Morphometric evaluation of C1 pedicle and lateral mass for screw fixation in Kelantan : Feasibility study using CT scan

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Morphometric evaluation C1 pedicle and lateral mass for screw fixation in Kelantan: Feasibility study using CT scan

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STUDY VENUE: HOSPITAL UNIVERSITI SAINS MALAYSIA

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TABLE OF CONTENTS

CHAPTER 3: MANUSCRIPT

CHAPTER 4: APPENDICES

ABSTRAK

Pengenalan

Teknik skru melalui ‘posterior arch screw’ adalah cara alternatif kepada skru melalui ‘lateral mass’ untuk tulang atlas (C1). Beberapa kajian telah membuktikan kelebihannya berbanding teknik skru ‘lateral mass’. Faktor yang paling penting untuk menentukan kemasukan skru dalam ‘posterior arch’ adalah ketinggian menegak pedikel, dan beberapa kajian telah membuktikan kepentingannya. Walaubagaimanapun, ia perlu digunakan dengan berhati-hati dalam populasi kita disebabkan saiz pedikel yang lebih kecil yang mungkin tidak dapat memuatkan skru bersaiz konvensional, iaitu 3.5mm. Oleh yang demikian, kami telah menjalankan satu kajian morfologi untuk veterbra C1 dengan menggunakan skan CT bagi menentukan kebolehlaksanaan untuk skru ‘posterior arch’.

Kaedah Kajian

Kami telah menjalankan kajian hirisan lintang ke atas vertebra C1 dengan menggunakan skan CT dengan ketebalan 1.0mm. Keadaan yang menjejaskan anatomi normal contohnya, patah C1, jangkitan C1, kanser yang melibatkan C1 atau masalah kongenital C1, dikecualikan dari kajian ini. Slaid skan CT (rentas dan menegak) yang dikehendaki didapatkan selepas rekonstrusi imej skan CT. Semua parameter telah diukur sehingga 0.1mm, analisa stastistik telah dijalankan dengan menggunakan SPSS versi 20. Selain itu, “independent t-test” telah dijalankan untuk menentukan sama ada perbezaan ketara wujud di antara jantina dan kiri atau kanan. Analisa deskriptif digunakan untuk mencari purata bagi ukuran numerik.

Keputusan

Purata ketinggian pedikel luar adalah 3.5mm untuk kiri dan kanan. Ketinggian 'lateral mass' untuk kesemua 82 pesakit lelaki adalah lebih dari 3.5mm. 19.5% (kanan) dan 25.6% (kiri) Ketinggian 'lateral mass' Di kalangan pesakit lelaki adalah kurang dari 4.0mm. Ketinggian pedikel luar bagi pesakit lelaki , 43.9% (kanan) dan 40.2%(kiri) adalah kurang dari 3.5mm, 79.3%(kanan) dan 78.0%(kiri) adalah kurang dari 4.0mm. Ketinggian lateral mass pesakit wanita, 12.9% (kanan) dan 9.7% (kiri) adalah kurang dari 3.5mm, 48.4%(kanan) dan 51.6% (kiri) kurang dari 4.0mm , 83.9% (kanan) dan 90.3% (kiri) adalah kurang dari 4.5mm. Ketinggian pedikel golongan pesakit wanita, 77.6% (kanan) and 74.2 % (kiri) adalah kurang dari 3.5mm, 90.3% (kiri dan kanan) adalah kurang dari 4.0mm. Kami juga mendapati bahawa kaviti medulari 'posterior arch' C1 tidak wujud dalam sekumpulan besar pesakit kami (Lelaki-28.0-31.7%, wanita-54.8-58.1%)

Kesimpulan

Kemasukan skru pada posterior arch C1 dalam populasi ini perlu dijalankan dengan berhati-hati dan skan CT wajib dijalankan sebelum prosedur ini dijalankan untuk mempastikan kesesuaian ketinggian pedikel dan kewujudan kaviti medulari posterior arch terutamnya dalam golongan wanita. Teknik skru lateral mass boleh dilakukan dan lebih selamat, maka ada pilihan untuk instrumentasi C1.

Key Words:

Atlas(C1), posterior arch screw, C1 pedicle screw, CT scan, Malaysians

ABSTRACT

Introduction

Posterior arch or pedicle screw is an alternative fixation method to lateral mass screw of the altas (C1). Several studies had shown its advantages over conventional C1 lateral mass screw. The most important factor to determine the feasibility of posterior arch screw insertion is the vertical pedicle height of posterior arch, which several studied had proved its feasibility . However, it must be used with caution in our population as the posterior arch size may not be able to accommodate the conventional 3.5mm pedicle screw. Hence, we performed a mophormetric study of C1 vertebrae using CT scan to determine the feasibility of screw insertion.

Materials and methods

We performed a cross sectional study to analyse 113 C1 veterbrae using CT using 1.0mm slice thickness. Those who had fracture of C1, infection of C1, tumorous condition of C1 and any congenital deformities of C1 were excluded from this study. Desired axial and sagittal CT scan slices was obtained for measurement after reconstruction of images and slice through the desired anatomical landmark. Each parameter was defined anatomically using appropriate landmark. All the parameters were measured up to 0.1mm twice and the mean was taken, and the statistical analysis was done using SPSS version 20. Independent t-test was use to determine the significant difference between sides and gender. Descriptive analysis for numerical variables were described as mean.

Results

The mean outer pedicle height were 3.5 mm for right and left sides. All lateral mass height in 82 male patients were more than 3.5mm. 19.5%(right) and 25.6%(left) of lateral mass height in male patients are smaller than 4.0mm. For outer pedicle height in 82 male patients, 43.9%(right) and 40.2%(left) were smaller than 3.5mm,79.3%(right) and 78%(left) were smaller than 4.0mm. For lateral mass height in 31 female patients, 12.9%(right) and 9.7%(left) were smaller than 3.5mm, 48.4%(right) and 51.6%(left) were smaller than 4.0mm, 83.9%(right) and 90.3%(left) were smaller than 4.5mm. For outer pedicle height in female patients, 77.6%(right) and 74.2 %(left) were smaller than 3.5mm, 90.3%(right and left) were smaller than 4.0mm. We also found out that C1 posterior arch medullary cavity were absent in a significant number of patients (male-28.0-31.7%, female-54.8-58.1%)

Conclusion

C1 posterior arch screw insertion in our population should be performed with caution and pre-operative CT scan is mandatory especially in female patients to determine the pedicle height and present of posterior arch medullary cavity before any posterior arch screw insertion. Lateral mass screw fixation is feasible and safer, therefore is the option of choice for C1 instrumentation

Key Words:

C1 screw, pedicle, lateral mass, feasibility

1.1 INTRODUCTION

Atlantoaxial articulation is the most mobile region in the vertebral column .It is responsible for the majority of neck rotation, of which 50% of total rotation occurs at the C1-C2 articulation. There are various causes for atlanto-axial instability, which can be broadly divided into traumatic, infection, malignancy, inflammatory and congenital malformations.

Treatment of atlanto-axial instability is either conservative or operative.

Operative fixation via posterior approach is preferable among surgeons. Various techniques of atlantoaxial fixation has been described including posterior wiring, interlaminar clamp, screw-plate construct, and screw-rod construct technique .

