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Does the Use of Ultrasound Guidance for Proper IUD Placement Reduce Pain in Women?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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ASTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not the use of ultrasound guidance for proper intrauterine device (IUD) placement reduces pain in women.

STUDY DESIGN: A systematic review of two randomized control trials and one cohort study published between the years 2016 and 2017.

DATA SOURCES: Two randomized control studies and one cohort study evaluating if ultrasound guidance for IUD placement will reduce pain in women. Using PubMed, Embase, and Cochrane Database, studies were selected based on relevance to the clinical topic and whether they included patient-oriented outcomes.

OUTCOMES MEASURED: The outcome measured in each study was pain using the visual analog scale a 0-10 scale, with 0 points = no pain and 10 = worst pain.

RESULTS: One study found that women in which ultrasound guidance was used during IUD insertion and 5 minutes post IUD insertion reported lower pain scores as compared to women who underwent the classic approach ($p < 0.0001$; Ali MK, Abbas AM, Abdalmageed OS, Farghaly TA, Yosef AH. *Middle East Fertil Soc J*. 2018;23(3):211-215. 2017.10.006. doi: 10.1016/j.mefs.2017.10.006). An additional study found that women who underwent IUD insertion with ultrasound guidance reported lower pain scores with a p-value of <0.001 (Dakhly DMR, Bassiouny YA. *Eur J Contracept Reprod Health Care.* 2017;22(5):349-535. doi: 10.1080/13625187.2017.1381234). A cohort study conducted by Christenson, Lerma, Shaw et al. found that women who chose the simplified IUD insertion technique without bimanual examination and uterine sounding reported low pain scores and high satisfaction rates with the overall procedure when TV/US was used post IUD insertion to ensure proper placement (*Int J Gynaecol Obstet*. 2016;134(1):29-32. doi: 10.1016/j.ijgo.2015.12.004).

CONCLUSIONS: The use of ultrasound guidance for proper IUD placement is a safe and effective method to reduce pain in women. Two randomized control studies found that women reported lower pain scores during IUD insertion with ultrasound guidance and one cohort study reported low pain scores during IUD insertion with the use of transvaginal ultrasound afterwards to ensure proper placement. Further research is needed utilizing a larger sample size in order to assess patient pain comparing IUD insertion with ultrasound guidance and without.

KEY WORDS: Intrauterine device, ultrasonography, obstetrics, and gynecology

INTRODUCTION

Intrauterine devices (IUDs) are long-term reversible forms of birth control where a device is inserted into the uterus by a healthcare professional. IUDs are available in both hormonal and copper form. Copper IUDs disrupt sperm motility into the uterus to prevent fertilization and can also make implantation of a fertilized egg more difficult.[1] Hormonal IUDs prevent pregnancy by thickening cervical mucosa thereby inhibiting sperm motility into the uterus, decreases sperm survival, thins the uterine lining, and in some cases disrupts ovulation.[1] Depending on the IUD type and brand, this form of reversible long-term birth control can be left within the uterus anywhere from 5 to 12 years.[1]

Over 70 million women aged 15-49 years in the United States use some form of contraception with only 10% of those women using long-acting reservable contraceptives.[2] IUDs are one of the most effective forms of reversible long acting contraception.[2] However, fear of pain associated with IUD insertion can become a barrier to healthcare for some women.[3] It is unknown what is the direct cause of pain for all women during IUD insertion. However, pain associated with IUD insertion can be due to several different factors including cervical manipulation and instrumentation, which results in grasping, traction, and stretching, as well as irritation to the endometrium during and after IUD insertion.[3] Additionally, some women may experience mild to moderate cramping or discomfort during IUD insertion.[1] Increased pain during IUD insertion may also correlate with the patient's prior pregnancy history.[3] Women whom have never had children or women with previous history of cesarean deliveries are more likely to report increased pain with IUD insertion.[4]

Cost of IUDs can become a barrier to healthcare for some women. The average cost of IUDs is between $718 to $844 not including the cost of the procedure or accompanying office

visit.[5] Yoost et al. reported that the number of individuals using IUDs were higher amongst women who received health insurance through their employer due to lower shared cost.[5] Yoost et al. concluded that women were more likely to choose longer acting forms of contraception such as IUDs when cost was reduced.[5] There is not an exact estimate of how many healthcare visits were attributable to IUD placements per year.[6] However, the use of long-acting reversible contraception (LARC) rose four-fold from 1982 to 2002 (0.6%) and then later doubled from 2011 to 2013 (5.0%).[6]

