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[Intervention Review]

Umbilical artery catheters in the newborn: effects of catheter materials

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ABSTRACT

Background

Umbilical arterial catheters (UACs) are among the most commonly used monitoring methodologies in neonatal intensive care. There seems to be significant variance between neonatal intensive care units in exactly how these catheters are used. This variance involves heparin dosing, catheter materials and catheter design, and positioning of the catheter.

Objectives

To determine whether the material used for construction of an umbilical arterial catheter influences the frequency of ischemic events, aortic thrombosis, mortality or necrotising enterocolitis in newborn infants.

Search methods

Randomized and quasi-randomized controlled trials of umbilical catheterization use were obtained using the search methods of the Cochrane Neonatal Review Group. *The Cochrane Library*, MEDLINE (search via PubMed), CINAHL and EMBASE were searched from 1999 to 2009.

Selection criteria

Randomized studies in newborn infants of any birthweight or gestation.

Comparison of different catheter materials.

Clinically important end points such as ischemic events, aortic thrombosis, or catheter occlusion.

Data collection and analysis

One non-randomized and one randomized study were retrieved.

Main results

There were no significant effects of substituting a heparin bonded polyurethane catheter for the standard PVC catheter. The non-randomized study suggested that there may possibly be a benefit of using a catheter constructed from Silastic, with a reduction in aortic thrombosis.

Authors' conclusions

There are no demonstrated clinically relevant differences in outcomes between the use of PVC catheters and other materials. Therefore, other considerations such as price and ease of availability may dictate the catheter chosen. An adequately powered randomized comparison of silastic to PVC should be performed.

PLAIN LANGUAGE SUMMARY

Umbilical artery catheters in the newborn: effects of catheter materials

A catheter (tube) placed in one of the arteries located in the umbilical cord is commonly used for monitoring blood pressure or drawing blood in sick newborn babies. There seems to be significant variation between neonatal intensive care units in exactly how these catheters are used. This variation involves whether drugs that decrease blood clotting are added, what catheter material is used, the catheter design, and the positioning of the catheter. This review looked at the effect of catheter material.

There were no significant effects of substituting a heparin bonded polyurethane catheter (a plastic catheter with anticoagulant medication built into the catheter) for the standard PVC catheter (a plastic catheter without the medication). The non-randomized study suggested that there may possibly be a benefit of using a catheter constructed from the material Silastic in reducing blood clots in the aorta.

Based on the limited information from this review, there are no demonstrated clinically relevant differences in outcomes between the use of PVC catheters and other materials. Therefore, other considerations such as price and ease of availability may dictate the catheter chosen. A trial that is large enough to demonstrate important clinical differences is warranted.

BACKGROUND

Description of the condition

Umbilical arterial catheters (UACs) are among the most commonly used monitoring methodologies in neonatal intensive care. There seems to be significant variance between neonatal intensive care units in exactly how these catheters are used. This variance involves heparin dosing, catheter materials and catheter design, and positioning of the catheter. Immediately after insertion of a UAC local vascular compromise is frequently evident, usually in the form of blue or white toes, but occasionally with more severe and extensive ischemic manifestations. Aortic thrombi and renal ischemia have also been described. Some epidemiologic and case control studies have also shown that use of umbilical artery catheterisation is statistically associated with the later development of necrotizing enterocolitis. In order to minimize these morbidities some aspects of the use of UACs have been subjected to a small number of randomized control trials.

Description of the intervention

This review will analyze the data regarding the rates of complications relating to the material from which the catheter is constructed.

How the intervention might work

Some newer plastics (carbon polymers) are said to be less thrombogenic than standard polyvinylchloride (PVC) and catheters may also be coated with heparin to further reduce 'thrombogenicity'. Heparin coated catheters may also decrease sepsis rates by inhibiting bacterial adherence to the catheter (Mermel 1993, Appelgren 1996). Thus, the availability of heparin bonded catheters made from newer plastics requires clinical testing to ensure that the safest catheters are used. In adult intensive care it has also been shown that bonding of antimicrobial agents to the surface of the catheter decreases catheter-associated sepsis. Both cefazolin (Kamal 1991) and chlorhexidine/silver sulphadiazine (Maki 1991) have been investigated and appear to be effective.

