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### RESEARCH ARTICLE

#### COMPARATIVE EVALUATION OF PATIENT COMFORT AND PROCEDURAL EASE IN ULTRASOUND-GUIDED VERSUS CONVENTIONAL IUI

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#### Abstract

**Background:** The importance of both patient comfort and clinician ease during intrauterine insemination (IUI) has received relatively little attention to date. IUI, through the current conventional "blind" method, can result in pain, cervical trauma, and difficulty for the clinician. Ultrasound-guided IUI (USG-IUI) allows for real-time visualization, possibly resulting in less discomfort, and increasing clinician control. This study's objective, is to assess patient comfort and clinician ease to compare ultrasound-guided intrauterine insemination (USG-IUI) and conventional method intrauterine insemination (CM-IUI).

**Materials and Methods:** A prospective cohort study was conducted on 100 infertile women ( $\leq 35$  years) at the Infertility Clinic, Department of Obstetrics and Gynaecology, GIMS, Greater Noida. The women were randomized to two groups - USG-IUI (n=50) and CM-IUI (n=50). Controlled Ovarian Stimulation (COS) was performed using letrozole (2.5 7.5mg/day) and an hCG trigger. Patient pain was assessed immediately following insemination using a Visual Analog Scale (VAS). Procedural parameters were also recorded for difficulty with catheter insertion, use of tenaculum, bleeding and time taken. Data were analyzed in SPSS version 28.

**Results:** Of the 96 evaluated cycles, the average pain level for the USG-IUI group was significantly reduced ( $2.6 \pm 1.2$ ) compared to the CM-IUI group ( $5.4 \pm 1.3$ ,  $p < 0.001$ ). The perceived ease of the procedure was rated as "more than somewhat" easier by 65.3% of the USG-IUI group and 46.8% of the CM-IUI group. The ultrasound-guided group had a lower proportion that required a tenaculum and also performed fewer attempts to complete the IUI compared to the CM-IUI group ( $p < 0.05$ ). The completed length of the procedure was slightly longer for the USG-IUI group (3.3 min compared to 2.3 min,  $p < 0.001$ ), but patient comfort and clinician satisfaction were rated higher.

**Conclusion:** Ultrasound guided IUI significantly improves patient comfort and ease of the procedure while remaining safe. We recommend its routine use in order to spare the patient experience and to improve the clinician experience.

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## Introduction:-

In the management of fertility, the effectiveness of assisted reproductive modalities depends on not only their clinical usage but also the patient experience and the ease for the clinician to perform the procedure.[1] Given the modalities available in the management of infertility, intrauterine insemination (IUI) still sits in the middle ground between basic fertility management and advanced assisted reproductive technologies such as in vitro fertilization (IVF). Its low cost, low risk, and low invasiveness relates to its appropriate use in low-resource settings and government-funded fertility clinics in India.[2] Usually, IUI is completed as a blind procedure that requires the clinician to use touch alone to advance the catheter through the cervix and into the uterine cavity. While useful, in some circumstances, using touch may cause cervical trauma and uterine contractions or lead to bleeding, causing discomfort and pain for patients. This may prolong the procedure and may be particularly true for women with difficult cervical anatomy or retroverted uterus that could limit the caretaker's ability to effectively complete the clinical procedure without the use of tenaculum instruments, which can contribute to patient discomfort.

To address these difficulties, ultrasound guidance entered into the realm of IUI. The clinician has real-time visualization of the cervix and uterine cavity to assist in providing the best placement of the catheter into the uterus, and potentially minimizing unnecessary hand or body movements.[5] This is particularly important when the cervix has anatomical variabilities that might contribute to cumbersome tubing placement and discomfort. Ultrasound-guided IUI (USG-IUI), has been associated with improved pregnancy rates and tolerability of the IUI, and has been demonstrated to improve the ability of the clinician to perform the IUI procedure.[6] Research that is justified has been conducted in many parts of the world that compares ultrasound-guided IUI (USG-IUI) to IUI with conventional methods (CM-IUI) and reports secondary outcomes associated with pain related to the procedures, time to complete, and clinician-related issues. Overall, studies support that patients undergoing insemination ultrasound reported less pain score on the Visual Analog Scale (VAS) and report few if any insertions that were traumatic. Clinicians also comment the procedure is more controlled even if it takes longer to perform to allow for coordination with ultrasonography.[7]

