A RANDOMIZED CONTROL TRIAL: INSERTION OF PERIPHERALLY INSERTED CENTRAL CATHETER (PICC) IN NEONATES; MATHEMATICAL FORMULA VERSUS DIRECT MEASUREMENT

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THE

PRELIMINARIES

TITLE PAGE

TITLE: A Randomized Control Trial: Insertion Of Peripherally Inserted Central Catheter (PICC) In Preterm Neonates; Mathematical Formula Versus Direct Measurement

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LIST OF ABBREVIATIONS AND NOMENCLATURE

PICC	peripherally inserted central catheter
NICU	neonatal intensive care unit
SD	standard deviation
HUSM	Hospital Universiti Science Malaysia
SASMEC	Sultan Ahmad Shah Medical Centre
UVC	umbilical venous catheter
MO	Medical Officer
IIUM	Islamic International University Malaysia

ABSTRACT

Introduction

Peripherally inserted central catheters (PICC) is commonly used in preterm infants. However, many studies have shown a high need for adjustment of their position after insertion. The aim of this study was to test a new method to estimate the ideal catheter depth for cubital PICC insertion in preterm infants.

Methods

A multi-center randomized, controlled trial was conducted, comparing direct measurement from insertion site to sternal notch (control group) versus a formula based on the length of the infant (intervention group) to estimate the ideal depth of cubital PICC in preterm infants with a birth of less than 1.5kg. The primary outcome was the rate of correctly placed PICCs. Catheter related complications were also monitored.

Results

There was no difference in baseline characteristics between the intervention group and the control group except for a significant lower birth weight in the intervention group. There was no significant difference in correct placement between the intervention and the control groups (6 out of 25 or 24% vs 10 out of 27 or 37% respectively, p=0.309). There was also no significant difference in complication rates between the two groups.

Discussion and conclusion

This study did not show benefits of using an alternative formula for estimation of catheter depth for cubital PICC insertion in preterm infants. As in previous studies the rate of correct initial placement was low and there is definitely a need for studies to identify better ways to estimate the depth of PICC insertion for preterm infants.

ABSTRAK

Pengenalan

Peripherally inserted central catheter (PICC) kerapkali digunakan dalam kalangan bayi pramatang. Walau bagaimanapun, banyak bukti menunjukkan bahawa kebanyakan kedudukannya selalu tidak tepat dan memerlukan pembetulan. Tujuan penyelidikan ini adalah untuk mengkaji kaedah baru bagi menentukan kedalaman tiub *PICC* pada bayi pramatang.

Kaedah

Kajian dijalankan secara pemilihan rawak melibatkan beberapa pusat kesihatan, di antara bayi yang menggunakan kaedah mengukur panjang dari tempat tusukan hingga ‘sternal notch’ (kumpulan kawalan) dengan bayi yang menggunakan kaedah baru iaitu dengan kiraan formula berpandukan panjang bayi (kumpulan kajian) bagi menentukan kedalaman *PICC* untuk bayi pramatang, yang mempunyai berat kurang dari 1.5kg. Hasil utama yang akan dilihat ialah kadar kemasukan *PICC* yang tepat. Kadar komplikasi juga dipantau.

Keputusan

Hasil kajian mendapati tidak ada perbezaan di antara ciri-ciri asas bagi kedua-dua kumpulan tersebut kecuali perbezaan berat lahir yang lebih kecil pada kumpulan rawatan. Didapati juga bahawa kadar kemasukan *PICC* yang tepat tidak menunjukkan perbezaan yang ketara di antara dua kumpulan tersebut (6 daripada 25 atau 24% vs 10 daripada 27 atau 37% masing-masing, p=0.309). Manakala komplikasi bagi kedua-dua kumpulan juga menunjukkan tiada perbezaan yang ketara.

Perbincangan dan Kesimpulan

Dapat disimpulkan melalui kajian ini bahawa, penggunaan kaedah alternatif iaitu formula, untuk menentukan kedalaman tiub *PICC* bagi bayi pramatang menunjukkan tiada penambahan faedah. Walaubagaimanapun, disebabkan masalah kedudukan *PICC* yang tidak tepat masih berlaku, kajian baru masih diperlukan untuk menentukan kaedah terbaik untuk dalam kemasukan *PICC*.

