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PERIPHERALLY INSERTED CENTRAL CATHETER (PICC) IN NEONATAL INTENSIVE THERAPY NEWBORNS: SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CLINICAL TRIALS

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ABSTRACT

Objective: to identify and evaluate the effectiveness of the use of peripherally inserted central catheter (PICC) compared to the use of other intravenous catheters in newborns hospitalized in neonatal intensive care units. **Method**: This is a bibliographic study, a systematic review carried out according to the Cochrane methodology and regulations of the PRISMA check list. The Databases PubMed, EMBASE, Cochrane, Latin American and Caribbean Literature on Health Sciences (LILACS) were consulted until March 2021. Reviewers independently tracked eligible randomized clinical trials (CRTs); extracted the data and assessed the risk of bias through the Cochrane approach. Associations were reported as relative risks (RR) and their 95% confidence intervals (CI). Heterogeneity was tested with the Cochrane χ2 test, and the degree of heterogeneity quantified with statistics I2 and its 95% CI. The Review Manager (RevMan) software was used for meta-analysis (version 5.3). The quality of the evidence was generated according to the Evaluation of the Classification of Recommendations, Development and Evaluation (GRADE). **Results**: There was no statistically difference for the occurrence of sepsis, mortality, catheter-related complications (infections) and catheter length of stay between groups. For the number of venopunctures required for catheter insertion, the findings indicate that for PICC there are lower numbers (RR -6.17, 95% CI:-7.75 to -4.59) and that there is low heterogeneity (I2=32%) among the studies. However, these results should be interpreted with caution, since the evaluation of the quality of the evidence was low. **Conclusion**: No moderate or high-quality evidence was found in ECRs that proves that there is differentiated effectiveness between PICC compared to the use of other intravenous catheters in newborns hospitalized in neonatal intensive care units, thus evidencing the need for further studies in the area.

KEYWORDS: Catheters. Peripheral catheterization. Neonatal Intensive Care Units. Newborn. Systematic Review

INTRODUCTION

Technological advances in neonatology have been addressed prominently around the world, causing mobilization of managers who seek to provide an increase in the survival of critically ill newborns.[1]

It is noteworthy with regard to newborns seriously ill to "prematurity (with gestational age less than 34 weeks), low weight (less than 1,500 grams), respiratory problems, neonatal asphyxia with systemic and/or neurological influences, systemic bacterial or viral infections or central nervous system, diseases requiring surgical intervention, hemorrhages or coagulopathies

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JOURNAL HEALTH AND TECHNOLOGY - JHT
ISSN 2764-7625

hyperbilirubinemia with indication for exuding transfusão, suspicion of congenital heart disease, convulsive conditions, persistent hypoglycemia or other metabolic disorders, and complex congenital anomalies.[2]

The survival of newborns is directly related to intravenous therapy, due to the need for intravenous medication sanding and parenteral nutrition for prolonged periods, however, this therapy is painful and there is a risk of major complications, and the need for repeated venopunctures compromises therapeutic efficacy.[3]

Considering all specialized care provided to newborns hospitalized in an Intensive Care Unit (ICU), one of the major challenges and concerns faced by the nursing team is intravenous therapy. This procedure is difficult to perform, considering that neonates present peculiarities in their physiology such as: vulnerability of the newborn due to immaturity of the skin, limited venous network, hemodynamic instability, greater probability of developing infections, attenuation of subcutaneous tissue and increased sensitivity to pain.[3-4]

For these reasons, in the last two decades has considerably increased the number of technologies produced and incorporated in intravenous therapy in the area of Neonatology, bringing benefits to high-risk newborns in need of safe and prolonged venous access. [3-6]

Thus, it is important that nursing professionals critically reflect on the technical-scientific and ethical-legal knowledge acquired on the subject, with the purpose of implementing new scientifically based care models, contributing to individualized, safe and humanized care. [3-6]

Considering intravenous therapy, there are several intravenous catheters such as peripheral venous catheter, umbilical catheter, central venous catheter and peripherally inserted central venous catheter.