Despite these findings, the data on the public healthcare use in India are limited when considering the impact of resource limitations, the patient load, and access to trained personnel on the procedure quality. The outcome assessment should critically consider patient-centered outcomes (patient comfort and satisfaction) and clinician-centered outcomes (procedure ease, and procedure duration) to support using ultrasound guidance in routine fertility practices.[8] We document a comparative assessment of patient tolerability and provider experience for either ultrasound guided or conventional IUI procedures based on findings from a prospective cohort study conducted at a tertiary teaching hospital in Greater Noida. By methodically assigning pain scores and documenting procedure duration, and technical difficulty, we substantiate the importance of clinical efficacy in the context of pain and patient comfort in this evolving landscape of reproductive medicine.

## Material and Methods:-

### Study Design and Location:

A prospective cohort analysis was conducted in the Infertility Clinic, Department of Obstetrics and Gynaecology, GIMS, Greater Noida over the duration of twelve months. The main aim of the study was to compare comfort for patients and convenience for the provider of ultrasound-guided IUI (USG-IUI) compared with conventional method IUI (CM-IUI). Women with infertility issues  $\leq 35$  years and with one or more patent fallopian tubes were included. Indications for treatment included unexplained infertility, anovulation, mild male factor, or mild endometriosis. Couples were excluded if they were found to have any of the following - bilateral tubal occlusion, uterine anomaly, endometriosis stage  $\geq 3$ , low ovarian reserve, chronic illness, or severe oligoasthenozoospermia. 100 couples were engaged through written consent (after randomization) and ethics approval through the Institutional Ethics Committee. Participants were randomized into two equal groups. Group I included women who had ultrasound-guided intrauterine insemination (USG-IUI) and Group II included women who had conventional method intrauterine insemination (CM-IUI). Controlled ovarian stimulation was initiated on cycle day 2 or 3 utilizing Letrozole 2.5-7.5 mg/day for 5 days. Follicular development was monitored via transvaginal sonography and once a leading follicle reached a size of  $\geq 18$  mm with an endometrial thickness  $\geq 7$  mm, the patient was triggered to ovulate with 5,000 IU of hCG intramuscularly. The IUI procedure was then performed 36 hours after the trigger. Semen samples were retrieved through masturbation following a three-day abstinence period. The samples were then subjected to density-gradient centrifugation for the separation of motile spermatozoa, with approximately 1 ml of motile spermatozoa suspension applied for insemination.

For the USG-IUI group, insemination was completed utilizing transabdominal ultrasound imaging with a patient having a bladder that was not completely full to visual uterine axis and catheter tip in real-time to ensure accurate intrauterine deposition with reduced trauma and manipulation to the uterus. In the CM-IUI group, insemination was completed without ultrasound; thus, the clinician relied on tactile sensation alone to guide the catheter tip from the cervix into the uterine cavity. Following insemination, all patients were instructed to remain supine for 15 minutes, and luteal phase support was provided with vaginal progesterone 300 mg twice a day. Patient comfort was the primary outcome measure assessed immediately after the procedure using a Visual Analog Scale (VAS) (1 = no pain; 10 = very painful). The second outcome measure assessment for provider difficulty was by recording the number of attempts to cannulate the cervix, with or without a tenaculum or vulsellum, blood on the catheter tip, and the duration of the procedure in minutes. Analysis was performed using SPSS version 28. Continuous data that were time and VAS scores were reported as means  $\pm$  standard deviation and compared using the Student's t-test, categorical data, procedural difficulty, bleeding, were reported as a percentage and compared by the Chi-square test. Statistical significance was determined by p-value  $\leq 0.05$ .

## Results:-

One hundred women with infertility were recruited, 50 in each treatment group (USG-IUI and CM-IUI). Four participants were lost to follow-up, resulting in 96 evaluable cycles (49 in the USG group and 47 in the CM group).

### Demographic and Clinical Characteristics at Baseline:-

The two treatment groups were similar in their age, body mass index, duration of and type of infertility ( $p > 0.05$ ), thus assuring valid comparison with respect to procedural comfort and ease (Table 1).

