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Name of Candidate : KHAW TEIK SENG (I.C/Passport No: [REDACTED])

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A randomized open-labelled trial.

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Name:

Dr Lucy Chan

PROFESSOR LUCY CHAN

Consultant Anaesthetist  
Department of Anaesthesiology  
Faculty of Medicine

Date: University of Malaya

Designation: 50503 Kuala Lumpur  
MALAYSIA

## ABSTRACT

**BACKGROUND:** The insertion of nasogastric tube (NGT) in anaesthetized, paralyzed and intubated or unconscious patients may be difficult due to loss of swallow reflex in these patients, with a reported failure rate of nearly 50% on the first attempt, with the head in neutral position. After a failure, subsequent attempts are usually unsuccessful due to coiling, kinking or knotting of the NGT as it loses stiffness due to warming to body temperature. The memory effect also contributes to subsequent failure: once kinked, the NGT is subsequently more likely to kink at the same place. Common methods used to facilitate NGT insertion include the use of a slit endotracheal tube, urethral guidewire as stylet, forward displacement of the larynx, head flexion, lateral neck pressure, head turning, direct laryngoscope with various forceps, use of gloved fingers to steer the NGT after impaction. In this study, we are comparing the success rate, average time of insertion, and incidence of complication between modified techniques (contralateral cricothyroid pressure and ipsilateral head turning) and conventional technique in NGT insertion.

**METHOD:** Hospital Ethical Committee approval was obtained and a valid written informed consent was obtained from each patient, who fulfilled inclusion criteria. This is a prospective, randomized and open-labelled trial. This power study was performed by using web based sample size calculator. 81 patients enrolled into this study were randomly allocated into three groups (the conventional techniques group, the contralateral cricoid pressure, and the ipsilateral head turning group) according to a computerized, random-allocation software program (n=27 per group). The investigators will be responsible to judge whether the attempt was a success or a failure, and whether any complication has occurred.

**RESULTS:** The modified techniques had a higher success rate and lower complications rates compared to conventional technique in NGT insertion in anaesthetized, paralyzed and intubated patients. The contralateral cricothyroid pressure had a highest success rate (66.6%), followed by ipsilateral head turning (63%), and the lowest rate was conventional technique (49.1%). These sequence were similar in first attempt success in NGT insertion, 51.9% for contralateral cricothyroid pressure, 48.1% for ipsilateral head turning and 25.9% for conventional technique. The conventional technique had the highest overall complications rate (74.1%) as well as the sub-complications [kinking (29.6%), coiling (48.1%) and bleeding (48.1%)]. However, there were no significant association between success rate and complications with the three techniques, except bleeding complication was statistically lower in the modified techniques compared to conventional technique in NGT insertion.

**CONCLUSION:** With this present study, the modified techniques has shown to be better than conventional technique in terms of higher success rate and lesser complications in NGT insertion. Only bleeding complication was statistically lower in modified techniques comparing to conventional technique, otherwise there were no statistically significant association between the success rate and complications among the three techniques. However, we will still consider modified techniques in NGT insertion in our clinical practice. The contralateral cricothyroid (CLCT) pressure will be the preferred method for NGT insertion in patients with cervical pathology and trauma patients on cervical collar.

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## LIST OF SYMBOLS AND ABBREVIATIONS

NGT Nasogastric tube

ETT Endotracheal tube



## CHAPTER 1: INTRODUCTION

### 1.1. Topic introduction

Nasogastric tube (NGT) insertion is a common procedure for anesthesiologist. However, this procedure might become difficult and challenging as most of the patients are anaesthetized, paralyzed and intubated. Loss of the swallowing reflex would make NGT insertion become difficult as lack of coordination of pharyngeal muscle activity to guide the NGT into esophagus and ultimately into the stomach. The most common failure of NGT insertion is coiling due to the tube impact on piriform sinus and the arytenoid cartilage<sup>4,6</sup>.

After first time failure, subsequent attempts are usually unsuccessful due to coiling, kinking, or knotting of the NGT as it loses stiffness due to warming by body temperature. The memory effect also contributes to subsequent failures; once kinked, the NGT is subsequently more likely to kink at the same place.

There are many manoeuvres applied to ensure a smooth NGT insertion - either making the NGT stiffer, expanding the parapharyngeal or retropharyngeal space, or in combination of all. Our hypothesis is that contralateral cricothyroid pressure (CLCT) to the selected nostril for NGT insertion will be to avoid impaction of the NGT at the piriform sinus and the arytenoid cartilage.

A different way of insertion was observed in a pilot study -contralateral cricothyroid pressure was carried out for 21 anaesthetized, paralyzed and intubated patients, 15 (71.4%) were successful. This method appeared smooth and was effective in NGT insertion. Therefore in this study, we included one arm for contralateral cricothyroid pressure technique to test its application compared to conventional technique (neutral position) and ipsilateral head turning technique<sup>1</sup>. We hypothesized

the contralateral cricothyroid pressure technique will be better than conventional technique and equivocal or not inferior to ipsilateral head turning technique.

