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Pain Management for Intrauterine Device Insertion and Endometrial Biopsy

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PAIN MANAGEMENT FOR INTRAUTERINE DEVICE INSERTION AND ENDOMETRIAL BIOPSY

by

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Student Date Advisor Date

DEDICATION

I would like to dedicate this EBP project to my family. My husband and kids have been supportive and understanding with all the time I had to spend on this project. My parents have also been very supportive and helped take care of the kids when I had to be at the clinic or working on this project. I couldn't have done this without them.

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I would like to thank my advisor, Dr. Kurtz for her patience with me and guidance throughout this project. I would also like to thank the faculty at Valparaiso University for all of their help guidance as well along the way. As well, a special thanks to the Crown Point, IN clinical site, their staff, and Dr. McCormack for allowing me to implement my project and assisting me in

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ABSTRACT

Intrauterine device (IUD) insertions and endometrial biopsies (EMB) can be painful in office gynecological procedures. In the clinical setting used for this evidence-based project (EBP) it was noted there was no consistent pain management being used for these procedures. For this EBP project a protocol for pain management during IUD insertions and EMBs was developed and implemented into this clinical setting. The protocol was created from an exhaustive literature search, which yielded six pieces of high-level evidence of good quality. The evidence supported the use of a 1% lidocaine paracervical block prior to IUD insertion and a 2% lidocaine intrauterine infusion prior to EMB. The sample included women age 18 and older receiving an IUD insertion or EMB. Pain scores were collected on 7 EMBs and 13 IUD insertions who did not receive the intervention. Pain scores were collected on 5 EMBs and 7 IUD insertions who received the intervention. Pain scores were recorded using the numeric pain rating scale. The non-intervention group and the intervention group contained different participants in each group. Because the groups contained different participants, the pains scores were analyzed using an independent *t-test*. Patients receiving the intervention for EMBs had statistically significantly lower pain scores compared to the non-intervention group for EMBs ($t(10)=2.759$, $p < .05$). There was no statistical significance in the intervention group for IUD insertions compared to the non-intervention group for IUD insertions ($t(18)=1.826$, $p > .05$). This EBP project was easily implemented as patients were very willing to participate, most providers were willing to participate, lidocaine was relatively inexpensive, and only about 5 minutes of extra time was added to each procedure. Application would include using the intrauterine infusion prior to EMBs in practice and future research in pain management while stratifying nulliparous and multiparous participants for IUD insertions and EMBs.

CHAPTER 1

INTRODUCTION

Background

Intrauterine device insertions (IUD) and endometrial biopsies (EMB) can be painful in office procedures. IUDs are a safe and effective long-term contraceptive that is reversible (Allen et al., 2013). They were recommended originally for multiparous women, but now are also appropriate for nulliparous women and adolescents (Allen et al., 2013). They are associated with high satisfaction and continuation rates (Allen et al., 2013). IUD use has increased in the United States recently, with 8% of women using contraception choosing IUDs (CDC, 2016). The one main barrier to the IUD is fear of pain (Allen et al., 2013). The procedure for IUD insertion includes tenaculum placement, inserting the uterine sound through the cervix to check depth, and then inserting the IUD insertion tube to place the IUD (Allen et al., 2013). Predictors of pain for IUD insertions include nulliparity, age greater than thirty, longer interval since last pregnancy or menses, history of dysmenorrhea, and not currently breastfeeding (Lopez et al., 2015). EMBs are a biopsy of tissue from inside the cervix. These are generally performed for abnormal uterine bleeding and then sent to pathology. The procedure for an EMB is tenaculum placement, insertion of either a Pipelle or Explora Curette into the cervix, and then aspiration of a tissue which can take one to two minutes (Allen et al., 2013). Somatic and visceral pain can both occur in the pelvic region (Kass-Wolff & Fisher, 2014). Somatic pain is nerve pain, which is usually more intense. Visceral pain is generalized aching or pressure, which in this case can be cramping. Moderate to severe pain can increase the risk of syncope and vasovagal reactions. The benefit to decreasing pain is the patient will be more relaxed and comfortable, which will allow her to participate better. It will also allow for a quicker procedure with fewer complications (Kass-Wolff & Fisher, 2014).

Statement of the Problem

Data from the Literature Supporting Need for the Project

The goals for office procedures are to safely and successfully perform these procedures and provide patient comfort. Patient comfort directly affects the providers ability to safely complete the procedure (Allen et al., 2013). Patients who endure high levels of pain may not be able to tolerate finishing the procedure leading to not receiving the necessary intervention. It can also impede a procedure due to involuntary muscle contraction, guarding, and movement (Allen et al., 2013). As mentioned earlier, patients enduring high levels of pain are also at increased risk for syncope and vasovagal reactions (Kass-Wolff & Fisher, 2014).

IUDs are a safe and effective long-term contraceptive (Allen et al., 2013). It is a public health goal to increase the use of IUDs because this method of birth control does not rely on the individual's consistency of use for effectiveness (Lopez et al., 2015; CDC, 2017). For other contraceptive options to be effective it is dependent on the individual, such as remembering to take a birth control pill every day. Once an IUD is in place, its effectiveness is long term (CDC, 2017). Fear of pain during insertion is a barrier keeping women from getting them (Lopez et al., 2015).

Data from the Clinical Agency Supporting Need for the Project

At the OB/GYN private practice in northwest Indiana used for this project, there are three physicians, one midwife, and one nurse practitioner. Although it is within the nurse practitioner's scope of practice to perform IUD insertions and EMBs, the nurse practitioner is new and does not yet perform them. All three physicians and the midwife do perform these procedures. On average about fifty patients per day are seen in the office among all the providers. This may vary depending on their schedules day to day. Each provider usually performs at least one IUD insertion or EMB per day. Among all the providers, there is not a set standard or protocol for pain management of pain during these procedures. Pain management is provided at the provider's discretion. Among the providers at this private practice, pain management varied from ibuprofen one hour prior to the procedure, ibuprofen immediately after the procedure, Cytotec

taken the night before and morning of the procedure and taking nothing pre or post procedure. From this DNP students' observations, there did not seem to be any pattern to which patients received ibuprofen and which received nothing. The Cytotec did seem to be given mostly to the nulliparous patients. A need exists for an evidence-based pain management protocol for these procedures to be used by all providers in the office. This will allow for all patients to have equal opportunity for appropriate pain management during these procedures.

Purpose of the Evidence-Based Practice Project

Compelling Clinical Question

The clinical question the project addresses is: what is the best way to decrease pain during IUD insertions and EMBs? An exhaustive search and appraisal of the current literature allows for the development of an evidence-based protocol to be used in this OB/GYN private practice in northwest Indiana.

PICOT Question

In women over 18 (P), what is the effect of a pain management protocol for IUD insertions and EMBs (I) compared to usual care (C) on pain levels (O) over a 12-week period (T)?

Significance of the EBP Project

As mentioned above, there is no consistent evidence-based pain management practice among the providers in this private practice for IUD insertions and EMBs. This can affect quality of care. Allen et al. (2013), Ireland & Allen (2016), Kass-Wolff & Fisher (2014), Lopez et al. (2015), Mercier & Zerden (2012), and Pergialiotis et al. (2014) mention how the pain of the procedure is a barrier for some patients getting an IUD.