Other materials such as 'Silastic', a silicon based polymer, are used for construction of many different medical devices, with the putative advantage of reduced biologic interactions. Such materials could also potentially decrease complication rates from umbilical arterial catheterization. Some of the early animal studies of silastic catheters showed a reduction in thrombosis rates (Welch 1974); however, others were unable to show any effect (Andrews 1973). There are no clear benefits in adults from the use of silastic catheters (Reed 1995).

Why it is important to do this review

This review updates the existing review of Umbilical artery catheters: catheter materials, which was published in *The Cochrane Library*, Disk Issue 1 1998 (Barrington 1999).

OBJECTIVES

To determine whether the material from which the umbilical arterial catheter is constructed influences morbidity with the use of umbilical artery catheters in terms of mortality, necrotising

enterocolitis, aortic thrombosis, or clinically recognized ischemic phenomena.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized and quasi-randomized clinical studies were selected. Clinically relevant outcomes were collated, with survival and long term disability being given the greatest weight. Both term and preterm infants were included.

Types of participants

Newborn infants, both preterm and term. Entry criterion was simply the 'need' for a catheter, as defined by the attending medical staff.

Types of interventions

Random or quasi-random assignment of catheters made from different materials.

Types of outcome measures

Clinical ischemic compromise, aortic thrombosis, catheter occlusion. Duration of catheter usability.

Search methods for identification of studies

The standard search method of the Cochrane Neonatal Review Group was used.

Electronic searches

Randomized and quasi-randomized controlled trials of umbilical catheterization use were obtained from the following sources: 1. Medline Search using Medline Plus and the keyword headings 'Umbilic#', 'Catheter#' and subject heading 'Infant, Newborn'.

The bibliography cited in each publication obtained was searched in order to identify additional relevant articles.

The original search was completed in November 1997. The search was updated in November 1998.

The search was updated in April 2009:

The Cochrane Library, MEDLINE (search via PubMed), CINAHL and EMBASE were searched from 1999 to 2009.

Search terms: umbilic* AND catheter. Limits: human, newborn infant and clinical trial. No language restrictions were applied.

Searching other resources

Randomized and quasi-randomized controlled trials of umbilical catheterization use were obtained from searching the following other resources:

1. Effective Care of the Newborn Infant, edited by JC Sinclair and MB Bracken
2. Search of personal data files

Clinical trials registries were also searched for ongoing or recently completed trials (clinicaltrials.gov; controlled-trials.com; and who.int/ictpr)

Data collection and analysis

The standard methods of the Cochrane Neonatal Review Group Guidelines were employed.

Selection of studies

Reports were first reviewed to determine whether there was a concurrent control group, and discarded if not. The method of assignment to control and intervention groups was then determined and if not random or quasi random, then the trial was discarded.

Data extraction and management

The review author extracted, assessed and coded all data for each study using a form that was designed specifically for this review. For each study, final data was entered into RevMan by the review author (KB).

Assessment of risk of bias in included studies

The standard methods of the Cochrane Neonatal Review Group were employed. Each identified trial was assessed for methodological quality with respect to a) masking of allocation b) masking of intervention c) completeness of follow-up d) masking of outcome assessment. This information is included in the Characteristics of Included Studies Table.

For the update in 2009, the risk of bias table was completed in order to address the following questions:

1. Sequence generation: Was the allocation sequence adequately generated?
2. Allocation concealment: Was allocation adequately concealed?
3. Blinding of participants, personnel and outcome assessors: Was knowledge of the allocated intervention adequately prevented during the study? At study entry? At the time of outcome assessment?
4. Incomplete outcome data: Were incomplete outcome data adequately addressed?
5. Selective outcome reporting: Are reports of the study free of suggestion of selective outcome reporting?
6. Other sources of bias: Was the study apparently free of other problems that could put it at a high risk of bias?