Lateral mass screw fixations of the cervical spine are effective and widely performed surgical procedures and became a standard way to stabilize the cervical spine in various clinical conditions. Transpedicular screw fixation is also performed by some surgeons in Caucasians population. However, the feasibility of transpedicular screw fixation of the atlas in our population has never been confirmed. The atlas pedicles in our population may be smaller than the Caucasians. Therefore, the exact diameter of the pedicles must be determined before transpedicular screw fixation is attempted. The morphology of the atlas for transpedicular srew fixation has been studied by both using cadavers and computerized tomography (CT) mostly performed in Caucasions , Japanese, Chinese and Indian populations

1.2 OBJECTIVE

General objective:

To determined the feasibility of convention 3.5mm polyaxial screw insertion via C1 pedicle

Specific:

1. To measure mean outer pedicle height (right and left)
2. To measure mean inner pedicle height (right and left)
3. To measure mean transverse pedicle diameter (right and left)
4. To measure mean pedicle screw length (pedicle length +lateral mass length, right and left)
5. To measure mean lateral mass height (right and left)
6. To measure mean transverse diameter of lateral mass (right and left)
7. To measure mean lateral mass length (right and left)
8. To determined the entry point of screw (distance of screw entry point from midline)
9. To measured the angle of screw trajectory (angle of pedicle axis)

2.1 DESERTATION PROTOCOL

DESERTATION PROPOSAL

TITLE: Morphometric evaluation of C1 pedicle and lateral mass for screw fixation in Kelantan : Feasibility study using CT scan

NAME : TEO YU MENG

SUPERVISOR : PROFESSOR MOHD IMRAN YUSOF

CO-SUPERVISOR: PROFESSOR MADYA MOHD SHAFIE ABDULLAH

Introduction

Atlantoaxial articulation the most mobile region in whole vertebral column .Atlantoaxial articulation is responsible for the majority of neck rotation, 50% of total rotation occurs at the C1-C2 articulation. Various causes can lead to atlanto-axial instability, which can be broadly divided into traumatic, infection, malignancy, inflammatory and congenital malformation. Trauma is the most common cause, including odontoid fracture (type II and type III), C2 pars interarticularis fracture and etc.

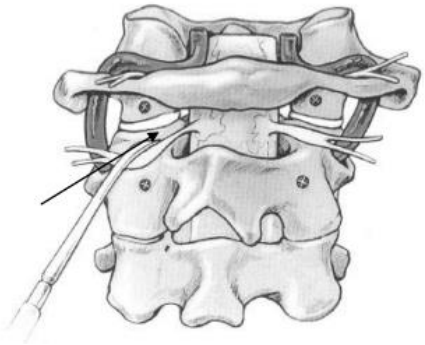
Treatment of atlanto-axial instability can be divided into conservative and operative management.

Operative fixation can be divided into anterior and posterior approaches. Posterior approach is more preferable among surgeons. Various technique of Atlantoaxial fixation has been describe including posterior wiring techniques, interlaminar clamp, screw-plate construct, screw-rod construct and etc .

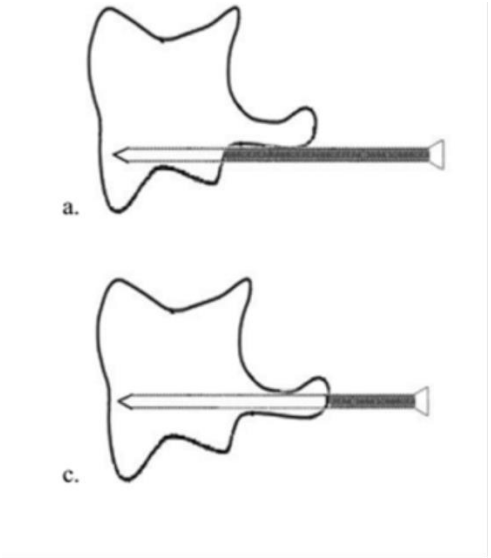
Lateral mass screw fixations of the cervical spine are effective and widely performed surgical procedures and becoming a standard way to stabilize the cervical spine in various clinical conditions such as trauma. Transpedicular screw fixation approach are performed by others but probably not as widely performed. However, the feasibility of transpedicular screw fixation of the atlas in our population has never been confirmed. The atlas pedicles in our population may be smaller than those in white populations. The exact diameter of the pedicles must be determined before any transpedicular screw fixation can be performed using stand polyaxial screw which is 3.5 mm in diameter. The morphology of the first cervical spine has been studied by both using cadavers and computerized tomography (CT) films and mostly performed in white populations and a few in Japan.

Literature review

1) Conventional lateral mass screw inserted directly via lateral mass under posterior arch. Harm et al described their technique in 2001 (Harms & Melcher, 2001). Exposure done to expose C1/C2 joint, which serve as an important landmark for accurate C1 lateral mass screw insertion. Dorsal root ganglion of C2 retracted caudally to exposed entry point, which was in the middle of the junction of C1 posterior arch and the midpoint of the posterior inferior part of the C1 lateral mass.



2) Tan el al in 2003 studied on 50 dried C1 human vertebra. Entry point was located 19.01 ± 1.88 mm lateral to midline and 2.03 ± 0.60 mm superior to the inferior border of C1 posterior arch or pedicle . Screw trajectories was perpendicular to the coronal plane and 5° cephalad to transverse plane (Tan et al., 2003).



Different entry point from lateral view. (a) conventional lateral mass screw

(b) Posterior arch screw/ pedicle screw

3) Ma et al compare the pullout strengths and the biomechanical stabilities of C1 lateral mass screw and C1 pedicle screw. He showed posterior arch screw offered statistically significant greater pull-out strength (Ma et al., 2009).
4) Several complication of lateral mass screw such as post operative occipital neuralgia and bleeding for venous plexus has been reported
(Conroy, Laing, Kenneally, & Poynton, 2010; Gunnarsson, Massicotte, Govender, Raja Rampersaud, & Fehlings, 2007)
5) Lee et al performed C1 pedicle screw technique in 12 patient and found out that no post operative occipital neuralgia and all have minimal blood loss. (Lee et al 2012)
6) Ma et al in 2005 , performed study on 50 dry C1 harvested from cadaver. He concluded that The heights of the C1 pedicle, the posterior arch under the groove and the posterior lamina at the screw entry point are the major determinants for the possibility of placing pedicle screws in C1 of a given patient. This study indicates that it is feasible to place a 3.5-mm pedicle screw safely in C1 in most patients

7) Serkan et al in 2009 , study on 40 C1 veterbra. He found out mean Height of the posterior arch of the C1 is 4.22mm $\pm$ 2.7mm, Mean Height of lateral mass is 3.66mm $\pm$ 0.8mm, Mean width of lateral mass is 12.32 mm$\pm$ 1.3mm. The entry point into the lateral mass of the atlas is the intersection of the posterior arch and the C1 lateral mass. The optimum medial angle is 13.5 ± 1.9 and maximal angle of medialization is 29.4 ± 3.0.

Justification of study

This study enable the us to choose the appropriate method of posterior screw fixation of Atlas (C1) in our population

Null hypotheses

3.5mm pedicle screw fixation is feasible for atlas fixation via the pedicles and the lateral mass

** A 3.5mm pedicle/lateral mass screw fixation is feasible for atlas if transverse and vertical diameter is >3.5mm*

Objective

General objective:

To determined the feasibility of convention 3.5mm polyaxial screw insertion via C1 pedicle

Specific:

1. To measure mean outer pedicle height (right and left)
2. To measure mean inner pedicle height (right and left)
3. To measure mean transverse pedicle diameter (right and left)
4. To measure mean pedicle screw length (pedicle length +lateral mass length, right and left)
5. To measure mean lateral mass height (right and left)
6. To measure mean transverse diameter of lateral mass (right and left)
7. To measure mean lateral mass length (right and left)
8. To determined the entry point of screw (distance of screw entry point from midline)
9. To measured the angle of screw trajectory (angle of pedicle axis)

Methodology

Research design

Cross sectional study

Study area

Hospital University Sains Malaysia

Study population

Reference population – All adults in Malaysia

Source population - All Malay adults who had done CT Scan of Cervical with bone window for Head Trauma in HUSM (from January 2015 to December 2015)

Informed consent – letter to Director of Hospital USM to use CT images for study purposes (as attached)

Subject criteria

1) **Inclusion criteria**
    - Age between 18 to 50
    - Male and female

2) **Exclusion criteria**
    - Fracture of C1 veterbra
    - Old fracture of C1 veterbra
    - Infection involved C1
    - Tumour conditions involved C1
    - Congenital abnormalities

Sample size estimation

For specific objective 1 – 9, determination of single mean.