Current methods used to treat pain associated with IUD insertion include vaginal misoprostol, intracervical or intrauterine local anesthetics such as lidocaine, and non-steroidal anti-inflammatory medications such as ibuprofen.[3] Prior studies discovered that IUD insertion was easier with the use of vaginal misoprostol but had no real effect on overall pain associated with the procedure.[4] Similar effects were observed with the administration of local anesthetics such as lidocaine during IUD insertion.[4] Additionally, the use of non-steroidal anti-inflammatory medications were found to decrease pain more during the post-insertion period as compared to during the procedure.[4] All of the previously mentioned treatment options have different effects on women with regards to reducing pain with IUD insertion. While some primary research has suggested that ultrasound guidance may reduce pain, no systematic review or meta-analysis has yet evaluated this question.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not the use of ultrasound guidance for proper IUD placement will reduce pain in women.

METHODS

Certain criteria with regards to population, intervention, comparisons, outcomes measured, and type of study were used for the selection of studies. The population included women who desired IUD placement for the purposes of contraception. Interventions were with ultrasound guidance. The comparisons were women who had IUD placement without the use of ultrasound guidance. The outcome measured was pain reduction with ultrasound guidance for IUD placement using the visual scale. The types of studies included two randomized control studies and one cohort study.

Key words used in data sources include "intrauterine device," "ultrasonography," and "obstetrics and gynecology." All articles were published in English and in peer reviewed journals. Articles were searched via PubMed, Embase, and Cochrane database. Articles were selected based on relevance to the clinical question and if the outcomes were patient-oriented (POEMS). Inclusion criteria consisted of studies that were published within the last 10 years, primary research studies, and studies that had human participants. Exclusion criteria consisted of studies published in 2007 or earlier, systematic reviews, meta-analysis studies, and studies where IUDs were used in post-partum women. Summary of statistics that were reported included p-values and mean ± standard deviation scores. Table 1 reflects patient demographics and characteristics of included studies.

OUTCOME

All three studies measured patient-oriented outcomes with regards to pain during IUD insertion with ultrasound guidance. Ali et al. measured pain using the visual analog scale where 0 points indicated no pain and 10 points indicated worst pain.[3] Pain was measured at three separate times including after the use of surgical forceps, during IUD insertion, and immediately after IUD insertion.[3]

Table 1. Demographics and Characteristics of Included Studies

Study	Type	#Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Ali[3] (2017)	RCT	92	20-45	Women requesting Cu-IUD for contraception in accordance with WHO guidelines	Women with any uterine abnormalities as congenital anomalies, endometrial lesions, adenomyosis, fibroids, and intrauterine adhesions	5	Classic method of Copper T380A IUD placement VS. USSA method of Copper T380A IUD placement with TV/US using a SonoAce x6 machine with transvaginal probe
Dakhly[4] (2017)	RCT	102	18+	All females desiring IUD as a method of contraception and attending the University outpatient clinic	Those refusing to participate, defined as category 3 and 4 of the WHO medical eligibility criteria for contraceptive use or females who desired an immediate replacement for a removed IUD	0	TAS-guided IUD insertion VS. traditional IUD insertion
Christenson[7] (2015)	Cohort study	50	18-60	Women aged 18 yrs and older presenting to the clinic between 6/1/13 to 6/30/14 for the insertion of a copper IUD or LNG-IUS	Patients with known contraindications to IUD insertion, who were unable to provide informed consent, or who were unable to comply with the study protocol	2	Choice of IUD inserted using the simplified technique w/o bimanual exam or uterine sounding. Transvaginal ultrasonography was performed following insertion to ensure the IUD was located in the uterine cavity

Dakhly et al. also measured pain during the procedure using the visual analog scale in which 0 represented no pain and 10 represented worst possible pain.[4]

Christenson et al. measured pain using a 100-mm visual analog scale where one end of the scaled represented no pain and the opposite end represented worse pain imaginable.[7] Scores were collected 5 minutes post-insertion using REDCap software that converted participant's answers in a score between 0 to 100.[7]

RESULTS

Ali et al. presented their outcome as continuous data that was not able to be converted to dichotomous data.[3] The study initially interviewed 100 female participants between the ages of 20 and 45 years requesting Cu-IUD for contraception.[3] However, 8 women were excluded before the start of the study since 5 women were unwilling to participate in the RCT and 3 women did not have menses at the time of IUD insertion.[3] Of the 92 women, 46 participants were then randomized into each group which consisted of either a control group with IUD insertion via the classic approach or experimental group with IUD insertion using the uterine sound-sparing approach.[3] Women with congenital abnormalities, uterine adhesions, endometrial lesions, fibroids, and adenomyosis were excluded from the clinical trial (Table 1).[3] Two women were lost for follow up in the control group and three women were lost to follow up in the experimental group making the final 95.5% and 93.5% in the US group (Group I) and the classic insertion group (Group II) respectively for the final analysis.[3] The female participants in both the control and experimental groups had similar demographics with no significant differences.[3]

