MEASUREMENT OF MIDDLE EAR VOLUME IN ADULTS USING THREE- DIMENSIONAL (3D) RECONSTRUCTION MULTI-DETECTOR COMPUTED TOMOGRAPHY (MDCT) SCAN

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I would also like to express deep appreciation to Prof Madya Dr. Mohd Ezane Aziz and Dr. Nik Adilah Nik Othman as co-supervisor of this dissertation for spending their precious time giving guidance and supervision.

My deepest gratitude to all lecturers/radiologists, Department of Radiology, School of Medical Sciences, HUSM of whom directly or indirectly contributed their ideas and comments to the success of this study.

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LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

MDCT	Multi-Detector Computed Tomography
CT	Computed Tomography
MEV	Middle Ear Volume
3D	Three- Dimensional
PACS	Picture Archive Communication System
RIS	Radiology Information System
HU	Hounsfield Unit
MPR	Multiplanar Reconstruction
HUSM	Hospital Universiti Sains Malaysia
SPSS	Statistical Package for Social Sciences
PNS	Paranasal Sinuses

ABSTRAK

Latar belakang: *Computed Tomography* (CT) telah menjadi kaedah untuk menganggar kumulatif isipadu telinga tengahdan sel-sel udara mastoid (*middle ear volume (MEV)*). Tujuan kajian ini adalah untuk menentukan MEVorang dewasa menggunakan pemeriksaan rekonstraksi imbasan CT Tiga Dimensi (3D) *Multi-Detector Computed Tomography (MDCT)* mengikut umur dan jantina yang berbeza.

Kaedah: Sejumlah 140 imbasan *CT Brain* pesakit dewasa diambil dari *Picture Archive Communication System (PACS*). Mesin imbasan CT Siemens SOMATOM Definition AS+ dengan algoritma tulang dan kernel yang tinggi serta ketebalan kepingan 1mm untuk *CT Brain*telahdigunakan . Imej- imej yang mempunyai keseluruhansel udara mastoid dimasukkan ke dalam kajian. Hanya imej yang berkualiti dianalisa. Imej-imej yang menunjukan patologi tengkorak, otak dan telinga dikecualikan. *Ear Review of 3D application(GE PACS Universal Viewer Versi 5.0 SP6)* digunakan untuk menentukan MEV.

Keputusan: Min untuk MEV telinga kanan ialah 3.845cm^3 (*SD*: 1.833) dan MEV telinga kiri 3.855cm^3 (*SD*: 1.843). Tiada perbezaan signifikan dalam kumulatif isipadu telinga tengah dan sel-sel udara mastoid kanan dan kiri di kalangan orang dewasa$p$ = 0.460,(95% CI: -0.035 to 0.016). Perbezaan MEV antara lelaki dan perempuan juga menunjukkan keputusan yang tidak signifikan dengan bacaan telinga kanan $p = 0.889$, (95% CI: -0.658 to 0.571) dan kiri $p = 0.934$, (95% CI: -0.644 to 0.592). Korelasi antara MEV dengan usia turut memberi keputusan yang tidak signifikan r = -0.101, p = 0.233 untuk telinga kanan dan r = -0.102, p = 0.232 untuk telinga kiri.

Kesimpulan: Kajian ini boleh menyumbang dalam menyediakan data asas bagi kajian lanjut mengenai telinga tengah dan sel-sel mastoid. Pengukuran MEV menggunakan rekonstruksi 3D MDCT adalah mudah untuk diperoleh dan boleh dihasilkan semula.

Kata kunci: mastoid, middle ear, temporal bone, tympanoplasty, otitis media, diagnostic imaging, computed tomography, three-dimensional

ABSTRACT

Background: Computed tomography (CT) has emerged as a method of estimation of middle ear volume (MEV). The purpose of this study is to determine middle ear volume of adults using Three- Dimensional (3D) reconstruction Multi-Detector Computed Tomography (MDCT) in different age and gender.

Methods: A total of 140 adult CT brain images were retrieved from Picture Archive Communication System (PACS). The CT brains were performed on Siemens SOMATOM Definition AS+ CT machine with a slice thickness of 1mm and high kernel bone algorithm. Images with complete mastoid air cells were included. Only good quality images were analysed. Images with abnormality of the skull, brain or ear were excluded. Ear Review of 3D application (GE PACS Universal Viewer Version 5.0 SP6) was used to measure the MEV.