In this study, we compare success rate, average time of insertion, and incidence of complication of 2 modified techniques [contralateral cricothyroid pressure (Group C) and ipsilateral head turning (Group H)] with conventional technique (Group A) in NGT insertion. If both modified techniques are shown to have increased in the success rate of NGT insertion in comparison to the conventional technique, then both modified techniques are better alternatives to conventional method for successful, quick and reliable NGT insertion with acceptable adverse events in anaesthetised, paralyzed and intubated adult patients. Hence, the contralateral cricothyroid pressure will be the preferred method for NGT insertion in patients with cervical pathology and trauma patients on cervical collar compared to ipsilateral head turning technique.

## **1.2 Objectives**

### Primary objectives

- I. Success rate of the selected technique at first, second attempt and overall
- II. Duration of successful insertion using selected technique

### Secondary objectives

- I. Complications during insertion of selected technique

## CHAPTER 2: LITERATURE REVIEW

The insertion of NGT in anaesthetized, paralyzed and intubated or unconscious patients may be difficult, with a reported failure rate of nearly 50% on the first attempt, with the head in neutral position (a.k.a conventional technique)<sup>1,3,5,6</sup>. A success rate within two attempts range from 60% to 72% was seen in neutral position<sup>1,3,5,6</sup>.

NGT enters the hypopharynx just lateral to the arytenoid cartilages. Consequently, the most common sites of impaction of the NGT are the piriform sinus and the arytenoid cartilage<sup>4</sup>.

Manoeuvres to keep the NGT along the lateral or posterior pharyngeal wall during insertion encourage the smooth passage into the esophagus.<sup>1-6</sup> Methods used to facilitate NGT insertion include the use of a slit endotracheal tube, urethral guidewire as stylet, forward displacement of the larynx, head flexion, lateral neck pressure, head turning, direct laryngoscope with various forceps, or use of gloved fingers to steer the NGT after impaction.<sup>1-6</sup> *Bong et al.* concluded that the passage of the NGT was successful during the first pass in 80% in the lateral head turning technique versus 40% patients in the conventional technique<sup>1</sup>.

## CHAPTER 3: METHODOLOGY

This study has obtained the approval of Malaysia Research Ethics Committee, Dissertation Committee ( NMRR ID 27761), Department of Anaesthesiology and Intensive Care, Faculty of Medicine, University of Malaya and Research and Ethnic Committee of University Malaya Medical Centre (MECID No. 201510-1718).

A valid written informed consent was obtained from each patient who fulfilled the inclusion criteria.

### 3.1. Study Design

This prospective, randomized and open-labelled trial was carried out from January 2016 till December 2016.

All patients enrolled into this study were randomly allocated into three groups [the conventional technique group (Group A), the contralateral cricothyroid pressure group (Group C), and the ipsilateral head turning group (Group H)] according to a computerized, random-allocation software program (<https://www.randomizer.org/>) (Table 3.1). The patient is aware of which group he or she was enrolled in. After the patient was anaesthetized, the investigator will perform the procedure according to the allocated technique in all three groups; however for the conventional technique, it can be performed by other experienced anaesthetist medical officers. The investigators will judge whether the attempt was a success or a failure, and whether any complication has occurred.

Preoperatively, the nostril to be used for NGT insertion was chosen based on the fluency of airflow felt by the patient through each nostril during respiration when the contralateral nostril was occluded. The nostril selected for NGT insertion will be the nostril with the higher fluency of airflow felt by the patient.

After induction of general anaesthesia with tracheal intubation and administration of appropriate intermediate- or long-acting muscle relaxant, the procedure of NGT insertion will include:

- Measure the distance from the patient's tragus to the bridge of the nose, plus the distance from the bridge of the nose to the bottom of the xiphisternum<sup>7</sup>.

In the conventional technique group (Group A), patient had a lubricated 14-French NGT inserted gently through the selected nostril, with the head being maintained in a neutral position.

For the ipsilateral head turning group (Group H), the patient will be positioned with the head turned to the ipsilateral direction of the selected nostril, then had a lubricated 14-French NGT inserted gently through the selected nostril.

Finally, in the contralateral cricothyroid pressure group (Group C), the patient's head being maintained in a neutral position and the lateral cricothyroid pressure will be pushing the cricoid and thyroid cartilages externally towards the contralateral direction of the selected nostril, then had a lubricated 14-French NGT inserted gently through the selected nostril.

The procedure start time will be defined as the time when the NGT insertion begins through the selected nostril.

The procedure end time will be defined as the time of successful insertion of NGT or the time after two failed attempts. A stopwatch was used to measure the procedure duration. Successful NGT insertion was confirmed by gurgling sound heard on auscultation over the epigastrium when injecting 10 cc of air through the NGT and fluid aspirated from the NGT will be checked with the litmus paper to confirm its acidity, pH of 5.5 or less indicates gastric acid and confirms the tube placement in the stomach.<sup>7</sup>

If the first attempt failed, the NGT will be withdrawn fully, cleaned with dry gauze and re-lubricated with K-Y jelly generously. The same lubricated NGT will be used and the procedure was repeated using the same technique. If both attempts at insertion using the same technique were unsuccessful, then the technique is considered a failure. After two unsuccessful attempts in the intended position, the anaesthetist was allowed to perform additional manoeuvres to aid the successful passage of the NGT.

