Impact of Cyanoacrylate Glue on PICC Line Dressing Care

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BACKGROUND

In the Neonatal Intensive Care Unit (NICU) and the Infant Cardiac Care Unit (ICCU) at Children's Hospital of New York (CHONY), a peripherally inserted central catheter (PICC) is a crucial way to provide high osmotic parental nutrition and to safely administer caustic medications. Almost all patients admitted to these units, from the extremely low birth weight infant to the full-term infant with congenital heart defects, require a PICC line during their hospitalization. The dwelling times for a PICC line in this population vary from less than 7 days to as long as 5 months according to an in-patient chart review. Maintenance of the PICC insertion site including the integrity of the PICC dressing are paramount in preventing iatrogenic complications such as infection, phlebitis, thrombosis, infiltration, catheter migration and catheter dislodgement. The neonatal population poses a unique challenge due to the small surface area of PICC sites, underdeveloped skin layer, and the inability to contain the child's movements during a dressing change. PICC line migration is the most common complication of PICC line maintenance in the NICU (Sharpe et al., 2017). The PICC migration/dislodgement mostly occurs during PICC dressing changes among the neonatal population (Acun et al., 2020). Inadvertent PICC line migration out of its central location into a peripheral vein as a result of dressing changes, increases PICC related complications by 3 to 8 times (Sharpe, 2014).

In our NICU/ 9North ICCU, the policy for PICC dressing change is every 7 days or whenever the integrity of the dressing is compromised (see the attached document for the NICU PICC dressing change guideline). Integrity is often compromised as a result of blood at the insertion site or lack of adherence of the dressing to the skin. For patients in the NICU/9 North ICCU, it is a common observation that PICC lines are often dislodged from their central position as a result of frequent dressing changes. Medical tissue adherence glue, Cyanoacrylate, has been safely used for hemostasis, wound closure, or fistula repair (ASGE, 2013; Nose et al. 2016) and has been shown to significantly reduce the incidence of catheter migration and insertion site bleeding of PICC lines in all age of patients including premature infants (Bierlaire et al., 2021; D'Andrea et al., 2021; Kleidon et al., 2017; Ostroff et al, 2020; Scoppettuolo et al., 2013). One of the tissue adhesive glues on the USA market is SecurePortIVTM by Adhezion Biomedical®. This product is the first FDA approved cyanoacrylate that is intended to secure venous catheters including PICC lines (Guido et al., 2020). This product is a mixture formula of n-butyl and octyl

cyanoacrylate that provides prevention of bleeding at the insertion site, a microbial barrier from a mechanical seal at the insertion site, and securement of both the catheter at the insertion site and the catheter hub (Guido et al., 2020). Despite the evidence of the efficacy of cyanoacrylate glue in bleeding control at the insertion site of PICC lines and reduction of catheter migration, there is still a gap of knowledge for our NICU to confidently adopt cyanoacrylate glue as our standard practice of PICC line maintenance care. The purpose of this study is to evaluate the efficacy of this FDA approved medical tissue adhesive glue applied to PICC insertion sites to reduce the number of dressing changes required due to bleeding at the insertion site and to reduce catheter migration. This study will focus strictly on those patients admitted to the 9 North ICCU who require PICC lines.

RESEARCH AIMS & ABSTRACTS

Research Question(s)/Hypothesis(es):

Research question: Does the use of a cyanoacrylate glue effect the interval time between routine PICC line dressing changes and the incidence of PICC line migration in patients admitted to the 9 North ICCU?

Hypotheses:

The application of micro drops of cyanoacrylate glue at the insertion sites prior to dressing a PICC line area with a standard transparent polyurethane film dressing will increase the longevity of the PICC line dressing and reduce the incidences of PICC line migration.

Scientific Abstract:

The most common complication related to PICC line maintenance and care is a catheter migration in the neonatal population. Frequent PICC dressing changes is a commonly observed culprit of PICC line migration in the NICU. This study is a randomized control study to investigate an application of a cyanoacrylate glue to determine its impact on the duration of the PICC line dressings and the occurrence of PICC migration. All patients in 9 North ICCU with PICC lines will be eligible to participate in this study.

Once patients needing a PICC line are enrolled into the study, they will be randomly assigned to two groups: control and study. The control group will receive the current standard method of securing a PICC line. The study group will receive a new way of securing PICC line with a cyanoacrylate glue in addition to a transparent film dressing over the PICC line site.

