

Heel prick versus venipuncture for blood sampling in neonates

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SUMMARY STATEMENT

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REQUEST

Heel prick versus venipuncture for blood sampling in neonates.

REQUESTED BY

Sue McNaught, Midwife, Birth unit, Womens Health program, Dandenong

METHODOLOGY

Search Strategy

The Centre for Clinical Effectiveness defines the 'best available evidence' as that research we can identify that is least susceptible to bias.

First, we search for systematic reviews, evidence based clinical practice guidelines, health technology assessments. Then we identify diagnostic studies with independent blind comparison of an appropriate spectrum of consecutive patients, who have undergone both the diagnostic test and the reference standard. If we identify sound, relevant material of this type, the search stops. Otherwise, our search strategy broadens to include studies that are more prone to bias, less generalisable, or have other methodologic difficulties. While we cite observational and case series studies, and narrative reviews and consensus statements, in our reports we do not critically appraise them. Some studies can produce accurate results but they are generally too prone to bias to allow determination of their validity beyond their immediate setting.

Details of Evidence Request

Patients (subjects): Neonates requiring blood sampling for diagnostic purposes
Diagnostic procedure: Venipuncture
Comparison procedure: Heel lance
Outcomes: Pain level, crying, bruising at local site

Search terms

Patient (Subject): Neonates
Diagnostic procedure: Venipuncture
Comparison procedure: Heel lance

Resources Searched

We searched the following database:
The Cochrane Library (CD-ROM) – Issue 2, 2001

Refinements, Searching & Reporting Constraints

Our electronic searching of the above database was performed on 14 June 2001. No restriction restriction was applied in our search strategy.

RESULTS:

From our source we identified 1 relevant systematic review by Shah and Ohlsson (2001). After examination of the full text, the article was critically appraised.

Table 1: Study design of articles retrieved by search

Study Design	Number included
Systematic reviews or meta-analyses	1
Evidence-based clinical practice guidelines	0
Randomised Controlled Trial	0
Cross sectional study	0

Based on our refinements, searching and reporting constraints, we are reasonably confident this article represents the most relevant findings published to date.

EVIDENCE SUMMARIES

Format

Evidence summaries are presented as spreadsheets attached to this report. Each spreadsheet contains the article citation, details of the study design, patient description, scientific validity of the article, results, and pertinent remarks from the authors and Centre for Clinical Effectiveness reviewer.

REFERENCES

ARTICLE CRITICALLY APPRAISED FOR THIS REPORT

Shah V, Ohlsson A (2001). Venepuncture versus heel lance for blood sampling in term neonates (Cochrane Review). In: The Cochrane Library, Issue 2. Oxford: Update Software.

APPENDIX 1

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<p>Evidence Summary</p> <p>Diagnosis</p> <p>Heel prick versus venipuncture for blood sampling in neonates</p>	<p style="text-align: center;">Study 1</p> <p style="text-align: center;">Shah V, Ohlsson A (2001). Venepuncture versus heel lance for blood sampling in term neonates (Cochrane Review). In: The Cochrane Library, Issue 2. Oxford: Update Software. .</p>
<p>STUDY DESIGN</p>	<p style="text-align: center;">Systematic review</p>
<p>DESCRIPTION: Patients (subjects), Diagnostic Test, Comparison, Outcomes</p>	<p>Patients (subjects): Neonates Diagnostic blood sampling procedure: Venepuncture (VP) Comparison procedure: Heel lance (HL) Outcomes: Primary outcome was neonatal pain response.</p> <ul style="list-style-type: none"> • Neonatal Infant Pain Score (NIPS) • Neonatal Facial Action Coding System (NFCS) • Premature Infant Pain Profile (PIPP) • Cry <p>Secondary outcomes:</p> <ul style="list-style-type: none"> • Need of repeated blood sampling • Bruising/hematoma at local site • Sample collection time • Parental perception of their own anxiety and infant's pain <p>Incl and excl criteria: Randomised & quasi-randomised controlled trials in which pain response from VP was compared to HL.</p>
<p>VALIDITY: Methodology, rigour, selection</p>	<p>Search strategy: Cochrane Neonatal Collaborative Review Group search strategy. MEDLINE, EMBASE, CINAHL, the Cochrane Library, reference lists of identified trials and personal files were searched. Search terms were stated. No language restrictions. Patient spectrum: Healthy Neonates of ≥ 37 weeks gestational age subjected to blood sampling Assessed validity: Yes, used the standard methods of the Cochrane Neonatal Collaborative Review Group to assess methodological quality of trials. Randomisation was blinded in all three studies included in the review. Neonatal pain response was assessed by a validated pain measurement. A meta-analysis to assess pain response to the two interventions could not be performed due to heterogeneity in pain measures used in these studies.</p>
<p>RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate</p>	<p>Four studies were identified and three were included in the review because they were a randomised controlled trial.</p> <ul style="list-style-type: none"> • In the Shah study (1997) statistically significant differences were noted in NIPS score during the procedure: 2.84 (SD 1.57) in VP group compared to 5.21 (SD 1.48) in HL group ($p < 0.001$). No differences between groups in the pain scores before or after the procedure. Maternal anxiety was higher in the VP group compared to HL prior to the procedure [VP group: 2.2 (SD 0.7) vs HL group: 1.4 (SD 0.5); $p < 0.001$]. However, after observing the procedure mothers rated their infant's pain to be lower in the VP group [VP 1.6 (SD 0.5) vs HL 2.4 (SD 0.5); $p < 0.001$]. Five neonates (one in the VP group and four in the HL group) required an extra skin puncture to obtain adequate blood volume. Two out of four infants with multiple HL required a VP due to hemolyzed samples. One neonate in the HL group had bruising at the local site. • In the Larsson study (1998) NFCS scores were statistically significantly lower in the VP group as compared to the HL group. The median NFCS score after the first skin puncture was 247 in the VP group, 333 in the small lancet group (SL) and 460 in the large lancet group (LL); $p < 0.0005$. Median NFCS score was 142 in the VP group, 420 in the SL group and 497 in the LL group during manipulation for blood sampling, $p < 0.001$. 44% of the infants cried in the VP group as compared to 72% and 85% in the SL and the LL groups respectively for the first 60 seconds after the skin puncture, $p < 0.0001$. In the VP group more than one skin puncture was needed to obtain sufficient blood sample for seven out of 50 neonates. In the LL group 12 out of 20 and in the SL group 38 out of 47 lances were unsuccessful on the first attempt. The results for both groups were combined in the meta-analysis.

