RANDOMIZED CONTROLLED TRIAL (RCT) COMPARING BETWEEN SHOULDER UMBILICUS LENGTH VERSUS BODY WEIGHT MEASUREMENT FOR OPTIMAL ENDOTRACHEAL TUBE (ETT) DEPTH IN VENTILATED INFANTS

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LIST OF ABBREVIATIONS

ETT	Endotracheal tube
BW	Birth weight
HUSM	Hospital Universiti Sains Malaysia
NICU	Neonatal Intensive Care Unit
RCT	Randomised Controlled Trial
SUL	Shoulder umbilical length
NRP	Neonatal Resuscitation Program

ABSTRAK

PENGENALAN: Penempatan yang optimum pada tiub endotrakeal (ETT) bagi bayi yang memerlukan bantuan pernafasan adalah penting, berat kelahiran (BW) mungkin bukan parameter terbaik untuk meramalkannya. Kajian terdahulu menunjukkan bahawa panjang tali pusat ke bahu (SUL) mungkin unggul. Kajian ini adalah perbandingan secara langsung dari SUL vs BW sebagai peramal untuk penempatan ETT yang optimum bagi yang memerlukan bantuan ventilasi di Malaysia.

KAEDAH: Semua bayi yang memerlukan bantuan pernafasan di NICU Hospital Universiti Sains Malaysia dalam tempoh kajian selama 5 bulan layak masuk ke dalam percubaan terkawal ini. Bayi-bayi yang termasuk dalam kajian ini adalah secara rawak dan dibahagikan kepada dua kumpulan: kedalaman tiub ditentukan berdasarkan SUL bagi kumpulan intervensi dan berdasarkan kepada BW untuk kumpulan kawalan. Ukuran hasil utama adalah posisi ETT yang tidak optimal, seperti yang dilihat pada rajah sinar dada yang dilakukan dalam masa 1 jam selepas intubasi. Penempatan tiub pernafasan dinilai oleh dua ahli neonatologi, dibutakan kepada peruntukannya. Data dianalisis dengan menggunakan SPSS, versi 24.

KEPUTUSAN: Seratus dan sepuluh bayi secara rawak, 55 dalam setiap kumpulan. ETT adalah mal-posisi (memerlukan pelarasan dalam 13/55 bayi (23%) untuk kumpulan SUL dan 22/55 bayi (40%) dalam kumpulan BW ($p = 0.06$)

KESIMPULAN: Di dalam kumpulan SUL, kurang bayi menunjukkan keperluan pelarasan tiub berbanding dengan kumpulan BW. Perbezaannya tidak mencapai maksud statistik. Walaupun kajian yang lebih besar mungkin diperlukan untuk menunjukkan kepentingan statistik, perbezaan yang ditunjukkan dalam kajian ini mungkin cukup besar kepentingan klinikal.

Kata kunci: Panjang tali pusat ke bahu, berat badan, penempatan tiub endotrakeal.

ABSTRACT

INTRODUCTION: The optimal placement of the endotracheal tube (ETT) in ventilated neonates is essential but birth weight (BW) may be not the best parameter to predict it. A previous study suggested that shoulder umbilical length (SUL) might be superior. The aim of this study is a direct comparison between SUL vs. BW as predictor of optimal ETT placement in Malaysian ventilated neonates.

METHODS: All neonates requiring ventilation in the NICU of Hospital Universiti Sains Malaysia during the 5 months study period were eligible to enter this randomized controlled trial. Babies included in this study were randomized in two groups: the tube depth was determined based on the SUL for the intervention group and based on the BW for the control group. The main outcome measure was mal-positioning of the ETT as seen on the chest x-ray performed within 1 hour after intubation. Tube placement was assessed by two neonatologists, blinded to the allocation. Data were analysed using SPSS, version 24.

RESULTS: One hundred and ten (110) babies were randomized, 55 in each group. The ETT was mal-positioned (requiring adjustment in 13/55 babies (23%) for the SUL group and 22/55 babies (40%) in the BW group (p=0.06)

CONCLUSION: In the SUL group, less babies showed a need for tube adjustment than in the BW group. The difference did not reach statistical significance. While, a larger study may be necessary to show statistical significance, the difference shown in this study may be large enough to be of clinical significance.

Key words: shoulder-umbilical length, body weight, endotracheal tube placement.

CHAPTER 1: INTRODUCTION

1.1 LITERATURE REVIEW

Neonatal intensive care has undergone a tremendous evolution over the past few decades. One of the major breakthrough in the history of neonatal care was the development of mechanical ventilation. The rate of the survival of the neonates especially the premature babies has substantially increased since its widespread usage in the 1960's and 1970's (Reid et al 1967). Another major milestone responsible for a significantly better prognosis of premature neonates is the introduction of exogenous surfactant administration. It is initially described by Fujiwara in 1980 (Fujiwara et al 1980).

Both mechanical ventilation and surfactant administration require the placement of an ETT. In new born babies and especially in the very low birth weight babies, the correct positioning of the tube is critical to the wellbeing of the child. Because of the short trachea, minor displacement of the ETT may cause a significant risk potentially leading to the life threatening complications for the baby.

Endotracheal intubation is often an indispensable component in the management of an ill neonate and is usually an emergency procedure. Optimum placement of the ETT is essential. If the ETT placement is too high (above T1 vertebral body) it may cause accidental extubation. On the contrary, if the ETT placement is too low (below T4 vertebral body) it may cause intubation of a main stem bronchus usually on the right side. Optimal placement of ETT is vital to allow the flexion and the extension of neck without significant tube displacement during these movements. This adds up to the safety to the neonate.

