Changing the Buffer in Buffered Lidocaine

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ABSTRACT

Hospitalized patients require venous access for procedures, treatments, or therapies. The use of lidocaine for pain relief during central vascular access device (CVAD) insertion is a standard of practice. Lidocaine buffered with sodium bicarbonate has been shown to provide significantly more pain relief in the sensation of pain upon injection. Shortages of lidocaine with bicarbonate provided an opportunity to explore other options to provide pain relief during CVAD insertion. The PICO question for this project was: In adult patients requiring CVAD insertion, how does lidocaine buffered with bicarbonate compare with lidocaine buffered with saline in minimizing pain with lidocaine injection? This study assessed how lidocaine buffered with bicarbonate compares with lidocaine buffered with saline in minimizing pain with lidocaine injection. Sixty patients received the buffered lidocaine before having a peripherally inserted central catheter inserted. Thirty patients received lidocaine buffered with bicarbonate and 30 patients received lidocaine buffered with saline. Pain and vasoconstriction were the 2 outcomes monitored during the project. Although the trial was only 2 wk due to the urgency of the rollout, the pilot was able to offer clinicians the opportunity to compare the 2 products. The saline-buffered lidocaine provided comparable pain relief compared with the lidocaine buffered with bicarbonate. The clinicians also measured the amount of vasoconstriction caused by the 2 products with similar outcomes.

Key words: bicarbonate, buffer, buffering, central vascular access device, lidocaine, peripherally inserted central catheter

More than 5 million central vascular access devices (CVADs) are placed per year in the United States.[1] Clinicians inserting CVADs are qualified and competent based on licensure, certification, and practice within their identified scope of practice.[2] The use of lidocaine for pain relief during CVAD insertion is a standard of practice.[2] Lidocaine buffered with sodium bicarbonate provides significantly more pain relief than lidocaine alone in the sensation of pain upon injection.[3] Recent drug shortages of lidocaine with sodium bicarbonate have created an opportunity to explore other options for pain relief during CVAD insertion. The pharmacy staff at the facility under study proposed an immediate change from bicarbonate-buffered lidocaine to saline-buffered lidocaine due to the national drug shortage in the United States. Due to the urgency caused by the shortage of bicarbonate-buffered lidocaine, a process improvement project was developed. The purpose of this article is to discuss the experience and results of an organization comparing lidocaine buffered with saline versus lidocaine buffered with bicarbonate for pain relief during CVAD insertion.

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BACKGROUND

A standard of practice for CVAD insertion is providing localized pain relief during the needle, introducer, and catheter insertion.[2] At the facility under study, lidocaine is available in the insertion kits for clinicians to use during the procedure. The pH of commercial lidocaine is 4.7. Due to its acidic properties, lidocaine can cause discomfort and pain upon administration. This pain is often described as a burning sensation.

As practice evolved with a focus on increasing patient satisfaction with CVAD insertion, patient response to buffered lidocaine indicated a decrease in pain associated with lidocaine injections. Buffering 1.0% lidocaine with 8.4% sodium bicarbonate at a 1:10 ratio decreases the sensation of pain upon injection.[3] The organization's vascular access team (VAT) adopted the practice of administering buffered

lidocaine for procedural pain relief for peripherally inserted central catheter (PICC) insertions in May 2016. The pharmacy staff prepared buffered lidocaine syringes. The syringes were then stored in the medication-automated dispensing cabinet refrigerator for use for the next 14 days. The implementation of buffered lidocaine versus lidocaine without a buffer for PICC insertion showed significantly decreased pain with lidocaine injection and decreased vasoconstriction. This change in practice also resulted in an increase in patient satisfaction for providing pain relief, making PICC insertion a nearly "painless procedure."

Shortages of lidocaine with sodium bicarbonate made it difficult for the pharmacy to provide buffered lidocaine syringes. The average time for pharmacy staff to prepare 200 buffered lidocaine syringes was 3 to 4 hours. Demand for lidocaine (primarily for use by interventional radiology and the VAT) required batches of 200 syringes to be made every 3 days. Syringes have a beyond-use date of 14 days when stored in the refrigerator. As a result of the shortage, the pharmacy worked to find an alternative for buffered lidocaine.