Results: The mean of right MEV was3.845cm^3 (*SD*: 1.833) and left MEV was 3.855cm^3 (*SD*: 1.843). The difference between the right and left MEV means are statistically not significant with p = 0.460, (95% CI: -0.035 to 0.016). No difference in mean MEV between male and female with p = 0.889, (95% CI: -0.658 to 0.571) and p = 0.934, (95% CI: -0.644 to 0.592) for right and left MEV respectively. Weak negative correlation with age was shown with r = -0.101, p = 0.233 for right MEV and r = -0.102, p = 0.232 for left MEV respectively.

Conclusion: This study can contribute to provide baseline data for further studies on mastoid pneumatisation. MEV measurement using 3D reconstructed MDCT is easily available and reproducible.

Keywords: mastoid, middle ear, temporal bone, tympanoplasty, otitis media, diagnostic imaging, computed tomography, three-dimensional

CHAPTER 1: INTRODUCTION

1.1 LITERATURE REVIEW

The middle ear cavity or tympanic cavity is an air filled space within the temporal bone. It contains the three auditory ossicles (malleus, incus and stapes) along with their attached muscles. It can be divided into the epitympanum, hypotympanum and mesotympanum. The mastoid air cell system is air filled space posterior to the middle ear cavity proper or tympanic cavity located in the mastoid part of the temporal bone. The mastoid air cell system has been well documented as an air reservoir for the middle ear and its volume plays an important role. It also serves to protect the inner ear structures from temperature changes (1). Other than that, it plays an important role as a pressure regulator by having a large surface area with respect to gas exchange. Therefore, it is reasonable that the degree of mastoid pneumatisation plays an important role in its function. Number, size, and volume of the mastoid air cells are unique. The growth is controlled by many complex factors e.g.: heredity, environment, nutrition, gas exchanges and frequency of infection(2).

The status of the middle ear cavity is dependent on the function of the mastoid air cell system and the degree of the mastoid pneumatisation is closely correlated with its function. Volume and pneumatisation of the mastoid air cell system are essential in understanding the physiology or pathology of the middle ear/mastoid disease. The mastoid air cell system plays important role in middle ear physiology. Mastoid cells provided an air reservoir for the middle ear and they have a role in the pressure regulation of the middle ear (3, 4). This hypothesis was also supported by (5, 6). Mastoid cavity buffers the effects of pressure changes in the middle ear by supplying air to the middle ear.

The preoperative volume of middle ear plays important role in predicting the outcome of middle ear reconstruction surgery namely tympanoplasty and mastoidectomy. A study done by Holmquist *et al* showed that the success of middle ear surgery depended on mastoid cell ventilation. Those who undergone tympanoplasty without mastoidectomy had lesser middle ear retraction compared to those who had undergone tympanomastoidectomy(3). Therefore, they suggested that well- ventilated mastoid cells should not be intervened during surgery.

There have been many reports regarding the measurement of the size of mastoid pneumatisation. Of the reports in which the size of mastoid pneumatisation has been measured quantitatively, several methods such as a water-weight method by insertion of a measured volume of fluid into mastoid cavity, a pressurized transducer method utilizing Boyle's law and an acoustic method have been used (7, 8).Molvaer *et al* used acoustical, liquid and pressure method to measure the middle ear volume and showed a wide range of volume (2-20mls)(8).

With the development of radiological tools, many methods that are capable of measuring the volume of the mastoid pneumatisation have been developed. As temporal bone has a pyramidal shape and the air cell system extends variably to all regions within it. The mastoid air cells also have a wide and irregular shape. Although all air cells are interconnected, it is very difficult to assess the size of mastoid pneumatisation directly. This is the reason why radiological method namely computed tomography is used.

Middle ear volume (MEV) defined as the continuous non opacified air space of the middle ear proper and the mastoid air cells collectively. Three- dimensional volume rendering (3D VR) has emerged as a method of estimation of MEV. Various studies that used CT scan as measuring tool to measures MEV also showed variable ranges of normal MEV(9-14).