To address this problem, a protocol for pain management during IUD insertions and EMBs will be developed. This protocol will be a standard for all providers to use in this private practice. With this protocol implemented, pain levels will be recorded using a numerical pain scale of zero to ten with zero being no pain and ten being the worst amount of pain. These pain

levels will then be compared to the pain levels of patients undergoing these procedures prior to implementation of the protocol. The objective of this project is to standardize pain management among the providers in this private practice to decrease pain levels during IUD insertions and EMBs.

CHAPTER 2

THEORETICAL FRAMEWORK, EBP MODEL, AND REVIEW OF LITERATURE

Theoretical Framework

Overview of Theoretical Framework

Kolcaba's Comfort Theory is used for the theoretical framework. This is a middle range theory developed in 1994 by Katharine Kolcaba. Kolcaba described comfort in three forms, which are relief, ease, and transcendence (George, 2011). Relief is having specific comfort needs met. In this EBP project, relief of pain during IUD insertion or EMB to meet the patient's comfort needs will be the main focus. Ease is feeling calm or content, which comes after relief is provided. Although, ease is not a focus of this project, it can be achieved during these procedures by providing relief of pain. Transcendence is when one rises above problems or pain. Like ease, transcendence is not a focus of the project. The focus is relief of pain during these procedures to provide comfort to the patient.

There are four contexts within the Comfort Theory consisting of physical, psychospiritual, environmental, and sociocultural comfort. The first context is physical comfort. This context is a main focus of the EBP project. Relieving pain during these procedures will meet the patient's physical comfort needs. This is a commonly understood and used context of comfort (George, 2011).

The second context is psychospiritual comfort. This is anything that gives life meaning for an individual and provides self-esteem, self-concept, and sexuality (George, 2011). Psychospiritual comfort is not a focus of this EBP project.

The third context is environmental comfort. This includes the surrounding environment, condition, and influences (George, 2011). Environmental comfort could be addressed by having calming pictures or artwork on the walls to look at during the procedures. Also, some soft calming music playing in the room may help.

The fourth context is sociocultural comfort. This includes interpersonal, family, and societal relationships (George, 2011). This is addressed by staff when checking insurance coverage for a procedure, assessing education level for best way to teach patient about the procedures, and assessing patient's support system.

Wilson and Kolcaba (2004) used the Comfort Theory in the peri anesthesia setting in a case study. The patient was a forty-five-year-old Hispanic male with colon cancer in the post-anesthesia care unit (PACU) following a sigmoid colon resection. With regard to relief, the physical comfort to be addressed was pain and nausea, the psychospiritual comfort to be addressed was anxiety, the environmental comfort to be addressed was a noisy PACU, bright lights, and cold temperature, and the sociocultural comfort to be addressed was absence of traditions/culturally sensitive care. With regard to ease, the physical comfort to be addressed was homeostasis, the psychospiritual comfort to be addressed was uncertainty of prognosis, the environmental comfort to be addressed was lack of privacy, and the sociocultural comfort to be addressed was that the family was not present and there was a language barrier. With regard to transcendence, the physical comfort to be addressed was that the patient was worried about how to deal with postoperative pain, the psychospiritual comfort to be addressed was need for spiritual support, the environmental comfort to be addressed was the need for calm, familiar environmental elements, and the sociocultural comfort to be addressed was the need for family support/information/consultation. Interventions they used to address these comfort needs include standard comforts, coaching, and comfort food for the soul. The authors described comfort food for the soul as therapeutic touch, music therapy, spending time with the patient, and making personal connections. Standard comforts were monitoring vital signs and laboratory results, conducting assessment, administering medications, and providing treatments. Monitoring vital signs and conducting assessments allows for signs of distress to be recognized and addressed quickly to keep the patient in homeostasis. Reviewing lab results allows for correction of abnormal values, which again is keeping the patient in homeostasis. Medications

are given to decrease pain and nausea, which will help to provide comfort. Providing treatments to improve the patient's well-being will help to achieve comfort when the patient feels better. Maintaining homeostasis, controlling pain, and controlling nausea keeps the body comfortable and at ease. If the body is in distress the patient will not be comfortable. Coaching involves emotional support, reassurance, education, and listening (Wilson & Kolcaba, 2004). Coaching and comfort food for the soul addresses ease and transcendence in the contexts of psychospiritual, environmental, and sociocultural comforts.

Application of Theoretical Framework to EBP Project

This EBP project addresses the physical comfort of patients during IUD insertion and EMB by decreasing pain levels to provide relief. Although pain relief is the main focus of this EBP project, ease and transcendence can follow. By relieving procedural pain, anxiety can be decreased and the patient can achieve ease. Being at ease allows for transcendence, which facilitates or allows the patient to think positively or spiritually. Wilson & Kolcaba (2004) give the example of music therapy. It provides relief by decreasing discomfort and anxiety. It provides ease by contentment when listening to one's favorite music. It facilitates transcendence by allowing patient to think positively and spiritually. By decreasing the patient's pain during IUD insertion or EMB, the patient's anxiety can be relieved. When the patient is at ease it can make the procedure easier to perform and cause less pain as the patient can then relax her body instead of tensing up.

Strengths and Limitations of Theoretical Framework for EBP Project

Kolcaba's Comfort Theory strongly applies to pain management. Pain management consists of relieving pain, which then facilitates ease in the patient. Pain is within the realm of physical comfort in this theory, which can be addressed by many interventions including pharmacology. Wilson and Kolcaba (2004) write about how this is a proactive theory, which minimizes negative aspects of surgery such as pain. Minimizing the negative aspects of pain for IUD insertions and EMBs will help enhance comfort. This is especially needed for IUD insertions

because patients frequently don't want them due to the pain associated with insertion (Lopez et al., 2015).

A limitation to the Comfort Theory for this EBP project is transcendence may not be reached. Relief of pain is the focus, which may lead to ease since relieving the patient's pain will help them reach contentment. Due to the fact these are short office procedures and the patient leaves right after, transcendence is not relevant. For EMBs there is a lot of uncertainty as these patients await results and prognosis.

Evidence-based Practice Model

Overview of EBP Model

The Promoting Action on Research Implementation in Health Services (PARIHS) is the EBP model being used for this project. "The PARIHS framework is premised on the notion that the implementation of research-based practice depends on the ability to achieve significant and planned behavior change involving individuals, teams, and organizations" (Melnyk & Fineout-Overholt, 2015, p. 294). There are three elements in this model, which are evidence, context, and facilitation. Evidence includes the sub elements of research, clinical experience, patients' and caregivers' experience, and local context information. Context includes the sub elements of culture, leadership, and evaluation. Facilitation includes the sub elements of purpose role, skills, and attributes. These elements and sub elements are assessed on a high-to-low continuum. The goal is to move to the high end of the continuum to increase the chances of successful implementation.

