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OPEN

Effectiveness of Buffered Lidocaine for Local Anesthesia During Liver Biopsy

ABSTRACT

The aim of this research study was to evaluate the effectiveness of lidocaine versus lidocaine with sodium bicarbonate in reducing anxiety and pain, using visual analog scales, in subjects receiving local anesthetic during liver biopsies. The project included 199 subjects presenting for percutaneous liver biopsy using local anesthesia. Subjects were randomized into 2 groups: the control group, which received lidocaine alone, and the experimental group, which received lidocaine buffered with sodium bicarbonate. Immediately after they received the lidocaine injection, both groups were asked to rate their preprocedure anxiety and pain using a 0–10 visual analog scale. Mean postprocedure pain was statistically significantly different between the two arms with the intervention group reporting less pain (1.65 vs. 2.27, $p = .037$). Change in pain scores between the two groups were also statistically significantly different with the intervention group reporting a mean change in pain score of 0.93 compared to 1.63 in the control group ($p = .021$). However, no differences were found for reported anxiety. This study has shown that using sodium bicarbonate with lidocaine significantly decreased pain sensation at the injection site when used for deep visceral anesthesia during percutaneous liver biopsy.

According to one study, "the most feared and uncomfortable part of a surgical procedure for subjects is the initial injection of the local anesthesia" (Welch, Czyz, Kalwerisky, Holck, & Mihora, 2012, p. 2048). This study further notes that "pain on initial injection during outpatient surgical procedures may even influence subject referral patterns (Welch et al., 2012, p. 2048). It has also been suggested that a previous poor experience may increase the subject's anxiety, interfere with cooperation, and prompt patients to refuse procedures due to anxiety and expected pain from local anesthesia. During liver biopsy procedures, subjects receive local anesthesia by localized infiltration of lidocaine. Subjects routinely complain more about the pain associated with the infiltration of the lidocaine than with the needle stick itself. To decrease the pain and anxiety related to the procedure, we conducted a literature search to determine whether there were other methods of providing effective local anesthesia with less injection site discomfort.

Background

Research suggests the pain that subjects experience during the injection is due to the pH of the lidocaine. A 1% lidocaine solution used during procedures has a pH of 6.5 (5.0–7.0) according to Hospira Incorporated, Lake Forrest, IL (Hospira, 2010, p. 2). The physiological pH is between 7.35 and 7.45. The acidic pH of the lidocaine creates the greatest amount of pain during liver biopsy procedures (Cepeda et al., 2010, p. 2). A number of studies have been conducted to test the efficacy of buffering lidocaine, primarily in peripheral

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The authors declare no conflicts of interest.

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nerve blocks and dermatology procedures (Gurda, 2013). This practice, however, had not been evaluated in deep visceral procedures such as percutaneous liver biopsy. These studies were collectively analyzed in a meta-analysis by the Cochrane Collaboration, which suggests that adjusting the pH of lidocaine decreased pain on injection and, in turn, improved subject comfort and satisfaction (Cepeda et al., 2010, p. 2).

With this information in hand, our unit conducted a preliminary quality improvement project (open-label pilot study) testing the use of lidocaine versus buffered lidocaine with sodium bicarbonate for local anesthesia. The quality improvement project consisted of 95 patients presenting for percutaneous liver biopsy using local anesthesia. These patients were placed into two groups: a control group, which received lidocaine only, and an experimental group, which received lidocaine buffered with sodium bicarbonate. The first 50 patients presenting for liver biopsies were placed in the control group. The second 50 patients presenting for liver biopsies were placed in the experimental group. Both groups were asked to rate their preprocedure anxiety and pain using a 1–10 Likert scale. They were again asked to rate their anxiety and pain immediately after they received the lidocaine injection using the same 1–10 Likert scale.

The results indicated the control group, which received lidocaine alone, rated their pain level at 4.2, whereas the experimental group, which received lidocaine buffered with sodium bicarbonate, rated their pain as a 3.2. This simple intervention reduced patient's pain level by 1 point. Although this finding may not be considerable in itself, the project showed a sizeable reduction in patient's anxiety when lidocaine was buffered with sodium bicarbonate. The control group rated their preprocedure anxiety level as a 5.3, whereas the experiential group rated their preprocedure anxiety at only 3.7. The biggest and most significant finding was the reduction in anxiety; however, this study was not blinded. Reducing patients' anxiety can have a positive effect on their experience. We were so intrigued with the significant decrease in patients' anxiety that this quality improvement project morphed into a double-blind research project, which would be more valid and reliable.