Formula use for sample size calculation for single mean as below:-

$$n = \left(\frac{z(SD)}{\Delta} \right)^2$$

Standard deviation from Previous literature was 2.7mm. we wish to estimate the true mean within 0.5mm with 95 % confidence

N = (1.96 x 2.7 /0.5)2

N =113

**No drop out calculated as study using data from CT suite*

Sampling method

Evaluation of plain CT cervical with bone window of patients admitted to our institution for head trauma (HUSM) between January 2015 and December 2015 for the assessment of the cervical spine

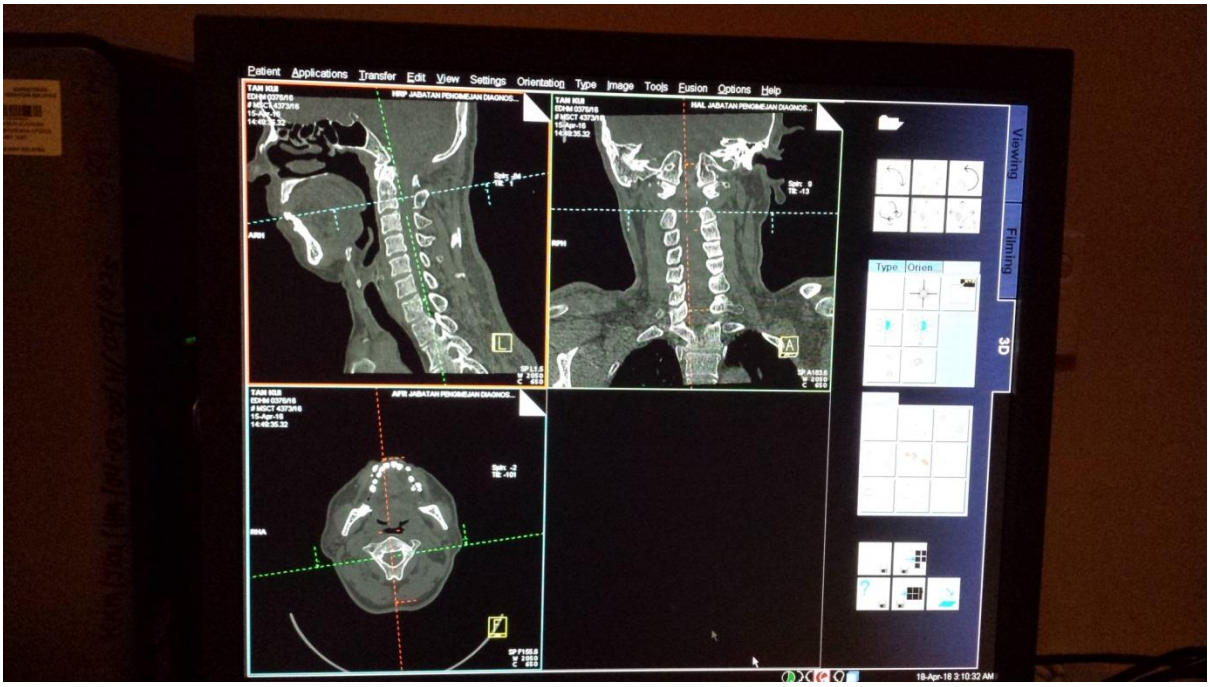
Sampling method – non probability

Research tool

- CT scan machine (TOSHIBA and SIEMEN)
- PACS system used for measurement
- Measurement will be done with manually computer mouse twice for each parameter, all measurement done in millimeter (mm), mean of 2 measurement will be taken

Data collection

1) Obtain desire slice for measurent (axial plane and sagittal plane)
   Reconstruction of bone window image done to obtain the desire slice for measurement (sagittal view and axial view)
   - Thickness of slice is 1mm for bone window
   - Adjustment of right and left similarity if there is rotation of the image



Obtaining Desired axial slice for measurement:-

- Desired axial slice is chosen after rotation and flexion-extension eliminated
- If both tubercles was not visualized in same image in case of rotation during CT scan, then clicking on tip of the visible tubercle, holding pointer in place while scrolling the image to locate another tubercle and complete the reference line
- Obtain sagittal slice throught midline (figure 1)
- drawing a line parallel to C1 posterior arch in sagittal plane to eliminate flexion-extension during CT scan (figure 2)
- reslicing through this line will get the desired axial slice for measurement