For evidence to be on the high end of the continuum the research has to be well conceived and conducted, have a consensus about it, and include clinical experience of the authors that was made explicit and verified through critical reflection, critique, and debate. Patient experience includes patients being a part of the decision-making process; patients' statements are a valid source of evidence. Local information and data can be part of the

evidence if it has been systematically collected, evaluated, and considered (Melnyk & Fineout-Overholt, 2015).

Context is where the change is to be implemented. To be on the high end of the continuum, the organization needs to have a culture of learning and be accepting of change. A learning organization facilitates the learning of its members and continuously transforms itself. Leaders of learning organizations are usually transformational leaders who inspire. Organizations with evaluative mechanisms that collect multiple sources of evidence of performance at the individual, team, and system levels meet the high end of the continuum (Melnyk & Fineout-Overholt, 2015).

Facilitation is the process of making implementation easier. For facilitation to be on the high end of the continuum a facilitator will help individuals, teams, and organizations apply evidence in practice. Facilitation can be task-oriented and/or developmental, process-oriented. Skilled facilitators should be able to adjust to fit the different stages of implementation and the needs of those they are working with (Melnyk & Fineout-Overholt, 2015).

Brown and McCormack (2005) developed an acute pain service to address the need to improve pain management practices using the PARIHS framework to integrate evidence into practice. Using this framework, it was discovered that elements of learning organizations are key to successful implementation along with facilitating change and examining relationships between nursing staff and outcomes. Multiple strategies targeting the aspects of the individual, organization, culture, and characteristics of the message should also be used to implement change. Brown and McCormack (2005) concluded that the three elements of evidence, context, and facilitation are vital to integrating evidence into practice. Successful implementation of pain management evidence relies on the facilitator's ability to lead changes in practice through action research (Brown & McCormack, 2005). Action research is conducted by and for those taking the action. This makes the action research relevant to the participants. For example, having a

meeting with staff to talk about and discuss what problems need to be addressed. Then addressing the problem with staff and making decisions with staff.

Application of EBP Model to EBP Project

During each phase of this EBP project the PARIHS model will be followed and each element will be aimed at the high end of the continuum to ensure successful implementation of the project and continuation of the EBP after the project is completed. The evidence for this project is on the high end of the continuum as it is all level one evidence, which includes systematic reviews and meta-analyses. The evidence was appraised and deemed moderate to high quality. Patients will be included in the decision-making process by choosing to participate or not. Data collected on the patients' pain levels during IUD insertion and EMB before protocol use will be considered part of the evidence. The context for this project is on the high end of the continuum because this is a learning organization that uses up to date evidence-based practice. As a learning organization lifelong learning is facilitated and practice changes are continuously made to keep up to date with best practice recommendations. Leadership in this organization is transformational and management style is facilitative. The provider who owns this practice works with the staff to address any issues, implement change, and make decisions. Everyone there works well together, is respectful, and on board for whatever needs to be done. The facilitator for this project has the skills and knowledge to help the individuals, teams, and organization apply the evidence into practice.

Strengths and Limitations of EBP Model for EBP Project

The PARIHS model serves as a guide for every step of an EBP project. It helps guide the project to the higher end of the continuum for successful implementation and sustainability of the EBP after the project is complete. Having a learning organization with a capable facilitator is key to successful implementation. The facilitator at this private practice will be important to addressing those in the practice who are resistant to change. To combat resistance there will also be continuous communication and education. A never let up approach will be taken. Once

IRB approval is received there will be a meeting held for all staff. At this meeting I will present all the evidence supporting the pain management protocol and answering all questions. At this meeting the facilitator will be there to help support this project and present to staff why it the practice change is important. This model is easily applicable to pain management during IUD insertion and EMB. There really does not seem to be a limitation of this model when related to this EBP project.

Literature Search

Sources Examined for Relevant Evidence

An exhaustive search of the literature was conducted to obtain the strongest evidence for the EBP project. The databases searched were CINAHL, JBI, Cochrane, MEDLINE, and National Guideline Clearinghouse. Keywords used in these searches were pain AND (“intrauterine device insertion” OR “IUD” OR “endometrial biops*”). The limiters used were date range 2000-2018, English language, and scholarly reviewed. These limiters were used in all databases. For each search the results yielded were not all relevant. Only the relevant titles and abstracts were reviewed applying inclusion and exclusion criteria. Inclusion criteria was pharmacological interventions for pain management for pain during IUD insertions and EMBs without another procedure. For example, some evidence was about EMBs with hysteroscopy. This evidence was then excluded because it contained the hysteroscopy. Evidence was also excluded if it was about IUD removal or pain before or after the procedures. Nonpharmacological interventions were also excluded. Evidence that met inclusion criteria was reviewed for acceptance, which entailed reading the entire piece and appraising it.

JBI and the National Guideline Clearinghouse yielded 0 results. CINAHL yielded 61 results. After reading titles and eliminating those that did not meet inclusion criteria, 10 studies were reviewed, and 1 was accepted. Cochrane yielded 14 results, 4 were reviewed, and 1 was accepted. MEDLINE yielded 100 results, 10 were reviewed, and 4 were accepted. A hand search of the American College of Obstetricians and Gynecologists (ACOG) at www.acog.org

yielded 21 results, 2 were reviewed, and 0 were accepted. On the ACOG website the clinical guidance page was searched, which included practice bulletins, committee opinions, practice advisories, obstetric care consensus series, task force and work group reports, and technology assessments. On the clinical guidance page there is a search box to type in what is being searched. The titles from the search were reviewed and 2 items of relevance were further reviewed. Neither of them were accepted.

Levels of Evidence

The six pieces of evidence accepted included four systematic reviews (Allen et al., 2013; Ireland & Allen, 2016; Lopez et al., 2015; Mercier & Zerden, 2012) and 2 meta-analysis (Kass-Wolff & Fisher, 2014; Pergialiotis et al., 2014), which are all level 1 evidence according to Schmidt & Brown's (2019) hierarchy of evidence.

Appraisal of Relevant Evidence

Melnyk and Fineout-Overholt's rapid critical appraisal of systematic reviews of clinical interventions/treatments was used to critically appraise the accepted evidence. Four pieces of evidence (Ireland & Allen, 2016; Lopez et al., 2015; Mercier & Zerden, 2012; Pergialiotis et al., 2014) were deemed good quality, while two pieces of evidence (Allen et al., 2013; Kass-Wolff & Fisher, 2014) were deemed moderate quality. The two that were assessed as moderate quality lacked a description of the literature search and how evidence was chosen.

Construction of Evidence-Based Practice

Synthesis of Critically Appraised Literature

Study design. The six pieces of evidence obtained were synthesized to develop the EBP. In the randomized controlled trials (RCTs), pain was measured using the visual analog scale (VAS) with the exception that the systematic review by Ireland & Allen (2016) contained studies using both the VAS and the numerical pain scale. Interventions were compared to a placebo of saline in most of the studies. A couple studies compared one intervention to another intervention. Allen et al. (2013) and Lopez et al. (2015) compared Naproxen versus Tramadol.