Measures of treatment effect

Statistical analysis was performed using Review Manager software. For categorical outcomes, estimates for relative risk and risk difference were calculated. For outcomes measured on a continuous scale, estimates for weighted mean difference were calculated. 95% confidence intervals were used.

Assessment of heterogeneity

Heterogeneity between trials was evaluated by inspecting the forest plots and quantifying the impact of heterogeneity using the I^2 statistic. A fixed effects model for meta-analysis.

Data synthesis

If multiple trials were found and meta-analysis was judged to be appropriate, the analysis would be done using Review Manager software (RevMan 5). All meta-analyses were to be done using the fixed effect model.

Subgroup analysis and investigation of heterogeneity

If data was available, subgroup analysis based on gestational age or birth weight were planned.

RESULTS

Description of studies

The original search strategy retrieved 849 articles. These were further reduced by restricting the search by use of the terms prospective, random#, control#, comparative or clinical. When studies of animal subjects and of epidural catheterisation were also removed, 233 reports remained. The abstract of each was read individually to determine if there was a possibility that the papers were reporting randomized prospective controlled trials. This final examination revealed two trials investigating catheter materials. The updated search in November 1998 revealed no new randomized trials of catheter materials.

Only one of the two trials which were detected was randomised (Jackson 1987). The authors compared standard PVC to heparin bonded polyurethane in 125 term and preterm infants in a single center over 16 months. This study was unblinded and used random assignment using sequentially numbered sealed envelopes. Catheter group assignment was not stratified by weight but well balanced groups were achieved. Catheter size was either 3.5 or 5 Fr at the discretion of the physician. Catheters were placed in a high position. Heparin was not used in the infusate and a small quantity was used in the flushing procedure. The primary outcome variable was "clots or associated complications" with aortic thrombosis being detected by routine ultrasound at about three and about 11 days of age. Secondary outcomes were hypertension, persistent blanching of the feet or legs, duration of useful catheter function. There were originally 144 infants randomized, 19 were excluded after randomization (16 of them because catheter insertion was unsuccessful, three because the physician changed his mind) to leave 125 in which a catheter was inserted; all data are reported from these 125 infants. There was a decrease in numbers between study entry and ultrasound examination which appears to be because many catheters were removed before the scheduled ultrasound examination dates; thus 114 early ultrasounds were performed and 105 at the later time. Other outcomes, such as hypertension and clinical ischemic compromise were reported on almost all the infants (122/125).

Boros et al (Boros 1975) compared the incidence of aortic thrombosis by aortography in 10 infants with PVC catheters and 10 infants with a silastic catheter. The study was not randomized; therefore, this study was excluded from the analysis. Contrast aortograms were performed at the time of removal of the catheter. During the period of the study there were other infants in the same NICU who had silastic catheters and were not included in the study. It appears that the reason for being included in this report was the performance of an aortogram. The aortograms showed that nine of the infants with PVC catheters had a thrombus compared to one of the infants with a silastic catheter.

Risk of bias in included studies

[Jackson 1987](#)

Masking of allocation: Yes, Opaque sequentially numbered envelopes opened after enrollment.

Masking of intervention: No, catheters have a different appearance.

Completeness of follow up: Yes

Masking of outcomes: Most of the outcomes were not masked.

Abdominal sonograms were read by radiologists masked as to group assignment.

Other comments: Clear description of determination of required sample size; this was actually achieved. Hypothesized a reduction in incidence of "aortic clots or associated complications" from 45% to 20%.