**Table 1. Baseline Profile of Participants**

Parameter	USG-IUI (n=49)	CM-IUI (n=47)	p-value
Mean Age (years)	28.6 $\pm$ 3.5	29.0 $\pm$ 3.1	0.61
BMI (kg/m <sup>2</sup> )	25.5 $\pm$ 2.5	26.0 $\pm$ 2.9	0.45
Duration of Infertility (years)	3.2 $\pm$ 1.4	3.4 $\pm$ 1.6	0.48
Primary Infertility (%)	71.4	65.9	0.53
Unexplained Infertility (%)	38.8	42.5	0.68

### Patient Comfort (Pain Perception):-

Immediately after the procedure, pain was assessed with the Visual Analog Scale (VAS) (1–10). Patients who received USG-guided IUI demonstrated significantly less pain (mean 2.6  $\pm$  1.2) compared to the patients in the conventional group (5.4  $\pm$  1.3) ( $p < 0.001$ ).

**Table 2. Pain Intensity and Distribution (VAS Score)**

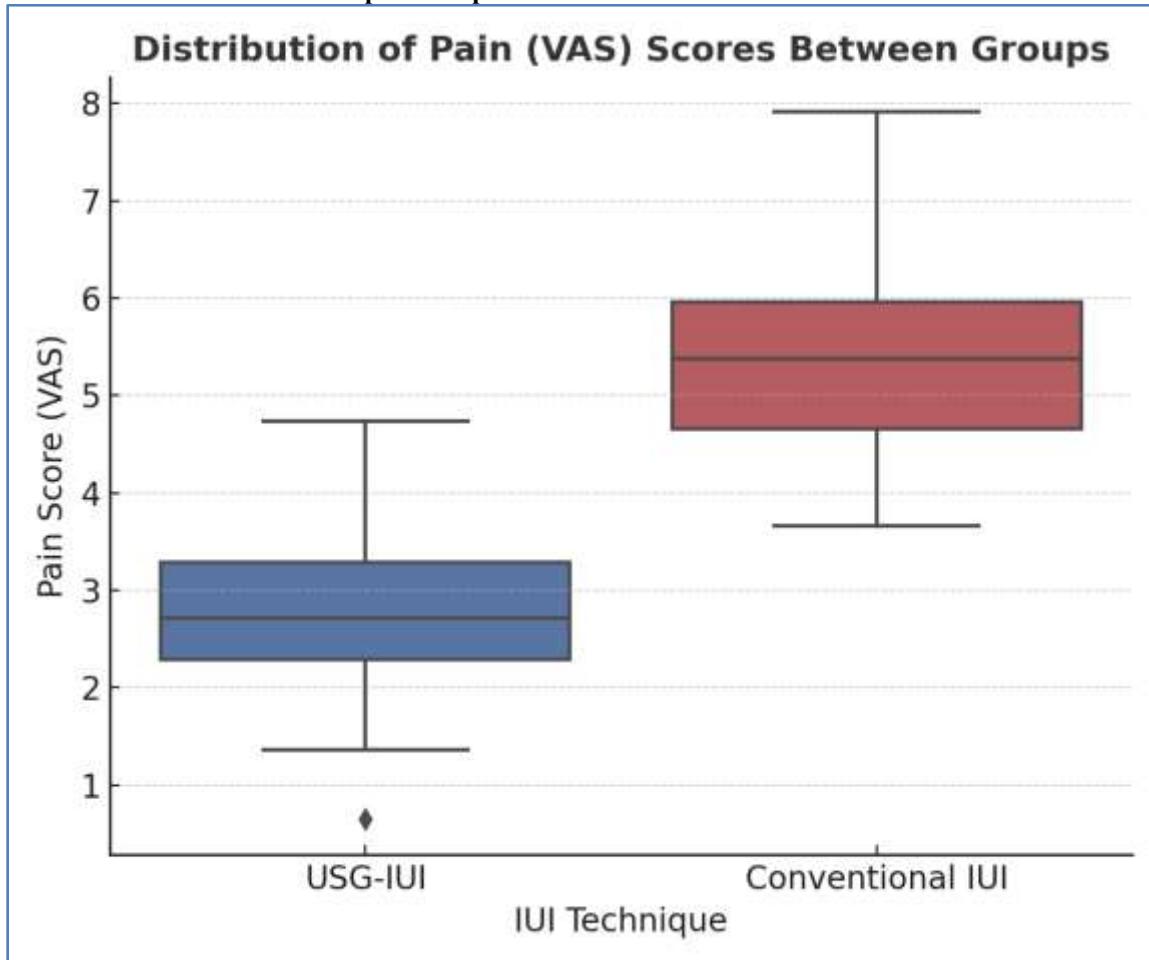
Pain Category	VAS Range	USG-IUI (n=49)	CM-IUI (n=47)
Mild	1–2	21 (42.9%)	3 (6.4%)
Moderate	3–4	26 (53.1%)	12 (25.5%)
Severe	5–6	2 (4.0%)	31 (66.0%)
Very Severe	>6	0	1 (2.1%)