Accurate positioning of the ETT in mechanically ventilated neonates is essential for optimal ventilation. However, half of the intubated babies may have atelectasis secondary to endobronchial placement of the ETT. Indeed, the malposition of the ETT is the most common unpredicted radiographic finding necessitating an intervention. The accepted optimal position for the tip of the ETT is in the midtrachea. Thus, a number of parameters are available to predict this depth from external body measurements such as weight, head circumference, crown-heel or crown-rump length (Goldiron et al 1969).

However, many of these studies have their limitations. The original cadaveric work included 15 infants but only one of them was less than 1000 g in weight. Today, a large number of infants admitted to the neonatal intensive care unit weigh less than 1000 g. Although studies show crown-rump or crown-heel length to be the best predictors of midtracheal distance, they are difficult to measure accurately especially in sick babies and they lack of reproducibility. The weight is easy to obtain accurately. Unfortunately, it is a non-linear measurement and predictions based on weight may be misleading in oedematous or growth retarded infants. Meanwhile, head circumference is related more to brain mass rather than body length. It may be misleading in infants with cephalohaematoma, caput succedaneum, and microcephaly or macrocephaly (Loew A et al 1974).

It has been shown that the birth weight, crown-rump and crown-heel lengths of neonates particularly in premature babies can be accurately estimated from measurement of their foot lengths. The latter measurement can be made simply, rapidly, and safely even in critically ill neonates. We hypothesized that foot length may provide a simple and accurate prediction of optimal ETT length. We evaluated the usefulness of this measurement in estimating the nose to midtracheal length in neonates during direct measurements of the upper airway at autopsy.

On top of that, we have tested its clinical relevance against the traditional weight derived estimates in a randomised clinical trial. (James D et al 1979)

In the direct measurements of the airway at the autopsy, foot length was a better predictor of nasotracheal distances (r^2 = 0.79) compared to body weight, gestational age, and head circumference (r^2 = 0.67, 0.58, and 0.60 respectively). Measurement of foot length was easy and was highly reproducible. In a randomised controlled trial, there were no significant differences between the foot length and body weight based estimates. For optimal ETT placement, it was 44% *v* 56% and as for the satisfactory ETT placement, it was 83% *v* 72% (Embleton et al 2001).

The American Academy of Pediatrics and the American Heart Association used the "7-8-9" rule to calculate the ETT length from tip-to-lip in the Neonatal Resuscitation Program (NRP) based on a formula devised by Tochen (Wyckoff et al 2017). The formula states that the tip-to-lip distance (in centimeters) is calculated as six plus birth weight of the baby (in kilograms). However, studies in low birth weight (LBW) infants (less than 2.5 kg) have shown the incidence of inadequate placement of the tip of the tube to be as high as 47 % when this formula is used.

The incidence of inadequate placement of the ETT tube is as high as 40 %. This was more prominent in the ELBW neonates (83.3 %) and in neonates born before 28 weeks of gestation (100 %). Birth weight, sternal length, and shoulder umbilical length correlated significantly with optimum ETT length. There are several parameters to calculate the optimum ETT length. The parameters include the birth weight, sternal length, and sternal umbilical length. Therefore, the formulae using these parameters are weight plus five centimeters, sternal length plus two and half centimeters and half of shoulder umbilicus length plus one and half

centimeters respectively. Future prospective studies are necessary to evaluate these formulae before they are applied in clinical practice (Dharamveer et al 2015).

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CHAPTER 2: STUDY PROTOCOL

2.1 TITLE

RANDOMIZED CONTROLLED TRIAL (RCT) COMPARING BETWEEN SHOULDER UMBILICUS LENGTH VERSUS BODY WEIGHT MEASUREMENT FOR OPTIMAL ENDOTRACHEAL TUBE (ETT) DEPTH IN VENTILATED INFANTS.

2.2 OBJECTIVE

2.2.1 General objective

The primary outcome is to compare the proportion of optimal ETT placement using shoulder-umbilical length in comparison to body weight in neonates.

Secondary outcomes included comparison of the proportion of satisfactory ETT placement and malpositioning of the ETT using SUL in comparison to using BW for determination of initial ETT depth.

2.2.2 Specific objective

The primary outcome is to compare the proportion of optimal ETT placement using shoulder-umbilical length in comparison to body weight in neonates.

2.3 METHODOLOGY

2.3.1 Study design

This parallel, randomised controlled trial with a one to one allocation ratio, was conducted in the neonatal intensive care unit (NICU) of Hospital Universiti Sains Malaysia (HUSM), a tertiary teaching hospital on the east coast of peninsular Malaysia. The study period was four months, from 4th April 2018 – 4th August 2018.

2.3.2 Study location and duration

Study was conducted in HUSM from 4th April 2018 – 4th August 2018.

2.3.3 Study population and sample

The inclusion criteria were inborn infants requiring ventilation. Infants with major congenital abnormalities and/or abnormal airways were not included in the study.

2.3.4 Sampling technique and randomization.

Infants included in the study were randomly divided into two groups: for the intervention group, optimal ETT depth was estimated using the shoulder-umbilicus length (SUL) formula while for the control group the body weight formula was used. A computer-generated table was used for the randomization of all subjects into the two groups. The random sequence was generated by a researcher who was not involved in the recruitment of patients, the data collection or the care of the NICU patients. The patients were recruited by the main investigator. Concealment of allocation was ensured by the use of sequentially numbered, sealed and opaque envelopes carrying the allocation which were opened only after

the patient was included in the study. The patients remained in the allocated group until they exited from the study, after the optimal ETT depth was measured by the chest radiograph.

2.3.5 Inclusion criteria

1. Inborn infants requiring ventilation.

2.3.6 Exclusion criteria

1. Infants with major congenital abnormalities and/or abnormal airways.

2.3.7 Sample size calculation

The required sample size was 55 subjects for each arm, calculated using PS Software version 24. From the database, there has been no study done to compare both methods in paediatrics population. The estimated sample size is 55 participants in each arm. Therefore, the total number of participants is about 110 including 20% dropouts (alpha =0.05, power 80%).

