Comparison of Hemolysis in Blood Samples Collected Using an Automatic Incision Device and a Manual Lance

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Objective: To evaluate the magnitude of hemolysis in blood specimens collected from the heels of newborns using an automated blood collection device that uses a spring-loaded lance with blood collected using a manual lance.

Design: A randomized controlled trial involving 134 newborns assigned to have blood collected using either an automated blood collection device or a manual lance. A single experienced individual performed all blood collections. Serum hemoglobin concentrations were measured in all samples to gauge the extent of hemolysis.

Setting: A neonatology unit in a 740-bed tertiary care teaching hospital.

Patients: Healthy newborns with gestational ages ranging from 33 weeks to 41 weeks. Blood samples were collected from study participants at between 7 and 126 hours postpartum. Group 1 consisted of 66 individuals who had blood collected using the manual lance. Group 2 contained 68 individuals with blood collected using a spring-loaded automatic lance.

Main Outcome Measure: Plasma hemoglobin content as an indicator of the extent of hemolysis.

Results: There were no significant differences between newborns in groups 1 and 2 with respect to gestational age, birth weight, or time interval between birth and time of blood collection. We found a highly significant difference with respect to plasma hemoglobin concentrations in specimens collected with an automated lance (hemoglobin, 2.35 g/L) vs that collected using the hand-held lance (hemoglobin, 4.85 g/L).

Conclusion: Use of an automated spring-loaded lance allows for the collection of blood specimens with smaller levels of plasma hemoglobin.

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HEEL PUNCTURE is the most common invasive procedure performed on newborns. This technique is necessary for blood collection for required neonatal biochemical screening. In addition, many newborns have blood samples collected for analysis of bilirubin, glucose, and other biochemical and hematological parameters. Infants who are sick or premature often receive repeated heel punctures. A lance is the most common device used for performing heel puncture, and heel puncture is most commonly performed manually. In addition to the use of manual lances, automatic spring-loaded devices are also available. One such device, called Tenderfoot (International Technidyne Corp, Edison, NJ), produces a small skin incision of defined length and depth from a spring-loaded surgical blade. The unit is self-contained and designed for single use. Numerous studies have been published describing the advantages of the spring-loaded lances in reducing stress and pain associated with blood collection.1-4 The controlled incision depth of the spring-loaded device is designed to reach superficial blood vessels while avoiding deeper dermal pain fibers. In addition to lessening the pain and distress associated with manual heel lancing, spring-loaded devices may reduce the risk of complications, such as osteomyelitis, by penetrating to a fixed and safe depth.5 Another advantage to using the spring-loaded device that has not been adequately addressed is that it may allow for the collection of blood less prone to hemolysis. In vitro hemolysis is recognized as a frequent source of error in many clinical laboratory analyses, and represents the most common cause for rejection of specimens within the clinical laboratory.6 It is especially prevalent in blood collected from

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newborns. Hemolysis in heelstick blood samples has been attributed in part to mechanical trauma and excessive squeezing at the puncture site. Analysis of hemolyzed specimens can result in erroneous results being reported, with the potential for adverse outcomes if these erroneous results are acted on. To evaluate the efficacy of the automated Tenderfoot spring-loaded device for the collection of blood samples that are less prone to hemolysis, we performed a randomized trial comparing the hand-held lance with this device. We assessed the occurrence and magnitude of hemolysis by measuring hemoglobin in samples collected with these devices.

**METHODS**

**PATIENTS**

The study protocol was approved by the University and Medical Center institutional review board. Written parental consent was obtained prior to enrollment in the study. The use of the lance or Tenderfoot device for blood collection was randomly assigned. Group 1 consisted of those individuals who had heel pricks performed manually with the handheld lance (Micro-lance; Becton Dickinson Vacutainer Systems, Franklin Lakes, NJ), while group 2 consisted of those newborns who had blood collected with the spring-loaded device. The manual lance had a blade length of 2.4 mm, while the Tenderfoot device produces a wound with a depth of 0.85 mm and a length of 1.75 mm.

**PROTOCOL**

A single individual with at least 6 months’ prior experience in the use of both blood collection devices performed all blood collections. All infants were resting quietly immediately prior to blood collection. Punctures were performed on the medial plantar aspect of the heel using a site not previously used for collection of blood. Blood was collected for routine biochemical screening. An aliquot of the same sample was used for measurement of serum hemoglobin concentrations using a procedure previously described.

**RESULTS**

One hundred thirty-four infants with gestational ages ranging from 33 weeks to 41 weeks (median, 38 weeks) and birth weights that ranged from 1254 g to 5267 g (median, 3231 g) were enrolled in the study. Blood was collected from study participants at between 7 and 126 hours (median, 48 hours) post partum. Sixty-six individuals had blood collected using the manual lance, while 68 had blood collected with the spring-loaded device. The Table presents the demographic data for the 2 groups. There was no significant difference between newborns in group 1 and group 2 with respect to gestational age, birth weight, or time interval between birth and collection of blood. However, a significant difference was noted in the levels of hemoglobin present in samples collected with the manual lance vs those collected with the automated device. Mean hemoglobin concentrations were more than 2-fold higher in the specimens collected with the manual lance, a difference that was significant (P < .001) (Table).