The following data were collected:

- i. Success rate of the selected technique - first, second attempt and overall.
- ii. Duration of insertion using the selected technique.
- iii. Complication during insertion - coiling, kinking and bleeding.

### **3.2. Study population**

We have used power study to determine the sample size. This is a very useful and frequently used tool in the medical research to prove the sample size adequacy for a study. This power study was performed using web based sample size calculator (<http://www.stat.ubc.ca/~rollin/stats/ssize/b2/html>). The success rate for the conventional technique Nasogastric tube insertion is 70% (Mandal, et al., 2015). Considering 85% power (type II error is 15%), 5% marginal error (type one error for  $\alpha$  value = 0.05) and using the referred value from published paper, this study gives a sample size of 27 subjects per group. Hence, we recruited 27 subjects in each group, giving a total of 81 patients.

### **3.3. Study Sites**

This study was conducted at operation theatre, University Malaya Medical Centre, Kuala Lumpur.

### **3.4. Patients selection criteria**

#### **3.4.1. Inclusion criteria**

- Patients with normal airway (Commack Lehane 1 or 2) and normal neck movements whom will be undergoing surgery and requiring general anaesthesia, intubation with nasogastric tube insertion as part of the procedure.

#### **3.4.2. Exclusion criteria**

- Refusal or inability to provide informed consent
- Age less than 20 years old or more than 70 years old
- Nasal stenosis, nares obstruction or obvious nasal septal deviation

- Known case of coagulopathy or abnormal coagulation blood result (abnormal prothrombin time, partial thromboplastin time, and platelet disorder)
- Upper respiratory tract disease or anomalies
- Esophageal disorders
- Difficult intubation (Cormack Lehane 3 or 4)
- Basal of skull fracture
- Head and neck pathology
- Obstetric patient

### 3.5. Instruments

- Nasogastric tube 14-French size
- KY - jelly
- Litmus paper
- Stethoscope
- 10 c.c. syringe

### 3.6. Statistics, Data Processing and Analysis

All data will be entered and analyzed using SPSS Version 23.0. Data management was done by researcher before analysing. Data normality, outlier incomplete information was checked using formal and informal methods (*Md Ashraful Islam et. al*).

Normally distributed of data will be reported in means (SD) while non-normally distributed data will be reported in median (IQR), and categorical data was reported in frequency and percentage.



Chi square test is used to determine the statistical significance of the success rate of the selected technique - first, second attempt and overall and complication during insertion. If the numerical data are distributed normal, Independent sample T test or One way ANOVA will be used to determine the number of attempts for successful insertion and duration of insertion in selected technique, otherwise Nonparametric Mann-Whitney or Kruskal-Wallis test will be used for non-normally distributed data. The level of statistic significance was set at 0.05.

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## CHAPTER 4: RESULTS

### 4.1. Demographic data

A total of 81 patients were recruited. The mean age of the subjects was 51.25 years old (SD 14, range 21 to 70 years old). 50.6% of the patients were male and remaining 49.4% were female. There were no statically significant differences with regards to age and gender among the three groups (Table 4.1.).

**Table 4.1.** Demographic parameters of the recruited patients

Parameter	Overall (n = 81)	Group A (n = 27)	Group C (n = 27)	Group H (n = 27)
<b>Age (years)</b>				
Mean	51.25	47.11	53.63	53
Median	52	46	57	57
SD	14	14.38	12.53	14.56
Min	21	23	28	21
Max	70	69	70	70
p-value	0.169			
<b>Gender</b>				
Male (%)	41 (50.6)	13 (48.1)	10 (37.0)	18 (66.7)
Female (%)	40 (49.4)	14 (51.9)	17 (63.0)	9 (33.3)
p-value	0.089			

Test done : One-Way ANOVA and Chi-square test. Results were considered significance when \*p value < 0.05. SD – standard deviation; Min –minimum; Max – Maximun

### 4.2. Success rates & number of attempts

In total, 48 patients had shown successful NGT insertion with the chosen technique. The Group A had a highest failure rate (51.9%) among three techniques. The success rate for the Group C and Group H was 66.6% (n=18) and 63.0% (n=17) respectively. The highest first attempt success rate was Group C (51%), followed by Group H (48.1%), and the lowest was still Group A (25.9%)

There was no association between the chosen techniques and the numbers of attempts and success rate (Table 4.2.).

**Table 4.2.** Procedure parameters (n=81)

Parameters	Group A n (%)	Group C n (%)	Group H n (%)	p-value
Overall success	13 (49.1)	18 (66.6)	17 (63.0)	0.342
1st attempt insertion	7 (25.9)	14 (51.9)	13 (48.1)	0.358
2nd attempt insertion	6 (22.2)	4 (14.8)	4 (14.8)	
Failure	14 (51.9)	9 (33.3)	10 (37.0)	

Test done : Chi-Square test.