2.3.8 Research tool

1. Measuring tape
2. Weighing scale
3. Laryngoscope
4. Adhesive tape
5. Endotracheal tube
6. Stethoscope

2.3.9 Statistical analysis

Data were analysed in SPSS version 24. After data entry, they were explored, checked and cleaned. Descriptive statistics were used to summarise the socio-demographic characteristics. Numerical data are presented as mean (SD) or median (IQR) based on normal distribution or not. Categorical data were presented as frequency (%). Simple linear regression was used to look for a correlation between the external body measurement and the appropriate ETT depth. The result is considered significant if the p-value <0.05.

2.3.10 Confidentiality and privacy

Patient was identified using study number. No identifiable data were expressed and shared to the public.

2.3.11 Ethical consideration

This trial was approved by the Research and Ethics Committee School of Medical Sciences, University Sains Malaysia (USM/JEPeM/18020118). The trial was conducted according to Good Clinical Practice Guideline and Declaration of Helsinki. Written informed consent was obtained from the parents of the infants included in the study. The trial was registered with Australian New Zealand Clinical Trial Registration ACTRN12611000676910 on 4th April 2018.

CHAPTER 3: ORIGINAL ARTICLE- PUBLISHED IN JOURNAL OF PAEDIATRICS AND CHILD HEALTH

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ORIGINAL ARTICLE

Randomised controlled trial: Shoulder–umbilicus length versus body weight measurement for optimal endotracheal tube depth estimation in ventilated infants

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Aim: The optimal placement of the endotracheal tube (ETT) in ventilated infants is essential, but birthweight may be not the best parameter to predict it. The aim of this study was a direct comparison of shoulder–umbilical length (experimental group) versus birthweight (control group) as predictor of optimal ETT placement in Malaysian ventilated infants.

Methods: All infants requiring ventilation in the neonatal intensive care unit of a tertiary hospital in Malaysia during the 4-month study period were eligible to enter this randomised controlled trial. All participants were randomised into two groups: experimental and control group. The main outcome measure was malposition of the ETT (requiring adjustment), as seen on the chest X-ray performed within 1 h after intubation. Tube placement was assessed by two neonatologists, blinded to the allocation.

Results: One hundred and ten infants were randomised, 55 in each group. The ETT was malpositioned in 13 of 55 infants (23%) for the experimental group and 22 of 55 infants (40%) in the control group ($P = 0.06$).

Conclusion: In the experimental group, fewer infants showed a need for tube adjustment than in the control group. While a larger study may be necessary to show statistical significance, the difference shown in this study may be large enough to be of clinical significance.

Key words: body weight; endotracheal intubation; new-born; shoulder–umbilical length.

What is already known on this topic

1 Birthweight is still commonly used to estimate the optimal endotracheal tube depth in infants.
2 Other body measurements have been proposed but have not been tested in a direct comparison through a clinical trial.

What this paper adds

1 Use of shoulder–umbilical length to estimate the optimal endotracheal tube depth was showing a trend towards less malposition of the tube when compared to the use of birthweight.
2 This trend was not statistically significant but may well be of clinical significance.

In infants requiring intubation, the correct positioning of the endotracheal tube (ETT) is critical to the wellbeing of the child. Because of the short trachea, even a minor displacement of the ETT may cause significant risk for life-threatening complications.[1] If the placement is too high, it may result in accidental extubation; if the placement is too low, it may cause unilateral ventilation with a collapse of the contralateral lung. Studies reporting the incidence of poor placement of the endotracheal tube (ET) tube showed it to occur very commonly (as high as 40%) and even more commonly in ELBW infants (up to 83.3%).[2,3]

The accepted optimal position for the tip of the ETT is in the mid-trachea. Up to very recently, the Neonatal Resuscitation Program (NRP) recommended the use of birthweight to calculate the initial ETT depth for oral intubation (Tochen formula: body weight (BW) in kg + 6 cm). The birthweight is easy to obtain accurately but is a non-linear measurement and predictions of optimal ETT depth, based on weight may be misleading in oedematous or growth-retarded infants.[4,5] The most recent 7th edition of the NRP recommends using the gestation-based 'initial endotracheal tube insertion depth' table or measuring the newborns' nasal tragus length and adding 1 cm to determine the correct ET insertion depth.[4] There is only limited clinical evidence that supports these methods and measurements may vary according to age and fat distribution among infants.

Some studies have assessed other external body measurements as potentially more reliable parameters for estimation of the optimal depth of the ETT in infants.[6,7] Crown-rump or crown-heel length was proposed but they are difficult to measure accurately especially in sick babies, and they lack reproducibility. Head circumference was related more to brain mass rather than body length. In the direct measurements of the airway at the autopsy,