Effects of interventions

Heparin bonded polyurethane catheter compared to polyvinylchloride (Comparison 1)

[Jackson 1987](#) showed no benefit of substituting a heparin bonded polyurethane catheter for the usual PVC catheter in terms of the incidence of aortic thrombosis in this trial involving 125 infants. RR for aortic thrombosis after a mean of 11.1 days was 0.63 (95% CI 0.34, 1.18) (Outcome 1.3). There was also no statistically significant effect on other outcomes: RR for persistent hypertension was 5.00 (95% CI 0.25, 102.4) (Outcome 1.1) and for clinical vascular compromise was 1.00 (95% CI 0.45, 2.23) (Outcome 1.4). The results do not clearly describe how many of the catheters themselves became occluded, although the duration of useful catheter function was said to be not different between groups.

Other important outcomes such as mortality, intraventricular hemorrhage, necrotising enterocolitis and sepsis were not reported.

DISCUSSION

This review provides no basis for choosing any catheter material over standard PVC at the present. As complications of umbilical arterial catheterization are frequent, further research into this issue is warranted. Heparin bonded catheters may be associated with a lower risk of infections in other populations. This is an important outcome which was not reported in Jackson's paper, and should be further investigated.

Silastic catheters could potentially have a much lower incidence of aortic thrombi than PVC; however, the research design of [Boros 1975](#) allows many potential biases which should be resolved by further study.

AUTHORS' CONCLUSIONS

Implications for practice

There are no demonstrated clinically relevant differences in outcomes between the use of PVC catheters and other materials. Therefore, other considerations such as price and ease of availability may dictate the catheter chosen.

Implications for research

Introduction of newer catheter materials should be compared to PVC in prospective randomized controlled trials. Silastic catheters, which are currently readily available, have not been demonstrated by reliable studies to be an improvement over PVC, and warrant adequately powered prospective investigation.

ACKNOWLEDGEMENTS

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REFERENCES

References to studies included in this review

Jackson 1987 {published data only}

Jackson JC, Truog WE, Watchko JF, Mack LA, Cyr DR, van Belle G. Efficacy of thromboresistant umbilical artery catheters in reducing aortic thrombosis and related complications. *Journal of Pediatrics* 1987;**110**:102-5.

References to studies excluded from this review

Boros 1975 {published data only}

Boros SJ, Thompson TR, Reynolds JW, Jarvis CW, Williams HJ. Reduced thrombus formation with silicone elastomere (silastic) umbilical artery catheters. *Pediatrics* 1975;**56**:981-6.

Additional references

Andrews 1973

Andrews E, Hughes H. Thromboembolic sequelae to indwelling silastic cannulas in sheep arteries. *Journal of Biomedical Materials Research* 1973;**7**:137-44.

Appelgren 1996

Appelgren P, Ransjo I, Bindslev L, Espersen F, Larm O. Surface heparinization of central venous catheters reduces microbial colonization in vitro and in vivo: Results from a prospective, randomized trial. *Critical Care Medicine* 1996;**24**:1482-9.

Kamal 1991

Kamal GD, Pfaller MA, Rempe LE, Jebson PJ. Reduced intravascular catheter infection by antibiotic bonding; a prospective randomized controlled trial. *JAMA* 1991;**265**:2364-8.

Maki 1991

Maki DG, Wheeler SJ, Stolz SM, Mermel LA. Prevention of central venous catheter-related bloodstream infection by use of an antiseptic-impregnated catheter. A randomized, controlled trial. *Annals of Internal Medicine* 1997;**127**:257-66.

Mermel 1993

Mermel LA, Stolz SM, Maki DG. Surface antimicrobial activity of heparin-bonded and antiseptic-impregnated vascular catheters. *Journal of Infectious Diseases* 1993;**167**:920-4.

Reed 1995

Reed CR, Sessler CN, Glauser FL, Phelan BA. Central venous catheter infections: concepts and controversies. *Intensive Care Med* 1995;**21**:177-83.

Welch 1974

Welch G, McKeel D, Silverstein P, Walker H. The role of catheter composition in the development of thrombophlebitis. *Surgery, Gynecology and Obstetrics* 1974;**138**:421-4.