A bimanual examination was performed in both groups prior to IUD insertion.[3] The experimental group underwent transvaginal ultrasound by an experienced sonographer who measured the uterine length and the IUD insertion tube was adjusted accordingly.[3] A speculum

and vulsellum were then utilized by an experienced physician for IUD insertion into the uterine cavity.[3] The control group underwent the same process, however, these women underwent a uterine sound prior to IUD insertion without the transvaginal ultrasound.[3] Due to three cases of cervical stenosis and one case of unmanageable pain, failed IUD insertion occurred in four women from the experimental group.[3] Additionally, there were three failed IUD insertions from the control group due to cervical stenosis.[3]

A transvaginal ultrasound was later done for all women in both groups 4 weeks following the procedure in order to ensure correct IUD placement.[3] Women from both the experimental and control groups were asked to rate their pain on three separate occasions; immediately following placement of the vulsellum, during IUD insertion, and 5 minutes post-insertion.[3] A p-value was found based on reported pain scores using the Visual Analog Scale (VAS).[3] Data revealed that compared to women from the experimental group, participants in the control group reported higher pain scores during IUD insertion with a mean ± standard deviation of 5.7 ± 1.0 vs. 3.6 ± 1.1 respectively.[3] Additionally, women in the control group also reported higher pain scores 5 minutes post-IUD insertion with a mean ± standard deviation of 3.1 ± 0.8 vs. 1.7 ± 0.7 as compared to the experimental group.[3] These numbers reflect greater reduction in pain by the women who underwent ultrasound guidance with IUD insertion as evidence by the statistically significant p value of <0.0001.[3]

Table 2. Visual analog patient-reported pain mean ± standard deviation scores and p-values[3]

	Classic Approach (n-46)	**Uterine sound sparring approach with TV/US (n=46)**	**p-value**
After vulsellum	2.5 ± 0.5	2.2 ± 0.6	0.32
During IUD insertion	5.6 ± 0.5	3.2 ± 0.6	0.0001
5 min post-insertion	4.2 ± 0.7	2.1 ± 0.6	0.0001

Dakhly et al. presented their research as continuous data that was not able to be converted into dichotomous data.[4] One hundred and twenty-four females attending the university clinic were initially invited to participate in the study.[4] However, 19 females declined to participate and 3 did not meet inclusion criteria.[4] One hundred and two women desiring IUD for contraception were then randomized into two groups with 51 women in the experimental group and 51 women in the control group.[4] Women who refused to participate, were defined as category 3 and 4 of the World Health Organization (WHO) medical eligibility criteria for contraceptive use or desired an immediate replacement for a removed IUD were excluded from the study.[4] Both groups were similar in demographics and no statistically significant difference was seen with regards to age, parity, or prior history of IUD use when comparing both groups.[4] TCu 380A IUD placement for both groups were done at a university clinic by an experienced physician.[4] The experimental group was asked to have a full bladder prior to the procedure in order to get an adequate view of the uterus and facilitate IUD insertion.[4] An assistant then placed a trans-abdominal probe over the suprapubic region of female participants in the experimental group during IUD insertion ensuring proper placement within the uterine cavity.[4] The control group underwent the classic approach with uterine sounding for IUD insertion without trans-abdominal sonography.[4] Immediately after the procedure and removal of the speculum, participants were asked to rate their pain from the procedure using the visual analog scale.[4] Similar to the prior study, data from this randomized clinical trial was presented as mean ± standard deviation.[4] The TAS group produced a pain score of 2.4 ± 2.1 as compared with the traditional group which produced a pain score of 5.0 ± 1.7.[4] Results from this data resulted in a statistically significant p-value of <0.001.[4] Overall, female participants in the experimental group reported lower pain scores with TAS IUD insertion as compared to their control counterparts.[4] Failed IUD insertion occurred in 1 (1.9%)

and 2 (3.9%) female participants from the experimental and control groups respectively with a p-value of 0.99.[4] Failure of IUD insertion was attributed to failure of passage of the uterine sound and failure of IUD insertion through the cervical os.[4] Additionally, IUD misplacement was reported in 3 (5.9%) participants from the control group with a statically insignificant p-value of 0.24.[4]