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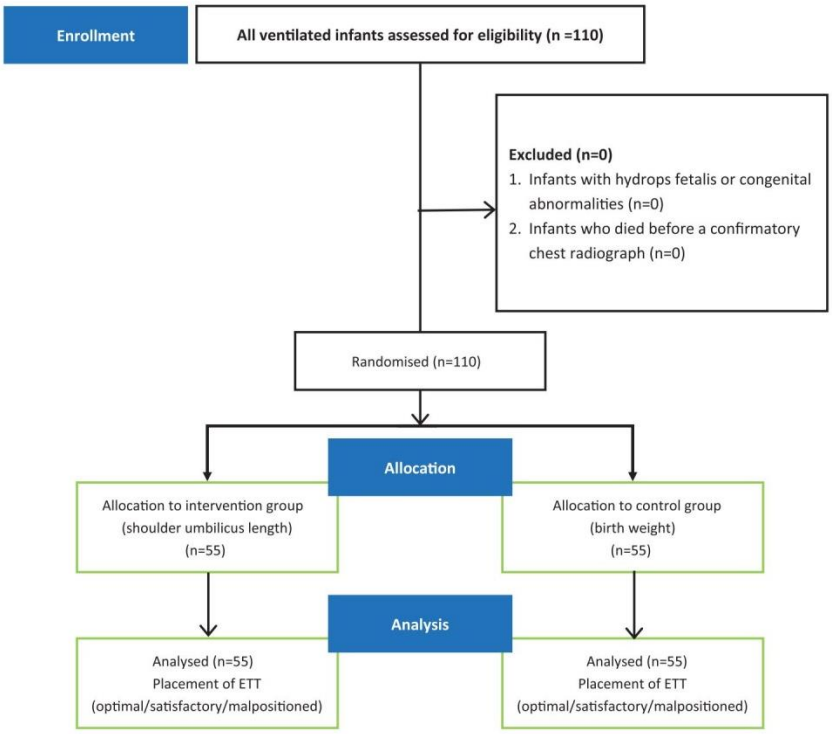

Fig. 1 Flow diagram of study participants.

foot length was a better predictor of nasotracheal distances (r^2 = 0.79) compared to body weight, gestational age and head circumference (r^2 = 0.67, 0.58 and 0.60, respectively). Measurement of foot length was easy and was highly reproducible. However, in a randomised controlled trial, there were no significant differences between the foot length and body weight-based estimates.[6]

In a recent study by Tatwavedi *et al.*[7] a variety of external body parameters were assessed as potential predictors of optimal ETT placement. Among all measured external parameters, shoulder–umbilical length (SUL) had the best correlation coefficient (r^2 of 0.836) followed by foot length, birthweight, occipitofrontal head circumference and sternal umbilical length. It seems that SUL was the best predictor by regression analysis.

This study aims to compare the proportion of optimal, satisfactory or malpositioned ETT placement using SUL in comparison to body weight (Tochen formula) in infants.

Trial designs and participants

This parallel, randomised controlled trial with a one to one allocation ratio was conducted in the neonatal intensive care unit (NICU) of a tertiary teaching hospital on the east coast of peninsular Malaysia. The study period was 4 months, from 4 April 2018 to 4 August 2018. The inclusion criteria were inborn infants requiring ventilation. Infants with major congenital abnormalities and/or abnormal airways were not included in the study.

Intervention

Infants included in the study were randomly divided into two groups: for the experimental group, optimal ETT depth was estimated using the SUL formula while for the control group the body weight formula was used. The SUL was measured from the tip of the right shoulder to the umbilicus in the supine position using a standard measuring tape. The babies were then weighed using an electronic weighing scale (SECA model 727) that has a precision of up to 0.001 kg. The formulas used to estimate optimal ETT depth, were as follows for SUL and BW, respectively:

- ETT depth (cm) = (SUL × 0.5) + 0.6 cm (Tatwavedi *et al.* 2015)
- ETT depth (cm) = BW (kg) + 6 cm (NRP 6th edition)

The infants were subsequently orally intubated with a tube depth, at the corner of the mouth, as close as possible to the estimated optimal depth.

The chest X-rays were performed as soon as possible, not later than 1 h after intubation. Extreme care was taken to ensure the optimal position of baby during the taking of radiograph. The placement of the ETT was considered as an outcome measure (optimum, satisfactory, malpositioned) based on chest X-ray and was described in more detail below. Figure 1 shows the flow diagram of study participants. For obvious reasons, the blinding of the main investigator and the staff in the NICU was not possible, but the outcome assessors (two neonatologists), who assessed the chest radiographs were blinded to the allocation of the participants. Meticulous care to position the baby correctly was taken during the orotracheal intubation and chest radiographs.

Outcomes/Objectives

The primary outcome was to compare the proportion of optimal ETT placement using SUL in comparison to body weight in infants.

Secondary outcomes included comparison of the proportion of satisfactory ETT placement and malposition of the ETT using SUL in comparison to using BW for determination of initial ETT depth.

ETT placement, either optimal, satisfactory or malpositioned, was classified as follows, based on chest X-ray: optimal placement – if the tip of the ETT was at the mid-trachea (corresponding to the body of the 1st thoracic vertebrae); satisfactory placement – if the tip of the ETT was not optimally placed but located in between the superior horizontal line through medial ends of the clavicles and the inferior lower border of the second thoracic vertebra. No tube adjustment was made; malpositioned ETT – if the tip of the ETT was superior to the horizontal line through the medial ends of the clavicles or inferior to the lower border of the second thoracic vertebra. In this case, the position of the ETT was adjusted.[2,6,8,9]

Sample size

The required sample size was 55 subjects (including 20% drop-outs) for each arm, calculated using PS Software version 24 (IBM Corp.) was required to detect (α = 0.05, power 80%) a decrease from 60 to 30% malpositioned tubes.[2]

Randomisation

A computer-generated table was used for the randomisation of all subjects into the two groups. The random sequence was generated by a co-researcher who was not involved in the recruitment of patients, the data collection or the care of the NICU patients. The patients were recruited by the main investigator. Concealment of allocation was ensured by the use of sequentially numbered, sealed and opaque envelopes, which were opened only after the patient was included in the study. The patients remained in the allocated group until they exited from the study, after the radiograph was taken for assessment of the ETT depth.

Evaluation of inter observer variability

Seven babies who fulfilled the inclusion criteria were chosen. Nine observers, either medical officers or staff nurses measured the same SUL within a 6-h period. Each observer took three measurements and the mean value was used for calculation.

Evaluation of intra observer variability

Four babies who fulfilled the inclusion criteria were chosen. The babies' SUL was measured on 10 occasions by different observers. Three measurements were taken during each occasion and the mean value was taken for calculation.

