the most anterior inferior part of the vertebral body. The angle of the line of measurement is not specified, but in their diagram, it appears to be perpendicular to the vertebral column, and/or parallel to the inferior endplates of the vertebrae.

Wholey et al[14] do not specify the angle at which measurement was taken, but in their diagram it appears to be parallel to the inferior border of the vertebra as well as perpendicular to soft tissue shadow. They measure retropharyngeal soft tissue from the antero-inferior aspect of C2 and retrotracheal soft tissue from the antero-inferior aspect of C6.

Templeton[26] measure retropharyngeal soft tissue at the anteroinferior borders of C2, C3 and C4. They do not specify the angle of the measurement line, but in their diagram it appears to be perpendicular to the soft tissue shadow and/or the vertebral column but *not* parallel to the inferior endplates. C5 diameter was measured at its middle.

Hay[3] gives a descriptive method: postpharyngeal tissue is measured “at a point where the soft tissues run parallel to the vertebra” – in their diagram it shows the measurement example at C4 mid-body. Hay’s measurement for postventricular tissue in children is measured as the distance between the posterior commissure of the larynx and the nearest portion of the cervical spine. In

their diagram, it shows the soft tissue anterior to the superior endplate of C5 as an example. C5 diameter was measured at its middle.

Some authors quote their techniques used to take the X-rays. Wholey et al[14] measured erect sitting films with the neck in neutral. The target-to-film distance was 60 inches and they did not correct for slight magnification. Templeton measured supine or erect films with the neck in neutral. The target-to-film distance was 40 inches and they do not mention correcting for magnification. Reyes et al[6] likewise disregarded magnification but do not specify their target-to-film distance. When using ratios, magnification and film distance is irrelevant.

Part 3: the diagnostic value of soft tissue swelling in identifying C-spine injury

It has been questioned if the appearance of soft tissue swelling correlates well with true C-spine injury. Some authors have examined or commented on the diagnostic value of published recommendations – often focusing on those pertaining to adults only.

Reyes, et al[6] measured 50 C-spine X-rays that were initially read as normal of patients aged 0-14 years that suffered trauma or child abuse (all ended up clinically well and were discharged from the emergency room). They compared their findings to guidelines currently used by their institution and found that they correlated well with Duncan's[5] and Wippold's[27] (actually Wholey's[14]) guidelines but very poorly with Keats'[7] (Hay's[3]) ratios.

DeBehnke and Havel[28] measured 166 adult X-rays with C-spine injury and compared them to 93 controls. They found using an upper limit of 6mm at c2 resulted in a sensitivity of 59% and a specificity of 84% for upper C-spine fractures. Using 22mm as the upper limit for c6 resulted in a sensitivity of 5% and a specificity of 95% for lower C-spine fractures. They then utilised a Receiver Operator Characteristic curve analysis in an attempt to find a better cut-off value but failed to demonstrate any that they deemed had adequate sensitivity and specificity.

Templeton tested various published rules and reported their true and false positive rates. The only ratio the authors tested was the one for the upper C-spine in adults as recommended by Hay[3]: that c3 or 4 should be less than 0.3 of C5. A positive predictive value of 56.6% (incidence of injury 22.3%) can be extrapolated from their analysis. Negative predictive value: 87.8%, Sensitivity: 71.9%, Specificity: 44.9%.

Penning[22] measured 50 normal adult X-rays to define normal values for prevertebral soft tissue (using the upper limits of quite wide ranges), then studied 30 X-rays of C-spine injury. They found that only 18 of the 30 injured patients had increased prevertebral soft tissue according to their aforementioned limits (a sensitivity of 60% can be extrapolated).

Patel, et al[18] analysed whether the prevertebral soft tissue measurements are reliable in the assessment of C-spine injuries in 99 patients over the age of 16. "No injury" was defined by a normal X-ray plus a clear spine according to the Canadian C-spine rule. They found that the "7mm at C2 and 2cm at C7" version of Penning's recommendations[22] had a sensitivity of only 7.6% but specificity of 93%. A ratio of unclear origin (soft tissue thickness should be 1/3 the adjacent vertebral body above C4 and equal to it below) tested by Patel also had a poor sensitivity of 7.6% but specificity of 98%.

Patel had excluded patients who had an endotracheal tube in situ at the time of the X-ray, and it has been commonly accepted that the projection of soft tissue thickness in intubated patients may not

be reliable. Di Mascio and Sivaraman[10] examined 43 intubated and 92 un-intubated adults and found that at C2 the soft tissue thickness is significantly widened but at C4 and C6 there was no difference.

In reference to adults, in The Radiology of Emergency Medicine, Harris[25] states that absolute measurements are of less clinical use than the contour of the soft tissue itself – which should follow the anterior cortex of the vertebrae. They also quote Hay and Penning as having established normal measurements but say that these are of limited practical use in emergency medicine due to the patients being supine and the target-to-film distance different. The authors also comment that a normal measurement of 2cm anterior to C7 (as described by Penning) does not reliably exclude even major injuries in the lower C-spine. These criticisms are unreferenced.

In reference to paediatrics, Harris, in their chapter "The normal cervical spine" in a different textbook[29], mentions that the normal laxity of the soft tissues of the cervico-cranium may result in "perplexing shadows on the lateral radiograph of the cervical spine" in infants and young children. They recommend extension and inspiratory films to lessen the occurrence of falsely increased soft tissue measurements.

Gopalakrishnan[30] found the presence of soft tissue swelling useful in diagnosing injury in 7 adult patients, using Penning's measurements. This sample size is unfortunately too small to make meaningful test characteristic estimates such as specificity.

Miles and Finlay[20] commented, "absence of soft tissue swelling should not be considered as evidence for no bony injury. Its presence does not necessarily indicate bony injury". They measured 58 patients (age 17 – 84 years). 41 patients had bony injury. They evaluated two sets of values for soft tissue swelling: absolute measurements recommended by Meschan[31] (roughly based on Wholey[14] and Oon[23]); and also a ratio: c2-3 equalling half and c5-7 equalling to the full width of the adjacent vertebral body. The ratio is unreferenced. In their results, however, they only seem to evaluate the diagnostic accuracy of soft tissue swelling as defined by the absolute measurements. Forty-nine percent of patients with bony injury had soft tissue swelling (sensitivity of 49%), and 24% of those without injury had apparent swelling (specificity of 76%). The only result pertaining to the ratios seems to be that the "overall incidence" of swelling using the ratio method was 45% and using ratios was therefore considered "less sensitive". The authors do not clarify the number or percent of true and false positives by the ratio rule, so test characteristics cannot be extrapolated.

