Independent Study Project: Description and Manuscript

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Background and Rationale

Intrauterine devices are a reliable, long-term, and highly effective form of birth control that are becoming increasingly popular worldwide. As with many medical procedures, patients receiving an IUD may experience anxiety prior to the procedure. This mindset may actually be a self-fulfilling prophesy such that high expectations of pain produce increased discomfort. Currently, there is no proven method that reduces pain felt during IUD placement. It is unclear whether the expectation of pain is a significant predictor for discomfort felt during IUD placement, but results may provide insight as to how to better prepare patients mentally prior to the procedure.

Maintaining high quality medical care depends on scientific research performed by physicians, PhDs, and other medical professionals who investigate ways to improve patient outcome and satisfaction. An understanding and appreciation for research is paramount to the education of medical students, and this project served as an introduction in order to build a foundation in research. Participation in the study project served to provide experience in research design, participant recruitment, data collection and analysis.

Description of objectives

1. For the medical student to gain experience as a research coordinator for original research project to better understand primary research.
2. Assist in the recruitment of participants and data collection.
3. Develop a research question that can be explored using a subset of data from the original research project.
4. Create an original manuscript to show results of independent study project research question.

Methods

A secondary analysis was performed using a subset of data from "20 cc 1% Paracervical Block for a 20 mm decrease in pain with IUD placement" (Mody, et al. 2018-under review). There were a total of 31 participants included in this subset of data that received either a levonorgestrel intrauterine device or the copper intrauterine device from the UCSD Health Systems or Planned Parenthood of the Pacific Southwest. The patients were asked to report their anticipated pain before intrauterine device placement as well as experienced pain at various points during and after the procedure on a 100-point visual analog scale. The data were then used to assess the association of anticipated pain with actual pain at various steps of the procedure.

Achievements

This project took place over the course of all four years in medical school. During this time, I gained a better understanding of primary research, and I can apply this understanding following graduation in order to develop future projects and critically analyze the work of other researchers.

In addition to gaining research experience, I am included as an author of the original project, "20 cc 1% Paracervical Block for a 20 mm decrease in pain with IUD placement" (Mody, et al. 2018-under review)." I also composed a written manuscript of my individual analysis of a subset of data from the above research project and submitted a written abstract that was accepted for presentation at the American Medical Women's Association 103rd meeting in March 2018.

Anticipated pain during IUD placement in nulliparous women

Introduction

The first Intrauterine devices (IUDs) were made over a century ago and consisted of various metals or silkworm gut.[1] Now, two main types exist: the copper and the levonorgestrel hormone-containing IUD. Both types can be used safely as long-term birth control with failure rates <1.0%.[2-4] Given the numerous benefits of IUDs, they have grown in popularity and are now are the second leading form of contraception worldwide, used by over 150 million women.[4]

Despite advances making IUDs highly effective, safe and reversible, some women choose not to use an IUD citing potential pain during and immediately following its placement as a deterrent.[3-,5] The experience of pain is purely subjective, and it may be present despite an absence of any physical damage. Pain is a multidimensional phenomenon influenced not only by the actual sensory input, but also by affect, previous experiences, and culture making it difficult to study and control.[7]

There is evidence that for medical and dental procedures, increased anxiety prior to starting increases pain scores.[8,9] By predicting increased levels of discomfort, patients may experience a self-fulfilling prophecy—the prediction increases anxiety, and the anxiety in turn increases actual discomfort. Attempts to control the pain during IUD placement have been inconclusive at best. Interventions such as the use of non-steroidal anti-inflammatory medication and anti-anxiety medications to lessen pain have not been found to help decrease pain with placement.[10,11]

A recent study by Dina et al,[5] a secondary analysis of the Contraceptive CHOICE Project, discovered that expectations of pain before IUD placement are related to actual pain scores of IUD placement reported a few minutes after the procedure. The purpose of this study is to further examine how expectations of pain prior to IUD placement influences the experience of pain. This study evaluated anticipated pain prior to the start of the procedure compared to actual pain scores at multiple time points during and following IUD placement. Unique to this study is that it provides real-time pain scores at each step of the IUD placement process. The specific hypothesis was that participants with higher levels of anticipated pain would score higher on the reported pain scale.

Materials and Methods

A secondary analysis was performed using a subset of data from "Pain control for intrauterine device placement: A randomized controlled trial of paracervical block," a project approved by University of California, San Diego Human Research Protections Institutional Review Boards. This study was a randomized control trial that examined if a 20cc paracervical block prior to IUD placement in nulliparous women decreased reported pain during and after the procedure. The goal of this study was to examine an alternative intervention to decrease pain during IUD placement.

Participants for this study were recruited from the UCSD Health Systems or Planned Parenthood Pacific Southwest who were received either a levonorgestrel intrauterine device or the copper intrauterine device. After being checked-in and roomed, patients were approached to gauge interest in the above study. All patients were asked to report their anticipated pain before intrauterine device placement as well as experienced pain at various points during and after the procedure on a 100-mm visual analog scale. The above study compared the experienced pain between women in the experimental arm who received the paracervical block to the women in the control arm who did not receive the paracervical block. This secondary analysis examined patients from the control arm of the above study who did not receive the paracervical block or any other form of pain control.