	<ul style="list-style-type: none"> • In the Eriksson study (1999) the duration of crying within the first three minutes after the skin puncture was significantly lower in the VP group (median 11 seconds, range 0-174) compared to the HL group (median 117 seconds, range 0-178), $p = 0.0041$. 39.3% in the VP group did not cry at all compared to four percent of the infants in the HL group, $p = 0.0022$. The mean PIPP score was 6.0 in the VP group vs 8.4 in the HL group. The mean sample collection time was 289 seconds in the VP group and 231 seconds in the HL group (difference not statistically significant). In the VP group 8/30 (26.6%) required more than one skin puncture compared to 10/30 (33.3%) in the HL group. • The relative risk (RR) for requiring more than one skin puncture for VP versus HL was 0.30 [95% CI 0.18, 0.49]. The risk difference (RD) was -39% (95% CI -50%, -28%). The number needed to treat to avoid one repeat skin puncture was 2.56 (95% CI 1.9, 3.57). For this outcome there was statistically significant between study heterogeneity (for RR, $p = 0.02$; for RD, $p = 0.0001$).
<p>AUTHOR(S) CONCLUSIONS: Limitations, implications for practice and research</p>	<p>“Venepuncture, when performed by a trained phlebotomist, appears to be the method of choice for blood sampling in term neonates. For each two to three venepunctures instead of heel lance, the need for one additional skin puncture can be avoided. In view of the promising results derived from these small studies with some methodological limitations, including statistically significant between study heterogeneity, further well-designed randomised controlled trials need to be conducted. The interventions should be compared in settings where several individuals perform the venepuncture and/or the heel lance.”</p>
<p>OUR COMMENTS: Opportunities for bias, weakness and strength</p>	<p>Potential for bias: Unpublished data from two studies were included in the review. Search was not restricted to English language articles, which reduces possible publication bias. The methodological qualities of the included studies were assessed and reviewers summarised potential biases of the included studies.</p> <p>Weakness:</p> <ul style="list-style-type: none"> • Blinding of the intervention and outcome assessments were not ensured in two of the three studies. In one study, blinding of the outcome assessment was ensured but not of the intervention. <p>Strengths:</p> <ul style="list-style-type: none"> • Clear research question • Clear inclusion criteria. • Used systematic search based on Cochrane Neonatal Collaborative Review Group search strategy • Acknowledged the limitations and implications of their results for practice and research. • A substantive amendment to this systematic review was last made on 25 January 2001. Data from one additional randomised controlled trial strengthens the evidence in favour of Venepuncture technique to obtain a blood sample from healthy term neonates.

S.D= Standard deviation
CI = Confidence interval

EXPLANATION OF TERMINOLOGY USED IN SPREADSHEET

Diagnosis: The determination of the nature of a case of disease.

Diagnostic test: Diagnostic procedures, such as laboratory tests and x-rays, routinely performed on all individuals or specified categories of individuals in a specified situation, e.g., patients being admitted to the hospital.

Reference test (Gold standard): A method, procedure or measurement that is widely regarded or accepted as being the best available. Often used to compare with new methods.

Patient spectrum: Was the diagnostic test evaluated in an appropriate range of patients (like those in whom it would be used in practice)?

Sensitivity: Proportion of people with a target disorder who have a positive test. It is used to assist in assessing and selecting a diagnostic test/sign/symptom.

Specificity: Proportion of people without the target disorder who have a negative test. It is used to assist in assessing and selecting a diagnostic test/sign/symptom.

Likelihood ratio: The likelihood that a given test would be expected in a patient with the target disorder compared with the likelihood that the same result would be expected in a patient without the target disorder.

All patients tested with both diagnostic and reference test: The reference test should be applied regardless of result of the diagnostic test (avoidance of verification bias).

Blinding of assessors: Blinding or masking is a process used in epidemiological studies and clinical trials in which the observers have no knowledge of which test (diagnostic or reference) they are assessing. It is undertaken in order to minimise bias occurring in assessor response.

Validity:

Of measurement: an expression of the degree to which a measurement measures what it purports to measure; it includes construct and content validity.

Of study: the degree to which the inferences drawn from the study are warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn (internal and external validity, applicability, generalisability).

Potential for bias: A systematic deviation of a measurement from the 'true' value leading to either an over or underestimation of the treatment effect. Bias can originate from many different sources, such as allocation of patients, measurement, interpretation, publication and review of data.