

Trial Protocol

1. Title

A clinical study on the tip localization of PICC guided by intracavitary electrocardiography in newborns: a randomised trial

2. Funding source

Kunming Science and Technology Bureau

3. Background

Perinatal inserted central venous catheter (PICC) is an important channel for high energy supply for low birth weight and extremely low birth weight infants in Neonatal Intensive Care Unit (NICU), providing a safe and reliable channel for drug and nutrition input, and has been widely used in clinical practice. The success of PICC placement depends on two aspects, i.e. whether the puncture is successful or not and whether the catheter tip is in the best position. At present, most domestic neonatal PICC placement is done blindly. In addition to the thin subcutaneous fat and narrow venous lumen of newborns, even those who have strong puncture skills still cannot avoid the pain caused by repeated punctures to the children. Even if the puncture is successful, it is difficult to ensure that the tip of PICC catheter reaches the optimal location at once, i.e., 0.5-1 cm above the right atrial inlet of the superior vena cava. The correct location of the PICC tip is essential to avoid catheter-related complications. A catheter placed too shallowly or in an ectopic location often means that the catheter is more prone to malfunction, venous thrombosis and fibrin sheath formation. Deep catheter placement, such as in the right atrium or ventricle, may result in complications such as arrhythmia, abnormal function or erosion of the tricuspid valve, and atrial thrombosis. The gold

standard for clinical determination of the PICC catheter tip position is X-ray chest radiograph, but this examination is not suitable for real-time operation during catheter placement. In recent years, the technique of intra-atrial electrocardiogram positioning of the tube end has been gradually adopted in adult PICC. Compared with the traditional methods, it is not only more economical, simple, convenient and accurate, but also can reduce patient pain, greatly shorten patient's hospitalization time and improve patient's quality of life. However, due to the special physiological and structural characteristics of the newborns, it is worth exploring whether this technique is feasible to be applied in the neonatal field.

4. Objective

The purpose of this study was to investigate the changes of P-wave in intracavitary electrocardiography (IC-ECG) during peripherally inserted central venous catheter (PICC) to help to locate the tip of PICC accurately.

5. Inclusion criteria

(1) newborns who needed PICC catheterization in our NICU between May 2015 and May 2017 and were selected to be catheterized via the vein route of the upper extremity or superficial temporal vein route; (2) newborns who needed parenteral nutrition treatment for seven days or more; (3) newborns with no arrhythmia in the ECG on the body surface and who had a heart rate of 90–180 bpm; (4) newborns with no lesions or scars on the local skin; (5) newborns with no fever, bacteremia, or physical activity disorders.

6. Exclusion criteria

(1) the legal guardian of the newborn refused to participate in the study; (2) newborns with arrhythmias, of various causes, that could affect the monitoring of the P-wave.

7. Sample size

n=106.

8. Measurement index

The accuracy, procedure duration, and cost of each catheter localization method.

9. Collection of participant information

This included the participant's name, gender, date of birth, age, diagnosis, weight, length, placement site and PICC tip location.

10. Randomization

The enrolled patients were randomly divided into two groups—a study group and a control group—of 53 patients each using a random number table. The sample size was calculated using PASS software.

11. Data management

(1) data collection: the original data were recorded by handwritten registration and computer input, and checked by two members of the research group; (2) data management: ResMan data management system was used.

12. Ethical information

The study was approved by institutional ethics board of Kunming Children's Hospital

(NO.: 2016-03-001-H01).

13. Recruitment of participants

From May 1, 2015, all the newborns who needed PICC placement in NICU of our hospital and met the inclusion criteria. The purpose and methods of the study were explained in detail to the family members of the children, and their consent was obtained and signed. The information of the children was kept confidential throughout the study and the families had the right to withdraw from the study at any time.

14. Participant management system

The privacy of the child is protected and the information of the child is kept confidential throughout. Data collection and management are managed exclusively by members of the research team, and data are not made public.

15. Research team

Research Center: Department of Neonatology, Kunming Children's Hospital

Principle Investigator: Li-Bo Zhu

Research members: Li-Bo Zhu, Ling Liu, Tie-Song Zhang, Yu-Ting Zheng, Chun-Yan Lu, Kun Lu, Shu-Xian Zhang, Liu-Yan Duan, Mei-Lin Yang

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