The use of the PeripheralLy Inserted Central Venous Catheter has been growing because it is the most advantageous option for maintaining venous access in a safe and prolonged manner in high-risk newborns. [7]

According to Rocha et al. (2006), the first report on PICC was in 1926, when the German physician Forssmann introduced a catheter through the left antecubital vein and verified its location on the right side of the heart by radiography. In the early 1950s, PICC became an appropriate option for infusion of intravenous fluids directly into the vena cava and central venous pressure measurements.[8]

According to Feitosa et al. (2002), because it is a vascular device of peripheral insertion with central location, picc has single or double lumen, made of polyurethane or silicone, and silicone provides greater flexibility and immobility causing fewer complications such as irritation to the vessel wall and drug interaction. [9]

The PICC used in neonatalogia is usually single lumen due to the small caliber, the most common being [1-9] French. The insertion should be performed in preserved peripheral vein, of adequate and non-tortuous caliber, and the most indicated are the basilica and cephalic veins. The procedure can be performed in the patient's room, without the need for surgery in the operating room.

JOURNAL HEALTH AND TECHNOLOGY - JHT
ISSN 2764-7625

It should be the first option when the vein is preserved, as the presence of phlogistic signs caused by previous venous punctures hinders catheter progression. [1]

Studies conducted with PICC describe numerous benefits such as: reduction in the number of daily venopunctures, reduction of algia in the newborn, maintenance of stable venous access and when compared to central catheters presents greater ease of insertion, prolonged usefulness, reduction of the risk of chemical phlebitis, extravasation and infiltration of liquids, among others.[10]

However, there are studies that describe the potential risks of complications related to the insertion of PICC as: "[...] phlebitis, extravasation, infection, thrombosis, premature displacement, sepsis, embolism, occlusion and rupture, and may be classified as local, systemic or circumstantial complications [...]" [10]. These complications when compared to those of other catheters are minor, but special attention is essential on the part of the team involved in providing care for newborns.[11]

The PICC can be inserted by qualified nurses and neonatologists. The nurse has technical and legal competence to perform the insertion and manipulation of picc, according to COFEN Resolution No. 258/2001.[11-12]

The objective of this study was to evaluate the effectiveness of the use of peripherally inserted central catheter (PICC) compared to the use of other intravenous catheters in newborns hospitalized in neonatal intensive care units.

METHOD

This is a bibliographic study, a systematic review with meta-analysis that was carried out according to the Cochrane methodology and regulations of the PRISMA check list.[12-13]

Eligibility Criteria:

Randomized clinical trials (CRFs) were selected to evaluate PICC when compared to the use of other intravenous catheters in newborns admitted to the Neonatal Intensive Care Unit (NICU). The acronym PICO was described in: Participants: newborns hospitalized in the Neonatal Intensive Care Unit; Intervention: PICC; Comparator: Intravenous Catheters; Outcomes: cost-effective. Primary outcomes: sepsis, number of venopunctures and mortality. Secondary outcomes: length of stay of intravenous devices, number of catheters used, and catheter-related complications.

Inclusion and exclusion criteria

Randomized clinical trials evaluating PICC were selected when compared to the use of other intravenous catheters in newborns hospitalized in the Neonatal Intensive Care Unit. Animal studies and in vitro studies were excluded. Studies addressing the following themes were excluded: intervention with adult or infant-juvenile population, comparative objective between catheter and medication or catheter and other technology (X-ray) and urinary catheter. Theses and dissertations were also excluded in full.

JOURNAL HEALTH AND TECHNOLOGY - JHT
ISSN 2764-7625

Search strategy

Electronic databases were consulted in March 2021: National Center for Biotechnology Information (NCBI/PubMed), Embase, Cochrane Library and Virtual Health Library (VHL). Information on ongoing clinical trials was retrieved through the clinical trial website of the National Institute of Health (http://clinicaltrials.gov) and through the Brazilian Registry of Clinical Trials-ReBEC (http://www.ensaiosclinicos.gov.br/). The gray literature included the search on health technology assessment (HTA) sites, being the Brazilian Network for Technology and Health Assessment (REBRATS), the National Institute for Clinical Excellence and Health (NICE/UK) and the International Network of Agencies for Health Technology Assessment (INAHTA). References from selected articles, including relevant review articles, will be reviewed to identify all relevant studies. A manual search of references from clinical trials was performed in relevant journals. There was no language restriction and year of publication of the article, but only human studies were selected.

The basic research strategy was developed for PubMed and modified as needed for other databases. Health descriptors available in Health Sciences Descriptors (DECs) and Medical Subject Heading (MeSH) were used. The descriptors used included: Newborn (Infant, Newborn); Intensive Care Units (Neonatal), Catheters; Vascular Access Devices; Central Venous Catheterization (Catheterization, Central Venous); Peripheral Catheterization (Peripheral) (Table 1).