Statistical analysis

Data were analysed in SPSS version 24. After data entry, they were explored, checked and cleaned. Descriptive statistics were used to summarise the socio-demographic characteristics. Numerical data are presented as mean (standard deviation) or median (inter quartile range) based on normal distribution or not. Categorical data are presented as frequency (%). Simple linear regression was used to look for a correlation between the external body measurement and the appropriate ETT depth. The result was considered significant if the *P* value is <0.05.

Ethical approval and registration of the trial

This trial was approved by the Research Ethics Committee of the institution where the study was conducted (USM/JEPeM/18020118). The trial was conducted according to Good Clinical Practice Guideline and Declaration of Helsinki. Written informed consent was obtained from the parents of the infants included in the study. The trial was registered with Australian New Zealand Clinical Trial Registration ACTRN12611000676910 on 4 April 2018.

Results

A total of 110 babies who fulfilled the inclusion criteria were recruited. Fifty-five babies were in the experimental (SUL) group and 55 babies were in the control (BW) group. Table 1 shows the baseline data of the included infants.

Baseline characteristics, shown in Table 1, were similar between both groups for age, gender, gestational age and birthweight. There was a statistical significant difference in weight for gestation and the causes of ventilation: there were more SGA babies and more babies with respiratory distress syndrome in the control group than in the intervention group (47.3 vs. 25.5%; *P* value 0.01 and 41.8 vs. 31.5%; *P* value 0.02, respectively).

Table 2 shows the outcome of ETT placement among 110 babies requiring ventilation. There was no statistically significant difference in the overall ETT placement outcome between both groups (*P* = 0.15), but there was at trend towards lower rates of malpositioned ETT placement needing adjustment, in the intervention group when compared to the control group (23.6 vs. 40.0%).

Table 3 shows the proportion of in-positioned versus malpositioned ETT placements among 110 babies requiring ventilation. In the BW group, 22 patients (40.0%) had a malpositioned ETT placement while in the SUL group and 13 patients (17.5%) had a malpositioned ETT. This difference in proportion between the two groups did not reach statistical significance (*P* = 0.065).

Table 4 shows the association of SUL and ETT depth using simple linear regression. The present study found a significant correlation between SUL and optimum ET length, and the regression equation (0.29SUL) + 4.35 was derived. Figure 2 shows the graph for the prediction of ETT length (with 95% prediction intervals) for endotracheal intubation based on measurement of SUL.

Subgroup analysis is shown in Table 5. For very low birth weight (VLBW) babies, the tube was mal-positioned in 11.2% of babies in the SUL group versus 37.5% in the control group. Also for the

3.6 DISCUSSION

Table 1 Demographic data of patients (n = 110)

Variable	SUL (n = 55), n (%)	BW (n = 55), n (%)	Total, n (%)	P value†
Age, days				
1–30	53 (96.4)	51 (92.8)	104 (94.5)	0.70
31–50	1 (1.8)	2 (3.6)	3 (2.7)	
>50	1 (1.8)	2 (3.6)	3 (2.7)	
Mean age	3.11	6.65	4.88	
Standard deviation	10.24	14.44	12.59	
Range	1–60	1–60	1–60	
Gender				
Male	33 (60.0)	28 (50.9)	61 (55.5)	0.33
Female	22 (40.0)	27 (49.1)	49 (44.5)	
Body weight, kg				
≤1.5	9 (16.4)	16 (29.1)	25 (22.7)	0.26
>1.5, ≤2.5	11 (20.0)	11 (20.0)	22 (20.0)	
>2.5, ≤4.0	33 (60.0)	24 (43.6)	57 (51.8)	
>4.0	2 (3.6)	4 (7.3)	6 (5.5)	
Mean body weight‡	2.75	2.41	2.58	
Standard deviation	0.96	1.19	1.09	
Range	0.84–5.42	0.44–5.39	0.44–5.42	
Weight to gestation				
AGA	41 (74.5)	27 (49.1)	68 (61.8)	0.01
SGA	14 (25.5)	26 (47.3)	40 (36.4)	
LGA	0 (0)	2 (3.6)	2 (1.8)	
Causes of ventilation				
RDS	17 (31.5)	23 (41.8)	40 (36.7)	0.02
Perinatal asphyxia	5 (9.3)	2 (3.6)	7 (6.4)	
Congenital pneumonia	17 (31.5)	5 (9.1)	22 (20.2)	
MAS	6 (11.1)	5 (9.1)	11 (10.1)	
Septicaemia	2 (3.7)	3 (5.5)	5 (4.6)	
Others	7 (13.0)	17 (30.9)	24 (22.0)	
Gestational week, weeks				
<28	5 (9.1)	11 (20.0)	16 (14.5)	0.26
29–32	6 (10.9)	9 (16.4)	15 (13.6)	
33–36	9 (16.4)	6 (10.9)	15 (13.6)	
37–40	35 (63.6)	29 (52.7)	64 (58.2)	
Median§	38	37	38	
IQR	5	9	7	
Range	26–42	25–40	25–42	

†Pearson's chi-squared test was applied for categorical variable. ‡Skewed to the left. §skewed to the right. AGA, appropriate to gestational age; BW, body weight; IQR, interquartile range; LGA, large for gestational age; MAS, large for gestational age; RDS, respiratory distress syndrome; SGA, small for gestational age; SUL, shoulder–umbilical length.

babies of more than 1.5 kg at birth, the rate of malposition was lower in the SUL group than in the control group (26.1 vs. 41.0%). None of these differences reached a statistical significance level.