Part 4: Selected measurements other than soft tissue thickness

Other measurements about the cervical spine are also of importance. Bulas[32] does not comment on prevertebral soft tissue measurements but rather studied basion-dens (BD) distance. They recommended a BD greater than 12.5mm to be suggestive of atlanto-occipital dissociation. They quote other authors to contrast their measurements:

Wholey[14] found an average of 5mm in adults and up to 10mm in children

Powers[33] found no difference in ages, with a mean of 9.0mm (+-SD 3.6)

Lee[34] reported increasing BD distance with age: a mean of 5mm in children (range 2-11) and 7.5mm in adults (range 2-15)

Kaufman[35] recommended occiput to atlas distance of no more than 5mm in children.

The atlanto-dens interval (ADI), if widened, indicates C1-C2 subluxation. Locke et al[36] measured 200 children between 3 and 15 years old. 100 were supine and 100 were erect. They found that the upper limit in their normal population was 5mm (in one 13-year-old boy). Most measurements were clustered around 2mm and on supine films none were more than 4mm. Age and sex did not make a difference to measurements. However, extension did change measurements and the authors recommend the neutral position for adequate assessment. Wang et al[37] followed children longitudinally and found that at six months of age the median ADI was 1.97mm in girls and 2.01mm in boys and by 15 years of age the median was 2.45mm for both.

Conclusion

A wide range of normal values for soft tissue thickness in paediatric trauma C-spine have been published, with varying methodologies and levels of evidence. The diagnostic value of these soft tissue measurements in diagnosis of C-spine injury has also been debated. Intubation may cause a significant change in measured soft tissue thickness. Measuring soft tissue thickness in mm may be cumbersome as children's sizes vary and a more consistent method may be to measure soft tissue as a ratio of vertebral body width. Research employing robust methodology to clarify if such normal ratios in children can be identified and are consistent, and whether these ratios correlate with injury, is required.

This is the aim of the CSPINE study: to determine whether measurement of prevertebral soft tissue as a ratio of vertebral body width on paediatric lateral C-spine trauma X-rays is consistent between uninjured, un-intubated patients and, as a secondary objective, if these measurements are of diagnostic value in identifying C-spine injury.

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Chapter 2: Publication-ready Manuscript

CSPINE

(Correlating Soft tissue Projections in Injured NEcks)

A descriptive study on measuring prevertebral soft tissue thickness as a ratio of vertebral body width in paediatric cervical spine trauma

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See Acknowledgements for detailed roles of co-authors.

Abstract

Background: In paediatric trauma, measured increase in prevertebral soft tissue thickness on a lateral cervical spine (C-spine) X-ray is interpreted as swelling, raising suspicion of C-spine injury[1,2]. Defining swelling in absolute measurements is cumbersome – children's sizes vary. Evidence for potentially more consistent tools measuring soft tissue thickness *as a ratio of vertebral body width* is lacking. Clinical decision rules should be based on best available evidence to minimize patient harms and improve health outcomes. This study determined whether consistent, measurable ratios exist for use as simple diagnostic tools in assessing paediatric soft tissue swelling and C-spine injury.

Methods: A pragmatic quantitative retrospective cross-sectional study randomly sampled C-spine trauma X-rays taken at a South African children's hospital. Seventy-one un-intubated X-rays from 85 controls were used to identify normal ratios. The authors measured vertebral bodies and soft tissue at each level, created all possible ratios, then chose the two least variable – one for the upper and one for the lower C-spine. Twenty cases aided in determining diagnostic accuracy for C-spine injury.

Results: Mean soft tissue at the second cervical vertebral level (c2) was 38% of the seventh vertebra (C7) (95%CI:34-41.9%, SE:2.0%, variance:2.5%). Mean c6 soft tissue was 65.6% of C7 vertebra (95%CI:61.9-69.3%, SE:1.9%, variance:2.3%). In diagnosing C-spine injury, a Receiver Operating Characteristic (ROC) curve calculation gave an empirical optimal cut-point of 53.9% and 74.4% respectively. Using practical cut-offs of 55% at c2 and 75% at c6 yield specificities of 93.8% (95%CI:84.8-98.3%) and 81.8% (95%CI:70.4-90.2%), with negative predictive values of 90.9% (95%CI:81.3-96.6%) and 91.5% (95%CI:81.3-97.2%) respectively.

Conclusions: Consistent and specific ratios exist in the upper and lower paediatric C-spine. Both ratios have extremely poor sensitivities and positive predictive values and so are poor screening tools, but can aid in ruling in injury in patients with clinical suspicion.

Level of evidence: Diagnostic Level III

Introduction

Background

Paediatric C-spine injury is relatively rare but potentially devastating. Although soft tissue swelling has been referred to as an aid in identifying injury, published measurement methods and recommendations on what constitutes increase in soft tissue vary. Measurements in millimetres (mm) may not be applicable across wide age ranges and an alternative is measurement as a ratio of vertebral body width. Some published normal values are based on primary evidence, but many statements regarding measurement norms are uncited or the publications listed as sources do not directly support the original statement. See Table 1 for a summary of published measurement recommendations. A lowercase measurement, e.g. c4, refers to the thickness of soft tissue adjacent to the numbered cervical vertebra (in this case, fourth). An uppercase measurement, e.g. C5, refers to the width of the numbered cervical vertebra (in this case, fifth).

Table 1: Published normal values for prevertebral soft tissue in children.