Selection of studies and data extraction

For this review, two researchers independently reviewed eligibility titles and summaries. Disagreements regarding the selection of articles were resolved by consensus or discussion with a third investigator. The study selection flowchart was created according to PRISMA guidelines.

Two researchers independently extracted the relevant data from each full-text article using a standardized form based on the Cochrane Handbook[12] with the following information: study characteristics (design, randomization method); participants; interventions; clinical outcomes (types of outcomes measured - i.e., dichotomous or continuous; adverse effects). The selection was compared for accuracy, and any discrepancies were resolved by consensus or discussion with another investigator.

Bias risk assessment

Two investigators independently assessed the risk of bias in each eligible CRT. The discrepancies were resolved by consensus or discussion with another investigator. The Cochrane Collaboration tool was used to assess the risk of bias in CRS[14]. Thus, the items evaluated were: generation of the allocation sequence (bias selection); concealment of the allocation sequence (bias selection); blinding (detection and performance bias); blinding participants and staff to evaluate results; incomplete results data (friction bias); reporting selective result (information bias). For each RCT, the item will be described and presented as low risk of bias, risk of uncertain bias or high risk of bias according to the classification obtained.

JOURNAL HEALTH AND TECHNOLOGY - JHT
ISSN 2764-7625

Data analysis

Random effects models and Mantel-Haenszel method were used. Associations were reported as relative risks (RR) and their 95% confidence intervals (CI). Heterogeneity was tested with the Cochrane χ2 test, and the degree of heterogeneity will be quantified with statistics I2 and its 95% CI. An I2 value between 30% and 60% was described as moderate heterogeneity. Standard deviation calculated when interquartile available. Publication bias was evaluated with funnel plots and formally tested with egger test[15]. For the variability in the results between the studies, i2 statistics were used and the P value obtained from the Chi-square Cochrane test. The Review Manager (RevMan) software was used for all analyses (version 5.3; Nordic Cochrane Centre, Cochrane)[16].

Evaluation of the quality of evidence

The evaluation of the quality of evidence was evaluated by the Grading of Recomendations, Assessment, Development and Evaluation (GRADE)[17] system for the outcomes of proven sepsis, number of venopuncture and mortality.