**Procedural Difficulty and Clinician Experience:-**

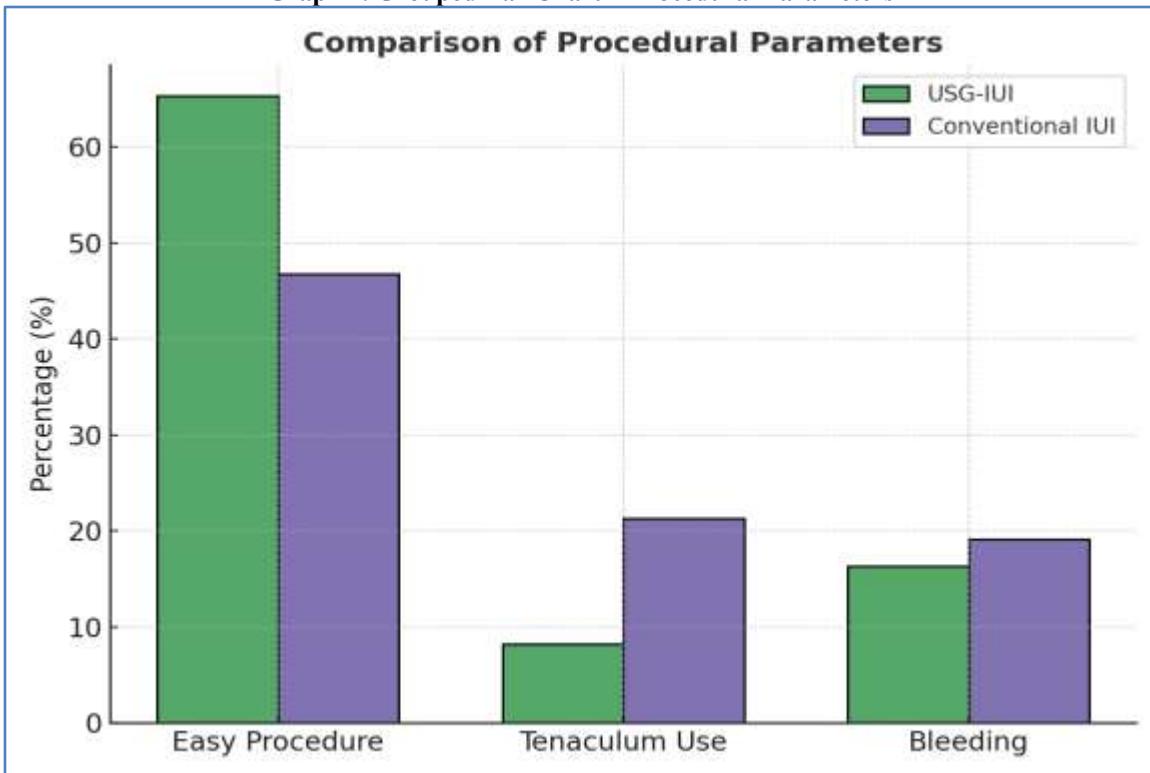
The convenience of catheterization, the number of attempts, utilization of tenaculum, and procedure time were all compared. Although procedure time was slightly longer for USG-IUI ( $3.3 \pm 0.2$  min vs  $2.3 \pm 0.2$  min), clinicians rated it easier to use and smoother in 65.3% of cases.

