Evaluation of a New Lancet Device (BD QuikHeel) on Pain Response and Success of Procedure in Term Neonates

Vibhuti Shah, MD, MRCP(UK); Anna Taddio, BScPhm, MSc, PhD; Karthik Kulasekaran, MD; Lisa O’Brien, BSc; Esther Perkins, CNE; Edmond Kelly, FRCPC

Objective: To evaluate 2 heel lancet devices in terms of pain response and success of the procedure in neonates undergoing the newborn screening test.

Design: Randomized trial.

Setting: Tenth level, mother-and-baby unit of a university-affiliated hospital.

Patients: Eighty term neonates.

Interventions: Heel lance using either the BD Safety-Flow lancet (SF) or the BD QuikHeel lancet (QH).

Main Outcome Measures: Facial grimacing score (brow bulge, eye squeezed shut, and nasolabial furrow [range, 0%-100%]), cry duration, duration of the procedure, and number of punctures required to collect the blood.

Results: Forty neonates were enrolled in each group. There were no differences in the demographic characteristics between groups. During the first skin puncture, the median score (25th-75th percentile) for facial grimacing was 100% (76%-100%) for the SF compared with 73% (42%-100%) for the QH ($P = .02$). For cry duration, it was 6 seconds (0-9 seconds) vs 0 seconds (0-6 seconds), respectively ($P = .01$). Pain scores during blood collection (ie, squeezing) did not differ between groups ($P = .09$). The procedure took less time to perform in the QH group (140 seconds [90-236 seconds]) than in the SF group (215 seconds [137-314 seconds]) ($P = .02$). The total crying time was shorter in the QH group (90 seconds [66-196 seconds] vs 148 seconds [92-267 seconds]; $P = .03$). Thirty-six (90%) of the neonates in the QH group received 1 puncture for blood collection compared with 21 (53%) in the SF group ($P < .001$).

Conclusion: The BD QuikHeel lancet is superior to the BD Safety-Flow lancet for blood collection in term neonates undergoing the newborn screening test.


Heel lance is the traditional method for obtaining blood samples in neonates for the newborn screening test and most other hematologic and biochemical tests. It is recognized that this technique causes substantial pain.1-3 Currently, the BD Safety-Flow lancet (SF) (Becton Dickinson Vacutainer Systems, Franklin Lakes, NJ) (Figure 1) is being used to perform heel lances in our institution. The SF is a partially retractable automatic lancet with a width of 1 mm and a depth of 2.2 mm. Recently, a fully retractable automatic lancet, the BD QuikHeel (QH) (Becton Dickinson Vacutainer Systems) (Figure 2), was designed for use during heel lance. Compared with the SF, the QH produces a wider but shallower incision (blade width is 2.5 mm and the depth is 1 mm). It is designed to reach the superficial dermal blood vessels while avoiding deep dermal pain fibers and therefore may cause less pain. In addition, the QH may reduce the risk of skin puncture and exposure to blood-borne pathogens for operators compared with the SF because of the fully retractable nature of its blade, and it may offer better visibility of the site location because of its tapered contact surface. On the basis of the superior design characteristics of the QH, we postulated that the use of the QH would lead to a reduction in infant pain and in the duration of the procedure.

The objectives of this trial were to compare the pain responses and success of the procedure (time for blood collection, number of punctures) in term neonates undergoing heel lance with the SF compared with the QH.
METHODS

This was a randomized, controlled trial conducted on the 10th level, mother-and-baby unit of a university-affiliated hospital. The study was approved by the local research ethics board, and informed parental consent was obtained for all participants. Healthy full-term neonates with a gestational age of 37 weeks or more and weighing 2500 g or more at birth, who were undergoing heel lance for the newborn screening blood test, were recruited. Neonates with congenital abnormalities and those exposed previously to a painful procedure other than the intramuscular administration of vitamin K (eg, infants of diabetic mothers requiring blood glucose monitoring) were excluded. By means of a computer-generated list, neonates were consecutively randomized to either the SF or the QH in blocks of 10.

The heel lance was performed in a standardized manner by the nurse responsible for the care of the infant on the day of the study, and 0.4 mL of blood was collected for the test. The heel lance consisted of 4 phases: baseline, cleaning the heel, heel lanceting, and squeezing the heel (blood collection). Neonates were videotaped during the entire procedure. A research assistant blinded to the study hypotheses and group allocation subsequently made pain assessments from the videotapes. Pain was assessed by means of facial grimacing score and cry duration. The presence or absence of 3 facial actions (brow bulge, eyes squeezed shut, and nasolabial frown) was scored in 2-second intervals for each phase of the procedure. The data were then collapsed for each facial action into the percentage of time the infant expressed the action. An overall pain score was then obtained by summing the percentage scores for the 3 facial actions and then dividing by 3. The score ranged from 0% to 100%. These 3 facial actions were chosen for the study, as they have been observed in 99% of neonates within 6 seconds of heel lance and are believed to be the most sensitive indicators of infant pain.2 Cry duration was expressed in seconds. In addition, the duration of the procedure and the number of punctures required to collect the blood sample were recorded.