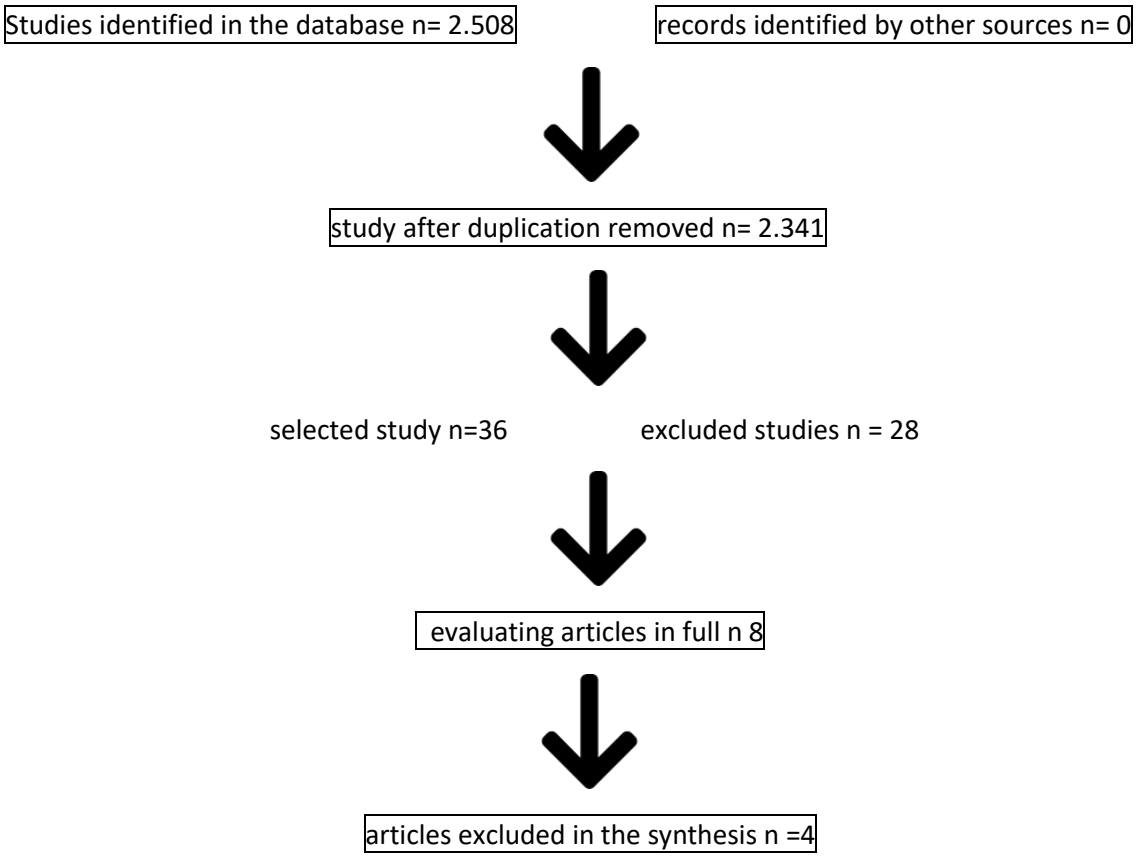
FINDINGS

Selection of studies

After searching the electronic health databases, 2,341 references were identified. Nine articles were potentially eligible for inclusion in this review and were therefore read in full. After reading and critical analysis, four articles were selected for qualitative analysis and three articles for quantitative analysis (meta-analysis). The grey literature did not report findings according to eligibility criteria. (Figure 1).

JOURNAL HEALTH AND TECHNOLOGY - JHT
ISSN 2764-7625

Figure 1- Selection diagram of the included studies:



Elaboration: the authors, 2021

After reading in full, four studies met the inclusion criteria and were included in this systematic review[18-21]. Five studies were excluded, three of which were excluded because they were not randomized controlled [22-23-24], a study compared between the picc insertion sites[25] and one study study population was composed of adolescents[26].

Description of the studies

The four CRFs included totaled 377 neonates admitted to neonatal intensive care units (NICU). Three studies analyzed PICC versus peripheral venous catheter (CVP)18-20 and one article compared PICC versus umbilical venous catheter (CVU)21. The years of publication learned from 2007 to 2017, in the countries Chile[18], Canada[19], United States[20] and India[21].

JOURNAL HEALTH AND TECHNOLOGY - JHT
ISSN 2764-7625

Table 2 describes the characteristics of the type of study, population, agent comparators of interest and outcomes analyzed in the included studies.

Studies (year)	Type of study/population	Comparator agents of interest	Out comes
Barria et al. (2007) [18]	Randomized Controlled Trial, including 74 high-risk newborns admitted NICU who required intravenous therapy for more than 5 days, regardless of age and weight at the Regional Hospital of Valdivia, Chile.	PICC vs CVP	-Suspected or proven sepsis; -Number of venopuncture; -Number of catheters used; -Insertion time of intravenous devices. -Complications (Phlebitis)
Janes et al. (2000)[19]	Randomized Controlled Trial, including 63 infants, who weighed between 400g and 1,251g at birth and who required intravenous therapy in the first week of life or when UVC was removed.	PICC vs CVP	- Suspected or proven sepsis; -Number of venopunctures; -Number of catheters used; -Complications (mechanical); -Mortality
Wilson et al. (2007)[20]	Randomized Controlled Trial, including of 96 infants admitted to the NICU in Texas who required intravenous therapy.	PICC vs CVP	-Systemic infection; - Mortality; -Catheter-related complications; - Number of venopunctures.
Dongara et al. (2017) [21]	Randomized Controlled Trial, including 144 neonates requiring vascular access for at least 7 days in a NICU in India.	PICC vc CVU	-Average time required for insertion; -Success rates; -Complications (displacement, suspected sepsis, necrotizing enterocolitis, bleeding, insertion failure, stool block); -Cost

PICC: central catheters of peripheral insertion UTIN: neonatal intensive care units; UVC :umbilical venous catheter. CVP: peripheral intravenous catheter

Risk of bias

The assessment of the risk of bias is sumarized in Figure 2. Regarding the randomization process, three[19-21] studies were considered low risk because they reported that they used computer software to generate the random sequence for randomization and one[18] study was classified as uncertain because they did not report the process.