The primary outcome of this study was the patient's score of the level of actual pain experienced during IUD placement. Other time points examined included pain felt during speculum placement, sounding, 5-minutes following placement, and overall pain. The pain experienced during these points were analyzed as 1) a continuous variable using linear regression models and 2) dichotomized into low (<50) versus high pain (≥ 50) scores. We chose a value of 50 as clinically significant on the VAS pain scale given the average pain score for IUD insertion was 50-mm in the analysis by Dina et al. and the average pain score of control groups in other randomized controlled trials range from 41-mm to 71-mm.[5,11,12] The relative risk was calculated according to Altman, 1991. Patient demographics were compared to patient anticipated pain using chi-square test.

Results

Of the 32 participants in the control arm of the original study, 1 was unable to tolerate the procedure. A total of 31 participants were included in this subset of data, all were nulliparous and receiving first IUD placement. Table 1 provides the demographics of the participants. The mean age was 24.6 years, 25.8% of participants identified as Hispanic; 64.5% identified as white, 16.1% as asian, and 19.4%. The demographics were unrelated to anticipated pain.

Variable	All (n=31) N	%	Low anticipated pain (<50mm)	High anticipated pain (≥50)	P value
Age					0.72
<25	13	41.9	5	8	
≥25	18	58.1	9	9	
Ethnicity					0.41
Hispanic	8	25.8	5	3	
Non-Hispanic	23	74.2	9	14	
Race					0.95
White	20	64.5	9	11	
Asian	5	16.1	2	3	
Other	6	19.4	3	3	
Education					0.95
Some college	7	22.6	3	4	
College degree	18	58.1	8	10	
Graduate degree	6	19.3	3	3	

Table 1: Patient demographics

The median anticipated pain score for procedure on the VAS was 51 (range 0-85; mean 50.4; standard deviation [SD] 23.4). The median experienced pain during speculum placement was 6 (range 0-75; mean 12.7; standard deviation 16.3). The median experienced pain during sounding was 47 (range 0-100; mean 46.6; SD 25.1). The median experienced pain during IUD placement was 54 (range 15-97; mean 54.7; SD 24.5). The median score on the VAS at, 5-minutes following IUD placement was 27 (range 1-75; mean 32.5; SD 21.9). The median score on the VAS rating overall pain was 51 (range 3-95; mean 47.7; SD 25.8).

Figures 1-4 show the results of the linear regression model comparing anticipated pain to pain scores at various points during the IUD procedure. Anticipated pain showed a weak correlation to speculum placement, sounding, IUD placement, and overall pain. There was no relationship between anticipated pain and 5-minutes following IUD placement. Table 2 shows the results of multivariable model with scores dichotomized at 50-mm.

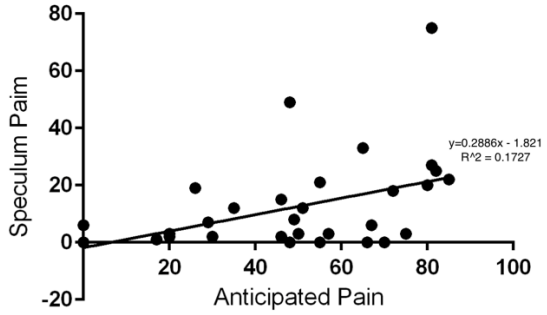

Figure 1: Relationship between anticipated pain and speculum insertion. Pain at speculum insertion could be predicted from anticipated pain by 0.29x – 1.8, $R^2 = 0.17$

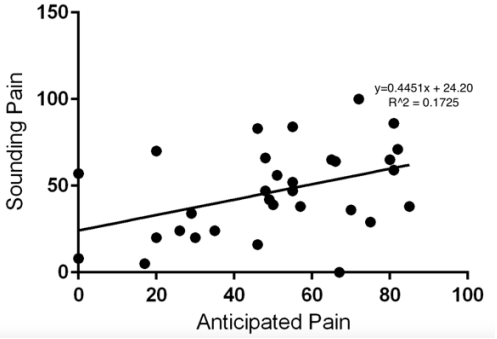

Figure 2: Relationship between anticipated pain and uterine sounding. Pain at sounding could be predicted from anticipated pain by 0.45x + 24.2, $R^2 = 0.17$

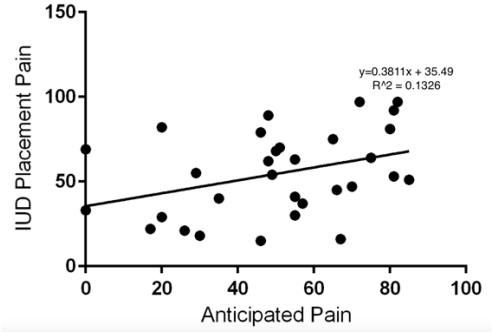

Figure 3: Relationship between anticipated pain and IUD insertion. Pain at IUD insertion could be predicted from anticipated pain by 0.38x + 35.5, $R^2 = 0.13$