In our study, a simple measuring tape was used to measure umbilical-to-shoulder length, but we found very little intra-observer and inter-observer variability in the measurements. Regarding intra-observer reliability, three measurements by a single observer was

Table 2 Outcome of endotracheal tube (ETT) placement among babies requiring ventilation (n = 110)

Variable	SUL (n = 55), n (%)	BW (n = 55), n (%)	Total, n (%)	P value†
ETT placement				
Optimal	25 (45.5)	17 (30.9)	42 (38.2)	0.15
Satisfactory	17 (30.9)	16 (29.1)	17 (30.9)	
Malpositioned	13 (23.6)	22 (40.0)	13 (23.6)	

†Pearson's chi-square test. BW, body weight; SUL, shoulder–umbilical length.

Table 3 Outcome of endotracheal tube (ETT) placement among babies requiring ventilation (n = 110)

Variable	SUL (n = 55), n (%)	BW (n = 55), n (%)	Total, n (%)	P value†
ETT placement				
In positioned	42 (76.4)	33 (60.0)	75 (68.2)	0.06
Malpositioned	13 (23.6)	22 (40.0)	35 (31.8)	

†Pearson's chi-square test. BW, body weight; SUL, shoulder–umbilical length.

reliable with one-way random model case 1 intraclass correlation coefficient (ICC)[1] of 0.987 (95% confidence interval: 0.979–0.992). Inter-observer measurement by three observers were reliable and in agreement with each other with two-ray random model case 2 ICC (A,1) of 0.987 (95% confidence interval: 0.979–0.992). The level of agreement among the three observers was excellent.[10]

Discussion

To the best of the authors' knowledge, this is the first study directly comparing SUL versus birthweight for the estimation of optimal ETT position in infants. Even though none of the primary outcomes in this study reached statistical significance, there were trends in all analyses and subgroup analyses towards a better tube placement in the SUL group.

We are aware that there are several methods for measuring the SUL as described in detail in the article by Lopriore in 2008. However for the purpose of this study, we used the method as

Table 4 Association of shoulder–umbilical length (SUL) and endotracheal tube (ETT) depth using simple linear regression

Measurement	Regression equation	R	R^2	P value	Unstandardized residual SD
SUL, cm	0.29SUL + 4.35	0.75	0.550	<0.001	0.64

Both SUL and ETT depth were normally distributed. Assumption of model was checked by plotting predicted ETT and residual value. SD, standard deviation.

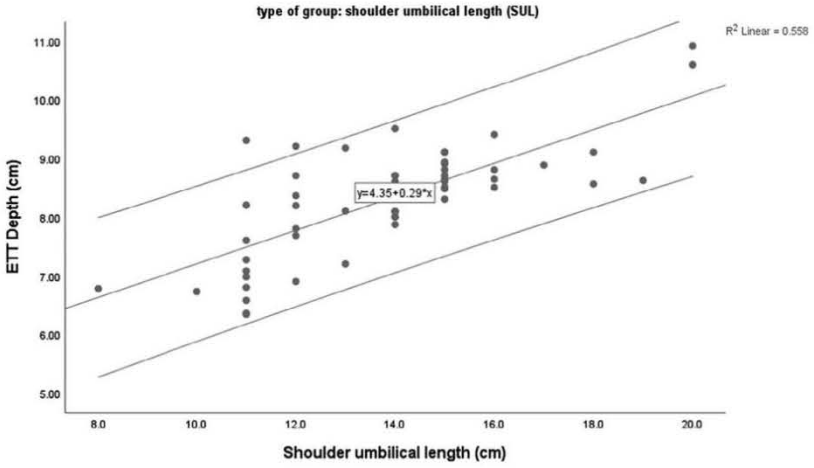

Fig. 2 Graph for prediction of endotracheal tube (ETT) length (with 95% prediction intervals) for endotracheal intubation based on measurement of shoulder–umbilical length.

Table 5 Subgroup analysis of outcome of endotracheal tube placement among babies requiring ventilation between birthweight <1.5 and ≥1.5 kg (*n* = 110)

Variable	SUL (*n* = 55), *n* (%)	BW (*n* = 55), *n* (%)	Total, *n* (%)	*P* value†
Birthweight < 1.5 kg				
Outcome				
In positioned	8 (88.9)	10 (62.5)	18 (72.0)	0.35‡
Malpositioned	1 (11.1)	6 (37.5)	7 (28.0)	
Outcome				
Optimal	4 (44.4)	7 (43.8)	11 (44.0)	0.25§
Satisfactory	4 (44.4)	3 (18.8)	7 (28.0)	
Malpositioned	1 (11.2)	6 (37.5)	7 (28.0)	
Birthweight ≥ 1.5 kg				
Outcome				
In positioned	34 (74.0)	23 (58.9)	57 (67.1)	0.36[2]
Malpositioned	12 (26.1)	16 (41.0)	28 (32.9)	
Outcome				
Optimal	21 (45.7)	10 (25.6)	31 (36.5)	0.14
Satisfactory	13 (28.3)	13 (33.3)	26 (30.6)	
Malpositioned	12 (26.1)	16 (41.0)	28 (32.9)	

†Pearson's chi-squared test was applied. ‡Fisher's exact test was applied. §more than 25% cells have expected count less than 5. BW, body weight; SUL, shoulder–umbilical length.

described in an article by Tatwavedi *et al.* Tatwavedi compared a series of body measurements with the ET length and found that the SUL as he measured it, had the best correlation with optimum ET length. Since the measurement was from the tip of the shoulder to the umbilicus, there was not much room for error. All researchers performing the measurement were trained in the method and inter and intra observer variation was minimal as mentioned in our results section. The time taken for measurement was below 1 min. The calculation is indeed a bit more complex than the Tochen formula but still within acceptable limits and quite user friendly. In emergency situations, measuring the SUL may be faster than weighing the baby.