THE

TEXT

SECTION A:

Introduction

INTRODUCTION

The need for central lines is high in preterm neonates. The umbilical vein is often used for initial central venous access but its use is limited in time and is not free of complications. If the initial insertion of umbilical catheters fails, or if there is a need for prolonged central venous access, commonly a peripherally inserted central catheter (PICC) is used as an alternative. [1]

The PICC is a catheter, of which the tip is in a central vein via percutaneous insertion from a peripheral vein. Tip placement is assessed using chest radiograph. [2] All peripheral veins from both upper limbs and lower limbs can be used for PICC. For lower limbs PICC, adjustments are usually not needed as the tip can be along the inferior vena cava but below T9 and lie to the right side of the spinal column. [3] [4] [5]

The placement of peripheral intravenous catheters in upper limbs for preterm infants can become a challenge for clinicians. Especially, there seems to be no reliable way to estimate the ideal depth of catheter insertion. Centrally placed for upper limbs should reside just above the superior vena cava, between T4 to T5. [6] Due to this narrow proper placement, it is important to study the best method to estimate the length of insertion. Studies assessing the need for catheter adjustment after its initial insertion using conventional method, which is direct measurement of the distance from insertion site to the sternal notch, showed that incorrect placement of the tip occurs in 85-95% of the cases. [7] [8] [9]

Incorrect placement of the catheter tip may be associated with complications, such as extravasation, pleural effusion, and perforation of major vessels. [10] [11] [12] The need to readjust the position of the PICC post insertion, poses extra risks to the baby, in terms of infection, thrombosis, and extra need for additional exposure to radiological investigations. There is a real risk where if catheters are inserted too deep, even for a short while, there are potential to cause major complications, such as perforation or arrhythmia.

Current practice in the Neonatal Intensive Care units (NICU), all over Malaysia, for estimation of the correct catheter depth upon insertion of PICC in the cubital vein, is to measure directly the distance from the insertion site to the sternal notch. However there is a study showing that the use of a formula, based on length of an infant, to estimate the ideal depth of central catheter insertion, had the potential to reduce the need for catheter adjustment. [13] [14] [15]

The objective of this study is to compare the conventional method of catheter depth estimation versus the methods suggested by Chen et al, [15] for insertion of right cubital PICCs in preterm neonates.

SECTION B:

Study Protocol

Dissertation Proposal

School of Medical Sciences, Universiti Sains Malaysia

Prepared in Partial Fulfillment of the Requirements for the Degree of Masters of Medicine (Pediatrics)

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Mathematical Formula versus Direct Measurement for Insertion of Peripherally Inserted Central Catheter (PICC) in Neonates

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Dissertation Research Proposal

TITLE: Mathematical Formula versus Direct Measurement for Insertion of Peripherally Inserted Central Catheter (PICC) in Neonates

1. INTRODUCTION

1.1 Background

A PICC (peripherally inserted central catheter) is a catheter in which the tip resides in a central vein via percutaneous insertion from a peripheral vein. It was introduced for the care of preterm infants in 1980. Neonatal patients often require long-term vascular access for the delivery of prolonged parental antibiotic treatment, total parenteral nutrition or blood product infusions. A neonatal PICC can be inserted at the patient's bedside and it can remain in place for several weeks. The small diameter of its lumen is ideal for the extremely small neonate. The tip location of PICC should be checked by an X-ray after the procedure.

However, the placement and maintenance of peripheral intravenous catheters in preterm infants is difficult and can become a challenge for clinicians. An umbilical venous catheter (UVC) is commonly used in the first week after birth as a central catheter in sick infants, however this is typically replaced with a PICC for long periods of intravenous catheter maintenance, as the complications of a UVC are closely related to the duration of its use.

The complications of PICC placement have been previously reported as infection, thrombosis, phlebitis, bleeding and misplacement. The complication rate of PICCs is associated with the location of their tips. Centrally placed catheter tips are associated with fewer complications compared with non-centrally placed catheter tips (Jumani, Advani et al. 2013). Therefore, the tip location of PICC is an important factor in reducing the complication rate of PICC.

In this study, the data of babies who had PICC inserted during their hospitalization in NICU HUSM were evaluated. Comparison will be made regarding measurement of PICC length inserted. Current measurement practice in NICU HUSM is by direct measurement. We will compare this with measurement using mathematical formula developed by I-Lun Chen et al published in July 2018 (Chen, Ou-Yang et al. 2019).

1.2 Justification to Conduct the Study

PICC insertion is important especially for preterm babies, to prevent frequent line insertion usually for total parenteral nutrition and medications. Therefore, it is important to make sure the PICC insertion is safe, with minimal complication. As mention, complications can be reduced by correct placement of the tip of PICC.