To achieve a clinically significant reduction in pain scores (20%) between groups, with 80% power and $P < .05$, we estimated a sample size of 35 neonates in each group. This sample size was based on the pain scores obtained from a previous study by our group.4 A total of 80 neonates were enrolled to account for possible dropouts and missing data, such as video recording errors.

Demographic characteristics were compared between groups by means of $\chi^2$ analysis for categorical data and unpaired $t$ test for continuous data. Pain scores were compared between groups by means of the Mann-Whitney test. A $P < .05$ was considered significant.

RESULTS

Eighty neonates participated in the study; 40 were treated with the SF and 40 with the QH. The demographic characteristics of participating infants are shown in Table 1. The median score (25th-75th percentile) for facial grimacing score during the first skin puncture was higher in the SF group than the QH group (100% [76%-100%] vs 73% [42%-100%]; $P = .02$). Neonates treated with the SF cried for significantly longer during the first skin puncture (6 seconds [0-9 seconds] vs 0 seconds [0-6 seconds]; $P = .01$) (Table 2). Pain scores during blood collection (ie, squeezing) did not differ between groups (Table 2). The procedure took less time to perform in the QH group than the SF group (140 seconds [90-236 seconds] vs 215 seconds [137-314 seconds]; $P = .02$) (Table 3). The total crying time was shorter in the QH group than in the SF group (90 seconds [66-196 seconds] vs 148 seconds [92-267 seconds]; $P = .03$) (Table 2). Ninety percent of the neonates in the QH group received 1 puncture for blood collection compared with 53% for the SF group ($P < .001$) (Table 3).

Table 1. Demographic Characteristics of Study Subjects*

<table>
<thead>
<tr>
<th>BD Safety-Flow Lancet (n = 40)</th>
<th>BD QuikHeel Lancet (n = 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age, mean ± SD, wk</td>
<td>39.7 ± 1.2</td>
</tr>
<tr>
<td>Birth weight, mean ± SD, kg</td>
<td>3.4 ± 0.4</td>
</tr>
<tr>
<td>Apgar score at 1 min, mean ± SD</td>
<td>8.8 ± 0.5</td>
</tr>
<tr>
<td>Apgar score at 5 min, mean ± SD</td>
<td>9 ± 0</td>
</tr>
<tr>
<td>Sex, No. (%) M</td>
<td>23 (58)</td>
</tr>
<tr>
<td>Vaginal delivery, No. (%)</td>
<td>31 (78)</td>
</tr>
<tr>
<td>Postnatal age, mean ± SD, h</td>
<td>30.6 ± 6.5</td>
</tr>
</tbody>
</table>

*BD Safety-Flow and BD QuikHeel are trademarks of Becton Dickinson Vacutainer Systems, Franklin Lakes, NJ.
This is the first study, to our knowledge, that compared 2 automatic heel lancet devices, one with a partially retractable blade (SF) and the other with a fully retractable blade (QH), for blood sampling in the newborn. In this study, the QH was superior to the SF. The QH was associated with less pain and a reduction in the blood collection time and number of repeat punctures. The median total duration of crying was reduced by 58 seconds (39%) and the time taken to obtain the blood sample was reduced by 75 seconds (35%) in the QH group.

Heel lancing is the most common method of blood sampling in the newborn and causes intense pain.1-3 There is accumulating evidence that untreated procedural pain in the newborn may lead to immediate and long-term consequences, including conditioning and hyperalgesia.5-7 Thus, caregivers should work toward preventing or reducing pain in neonates. In recent reviews and consensus statements, the regular provision of analgesia and pain-preventive strategies has been strongly recommended.8-10

This study clearly demonstrated that the use of an alternative instrument (ie, the QH) for heel lancing can significantly reduce pain from this procedure.