Obtaining Desired axial slice for measurement:-

Figure 1

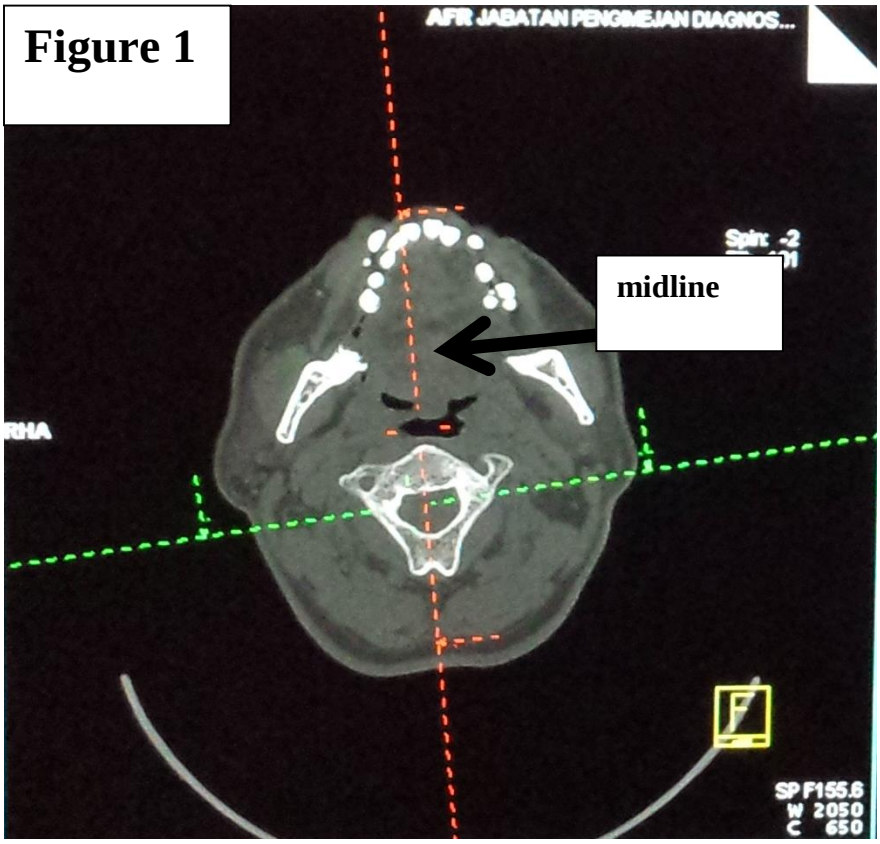
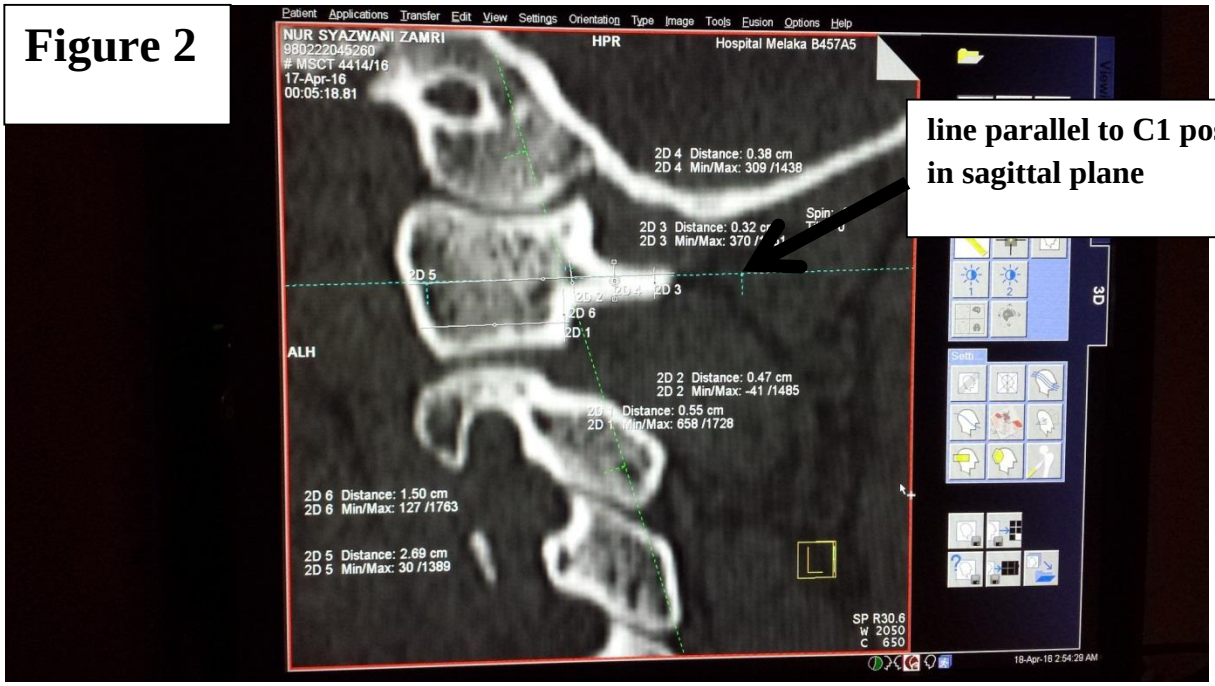


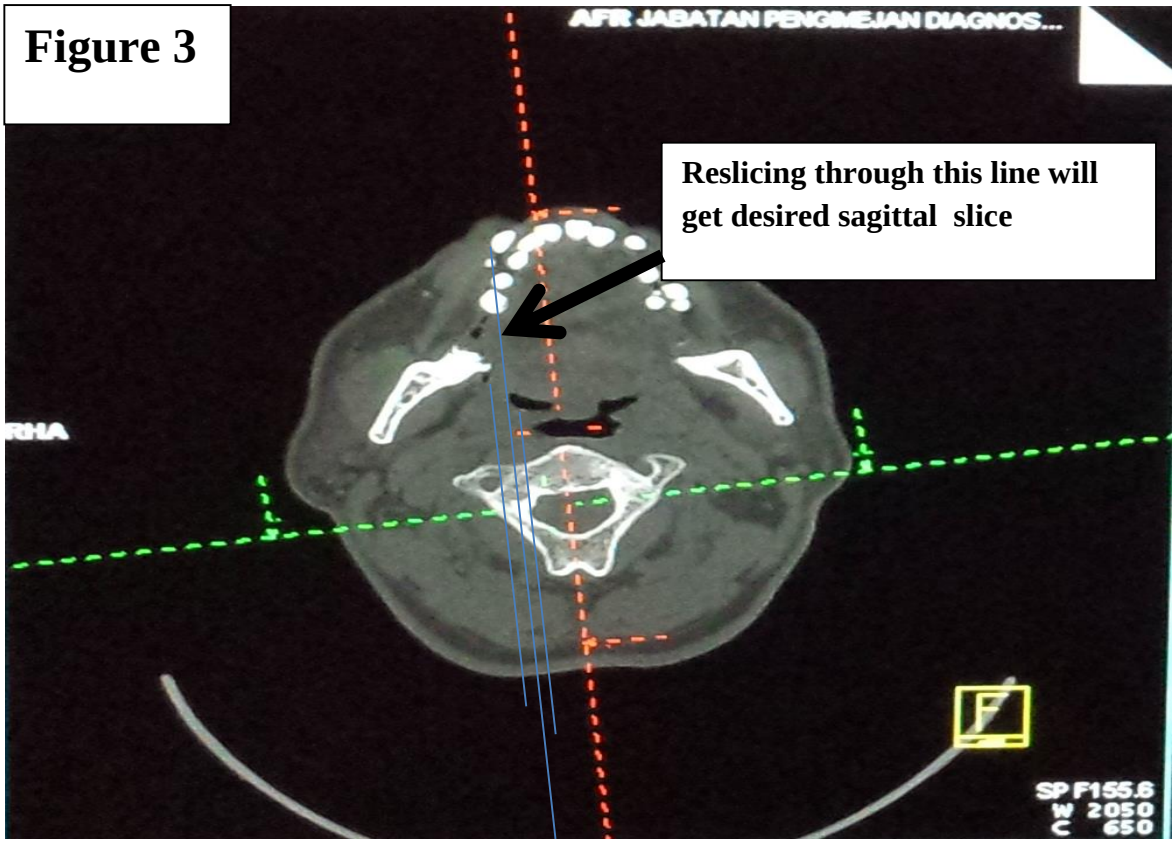
Figure 2



Obtaining Desired sagittal slice for measurement:-

- desired sagittal slice is chosen after rotation and flexion-extension eliminated
- a middle line is drawn connecting anterior and posterior tubercle on desired axial slice chosen
- 2 parallel line to the middle line is drawn touching inner cortex of canal of atlas and inner border of veterbral foramen
- another parallel line to the middle line is drawn between these 2 line
- reslicing of this line will get the desired sagittal slice (figure 3)

Figure 3



Measurement

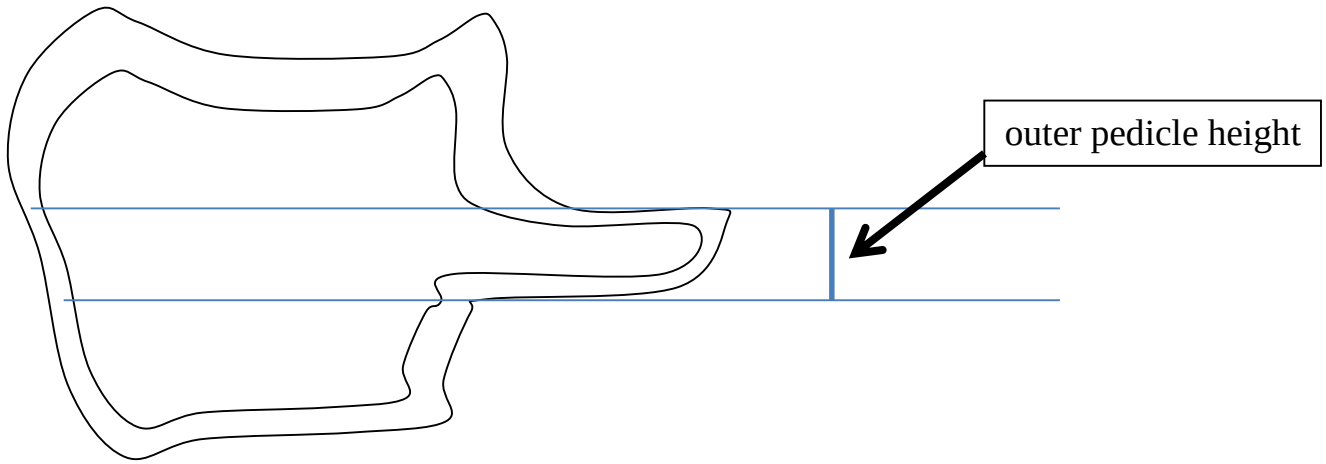
Specific Objective 1 -To measure mean outer pedicle height (**A)**