The current practice is using direct measurement. It measured the length of insertion site up to sternal notch. This measurement can have discrepancies among operators as it is operator dependent. Using a formula can have a standardized measurement and higher chance of better estimation as expected from the literature review below.

The reason of conducting the study is to determine the best method of PICC insertion length measurement; comparing direct measurement and mathematical measurement.

1.3 Literature Review

The formula for PICC measurement used in this study was developed in July 2018 by I-Lun Chen et al (Chen, Ou-Yang et al. 2019). Therefore, there is limited literature review comparing PICC insertion with direct measurement and mathematical measurement.

There is one study done in adult population by Philip Lum et al in 2004 at a cancer centre in Houston, Texas. It is a prospective observational study of three percutaneous insertion sites including PICC, subclavian catheter and jugular catheter. Formula based height measurement was used to determine catheter length. A total of 382 patients included in the study. Out of that, 373 (97%) of them were successfully placed with the tip in distal/ optimal location, based solely on the calculated formula-based measurement guide for determining catheter length. For PICC, total of 134 catheterizations done. Results show that 129 (96%) of the catheter tips were within distal superior vena cava (within carina and atrio-cava junction). This study concluded that the tailored-fit formula to individual patient height is a reliable tool to predict central venous catheter length (Lum 2004).

Another study done in 2005, by Kim et al, a team of paediatric anaesthesia, to determine accuracy of central venous catheter placement in infants less than 5 kg who were scheduled for elective repair of ventricular septal defect or atrial septal defect. CVC is inserted infraclavicular approach, subsequently SVC-RA junction was observed using transesophageal echocardigraphy. Distance from skin puncture to SVC-RA junction is measured. By using linear regression, a formula using height and weight was developed. Out of 50 patients, 49 of them (98%) the CVC was placed in the SVC above right atrium when CVC length measured using the formula. (Yoon, Shin et al. 2005)

In a prospective observational study in paediatric patients, Andropoulos et al, 456 central venous catheters that were inserted at right internal jugular or right subclavian veins and the catheters position was confirmed using chest radiograph. By using linear regression, an equation using height

of the patients were developed. The used of this formula predicted that 94.0% (95%CI, 88.0%–97.5%) of CVC inserted from right subclavian vein terminated at Superior vena cava and 99.4% (95%CI, 97.8–99.9%) of CVC inserted at right internal jugular terminates at superior vena cava (Andropoulos, Bent et al. 2001).

Hyun Hwan Cho et al has developed a formula for PICC length according to height in adult population through a retrospective study. A total of 124 patients was inserted with PICC through the right basilic vein under fluoroscopy were included. Relationship between PICC length and patient height are analyzed using linear regression and was found to be significantly correlated ($p<0.01$) (Cho, Jeon et al. 2012).

A retrospective observational study in paediatric patients, Fricke et al, has placed 843 PICCs in 698 patients according to clinical protocol, by a specialized team of PICC nurses and interventional radiology technologists, and the initial PICC tip location was then determined by means of spot fluoroscopy. All catheters were then manipulated with intermittent fluoroscopic guidance to achieve a final central position. A chi-square test was used to compare initial and final PICC tip locations according age, catheter size, accessed vein, and need for radiological assistance. Out of 843 PICCs, 723 (85.8%) required additional manipulation (Fricke, Racadio et al. 2005).

1.4. Research Hypothesis

We hypothesized that determination of the length of insertion of PICC in neonates using mathematical formula based on body measurement has higher successful rate with lower rate of complication compared to direct measurement.

1.5. General Objective

To compare the outcome of mathematical formula versus direct measurement for length of PICC insertion

1.6. Specific Objectives

Primary objective

1. To compare the proportion of successful PICC insertion when using mathematical formula versus direct measurement. ***Successful PICC insertion is when there is no need for readjustment after initial insertion.**

Secondary objectives

2. To compare the proportion of ***complications in relation to PICC** when inserted using mathematical formula versus direct measurement.

3. To compare the rate of ***early** removal of PICC when inserted using mathematical formula versus direct measurement in neonates.

4. To compare the mean number of PICC readjustment when PICC is inserted using mathematical formula versus direct measurement.

2. METHODOLOGY

2.1. Trial Design

Two centres, parallel design, randomised control trial (RCT) with one to one allocation ratio. Participants will be divided into control and intervention group.