Methods

Study Design

The sampling design had a 200-study-participant goal in a two-arm, double-blind, randomized controlled trial from patients receiving local anesthesia during liver biopsies. The control arm was the standard of care with lidocaine and the experimental arm was sodium bicarbonate and lidocaine. Random assignment to the study arms was drawn from a randomized block design using nQuery (2017) Advisor 7.0. Randomized study IDs denoting assignment to the two arms were given to the pharmacy department, which prepared each treatment as subjects were enrolled.

Sample

The sampling frame was 200 randomly assigned subjects with equal balance between the arms (100 cases and 100 controls). The inclusion and exclusion criteria are shown as follows:

Inclusion

- All subjects older than 18 years presenting for liver biopsies;
- Subjects undergoing local anesthesia using lidocaine;
- Subjects who agree to participate in the research by signing the informed consent; and
- Subjects able to speak and read English.

Exclusion

- Subjects younger than 18 years;
- Subjects not agreeing to participate; and
- Subjects receiving intravenous sedation prior to or during the procedure.

One study ID was double counted and has been removed from analysis for a final count of 199 (99 cases and 100 controls).

Procedure

The institutional review board protocol was submitted for full review and approved. Patients who were routinely scheduled for a liver biopsy in the endoscopy unit were approached by the primary investigator to participate in the study. This preparation included an introduction and discussion of the overview of the study protocol, including informed consent, methodology, and expectations throughout the study. A patient education handout was given to the patient. The consent was explained to the patients including that voluntary participation or refusal would not in any way impact their care. If a patient agreed to participate, research consent was signed and the subject was randomized to the control or experimental group. A registered nurse initated data collection by gathering the subject's demographic information and assigning a randomized vial number. The nurse also educated subjects about how to complete the visual analog scale (VAS) to rate their pain and anxiety. A pretest survey was also administered.

The subject was then transferred to the procedure room for the liver biopsy procedure. The pharmacy provided the medication for local anesthesia containing either 5 ml of 8.4% sodium bicarbonate or 5 ml of

sterile water depending upon the randomized treatment. The vials were sealed, labeled, and randomized by pharmacy. No other identifying information was noted on the vials. Pharmacy maintained a list of the vial number with contents. The physician administered the local anesthetic. The control group received 9 ml of lidocaine and 1 ml of sterile water. The experimental group received 9 ml of lidocaine and 1 ml of sodium bicarbonate. After the procedure, the subject was asked to rate his or her anxiety and pain using the visual analog pain scale. The subject was then returned to the postanesthesia care unit area for standard recovery care of liver biopsy patients.

Instrument

The primary instrument to measure both pain and anxiety was the VAS, containing a 10-cm line with right angle stops or anchors at either end (Figure 1). The end anchors contained the sensation range (e.g., no anxiety, worst anxiety ever; no pain, worst pain ever) (Burns & Grove, 2007, p. 391). There were four scales; one sheet of paper contained two scales for preprocedure anxiety and pain. An identical but separate piece of paper contained the same two analog scales for postprocedure anxiety and pain. The subject was asked to place a mark through the line on the scales to indicate the intensity of his or her anxiety and pain preprocedure and then again postprocedure. The subject was not able to see the preprocedure mark, so as not to influence the postprocedure response. A ruler was used to measure the distance in millimeters between the left end of the lines to the subject's mark, which represents the value of his or her stimulus. This value in centimeters depicted the level of pain and anxiety pre- and postprocedure.

Analysis

Demographic and covariate variables were summarized with means, standard deviations, numbers, and percentage. Pain and anxiety scores were analyzed for mean changes pre/postprocedure. Both measures were assessed in terms of changes on the10-cm VAS (scored 0–10; lower scores indicate less pain). Changes in both pain and anxiety scores were assessed using independent-samples *t* tests. Potential confounding variables were included in a multivariate model that adjusts for differences. All results were analyzed using the two-sided test, with a significance cutoff value of $p \leq .05$ using STATA 12.0 (StataCorp, 2011).

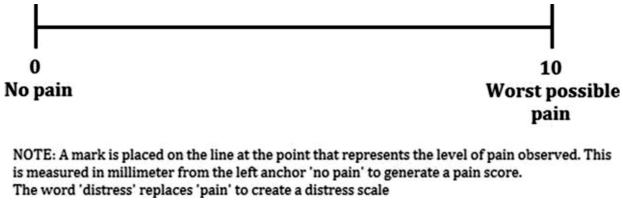

FIGURE 1. visual analog scale.

