Evaluation of Lancets for Pain Perception and Capillary Blood Volume for Glucose Monitoring

DAVID WARUNEK, ANA K STANKOVIC

OBJECTIVE: The purpose of this study was to assess patient pain perception and capillary blood volume of four currently marketed lancets [BD Microtainer Contact-Activated Lancet, Low Flow (Contact-Activated Lancet); LifeScan OneTouch SureSoft Gentle (OneTouch SureSoft Gentle); BD Genie Blue; SurgiLance Safety] in a diabetic population following routine finger-puncture procedures and glucose monitoring.

METHODS: Data were collected from adult subjects diagnosed with type I or type II diabetes mellitus at a 300-bed US hospital following finger-puncture procedures for glucose monitoring. Based on quantitative and qualitative measurements, each blood collection device was evaluated for pain perception and calculated total capillary blood volume.

RESULTS: A total of 80 subjects received four skin punctures in an alternating finger and hand sequence using each lancet. The ten clinicians (nurses and phlebotomists) conducted the study, collected and then calculated total capillary blood volume. It was determined that the Contact-Activated Lancet produced less perceived pain and bleeding, while obtaining an adequate capillary blood volume for glucose monitoring.

CONCLUSION: This study demonstrated that the Contact-Activated Lancet provided an adequate sample volume required for blood glucose monitoring. In addition, less perceived pain was elicited with this lancet when compared with the other lancets evaluated in the study.

INDEX TERMS: glucose monitoring, lancets, pain perception, capillary blood sampling

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Clin Lab Sci 2008;21(4):215

David Warunek PhD MBA MT(ASCP) *is the* ***worldwide director****, Scientific Affairs, BD Diagnostics – Preanalytical Systems, Franklin Lakes NJ.*

Ana Stankovic PhD MD MSPH *is the* ***vice president****, Medical, Scientific Affairs and Clinical Operations, BD Diagnostics – Preanalytical Systems, Franklin Lakes NJ.*

Address for correspondence: *David Warunek PhD MBA MT (ASCP), worldwide director, Scientific Affairs, BD Diagnostics – Preanalytical Systems, 1 Becton Drive, Franklin Lakes NJ 07417. (201) 847-4376. David_Warunek@bd.com.*

ACKNOWLEDGEMENTS: *The authors wish to acknowledge Karen Byron for her help in the statistical analysis and Julie Ravo for her editorial assistance.*

Approximately 20.8 million adults and children in the US (or seven percent of the population) suffer from diabetes and depend on routine blood glucose monitoring to manage the condition and to reduce potential disease complications.[1-4] Circumstances may present, however, in which patients fail to assess their blood glucose levels on a consistent basis, with real or perceived pain during finger punctures for low blood volume collection as a major factor.[5-7] In addition, these situations may result in an inability to retrieve an adequate blood sample for glucose testing.

In reference to this, the purpose of the study was to assess four currently marketed lancets for subjects' relative pain perception and capillary blood flow (volume) when used to perform finger punctures for glucose monitoring.

MATERIALS AND METHODS

A total of 10 nurses and phlebotomists, who currently perform finger-puncture procedures for the collection of low blood volumes, each performed four skin punctures on each of eight adult subjects utilizing four different lancets (BD Microtainer Contact-Activated Lancet, Low Flow; LifeScan OneTouch SureSoft Gentle; BD Genie Blue; SurgiLance Safety). All subjects were previously diagnosed with type I or

type II diabetes mellitus and routinely underwent finger-puncture procedures for glucose monitoring. Following receipt of written informed patient consent, a skin puncture was achieved on each subject using all four devices in a randomized schedule that integrated the device, finger (third/middle or fourth/ring), and hand rotation.

Prior to the punctures, a total of 80 subjects washed their hands with warm soapy water. Immediately prior to each skin puncture, the site was cleansed with 70% isopropyl alcohol and allowed to air dry. Each skin puncture was performed in accordance with the manufacturer's instructions for the specific device. To obtain the first drop of blood after device penetration, the clinician applied pressure above the puncture site for three to five seconds; pressure was then released. The first drop of blood was collected into a 75 µL microcapillary tube; the fill height was measured against a scale (in millimeters), and the total volume was calculated.

After the puncture site was cleansed and bandaged, the subject assessed the perceived pain upon initial skin puncture (t_0) using a Gracely Pain Scale—a nominal 0-20 rating scale, where 0 was defined as "no pain" and 20 as "excruciating pain."[8]

The skin puncture procedure was repeated until the subject received one puncture from each of the four devices. The pressure above the puncture site was kept at a constant time for each subject and among the four devices. This was accomplished by recording the pressure time for the first skin puncture and applying the same time to the three remaining device punctures. Upon completion of all four finger punctures, the subject was asked to identify the most and least painful of the four devices. In addition, each subject assessed lingering pain by gently rubbing the thumb over the skin puncture after approximately 5 min ±1 min ($t_{5\ min}$) and 10 min ±1 min ($t_{10\ min}$) after the first puncture for each hand.