We investigated various factors that might influence the occurrence of hemolysis. Thus, we evaluated the effects of gestational age, birth weight, and time after birth that blood was collected on the concentrations of hemoglobin present in samples. Evaluating groups 1 and 2 separately, none of these parameters showed any relationship to the levels of hemoglobin present in the samples. Correlation coefficients obtained by plotting gestational age, birth weight, and time after birth that blood was collected vs hemoglobin were all within ±0.10, and none of the slopes of the regression lines were significantly different from 0.

**COMMENT**

Numerous studies have documented the risks and complications associated with heel lancing. Compared with manual lancing, spring-loaded devices have been found to cause less bruising and inflammation on the heel, ankle, and leg; significantly more complication-free sampling times; and significantly lower scores for pain and distress. Other studies have shown that those infants who have blood collected using a manual lance require, on average, 2.6 times more heel punctures to obtain the required specimen when compared with those infants who have blood collected with the Tenderfoot device. However, despite all these drawbacks, heelstick with the use of a handheld lance is still the conventional method for the collection of blood from neonates.

Few studies have been performed comparing spring-loaded incision devices vs manual heel lancing with respect to the amount of hemolysis in samples collected with each device. Paes et al studied 40 healthy, full-term newborns who had blood collected with either the manual lance or the Tenderfoot device. Like us, they found a significant decrease in the amount of hemoglobin present in specimens collected with the spring-loaded device compared with the manual lance (0.041 g/L vs 0.068 g/L, respectively). The lower incidence of hemolysis associated with use of the Tenderfoot device may be due to increased blood flow from the cut, with less heel manipulation and squeezing required to obtain the sample. Other advantages of the Tenderfoot device that these investigators noted was a significant increase in the average amount of blood collected with the spring-loaded device vs the manual lance (1.1 mL vs 0.6 mL, respectively), and a significant reduction in the time spent collecting the specimen (120 seconds vs 212 seconds).
Heel puncture with use of a manual lance is the most common technique for the collection of blood from newborns. Unfortunately, this technique is frequently associated with sample hemolysis that may result in erroneous measurement of many biochemical analytes. Studies on the use of automated lancing devices have primarily focused on the advantages of these devices in reducing stress and pain associated with heel puncture and in reducing complications such as osteomyelitis.

This study evaluates the utility of an automated lancing device in reducing the amount of hemolysis present in samples collected via heel puncture. We found that the use of an automated heel lancing device reduced the amount of free hemoglobin due to hemolysis almost 2-fold when compared with heel puncture performed using a manual lance.

In vitro hemolysis may affect the measurement of laboratory tests by one or more mechanisms. These mechanisms include the release of large quantities of a particular analyte from erythrocytes. Spurious increases in measured potassium, lactate dehydrogenase, and aspartate aminotransferase can occur with minimal hemolysis. Release of hemoglobin and other intracellular compounds from lysed erythrocytes can interfere with measurement of analytes such as albumin, bilirubin, cholesterol, creatinine, and total protein. The minimum level of hemoglobin resulting in visually detectable hemolysis is approximately 0.100 g/L. Significant interference with measurement of biochemical analytes can occur at this level of hemolysis. Serum or plasma from patients who are jaundiced can mask even greater concentrations of hemoglobin when the magnitude of hemolysis is estimated by visual means. Thus, it is imperative that nonhemolyzed specimens be obtained if reliable measurement of biochemical analytes is to be performed.

The cost difference between the manual lance vs the automated device is often quoted as being the main impediment to its routine use for blood collection in newborns. Estimates suggest that the cost associated with use of an automated incision device is approximately 10 times greater when compared with use of a manual lance. Unfortunately, these estimates do not take into account the greater quantity of specimens collected with the automatic device—factors that may obviate the need for repeat collection of blood and allow for more rapid turn around of specimens originally submitted for analysis.

These advantages, along with a decrease in pain and distress and a reduction in the risk of complications such as osteomyelitis associated with manual lancing of the heel, are more difficult to quantitate monetarily. However, these aspects need to be considered when evaluating the costs of using an automated collection device.

The use of the automated incision device allows for the collection of specimens containing less hemolysis and a greater volume of blood when compared with the use of a manual lance. These attributes lessen the likelihood that blood specimens will be rejected by the clinical laboratory as being unsuitable for analysis owing to hemolysis or insufficient quantity of a specimen. In addition, several other studies have shown that the automatic device allows for collection of samples in a significantly shorter time interval when compared with use of the manual lance. We also found that the use of the Tenderfoot device allowed for the collection of blood containing significantly less hemolysis when compared with specimens collected with a manual lance. In addition, we found that factors such as gestational age, birth weight, or time after birth that blood was collected, did not influence the likelihood of hemolysis, regardless of which device was used for blood collection.

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