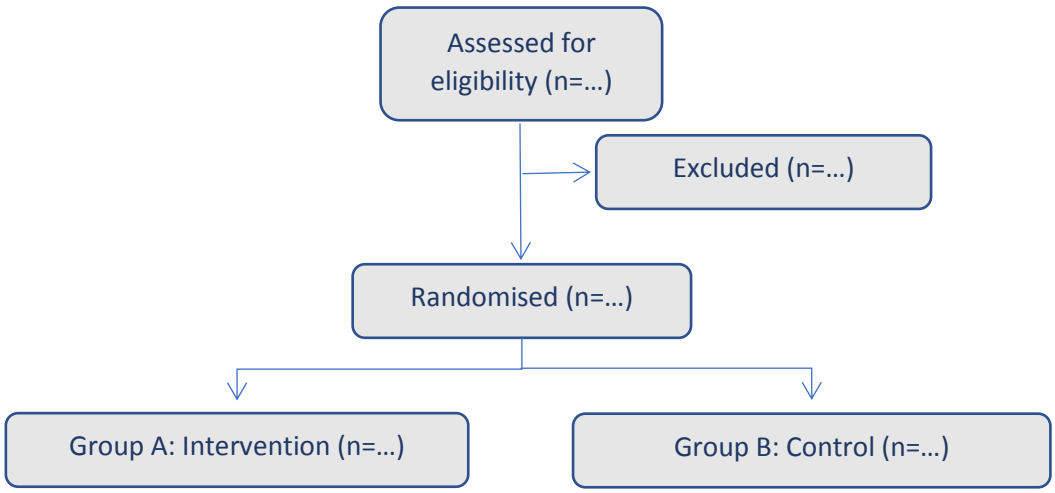


Figure 1: Study flow chart

2.2. Eligibility Criteria for Participants

Participants of the study are neonates admitted in NICU of participating centres with PICC insertion.

2.2.1 Inclusion criteria for the study;

1. Infants weigh equal or less than 1500g admitted to NICU that require PICC insertion in the participating NICUs within the study the period

1.2.2 Exclusion criteria for the study;

1. Congenital anomaly that is expected to interfere with study outcome as listed;
   -Orthopaedic problems: Arthrogryposis multiplex congenita, fixed congenital talipes equinovarus, development dysplasia of the hip (DDH), skeletal dysplasia,
   -Chromosomal aneuploidy or genetic disorders : Any recognized or unrecognized dysmorphism , i.e. Down Syndrome, Patau Syndrome, Edward Syndrome, Single gene or polygenic defects, ie: Cri-du chat, Di George syndrome, Prader Willi Syndrome etc
2. Patient with vascular anomaly
3. Hydrops Fetalis
4. Asymmetrical Small for Gestational Age neonates

2.3. Study Period/Area

The study will be conducted in Neonatal Intensive Care Unit (NICU) at Hospital USM, Kubang Kerian Kelantan and Sultan Ahmad Shah Medical Centre (SASMEC). Hospital USM is a teaching hospital in Kubang Kerian, Kelantan, a state in Malaysia where majority of its population are Malays from different socio-economic background. The Neonatal Intensive Care Unit provides

level 1 to level 4 intensive care to neonate patient and received referral from all parts of Kelantan and all over the country. The study is planned to be conducted in the period between 1st December 2020 to 1st December 2021.

2.4. Intervention

Neonates who fulfilled inclusion and exclusion criteria will be assigned randomly into either two groups. All PICC that will be inserted for any reason either for total parenteral nutrition, for medication or inotropes will be included in the study.

When eligibility to be in the study is confirmed, consent will be taken from the parents. The medical officer in charge will call the investigator to take consent. In case the investigator is not available, a trained Registrar will help to take the informed consent. Training will provided to registrars in the NICU before trial starts.

Group A will be the intervention group who will use mathematical formula. Group B will be the control group who will use direct measurement. All infants will have PICC inserted into the right antecubital fossa. Vygon Premicath 1 Fr PICC with the maximum length of 20 cm will be inserted in all the infants. For neonates randomized to Group A, the length of PICC insertion will be based on the formula;

Length (cm) = -1.45 + (0.36 x body length (cm))