#### 4.3. Duration of procedure

Overall median was 32 seconds (IQR 33, range 12 to 145 seconds ). The shortest median duration was Group H 28 seconds (IQR 31, range 12 to 90 seconds); followed by Group C 33.5 seconds (IQR 38, range 12 to 145 seconds); Group A 46 seconds (IQR42, range 15 to 87 seconds). There was no significant difference in the procedure times between three techniques (Table 4.3.).

**Table 4.3.** Procedure times for successful selected technique

Parameter	Overall n =48	Group A n = 13	Group C n = 18	Group H n = 17
<b>Duration (sec)</b>				
Median	32	46	33.5	28
IQR	33	42	38	31
Min	12	15	12	12
Max	145	87	145	90
p-value	0.355			

Test done: Nonparametric Kruskal-Wallis test. IQR- Interquartile range; SD-Standard deviation; Min-minimum; Max-Maximum

#### 4.4. Complications

The highest overall complication rate was Group A (74.1%). The complication rate for Group C and Group H were 55.6% and 51.9% respectively. However, there was no statistically association between complication rate and the three techniques of insertion.

We further looked into the complication detail (kink, coil and bleed) during insertion of NGT. Among three techniques, Group A had a highest complication rate for kink, coil and bleed; 29.6%, 48.1% and 48.1% respectively. The commonest complication caused by Group C technique was bleeding (29.6%). Coiling was the commonest complication in Group H (44.4%).

Bleeding was the only complication found to be associated with technique of insertion ( $p=0.012$ ). Further sequential crosstabulation Chi-square tests revealed Group H was statistically better compared to Group A (Table 4.4.).

**Table 4.4.** Complications

Complications	Group A n (%)	Group C n (%)	Group H n (%)	p-value
<b>OVERALL</b>	20 (74.1)	15 (55.6)	14 (51.9)	0.202
<b>KINK</b>	8 (29.6)	5 (18.5)	7 (25.9)	0.628
<b>COIL</b>	13 (48.1)	10 (37)	12 (44.4)	0.703
<b>BLEED</b>	13 (48.1)	8 (29.6)	3 (11.1)	0.012*

Test done : Chi-Square test. \*P-value < 0.05 considered significant.

## CHAPTER 5: DISCUSSION

Nasogastric tube (NGT) insertion is a common procedure for an anaesthesiologist, either in operation theatre, intensive care units or emergency department. Most of the anaesthesiologists will encounter difficulty in inserting NGT in anaesthetized, paralyzed or sedated patient. In these groups of patients, this procedure may require multiple attempts, time-consuming and sometimes can be a frustrating experience. This is due to loss of the pharyngeal muscle activities to steer the NGT into oesophagus in awake and cooperative patients. Ozer and Benumof have found that the most common sites of impacted NGT are piriform sinuses and arytenoids cartilages, rendering its coiling in the nasopharynx or oropharynx<sup>4</sup>.

In our centre, a neutral position(a.k.a. conventional technique), external laryngeal manipulation of cricothyroid cartilage or direct vision using a laryngoscope and Magill's forceps are still widely used techniques in NGT insertion in anaesthetised, paralyzed and intubated patients.

This study was created to look into three different techniques (two modified techniques versus conventional technique) in inserting NGT without extra gadget or putting gloved fingers into the mouth to guide NGT.

### 5.1. Demographic data

There were no statically significant differences with regard to age and gender among the three techniques (table 4.1).

## 5.2. Success rates

In this study a highest success rate for NGT insertion was found in Group C (66.6%); followed by Group H (63.0%) compared to Group A (49.1%). Although the percentages of the modified techniques were higher than the conventional technique, there was no association between success rate and three techniques.

For the first attempt, Group C had the highest success rate (51.9%), followed by Group H (48.1%) and the lowest was Group A (25.9%).

The success rate of Group A (49.1%) was relatively lower compared to *Mahajan et.al. 2005* (70%)<sup>3</sup>. This cited paper was chosen due to the similar sample sizes (n=30 per group) with this present study (n = 27 per group). The main difference was a different continent population was studied which resulted in anatomy difference in the passage of NGT. Moreover, a bigger size NGT (16-French) was inserted compared to present study 14- French size.

For the Group H, the success rate was 64% which is far more lower compared to *Bong.et.al., 2004*<sup>1</sup> which was 86.6% within two attempts. Although this study was done in our neighbour country with the same size 14-French NGT been used, there was a difference in the sample size with n=27 per group in our study and n=15 per group in the mentioned paper. Moreover, the cited study had chosen right nostril with right lateral head turning while performing the procedure. In contrast, the nostril selected for NGT insertion in our study will be the nostril with the higher fluency of airflow felt by the patient. From this perspective, nostril selection may influence the success rate for NGT insertion. In future, we may need to consider endotracheal tube (ETT) sizes, cuff pressure, side of the ETT anchored and which side of the ventilator tubing harboured in affecting success rate for NGT insertion.

