Look before you LEEP: patient reported pain with IV sedation vs local analgesia

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Abstract

Objective: *Examine the effectiveness of IV sedation in addition local analgesia compared to local analgesia alone for LEEP pain management.*

Methods: *This quality improvement project surveyed 89 patients who underwent a LEEP procedure: 26 in the local only group and 63 in the IV + local group. Patients completed a visual analog scale and pain survey immediately following their LEEP.*

Results: *The local analgesia + IV sedation group reported a lower average pain score compared to the local analgesia only group (2.4 ± 2.2 v 3.6 ± 2.7). However, this was not statistically significant, p 0.47. Patients found it was helpful to know what to expect prior to the LEEP and utilized various means of pain relief in addition to the primary treatments assessed.*

Conclusions*: There is a need for high quality trials to determine best practices of pain management.*

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Introduction

The cervical loop electrosurgical excision procedure (LEEP) is performed to treat high-grade cervical intraepithelial neoplasia (CIN).[1] These procedures are generally performed in the outpatient setting with the use of paracervical block or intracervical injections with local anesthetic (lidocaine) to reduce procedural discomfort. Many providers also employ injections of vasoconstricting agents directly into the cervix.

Others have explored various pain management methods in efforts to find the optimal method of decreasing pain caused by LEEP. Studies on oral mefenamic acid and buffered lidocaine injections found that neither approach decreased pain by a statistically significant amount compared to traditional nonbuffered lidocaine

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injection.[2,3] Two other studies exploring the use of lidocaine spray during LEEP had conflicting findings; one found that patients experienced a significantly greater amount of pain with lidocaine spray compared to a paracervical block, while another found that there was no statistically significant difference in pain experienced.[4,5]

Thus far, there has been little success in finding a modality of pain management that is significantly or more effective than a paracervical block alone. The aim of this study was to examine the effectiveness of combining a paracervical block with IV pain medications in reducing pain during LEEP compared to paracervical block alone.

Methods

At the beginning of this project the standard of care for LEEP pain management at the University of Iowa Health Care OBGYN clinic was local analgesia with paracervical block using lidocaine 1% 20mL and lidocaine 1% with epinephrine (1:100,000) 5mL directly into the cervical area of planned excision. With the aim of improving procedural availability and patient comfort, the clinic transitioned to a setting with the availability to provide IV sedation in addition to local analgesia. Prior to the initiation of the transition, a quality improvement project was implemented to evaluate if patient pain was improved with the addition of IV sedation. LEEP procedures were performed by OBGYN residents in both clinic settings.

All patients who underwent a LEEP at University of Iowa Hospitals and Clinics (UIHC) during a 14-month period took an anonymous survey after completion of the LEEP procedure. Surveys were taken by patients four months prior (March 2018 to June 2018) to the addition of IV sedation and nine months after the change (July 2018 to March 2019). Twenty-six patients in this study had LEEP performed during the initial four-month period; therefore, data were collected from 26 patients who received local analgesia only. In July of 2018, the switch was made from local analgesia only to IV sedation and local analgesia. From that point on, patients received this method of pain management. Data from 63 patients who received both IV sedation and local analgesia were collected during the latter nine months of the study.

The survey utilized a visual analogue scale (VAS) for patients to rate pain on face scale. The scale ranged from 0 (no pain) to 10 (worst pain imaginable). The survey also contained questions regarding other means of pain management used for the LEEP including NSAIDs, warm packs and oral pain medications. The survey asked about different feelings experienced while undergoing the LEEP.

The Pearson Chi-square test or Fisher exact test was used, as appropriate for continuous and categorical variables. OpenEpi (https://www.openepi.com) was used for statistical comparison of categorical data.[6] Means were compared using the t-test. A p-value less than or equal to 0.05 was considered statistically significant.

Results

This project included 89 patients total: 26 in the local only group, and 63 in the IV + local group (Table 1). The local analgesia with IV sedation group reported a lower average pain score compared to the local analgesia only group (2.4 ± 2.2 v 3.6 ± 2.7; p=0.47), however, this was not statistically significant.

Table 1.