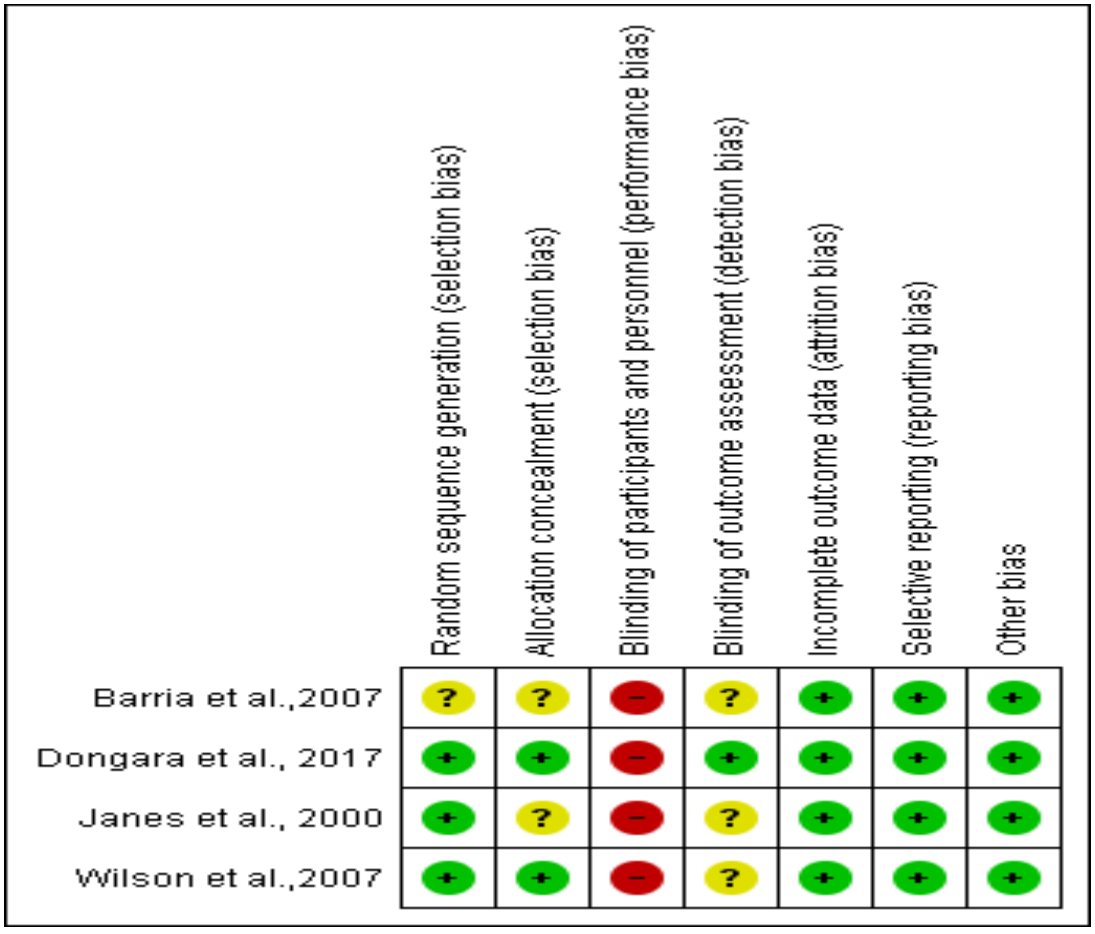
JOURNAL HEALTH AND TECHNOLOGY - JHT
ISSN 2764-7625

In the concealment of allocation, two[18-19] studies were considered uncertain for not reporting the process and two[20-21] low risk, because they reported that the concealment was preserved by the existence of sequentially numbered opaque envelopes.

In the blinding of participants and professionals, the four[18-21] studies included in the present review were considered high risk, because the intervention under analysis does not allow blinding of participants and professionals. In blinding outcome evaluators, three [18-20] studies were considered uncertain because they did not report these data in the article and a [21] article was reported as low risk, as it brought that the analyses were performed by blind statisticians.

Regarding incomplete outcomes, the four[18-21] studies were considered low risk, where two[18-20] reported that they performed analysis by intention to treat and two[19-21] describe their losses and reasons, not generating unbalance between the intervention control groups. For selective outcome reporting, the four[18-21] studies were classified as low risk of bias, with three [18-20] even without registration reporting outcomes compatible with the intervention and one[21] presented a record and reported all outcomes initially proposed in the protocol. Regarding other sources of bias, no study was identified, and the four[18-21] classified as low risk of bias.