The subjects who do not participate in the research will receive regular medical care. Also, NICU providers who perform a PICC insertion procedure and designated nursing staff who perform a PICC line dressing change will be surveyed anonymously to assess the acceptability of the use of the glue. The survey will be filled out voluntarily.

If the application of cyanoacrylate glue at the insertion site demonstrates an increase in longevity of PICC line dressing and a reduction of PICC line migration, then its use can be incorporated as a standard care of neonatal PICC insertion and maintenance in 9 North ICCU.

Study Design:

The proposed study is a randomized control study with aimed data collection of 60 subjects; of the 60 subjects, 50 subject data are to be used for statistical analysis and additional 10 subjects to account for withdrawals.

The subjects will be randomly assigned to one of two groups: one (the control group) receiving our standard PICC dressing method and the other (the study group) receiving cyanoacrylate glue at the PICC insertion sites prior to dressing a PICC line area with a standard transparent film dressing. The control group will reflect our standard practice of PICC insertion and dressings using a standard transparent polyurethane film dressing, 3MTMTegadermTM Film. The study group will reflect the application of micro drops of cyanoacrylate glue, SecurePortIVTM by Adhezion Biomedical® at the insertion sites prior to dressing a PICC line area with a standard transparent polyurethane film dressing. The data will be collected from the electronic medical records. This study will be conducted in the 9 North Infant Cardiac Care unit at CHONY.

Sample: Patients in the 9 North ICCU who have a PICC line placed during their hospitalization.

Inclusion and exclusion criteria:

Inclusion: All patients admitted to the 9 North ICCU greater than 35 weeks of corrected gestational age who have a PICC line placed by a NICU provider.

Exclusion: Any patient with a PICC line in situ from an outside hospital. Any patient with a PICC line placed by an outside department, namely the interventional radiology department. Any patient with a PICC line that is silicon material catheter, such as Vygon Epicutaneo-Cava catheter because of limited accuracy of measuring a movement of the catheter migration after 25 centimeter mark due to absence of a centimeter mark on the catheter.

Study variables:

Independent variables: Gestational age, Postconceptural age, Sex, Diagnosis, Catheter size, PICC insertion site, Cyanoacrylate glue, and 3MTMTegadermTM Film dressing.

Dependent variables: The interval of time between initial insertion and first dressing change, the interval of time between dressing changes after the first dressing change, and the incidence of catheter migration from the initial documented insertion measurement.

Statistical analysis plan:

Data will be analyzed by utilizing unpaired T-test to compare control group (standard transparent film dressing, 3MTMTegadermTM Film) and study group (micro drops of cyanoacrylate glue in addition to the standard transparent film dressing) on the interval of time between each dressing change and the incidence of catheter migration.

Also, multiple general linear regression will be used to control for the effects of potential covariates (age, sex, diagnosis, catheter size, & PICC insertion site) on the outcome.

As per our CLABSI (central line-associated bloodstream infections) surveillance quality assurance data of PICC lines previously inserted in 34 randomly chosen patients in the ICCU. Findings were that the average day patients were getting their first dressing change after the insertion was at 2.7 days with a standard deviation of 1.66 days. Our hypothesis (Hypothesis I) is that using the cyanoacrylate glue, we expect that the day of first dressing change will be significantly longer, approaching 7 days which is the current practice standard of recommended PICC line dressing change. Using this information, if we were to hypothesize that using the glue would extend the mean dressing change to 4 days in the experimental group, assuming an alpha of 0.05 and Power of 80%, we would need to include 24 study subjects in each group.

We further hypothesize (Hypothesis II) that over the course of the stay for any patient for whom the glue was used, that patient will have experienced fewer dressing changes per week compared to patients receiving the standard care.

Lastly, based on available quality assurance data showing the average centimeter of catheter migration was 0.875 cm with a standard deviation of 0.777 cm, we hypothesize that patient receiving the cyanoacrylate glue will experience significantly reduced catheter migration. Based on this assumption, if we were to aim for a mean catheter migration in a study group of 0.25 cm, assuming an alpha of 0.05 and Power of 80%, we would need to study 25 subjects each group to prove this hypothesis.

We are planning to recruit total of 60 subjects to allow for up to 10 withdrawal due to failure to use the glue or missing follow up data in the medical records.

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