Ireland & Allen (2016) compared paracervical block to intrauterine infusion and Naproxen versus Tramadol versus Ketolorac. Most of the researchers (Allen et al., 2013; Ireland & Allen, 2016; Kass-Wolff & Fisher, 2014; Mercier & Zerden, 2012) did not specify which statistical tests were run in the studies, however, p values were provided to define significance. In the systematic review conducted by Lopez et al. (2015), odds ratio was used to compare pain scores between the intervention and control groups. In another systematic review conducted by Pergialiotis et al. (2014), chi square tests were used to compare pain scores between the intervention and control groups.

IUD Insertion. For IUD insertion there were seven interventions recommended as effective treatments for pain relief and two interventions that were not recommended based on study results. Four pieces of evidence supported 10 ml of 1% lidocaine paracervical block prior to insertion (Allen et al., 2013; Ireland & Allen, 2016; Lopez et al., 2015; Pergialiotis et al., 2014). Ireland & Allen (2016); Lopez et al. (2015) supported Naproxen 550mg by mouth one-hour prior to insertion, Tramadol 50mg by mouth one-hour prior to insertion, and in nulliparous patients specifically, Ketorolac 30mg via intramuscular injection thirty minutes prior to IUD insertion. Lopez et al. (2015) supported EMLA cream 5g applied to the cervix and cervical opening seven minutes prior to insertion and 10% lidocaine spray with three puffs to the cervix and one puff to the cervical opening three minutes prior to insertion. Mercier & Zerden (2012) supported 1.5ml of 2% lidocaine gel prior to insertion. Three pieces of evidence concluded ibuprofen in doses of 400mg, 600mg, and 800mg prior to insertion does not decrease pain (Allen et al., 2013; Ireland & Allen, 2016; Lopez et al., 2015). In five studies it was found that misoprostol prior to insertion does not decrease pain (Allen et al., 2013; Ireland & Allen, 2016; Kass-Wolff & Fisher, 2014; Lopez et al., 2015; Pergialiotis et al., 2014).

EMB. For EMB there was one recommended intervention and one intervention that was not recommended. Four pieces of evidence supported intrauterine infusion using 2% lidocaine left in place for three to five minutes prior to biopsy (Allen et al., 2013; Ireland & Allen, 2016;

Kass-Wolff & Fisher, 2014; Mercier & Zerden, 2012). Three pieces of evidence concluded misoprostol prior to biopsy does not decrease pain (Allen et al., 2013; Ireland & Allen, 2016; Kass-Wolff & Fisher, 2014).

Table 2.1

Review of Literature and Appraisal Results

Citation	Purpose	Sample	Design	Measurement	Results/Findings	LOE
Allen, R.H., Micks, E., Edelman, A. (2013). Pain relief for obstetric and gynecologic ambulatory procedures. *Obstetrics and Gynecology Clinics of North America*, 40(4), 625-645. doi:10.1016/j.ogc.2013.08.005	Pain management for the most common gynecologic procedures performed in the office	Systematic Review	19 RCTs pertaining to IUD insertion and EMB Pharmacological intervention versus placebo or no intervention was used for most RCTs 1 RCT compared Naproxen versus Tramadol	Measured pain during gynecological procedures using VAS/p value was used to determine significance, statistical test used was not stated	For IUD insertion 20ml of 1% lidocaine paracervical block decreased pain significantly For EMB intrauterine infusion of 2% lidocaine infused with angiocatheter left in for 3-5 minutes prior to procedure decreased pain significantly Ibuprofen 400mg, 600mg, and 800mg does NOT decrease pain significantly Misoprostol does NOT decrease pain significantly	Level I moderate quality
Ireland, L.D. & Allen, R.H. (2016). Pain management for gynecologic procedures in the office. *Obstetrical and Gynecological Survey*, 71(2), 89-98. doi:10.1097/OGX.0000000000000272	Pain management for endometrial biopsy, intrauterine device insertion, colposcopy and loop electrosurgical excision procedure, uterine aspiration, and hysteroscopy	Systematic Review	6 RCTs pertaining to IUD insertion and EMB Pharmacological intervention versus placebo or no intervention for most RCTs 1 RCT compared paracervical block versus intrauterine infusion 1 RCT compared	Measured pain during office gynecological procedures using VAS and numerical pain scale/p value was used to determine significance, statistical test used was not stated	For IUD insertion 550mg of Naproxen or 50mg of tramadol given 1 hour prior to multiparous women decreased pain significantly, 30mg ketorolac given IM 30 minutes prior to nulliparous women decreased pain significantly, and a paracervical block using 20ml of 1% lidocaine decreased pain significantly For IUD insertion Ibuprofen and misoprostol does	Level I Good quality

			Naproxen versus Tramadol versus Ketolorac		NOT decrease pain significantly For EMB intrauterine lidocaine infusion using an angiocatheter with 2% lidocaine left in place for 3-5 minutes prior to procedures decreased pain significantly For EMB misoprostol does NOT decrease pain significantly	
Kass-Wolff, J. & Fisher, J.E. (2014). Evidence-based pain management for endometrial biopsies and IUD insertions. *The Nurse Practitioner*, 39(3), 43-50. doi:10.1097/01.NPR.0000434094.19101.d1	Pain management for IUD insertion and endometrial biopsies	Meta-Analysis	9 RCTs Pharmacological intervention versus placebo	Measured pain during EMB and IUD insertion using VAS/p value was used to determine significance, statistical test used was not stated	For EMB 5ml of 2% lidocaine inserted into uterine cavity 3 minutes prior decreased pain, 550mg naproxen and intrauterine 2% lidocaine prior decreases pain significantly For EMB and IUD misoprostol does NOT decrease pain significantly	Level I Moderate Quality
Lopez, L.M., Bernholc, A., Zeng, Y., Allen, R.H., Bartz, D., O'Brien, P.A., & Hubacher, D. (2015). Interventions for pain with intrauterine device insertion. *Cochrane Database of*	Interventions for reducing IUD insertion-related pain	Systematic Review	17 RCTs Pharmacological intervention versus placebo 1 RCT compared Naproxen versus Tramadol	Measured pain during IUD insertions using VAS Dichotomous variables were calculated with odds ratio with a confidence interval of 95%, continuous variables were calculated with mean differentials	For IUD Insertion: Naproxen 550mg 1 hour prior decreases pain significantly Tramadol 50mg decreases pain significantly 1% lidocaine paracervical block decreases pain significantly	Level I Good Quality