TABLE 1. Demographic and Potential Confounding Variables in the Sample of Study Participants ($N = 199$)

	Intervention *n* (%)	Controls *n* (%)	Significance
Gender			
Male	42 (42.4)	39 (39.0)	.884
Female	55 (55.6)	59 (59.0)	
Missing	2 (2.0)	2 (2.0)	
Race			
White	74 (74.7)	73 (73.0)	.725
Asian	2 (2.0)	4 (4.0)	
African American	19 (19.2)	18 (18.0)	
Hispanic	3 (3.0)	4 (4.0)	
Other	1 (1.0)	0 (0.0)	
Missing	0 (0.0)	1 (1.0)	
NPO (fasting)			
Yes	31 (31.0)	17 17.2)	.018
No	68 (68.0)	83 (83.8)	
Previous biopsy experience			
Yes	30 (30.0)	25 (25.3)	.704
No	68 (68.0)	74 (74.7)	
Missing	1 (1.0)	1 (1.0)	
	Mean (*SD*)	Mean (*SD*)	
Age	53.2 (12.9)	54.1 (13.5)	.626

Note. NPO = nothing per oral.

Results

One hundred ninety-nine participants are summarized in Table 1 by the study arm for demographic and potential confounding variables. The sample was majority female (57.3%) and Caucasian (73.9%) and had a mean age of 53.7 ($SD = 13.2$) years. There were no statistically significant differences in the demographic makeup of the sample by the study arm. Patients in more than a quarter of the sample (27.6%) reported having had a previous liver biopsy, but results were not statistically significantly different by the study arm (30% vs. 25.3%; $p = .704$). Finally, instructions for nothing per oral (NPO) were significantly greater in the intervention arm (31% vs. 17.2%; $p = .018$).

Mean preprocedure pain in the intervention group was 0.72 compared with 0.64 in the control group (NS)

TABLE 2. Mean Reported Pain and Anxiety Scores Pre- and Postintervention in the Study Sample ($N = 199$)

	Intervention		Controls			
	Mean	*SD*	Mean	*SD*	Significance[a]	Significance[b]
Pain						
Pre	0.72	1.60	0.64	1.38	.692	.807
Post	1.65	1.94	2.27	2.25	.037*	.034*
Pain change	0.93	2.00	1.63	2.24	.021*	.026*
Anxiety						
Pre	2.56	2.71	2.87	2.93	.442	.381
Post	2.55	2.60	2.84	2.72	.436	.384
Anxiety change	0.01	2.81	−0.03	2.91	.921	.900

Note. NPO = nothing per oral.
[a]Independent-samples *t* test.
[b]Multivariate linear regression adjusting for NPO. *indicates statistically significant finding.

(Table 2). However, mean postprocedure pain was statistically significantly different between the two arms, with the intervention group reporting less pain (1.65 vs. 2.27; $p = .037$). Change in pain scores between the two groups were also statistically significant with the intervention group reporting a mean change in pain score of 0.93 compared with 1.63 in the control group ($p = .021$). In a multivariate model that adjusts for the NPO status, results remained statistically significant ($p = .034$ and $p = .026$, respectively, for postintervention and change scores). Mean anxiety scores ranged from 2.55 to 2.87 pre- and postintervention and did not change, nor vary, by the study group.

Discussion

This study was conducted in an inner-city community hospital with a diverse population and a bed size of approximately 300 patients. The endoscopy unit specialized in hepatology patients who were being evaluated for such conditions as viral hepatitis, fatty liver disease, and abnormal liver function tests. Our study population was 42% male and 56% female, mean age of 53.2 years, and 2% missing data.

The mean reported pain scores show a statistically significant difference, with the intervention group reporting a lower change in pain score than the control group. This clearly supports the evidence that the acidic level of the lidocaine created the greatest amount of pain. The scores related to anxiety were not statistically significant between the control group and the intervention group. This finding was not surprising, as we did not expect the change in pH associated with buffered lidocaine to affect the anxiety scores. Although we did not demonstrate a reduction in anxiety, further study of inventions specifically related to anxiety should be explored as the anticipation of pain and the fear of the unknown contributes to increased anxiety.

Implications for Clinical Practice

The use of sodium bicarbonate in lidocaine has been successful in reducing pain at the injection site. This type of local anesthesia may be applicable to other procedures such as thoracentesis and paracentesis where injection site pain is a patient concern.

Clinical Limitations

Sodium bicarbonate mixed with lidocaine is not commercially available. The preparation needs to be combined just prior to administration, which requires coordination with pharmacy and the procedure in an efficient manner. The preparation would be stable for 24 hours if kept refrigerated in the unit.

Conclusion

The addition of sodium bicarbonate to lidocaine significantly reduces pain at the injection site during liver biopsies. Reducing patients' pain and increasing their comfort level is a core essential function of a nurse. The use of buffered lidocaine allows nurses and physicians to perform their job more effectively with greater patient satisfaction. ✪

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