

A NEW SYSTEM FOR DECREASING THE LEVEL OF INJECTION PAIN ASSOCIATED WITH LOCAL ANESTHESIA OF A TOE*

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INTRODUCTION

Local anesthetics in particular, provide fast, safe, and effective protection from otherwise intolerable minor procedures. However, many patients find that even the relatively minor discomfort associated with the process of achieving a local nerve conduction block is intolerable. This pain typically occurs in two stages; needle stick and dispensing of medication. Needle sticks are always problematic due to the difficulty of advancing the needle through the relatively tough skin barrier, into the deeper tissues. Although the needle stick is the part of the injection that many patients fear, it is typically not the greatest source of pain. Dispensing of medications often is much more painful, and is sustained over a greater period of time. Pain associated with variations in pH is believed to cause a severe burning sensation, exacerbated by rapid administration. Back pressure during the dispensing process also causes painful separation of the tissue planes by hydrostatic pressure. Reduction of pain during the dispensing phase of injection is largely a result of slow administration and careful placement of smaller volumes of the anesthetic.

In 1997, a Computer Controlled Local Anesthetic Delivery System (CCLADS) (CompuDent™; The Wand®; Milestone Scientific, Inc. Livingston, NJ) was introduced to precisely regulate the flow of anesthetic into sensitive oral tissues. Hochman, et al. demonstrated that CCLADS could be used to perform a "virtually pain-free" dental injection, even in dense fibrous connective tissue¹. Froum, et al.⁷ confirmed a substantial reduction in tissue damage during dental injections when using a CCLADS. The CCLADS system can deliver and maintain a consistent slow flow rate of anesthetic fluid over a period of time, even in tissues of high density. The controlled pressure and volume characteristics of a CCLADS account for reports of more comfortable dental injections compared to a syringe^{1,2,3,4}.

One benefit of using a CCLADS is that your thumb does not have to be used to apply pressure to a plunger. The needle holder used in this study is an ultra light handpiece (The Wand™) which is grasped as one would hold a pen. When used with a rotational insertion technique as described by Hochman and Friedman^{5,6}, the force and deflection produced by the needle is substantially reduced. The precise control of the ergonomically designed needle holder is associated with a reduction of pain. The focus of the current study is the next generation of CCLADS systems to be used in the foot and other sensitive areas. Thus, the following hypothesis is proposed:

HYPOTHESIS

CCLADS and a precision handpiece will produce a significant reduction in injection pain as compared to normal injection techniques for obtaining regional anesthesia in the hallux.

METHODS

A blinded study was performed in which 100 subjects between age 18 and 50 were injected by an experienced podiatric physician, using both a conventional injection technique and a CCLADS device with an ergonomic handpiece (CompuMed™; The Wand®; Milestone Scientific, Inc. Livingston, NJ) (FIG. 1,2). In each case, 2% lidocaine was dispensed through identical 30 gauge x 1" hypodermic needles. Each subject underwent two injections, one medial and one lateral, into the hallux. One injection was performed in the traditional manner using a 3 cc syringe, and the other utilized the CCLADS device in conjunction with the ergonomic handpiece (The Wand®; Milestone Scientific, Inc. Livingston, NJ). The order of the injections and the device used for the medial or lateral injection was randomized.

Subjects with neuropathy or related conditions (e.g. diabetes) were excluded. Subjects completed a quality of life assessment prior to receiving any injections, in order to assess one's state of mind, level of injection anxiety, and tolerance for discomfort. In addition, subjects were asked questions to determine their past experiences and

concerns about injections. A barrier was erected between the subject and the clinician to prevent the subject from observing the injection, and knowing which device was being used.

Evaluation of symptoms was based on a validated 11-point Visual Analog Scale (VAS). Symptoms associated with needle sticks were evaluated separately from symptoms related to dispensing of medications. Overall evaluations of each injection procedure, and impressions about these injections were assessed upon completion of each injection as well. Because each subject received one of each type of injection, they served as their own control. Data was analyzed as matched pairs, with student's t test for paired data. Analysis of variance and covariance was utilized to determine the impact that mental outlook and other psychosocial factors may have had on the outcome.

RESULTS

Overall the pain associated with injections using the CCLADS/ergonomic handpiece was decreased from moderate levels to nearly non-existent. Pain associated with standard injections was rated at 3.94 (moderate) (SD=2.09) (reported range was 0 to 10 on an 11 point VAS scale), while the CCLADS with ergonomic handpiece reduced the pain to approximately 2.87 (mild) (SD=1.95) (reported range was 0 to 7 on an 11 point scale). This represents an overall reduction in pain of 26.3% ($p < 0.01$) as perceived by the subjects on a 0-10 VAS score (FIG 3).

Analysis of pain associated with the actual needle stick showed that there was a statistically significant decrease in pain associated with the needle stick using The Wand™ (3.75, SD=2.14) versus the control (4.36, SD=2.09). This represents a reduction in pain of 13.3% ($p = 0.049$). When the pain associated with dispensing of anesthetic was considered, the CCLADS was far superior. Test subjects indicated that there was a reduction of 34.9% ($p < 0.0001$) when CCLADS was used (2.29, SD=1.97), as compared to the Control (3.54, SD=2.32). Even more compelling was the fact that 37 out of 100 subjects rated their pain level at 0 or 1 with CCLADS injection, while only 23 out of 100 subjects in the Control group rated their pain at 0 or 1.

Among those who rated their fear of injections more highly, the results were much more dramatic. Subjects were asked to rate their level of apprehension to injections prior to receiving the first injection. The group which described their pre-injection feelings as very nervous, scared, or terrified were included in this portion of the analysis. We found that they rated the difference in pain associated with dispensing of medication was significant ($p = 0.036$; CCLADS was 3.25 (SD=2.95) vs. Control score of 7.00 (SD=2.12)). In addition, there was a statistically significant difference in the overall perception of pain associated with each injection, with all preferring the CCLADS with ergonomic handpiece over the Control ($p = 0.032$, Wand 2.75 (SD=2.05) vs. Control 7.25 (SD=1.48)).

Among those members of this group who were randomized to receive CCLADS injections first, their apprehension for injections dropped from a pre-injection level of 6.7 to a post-injection level of 2.0. When asked if they would go out of their way to seek a physician who could give an injection with the less painful technique (CCLADS with ergonomic handpiece), approximately 50% indicated that they would, and nearly all indicated that they would prefer to be treated by a physician who could give the less painful CCLADS injection method. All subjects indicated that they would be likely to recommend a physician who used the CCLADS system to friends or family. When asked what their opinion of a physician who used the CCLADS system, nearly all indicated that they would perceive the Doctor as someone who cares about their patients, and is practicing "state-of-the-art" medicine.

DISCUSSION & CONCLUSION

Our data clearly illustrates a difference in the levels of pain and anxiety experienced by patients treated with the CCLADS, as compared to the standard syringe injection system. We have demonstrated a statistically significant reduction in the level of pain experienced by our subjects during both needle insertion and dispensing of medication. Ultimately, we feel that this will lead to more involved surgical procedures such as bunionectomies, plantar fascia releases, neuromas, and other types of foot surgery being performed under straight local anesthetic as opposed to local anesthetic in conjunction with intravenous, epidural, or general anesthesia. This results in safer surgery with fewer anesthetic complications, while greatly increasing the potential scope of office based surgery.

Based on our experience with 100 subjects, it is clear that the level of pain associated with injections is greatly reduced when using CCLADS system with ergonomic handpiece, as compared to the Control group. Based on this positive experience, it is anticipated that the potential for use of CCLADS for outpatient surgery under local anesthesia is tremendous.

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