Several studies have evaluated the effect of conventional manual lancets with automated devices on pain and distress, duration of the sampling time, and the amount of hemolysis. McIntosh et al11 showed that spring-loaded lancets (Autolet; Owen Mumford Ltd, Oxford, England) reduced pain and distress associated with heel lancing. In another study, Paes et al12 showed that an automated incision device (Tenderfoot; International Technidyne Corporation, Edison, NJ) was associated with an increase in the amount of blood collected within a shorter period and a decrease in the incidence of hemolyzed sample in full-term neonates. Similarly, Vertanen et al13 evaluated a manual lancet (Microlance; Becton-Dickinson, Meylan, France) and an automatic incision device (Tenderfoot) in preterm infants undergoing repeated heel lances for blood sampling. The automated incision device was associated with less bruising on the heel, ankle, and leg and decreased heel inflammation. The number of punctures to obtain a sufficient blood sample was also reduced. Kazmierczak et al14 evaluated the extent of hemolysis by measuring the hemoglobin content in blood specimens collected with the Microlance or Tenderfoot and found that the use of the automated lance was associated with lower levels of hemoglobin. The extent of hemolysis in blood samples was not evaluated in our study.

Our study was not designed to evaluate nursing preferences for the 2 lancets. However, anecdotal comments were made by nurses that the QH was superior to the SF. In fact, before the data analysis, nurses requested a change in clinical practice from the SF to the QH. The approximate cost (in Canadian dollars) of an SF is $0.50 compared with $2 for the QH. In our study, 47% of neonates treated with the SF required more than 1 puncture to obtain a blood sample, as compared with only 10% of neonates in the QH group. Taking into consideration the cost of repeat punctures for each group, the additional cost per neonate to the health care system if the QH is used instead of the SF is $1.50. We believe that this additional cost is justified because of the reduced procedure time and reduced pain associated with it.

Our study population was limited to healthy full-term infants. The effectiveness of this device in the preterm population is unknown. The QH device is available for use in the preterm population with a blade width of 1.75 mm and a depth of 0.85 mm; however, it has not been evaluated in a randomized controlled trial. Future studies that address the effectiveness and safety (ie, repeated use) of this device in different populations should be considered.

In conclusion, this study demonstrated that the BD QuikHeel lancet causes less pain and a shorter procedure than the BD Safety-Flow lancet in newborn infants undergoing the newborn screening test. On the basis of these results, our institution will now change to the BD QuikHeel lancet for collection of blood in term neonates.

Accepted for publication July 21, 2003.

This study was partially funded by BD Vacutainer Systems, Preanalytical Solutions, Franklin Lakes, NJ.

This study was presented at the annual meeting of the Paediatric Research Societies; May 6, 2002; Baltimore, Md; and the annual meeting of the Canadian Paediatric Society; June 13, 2002; Toronto, Ontario.
We are grateful to the parents of the participating neonates, to the nursing staff from the 10th level, mother-and-baby unit of Mount Sinai Hospital, Toronto, and to Lucia Taddio and Erwin Darra for aspects of videotape analysis.

Corresponding author: Vibhuti Shah, MD, MRCP(UK), Department of Paediatrics, Room 775A, Mount Sinai Hospital, 600 University Ave, Toronto, Ontario, Canada MSG 1X8 (e-mail: vshah@mtsnyai.on.ca).

REFERENCES


8. American Academy of Pediatrics (Committee on Fetus and Newborn; Committee on Drugs; Section on Anesthesiology; and Section on Surgery), Canadian Paediatric Society (Fetus and Newborn Committee). Prevention and management of pain and stress in the newborn infant. Pediatrics. 2000;105:454-461.

9. American Academy of Pediatrics (Committee on Fetus and Newborn; Committee on Drugs; Section on Anesthesiology; and Section on Surgery), Canadian Paediatric Society (Fetus and Newborn Committee). Prevention and management of pain and stress in the newborn infant. Pediatrics. 2000;105:454-461.


What This Study Adds

Heel lance, the conventional method of blood collection in newborns, is a very painful procedure. Previous studies have demonstrated that automatic lancets are better than manual lancets. This is the first study, to our knowledge, to compare 2 automatic heel lancet devices, one with a partially retractable blade and the other with a fully retractable blade, for blood sampling in the newborn. The fully retractable automatic lancet was associated with less pain, a reduction in sampling time, and fewer repeat punctures. On the basis of the results of the study, our institution is using the fully retractable automatic lancet for blood collection in term newborns.

Call for Papers

The Archives of Pediatrics & Adolescent Medicine will publish a theme issue on mental health in August 2004. Our call for papers includes studies that provide new information on office screening for mental health problems, and guidance to practitioners on appropriate care and referral of patients with mental illness. We are especially interested in randomized trials that test new interventions, particularly those that can be provided by primary care physicians. For the best chance of consideration for this theme issue, papers should be received by January 1, 2004. Please consult our Web site (www.archpediatrics.com) for detailed instructions for authors.