For Group C had a highest in success rate but statistically not significant comparing with other techniques. The initial intention of this technique was to avoid false cord in the passage of the NGT into oesophagus. However, there is a possibility that this manoeuvre may indirectly cause a narrowing of the parapharyngeal space during NGT insertion with the passage of NGT felt by performers' fingers externally. Hence this technique may need to be modified to increase the success rate. *Mandel et al.* has shown reverse Sellick's manoeuvre had a high success rate of 96%<sup>6</sup>. The reverse Sellick's manoeuvre will anteriorly displace (lifting) the cricoid cartilage to facilitate the insertion of NGT.

Hypothetically the combination of contralateral cricothyroid displacement with reverse Sellick's manoeuvre will further increase the success rate of NGT insertion compared to contralateral cricothyroid pressure or reverse Sellick's manoeuvre alone. Further study will be needed in future to evaluate the effectiveness of contralateral cricothyroid displacement with reverse Sellick's manoeuvre versus reverse Sellick's manoeuvre alone. Hemodynamic status of the patient may need to be considered as the reverse Sellick's manoeuvre can be a painful manoeuvre.

Further studies need to be conducted to look for better manoeuvre in NGT insertion with a higher success rate and lower complication rate in our population. We have found an idea for NGT insertion without manipulating the neck, using extra gadget or inserting gloved fingers into oral cavity – reverse Sellick's maneuver with contralateral cricothyroid displacement. Furthermore, we also look into other factors affecting NGT insertion, for instance, sizes of endotracheal tubes (ETT), ETT cuff pressure, site of ETT anchored and ventilator tubing. We also like to look into whether frozen NGT will improve the success rate.

To date, in our practise among the investigators, we will still prefer modified techniques in inserting NGT although there was no statistical difference in the success rate but the percentage of the modified techniques were higher than conventional technique and the complications were lower in the modified techniques groups especially bleeding. An anaesthetised, paralyzed, and intubated patient who needs NGT insertion, ipsilateral head turning technique will be used if no contraindication in neck movement. If there is a cervical pathology, contralateral cricothyroid pressure technique may be considered.

### **5.3. Procedure duration for success selected technique.**

The median time for the overall success duration in inserting NGT was 32 seconds. The fastest will be Group H (28 seconds), followed by Group C (33.5 seconds), and the slowest will be Group A (46 seconds), but there was no statistical significant between each technique. The success duration of different techniques for NGT insertion in the present study is less than a minute duration and is in accordance with *Mandel, et. al.*<sup>6</sup>

Procedurist may feel frustrated the longer duration it took for NGT insertion. However, this is not a life saving procedure; hence, timing of NGT insertion within minutes is still acceptable.



#### 5.4. Complications

Kinking, coiling and bleeding were common complications during NGT insertion.

Group A had the highest overall complications rate (74.1%) and highest for each subgroups (kinking =29.6%, coiling=48.1% and bleeding=48.1%). There was no significant association between complication rate and the three techniques of insertion except bleeding.

Kinking and coiling were less seen in Group C (18.5% and 37% respectively). Kinking was due to the weakness part of the distal end NGT and became soft when exposed to body temperature. The frozen NGT or putting in a guide wire into NGT will reduce flexibility of the tube. In future, we might need to look into this aspect in our future study.

An unrecognised coiled NGT will be accidentally dislodged while extubating the patients. The coiling of the NGT in post extubated patients might cause discomfort, retch, choke, cough and respiratory distress leading to morbidity and mortality.

Bleeding was the only factor that has shown significant association between the three techniques (p-value 0.012). Group H had the lowest incident of bleeding (11.1%), followed by Group C (29.6%) and the highest was Group A (48.1%). Further evaluation of the data, we found out the Group H was statistically lower than Group A (p-value 0.003).

Bleeding is mainly due to bleed of the mucosa and will cause painful mucosa ulcer during the post operation period. This will affect patients' oral intake. The bleeding might be contaminating the endotracheal plaster. This is particular important in patient with borderline coagulopathy or bleeding tendency.

Complication occurs in every group. What we can conclude overall is that ipsilateral head turning technique has marginal less complication. However, bleeding is statistically lower than conventional technique.

### **5.5. Limitation**

We did not standardize the ETT cuffed pressure in which might affect the success rate of NGT insertion in anaesthetised, paralysed and intubated patients. NGT insertion supposedly is a 'simple procedure', however it is in fact a meticulous process which needs special attention, certain degree of skill and some level of experience in order to have a higher success rate. In this study, only the single investigator performed NGT insertion for the modified technique; NGT insertion in intubated patients will have inter-individual variability and is operator dependent. Further evaluation will be needed to look into the whole process and compounding factors of NGT insertion in anaesthetised, paralysed and intubated patients. Perhaps in future, study may need to involve other anaesthetist colleagues in performing NGT insertion to evaluate the effectiveness of the technique applied by anaesthetic providers.