The main limitations of this study include the small sample size. The study was powered 80% to detect a 30% reduction in tube malposition, based on a previous study[2] which had a malpositioned tube in 58% of babies. The malposition rate in the current study was lower, resulting in an effect size not reaching statistical significance. If these difference are confirmed in other studies, they maybe clinically significant. More studies and a meta-analysis of all study results may be necessary to make conclusions on which method is preferred to estimate optimal tube position in infants.

Randomisation was reliably carried out and the concealment of allocation was adequately ensured. Still there were differences

in baseline data for this study (more SGA infants and infants with respiratory distress syndrome in the control group than in the intervention group). These differences may have had an influence on the results. However, results of a subgroup analysis for VLBW babies showed a similar trend towards better tube placement in the SUL group.

The outcomes were measured through standardised chest radiographs, interpreted by two neonatal specialists who were blinded to the allocation. The trial was of sufficient quality to assume that the results can be extrapolated to other NICUs in other places, except if one would assume that there are interracial differences in body proportions resulting in different relationship between body weight, SUL and distance from lips to mid-trachea. Also in syndromic babies, which were excluded from this study, the results may not apply.[11–15]

The only randomised controlled trial comparing two methods of estimating the optimal ETT depth used foot length versus body weight for babies who were intubated nasally.[2] They found, similar to our study that there were trends which may be clinically significant towards better tube placement using the foot length compared to using the BW. Foot length was chosen for this study based on a study on autopsied infants by Embleton.[6]

Conclusion

In conclusion, this study showed no statistically significant differences in tube placement when SUL was used versus BW for estimation of optimal ETT depth. There was a trend towards better placement in the SUL group. If other studies confirm this trend, a subsequent meta-analysis of studies could help in making recommendations for clinical use of the best parameter to estimate optimal depth of the ETT in infants.

Acknowledgement

The authors want to thank the hospital director and Head of the Paediatric Department in Hospital Universiti Sains Malaysia for their permission and also the nurses and medical officers who were working during the study period in the NICU Hospital Universiti Sains Malaysia for their support. This study was carried out without grant.

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3.10 APPENDICES

3.10.1 Appendix 1: Data collection form

Proforma:

1. Study Number : _____
2. Group : Shoulder umbilical length(SUL)/body weight
3. Demographic data:
    1. Age : _____
    2. Gender : _____
    3. Race : _____
4. Birth weight : _____
5. Gestational age : _____
6. Weight to gestation :
    1. AGA
    2. SGA
    3. LGA
    4. Others : _____
5. Causes of ventilation:
    1. RDS
    2. Perinatal asphyxia
    3. Congenital pneumonia
    4. MAS
    5. Septicemia
    6. SGA
    7. Others : _____

6. Measurement of :
    1. Shoulder umbilical length : _____
    2. Body weight : _____
3. Appropriate endotracheal tube depth:
    1. Optimum : _____
    2. Satisfactory : _____
    3. Malpositioned : _____

3.10.2 Appendix 2: Ethic Approval Letter (USM)

UNIVERSITI SAINS MALAYSIA

JAWATANKUASA ETIKA PENYELIDIKAN MANUSIA

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

Universiti Sains Malaysia
Kampus Kesihatan,
16150 Kubang Kerian, Kelantan, Malaysia
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F : (6)09-767 2351
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L : www.jepem.kk.usm.my
www.usm.my

4th April 2018

Prof. Dr. Hans Amin Van Rostenberghe
Department of Pediatrics
School of Medical Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

JEPeM Code : USM/JEPeM/18020118
Protocol Title : Randomized Controlled Trial (RCT) Comparing between Shoulder Umbilicus Length vs Body Weight Measurement for Optimal Endotracheal Tube (ETT) Depth in Ventilated Neonates.

Dear Prof.,

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/18020118**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **4th April 2018** until **3rd April 2019.**

Study Site: Hospital Universiti Sains Malaysia.

The following researchers also involve in this study:

1. Assoc. Prof. Dr. Ariffin Nasir
2. Assoc. Prof. Dr. Noraida Ramli
3. Dr. Adam Al-Anas Mat Ali

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. Parental/Guardian Information Sheet and Consent Form (English version)
2. Parental/Guardian Information Sheet and Consent Form (Malay version)

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) 2017: 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) 2017: Study Protocol Amendment Submission Form.**

CERTIFIED BY:

NPRA MALAYSIA
National Pharmaceutical Regulatory Agency (NPRA)

Forum for Ethical Review Committees in Asia & Western Pacific Region

3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2017: Study Protocol Amendment Submission Form.**
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2017: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2017.**
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) 2017: 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"

Very truly yours,

ASSOC. PROF. DR. AZLAN HUSIN
Deputy Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia

UNIVERSITI SAINS MALAYSIA

JAWATANKUASA ETIKA PENYELIDIKAN MANUSIA

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Date of meeting : 13th March 2018
Venue : Meeting Room, Division of Research & Innovation, USM Kampus Kesihatan.
Time : 9.00 a.m – 2.00 p.m
Meeting No : 383

Members of Committee of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia who reviewed the protocol/documents are as follows:

Member (Title and Name)		Occupation (Designation)	Male/ Female (M/F)	Tick (✓) if present when above items, were reviewed
Deputy Chairperson: Associate Professor Dr. Azlan Husin		Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Deputy Chairperson)
Deputy Chairperson: Professor Dr. Narazah Mohd Yusoff		Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	F	✓ (Deputy Chairperson)
Secretary: Mr. Mohd Bazlan Hafidz Mukrim		Science Officer	M	✓
Members :				
1.	Associate Professor Dr. Hamid Jan Jan Mohamed	Lecturer, School of Health Sciences	M	✓
2.	Tuan Haji Ismail Hassan	Community Representative	M	✓
3.	Professor Dr. Nik Hazlina Nik Hussain	Lecturer, School of Medical Sciences	F	✓
4.	Professor Dr. Nor Hayati Othman	Lecturer, School of Medical Sciences	F	✓
5.	Associate Professor Oleksandr Krasilshchikov	Lecturer, School of Health Sciences	M	✓
6.	Assoc. Prof. Dr. Sarimah Abdullah	Lecturer, School of Medical Sciences	F	✓
7.	Dr. Soon Lean Keng	Lecturer, School of Health Sciences	F	✓
8.	Mrs. Zawiah Abu Bakar	Community Representative	F	✓

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.