- defined as the distance between outer to outer cortex of pedicle

-desired sagittal slice chosen as mentioned above (right and left)

-a line is drawn antero-posteriorly touching the outer cortex of pedicle for both upper and lower borders

- a vertical line perpendicular to these line is drawn and the distance is measured in millimetre



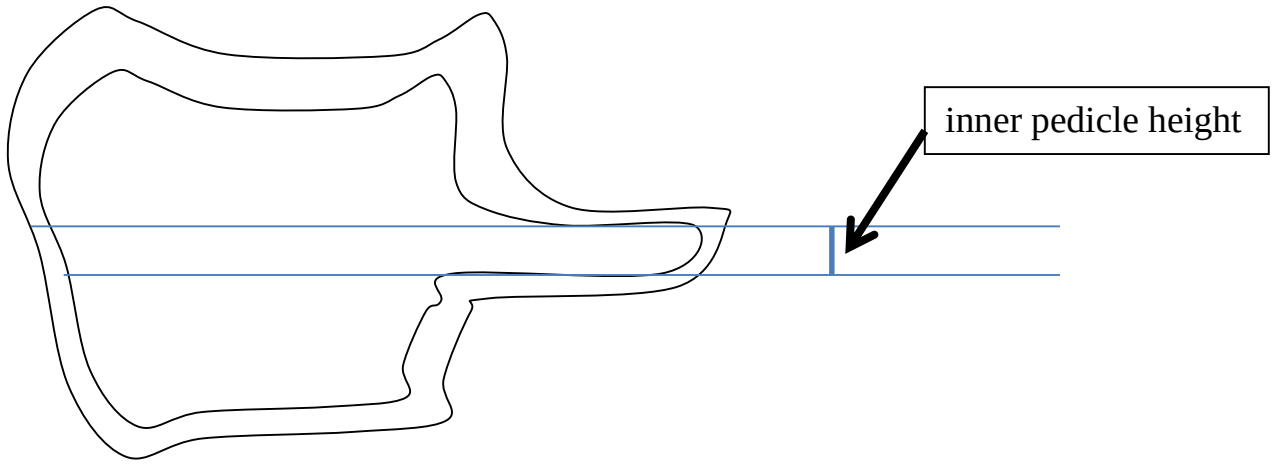
Specific Objective 2 -To measure mean inner pedicle height **(B)**

-defined distance between inner to inner cortex of pedicle

-desired sagittal slice chosen as mentioned above

-a line is drawn antero-posteriorly touching the inner cortex of pedicle for both upper and lower borders

- a vertical line perpendicular to these line is drawn and the distance is measured in millimeter



Specific Objective 3 - To measure mean transverse pedicle diameter **(C)**

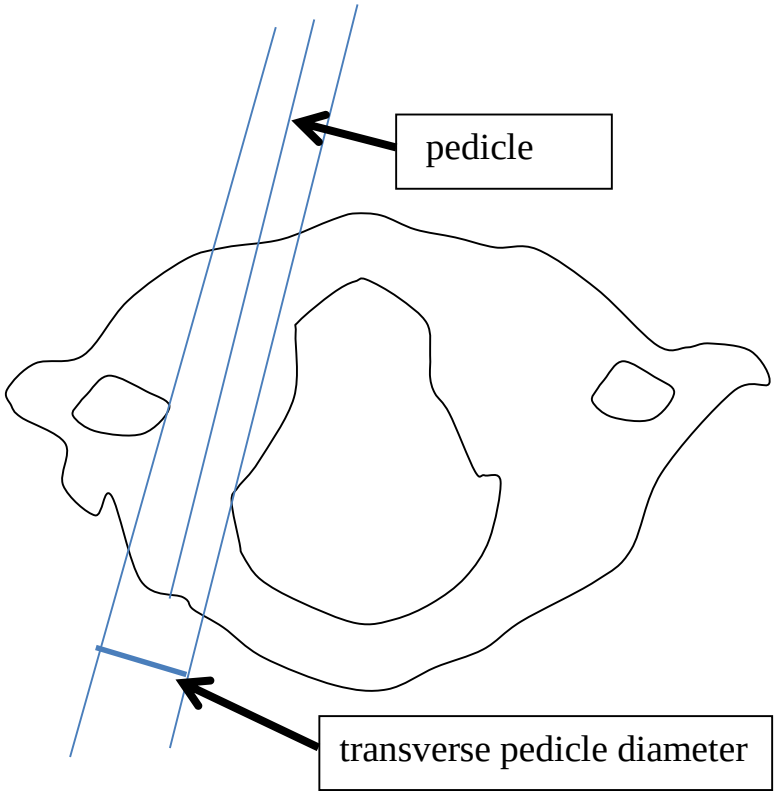
-determination of pedicle axis as mentioned in specific objective 9

- 2 parallel line drawn parallel to pedicle axis

-medial line parallel to pedicle axis and touching the most lateral part of inner cortex of atlas

-lateral line parallel to pedicle axis and touching the most medial part of inner border of vertebral foramen

-a perpendicular line to these 2 line is drawn and the distance measured in milimeter



Specific Objective 4 - To measure mean pedicle screw length **(F)**

- Pedicle length+ Lateral mass length (pedicle screw length)

- pedicle length is the distance between the tip of pedicle to posterior cortex of body of atlas

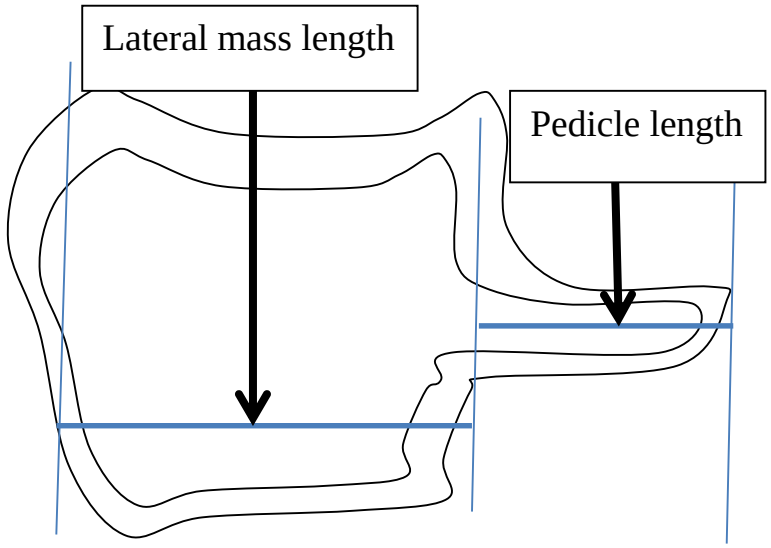
- lateral mass length is measured as in specific objective 7

-desired sagittal slice chosen as mentioned above

-a line is drawn vertically touching the tip of pedical and posterior cortex of body of atlas