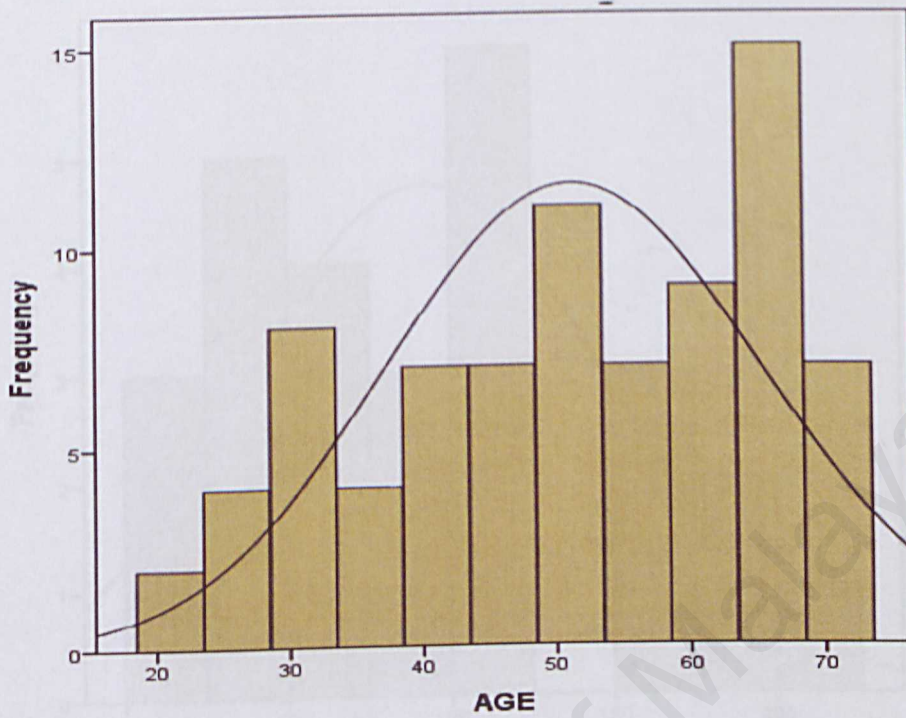
## CHAPTER 6: CONCLUSION

With this present study, the modified techniques (contralateral cricothyroid pressure and ipsilateral head turning) has shown to be better than conventional technique in terms of higher success rate and less complications in NGT insertion. Although there were statistically insignificant for the success rate and complications, except for the bleeding, the modified techniques were statistically better than conventional technique. We will still consider modified techniques in NGT insertion in our clinical practice. The contralateral cricothyroid pressure will be the preferred method for NGT insertion in patients with cervical pathology and trauma patients on cervical collar.

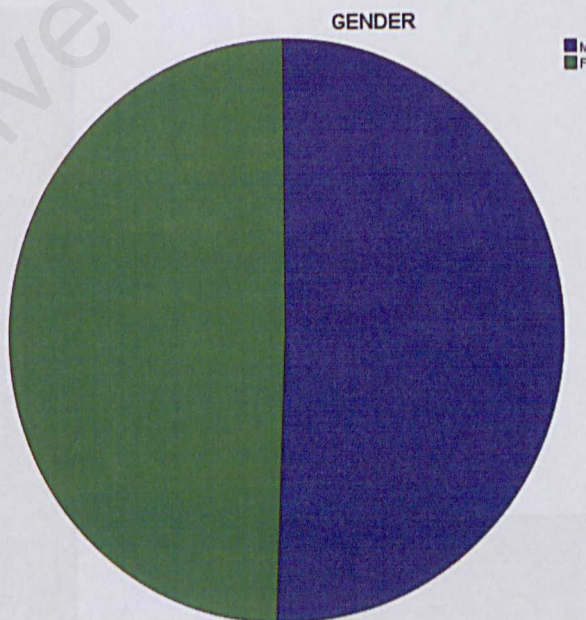
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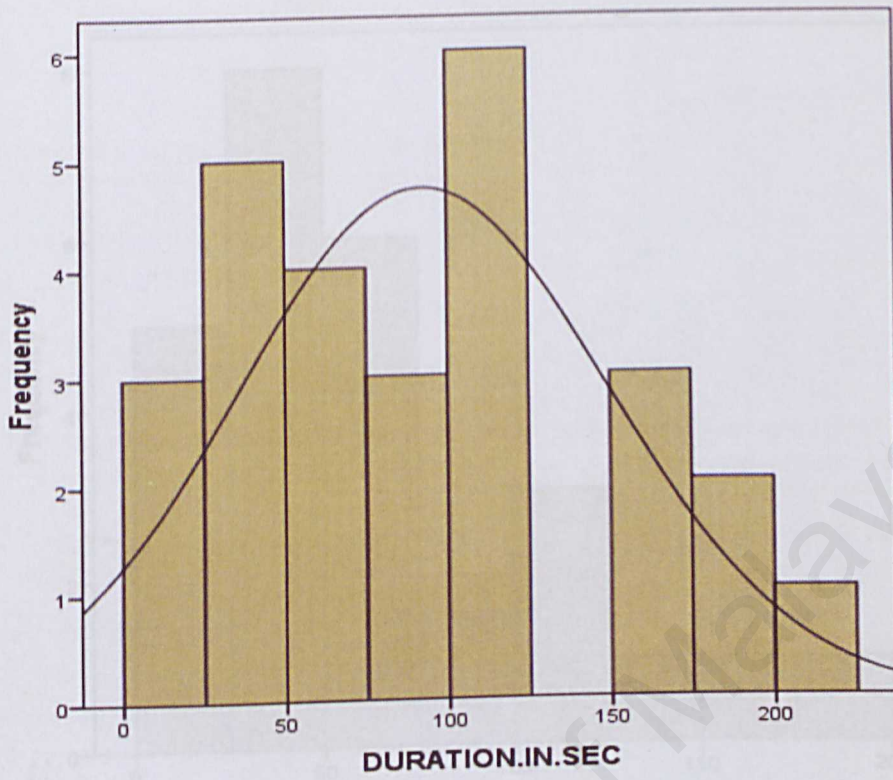
Appendix A: Histogram for patient's age