Type of measurement	Recommendation	Source	Evidence base
Ratios in children	Postpharyngeal tissue (c4): = 1.5 C5 (age 0-1) = 0.5 C5 (age 1-3) = 0.4 C5 (age 3-6) = 0.3 C5 (age 6-14) Postventricular soft tissue (c5): = 2.0 C5 (age 0-1) = 1.5 C5 (age 1-2) = 1.2 C5 (age 2-14)	Hay[3] (as re-drawn in Keats and Lusted[4]	Measurements of 25 paediatric C-spine X-rays
	c2 = 0.3 C3 c6 = C6	Hoffman and Dix-Peek[5,6]	No citation
	c1-4 = <0.5 adjacent vertebra c5-7 = adjacent vertebra	Di Mascio and Sivaraman[7]	No citation
	Below cricoid cartilage = < 0.75 adjacent vertebra	Phelps[8]	No citation. Possibly also applied to adults
	c3 ≤ 0.33-0.5 C3 c5 is ≤ 1.25 C5 or C6	Baren et al[9]	No citation
	Retropharyngeal tissue = < adjacent vertebra Retropharyngeal abscess only when retropharyngeal tissue = 2 x adjacent vertebra	Yeoh et al[10]	First bullet point: incorrect citation. Second bullet point: possibly based on measurements in cases of retropharyngeal abscess in 9 paediatric (<6 years old) C-spine X-rays. No actual measurements quoted or analysed in the original text
	Retropharyngeal tissue = 0.5-0.66 adjacent vertebra	Egloff et al[11]	Incorrect citation*

Absolute measurements in children	c2 upper limit = 7mm c6 upper limit = 14mm	Wholey et al[12]	Measurements of 120 normal paediatric (<15 years old) C-spine X-rays
	c3 < 6mm c6 < 14mm	Rockwood and Wilkins[1]	No citation
	c3 ≤ 5–7 mm c5 ≤ 14 mm	Baren et al[9]	No citation
	Mean retropharyngeal tissue = 6.2mm (infant) Mean retrotracheal tissue = 9.2mm (preschool children)	Haug et al[13]	Measurements of 86 normal paediatric and adult C-spine X-rays (results stratified to age groups)
	Soft tissue (rounded to nearest 0.1 mm) at c2, c5 and c6 for age groups (in years): Age 0-1: c2 = 4.5-10.5, c5 = 9.2-12.6, c6 = 7.7-13 Age 1-2: c2 = 4.1-12.2, c5 = 6.6-9.7, c6 = 4.7-9.6 Age 2-3: c2 = 3.7-4.3, c5 = 7.9-13.2, c6 = 9.2-10.6 Age 3-6: c2 = 3.7-6.6, c5 = 4.5-13.4, c6 = 3.8-10.2 Age 6-14: c2 = 3.7-7.7, c5 = 7.8-16, c6 = 6.1-14.8	Reyes et al[14]	Measurements of 50 normal paediatric (0-14 years old) C-spine X-rays
	Mean c3 (similar at c2 and c4) = 3.7mm – 0.02 x age (years) + 0.01 X weight (pounds)	Sistrom et al[15]	Measurements of 227 randomly selected normal paediatric and adult (age 8-97) C-spine X-rays. Formula based on stepwise regression model. Also applicable to adults
	Above cricoid cartilage = <4mm after the age of 2 or 3 years	Phelps[8]	No citation, possibly also applied to adults

* One citation listed could not be accessed at time of publication

Objectives

The purpose of this study was to determine whether measurement of prevertebral soft tissue as a ratio of vertebral body width on paediatric lateral C-spine trauma X-rays is consistent between uninjured, un-intubated patients and, as a secondary objective, if these measurements are of diagnostic value in identifying C-spine injury. The hypothesis was that one such measurement would be identified for the upper C-spine and one for the lower C-spine, that these would have clinically acceptably narrow ranges of variability across age groups and genders and that measurements greater than these values would be correlated with C-spine injury.

Other secondary objectives were to describe the atlanto-dens interval (ADI) and basion-dens interval (BD) in our sample, and to examine the effect of intubation on soft tissue thickness.

Methods

Study design and setting

This was a retrospective pragmatic quantitative cross-sectional study. Random sampling of digital lateral C-spine X-rays taken in patients under 13 years old at Red Cross War Memorial Children's Hospital in Cape Town, South Africa between December 2012 and February 2016 was performed. All X-rays were assigned consecutive numbers, then selected according to a random number series generated by Microsoft Excel. X-rays taken for non-traumatic reasons (such as torticollis or swallowed foreign bodies) were excluded. Additional X-rays of injured patients from the same period were added from pre-existing records. Patient folders were reviewed for additional data. No further follow up was performed. Ethical clearance was obtained (HREC REF 118/2016).

Participants

Dedicated erect or supine lateral C-spine views on conventional, mobile unit and whole-body low dose digital X-rays (LODOX) of patients both with and without C-spine injury were included in the study. Uninjured controls were defined in two ways. Those assessed as being clinically clear according to the Canadian C-spine[16], National Emergency X-Radiography Utilization Study Group (NEXUS)[17] or other pragmatic criteria and that were finally managed and discharged as having no C-spine injury were classified as controls. Those that had a normal C-spine X-ray, computerised tomography (CT) scan or magnetic resonance imaging (MRI) report were also classified as controls. Patients that had bony, ligamentous, cervical cord or cervical nerve injury clinically or on imaging were classified as cases. 85 X-rays of uninjured patients and 20 with injuries were included.

Data sources, measurement and variables

Measurements were performed on the Phillips iSite® Enterprise radiology system using the ruler tool. If an area could not be visualised and measured, those specific measurements only were treated as missing data. All measurements were in mm up to one decimal point.

The soft tissue thickness was measured parallel to the adjacent vertebral body's inferior endplate, from the most anterior-inferior aspect of that vertebral body to the most anterior edge of the tissue shadow. As the first cervical vertebra (C1) has no body, measurement started from the most anterior inferior aspect of C1's anterior arch to the anterior edge of the soft tissue, along a line extended from the most inferior projections of C1 anterior and posterior arches. The soft tissue measurements were labelled c1-c7 according to the adjacent vertebra. In intubated cases, if the anterior edge of the soft tissue shadow was obscured by the tube, the measurement was taken up to the most posterior edge of the tube.

The vertebral body width was measured from the most posterior-inferior corner to the most anterior-inferior corner. C1 has no body, therefore was excluded. Vertebral body measurements were labelled C2-C7.