Figure 2- Assessment of the risk of bias in randomized clinical trials included

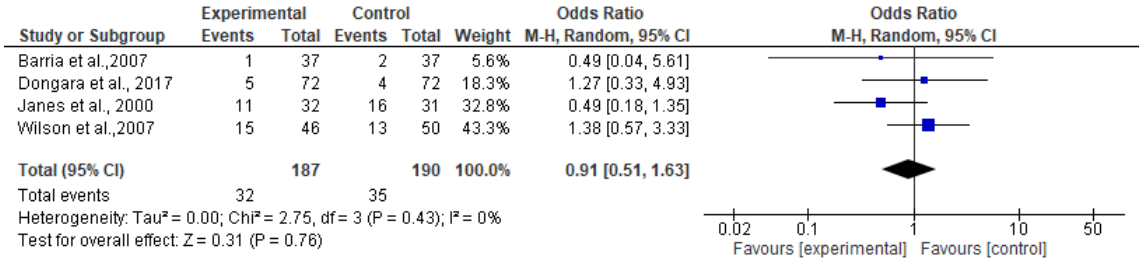


JOURNAL HEALTH AND TECHNOLOGY - JHT
ISSN 2764-7625

Meta-analyses

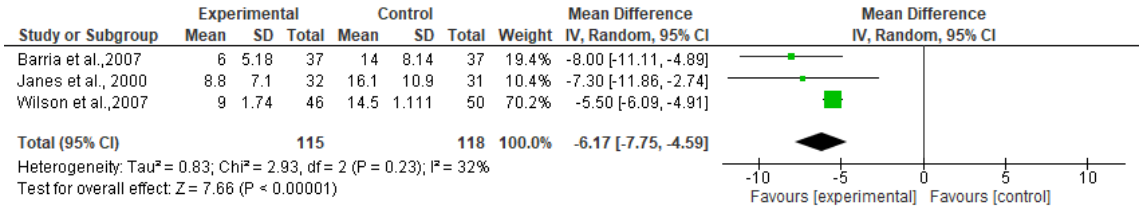
Primary outcomes were considered sepsis, number of venopunctures and mortality. The four[18-21] studies included in the present review reported the occurrence or suspicion of sepsis, where the meta-analysis identified that there was no difference between the control and intervention group (RR 0.91, 95% CI:0.51 to 1.63) with null heterogeneity (I2= 0%) between studies (Figure 3).

Figure 3. Meta-analysis of the occurrence or suspicion of sepsis



The number of venopunctures was reported in three[18-20] articles and proved to be favorable to the peripheral insertion central catheter (PICC) in newborns (RR -6.17, 95% CI:-7.75 to -4.59) with low heterogeneity (I2=32%) among the studies (Figure 4).

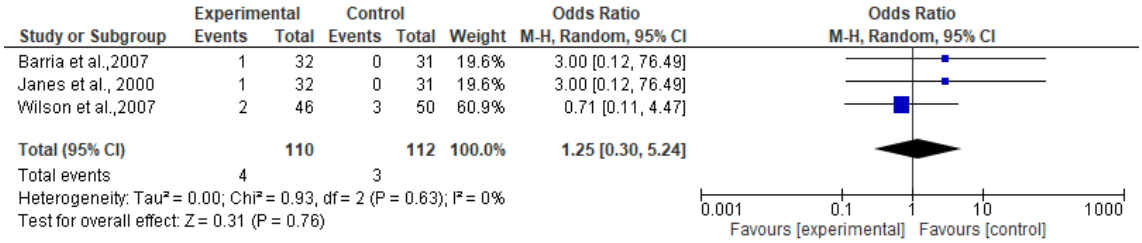
Figure 4. Meta-Analyse number of venopunctures



The outcome mortality was reported in three[18-20] articles and showed no significant difference between the groups (RR 1.25, 95% CI: 0.30 to 5.24) with null heterogeneity (I2= 0%) between the studies (Figure 5).

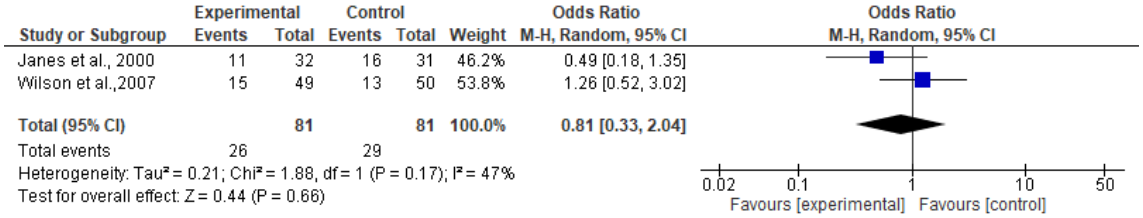
JOURNAL HEALTH AND TECHNOLOGY - JHT
ISSN 2764-7625