References to other published versions of this review

Barrington 1998

Barrington KJ. Umbilical artery catheters in the newborn: effects of catheter materials. *Cochrane Database of Systematic Reviews* 1998, Issue 1. [DOI: [10.1002/14651858.CD000949](https://doi.org/10.1002/14651858.CD000949)]

Barrington 1999

Barrington KJ. Umbilical artery catheters in the newborn: effects of catheter materials. *Cochrane Database of Systematic Reviews* 1999, Issue 1. [DOI: [10.1002/14651858.CD000949](https://doi.org/10.1002/14651858.CD000949)]

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Jackson 1987

Methods	Single center randomised study. Masking of allocation: Yes Masking of intervention: No Completeness of follow up: Yes Masking of outcomes: No
Participants	144 term and preterm infants.
Interventions	Heparin bonded polyurethane catheter compared with standard PVC catheter.
Outcomes	Aortic thrombosis, blanching of feet or legs, persistent hypertension.
Notes	
Risk of bias	
Bias	Authors' judgement Support for judgement

Jackson 1987 (Continued)

Allocation concealment?	Low risk	Masking of allocation: Yes, Opaque sequentially numbered envelopes opened after enrollment.
Blinding? All outcomes	High risk	Masking of intervention: No, catheters have a different appearance. Masking of outcomes: Most of the outcomes were not masked. Abdominal sonograms were read by radiologists masked as to group assignment.
Incomplete outcome data addressed? All outcomes	Low risk	Completeness of follow-up: Yes.
Free of selective reporting?	Low risk	
Free of other bias?	Unclear risk	Clear description of determination of required sample size; this was actually achieved. Hypothesized a reduction in incidence of "aortic clots or associated complications" from 45% to 20%

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Boros 1975	Non- randomized study, catheter type determined by availability of catheter and house staff preference.

DATA AND ANALYSES
Comparison 1. Heparin bonded polyurethane catheter compared to polyvinylchloride

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Persistent hypertension	1	122	Risk Ratio (M-H, Fixed, 95% CI)	5.0 [0.25, 102.04]
2 Aortic thrombosis after 3.5 (SD 1.2) days	1	114	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.24, 5.46]
3 Aortic thrombosis after 11.1 (SD 2.3) days	1	105	Risk Ratio (M-H, Fixed, 95% CI)	0.63 [0.34, 1.18]
4 Clinical vascular compromise	1	122	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.45, 2.23]

Analysis 1.1. Comparison 1 Heparin bonded polyurethane catheter compared to polyvinylchloride, Outcome 1 Persistent hypertension.

Analysis 1.2. Comparison 1 Heparin bonded polyurethane catheter compared to polyvinylchloride, Outcome 2 Aortic thrombosis after 3.5 (SD 1.2) days.

Analysis 1.3. Comparison 1 Heparin bonded polyurethane catheter compared to polyvinylchloride, Outcome 3 Aortic thrombosis after 11.1 (SD 2.3) days.

Analysis 1.4. Comparison 1 Heparin bonded polyurethane catheter compared to polyvinylchloride, Outcome 4 Clinical vascular compromise.

WHAT'S NEW

Date	Event	Description
4 August 2009	New search has been performed	<p>This review updates the existing review "Umbilical artery catheters in the newborn: effects of catheter materials" published in the Cochrane Database of Systematic Reviews, Issue 1, 1999 (Barrington 1999).</p> <p>Updated search found no new trials.</p> <p>No changes to conclusions.</p>

HISTORY

Protocol first published: Issue 1, 1999

Review first published: Issue 1, 1999

Date	Event	Description
22 October 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Keith Barrington (KB) wrote the original review.

The 2009 update was conducted centrally by the Cochrane Neonatal Review Group staff (Yolanda Montagne, Roger Soll, Diane Haughton) and reviewed and approved by KB.

DECLARATIONS OF INTEREST

None

INDEX TERMS

Medical Subject Headings (MeSH)

*Umbilical Arteries; Catheterization [*instrumentation]

MeSH check words

Humans; Infant, Newborn