Table 3. Visual analog patient-reported pain mean ± standard deviation scores and p-values[4]

	TAS guided IUD insertion (n=51)	**Traditional IUD insertion (n=51)**	**p-value**
Pain during IUD insertion	2.4 ± 2.1	5.0 ± 1.7	<0.001

Christenson et al. conducted a cohort study using continuous data that could not be converted into dichotomous data.[7] A total of 50 female participants 18 years or older attending the clinic at Stanford University were enrolled in the study and 2 women were lost to follow-up during the study.[7] Women who were not able to give informed consent, had contraindications to IUD insertion, or were unable to adhere to the protocols provided by the study were excluded from participating in the study (Table 1).[7] IUDs were placed by an experienced healthcare provider.[7] The mean age of all participants in the study was 29.9 years and the majority of women enrolled reported never having had children before.[7] During the simplified technique, the healthcare provider inserted the IUD directly into the fundus without uterine sounding.[7] Immediately after IUD insertion, transvaginal ultrasonography was utilized in order to ensure proper placement in the uterine cavity and help prevent IUD expulsion. If the IUD was found to be misplaced, it was immediately removed and replaced.[7] The participants were asked to report their pain score using the Visual Analog Scale during placement of the speculum prior to IUD insertion and again during IUD insertion.[7] As a result, the mean ± standard deviation pain score during speculum placement was 20.2 ± 17.4 and the pain score during IUD placement was 55.3

± 22.[7] The participants were then asked to return in 4 to 6 weeks for a post-insertion assessment.[7] Out of the total 47 participants available during the 4 to 6-week post-insertion follow-up, transvaginal ultrasound revealed proper IUD placement in 44 (94%) women.[7] IUD misplacement in the cervix was found in 5% and complete expulsion was found in 3%.[7]

Table 4. Visual analog patient-reported pain mean ± standard deviation score[7]

	Pain during speculum placement	**Pain during IUD insertion**
All participants (n=50)	20.2 ± 17.4	55.3 ± 22

DISCUSSION

Both randomized control trials performed by Ali et al. and Dakhly et al. concluded that the use of transvaginal ultrasonography during IUD insertion was effective in reducing pain in women.[3,4] Christenson et al. also utilized transvaginal ultrasonography after IUD insertion to ensure proper placement within the uterine cavity in a cohort study.[7] They concluded that using a simplified technique whereby omitting the bimanual exam and uterine sounding process, women reported less pain during IUD insertion as compared to similar studies.[7] Additionally, eliminating uterine sounding with IUD insertion may reduce part of the procedure cost associated with IUD placement which can be a barrier to access for some women.[7] The cost of IUDs can vary depending on what type of insurance a patient might have, not including the cost of IUD placement.[1] Uterine perforation, IUD expulsion, and IUD misplacement are all risks associated with IUD insertion.[3,4,7] However, ultrasound guidance prior to IUD insertion could potentially decrease the risk of uterine perforation.[4]

Limitations must be considered for all of the previously mentioned studies. Christenson et al. did not utilize uterine sounding during IUD insertion and then reported IUD misplacement in 5% and complete expulsion in 3% of female participants.[7] Additionally, Christenson et al. did not mention if these rates were a result of lack of direct visualization of the uterine cavity.[7] Ali et

al. reported that increased pain with IUD insertion may be associated with repetitive manipulation of the cervical os.[3] However, they failed to mention what procedures were associated with this pain.[7]

There were also limitations with regards to the cost of IUD insertion. All three studies failed to mention cost of IUDs along with the associated procedure cost.[3,4,7] Unfortunately, not many studies have been done evaluating pain in women who have IUD insertion with ultrasound guidance. Small sample size limits the generalizability of all three studies.[3,4,7] Dakhly et al. had the largest sample size with a total of 102 participants.[4] Additionally, only female participants were blinded in the randomized control trial by Dakhly et al. and not the physicians who performed the procedure.[4]

CONCLUSION

After evaluating two randomized control trials and one cohort study, the evidence supports that the use of ultrasound guidance with IUD insertion can reduce pain in women. Unfortunately, very few randomized control studies exist exploring the use of ultrasound guidance for the reduction of pain in women desiring IUD placement. Using larger sample sizes to include nulliparous females, women with intrauterine congenital abnormalities, and women living in the United States will strengthen evidence in future studies. Expanding on this research could prove beneficial for women who desire IUD placement for contraception but use pain as a barrier to care.

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