The rationale of this study is to provide baseline data that would be useful for better understanding of physiology and pathological process of middle ear diseases. Other than that it would also have clinical and surgical benefit especially for the middle ear surgery.

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CHAPTER 2: STUDY PROTOCOL

2.1 TITLE

Measurement of middle ear volume in adults using Three-Dimensional (3D) reconstruction Multi-Detector Computed Tomography (MDCT) scan.

2.2 OBJECTIVE

2.2.1 General objective

To determine middle ear volume of adults using 3D reconstruction MDCT in different age and gender.

2.2.2 Specific objectives

1. To compare the mean of middle ear volume between right and left.

2. To compare the mean of middle ear volume between male and female.

3. To correlate the middle ear volume with age.

2.3 METHODOLOGY

2.3.1 Study design

This was a cross sectional study that was conducted in Hospital Universiti Sains Malaysia (HUSM) from January 2015 until December 2016.

2.3.2 Study location and duration

Study was conducted in Hospital Universiti Sains Malaysia (HUSM) from January 2016- December 2016

2.3.3 Study population and Sample

Reference Population: Subject age 18 years old and more in Kelantan

Source Population: Subject who underwent CT brain/ CT temporal bone in Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan

2.3.4 Sampling technique

Stratified systematic random sampling.

2.3.5 Inclusion Criteria

1. Age 18 and above.
2. Both mastoid air cells must be completely included in the CT brain images.
3. Slice thickness of 1mm for CT brain.
4. CT brain with high kernel bone algorithm.

2.3.6 Exclusion criteria

1. Subjects with congenital abnormality of the skull/ brain/ ear.
2. Subjects who has fracture to the temporal bone.
3. Subjects with previous operation at temporal bone.
4. Subjects with diseased or acquired pathology of the middle ear/ mastoid air cells.
5. Missing image/s from PACS.
6. Suboptimal image/s due artifacts.

2.3.7 Sample Size Calculation

For objective 1:

Sample Size Calculator version 1.7, updated August 2015 from website: www.medic.usm.my/biostat was used to calculate the sample size using two means comparison (paired) with power of study (1-β) of 80%, significance level (α) of 0.05, standard deviation of difference (σ) of 0.8 (12)expected difference/ effect size(Δ) of 0.2 and added drop out 10%. The corrected sample size is 140 subjects.

For objective 2:

Sample Size Calculator version 1.7, updated August 2015 from website: www.medic.usm.my/biostat was used to calculate the sample size using two means comparison (independent) with power of study (1-β) of 80%, significance level (α) of 0.05, standard deviation (σ) of 7.24 expected difference/ effect size(Δ) of 4.32 and added drop out 10%.(15) The corrected sample size is 50 x 2 = 100 subjects.

For objective 3:

Sample size calculator from website: www.sample-size.net/correlation sample size was used to calculate sample size using correlation formula with power of study (1-β) of 80%, significance level (α) of 0.05 and correlation coefficient (r) of 0.3(12). The sample size calculated is 85.

Therefore, largest sample size calculated which is 140 subjects was used in this study.

2.3.8 Research Tools

1. Reconstructed images from CT scan protocol were used in this study. The protocol was CT Brain protocol with tube voltage of 120kvp, effective mAs: 120mAs, acquired slice 0.6mm x 128. The reconstructed high Kernel, bone algorithm with 1mm slice thickness was used for image analysis. CT scan machine used was Siemens SOMATOM Definition AS+ which was capable of producing 128 slices of images per rotation.

2. Picture Archive Communication System (PACS) in HUSM (PACS Universal Viewer Version 5.0 SP6) was used for image analysis.

3. Diagnostic workstation with 2 Mega Pixel monitors- (Barco MPG 2121 monitor–resolution 2048 x 1536).

2.3.9 Variable definition

Middle ear volume

The term "Middle Ear Volume" refers to the volume of the air contained within the tympanic cavity (including the epitympanum, hypotympanum and mesotympanum) and the mastoid air cells collectively.

2.3.10 Data Collection

1. Data of age, gender, and race were collected from Radiology Information System (RIS) and Picture Archive Communication System (PACS) in HUSM.
2. All subjects were with serial number in order to maintain privacy and confidentiality of subject.
3. Data collected were kept in subjects' data sheet.