Infants in group B will have the length of PICC based on direct measurement of the length between the PICC insertion site to sternal notch. All PICC will be inserted by well-trained medical officers working in NICUs with at least one year experiences in PICC insertion. All the medical officers (MO) will be trained on the correct method to measure the length from the insertion site to

the sternal notch. Inter and intra-observer reliability of the measurement will be assessed and repeat training session will be conducted if there is a poor reliability. For inter-observer reliability, we will use Bland-Altman plot analysis. Two MOs will be asked to measure the PICC insertion length of an infant. The procedure will be repeated on 10 infants. The difference of the two paired measurements is plotted against the mean of the two measurements. We will accept if all the plot lies within 95% CI of agreement limits. We will be using correlation analysis to determine intra-observer reliability. Ten babies and a random MO will be chosen. The MO will measure the insertion length of the PICC twice within 6 hours period and correlation coefficient (r) value will be measured. 'r' value of >0.8 is acceptable. Other steps of PICC insertion including the type of antiseptic solution, the dressing that will be used and post insertion care and maintenance will be according to the standard care in NICU.

For standardisation of the length measurement of the infants, we will use the same scale in both centres. Length is measured from tip of head until the bottom of one of the heel in lying position. All nurses working in all the participating NICUs will be trained on the correct method of length measurement. Similar intra and inter-observer reliability assessment will be conduct after the training session. Training session will be repeated until optimal reliability is achieved.

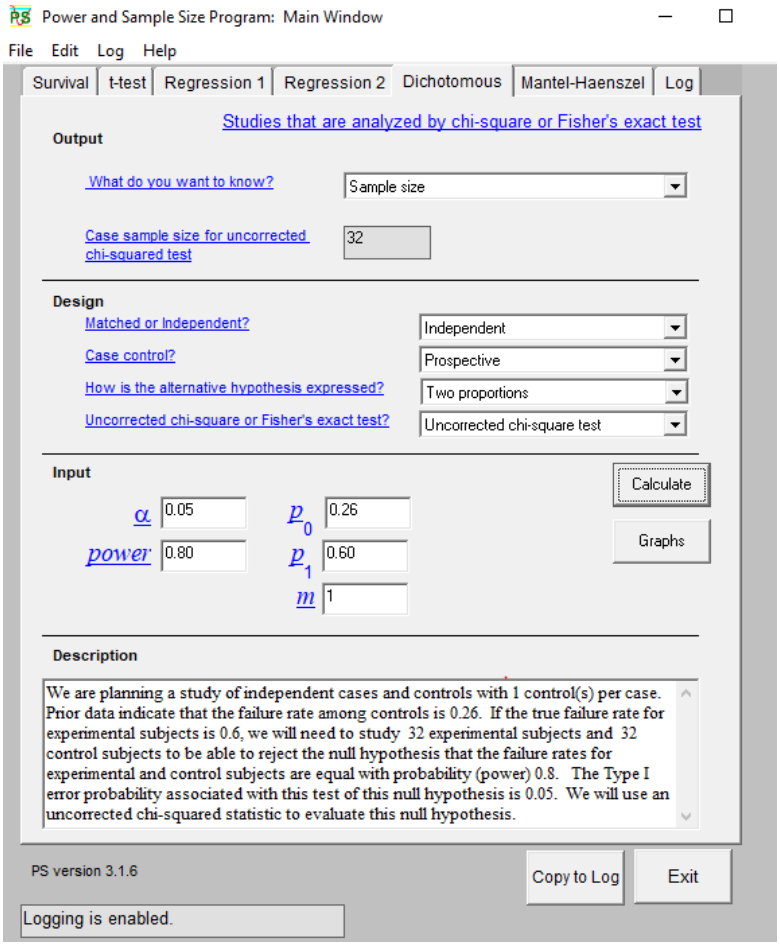
2.5. Outcomes

The primary outcome of this study is the proportion of successful PICC insertion; defined as the correct placement of PICC tip without the need for readjustment. This will be assessed by a designated radiologist that were blinded from the infant group allocation by reviewing the chest radiograph. Correct placement is confirmed if the catheter tip resides within the superior vena cava but above the level of T4 (Powls 2018). Outcomes will be divided into two categories; correctly placed or incorrectly placed PICC.

Secondary outcomes include the proportion of PICC that develop any complication attributable to the initial misplacement within two weeks of insertion, the rate of removal of PICC due to complications, and the mean number of PICC readjustment when PICC is inserted using mathematical formula compared to by direct measurement. The complications include arrhythmia, thrombosis, pleural and pericardial effusion, extravasation, catheter rupture, and catheter displacement. These outcomes will be measured by a neonatologist managing the infants in the NICU that is blinded from the randomization.

2.6. Sample Size

Sample size is calculated using PS-Power software version 3.1.6. for dichotomous outcomes.



In a previous study, proportion of correctly place PICC with the direct measurement, p0 was 0.26 (Chen, Ou-Yang et al. 2019). We wish to detect a proportion of outcome with intervention of 0.60 (p1 = 0.60), we will need to study 32 subjects in each group to be able to reject the null hypothesis that the proportion between the groups are equal, with the power of study 0.80. The Type 1 error probability associated with the test of this null hypothesis is 0.05. Taking into accounts 10% drop rate, total sample size required is 36 in each group.

Total participant needed will be 72 subjects. Around 80% of subject will be recruited from Hospital USM, and another 20% of subject from SASMEC, Kuantan. The number of subjects recruited is lesser in SASMEC because the hospital capacity is about 20% compared to the NICU in USM Hospital.

2.7. Research Tools

Direct measurement of PICC length insertion will be measured from insertion site, to sternal notch. Measuring tape prepared bedside in NICU will be used to measure the distance.

The placement of PICC will be confirmed by imaging. Portable X-ray (Brand Shimazu) will be used instead of non-portable, because neonates who need PICC insertion are usually not very stable for transfer.

Research Proforma;

Patient ID		
Date of insertion		
Gestational age		
Chronological age		
Weight		
Length		
Gender		
Purpose of insertion		
Length of insertion		
Vital sign	**BEFORE**	**1 HOUR AFTER**
HR		
SPO2		
BP		
PICC insertion (successful/ satisfactory no need adjustment/ need readjustment)		
Presence of complications;	**YES**	**NO**
Arrhythmia		
Thrombosis		
Pleural and pericardial effusion		
Extravasation		
Catheter displacement		
Catheter removal (yes/no) State reason if YES		
Number of readjustment		

3. RANDOMISATION

3.1. Sequence Generation

No sampling will be used in this study. All infants admitted that fulfilled the inclusion and exclusion criteria will be included in the study. The random sequence will be generated by a research coordinator who is not involved in the recruitment of patients, neither in the data collection nor care of the NICU patients using variable block randomization known only to that person.

3.2 Allocation Concealment Mechanism and Implementation

Patients will be recruited by the investigators, and only after inclusion in the study, consecutively numbered, sealed and opaque envelopes, carrying the allocation number will be opened. This number will determine the participant's group allocation.

3.3 Blinding

The outcome assessor, nursing staff, and family were blinded from patient's group allocation.

3.4 Statistical Methods

Data will be entered and analysed using SPSS version 24. The demographic and numerical data will be presented by mean (SD) and median (IQR) according to data distribution. The categorical data will be expressed as number and percentage. P-value $\leq$ 0.05% will be considered statistically significant. Chi Squared Test or Fisher-exact test will be used to compare the proportion of successful PICC insertion, the proportion of catheter that end up with complication attributed to the misplacement of the catheter or the readjustment procedure, and the proportion of catheter removed due to complication. Independent t-test or Mann-Whitney Test will be used to compare the mean number for readjustment attempted in both groups depending on the distribution of the data.

4. RESULTS

4.1. Data Collection Method

Data will be collected using a specific research data collection form that will be kept in a research folder not accessible to anyone apart from the research team. Every steps in PICC insertion will be documented together with details description on the method of insertion length measurement, size of the catheter, and the exact site and length of insertion of the PICC. Any immediate and post insertion complication such as arrhythmia and trauma and daily monitoring and assessment for development of delayed complications in the next two weeks post PICC insertion will also be documented by the investigator. Only research researchers can access the data to ensure confidentiality and to prevent bias. Data will be presented as grouped data and will not identify individual subject. Unit of analysis of this study is the recruited infant.

4.2. Baseline Data

Table 1: Baseline demographic data

Characteristic	**Frequency, n(%)**		**p-value**
	Formula	**Direct measurement**	
*Gestational age (week)			
*Chronological age (day)			
*Weight			
*Length			
Gender -male -female			

***Mean (SD) or Median (IQR)**

4.3. Dummy Tables

Table 2: Outcomes of PICC insertion

Outcome	**Frequency, n(%)**		**p-value**
	Formula	**Direct measurement**	
Successful PICC insertion			
Type of complication			
Arrhythmia Yes No			
Thrombosis Yes No			
Pleural and pericardial effusion Yes No			
Extravasation Yes No			
Catheter displacement Yes No			
Catheter Rupture Yes No			
Extravasation			
Catheter electively removed Yes No			
*Number of readjustment			

*Mean (SD) and median (IQR)