- a horizontal line parallel to inferior border of body of atlas is drawn from tip of pedicle and the distance is measured in millimetre

- pedicle screw length obtained by adding pedicle length and lateral mass length



Specific Objective 5 - To measure mean lateral mass height **(D)**

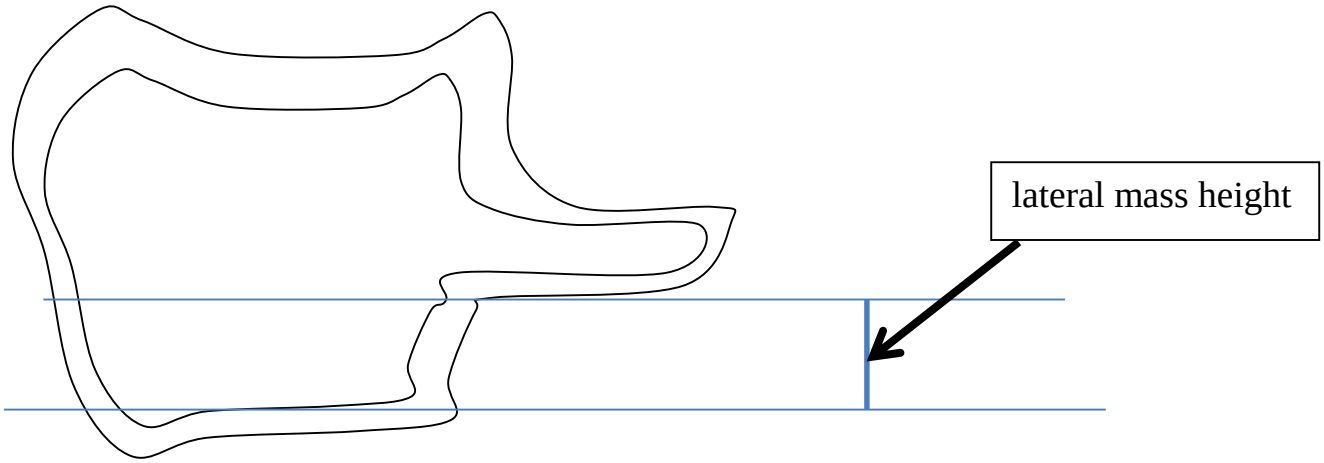
- defined as the distance between lower border of pedicle to inner cortex of inferior atlas body

-desired sagittal slice chosen as mentioned above

-a line is drawn antero-posteriorly touching the outer cortex of inferior border of pedicle

-another line is drawn parallel to the first line touching inner cortex of inferior atlas body

- a vertical line perpendicular to these line is drawn and the distance is measured in millimeter



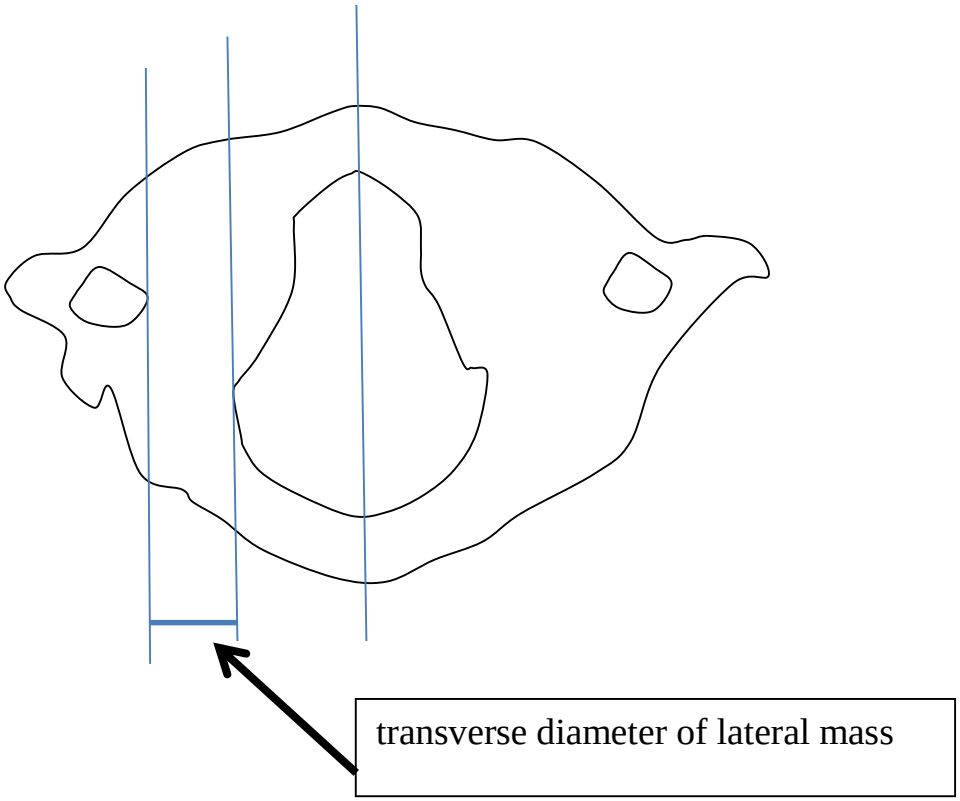
Specific Objective 6 - To measure mean transverse diameter of lateral mass **(E)**

- defined as distance between outer cortex of canal of atlas and inner border of veterbral foramen

-midline is a line connecting anterior and posterior tubercle of C1

-2 parallel line to the middle line is drawn touching outer cortex of canal of atlas and inner border of veterbral foramen

- a horizontal line perpendicular to these line is drawn and the distance is measured in millimeter



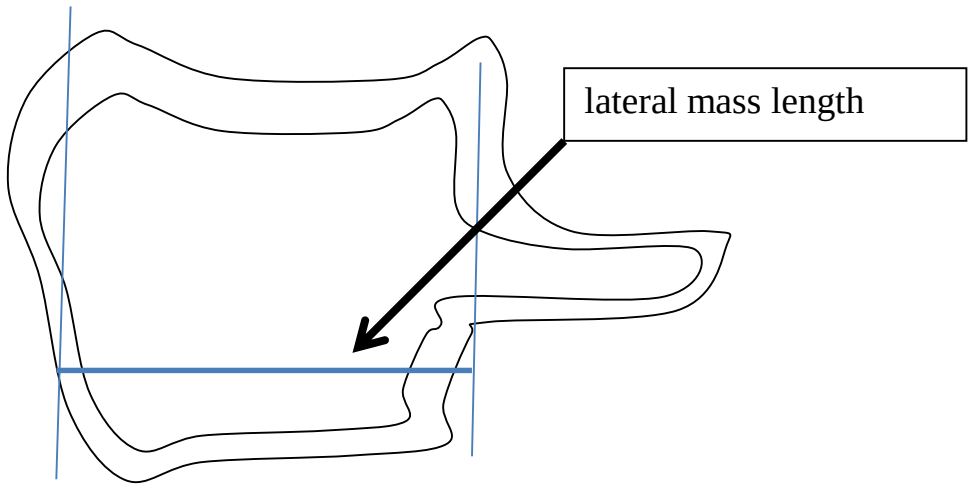
Specific Objective 7 - To measure mean lateral mass length **(G)**

-defined as the distance between anterior cortex to posterior cortex of body of atlas

--desired sagittal slice chosen as mentioned above

-a line is drawn vertically touching the anterior and posterior cortex of body of atlas

- a horizontal line parallel to inferior border of body of atlas is drawn to connect those 2 lines and the distance is measured in millimetre



Specific Objective 8 - To determined the entry point of screw (distance of screw entry point from midline, **H**)