ASSOC. PROF. DR. AZLAN HUSIN
Deputy Chairperson
Jawatankuasa Etika Penyelidikan (Manusia), JEPeM
Universiti Sains Malaysia

CERTIFIED BY: National Pharmaceutical Regulatory Agency (NPRA) | Forum for Ethical Review Committees in Asia & Western Pacific Region

3.10.3 Appendix 3: Journal format

Author Guidelines

CONTENTS

1. SUBMISSION

Authors should kindly note that submission implies that the content has not been published or submitted for publication elsewhere except as a brief abstract in the proceedings of a scientific meeting, conference or symposium.

Once the submission materials have been prepared in accordance with the Author Guidelines, manuscripts should be submitted online at: https://mc.manuscriptcentral.com/jpch

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By submitting a manuscript to or reviewing for this publication, your name, email address, and affiliation, and other contact details the publication might require, will be used for the regular operations of the publication, including, when necessary, sharing with the publisher (Wiley) and partners for production and publication. The publication and the publisher recognize the importance of protecting the personal information collected from users in the operation of these services, and have practices in place to ensure that steps are taken to maintain the security, integrity, and privacy of the personal data collected and

processed. You can learn more at **https://authorservices.wiley.com/statements/data-protection-policy.html**.

2. AIMS AND SCOPE

Journal of Paediatrics and Child Health is the official journal of the Paediatrics and Child Health Division (The Royal Australasian College of Physicians) in affiliation with the Perinatal Society of Australia and New Zealand, the Paediatric Research Society of Australia and the Australasian Association of Paediatric Surgeons, and publishes original research articles of scientific excellence in paediatrics and child health. Research Articles and Editorial Correspondence are published, together with invited Reviews, Annotations, Editorial Comments and manuscripts of educational interest.

3. MANUSCRIPT CATEGORIES AND REQUIREMENTS

Viewpoint

Word limit: 2,500 words maximum
Abstract: 250 words maximum; unstructured
References: Referenced only if appropriate (Vancouver style).
Description: Viewpoint is available for papers expressing a personal practice or personal view on medical or non-medical topics that are relevant to the readers. They can be up to 2,500 words long, with an unstructured abstract, and referenced if appropriate.

Annotations

Word limit: 1,500 words maximum (excludes 5 required keywords, abstract & references)
Abstract: 150 words maximum; unstructured
References: Maximum of 12 references (Vancouver style).
Key Points: Summarise the main points raised in the manuscript
Multiple choice questions: 3 multiple choice questions preferably 'A-type' single best of 5 alternatives with brief explanations for each answer) based on the article. Ensure that brief explanations are provided for both correct and incorrect answers.

Ethical Debate

Word limit: 2,500 words maximum
Abstract: 250 words maximum; unstructured
References: Referenced only if appropriate (Vancouver style).
Description: Ethical Debate is available for papers describing an ethical dilemma in clinical practice. They may argue only one perspective or two different viewpoints.

Position Paper

Word limit: 2,500 words maximum
References: Maximum of 50 references (Vancouver style).
Description: Position Papers express the consensus view of an organisation, e.g. about the management of a condition. Any recommendations should be evidence-based and should state the Level of Evidence (using NHMRC criteria).

Review Article

Word limit: 2,500 words maximum
Abstract: 150 words maximum; unstructured or structured using sub heads: Aim, Methods, Results, Conclusions. (Abstract must state: The purpose, basic procedures, main findings and principal conclusions of study.)
References: Maximum of 50 references (Vancouver style).
Key Points: Summarise the main points raised in the manuscript with 3 brief Key Points.

Original Article

Word limit: 2,500 words maximum
Abstract: 250 words maximum; structured using sub heads: Aim, Methods, Results, Conclusions. (Abstract must state: The purpose, basic procedures, main findings and principal conclusions of study.)
References: Maximum of 24 references (Vancouver style).
Brief Points: Authors are to provide up to 3 separate points for each Brief Point: 'What is already known on this topic' and 'What this paper adds'.

Instructive Cases

Word limit: 1,200 words maximum
Abstract: No abstract or key words required
References: Maximum of 8 references (Vancouver style).
Figures/Tables: Maximum combined limit of 3 figures/tables
Learning Points: A Summary listing learning points should be included at the end of the Instructive Case.
Description: Instructive Cases involve a clinical problem or issue of clear educational benefit. There is an initial case report, then a brief discussion with appropriate references.

Research Methods

Abstract: 250 words, unstructured
Word limit: 2,500 words maximum
References: Maximum of 25 references (Vancouver style).
Description: We invite Research Methods papers which should describe methodological aspects of clinical trials or data analysis of interest to readers.

Guidelines

Abstract: 250 words, unstructured
Word limit: 2,500 words maximum
References: Maximum of 50 references (Vancouver style).
Description: Guidelines regarding management or clinical practice should be evidence-based and should state the Level of Evidence (using NHMRC criteria).

Journal Club

Word limit: 2,500 words maximum
Abstract: 250 words maximum; structured using sub heads: Aim, Methods, Results, Conclusions. (Abstract must state: The purpose, basic procedures, main findings and principal conclusions of study.)
References: Maximum of 24 references (Vancouver style).
Description: They should reflect what happens at journal clubs where doctors come with a clinical