Table 1. Pain perception: device, mean and ± standard deviation (SD)

Device	Contact-Activated Lancet	OneTouch SureSoft Gentle	BD Genie Blue	SurgiLance Safety Lancet
Study range across each device (Gracely Pain Scale)	0-15	0-19	0-20	0-19
Mean ± SD (n=80)	1.80 ± 3.23	2.66 ± 3.28	2.40 ± 3.45	3.14 ± 4.33
p value*	------	0.0089	0.0464	0.0026

*All data were expressed as mean ± SD. The difference between the Contact-Activated Lancet and other devices for pain perception was evaluated using the Dunnett's simultaneous test. *p* value <0.05 was considered significant.

Table 2. Lingering pain, Response (n=80)*

Device	Contact-Activated Lancet	OneTouch SureSoft Gentle	BD Genie Blue	SurgiLance Safety Lancet
$T_{5\ minutes}$				
No	40	38	39	32
Yes	0	2	1	8
Percent	100%	95%	97.5%	80%
$T_{10\ minutes}$				
No	40	39	40	36
Yes	0	1	0	4
Percent	100%	97.5%	100%	90%

*Total values obtained = 160: 80 subjects, two hands. Question was asked after each skin puncture with the first lancet on each hand.

The lower limit for blood volume collected from each device was not predetermined. Instead, this was assessed by each clinician based on the volume collected and their personal experience using point-of-care devices to determine glucose value.

DATA ANALYSIS

Data from the subjects for perceived pain and data from clinicians for capillary blood flow (volume) were obtained. Subjects' perceived pain evaluations on the Gracely Pain Scale (0-20 scale) were analyzed with a general linear model performed on the log transformed data. Analysis of variance (ANOVA) procedures, followed by a predetermined set of multiple comparisons, were used to determine whether there were significant differences among the four lancet types. The model used for the ANOVA was:

y = Order + Clinician+ Subject+ Hand + Finger+ Lancet Type.

Dunnett's simultaneous tests were used for comparing the Contact-Activated Lancet with the other three lancet types. Descriptive statistics for the blood volume collected after each skin puncture, along with 95% confidence intervals for the mean volume were computed for each lancet type.

RESULTS AND DISCUSSION

Data were collected to assess pain perception (comfort) and capillary blood volume of the four lancets. Table 1 presents the range of study scores obtained for subjects' pain perception, which was the range of results obtained for each device for all subjects (80 subjects, four devices = 320 reported values). Also documented are the mean and standard deviation for each device, as well as the size of the study population.

Examination of the data revealed the mean value of subjects' perceived pain, with the Contact-Activated Lancet at the lowest with a scale mean of 1.80. In addition, this lancet had the lowest range in subjects' intensity of perceived pain, with a maximum Gracely Pain Scale score of 15 versus maximum scores of 19 and 20 for the remaining devices.

Results were then obtained for subject responses to the questions regarding lingering pain: Any pain on first finger puncture or following the first puncture on each hand? These questions were asked of each subject at 5 min ($t_{5\ min}$) and 10 min ($t_{10\ min}$) (Table 2). Results were then documented for all subjects, each device, each hand, and for each question (or question interval). None of the subjects felt lingering pain at $t_{5\ min}$ or at $t_{10\ min}$ when the Contact-Activated Lancet was used for skin penetration. Thirty-eight subjects (95%) felt no lingering pain at $t_{5\ min}$ and 39 subjects (97.5%) experienced no lingering pain at $t_{10\ min}$ when the OneTouch SureSoft Gentle Lancet was used. Thirty-nine subjects (97.5%) and 40 subjects (100%) felt no lingering pain at $t_{5\ min}$ and at t_{10min} respectively when using BD Genie Blue. Thirty-two subjects (80%) and 36 subjects (90%) reported no lingering pain at $t_{5\ min}$ and at $t_{10\ min}$ respectively when using the SurgiLance Safety lancet.

Table 3 presents the units and range of results obtained for total blood volume, which was the range of results obtained for each device for all subjects using the

Table 3. Blood volume (µL): device, range, mean and 95% confidence intervals (95% CI), ± standard deviation (SD), and median

Device	Contact-Activated Lancet	OneTouch SureSoft Gentle	BD Genie Blue	SurgiLance Safety Lancet
Study range across each device (µL)	0-26	0-25	0-38	0-28
Mean (µL) (95% C.I.)	6.39 (5.26, 7.51)	8.09 (6.96, 9.21)	7.15 (6.02, 8.28)	8.75 (7.62, 9.88)
SD	6.22	6.35	6.21	7.17
Median (µL)	4.5	6.0	5.0	6.0
p value*	------	0.0923	0.6633	0.0104

*All data were expressed as mean ± SD. The difference between the Contact-Activated Lancet and other devices for blood volume (µL) was evaluated using the Dunnett's simultaneous test. *p* value <0.05 was considered significant.

same puncture pressure time across all lancets for each subject. Also shown are the mean, standard deviation, and median values for each device. Subjects' skin punctures from the Contact-Activated Lancet had the smallest amount of blood volume (bleeding) when compared to the other devices (mean = 6.39 µL, median 4.5 µL), while successfully providing an adequate sample volume when evaluated by the clinicians. The Contact-Activated Lancet generated significantly less blood than the SurgiLance Safety lancet. There were no significant differences between the other evaluated lancets.

CONCLUSION

This study demonstrated that the Contact-Activated Lancet elicited less perceived pain than the other lancet devices, which were evaluated in the research examination. In addition, the study confirmed the acquisition of an adequate capillary blood volume required for glucose monitoring in a diabetic population.

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