Figure 5. Meta-analysis mortality



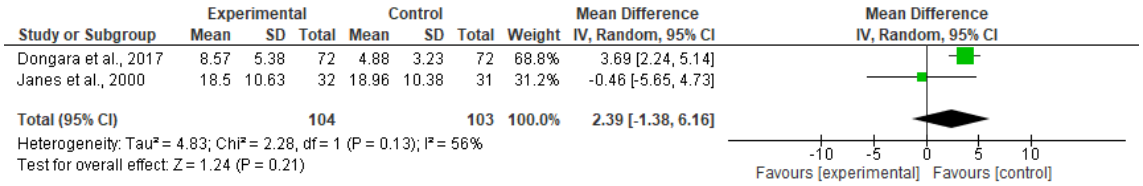
Among the secondary outcomes, the number of catheters used was not reported in any study analyzed. For the outcome catheter-related complications, it was possible to analyze the occurrence of catheter-related infections, where two[19-20] studies showed that there is no statistically significant difference between the groups (RR 0.81, 95% CI: 0.33 to 2.04), with moderate heterogeneity in the studies (I2 = 47%) (Figure 6).

Figure 6- Meta-analysis complications related to catheters (infections)



For catheter permanence time, there was analysis in two[19-21] studies, where meta-analysis showed no statistically significant difference between groups (RR 2.39, 95% CI: -1.38 to 6.16) with moderate heterogeneity (I2=56%) between studies (Figure 7).

Figure 7- Meta-analysis for catheter permanence time



Evaluation of the quality of evidence according to the GRADE

The evaluation of the quality of evidence was performed for the primary outcomes. The quality of the evidence was considered low for sepsis, number of venopunctures and mortality. As fewer than ten ECRs were included in this review, it was not possible to analyze the presence of publication bias (Table 2).

JOURNAL HEALTH AND TECHNOLOGY - JHT
ISSN 2764-7625

Table 2-Summary of the Evaluation of the Quality of Evidence according to the GRADE

Outcomes	Patients (n˚)	Risk of bias	Inconsistency	Indirect evidence	Inaccuracy	Risk of Publication Bias	Quality of evidence
Sepse							
	377 (4 ECRs)	not serious	not serious	not serious	Very serious a (-2)*	Probably not	⊕⊕◯◯ low
Number of venopunções							
	233 (3 ECRs)	not serious	not serious	not serious	Very serious a (-2)*	Probably not	⊕⊕◯◯ low
Mortality							
	222 (3 ECRs)	not serious	not serious	not serious	Very serious a (-2)*	Probably not	⊕⊕◯◯ low

a. Amplitude in 95% confidence interval
Note: To determine a GRID quality of evidence, the GRADE approach begins by assigning findings to one of the two initial levels of quality, depending on the study design. Randomized trials are of high quality, while observational studies are of low quality. Evidence can be considered at four levels: High, Moderate, Low, and Very Low. Studies can be updated or demoted based on certain factors:
a) Risk of bias (-1 if serious risk of bias, -2 if very serious risk of bias).
b) Inconsistency or heterogeneity of evidence (-1 if severe inconsistency, -2 if very severe inconsistency)
c) Indirect evidence (-1 if severe, -2 if very severe)
d) Inaccuracy of results (-1 if wide confidence interval, -2 if very wide confidence interval)
e) Publication bias (-1 if likely, -2 if most likely) * Small events and large confidence interval. Low quality of evidence: the authors do not trust the estimation of the effect and the actual value may be substantially different from that.

DISCUSSION

Summary of evidence

In the literature, this is the first published systematic review evaluating PICC compared to the use of other intravenous catheters in newborns hospitalized in the NICU.

Central insertion catheters and umbilical and peripheral venous catheters are often used for vascular access in neonatal intensive care units. Although there is a significant need for these devices for severely ill newborns, there are many complications associated with their use and unknown effectiveness.

A non-randomized study that aims to identify the incidence of PICC complications and umbilical venous catheters (CVU) in infants with low birth weight, identified that causes of catheter removal, length of catheter stay or incidence of hospital infection were the same between groups, evidencing that the complications associated with the use of CVU and PICCs in low birth weight newborns did not differ[27].

JOURNAL HEALTH AND TECHNOLOGY - JHT
ISSN 2764-7625

Our findings indicate that there is no difference in the occurrence of sepsis, mortality, catheter-related complications (infections) and catheter length of stay between groups. However, for the number of venopunctures required for catheter insertion, the findings indicate that for PICC, there are smaller numbers (RR -6.17, 95% CI:-7.75 to -4.59) and that there is low heterogeneity (I2=32%) among the studies plotted in the meta-analysis. However, these results should be interpreted with caution, since the evaluation of the quality of the evidence was low. This limitation occurred due to the low number of studies included in the present review, as well as a small population included in the studies, thus contributing to the extensive intervention of trust between studies.