2.3.11 Image analysis

1. CT Brain images were retrieved from PACS, using diagnostic PACS workstation.
2. Ear Review of 3D application (GE PACS Universal Viewer Version 5.0 SP6) was used to analyze the images.
3. Images of the right and left ear were analyzed separately by researcher.

4. In the 3D application, unwanted regions (air outside the skull, in paranasal sinuses and external ear canal) were removed using manual cut.
5. MPR images were used to assist during the manual removal of the unwanted regions.
6. Automated segmentation of area with air was performed using air threshold (-1023HU to -800HU).
7. Volume of the remaining air in the middle ear cavity and mastoid air cells was measured using volume measurement tool.
8. Volume was generated automatically.
9. For each ear, the volume was measured twice and averaged.
10. The technique performed by the researcher was authenticated by Senior Radiologist with 11 years working experience. It was performed at the initial of the study. The researcher performed the image analysis and the technique was repeated in the same setting by the radiologist. (16)

2.3.12 Statistical analysis

Data from data sheet were entered and analysed using statistical software (IBM SPSS 22.0 for windows, SPSS Inc., Chicago, IL, USA).Numerical socio-demographic data (age of study sample and volume of both middle ear) were analysed using descriptive analysis and expressed with mean, standard deviation and frequency/ percentage). The minimum mean, maximum mean and standard deviation of age and both middle ear volume were calculated and presented in table. The normality of age and middle ear volume were tested.

The categorical socio-demographic data (gender and race of the study sample) were expressed in percentage and presented by tabulation. The middle ear volume of right and left were compared using paired t- test. The mean differences of middle ear volume between genders were compared using independent t-test. The correlation between middle ear volume and age were determine using Pearson correlation. The results of t–test (paired and independent) and Pearson correlation were presented using tables.

2.3.13 Confidentiality and Privacy

Serial number we given for each CT Brain. No identifiable data were expressed and shared to the public. Neither name nor any identifying information was used in any publication or presentation resulting from this study.

2.3.14 Ethical Consideration

This study was approved by Jawatankuasa Etika Penyelidikan (Manusia) of Universiti Sains Malaysia (JEPeM) which is the Research and Ethical Committee of Universiti Sains Malaysia (JEPeM code: USM/JEPeM/15120551) which complies with the Declaration of Helsinki (Appendix B).

CHAPTER 3: MANUSCRIPT

3.1 TITLE PAGE

MEASUREMENT OF MIDDLE EAR VOLUME IN ADULTS USING THREE-DIMENSIONAL (3D) RECONSTRUCTION MULTI-DETECTOR COMPUTED TOMOGRAPHY (MDCT) SCAN.

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MAIN DOCUMENT

3.2 TITLE

MEASUREMENT OF MIDDLE EAR VOLUME IN ADULTS USING THREE-DIMENSIONAL (3D) RECONSTRUCTION MULTI-DETECTOR COMPUTED TOMOGRAPHY (MDCT) SCAN.

3.3 ABSTRACT

Background: Computed tomography (CT) has emerged as a method of estimation of middle ear volume MEV. The purpose of this study is to determine middle ear volume of adults using Three- Dimensional (3D) reconstruction Multi-Detector Computed Tomography (MDCT) in different age and gender.

Method: A total of 140 adult CT brains images were retrieved from Picture Archive Communication System (PACS). The CT brains were performed on Siemens SOMATOM Definition AS+ CT machine with a slice thickness of 1mm and high kernel bone algorithm. Images with complete mastoid air cells were included. Only good quality images were analysed. Images with abnormality of the skull, brain or ear were excluded. Ear Review of 3D application (GE PACS Universal Viewer Version 5.0 SP6) was used to measure the middle ear volume.

Results: The mean of right MEV was3.845cm^3 (*SD*: 1.833) and left MEV was 3.855cm^3 (*SD*: 1.843). The difference between the right and left MEV means are statistically not significant with p = 0.460, (95% CI: -0.035 to 0.016). No difference in mean MEV between male and female with p = 0.889, (95% CI: -0.658 to 0.571) and p =

0.934, (95% CI: -0.644 to 0.592) for right and left MEV respectively. Weak negative correlation with age was shown with r = -0.101, p = 0.233 for right MEV and r = -0.102, p = 0.232 for left MEV respectively.