REVIEW OF LITERATURE

Several studies have compared saline-buffered lidocaine and different techniques for decreasing pain associated with lidocaine administration. The study guiding this project was conducted by Zaiac et al,[4] who explored the use of lidocaine diluted with saline. The study was a single-center crossover trial comparing the pain associated with lidocaine diluted with normal saline to the pain associated with lidocaine buffered with sodium bicarbonate. Each patient received 2 lidocaine injections: 1 with 1.0% lidocaine diluted with 8.4% sodium bicarbonate in a 1:10 ratio and 1 with 1.0% lidocaine diluted with saline in a 1:10 ratio. Results of the Zaiac et al[4] study showed that 28 of 31 patients reported that saline-diluted lidocaine was less painful upon injection than lidocaine buffered with sodium bicarbonate. One patient reported no difference, and 1 reported a difference of 0.5 on the visual analog scale (VAS). Diluted lidocaine resulted in an average VAS score of 2.7 points lower than buffered lidocaine ($P < .001$). Investigators concluded that saline-diluted lidocaine is superior to lidocaine buffered with sodium bicarbonate for attenuating pain. Saline is a low-cost alternative to sodium bicarbonate that is readily available in the insertion kits.

Patel et al[5] compared 2 lidocaine administration techniques on perceived pain from bedside procedures. In this single-center randomized controlled trial, the researchers evaluated the pain perception of traditionally administering subcutaneous lidocaine versus dripping 1 to 2 mL of room-temperature lidocaine onto the skin immediately before lidocaine injection. Results showed that the VAS score for pain perception was significantly reduced in the intervention group versus the control group (16.6 $\pm$ 24.8 mm vs 12.2 $\pm$ 19.4 mm; $P = .03$). Investigators concluded that the simple intervention of dripping lidocaine onto the skin before injection resulted in a 26% relative pain reduction. They postulated that this reduction was due to the sensation of cooling and wetness, which activates inhibitory neurons and decreases propagation of pain sensations.

Strazar et al,[6] Lundbom et al,[7] and Wago et al[8] provided additional alternative methods shown to minimize pain upon lidocaine injection. Techniques included:

- Warming the solution
- Using a small-diameter needle
- Distraction techniques
- Use of anesthetic creams/ice
- Injection perpendicular to the skin
- Injecting slowly

Literature supports the use of buffered lidocaine to decrease pain associated with lidocaine injection. The technique of buffering lidocaine with saline was selected for this process improvement project. The PICO (Population or Problem Intervention Comparison Outcome) question for this project was: In adult patients requiring CVAD insertion, how does lidocaine buffered with bicarbonate compare with lidocaine buffered with saline in minimizing pain with lidocaine injection?

IMPLEMENTATION

The stakeholders for the project included physicians, pharmacists, and vascular access nurses. The pharmacy proposed the project to multiple medical staff committees and received approval from all committees. Institutional review board approval was not required because this work was deemed a process improvement project. Due to the decreasing supply of lidocaine with bicarbonate, the pharmacy recommended expediting the removal of buffered lidocaine from the formulary by the end of January 2020. With constrained time for project completion, the team had 2 weeks to implement the project, which limited the number of subjects accordingly. The plan was to compare 60 patients. Thirty patients would receive lidocaine buffered with saline and 30 patients would receive lidocaine buffered with bicarbonate. The goal would be to complete the project before the removal of bicarbonate-buffered lidocaine from the medication automated dispensing cabinet.

The project was discussed with the VAT and radiologists. The radiologists deferred the project to the VAT. The VAT discussed the project and voiced concerns. Despite the research supporting the use of saline to buffer lidocaine, several team members thought the saline would not work and that the veins would vasoconstrict, causing increased difficulty with PICC insertion. With this concern, the project was set up so the clinician placing the PICC would not know if they were using lidocaine buffered with saline or

lidocaine buffered with bicarbonate. In addition, the clinician would observe and document apparent vasoconstriction of the vein after injection of the lidocaine.