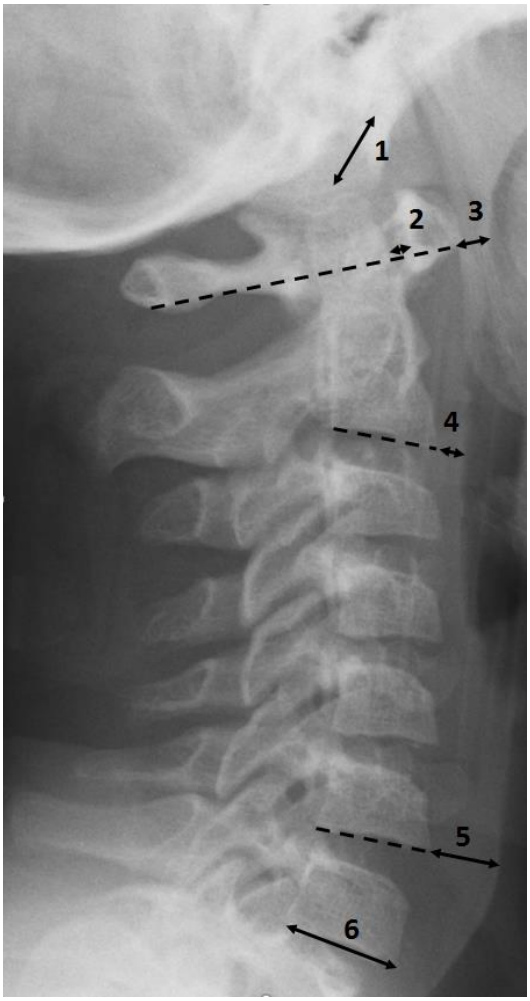
The atlanto-dens interval (ADI) was measured as drawn from the posterior inferior corner of the anterior arch of C1 to the adjacent anterior border of the odontoid, along the line between the most inferior projections of C1 anterior and posterior arches.

The basion-dens distance (BD) was measured from the anterior rim of the foramen magnum to the most prominent superior projection of the dens. See Figure 1 for measurement examples.

Age of the patient was extrapolated from the dates of birth and of the X-ray. Gender was recorded for all patients and, where available, weight in kilograms up to one decimal point. Mechanism of injury was extracted from the clinical information.

Digital radiology reports attached to X-ray, CT and MRI images were examined and any comments on soft tissue and adequacy of images noted. It was recorded whether an injury was identified, excluded or if the assessment was unclear. This was correlated with clinical information regarding the examination and presence and management of any injury.

Figure 1: Measurements on X-ray



Solid arrows: measurement lines for:

1. **BD**
2. **ADI**
3. **c1 soft tissue**
4. **c2 soft tissue**
5. **c6 soft tissue**
6. **C7 vertebral body**

Dashed lines: guides for measurement lines

Bias

Blinding during measurement was not possible as clinical information was digitally linked to images measured, however strict measurement protocols as above minimised risk of bias. A single author measured all images.

Study size, variables and statistical methods

A sample size of 60 was calculated by hypothesising what clinically acceptably accurate ratios and confidence intervals might be. A 99% confidence interval (CI) of +- 15% around a hypothesised mean of 90% and standard deviation (SD) of 45% was considered sufficient, based on anticipated estimated minimum and maximum values of 20% and 200%. Random sampling was performed until 60 uninjured, un-intubated patients were identified. During this phase 13 intubated patients were also included as they were randomly interspersed. Provisional data analysis was performed. Random sampling then continued until another 10 un-intubated (and 1 intubated) patients were added. Due to counting error, 11 un-intubated patients were added. Repeat data analysis failed to show a clinically significant difference in the consistency of measured soft tissue-to-vertebral body ratios with the increase of the sample size so data collection was concluded. 20 injured patients were captured during random sampling as well as additions from pre-existing records.

Data management and analysis was conducted in Stata 14. Simple descriptive statistics were used `for demographic data. Age in years was grouped into categories according to international conventions[18,19]. The primary outcome was reported using means and 95% confidence intervals. The appropriate parametric and non-parametric tests were used and a *p*-value of < 0.05 was considered statistically significant. Ratios for every soft tissue thickness to every vertebral body width (42 ratios) were created in un-intubated controls. Two ratios with the lowest standard error (one for upper and one for lower C-spine) were defined as the most consistent. ROC analysis was used to compare these ratios against un-intubated cases in identifying the optimal diagnostic cut-point. A sensitivity analysis was conducted by excluding poor quality X-rays. Missing data was excluded.

Funding

No funding was necessary for this study.

Results

Participants and selected descriptive results

A total of 2570 C-spine X-rays were digitally accessible. 893 were conventional or mobile C-spine X-rays and 1731 were LODOX which included dedicated lateral C-spine views. During random sampling, 48 patients with X-rays taken for non-traumatic reasons were excluded. Four patients with injury were identified by chance and added to the 16 known cases. See Flow diagram 1.

Table 2 provides a summary of demographic data.