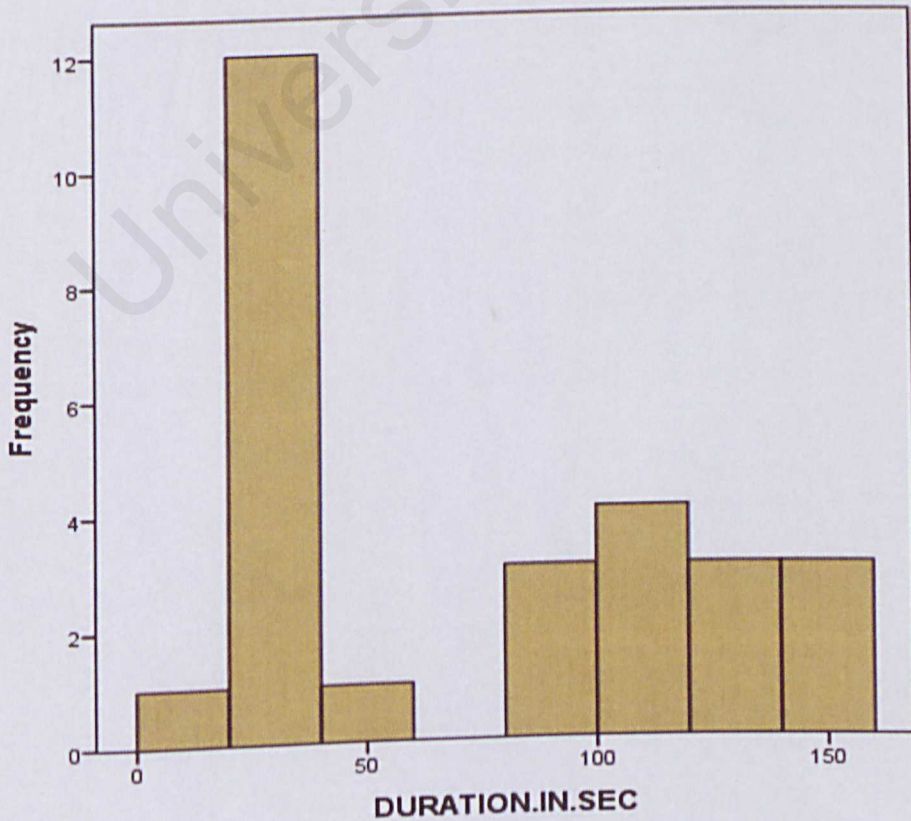
Appendix B: Pie chart for patient's gender



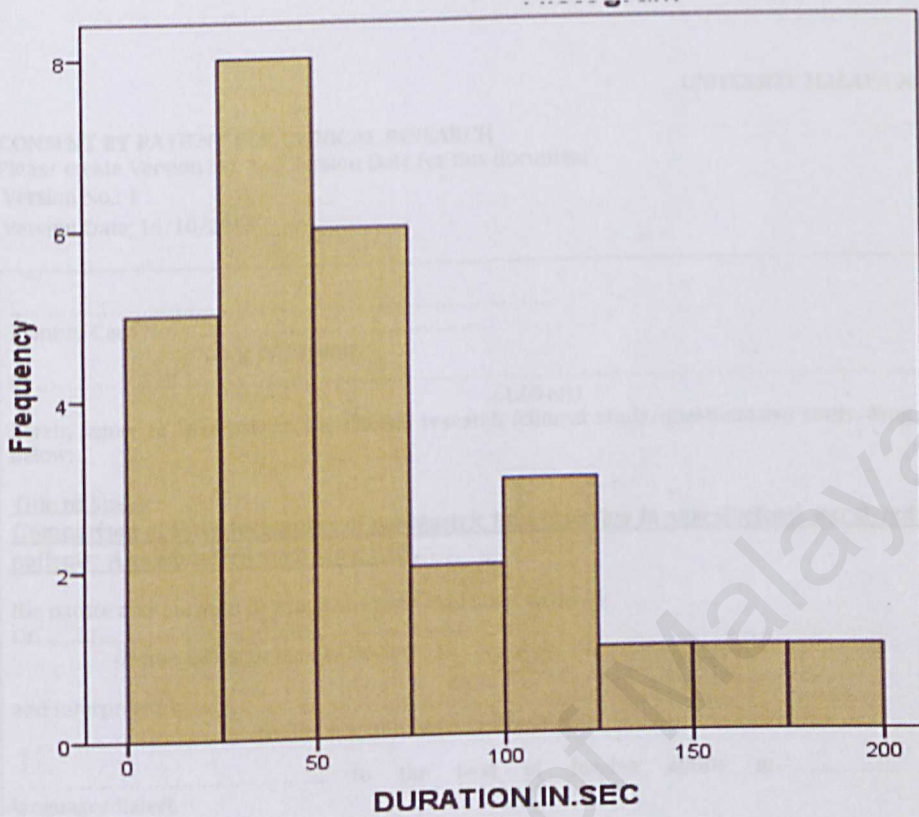
**Appendix C: Duration of insertion for Conventional technique**