Only PICC insertions were evaluated as a part of the project. The VAT consisted of 4 registered nurses (RNs), of whom 3 RNs had more than 10 years of experience placing PICCs and the other member had 3 years placing PICCs. The VAT reviewed the process of routine PICC placement. An order is received for the VAT to place the catheter. A single-, double-, or triple-lumen catheter is placed depending on the therapy, compatibility of the medications, and catheter-to-vessel ratio. The VAT places PICCs using 2 team members and places 7 to 12 PICCs per day, depending on the number of PICCs ordered. For the procedure, 1 team member focuses on the insertion of the PICC. The second team member focuses on patient knowledge and comfort, consent, sterile placement of the PICC, pictures of the accessed vein, and documentation. Using ultrasound technology, 3 pictures of the vessel used for the procedure are taken. Two pictures are taken to verify and document patency of the vessel (1 with the vessel open and 1 pushing down on the vessel with the ultrasound probe to verify vessel patency). A third picture is taken once the vessel has been accessed with the needle, showing the needle in the vessel, as recommended in current procedural technology code 76937.[9]

It was determined that to help defer the bias of the inserter and the second clinician adding the buffered lidocaine to the setup, the lidocaine would need to be mixed in advance by an independent clinician. The pharmacy was consulted to ensure that the process would not violate any mixing procedures, and none were violated during this process.[10] At the beginning of the shift, the clinical nurse specialist (CNS) would prepare 10 labeled and dated syringes for use during the day. Five of the syringes were premixed by pharmacy and dispensed out of the medication automated dispensing cabinet with buffered lidocaine in a 10-mL syringe with 5 mL of 1:10 concentration of lidocaine and bicarbonate. Five more sterile syringes were then used to mix the concentration of 5 mL of 1:10 concentration of 1% lidocaine and saline. The syringes were labeled with a number from 1 to 60. The corresponding number was then added to a document located within the CNS's computer to keep track of which syringes contained bicarbonate versus saline. No other employee had access to the document. The syringes looked the same with the same amount of fluid. They then were randomized so neither the clinician selecting the syringe for the procedure nor the clinician inserting the PICC could tell which syringe contained which solution. All 4 members of the VAT participated in the project and had the opportunity to inject both types of buffered lidocaine. All 4 members commented that they could not tell the difference in the syringes and were surprised by the outcome of the project.

The process for determining the patient's pain perception for the lidocaine injection was discussed by the team to determine pain of the injection or the procedure. The focus of this project was to determine the effectiveness of the lidocaine and to ensure that the buffer continued to minimize the pain with the injection. For the project, pain was rated using a VAS from 0 to 10 with the Wong-Bakers FACES scale[11] incorporated (Figure 1). The clinician asked the patient to rate the pain after, during, and at the end of the procedure.

The process for determining vasoconstriction after lidocaine injection occurred during vein assessment and pictures of vessel patency captured for documentation. The first picture, used as the baseline for vessel size, was taken of the vessel open. The second picture was taken while the vein was compressed, confirming vessel patency. During the procedure, the buffered lidocaine was administered. One minute after injection, the vessel was visualized with ultrasound and accessed with the needle within the kit. When possible, a picture was taken showing the needle in the center of the vessel (Figure 2). If the tip of the needle was not visualized but the wire passed, the picture was taken of the vein once the wire was in the vessel. After the procedure, pictures A and C were compared in size. Rather than measuring in millimeters, the 2 VAT team members present during the insertion visually approximated the amount of vasoconstriction. The team developed a standardized description to document the amount of vasoconstriction as follows: (1) 0%, or no vasoconstriction; (2) 25% vasoconstriction; (3) 33% vasoconstriction; (4) 50% vasoconstriction; (5) 66% vasoconstriction; (6) 75% vasoconstriction; and (7) 100%, or complete vasoconstriction.