**Table 3. Comparison of Procedural Parameters**

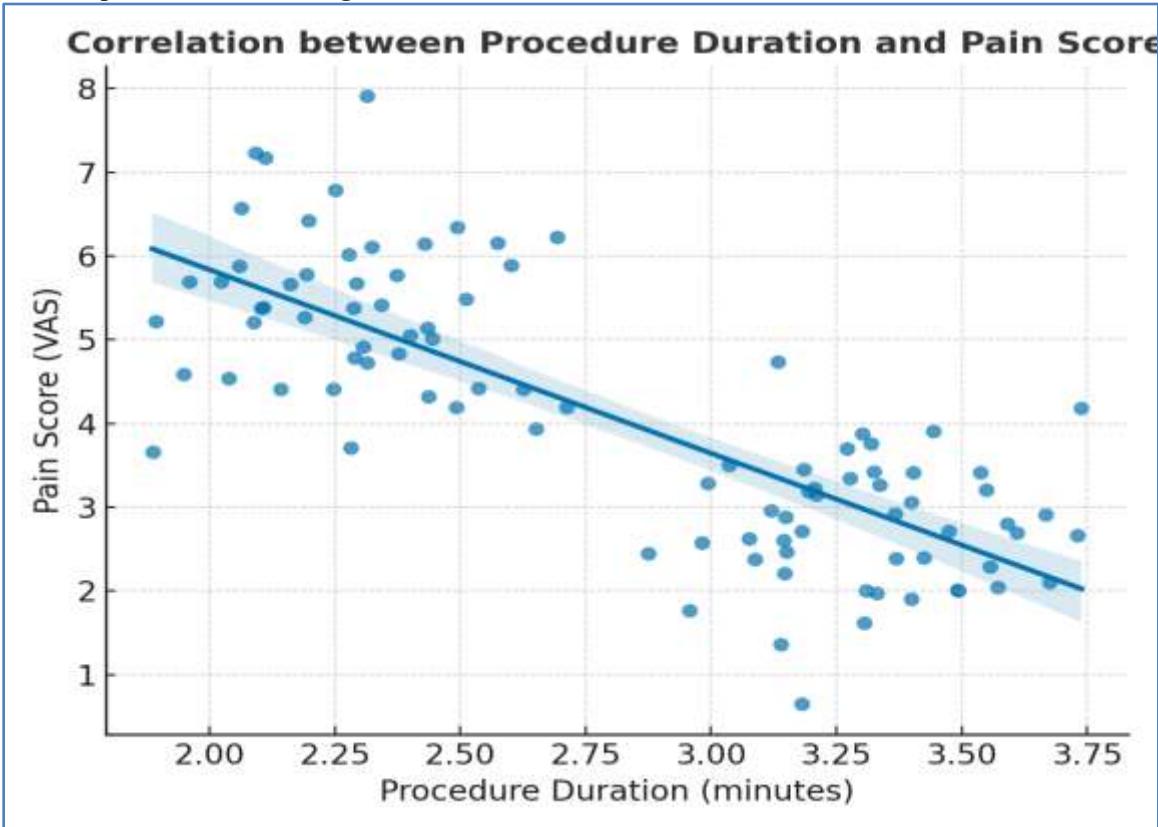
Parameter	USG-IUI (n=49)	CM-IUI (n=47)	p-value
Easy Procedure (%)	65.3	46.8	0.067
Tenaculum Use (%)	8.2	21.3	0.04
Bleeding on Catheter (%)	16.3	19.1	0.71
Duration (minutes)	$3.27 \pm 0.20$	$2.30 \pm 0.23$	<0.001
Multiple Attempts Required (%)	10.2	27.7	0.03

**Graph 1. Boxplot – Distribution of Pain Scores**

Graph 2. Grouped Bar Chart – Procedural Parameters



Graph 3. Scatter with Regression – Correlation between Pain Score and Procedure Duration



**Discussion:-**

This prospective study investigated the influence of ultrasound guidance (USG) on the clinicians' ease and patient comfort level experienced with intrauterine insemination (IUI). Pain perception was statistically lower for the USG-IUI group (mean VAS  $2.6 \pm 1.2$ ) vs the conventional method ( $5.4 \pm 1.3$ ,  $p < 0.001$ ). Clinician's assessed the procedure easier among the ultrasound guidance (65% USG-IUI patients felt the procedure was easy compared to only 47% for conventional), decreased their use of tenaculum, and made less multiple attempts. These findings are consistent with Kumar et al. (2018) and Maher et al. (2020) demonstrating transabdominal ultrasound guidance reduces cervical manipulation and results in lower pain scores and a more efficient catheterization.[9,10] Yavangi et al. (2014) showed ultrasound guided insemination significantly improved discomfort during the insemination; patient satisfaction, while also noting no significant difference in pregnancy outcome. [11]The proposed rationale for why these improvements occurred is an improved alignment of the catheter with the axis of the uterus for the procedure, less probing in a blind fashion, and fewer uterine contractions. Seeing the catheter tip allowed us to insert the catheter more gently, and we did not need to use force, while the elimination of use of instruments such as tenacula, minimized all possible discomfort. In our study, we demonstrated that the percentage of cases requiring this additional instrument decreased from 21 % during the conventional method to 8 % using ultrasound to guide the catheter ( $p=0.04$ ).