**Appendix D : Duration of insertion for Contralateral cricothyroid pressure**



### Appendix E : Duration of insertion for Ipsilateral Head turning



## Appendix F : Consent form English Version

UNIVERSITY MALAYA MEDICAL CENTRE

### CONSENT BY PATIENT FOR CLINICAL RESEARCH

Please create Version No. and Version Date for this document:

Version No.: 1

Version Date: 15/10/2015

I, .....  
Identity Card No. ....  
*(Name of Patient)*

of .....  
*(Address)*

hereby agree to take part in the clinical research (clinical study/questionnaire study/drug trial) specified below:

**Title of Study:**  
**Comparison of three techniques of nasogastric tube insertion in anaesthetised, paralyzed and intubated patients: A randomized open-label trial.**

the nature and purpose of which has been explained to me by  
Dr. ....  
*(Name & Designation of Doctor)*

and interpreted by .....  
*(Name & Designation of Interpreter)*

..... to the best of his/her ability in .....  
language/dialect.

I have been told about the nature of the clinical research in terms of methodology, possible adverse effects and complications (as per patient information sheet). After knowing and understanding all the possible advantages and disadvantages of this clinical research, I voluntarily consent of my own free will to participate in the clinical research specified above.

I understand that I can withdraw from this clinical research at any time without assigning any reason whatsoever and in such a situation shall not be denied the benefits of usual treatment by the attending doctors.

Date: ..... Signature or Thumbprint .....  
*(Patient)*

**IN THE PRESENCE OF**

Name ..... )  
Identity Card No. .... )  
Designation ..... )

Signature  
*(Witness for Signature of Patient)*

I confirm that I have explained to the patient the nature and purpose of the above-mentioned clinical research.

Date ..... Signature .....  
*(Attending Doctor)*

CONSENT BY PATIENT  
FOR  
CLINICAL RESEARCH

R.N.  
Name  
Sex  
Age  
Unit

BK-MIS-1117-E02



**Appendix F : Consent form  
Malay Version**

UNIVERSITY MALAYA MEDICAL CENTRE

**KEIZINAN OLEH PESAKIT UNTUK PENYELIDIKAN KLINIKAL**  
Sila letakkan Nombor Versi dan Tarikh Versi untuk dokumen ini:  
Nombor Versi: 1  
Tarikh Versi: 15/10/2015

Saya.....  
No. Kad Pengenalan .....  
(Nama Pesakit)

beralamat.....  
(Alamat)

dengan ini bersetuju menyertai dalam penyelidikan klinikal (pengajian klinikal/pengajian soal-selidik/percubaan ubat-ubatan) disebut berikut:

**Tajuk Penyelidikan:**  
**Comparison of three techniques of nasogastric tube insertion in anaesthetised, paralyzed and intubated patients: A randomized open-label trial.**

yang mana sifat dan tujuannya telah diterangkan kepada saya oleh  
Dr.....  
(Nama & Jawatan Doktor)

mengikut terjemahan .....  
(Nama & Jawatan Penterjemah)

..... yang telah menterjemahkan kepada saya dengan sepenuh kemampuan dan kebolehannya di dalam Bahasa / loghat.....

Saya telah diberitahu bahawa dasar penyelidikan klinikal dalam keadaan methodologi, risiko dan komplikasi (mengikut kertas maklumat pesakit). Selepas mengetahui dan memahami semua kemungkinan kebaikan dan keburukan penyelidikan klinikal ini, saya merelakan/mengizinkan sendiri menyertai penyelidikan klinikal tersebut di atas.

Saya faham bahawa saya boleh menarik diri dari penyelidikan klinikal ini pada bila-bila masa tanpa memberi sebarang alasan dalam situasi ini dan tidak akan dikecualikan dari kemudahan rawatan dari doktor yang merawat.

Tarikh: ..... Tandatangan/Cap Jari .....  
(Pesakit)

**DI HADAPAN**

Nama .....  
No. K/P.....  
Tandatangan  
(Saksi untuk Tandatangan Pesakit)

Jawatan .....  
Saya sahkan bahawa saya telah menerangkan kepada pesakit sifat dan tujuan penyelidikan klinikal tersebut di atas.

Tarikh: ..... Tandatangan .....  
(Doktor yang merawat)

**KEIZINAN OLEH PESAKIT  
UNTUK  
PENYELIDIKAN KLINIKAL**

No. Pend.  
Nama  
Jantina  
Umur  
Unit

BK-MIS-1117-E02