Systematic Reviews, 7, 1-123. doi:10.1002/14651858.CD007373.pub3				with a confidence interval of 95%, and meta-analysis of trials with different measurement scales were calculated with standardized mean difference.	Ketorolac 30mg IM 30 minutes prior in nulliparous women decreases pain significantly Ibuprofen 400-800mg does NOT decrease pain significantly Misoprostol does NOT decrease pain significantly	
Mercier, R.J. & Zerden, M.L. (2012). Intrauterine anesthesia for gynecologic procedures: A systematic review. *Obstet Gynecol*, 120(3), 669-677. doi:10.1097/AOG.0b013e3182639ab5	Intrauterine local anesthesia for reducing pain associated with outpatient gynecologic procedures	Systematic Review	5 RCTs pertaining to IUD insertion and EMB Pharmacological intervention versus placebo	Measured pain during gynecologic procedures using VAS/p value was used to determine significance, statistical test used was not stated	For EMB Intrauterine anesthesia of 100-200mg of lidocaine decreases pain significantly	Level I Good Quality
Pergialiotis, V., Vlachos, D.G., Protopappas, A., & Vlachos, G.D. (2014). Analgesic options for placement of an intrauterine contraceptive: A meta-analysis. *The European Journal of Contraception and Reproductive Health Care*, 19(3), 149-160.	Pain management for the insertion of an intrauterine contraceptive	Meta-Analysis	11 RCTs Pharmacological intervention verses placebo or no intervention	Measured pain during IUD insertion using VAS/mean difference, CI of 95%, Chi squared test, I-squared test, and odds ratio were used.	For IUD insertion lidocaine injected paracervical block decreases pain significantly Misoprostol does NOT decrease pain significantly	Level I Good Quality

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3625187.201
4.903238

Best Practice Recommendation

For IUD insertion the evidence supports using a 10ml 1% lidocaine paracervical block to the cervix (Allen et al., 2013; Ireland & Allen, 2016; Lopez et al., 2015; Pergialiotis et al., 2014). Paracervical blocks may be performed by the physician, nurse practitioner, or midwife as they will be performing the IUD insertion and it is within their scope of practice. Paracervical blocks are injected evenly at eight o'clock and four o'clock at the cervical-vaginal junction three minutes prior to insertion (Allen et al., 2013; Ireland & Allen, 2016; Lopez et al., 2015; Pergialiotis et al., 2014). For EMB, the most consistent recommendation is 5ml of 2% lidocaine intrauterine infusion left in for 3-5 minutes prior to obtaining the biopsy (Allen et al., 2013; Ireland & Allen, 2016; Kass-Wolff & Fisher, 2014; Mercier & Zerden, 2012). As above, the physician, nurse practitioner, or midwife may give the uterine infusion as they will be performing the EMB and it is within their scope of practice.

How the Best Practice Model will Answer the Clinical Question

The clinical question will be answered by applying the best practice recommendations found in the literature. Implementing this as a standardized protocol to be used by all providers in the practice will provide quality of care and equal opportunity to pain management for all patients receiving IUD insertions and EMBs. The outcome will be measured with the numerical pain scale for consistency in data collection as data collected before implementation was done using the numerical pain scale. Patients will be asked their pain level from zero to ten with ten being the worst pain ever during these procedures. This number will be recorded. Pain levels collected from patients undergoing these procedures before the protocol was implemented will be compared to pain levels of patients for whom the protocol was used.

CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

The practice change that will be implemented is a protocol for pain management during IUD insertions and EMBs. The protocol for IUD insertions will consist of using a 10ml 1% lidocaine paracervical block to the cervix (Allen et al., 2013; Ireland & Allen, 2016; Lopez et al., 2015; Pergialiotis et al., 2014). The protocol for EMB will consist of a 2% lidocaine intrauterine infusion left in for 3-5 minutes prior to obtaining the biopsy (Allen et al., 2013; Ireland & Allen, 2016; Kass-Wolff & Fisher, 2014; Mercier & Zerden, 2012).

Participants and Setting

The setting for this evidence-based project is an OB/GYN private practice located in Crown Point, Indiana. Providers employed at the practice and participating in the project are three physicians who are board certified in obstetrics and gynecology and also fellows in the American College of Obstetricians and Gynecologists and one midwife who is board certified and a member of the American College of Nurse Midwives. Participation of these four providers will allow for a larger number of IUD insertions and EMBs to be included in this project.

Patients participating in this project will be women age 18 years and older receiving an IUD insertion or EMB. Exclusion criteria for the project will be anyone with a known lidocaine allergy and age younger than 18.

Outcomes

The goal of this project is to establish a protocol for pain management during IUD insertions and EMBs that will decrease pain during these procedures. Pain levels will be assessed by the project manager, providers, and nurses. The providers at the practice use paper charting; therefore, a paper protocol will be placed in the front of each patient's chart when the decision is made to perform an IUD insertion or an EMB. The provider will follow the protocol and check off each step they do on the paper protocol. The patient's pain level during

the procedure will be recorded at the bottom of this form using the numeric pain scale of zero to ten with ten being the worst pain ever. These pain levels will be compared to the pain levels collected prior to protocol use.

Intervention

When the decision is made to do an IUD insertion or EMB, the physician or midwife and nurse will obtain consent to participate in the project. A paper copy of the protocol (see Appendix B) and data collection sheet (see Appendix C) will be placed in the front of the patient's chart. For IUD insertions, patients will receive a 10ml of 1% lidocaine paracervical block to the cervix evenly injected at eight o'clock and four o'clock at the cervical-vaginal junction three minutes prior to insertion (Allen et al., 2013; Ireland & Allen, 2016; Lopez et al., 2015; Pergialiotis et al., 2014). For patients receiving an EMB, 5ml of 2% lidocaine will be instilled intrauterine for 3-5 minutes prior to the biopsy (Allen et al., 2013; Ireland & Allen, 2016; Kass-Wolff & Fisher, 2014; Mercier & Zerden, 2012). During the insertion of the IUD and the biopsy of the EMB, the patients will be shown the numeric pain rating scale by the nurse or project manager and asked to rate their pain level using the scale, which will then be recorded on the data collection form in the front of the patient's chart.

Planning

Ideally a set meeting time for all staff together was the goal, but due to everyone's schedules and time frames this was not feasible. For this reason, individual meetings were setup. A meeting will be held by the project manager with the providers and nurses individually to present the evidence supporting the practice change, explain the protocol, review the consent form, review the script for explaining the project to patients, and how to complete the data collection form once IRB approval is obtained. It will be important to take the time to allow for all questions and discussion of the protocol. Thus far, the project manager has informally talked with staff individually about the project while on site collecting pre-implementation data. The individual meetings will allow for staff to be reeducated and informed of the entire project.

Data

Measures

The numeric pain rating scale has high validity and reliability. There is high test-retest reliability with a correlation coefficient of 0.95 to 0.96 (Hawker et al., 2011). Construct validity was shown to be highly correlated with the visual analog scale with correlation coefficients of 0.86 to 0.95 (Hawker et al., 2011). This pain scale is also easy to administer and score. The numeric pain rating scale is also being used because this was the tool used to collect data before project implementation.

Collection

To collect the pain scores the nurse or project manager will show the patient the numeric pain rating scale during the actual IUD insertion and endometrial biopsy and ask the patient to rate her pain on the scale. The nurse or project manager will then record the score and procedure on the data collection form (see Appendix C). The provider will sign the data collection form upon completion. The nurse or project manager will place the completed data collection form in the manila envelope marked completed IUD and EMB forms.

Management and Analysis

Data collection forms and consents will be kept in a clearly labeled folder at both workstations and in the front office. When there is a decision made to do an IUD insertion or EMB, a protocol, data collection form, and consent form will be placed in the front of the chart by the secretary or nurse. These forms will be kept at the facility and locked in the providers desk drawer after business hours. After the procedure is performed and all data are collected, the data collection form and signed consent will be placed in a manila folder clearly labeled “completed data collection forms and consents.” These completed forms and consents will remain in this folder for the duration of the project until picked up by the project manager. There will be a manila folder for completed forms and consents placed at each work station.