	Entire Cohort (n=89)	Local Only (n=26)	IV + Local (n=63)	P-values
Average pain scale (VAS in mm)	**2.8 ± 2.4**	**3.6 ± 2.7**	**2.4 ± 2.2**	**0.47**
LEEP in past	9 (10.1%)	1 (3.4%)	8 (12.7%)	**0.196**
Used acetaminophen	5 (5.6%)	5 (19.2%)	0	**0.00017**
Used oral anti-anxiety	6 (6.7%)	6 (23.1%)	0	**0.00004**
Used hot packs	76 (85.4%)	21 (80.8%)	55 (87.3%)	**0.313**
Used other means of pain relief	29 (3.26%)	2 (7.7%)	27 (42.9%)	**0.0006**
Discomfort from legs in stirrups	5 (5.6%)	2 (7.7%)	3 (4.8%)	**0.45**
Discomfort from injections	45 (50.6%)	16 (61.5%)	29 (46.0%)	**0.092**
Experienced cramping	20 (22.5%)	7 (27.0%)	13 (20.6%)	**0.353**
Felt scared	16 (18.0%)	5 (19.2%)	11 (17.5%)	**0.49**
Felt nervous or anxious	51 (57.3%)	14 (53.5%)	37 (58.7%)	**0.174**
Helpful to know what to expect	86 (99.0%)	26 (100%)	60 (98.4%) 2 did not respond	

Acetaminophen and oral anti-anxiety medication were used by 19.2% and 23.1% of patients in the local only group, respectively. None of the patients in the IV sedation group used these medications. Hot packs were used by more than 80% of patients in both groups to alleviate pain. Other means of pain relief, primarily including aromatherapy and hand holding, were used more commonly by patients receiving IV sedation.

A relatively small number of patients in both groups experienced discomfort from having their legs in stirrups for the procedure. Although not significant, a larger percentage of patients in the local only group reported discomfort from injections compared to patients in the IV group (61.5% v 46.0% p=0.092). Cramping was experienced by similar numbers of patients from both groups. A majority of the patients found that it was helpful to know what to expect prior to the LEEP.

Interestingly, four participants reported that they did not have local injections placed, despite the fact that all patients did, per clinic policy. All four of these patients were in the local only group.

Discussion

Although not statistically significant, the data addressing the aim of this study did show a decrease in the average amount of pain experienced by patients in the IV with local analgesia group compared to the local analgesia only group. A post hoc power analysis showed that we would require 65 participants in each group to have power to find a p value of 0.05.

The statistically significant differences observed for the use of acetaminophen and oral anti-anxiety medication are explained by the practices of the UIHC OBGYN clinic. Neither of these medications are typically used in conjunction with IV sedation, thus none of the patients in the IV sedation + local analgesia group received either. Acetaminophen is generally safe as a component of multi-modal analgesia, so the UIHC OBGYN team is considering adding this medication to the IV regimen.[7] Oral anti-anxiety medication is not given to patients in the IV sedation group because anti-anxiety medication is given through the IV.

Other means of pain relief, especially aromatherapy, were likely used more often by those in the IV sedation group due to increased availability in the procedure clinic setting following the transition to IV sedation for LEEP procedures. While we were unable to ascertain whether aromatherapy was specifically helpful for reducing pain associated with LEEP, aromatherapy has been used successfully to reduce discomfort in other gynecological and procedural settings.[8]

Similarly, most patients found knowledge of the procedure was helpful. Patient experience and fear play an integral part in pain perception.[9] While the same information is provided to all patients regarding the LEEP procedure and expectations, we (and others) have identified from prior studies that patients do not always receive the information provided at the time of education.[10]

There was a greater percentage of patients who experienced discomfort from paracervical block injections in the local only group. However, a Cochrane review on pain relief for women with CIN undergoing colposcopy treatment found that intracervical injection of local anesthetic with a vasoconstrictor appears to be the optimum analgesia for treatment in an outpatient colposcopy clinic setting.[11]

This project does have limitations. The decision to study patient LEEP experiences was made after it was determined that IV sedation would be added to the standard of care for LEEP pain management. This timeline resulted in a small sample size of local analgesia only patients as there were only 26 patients scheduled for LEEP between the starting point of the study and the point at which the transition to IV sedation and local analgesia occurred. Additionally, this project was not randomized or blinded so there is a chance that bias may have played a role in treatment assignments. As this study was not blinded, one confounding variable was pain associated with IV placement. Patients in the local only group did not have an IV placed; this (or future) studies would be stronger if IV saline without sedation medications

were used to control for pain with IV placement. Another confounding variable is the information that patients were given regarding the procedure. The same general information was provided to all patients; however, there were provider specific nuances with counseling that cannot be controlled for.

Overall, the addition of IV sedation may be an effective method of reducing pain experienced by patients undergoing LEEP, but a larger sample size with sufficient numbers (at least 65 participants in each group) is needed to determine the best pain option.

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