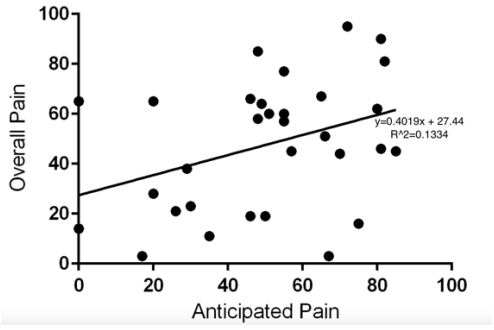

Figure 4: Relationship between anticipated pain and overall reported pain. Overall pain could be predicted from anticipated pain by 0.40x + 27.4, $R^2 = 0.13$

Variable	Relative Risk	Confidence interval	z-score	P value
Speculum Placement	2.8235	0.1238-64.3925	0.651	0.5153
Sounding	2.3438	0.9330-5.8874	0.813	**0.0699**
IUD Placement	1.1719	0.6388-2.1498	0.512	0.6084
Post-5 minutes	0.7031	0.1877-2.6344	0.523	0.6012
Overall	1.5625	0.7554-3.2319	1.204	0.2288

Table 2: Relationship between anticipated pain and different steps of procedure when pain scores were dichotomized as low (<50) versus high (≥50).

Discussion

In this analysis of 31 nulliparous patients who did not receive any form of pain control prior to IUD placement, we found no significant relationship between anticipated pain at any point of the placement procedure. This is likely due to the small group included in the analysis, which is one limitation of this study. This analysis showed a weak positive correlation between anticipated pain and experienced pain at speculum placement, sounding, IUD placement, and overall. In addition, there was a trend to significance between anticipated pain and experienced pain during sounding when the data was dichotomized between high and low expected pain.

Interestingly, women experienced the greatest pain on average during IUD placement, but anticipated pain was more closely related to experienced pain at sounding. One explanation for this is the participants were all nulliparous, so the first mechanical entry past the cervix was by the sounding implement. Women expecting increased pain may have catastrophized the pain the first time their cervix was manipulated. The expectation of pain during the placement of the IUD would then be better predicted by the pain felt during sounding rather than the earlier prediction. Indeed, the pain scores of sounding and

IUD placement were shown to be tightly correlated such that sounding pain may serve as a predictor for pain during IUD placement.

The pain scores obtained during this study were in real-time such that the pain reported at speculum placement, sounding and IUD placement was recorded immediately. This may be more accurate than having patients attempt to recall pain of IUD placement at the end of the procedure. The most painful part of the procedure was shown to be on average the IUD placement, but this score was very similar to the pain felt at sounding. Patients can be counseled during the procedure following sounding in order to create realistic expectations of IUD placement pain.

Women's prediction of the expected pain of the procedure was similar to the actual overall pain felt. The results of this study suggest that women are largely accurate in their predictions of pain, and practitioners can counsel patients regarding each individual step of the procedure to help create realistic expectations. Researchers should focus future studies on proper counseling of patients regarding each step of the procedure and perhaps include mid-procedure counseling to readjust patient's expectations of discomfort with IUD placement.

References

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Copy of Abstract

Presented as Poster at American Women's Association 103rd Annual Meeting

Background: Despite advances making intrauterine devices (IUDs) highly effective, safe, and reversible, some women choose not to use an IUD citing potential pain during and immediately following its placement as a deterrent. The fear of experiencing high levels of pain often make women anxious, a state of mind which has been shown to actually increase the experience of pain during medical procedures. It is unclear whether the expectation of pain is a significant predictor for discomfort felt during IUD placement, and there is currently no data regarding pain felt at different steps of the procedure or which step is considered the most painful.

Hypothesis: Patients with higher levels of anticipated pain will report a high level of discomfort during all steps of placement.

Methods: There were a total of 32 nulliparous participants included in this study that received either a levonorgestrel intrauterine device or the copper intrauterine device from the UCSD Health Systems or Planned Parenthood Pacific Southwest. Participants received no form of pain management during procedure. The patients were asked to report their anticipated pain before intrauterine device placement as well as experienced pain at various points during and after the procedure on a 100-point visual analog scale. These reports were then used to assess the association of patient demographics, expected pain, and experienced pain.

Results: The mean age of participants was 24 years. The median expected pain score was 53. The median experienced pain score during speculum placement, sounding, IUD placement, 5 minutes after placement, and overall was 6, 47, 54, and 27, and 51 respectively. Patient anticipated pain was weakly associated with increased experienced pain.

Conclusions: High levels of anticipated pain were related with high levels of experienced pain at different points during procedure. Interventions to reduce pre-procedural anxiety can be addressed in future research.

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