An independent t-test will be used for statistical analysis. This test is appropriate because the level of data being collected is interval, which is the pain scores from the numeric pain rating scale. For interval data a parametric test should be used. The independent t-test is a parametric test. It is also the statistical analysis used in the evidence. The independent t-test determines whether there is a statistically significant difference between the means in two unrelated groups. This fits because the pain scores collected from the pre-intervention group and intervention group are not the same patients. The pre-intervention group and intervention group are unrelated.

Protection of Human Subjects

IRB approval was granted by Valparaiso University and prior permission to conduct the project at the clinical site was given by the owner of the practice prior to project implementation. All patient participants were provided a consent which stated the project's purpose, procedures, risks, benefits, voluntary participation and freedom to withdraw, and assurance of patient confidentiality. The manila folders containing completed forms and consents will be kept at the clinical site in a locked file desk after business hours. Patient information at the time of project completion will be taken from the office to the project manager's home and kept in a locked desk drawer to maintain patient privacy and confidentiality. Demographic and data forms will be destroyed at the completion of the project.

CHAPTER 4

FINDINGS

The purpose of this project was to implement a protocol for pain management for IUD insertions and EMBs. The goal of implementing the pain management protocol was to lower pain scores during IUD insertions and EMBs measured using the numerical pain rating scale. There was a statistically significant difference in pain levels with use of the protocol for EMBs. However, there was no statistically significant improvement in pain levels for IUD insertions.

Participants

Size

At the beginning of the project, 20 patients consented to participate and completed the demographic form. Numeric pain rating scale scores were obtained from them during the procedures before the new EBP was implemented. Of those 20 patients, 13 received an IUD insertion and seven patients received and EMB. After the protocol for pain management was implemented, another 12 patients consented to participate, completed the demographic form, and allowed for numeric pain rating scale scores to be obtained during the procedures. Of those 12 patients, seven received an IUD insertion and 5 patients received an EMB. There was an attrition rate of 0%. All patients asked to participate agreed and competed the full project.

Characteristics

Descriptive statistics were used to describe the demographic characteristics of participants in this EBP project (N=32). All 32 (100%) participants were Caucasian with ages ranging from 19 to 54. The pre-intervention group for IUD insertions (n =13) had 1 nulliparous participant and 12 multiparous participants. This group had a mean age of 33. The post-intervention group for IUD insertions (n=7) had 4 nulliparous participants and 3 multiparous participants. This group had a mean age of 28. The pre-intervention group for EMBs (n=7) had 1 nulliparous participant and 6 multiparous participants. This group had a mean age of 40. The

post-intervention group for EMBs (n=5) had 0 nulliparous participants and 5 multiparous participants. This groups had a mean age of 49 (see Table 4.1).

An independent *t-test* was calculated for age to compare the different groups. There was no statistical significance when comparing the ages of the pre-intervention group and post-intervention group for IUD insertion ($t(18) = 1.201$, $p > .05$). The results indicate that there is no statistically significant difference in age between these groups. There was statistical significance when comparing the ages of the pre-intervention group and post-intervention group for EMB ($t(10) = -3.758$, $p < .05$). The results indicate that there is a statistically significant difference in age between these groups. The mean age for the pre-intervention group was 40.0 with ages ranging from 36 to 48 and the mean age for the post-intervention group was 49.2 with ages ranging from 44 to 54. A possible explanation is the small sample size and a short time frame of the project. A larger sample size and longer time frame would allow for more variety in age to balance the groups (see Table 4.2).

A chi square was calculated for gravida to compare the different groups. There was no statistical significance when comparing the gravida of the pre-intervention group and post-intervention group for EMB ($x^2(1) = .779$, $p > .05$). The results indicate there is no statistically significant difference for gravida between these groups. There was a statistical significance when comparing the gravida of the pre-intervention group and post-intervention group for IUD insertion ($x^2(1) = 5.934$, $p < .05$). The results indicate that there is a statistically significant difference in gravida between these groups. A possible explanation for this is the small sample size and a short time frame for the project. Having a larger sample size and longer than 12 weeks for the project would allow for more of a variety of nulliparous and multiparous participants. During the time frame that the project was done there was 1 nulliparous and 12 multiparous in the pre-intervention group compared to 4 nulliparous and 3 multiparous in the post-intervention group (see Table 4.3).

Table 4.1

Demographics Characteristics

Characteristics	**IUD**	**EMB**
Pre-intervention Mean Age	33	40
Post-Intervention Mean Age	28	49
Pre-intervention Gravida	1 nulliparous 12 multiparous	1 nulliparous 6 multiparous
Post-intervention Gravida	4 nulliparous 3 multiparous	0 nulliparous 5 multiparous
Caucasian	100%	100%

Table 4.2

Independent t-test for Age

Procedure	**Pre**		**Post**		**t**	**df**	**p**
	Mean	**SD**	**Mean**	**SD**			
IUD	33.15	8.11	28.57	8.18	1.201	18	.245
EMB	40.0	4.50	49.2	3.63	-3.758	10	.004

Table 4.3

Chi Square for Gravida

Procedure	Pre Nulliparous	Post Nulliparous	Pre Multiparous	Post Multiparous	X^2	df	p
IUD	1	4	12	3	5.934	1	.015
EMB	1	0	6	5	.779	1	.377

Changes in Outcomes

The numeric pain rating scale was used to measure participants' pain level during IUD insertions and EMBs. This tool is a numerical scale from 0-10, with zero representing no pain and 10 representing the worst pain possible.

Statistical Testing

Effectiveness of the pain management protocol was assessed statistically with the use of SPSS. An independent *t*-test was calculated comparing the mean of participants' pain scores for IUD insertions and EMBs before implementation of the pain management protocol to the mean of participants' pain scores after implementation of the pain management protocol. To compare the groups' demographic characteristics, an independent *t*-test was calculated for age and a chi square was calculated for gravida.

Significance

The results of the statistical analysis answer the PICOT question: In women over 18 (P), what is the effect of a pain management protocol for IUD insertions and EMBs (I) compared to usual care (C) on pain levels (O) over a 12-week period (T)? Patients receiving the 2% lidocaine intrauterine infusion prior to EMB had statistically significantly lower pain scores ($M = 3.2$) compared to the patients who did not receive the 2% lidocaine intrauterine infusion prior to EMB ($M = 7.42$) ($t(10) = 2.759$, $p < .05$). There was no statistically significant difference in pain scores in patients who received a 1% lidocaine paracervical block prior to IUD insertion ($M = 1.71$) compared to patients who did not receive the 1% lidocaine paracervical block prior to IUD insertion ($M = 3.38$) ($t(18) = 1.826$, $p > .05$).