OUTCOMES

A total of 60 inpatients received the buffered lidocaine for PICC insertion. Thirty patients received lidocaine buffered with bicarbonate, and 30 patients received lidocaine buffered with saline. All of the patients were alert and oriented. All patients had 5-French dual-lumen PICCs inserted in the basilic or brachial vein in the upper arm.

Thirty patients who received the lidocaine buffered with bicarbonate rated the pain with injection less than 1 on a scale of 0 to 10. Most patients reported no pain, with 4

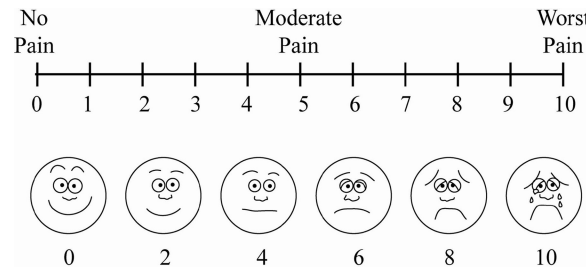

Figure 1 Wong-Baker FACES Pain Rating Scale. From Wong-Baker FACES Foundation. Wong-Baker FACES Pain Rating Scale. Updated 2020. Accessed June 23, 2021 with permission.

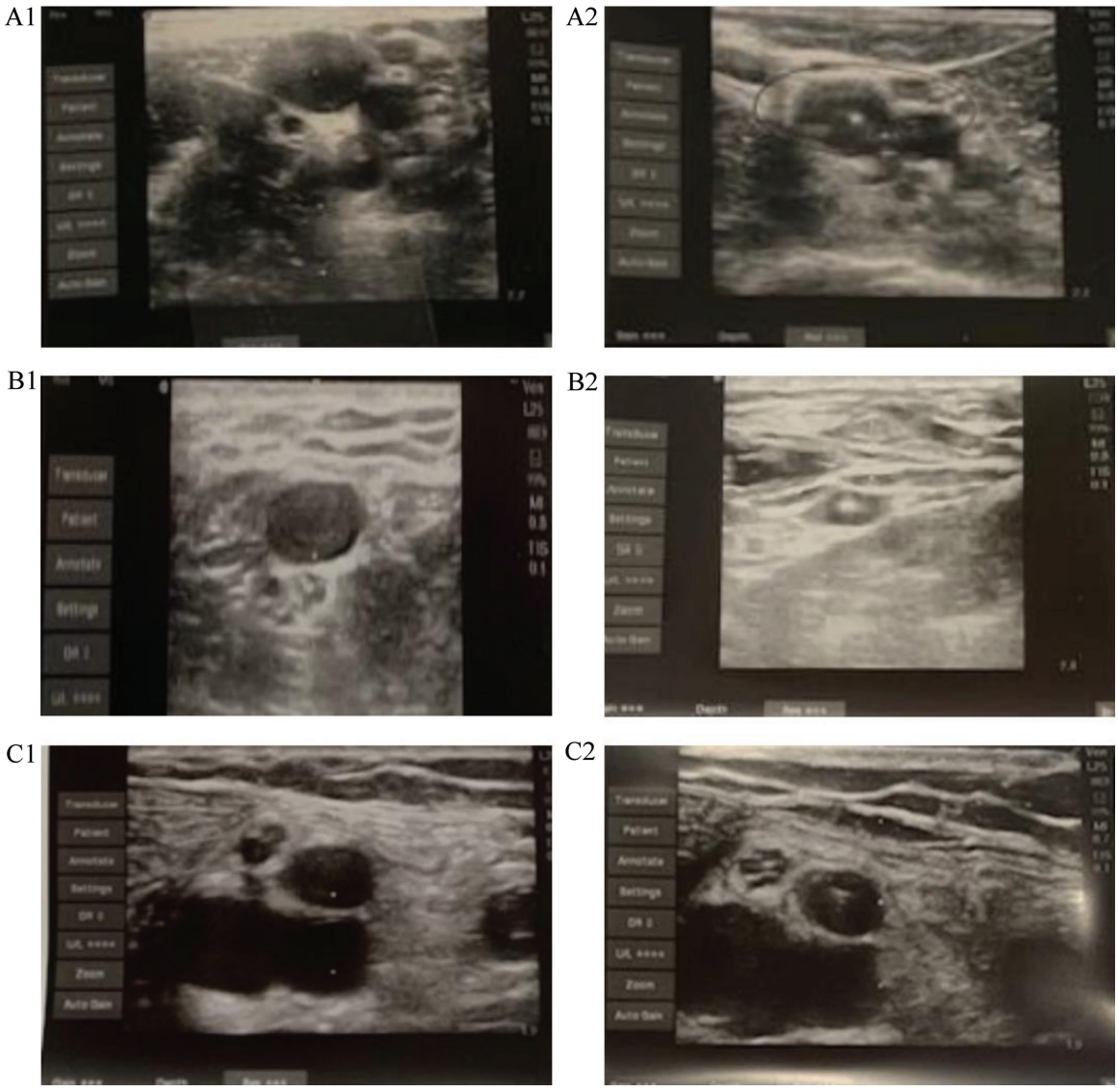

Figure 2 Examples of veins cannulated for CVAD insertion, before injection, and 1 minute after injection with needle identified in vessel. (A1) Brachial vein before injection. (A2) Brachial vein after injection with lidocaine with bicarbonate, needle in center of vein, no vasoconstriction noted. (B1) Basilic vein before injection. (B2) Basilic vein after injection with lidocaine with bicarbonate, needle in center of vein; vein vasoconstriction; noted at half of original size. (C1) Brachial vein before injection. (C2) Brachial vein after injection with lidocaine with sterile saline, needle in center of vein; no vasoconstriction noted.