Conclusion: This study can contribute to provide baseline data for further studies on mastoid pneumatisation. MEV measurement using 3D reconstructed MDCT is easily available and reproducible.

Keywords: mastoid, middle ear, temporal bone, tympanoplasty, otitis media, diagnostic imaging, computed tomography, three-dimensional

3.4 INTRODUCTION

The middle ear cavity or tympanic cavity is an air- filled space within the temporal bone. It contains the three auditory ossicles (malleus, incus and stapes) along with their attached muscles. It can be divided into the epitympanum, hypotympanum and mesotympanum.

The mastoid air cell system is air filled space posterior to the middle ear cavity proper or tympanic cavity located in the mastoid part of the temporal bone. The mastoid air cell system has been well documented as an air reservoir for the middle ear and its volume plays an important role.

It also serves to protect the inner ear structures from temperature changes(1). Other than that, it plays an important role as a pressure regulator by having a large surface area with respect to gas exchange. Therefore, it is reasonable that the degree of mastoid pneumatisation plays an important role in its function. Number, size and volume of the mastoid air cells are unique. The growth is controlled by many complex factors e.g.: heredity, environment, nutrition, gas exchanges and frequency of infection(2).

The status of the middle ear cavity is dependent on the function of the mastoid air cell system and the degree of the mastoid pneumatisation is closely correlated with its function. Volume and pneumatisation of the mastoid air cell system are essential in understanding the physiology or pathology of the middle ear/mastoid disease.

The mastoid air cell system plays important role in middle ear physiology. Mastoid cells provided an air reservoir for the middle ear and they played a role in the pressure regulation of the middle ear (3, 4). This hypothesis was also supported by (5, 6). Mastoid cavity buffers the effects of pressure changes in the middle ear by supplying air to the middle ear.

The preoperative volume of middle ear plays important role in predicting the outcome of middle ear reconstruction surgery namely tympanoplasty and mastoidectomy.

A study done by Holmquist *et al*. showed those who undergone tympanoplasty without mastoidectomy had lesser middle ear retraction compared to those who had undergone tympanomastoidectomy(3). Therefore, they suggested that well- ventilated mastoid cells should not be intervened during surgery.

There have been many reports regarding the measurement of the size of mastoid pneumatisation. Of the reports in which the size of mastoid pneumatisation has been measured quantitatively, several methods such as a water-weight method by insertion of a measured volume of fluid into mastoid cavity, a pressurized transducer method utilizing Boyle’s law and an acoustic method have been used (7, 8).

However, with the development of radiological tools, many methods that are capable of measuring the volume of the mastoid pneumatisation have been developed. As temporal bone has a pyramidal shape and the air cell system extends variably to all regions within it. The mastoid air cells also have a wide and irregular shape. Although all air cells are interconnected, it is very difficult to assess the size of mastoid pneumatisation directly. This is the reason why radiological method namely computed tomography is used.

The rationale of this study is to provide baseline data that would be useful for better understanding of physiology and pathological process of middle ear diseases. Other than that it would also have clinical and surgical benefit especially for the middle ear surgery.

3.5 MATERIALS/ SUBJECT METHODS

3.5.1 Data collection

This was a cross- sectional study which was conducted in Hospital Universiti Sains Malaysia (HUSM). This study was approved by Jawatankuasa Etika Penyelidikan (Manusia) of Universiti Sains Malaysia (JEPeM) which is the Research and Ethical Committee of Universiti Sains Malaysia (JEPeM code: USM/JEPeM/15120551) (Appendix B). Stratified systematic random sampling was done and a total of 140 CT brain images (280 ears) were studied. The images which include the middle ear and mastoid air cells were retrieved from Picture Archive Communication System (PACS). All subjects were 18 years of age and above. Images with congenital abnormalities of the skull, brain or ear, fracture of the temporal bone, previous temporal bone operation and those with diseased or acquired pathology of the middle ear/ mastoid air cells were excluded from this study. Missing image/s from PACS and suboptimal images/s due to artefact were also excluded.