Flow diagram 1: Sampling of X-rays

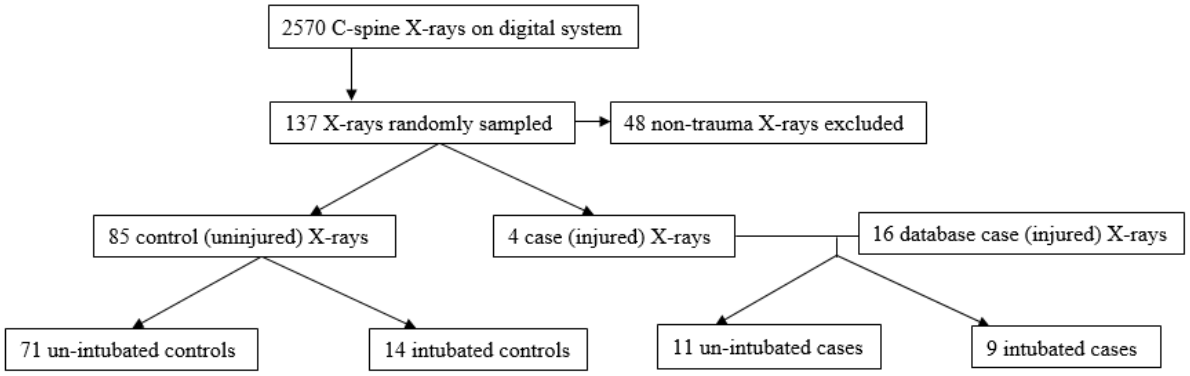


Table 2: Sample Demographics

	Controls n (%)	Cases n (%)
Gender		
Male	60 (70.6)	18 (90)
Female	25 (29.4)	2 (10)
Age		
0 – 1 month	0 (0)	0 (0)
1 month – 2 years	10 (11.8)	0 (0)
2 – 6 years	38 (44.7)	13 (65)
6 – 12 years	35 (41.2)	7 (35)
12 – 18 years	2 (2.3)*	0 (0)
Mechanism of Injury		
Pedestrian vehicle accident	56 (65.9)	10 (50)
Motor vehicle accident	7 (8.2)	8 (40)
Fall from Height	12 (14.1)	1 (5)
Fall from Same Level	4 (4.7)	0 (0)
Blunt Trauma	3 (3.5)	1 (5)
Crush	1 (1.2)	0 (0)
Bicycle to Car	1 (1.2)	0 (0)
Unknown	1 (1.2)	0 (0)
Intubation status		
Not intubated	71 (83.5)	11 (55)
Intubated	14 (16.5)	9 (45)
Type of injury		
Upper cord oedema/contusion	n/a	5 (25)
Cord transection at medulla oblongata	n/a	1 (5)
Atlanto-occipital dissociation	n/a	3 (15)
Upper spine ligamentous injury	n/a	1 (5)
C1/2 subluxation	n/a	1 (5)
Dens fracture	n/a	3 (15)
C1 lamina/anterior arch fracture	n/a	1 (5)
C2 fracture	n/a	1 (5)
Cord oedema/contusion C3-T2	n/a	1 (5)
C3/4 unifacet dislocation	n/a	1 (5)

C6/7 dissociation (100% anterolisthesis)	n/a	1 (5)
C7/T1 fracture-dislocation	n/a	1 (5)

* Both patients were under 13 years old and were analysed together with the 6 – 12 years group during subgroup analysis.

Eighteen of the 735 potential soft tissue measurements were not possible due to poor visualisation (six at c1, one each at c2-c6 and nine at c7). Ten of the 630 possible vertebral body measurements were similarly unmeasurable (one each at C5 and C6 and eight at C7).

The ADI could be measured in 78 controls and the mean was 2.6mm (SD 1.1). ADI could be measured in all 20 cases and had a mean of 3.6mm (SD 3.3). BD could only be measured in 48 of the 85 controls and had a mean of 9.4mm (SD 2.8). BD was measurable in 13 cases with a mean of 11.3mm (SD 5.8).

Main outcome results

The soft tissue / vertebral body ratio for the upper C-spine with the lowest variance in un-intubated control patients was c2/C7, with mean c2 soft tissue being 38% of C7 vertebra (95%CI:34-41.9%, SE:2.0%, variance:2.5%). For the lower C-spine the most consistent ratio was c6/C7 with mean c6 soft tissue being 65.6% of C7 vertebra (95%CI:61.9-69.3%, SE:1.9%, variance:2.3%). As a sensitivity analysis, excluding X-rays reporting that the neck was flexed or the patient was crying resulted in more precision and very slightly lower mean in c2/C7 (2% less) but no clinical or statistical difference. For these reasons, and as the study is pragmatic, it was decided to keep these X-rays in the overall analysis. In the study sample, those poor X-rays were not repeated before further clinical decisions were made. See Table 3 for a summary of these ratios in different patient groups.

Table 3: c2/C7 and c6/C7 Ratios in Subgroups

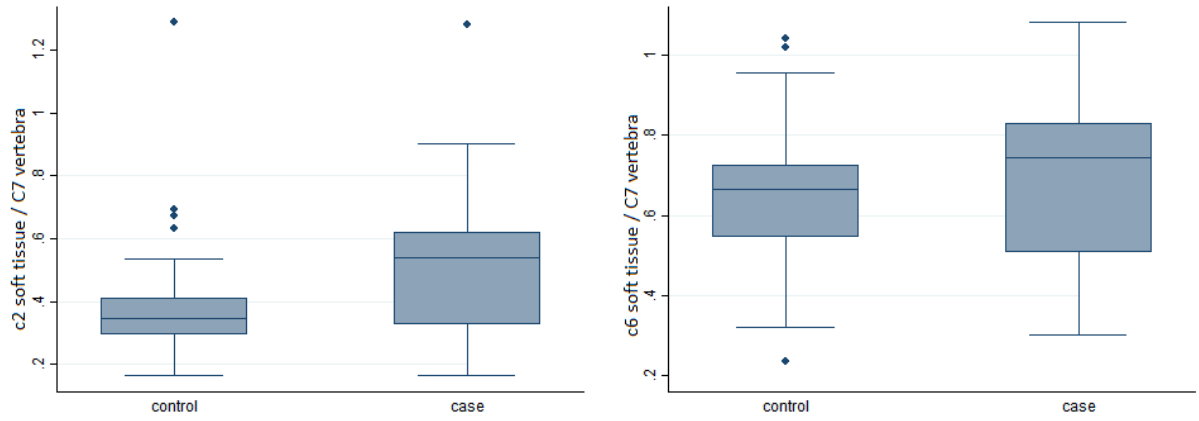
	c2 Soft Tissue as % of C7 Vertebra*	c6 Soft Tissue as % of C7 Vertebra*
No C-spine Injury (n=85) Not Intubated (n=71) Intubated (n=14)	42.7 (37.4 – 48) 38 (34 – 41.9) 65.9 (44.5 – 87.3)	62.2 (58.3 – 66.1) 65.1 (61.5 – 68.8) 44.9 (34.6 – 55.2)
C-spine Injury (n=20) Not Intubated (n=11) Intubated (n=9)	65.2 (48.5 – 81.1) 56.3 (33.5 – 79) 74.0 (50 – 98)	59.3 (47 – 71.6) 71 (54.6 – 87.3) 47.7 (32.2 – 63.2)

* Means and 95% confidence intervals.

Secondary outcome results: correlation and diagnostic accuracy

Soft tissue ratios at c2 and c6 in un-intubated controls were compared to un-intubated cases to determine the correlation between soft tissue thickness and the presence of injury. The point-biserial correlation coefficient for c2/C7 was 0.3060 (*p*-value:0.0085) and for c6/C7 was 0.1059 (*p*-value:0.3660). See Box Plot 1 for a visual representation of the relationship between these ratios and C-spine injury in un-intubated patients.

Box Plot 1: c2/C7 and c6/C7 in Un-Intubated Controls and Cases



Soft tissue thickness at these levels (as a ratio of C7 vertebra) in un-intubated controls were again compared to un-intubated cases in order to determine cut-off points with optimal sensitivity and specificity to diagnose C-spine injury. Most importance was placed on specificity. A ROC curve calculation gave empirical optimal cut-points of 53.9% for c2/C7 and 74.4% for c6/C7. To create a clinically practical and easy-to-remember "CSPINE Rule", these values were rounded up to a cut-off of 55% at c2 and 75% at c6, which yields specificity of 92.3% (95%CI:83-97.5%) and 81% (95%CI:70.4-90.2%) respectively, with negative predictive values of 90.9% (95%CI:81.3-96.6%) and 91% (95%CI:81.3-97.2%). See Tables 4,5 and Box 1 for a summary of the diagnostic test characteristics and Graph 1 for the ROC curve.