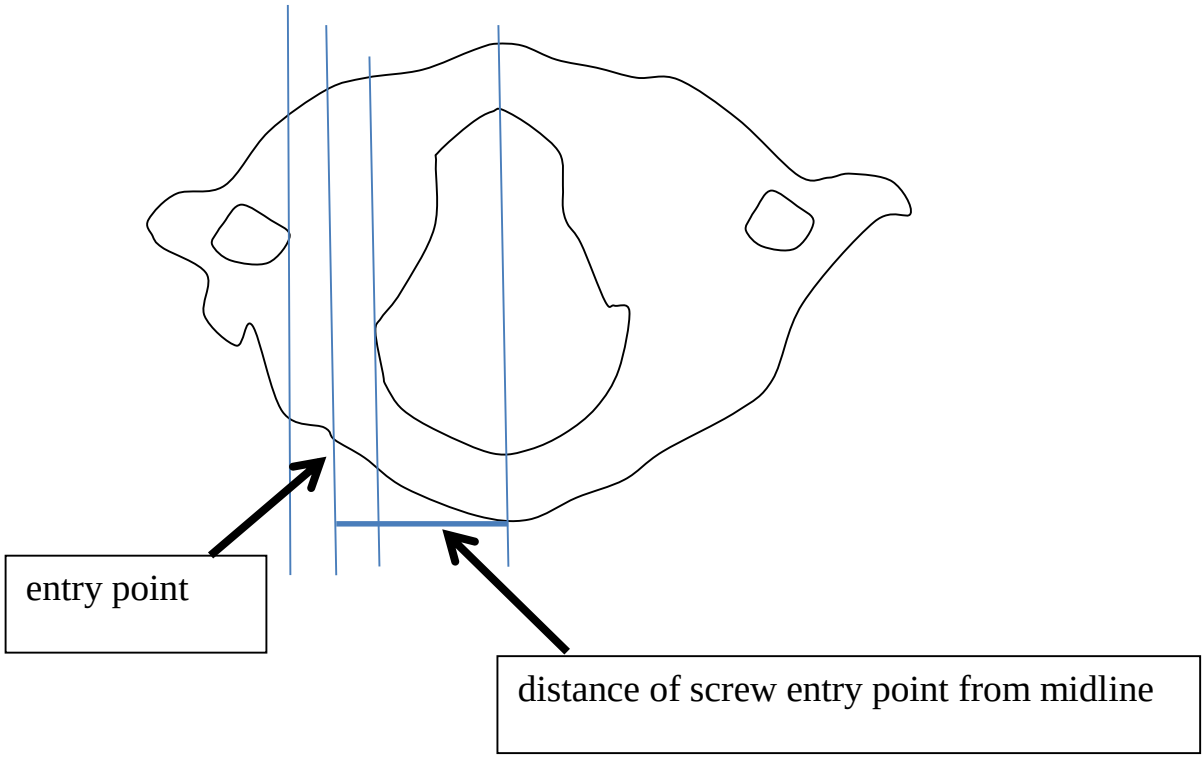
-midline drawn as mentioned in specific objective 6

-2 parallel line to the middle line is drawn touching inner cortex of canal of atlas and inner border of veterbral foramen (as above)

- another parallel line drawn bisecting the transverse diameter of lateral mass

-entry point is identified when this line touching the posterior cortex of lateral mass

-distance between the bisecting line and midline is measured



Specific Objective 9 - To measured the angle of screw trajectory (angle of pedicle axis, **I**)

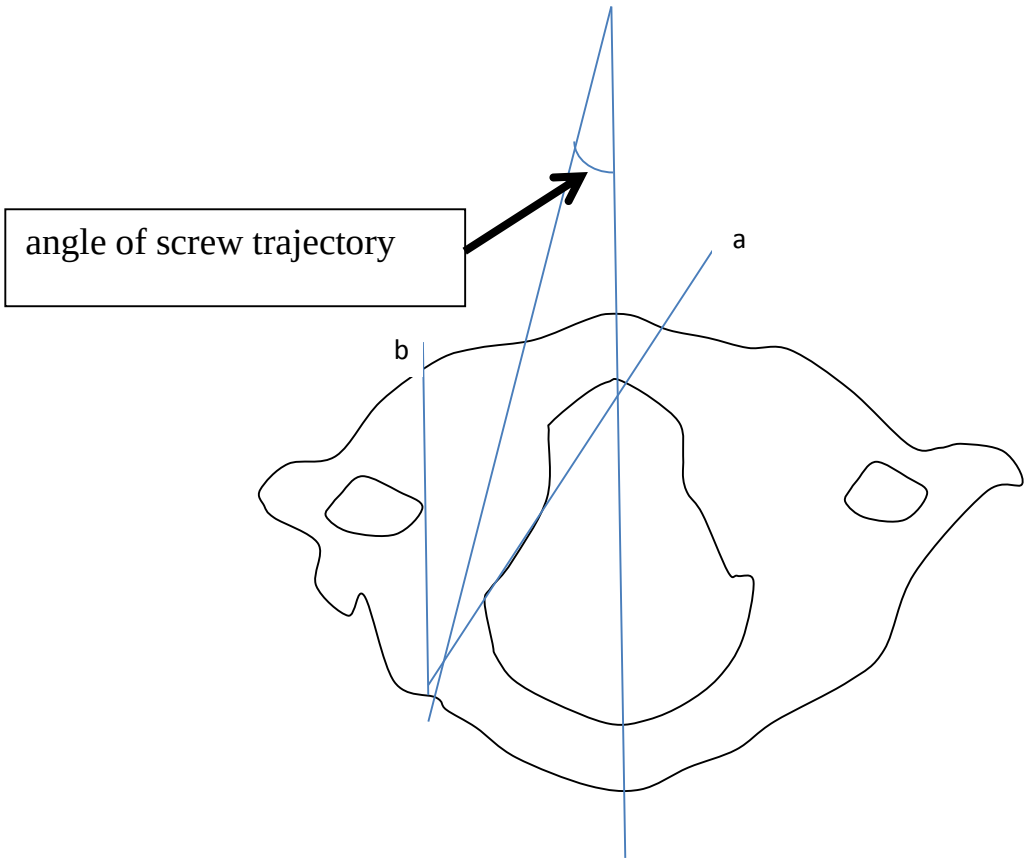
- defined as angle between axis of C1 pedicle and the midline

- one line is drawn connecting entry point of screw to the most lateral part of canal of atlas (a)

-second line is drawn connecting entry point of screw to the most medial part of inner border of vertebral foramen (b)

-pedicle axis is determine by drawing a line from entry point of screw bisecting the first and second line

- angle between pedicle axis and midline is measured



Measurement of parameter

- Manual measurement with computer mouse
- Each diameter are measure twice , the mean is taken
- Mean will be recorded in Data Collection Sheet
- Validation for PI will be done for 10% from all subject(12 sample) with Prof Madya Mohd Shafie Abdullah , Radiologist

Data Collection Sheet

Registration no:

Age :

Sex :

PEDICLE

	RIGHT (mm)	LEFT (mm)
OUTER PEDICLE HEIGHT (A)		
INNER PEDICLE HEIGHT (B)		
TRANSVERSE DIAMETER (C)		
PEDICLE LENGTH (F)		
DISTANCE OF ENTRY POINT FROM MIDLINE (H)		
MEDIAL ANGULATION OF PEDICLE AXIS (I)		

LATERAL MASS

	RIGHT (mm)	LEFT (mm)
LATERAL MASS HEIGHT (D)		
TRANSVERSE DIAMETER (E)		
LATERAL MASS LENGTH (G)		

Data analysis

Data will be entered and analysed using SPSS version 20.