3.5.2 CT scan protocol

CT Brain protocol with a tube voltage of 120kvp, effective mAs: 120mAs, acquired slice 0.6mm x 128. The reconstructed high Kernel with a bone algorithm with 1mm slice thickness was used for image analysis. The subjects were scanned in a supine position to obtain the image plane parallel to the orbitomeatal line. All the image data sets were transferred from the CT scanner to the PC workstation. CT scan machine used was Siemens SOMATOM Definition AS+ which was capable of producing 128 slices of images per rotation. Picture Archive Communication System (PACS) in HUSM (PACS Universal Viewer Version 5.0 SP6) and diagnostic workstation with 2 Mega Pixel monitors- (Barco MPG 2121 monitor– resolution 2048 x 1536) were used for image analysis.

3.5.3 Measurement of middle ear volume

The middle ear volume (MEV) was defined as the continuous non opacified air spaces from middle ear cavity proper to mastoid air cells of the temporal bone. Ear Review of 3D application (GE PACS Universal Viewer Version 5.0 SP6) was used to analyse the images with images of the right and left ear being analysed separately by the researcher. In the 3D application, manual cutting was done to remove unwanted regions (air outside the skull and external ear canal). Multiplanar reconstruction (MPR) images were used to assist during the manual removal of the unwanted regions. Automated segmentation of area with air was performed using air threshold. The threshold generated by the software was from -1023HU to -800HU. This threshold range excluded the bone and soft tissue attenuation. The volume of the remaining air in the middle ear cavity and mastoid air cells was measured using volume measurement tool which was generated automatically (16). For each ear, the volume was measured twice and averaged. A single researcher measured the MEV. The technique performed by the researcher was authenticated by Senior Radiologist with 11 years working experience. It was performed at the initial of the study. The researcher performed the image analysis and the technique was repeated in the same setting by the radiologist. Figure 1-5 showed the sequential methods of measuring MEV.

3.5.4 Statistical analysis

Statistical software (IBM SPSS 22.0 for windows, SPSS Inc., Chicago, IL, USA).was used for data analysis. The MEV of right and left were compared using dependent t-test. The mean differences of MEV between genders were compared using independent t-test. Pearson's correlation was used to determine correlation between MEV and age.

3.6 RESULTS

3.6.1 Demographic Data

Hundred and forty CT brain images were reviewed. For each of the studies, both ears were analysed. Ninety five point seven percent (n = 134) were Malay, 3.6% (n = 5) were Chinese and the rest was Indian ethnicity. There was equal number of male and female in this study. Mean age of subjects was 42.34 years old. Minimum age for subjects was 18years old and maximum age was 93 years old. The mean of right MEV was 3.845 cm^3 (*SD*: 1.833) and left MEV was 3.855cm^3 (*SD*: 1.843). These results were shown in Table 1.

3.6.2 Comparison of right and left MEV

To assess the difference between MEV of right and left ear a dependent t- test was performed with $p< 0.05$ taken as significant. The alternative hypothesis of difference MEV means between right and left ear was rejected, $p = 0.460$, (95% CI:-0.035 to 0.016). Thus, the difference between the right and left MEV means are statistically not significant.

3.6.3 Comparison of MEV between genders

Female subjects (n= 70) had right MEV of 3.867cm^3 (*SD*: 1.868) and left MEV of 3.867cm^3 (*SD*: 1.875). For male ($n= 70$) the right MEV was 3.823cm^3 (*SD*: 1.811) and left MEV was 3.842cm^3 (*SD*: 1.824) respectively. Independent t-test was performed to test whether there is any difference between mean MEV of right and left ears and genders. Significant level taken at *p*- value < 0.05. Prior to conducting the test, the assumption of homogeneity of variances was conducted and considered satisfied as the Levene's F test of right MEV (F =0.015, $p = 0.902$) and left MEV ($F = 0.028$, $p = 0.866$) respectively which showed $p>0.05$ for both. The result showed no-statistical significant outcome as shown in Table 4. The mean of right MEV between male and female showed p = 0.889, (95%CI:-0.658 to 0.571) and left $p = 0.934$, (95% CI-0.644 to 0.592).