Table 4.4

Independent t-test for NPRS

	Pre		Post				
Variable	**Mean**	**SD**	**Mean**	**SD**	**t**	**df**	**p**
IUD	3.38	2.21	1.71	1.25	1.826	18	.084
EMB	7.42	2.63	3.20	2.58	2.759	10	.020

CHAPTER 5

DISCUSSION

The purpose of this EBP project was to find the best evidence-based intervention to decrease pain during IUD insertions and EMBs. In this chapter findings will be discussed and linked to the theoretical and EBP frameworks used to guide the EBP project. Strengths and limitations of the EBP project will be described along with implications for future utilization of the new practice in clinical practice, theory, research, and education.

Explanation of Findings

The findings of this EBP project indicate that intrauterine infusion of 2% lidocaine resulted in decreased pain during EMBs. Patients receiving the 2% lidocaine intrauterine infusion prior to EMB had statistically significantly lower pain scores compared to the patients who did not receive the 2% lidocaine intrauterine infusion prior to EMB (p <.05). There was no statistically significant difference in pain in patients who received a 1% lidocaine paracervical block prior to IUD insertion compared to patients who did not receive the 1% lidocaine paracervical block prior to IUD insertion (p >.05). The findings of the EBP project answer the PICOT question by showing the effect the use of a pain management protocol for IUD insertions and EMBs had on pain levels over a 12-week period.

The results of the use of intrauterine infusion of 2% lidocaine during EMB were similar to those found in the literature. The EBP project findings and the literature both showed statistically significant decreased pain scores with the use of the 2% lidocaine intrauterine infusion prior to EMBs (Allen et al., 2013; Ireland & Allen, 2016; Kass-Wolff & Fisher, 2014; Mercier & Zerden, 2012). The findings for IUD insertions were inconsistent with those found in the literature. While pain scores did decrease with the use of the pain management protocol for IUD insertions, they

were not statistically significant. The literature showed statistically significant decreased pain scores for IUD insertions using a 1% lidocaine paracervical block prior to IUD insertions (Allen et al., 2013; Ireland & Allen, 2016; Lopez et al., 2015; Pergialiotis et al., 2014). A possible explanation for the findings in this EBP project is that the sample size for this project was small (n =7). The number of nulliparous participants could have also affected the results. In the pre-intervention group (n =13) there was only one nulliparous participant and in the post-intervention group (n =7) there was four nulliparous participants. When a patient is nulliparous, they have not had any pregnancies. The cervical os is a tight circle-shaped opening in nulliparous women, which makes it more difficult and more painful to get through (Fleischer et al., 2011). Multiparous means women have had one or more pregnancies causing their cervical os to change shape. It causes the cervical os to become more open, which makes it easier to get through. The pre-intervention group had more multiparous participants and lower pain scores without use of the pain management protocol, which may have affected the results. Also, the post-intervention group having more nulliparous participants may have affected the results. The literature contained studies with larger sample sizes and more of a balance in the number of nulliparous versus multiparous participants.

Evaluation of Applicability of Theoretical and EBP Frameworks

Theoretical Framework

Kolcaba's Comfort Theory provided the framework for this EBP project. The Comfort Theory consists of the three phases relief, ease, and transcendence (George, 2011). The focus of the EBP project was relief of pain. One of the contexts under relief is physical comfort. By decreasing pain during IUD insertions and EMBs physical comfort is achieved providing relief. Patients get anxiety about feeling pain during the procedure. By providing relief from pain anxiety is also decreased, which puts the patient at ease. Being at ease allows for transcendence, which allows the participant to think positively.

Participants in the pre-intervention group reported their anxiety about the procedure and fear of pain to the project manager. Some participants during the procedure tensed up and start pushing themselves up the table away from the physician, making the procedure difficult due to pain.

Participants in the intervention group also reported anxiety about the procedure and fear of pain. After explaining the EBP project and the intervention for pain management to the participants, 100% of them agreed to the intervention. After telling them they would be given something for the pain during the procedure, it seemed to put them at ease about the procedure. The pain management protocol was used to provide pain relief and physical comfort during the procedures. By providing the pain relief and physical comfort the participants anxiety decreased even more putting them at ease. These participants had relaxed bodies and were staying in position during the procedure as opposed to pushing up the table away from the physician. This allowed for easier more successful procedures.

EBP Framework

The PARIHS model was used to guide the process of the EBP project. The PARIHS model uses a high to low continuum to evaluate criteria for evidence, context, and facilitation (Melnyk & Fineout-Overholt, 2015). Meeting the criteria on the higher end of the continuum increases chances of successful implementation and sustaining the implementation over time. For evidence to be on the high end of the continuum the research has to be well conceived and conducted, have a consensus about it, and include clinical experience of the authors that was made explicit and verified through critical reflection, critique, and debate. Context is where the change is to be implemented. To be on the high end of the continuum, the organization needs to have a culture of learning and be accepting of change. A learning organization facilitates the learning of its members and continuously transforms itself. Leaders of learning organizations are usually transformational leaders who inspire. Facilitation is the process of making implementation easier. For facilitation to be on the high end of the continuum a facilitator will

help individuals, teams, and organizations apply evidence in practice (Melnyk & Fineout-Overholt, 2015). The evidence for the EBP project was on the high end of the continuum with an exhaustive literature search, which yielded high level evidence of good quality. For context, to be on the high end of the continuum requires a culture of learning and accepting change. This was demonstrated for the most part. All nurses and providers were willing to learn and change their practice to implement the protocol with the exception of one provider. When it came to doing a paracervical block for the IUD insertions this provider did not want to do it and did not want to spend the extra time. This provider felt the paracervical block would be more painful than the actual procedure. This provider would not allow the project manager to explain or present the evidence. When the project manager attempted to explain, the provider would cut the project manager off. The organization as a whole seems to have a culture of learning and accepting change despite this provider. For facilitation the high end of the continuum requires a facilitator who helps apply the practice and encourage others in the organization. The facilitator for the EBP project was very helpful at applying the practice and being in communication with the project manager. The facilitator performed the paracervical blocks and intrauterine infusions for all IUD insertions and EMBs who consented to participate in the EBP project. When there were days the project manager could not be there, the facilitator would text the project manager how many procedures were completed that day. The facilitator also encouraged others in the practice to implement the EBP project. The facilitator addressed the provider who did not want to participate and unfortunately was not successful with that provider.

Strengths and Limitations of the EBP Project

Strengths

This EBP project was easily implemented. The pain management protocol was very simple to use because all you had to do was go to the procedure to be done and follow the step by step instructions. The numeric pain rating scale was also very simple and fast to use for both the participant and provider. The providers and nurses in the organization also made this EBP

project easy to implement by collecting pain scores, ordering the lidocaine, performing the paracervical blocks and intrauterine infusions, and educated patients on the EBP project while obtaining consent when the project manager could not be there. Another strength is time because both the paracervical block and intrauterine infusion only add about five minutes more to the procedures. Funding for this project was not needed since the supplies needed were inexpensive. All supplies needed were already something the office carried except the 2% lidocaine, which was ordered from custom dosing at a relatively low expense.