Limitations

This systematic review has limitations, the main one being related to the small number of clinical trials and patients included in the analysis. The option to insert only CRT may also be a limiting factor for the analyses, but the choice was based on the search for studies that reported the best delineate to obtain the best available evidence.

CONCLUSION

Implications for practice

No moderate or high-quality evidence was found in THE rS that proves that there is superior effectiveness for PICC when omparated to the use of other intravenous catheters in newborns hospitalized in intensive care units of neonatology.

Implications for future Research

It is recommended the elaboration of NRTs with the inclusion of large populations and well-designed designs comparing PICC to the use of other intravenous catheters in newborns hospitalized in neonatal intensive care units to determine the effectiveness and safety of the device.

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Table1- Search strategy developed for Pubmed and adapted to other bases:

#1 "Catheters"[Mesh] OR (Catheter) OR (Cannula) OR (Cannulas)
#2 "Vascular Access Devices"[Mesh] OR (Device, Vascular Access) OR (Devices, Vascular Access) OR (Vascular Access Device) OR (Port Catheters) OR (Catheter, Port) OR (Catheters, Port) OR (Port Catheter) OR (Venous Reservoirs) OR (Reservoir, Venous) OR (Reservoirs, Venous) OR (Venous Reservoir) OR (Vascular Access Ports) OR (Port, Vascular Access) OR (Ports, Vascular Access) OR (Vascular Access Port) OR (Vascular Catheters) OR (Catheter, Vascular) OR (Catheters, Vascular) OR (Vascular Catheter) OR (Intra-Arterial Lines) OR (Intra Arterial Lines) OR (Intra-Arterial Line) OR (Line, Intra-Arterial) OR (Lines, Intra-Arterial) OR (Arterial Lines) OR (Arterial Line) OR (Line, Arterial) OR (Lines, Arterial) OR (Pharmacia Brand of Port Catheters) OR (Port-A-Cath)
#3 "Central Venous Catheters"[Mesh] OR (Catheter, Central Venous) OR (Catheters, Central Venous) OR (Venous Catheter, Central) OR (Venous Catheters, Central) OR (Central Venous Cathete)
#4 "Catheterization, Peripheral"[Mesh] OR (Peripheral Catheterization) OR (Catheterizations, Peripheral) OR (Peripheral Catheterizations) OR (Catheterization, Bronchial) OR (Bronchial Catheterization) OR (Bronchial Catheterizations) OR (Catheterizations, Bronchial) OR (Peripherally Inserted Central Catheter Line Insertion) OR (PICC Placement) OR (PICC Placements) OR (Placement, PICC) OR (Placements, PICC) OR (PICC Line Placement) OR (PICC Line Placements) OR (Placement, PICC Line) OR (Placements, PICC Line) OR (PICC Line Catheterization) OR (Catheterization, PICC Line) OR (Catheterizations, PICC Line) OR (PICC Line Catheterizations) OR (Catheterization, Peripheral Arterial) OR (Peripheral Arterial Catheterization) OR (Arterial Catheterizations, Peripheral) OR (Catheterizations, Peripheral Arterial) OR (Peripheral Arterial Catheterizations) OR (Arterial Catheterization, Peripheral) OR (Peripheral Venous Catheterization) OR (Catheterizations, Peripheral Venous) OR (Peripheral Venous Catheterizations) OR (Venous Catheterizations, Peripheral) OR (Venous Catheterization, Peripheral) OR (Catheterization, Peripheral Venous)
#5 "Infant, Newborn"[Mesh] OR (Infants, Newborn) OR (Newborn Infant) OR (Newborn Infants) OR (Neonate) OR (Neonates) OR (Newborns) OR (Newborn)
#6 "Intensive Care Units, Neonatal"[Mesh] OR (Neonatal ICU) OR (Neonatal Intensive Care Units) OR (Newborn Intensive Care Units) OR (Newborn Intensive Care Units (NICU)) OR (ICU, Neonatal) OR (ICUs, Neonatal) OR (Neonatal ICUs) OR (Newborn ICU) OR (ICU, Newborn) OR (ICUs, Newborn) OR (Newborn ICUs)
#1 OR #2 OR #3 OR #4 = #7 #7 AND (#5 OR #6)