Although the mean time of the procedure was slightly longer in the ultrasound group (3.3 minutes vs. 2.3 minutes;  $p < 0.001$ ), we presume this increase in time is warranted as both patient comfort and control during the procedure was greatly improved. Moreover the strong correlation between intensity of pain and time of procedure ( $r=0.72$ ;  $p < 0.001$ ), underscores our conclusion that the increased complexity of the task is likely increasing discomfort. Our results are in line with those of Abdalla et al. (2012), where the authors indicated that ultrasound guidance provides a situation which is more favorable for patient compliance and relaxation, allowing for a more tranquil atmosphere in which procedures can be performed.[12] Similarly, Al-Inany et al. (2016) noted that ultrasound guidance could decrease anxiety and pain, which may in turn, improve the odds of uterine receptivity.[13]We also noted that procedural bleeding was slightly lower in the USG-IUI group (16%) than in the CM-IUI group (19%), although this was not statistically significant. This correlates with the finding of Rashidi et al. (2013), who reported a higher incidence of traumatic placements of the catheters with the blind technique.[14]Viewing the cervix and uterine cavity in real-time, from the physician's viewpoint, revitalizes confidence, particularly in inexperienced trainees and a distorted uterine anatomy. Viewing the cervix and uterine cavity renders the IUI procedure relevant to "precision-based" versus just "feel-based". The learning curve is small and the benefit the patient and the practitioner receive is substantial.

Strengths of this study include a prospective design, a standard assessment tool (VAS), and quantifiable operator feedback. Limitations include a single-center setting, sample size, and subjectivity in pain scoring. However, the fact that these results correlate with previous literature adds to the credibility and strength of the conclusions. Clinical significance: The comfort of patients is now a fundamental measure of quality of care in contemporary reproductive medicine. While the ultrasound-guided IUI may add time to the procedure, it will help mitigate pain and discomfort, all of which promotes patient compliance and satisfaction - qualities which have been found to be associated with psychological health and continuation of care. The ultrasound-guided insemination process has evidenced several advantages in improving the patient's experience, including reduced discomfort, as well as greater control for the clinician. This process will inevitably take slightly longer than a non-ultrasound guided IUI, but the benefit of the patient's ease and overall satisfaction for the clinician is invaluable. Therefore, using ultrasound in care delivery for insemination is warranted for patient-centered and provider-centered outcomes. Moreover, the recommendations which stem from this pilot study involves encouraging randomized controlled studies looking at patient satisfaction, cost-benefit analysis, and long-term reproductive outcomes in order to solidify supporting evidence and implement ultrasound-guided IUI standard practice in gynecologic reproductive medicine.

**Conclusion:-**

The current study showed that ultrasound-guided intrauterine insemination (USG-IUI) significantly improves patient comfort and makes the procedure easier for the operator compared to the traditional blind technique. The average discomfort score (VAS) was much lower in the ultrasound-guided group ( $2.6 \pm 1.2$ ) than in the conventional group ( $5.4 \pm 1.3$ ;  $p < 0.001$ ). This indicates a clear benefit for patients. Moreover, the ultrasound-guided procedure required fewer attempts, less cervical instrumentation, and less tenaculum use (8.2% vs 21.3%), confirming USG superiority in ease of performance. The mean time for the procedure was slightly longer for USG-IUI, 3.3 min versus 2.3 min;

however, the improvement in comfort and control for the clinician outweighed the increase in duration for the procedure. Further, the positive correlation between pain score and difficulty score further emphasizes the subtle interplay between precision procedure and patient comfort. Findings of this study are also in concert with results from previous studies from other geographical regions; these findings support the concept of reproducibility as one definite advantage of ultrasound guided interventions over the conventional blind technique. However, aside from potential clinical benefits of using a superior technique for intrauterine insemination, other factors such as patient satisfaction, less anxiety, and compliance with continued fertility treatments, which indirectly impact longer-term outcomes, may be influenced.

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