patients reporting a level of pain of 1 on a scale of 0 to 10. Thirty patients who received lidocaine buffered with saline rated the pain with injection less than 1 on a scale of 0 to 10. Again, most patients reported no pain, with 4 patients reporting a level of pain of 1 on a scale of 0 to 10 (see Figures 3 and 4).

The other measured outcome was vasoconstriction from the injection. Thirty patients received the lidocaine buffered with bicarbonate with 5 occurrences of vasoconstriction. The results were as follows:

- 0% vasoconstriction: 25 patients (83.3%)
- 25% vasoconstriction: 1 patient (3.3%)
- 50% vasoconstriction: 3 patients (10.0%)
- 75% vasoconstriction: 1 patient (3.3%)

Thirty patients received the lidocaine buffered with saline with 7 occurrences of vasoconstriction. The results were as follows:

- 0% vasoconstriction: 23 patients (76.7%)
- 25% vasoconstriction: 3 patients (10.0%)
- 33% vasoconstriction: 1 patient (3.3%)
- 50% vasoconstriction: 2 patients (6.7%)
- 75% vasoconstriction: 1 patient (3.3%)

Patients receiving the lidocaine with saline were observed to have 2 more instances of vasoconstriction, but the level of vasoconstriction was observed to occur with vasoconstriction in the 25% to 33% range (Figure 5).

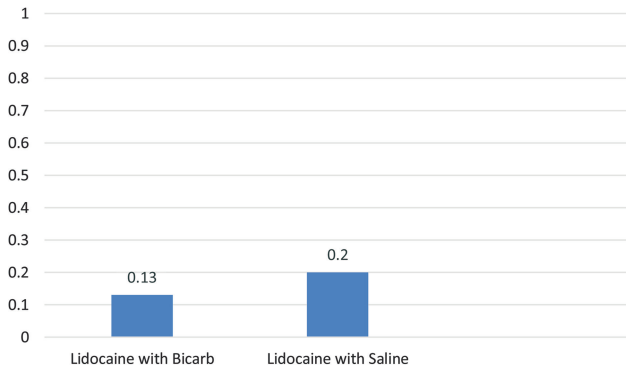

Figure 3 Pain level average comparison for 30 patients receiving lidocaine buffered with bicarbonate versus saline for peripherally inserted central catheter (PICC) insertion.