Table 4: Diagnostic Accuracy of the CSPINE Rule at c2

	C-spine Injury	No C-spine Injury	Total
c2 Soft Tissue >= 55% C7 Vertebra	3	4	7
c2 Soft Tissue < 55% C7 Vertebra	6	60	66
Total	9	64	73

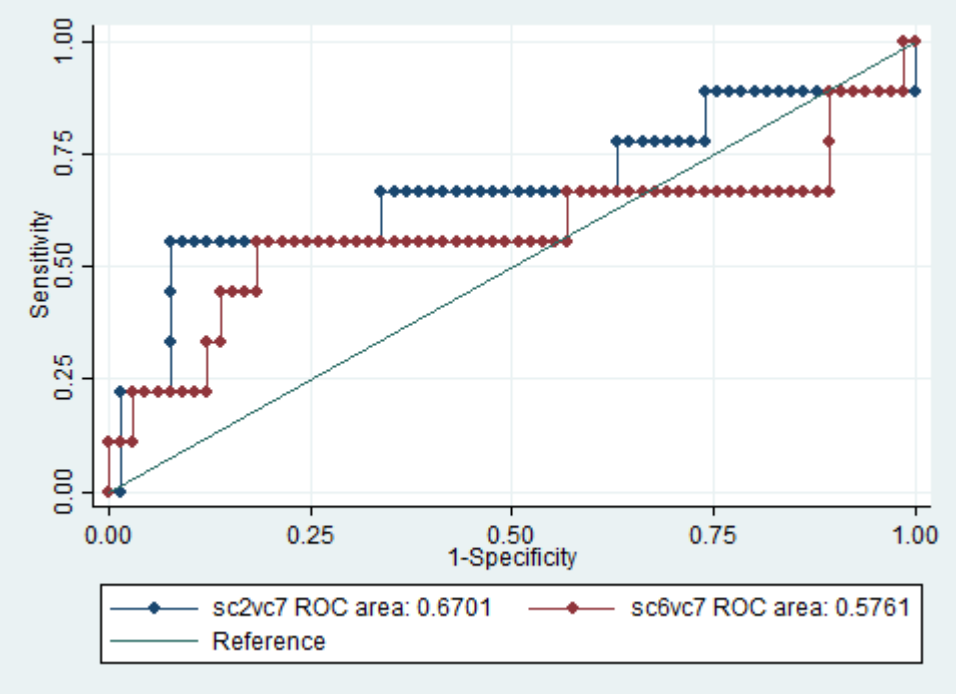
Table 5: Diagnostic Accuracy of the CSPINE Rule at c6

	C-spine Injury	No C-spine Injury	Total
c6 Soft Tissue >= 75% C7 Vertebra	4	12	16
c6 Soft Tissue < 75% C7 Vertebra	5	54	59
Total	9	66	75

Box 1: Test Characteristics of the CSPINE Rule

c2/C7 < 55%:	Sensitivity 33.3% (95% CI 7.5 – 70.1%)
	Specificity 93.8% (95% CI 84.8 – 98.3%)
	Positive predictive value 42.9% (95% CI 9.9 – 81.6%)
	Negative predictive value 90.9% (95% CI 81.3 – 96.6%)
c6/C7 < 75%:	Sensitivity 44.4% (95% CI 13.7 – 78.8%)
	Specificity 81.8% (95% CI 70.4 – 90.2%)
	Positive predictive value 25% (95% CI 7.27 – 52.4%)
	Negative predictive value 91.5% (95% CI 81.3 – 97.2%)

Graph 1: ROC curves for c2/C7 and c6/C7



sc2vc7: soft tissue of c2 as a ratio of C7 body; sc6vc7: soft tissue of c6 as a ratio of C7 body

Secondary outcome results: effect of intubation on soft tissue thickness

Soft tissue thickness at each level was, for convenience, expressed as a ratio of C7 vertebra and compared between un-intubated and intubated patients. See Table 6.

Table 6: Soft Tissue Thickness in Intubated vs Un-Intubated Control Patients

Soft Tissue Thickness	Un-intubated mean (SD)	Intubated mean (SD)	*p*-value*

(as a Percentage of C7 Vertebra)			
c1	55.6 (38.1)	109.6 (82)	0.0213
c2	38 (15.8)	65.9 (38.9)	0.0098
c3	48 (28)	67.2 (29.7)	0.0239
c4	68.4 (24.8)	64.3 (23)	0.2926
c5	73.5 (18.4)	53.5 (19.8)	0.0005
c6	65.6 (15.1)	44.9 (18.7)	0.0006
c7	52 (22.2)	39.9 (17.5)	0.0445

* Despite some ratios being normally distributed and others not, for the sake of consistency with other tables the mean is reported. However, *p*-values for the Wilcoxon rank-sum test are reported for all variables in this table as it provided the more conservative measure of significance compared to the t-test. Both tests also had the same result for significance or non-significance except c7, but as it followed the general trend it was assumed to be significant.

Subgroup and confounder analysis

Subgroup analysis was performed for infants (1 month – 2 years), young children (2-6 years) and older children (6-13 years). See Table 7 for a summary of c2/C7 and c6/C7 in un-intubated control patients in these age groups.

Table 7: c2/C7 and c6/C7 by Age Groups (un-intubated controls)

	c2 Soft Tissue as % of C7 Vertebra*	c6 Soft Tissue as % of C7 Vertebra*
Infants (1 month – 2 years)	46.3 (38.2 – 54.5)	57.6 (36.2 – 78.9)
Young children (2 – 6 years)	41 (32.6 – 49.4)	68.1 (62.1 – 74.2)
Older children (6 – 13 years)	34 (30.7 – 37.2)	64.1 (60.4 – 67.8)

* Means and 95% confidence intervals.

Weight in kilograms was available for 36 out of 105 patients. The correlation coefficient for weight compared to soft tissue thickness in un-intubated control patients was -0.2111 (*p*-value 0.3582) for c2/C7, and -0.3056 (*p*-value 0.1667) for c6/C7.