For objective 1 to 9, using descriptive statistic to determine single mean of all parameter

DUMMY TABLE

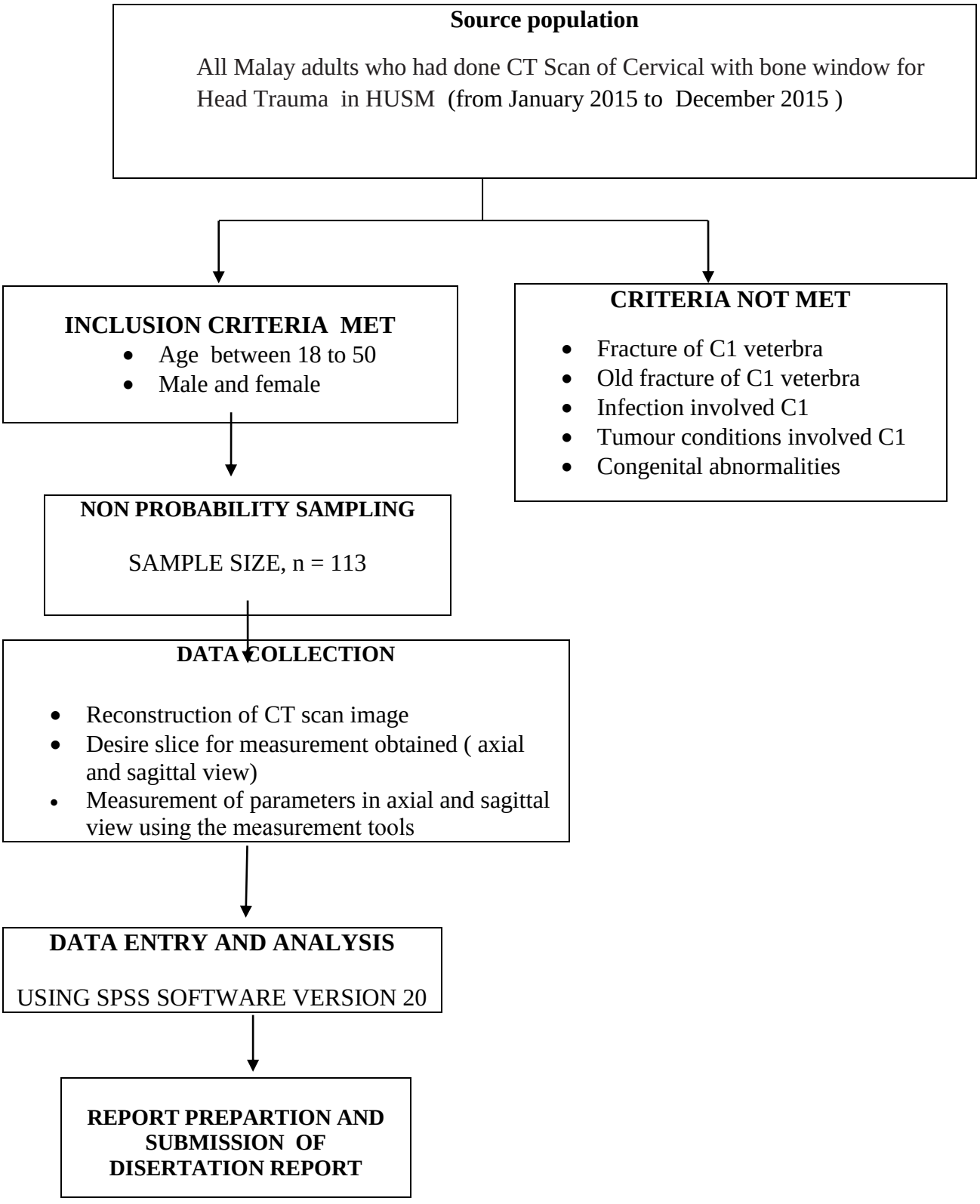
1) PEDICLE

	RIGHT (MEAN ± SD)	LEFT (MEAN ± SD)
VERTICAL OUTER DIAMETER (A)		
VERTICAL INNER DIAMETER (B)		
TRANSVERSE DIAMETER (C)		
PEDICLE LENGTH (F)		
DISTANCE OF ENTRY POINT FROM MIDLINE (H)		
MEDIAL ANGULATION OF PEDICLE AXIS (I)		

2) LATERAL MASS

	RIGHT (MEAN ± SD)	LEFT (MEAN ± SD)
VERTICAL DIAMETER (D)		
TRANSVERSE DIAMETER (E)		
LATERAL MASS LENGTH (G)		

STUDY FLOW CHART



GANTTZ CHART

Activities	Time																			
	2016												2017							
Month	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A
Research proposal																				
Correction																				
Presentation proposal at department and correction																				
Ethical presentation and approval																				
Data collection																				
Data entry																				
Data analysis																				
Write up																				
Submission																				

REFERENCES

1) Harms J[1], Melcher RP. Posterior C1-C2 fusion with polyaxial screw and rod fixation. *Spine (Phila Pa 1976). 2001 Nov 15;26(22):2467-71.*

2) Tan M[1], Wang H, Wang Y, Zhang G, Yi P, Li Z, Wei H, Yang F. Morphometric evaluation of screw fixation in atlas via posterior arch and lateral mass. *Spine (Phila Pa 1976). 2003 May 1;28(9):888-95*

3) Ma XY[1], Yin QS, Wu ZH, Xia H, Liu JF, Xiang M, Zhao WD, Zhong SZ. C1 pedicle screws versus C1 lateral mass screws: comparisons of pullout strengths and biomechanical stabilities. *Spine (Phila Pa 1976). 2009 Feb 15;34(4):371-7.*

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5) Lee SH[1], Kim ES, Eoh W. Modified C1 lateral mass screw insertion using a high entry point to avoid postoperative occipital neuralgia. *J Clin Neurosci. 2013 Jan;20(1):162-7.*

6) Conroy, Laing, Kenneally, & Poynton. C1 lateral mass screw-induced occipital neuralgia. *European Spine Journal March 2010, Volume 19, Issue 3, pp 474-476*

2.2 ETHICAL APPROVAL LETTERS :

Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM)
Human Research Ethics Committee USM (HREC)

Universiti Sains Malaysia
Kampus Kesihatan,
16150 Kubang Kerian,
Kelantan. Malaysia.
T: 609 - 767 3000 *samb.* 2354/2362
F: 609 - 767 2351
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26th October 2016

Dr. Teo Yu Meng
Department of Orthopaedics
School of Medical Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

JEPeM Code : USM/JEPeM/16060214
Protocol Title : Morphometric Evaluation of Screw Fixation in Atlas via Pedicle and Lateral Mass in Malay Population in Kelantan State: Feasibility Study using CT Scan.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/16060214**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **26th October 2016** until **25th October 2017.**

Study Site: Hospital Universiti Sains Malaysia.

The following researchers also involve in this study:
1. Prof. Dr. Mohd Imran Yusof
2. Assoc. Prof. Dr. Mohd Shafie Abdullah

The following documents have been approved for use in the study.
1. Research Proposal

In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:
1. Data Collection Sheet

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:
1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2015: Continuing Review Application Form.** Subsequently this need to be done yearly as long as the research goes on.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2015: Study Protocol Amendment Submission Form.**
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2015: Study Protocol Amendment Submission Form.**
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2014: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2015.**
6. Any event which may have ethical significance.

7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2014: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website: **www.jepem.kk.usm.my**

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

"ENSURING A SUSTAINABLE TOMORROW"

PROF. DR. MOHD SHUKRI OHMAN
Deputy Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia