INPLASY PROTOCOL

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None.

Appliance of Real-time Ultrasound in Determining the Position of PICC tip in Premature Infants Nursing: Protocol for A Systematic Review and Meta-Analysis

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Review question / Objective: **Will real-time ultrasound help determine the position of PICC tip in premature infants nursing: protocol for a systematic review and meta-analysis.**
Rationale: **The pooled sensitivity, specificity and accuracy of Raman spectroscopy will be calculated based on the extracted values of true positive, true negative, false positive and false negative values in the clinical trials. The aforementioned data can be extracted based on the charts that contain the primary data in the clinical trials.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 December 2020 and was last updated on 03 December 2020 (registration number INPLASY2020120013).

INTRODUCTION

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Condition being studied: Peripherally inserted central catheter (PICC) is regarded as an important method applied in premature infants especially very low birth weight infants (VLBWs) nursing and caring for nutritional purposes since it directly transports nutrient into the cardiovascular system. However, several complications like pulmonary edema would occur if the tip of the catheter deviates from the original position. Thus, ensuring the position of the catheter tip as well as observing the position shifting of the catheter is of great significance in PICC nursing. Normally, imaging techniques like X-ray is applied aiming to determine the exact position of the tip of the catheter, which is proved to have satisfactory diagnostic efficiency and accuracy. However, X-ray is questioned for the potential radiation harm, especially when it is applied several times for the purposes of catheter tip position determination. As a result, looking for a relatively safer, less harmful way to help monitor the change of the catheter tip position is of paramount importance. Ultrasound is applied in many invasive operations, especially in catheter placement, puncture and tissue biopsy and is understood as a radiation free, trauma free diagnostic method. Lately, ultrasound including echocardiography, transesophageal ultrasonography is increasing being used in determining and observing catheter.

METHODS

Search strategy: Based on the guidelines for performing meta-analysis, we intend to search extensively acknowledged authenticated databases including PubMed/Medline, Cochrane Library, Web of Science, Ovid, ClinicalTirals.gov (http://www.ClinicalTrials.gov), China National Knowledge Infrastructure (CNKI) for related articles published from January 2008 to November 2020. The keywords (query) of our primary search will be as follows: ((((((Peripherally inserted central catheter[Title]) OR (PICC[Title])) AND (Tip[Title])) AND (Position[Title])) OR (Place[Title])) AND (Ultrasound[Title])) AND (US[Title]). Articles selected at the first place and identified will be subsequently screened for their quality, relevancy and availability. No language restriction will be used.

Participant or population: We include premature infants who needed PICC and went through both US and X-ray to determine the place of the tip of PICC.

Intervention: As far as we are concerned, our research is a diagnostic test. Therefore, the only intervention will be that the patients should undergo at least once US.

Comparator: As far as we know, there is no need of a comparator group.

Study designs to be included: Randomized controlled trial or applying any kind of observational designs, including cross-sectional, case-control and cohort designs.

Eligibility criteria: 1) reporting the use of ultrasound in PICC tip position determination; 2) being a randomized controlled trial and/or using any observational designs, including cross-sectional, case-control and cohort designs; 3) the position of the tip of PICC has simultaneously been tested by golden comparator, which is the X-ray; 4) reporting the sensitivity, specificity values or true positive (TP), false positive (FP), true negative (TN) and false negative (FN) values, based on which sensitivity and specificity values can be calculated.

Information sources: PubMed/Medline, Cochrane Library, Web of Science, Ovid, ClinicalTirals.gov (http://www.ClinicalTrials.gov), China National Knowledge Infrastructure (CNKI).

Main outcome(s): The diagnostic sensitivity, specificity and accuracy.

Additional outcome(s): The positive likelihood ratio, negative likelihood ratio, diagnostic odds ratio.

Data management: Two independent investigators will analyze the included studies for original parameters which indicate the diagnostic efficiency as well as basic information concerning the article itself. During the process, unexpected discrepancies will be carefully discussed and resolved. More specifically, diagnostic sensitivity, specificity, accuracy, TP, TN, FP, FN values will be extracted. In addition, the title, first author, nationality, department, ethnicity, study design, sex and median age of the patients and enrollment year will also carefully be extracted.

Quality assessment / Risk of bias analysis: Quality assessment will be performed based on the Quadas-2 tool. In addition, the risk of bias will be evaluated by RevMan 5.3 (The Cochrane Collaboration). The articles will be assessed in the following processes: 1) sequence generation (selection bias), 2) allocation concealment (selection bias), 3) blinding of participants and personnel (performance bias), 4) blinding of outcome assessment (detection bias), 5) incomplete outcome data (attrition bias), 6) selective reporting (reporting bias) and others.

Strategy of data synthesis: The forest plots will be generated to display sensitivity and specificity estimates using Meta-Disc version 1.4 (Clinical Biostatistics Unit, UK). The bivariate model and the hierarchical summary receiver operating characteristic (HSROC) model will be used to summarize test performance. We intend to apply these methods to respect the binomial structure of diagnostic accuracy data, which allow us to jointly summarize paired measures simultaneously, e.g. sensitivity and specificity or, positive and negative likelihood ratios (LRs). Meanwhile, as a random effects approach, the bivariate/ HSROC meta-analysis allows pooling results in view of knowing that heterogeneity is universal across included studies due to different or implicit thresholds. The said approach will be carried out by metandi (Meta-analysis of diagnostic accuracy using hierarchical logistic regression) command in STATA 14.2 (StataCorp, USA). Additionally, summary receiver operator characteristics (SROC) curves will be generated to assess the relationship between sensitivity and specificity. Meanwhile, the area under curve (AUC) will be simultaneously calculated to evaluate the overall performance of US. The SROC curved is made through Meta-Disc version 1.4 (Clinical Biostatistics Unit, UK).

Subgroup analysis: None.

Sensibility analysis: Not intend to do the sensitivity analysis.

Language: English.

Country(ies) involved: China.

Other relevant information: None.

Keywords: Ultrasound; tip; peripherally inserted central catheter; sensitivity, specificity; accuracy.

Dissemination plans: We intend to publish the protocol, which will be the main dissemination plan.

Contributions of each author:

Author 1 - Hongyu Jin - The author came up with the plans of the research and did preliminary research. In the meantime, Hongyu Jin took charge of writing the original draft. Additionally, Hongyu Jin assisted Man Zhang in data processing and cross check the data extracted.
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Author 2 - Man Zhang - The author is responsible to research relevant clinical trials published so far and extract the original data.
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