Discussion

Summary and interpretation of key results

In our sample of un-intubated and uninjured patients, very consistent soft tissue to vertebral body ratios for both the upper and lower C-spine could be selected. Both were normally distributed and confidence intervals were much narrower than what was anticipated as acceptable in the sample size calculation hypothesis. At c2, mean soft tissue was 38% of C7 vertebra (95%CI:34-41.9%) and c6 was 65.6% of C7 vertebra (95%CI:61.9-69.3%). The serendipitous fact that both ratios with least variability have C7 as a denominator make them extremely convenient. It also indirectly reinforces the need for adequate C-spine X-rays, i.e. where the C7 and first thoracic vertebra interface is visible.

The upper C-spine ratio, c2/C7, was significantly larger in injured compared to uninjured patients regardless of intubation status. When considering only un-intubated patients, this increase was much more marked, with a statistically significant correlation coefficient of 30.6% (moderate positive relationship). The lower C-spine ratio, c6/C7, was not significantly different between uninjured and injured patients, even when only un-intubated patients were considered. The very slight trend towards a larger mean soft tissue in injured patients had a statistically non-significant correlation coefficient of 10.6% (weak positive relationship). The fact that upper C-spine swelling correlated more with injury than lower C-spine swelling is likely since most of the injuries in our sample were in the upper C-spine. This pattern of injury is consistent with international literature[20].

When testing sensitivity and specificity with the ROC curve, the mean value of c2/C7 at 38% scored poorly with a sensitivity of 66.7% and specificity of 60.9%. Even using the upper limit of the confidence interval, 41.9%, resulted in improving specificity only to 76.6% at the cost of dropping sensitivity to 55.6%. The ROC curve was used to calculate the optimal cut-point for specificity as a C-spine X-ray is not a screening test for the general population – it should be a diagnostic test for patients who have already been screened and suspected of C-spine injury by history and examination. The calculated optimal cut-point of 53.9% gave a specificity of 94% without worsening sensitivity further. Rounding up to a more memorable 55% (or even 54%) unfortunately dropped the sensitivity down to the next bracket (33.3%). However, the confidence intervals for sensitivity are extremely wide due to the low prevalence of injury, so the drop is statistically non-significant. The decision was made to suggest a rule that c2 soft tissue should be less than 55% of C7 vertebra. The method to develop the rule to suggest that c6 soft tissue should be less than 75% of C7 vertebra followed similar patterns. DeBehnke and Havel[21] employed comparable methodology in adults and found similar patterns but did not accept any point on the ROC curve as adequate. Patel, et al[22] also demonstrated similar high specificities and low sensitivities in testing adults using the "7mm at C2 and 2cm at C7" rule.

Both ratios have extremely poor sensitivities, therefore are poor screening tools, but can aid in ruling in injury in patients with high clinical suspicion of injury due to high specificity. The good negative and poor positive predictive values reflect low prevalence of injury.

The effect of intubation in uninjured controls was to clinically and statistically significantly increase soft tissue thickness in the upper C-spine (c1-3). At c4 there was no difference. Below c4 intubation significantly decreased soft tissue thickness. The lack of difference at c4 is possibly due to the inherent anatomic variability at the level of c4 due to the position of the glottis, or due to its fulcrum-like mid-position in the trend of upper C-spine tissue increasing and lower C-spine tissue decreasing after intubation. In injured patients, the effect of intubation at c2 and c6 followed the same trend, but without statistical significance. These findings in the upper C-spine are similar to Di Mascio and Sivaraman's[7] findings in adults, but the lower C-spine trend of decreased soft tissue thickness below c4 is in contrast to their findings of no difference.

Confounder analysis determined whether weight or age influenced soft tissue thickness. Weight was unavailable in about two-thirds of patients, possibly due to difficulties in placing polytraumatised patients on scales. In our sample, weight and soft tissue thickness were found to have a weak negative correlation but without statistical significance.

Age had no effect on c6/C7, as evidenced by the overlap of all three confidence intervals for available age groups. At c2, however, there seemed to be a trend towards decreasing soft tissue thickness as age increased. Confidence intervals overlapped between infants and young children, and between young and older children, but were statistically different with no overlap between

infants and older children. These, however, come very close to overlapping, with the upper limit in older children being 37.2% and the lower limit in infants being 38.2%. As these values are so close to the all-ages population mean it was decided that the difference between ages was not clinically significant. The finding of a single useful ratio across age groups is in contrast with Hay's[3] recommendations which are different between age groups.

Limitations and generalisability

The study sample consisted of a much smaller group of cases than controls. This, however, is more closely representative of clinical practise where C-spine injury has a relatively low prevalence, and as this is a cross-sectional study it was considered a minor limitation. The study was powered to measure normal values for soft tissue thickness in uninjured, un-intubated patients. Testing diagnostic accuracy and development of the optimal cut-point as a rule in diagnosing C-spine injury were secondary objectives, so the sample size was not designed for that purpose. However, the specificity has an acceptably narrow confidence interval to be of clinical use. There would need to be 95 cases in order to determine a similarly narrow interval for sensitivity, and there has anecdotally not been that many cases in the history of the hospital since their introduction of digital X-rays. The findings are specific to children between the ages of 1 month and 13 years and may not be generalisable to neonates, adolescents or adults.

There were only four lower C-spine injuries and they were not specifically sub-analysed. No recommendation can therefore be made regarding the use of these findings in patients with lower C-spine injuries. Comments and conclusions about the diagnostic accuracy of the CSPINE rule and the correlation of soft tissue thickness and the presence or absence of injury in this study refers only to the possibility of an injury *somewhere* in the C-spine rather than being directly related to an anatomical area. There is potential for further research in the diagnostic value of these ratios in different types of paediatric C-spine injuries.

Word count

3200 (excluding headings, tables and legends)

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Appendices

Data capture sheet

CSPINE Data Collection Sheet																								
Study Number	Folder Number	Date of Birth	Date of X-ray	Gender	Weight	Mechanism of Injury	Soft Tissue Thicknesses							Vertebral body width										
							C1	C2	C3	C4	C5	C6	C7					C2	C3	C4	C5	C6	C7	
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CSPINE Data Collection Sheet							
ADI	BD	Report of soft tissue swelling	Report of bony abnormality	CT abnormality (Y/N/I or N/A)	MRI abnormality	C-spine clinically clear	Nature of C-spine injury	Comments

Ethics approval letter

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07 March 2016

HREC REF: 118/2016

Dr S Mears
Division of Orthopaedics
H-49
OMB

Dear Dr Mears

PROJECT TITLE: CSPINE: CORRELATING SOFT TISSUE PROJECTIONS IN INJURED NECKS (MMeD candidate Dr J McCaul)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

Thank you for an excellent synopsis.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study. This approval is subject to data collection period starts February 29th 2016, and work backwards. The HREC have provided this date, as no date for the retrospective period has been provided.