Limitations

A limitation to this project was that one provider would not participate as described previously. Due to this provider not participating the sample size was made smaller. There were 12 EMBs in total and 20 IUD insertions performed during the implementation period Another limitation is that the number of nulliparous verses multiparous women was unbalanced. Most of the participants in all groups were multiparous. Multiparous and nulliparous women can experience different levels of pain due to the anatomy of their cervix being different. As mentioned above, a larger sample size and a more balanced sample of nulliparous verses multiparous may have changed the finding for IUD insertions.

Implications for the Future

Practice

Implications for future practice include increased focus on patient comfort during these procedures and patient satisfaction. The organization has decided to adopt the new practice and continue using the pain management protocol except for the provider who did now want to participate in the project. The project manager has been in the clinic after implementation was completed and witnessed the pain management protocol being used. The new practice seems to be sustaining.

Theory

The main parts of the Kolcaba's Comfort Theory used were relief and physical comfort by relieving pain. By relieving pain and providing relief, this led to the next stage of ease. Although ease was reached, in the future interventions to help with ease could easily be incorporated to enhance the relief phase. Wilson & Kolcaba (2004) give the example of using music to provides relief by decreasing discomfort and anxiety. It provides ease by contentment when listening to one's favorite music. It facilitates transcendence by allowing patient to think positively and spiritually. Music is an intervention that can easily be added in the future, is non-invasive, and inexpensive. Playing the patients favorite type of music helps to distract them from the procedure and help them to relax. During this EBP project transcendence was not evaluated in the time frame of this project. In the future, follow up phone calls to measure transcendence may be appropriate.

Research

Implications for future research include more research about the difference in pain management for nulliparous versus multiparous women. Nulliparous and multiparous patients have different size cervical os due to child birth (Allen et al., 2013). Nulliparous patients have a smaller and tighter cervical os, which could make IUD insertions and EMBs more difficult and more painful (Allen et al., 2013).

Education

Implications for future education would focus on the patients. Patients should be educated about their options for pain management for these procedures and that it is best practice. They should be educated on how decreasing their pain during the procedure allows for them to relax their body making the procedure attempt more successful (Kass-Wolff & Fisher, 2014). When patients are in pain, they may tense their muscles, start moving up the table away from the provider, and bring their thighs in making it very difficult for the provider to do the procedure successfully. For IUD insertions it is very important to insert the IUD into the right position in the uterine cavity. For the EMB it is very important to get a good endometrial sample

for pathology, so the procedure doesn't have to be repeated due to an insufficient sample (Kass-Wolff & Fisher, 2014).

Conclusion

In conclusion, this EBP project answered the EBP question asking what the best way was to decrease pain during IUD insertions and EMBs. According to the literature, best practice for decreasing pain during these procedures was a 1% lidocaine paracervical block prior to IUD insertion (Allen et al., 2013; Ireland & Allen, 2016; Lopez et al., 2015; Pergialiotis et al., 2014) and a 2% lidocaine intrauterine infusion prior to EMB (Allen et al., 2013; Ireland & Allen, 2016; Kass-Wolff & Fisher, 2014; Mercier & Zerden, 2012). This EBP project findings showed the intrauterine infusion to be statistically significant in decreasing pain during EMBs. Although the EBP project did not find the paracervical block to be statistically significant in decreasing pain during IUD insertions, it was possible the small sample size and lack of nulliparous participants affected this. The pain management protocol will increase the quality of care for the patients receiving IUD insertions and EMBs. It will standardize care, so all patients are offered the same evidence-based pain management during their procedure. Decreasing pain during these procedures allows for ease of the procedure and patient satisfaction.

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BIOGRAPHICAL MATERIAL

Mrs. Lipton-Carroll is an Indiana native and graduate of Valparaiso University in 2011, where she earned a Bachelor of Science in Nursing. She is a member of Sigma Theta Tau International Honor Society of Nursing and the American Association of Nurse Practitioners. As a registered nurse, she gained extensive experience in the intensive care unit. Mrs. Lipton-Carroll returned to Valparaiso University to pursue her Doctor of Nursing Practice (DNP) as a family nurse practitioner. Mrs. Lipton-Carroll currently works in the intensive care unit at Porter Regional Hospital in Valparaiso, Indiana. Her post-graduate interests include primary care, cardiology, and women's health. Mrs. Lipton-Carroll became interested in women's health after doing her clinical rotation in an obstetrics/gynecology office. She quickly realized the need for pain management during intrauterine device insertions and endometrial biopsies. As a result, Mrs. Lipton-Carroll's evidence-based practice (EBP) project involved the implementation of a best practice protocol for pain management during these procedures. Mrs. Lipton-Carroll's protocol includes a 1% lidocaine paracervical block prior to intrauterine device insertion and a 2% lidocaine intrauterine infusion prior to endometrial biopsy.

ACRONYM LIST

APRN: Advanced Practice Registered Nurse

EBP: Evidence-Based Practice

EMB: Endometrial Biopsy

IUD: Intrauterine Device

PARIHS: Promoting Action on Research Implementation in Health Services

RCT: Randomized Controlled Trial

VAS: Visual Analog Scale

Appendix A

Demographic Information Form
Pain Management for Intrauterine Device Insertion and Endometrial Biopsy

Code # _____

Please provide a response for each of the following questions.

1. Please state your age: _____
2. Circle your gender: Male Female
3. How many pregnancies have you had: _____
4. If you have been pregnant, please answer the following:
    a. How many births: _____
    b. How many abortions or miscarriages: _____
5. With which racial or ethnic category do you identify? Please place an (x) on the line.

    _____African American

    _____Asian/Pacific Islander

    _____Caucasian

    _____Latino

    _____Native American

    _____Other

    If you checked other, please specify: _____

Appendix B

Pain Management Protocol for IUD Insertions and Endometrial Biopsies

For women 18 years of age or greater with no known allergy to lidocaine.

IUD Insertions

1. The anesthetic solution is drawn into the syringe with the short needle, which is then replaced with the spinal needle.
2. The patient is placed in the lithotomy position.
3. A vaginal speculum and tenaculum are used for optimal exposure.
4. The physician or midwife preps the cervix and vaginal vault with povidone iodine or a low alcohol chlorhexidine solution; selection is based upon patient allergy profile and clinician preference.
5. Inject 10ml of 1% lidocaine paracervical block about 10mm deep to the cervical-vaginal junction evenly at eight o'clock and four o'clock three minutes prior to insertion.

Endometrial Biopsies

1. Place the patient in the dorsal lithotomy position.
2. Insert a speculum and visualize the cervix.
3. The physician or midwife preps the cervix and vaginal vault with povidone iodine or a low alcohol chlorhexidine solution; selection is based upon patient allergy profile and clinician preference.
4. Insert an 18-gauge angiocatheter through the endocervix into the uterine cavity.
5. Instill 5ml of 2% lidocaine intrauterine and leave in for 3-5 minutes to limit backflow prior to biopsy.

Appendix C

Data Collection

Code # _____

Check procedure performed:
_____IUD insertion
_____Endometrial Biopsy

Pain score during actual IUD insertion or Endometrial biopsy (NOT during paracervical block or placement of intrauterine infusion) on the numeric pain rating scale 0-10 with 0 being no pain and 10 being the worst pain
_____Patient's pain score

_____
Provider's signature upon completion