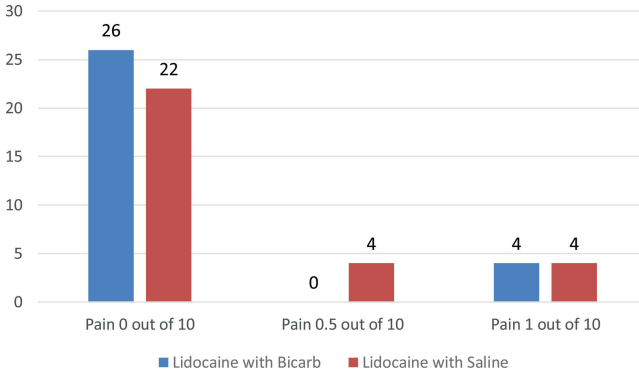

Figure 4 Comparison of 30 patients' pain ratings (0-10) using lidocaine buffered with bicarbonate versus saline for local anesthetic before peripherally inserted central catheter (PICC) insertion.

COST SUMMARY

The insertion of a PICC with either saline-buffered lidocaine or bicarbonate-buffered lidocaine both require the use of a PICC insertion kit. The cost per PICC kit varies with volume and contract and currently averages between $250 and $350. The PICC kit used by the organization contains all of the supplies needed for the insertion, including the PICC, maximal sterile barriers, preparation solutions, sterile dressing, lidocaine, and saline. The technique for lidocaine buffered with saline is to use the saline and lidocaine within the kit. The cost for lidocaine buffered with saline is the cost of the PICC kit, and there are no other associated costs. Additional supplies are required for lidocaine buffered with bicarbonate. The following is a compilation of the additional costs associated with the use of lidocaine buffered with bicarbonate.

The cost to use lidocaine buffered with bicarbonate includes the cost of the PICC kit in addition to the cost associated with preparing the additional syringe of premixed buffered lidocaine. The lidocaine buffered with bicarbonate is prepared by the pharmacy and not part of the PICC insertion kit. The following supplies are used to prepare the lidocaine buffered with bicarbonate: lidocaine 1% 10-mL

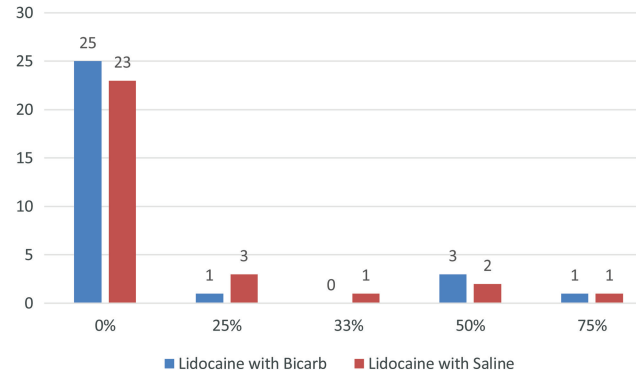

Figure 5 Comparison of vasoconstriction percentage in 30 patients receiving lidocaine buffered with saline versus bicarbonate.

syringes, 3% sodium bicarbonate 50-mL bottle, and 5-mL sterile syringes. According to current use, 200 doses of lidocaine buffered with bicarbonate are prepared every 3 days.

The following is a breakdown of the approximate cost for the pharmacy preparing lidocaine buffered with bicarbonate. The first component is lidocaine. The lidocaine comes in a 10-mL syringe costing $5. Each dose of lidocaine buffered with bicarbonate contains 5 mL of lidocaine per dose. Therefore, 200 doses would cost $500.

The next component is sodium bicarbonate. Each dose of lidocaine buffered with bicarbonate contains 0.5 mL of bicarbonate per dose. The 50-mL bottle provides 100 doses at $14 per bottle; therefore, 200 doses would cost $28.

The next component are syringes. Each dose was mixed in a 5-mL syringe. Prices vary per buyer, but for purposes of calculation, boxes of 125 syringes cost approximately $20. Therefore, 200 syringes costs $32. Other supplies may include needles for mixing and caps to keep the syringes covered; however, these items were not included in this cost analysis.