Approval is granted for one year until the 30 March 2017.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the following student, Dr Jeanine McCaul will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC/REF:134/2016

Study staff change approval

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS007: Amendment – study staff

HREC office use only (FWA00001637; IRB00001938)			
☑ Approved			
This serves as notification that all changes to the study staff and documentation described below are approved.			
Chairperson of the HREC signature	pp T Burgess	Date	09/01/2017

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	12/12/16
HREC REF Number	118/2016
Protocol title	CSPINE (Correlation of Soft tissue Projections in Injured Necks
Protocol number (if applicable)	
Principal Investigator	Anria Horn (Supervisor of Student Jeannie McCaul)
Department / Office Internal Mail Address	Orthopaedics, Red Cross hospital jkmccaul@gmail.com

06 JAN 2017
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

1.1 Does this protocol receive US Federal funding?	☐	☐ No

2.1 Staff changes (tick ✓)

Are new personnel being added to this research?	☐ Yes	☐
Are current personnel being removed from this research?	☐ Yes	☐
Is the principal investigator for this research being changed? If yes, please attach revised conflict of interest and PI declaration statements. (Refer: sections 7 and 8.3 in the New Protocol Application Form - FHS013)	☐ Yes	☐
Do the consent and assent forms need modification to reflect these staff changes? If yes, please attach copies of the revised forms, with all changes highlighted or tracked and listed in the documents for approval.	☐	☐ No

2.2 Amended study staff details

Title, first name, surname	Department/Division	E-mail	Role of new staff member
Dr Anria Horn	Orthopaedics, Red Cross Hospital	anriahorn@gmail.com	Supervisor and PI

3. List of documentation for approval

Please list below all staff documentation such as CVs, declarations, GCP certificates and revised consent forms which need approval. This information must correspond to all 'yes' answers in 2.1 above. This form will be signed and returned to the PI as notification of approval. Please add extra pages if necessary.

No Consent forms necessary
Not a clinical trial therefore GCP not mandatory
CV: Attached CV of Dr Anria Horn

4. Signature

My signature certifies that I will maintain the anonymity and/ or confidentiality of information collected in this research. If at any time I want to share or re-use the information for purposes other than those disclosed in the original approval, I will seek further approval from the HREC.

Signature of PI		Date	12/12/16

Permission to conduct research at Red Cross Hospital

Dr AS Booysen
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Dr McCaul
Red Cross War Memorial Children's Hospital

Dear Dr Dr McCaul

APPROVAL OF RESEARCH

PROJECT TITLE: CORRELATING SOFT TISSUE PROJECTIONS IN INJURED NECKS

It is a pleasure to inform you that approval is hereby granted to conduct the above-mentioned study at Red Cross War Memorial Children's Hospital.

Yours sincerely,

Dr AS Booysen
Manager: Medical Services
Date: 06.06.16

Instructions to Authors, Journal of Bone and Joint Surgery

Journal chosen due to its high impact factor

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Manuscripts must be submitted as a Word file, and cannot exceed 3,200 words, including the Abstract but excluding references and figure legends. Manuscripts not meeting these specifications will be returned for modification. JBJS does not consider manuscript proposals or abstracts submitted online or via e-mail.

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A **Structured Abstract** consisting of 5 paragraphs, totaling no more than **325** words, with the headings: *Background* (stating the primary research question), *Methods*, *Results*, *Conclusions*, and Level of Evidence (for clinical articles) or Clinical Relevance (for basic-science articles).
The **Level of Evidence** should be assigned according to the definitions in the *Level of Evidence* table. This rating will be reviewed by a JBJS Deputy Editor, who will make the final determination.

The **body** should consist of:

Introduction: State the problem that led to the study, including a concise review of only the relevant literature. State your hypothesis and the purpose of the study. It is preferable that this be done in the form of a research question that describes the setting of the study, the population or sample studied, and the primary outcome measure.

Materials and Methods: Describe the study design in detail using standard methodological terms. Reports of randomized controlled trials should follow the *twenty-five-item checklist* developed by the *CONSORT* Group. Submissions reporting cohort, case-control, and cross-sectional studies should conform to the format suggested by the *STROBE* panel. Reporting of meta-analyses should conform to the *PRISMA* Statement criteria. Refer to our detailed guidelines for writing a *Materials and Methods* section for additional guidelines.

Source of Funding: Include a brief statement explaining the role of the funding source for the study (if none, or if funding source did not play a role in investigation, that should be stated).

Results: Provide a detailed report on the data obtained during the study. All measurements should be presented in metric values. Results of many reconstructive procedures, such as total joint arthroplasty, should be based on at least a 2-year follow-up of each patient. An average of two years of follow-up is generally not sufficient. If the follow-up is shorter, provide a strong scientific justification for why the focus on shorter follow-up is clinically relevant.

Discussion: Be succinct. What does your study show? Is your hypothesis affirmed or refuted? Discuss the importance of this article with regard to the relevant world literature; however, a complete literature review is unnecessary. Analyze your data and discuss their strengths, their weaknesses, and the limitations of the study.

A reference section, in PubMed/Index Medicus format, must be included after the manuscript text. Number the references according to the order of citation in the text (not alphabetically), and cite all references in the text.

Figure legends must be included at the end of the manuscript text file, after the References section, for all images. Explain what each figure shows. Identify machine settings for magnetic resonance images, and give the magnification of all photomicrographs. Define all arrows and other such indicators appearing on the figure.

Figures must be submitted in TIFF or EPS format. No more than 10 separate image files may be submitted. Cite all figures, in order, in the text. See *Guidelines for Figures* for detailed instructions.

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There is a general limit of 6 authors. If more than 6 are listed, include a table detailing each author's contribution in the cover letter.

Each author must have contributed significantly to, and be willing to take public responsibility for, one or more aspects of the study: its design, data acquisition, and analysis and interpretation of data. All authors must have been actively involved in the drafting and critical revision of the manuscript, and each must provide final approval of the version to be published. If a research group is designated as the author of an article, see our *Group Authorship* instructions for guidance.

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