The final expense is the cost of the pharmacy technician to prepare the doses of lidocaine buffered with bicarbonate. Pharmacy technician wages average $15 to $25 per hour, based on years of experience. An additional 20% is added to approximate the cost of benefits. For this cost analysis, the wage plus benefits was averaged at $24. On average, it took the pharmacy technicians 3.5 hours to prepare 200 syringes. Therefore, 200 doses would cost $84 to prepare.

The cost to prepare 200 doses of lidocaine buffered with bicarbonate for 3 days is $644. Based on this number, the cost of 1 dose is $3.22. The pharmacy prepares 200 doses 122 times a year for an annual cost of $78 568 (Table 1).

DISCUSSION

The new process for preparing the lidocaine buffered with saline began in February 2020. Rather than the second clinician adding the lidocaine buffered with bicarbonate to the setup tray, the clinician placing the PICC prepared the lidocaine buffered with saline while setting up the procedure

TABLE 1

Bicarbonated Lidocaine Syringe Preparation Cost Summary

Product	Per Dose	Per Batches of 200 Doses
Lidocaine	$2.50	$500
Bicarbonate	$0.14	$28
Syringes	$0.16	$32
Tech wages plus benefits	$0.42	$84
Total	$3.22	$644
Batches per year		122
Annual cost		$78 568

tray for the PICC insertion. The procedure tray has 1, 2, 3, or 4 syringes of sterile saline to flush the lumens depending on whether the procedure tray is a single, double, or triple lumen kit. The clinician uses 1 mL of saline from one of these syringes to buffer the lidocaine. Using the mixing technique recommended by the pharmacy, 1 mL of saline is injected into a separate compartment of the sterile PICC tray. A 5-mL vial of lidocaine 1% is provided in the PICC insertion kit. The lidocaine is drawn into a 5-mL syringe. Then 0.5 mL of saline is drawn into the lidocaine syringe from the saline in the tray, and this provides a 1:10 solution of lidocaine buffered with saline.

Before the implementation of the buffered lidocaine with saline, the team was concerned about the effectiveness of the buffer despite the literature supporting the outcome. Having used both products in a blinded method throughout the trial, the team discussed how they could not distinguish between the products. Part of the standard of care for the team was asking the patient at the end of the procedure regarding pain and inquiring whether the pain was controlled to the patient's expectation. After the implementation of the lidocaine buffered with saline, the team reported PICC insertion as a near painless procedure, hurting much less than a short peripheral intravenous catheter.

One barrier identified after the rollout and removal of lidocaine buffered with bicarbonate was and continues to be a belief that lidocaine buffered with saline does not relieve pain as well as lidocaine buffered with bicarbonate. Within nuclear medicine, when patients come in for scans of lymph nodes of the breast, physicians inject the area near lymph nodes within the breast with nucleotides.[12] Before injecting the site near the lymph nodes, the physician numbs the site with lidocaine buffered with bicarbonate. After the rollout, physicians were concerned with the efficacy of the lidocaine buffered with saline because they believed it would not relieve pain. The results of this project were shared with these physicians and the hospital pharmacy committee. The results were also shared with physicians, practitioners, and VATs within the organization. Other options shared with the physicians included the use of the smaller needles and lidocaine creams.

CONCLUSION

As medication and supply shortages challenge health care professionals, it is imperative that innovation, process improvement, and evidence-based practice be a part of everyday management.[13] A product shortage required immediate change within the organization. The process improvement project was completed in only 2 weeks. However, the clinicians were able to effectively trial the 2 products and compare outcomes. The lidocaine buffered with saline was shown to provide comparable pain relief to lidocaine buffered with bicarbonate. The clinicians also measured the amount of vasoconstriction caused by the 2 products, which resulted in similar outcomes. The facility has successfully implemented the use of saline-buffered lidocaine for CVAD/PICC insertion. Little to no change occurred in patient satisfaction with the change in medication. However, a cost savings of $78 568 was realized when switching from bicarbonate to saline.

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