Virtual Reality for analgesia during intrauterine device insertion: A randomised controlled trial

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Table of Contents

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Abstract

Background: Intrauterine devices (IUD) are safe and effective contraceptive therapies which are also used for treatment for heavy menstrual bleeding, endometrial hyperplasia and early-stage endometrial cancer. Barriers to insertion of IUDs in the outpatient setting are predominantly due to patient discomfort and there is little consensus on effective analgesic strategies to address this. Virtual reality (VR) has demonstrated moderate benefits in acute pain management and has been explored for similar gynaecological procedures including outpatient hysteroscopy with some promising results.

Objective: To explore the effectiveness of VR at improving patient pain and anxiety during outpatient IUD insertion.

Methods: This randomised control trial compared the use of a VR headset to standard care during IUD insertion in the outpatient clinic setting. Outcomes measured were patient reported pain and anxiety. Secondary outcomes included clinician reported ease of insertion and time required to complete the procedure.

Results: A total of 70 patients were recruited with 34 randomised to the control and 36 randomised to VR headset use. Patients with VR headsets reported a pain score of 5.5 +/- 3.2 during IUD insertion, which was not significantly different to 4.3 +/- 3.2 for the control group. Anxiety scores during the procedure were 4.0 +/- 3.0 in the VR group, compared to 4.8 +/- 3.5 in the control group, which was also not significantly different. Anxiety was the most significant predictor of pain and this in turn significantly increased insertion time ($p < 0.001$). Of the patients who did respond and benefit from VR use, their baseline anxiety was significantly less than in those who did not ($p < 0.05$).

Conclusions: The use of VR headsets did not significantly alter the pain or anxiety experienced by patients during IUD insertion, however satisfaction and recommendation that others use VR was high which may suggest other benefits to their use. Additionally, pre-procedural anxiety appears to have a significant adverse impact on pain scores and the ability of patients to benefit from the VR headsets. This importantly contributes to the previously ambiguous data regarding VR use for gynaecological procedures and highlights a new important avenue for further research into alleviating anxiety prior to procedures to improve pain and patient experience. Clinical Trial: Australia and New Zealand Clinical Trial registration: ACTRN12622000088741p. https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=383191

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Original paper

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ABSTRACT

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Conclusions: The use of VR headsets did not significantly alter the pain or anxiety experienced by patients during IUD insertion, however satisfaction and recommendation that others use VR was high which may suggest other benefits to their use. Additionally, pre-procedural anxiety appears to have a significant adverse impact on pain scores and the ability of patients to benefit from the VR headsets. This importantly contributes to the previously ambiguous data regarding VR use for gynaecological procedures and highlights a new important avenue for further research into alleviating anxiety prior to procedures to improve pain and patient experience.

Trial registration: ANZCTR Trial registration: ACTRN12622000088741p. https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=383191

Keywords: Virtual reality, intrauterine device, pain, anxiety.

Introduction

Intrauterine devices (IUD) are extremely effective long-acting reversible contraceptives, which have been shown to be safe and convenient [1-4].
Levonorgestrel IUDs are also used as minimally-invasive and fertility-preserving management options for gynaecological conditions including heavy menstrual bleeding, endometrial hyperplasia and early stage endometrial cancer [5].

Despite being the most used reversible contraceptive method globally and having substantial potential benefits, IUDs continue to be underutilised in many settings including developed countries [4,6]. Several barriers to IUD use have been hypothesised, namely accessible and acceptable insertion for patients [2,4]. Other barriers include misinformation of IUD risks, access to appropriate insertion clinics and clinician perspectives [2,4].

Gynaecological procedures including IUD insertions are increasingly being undertaken in the outpatient clinic setting. The outpatient setting is cheaper, more convenient and avoids the risks of a general anaesthetic or procedural sedation for patients [7]. Despite being more accessible, insertion in this setting is associated with patient discomfort and anxiety with pain scores usually ranging from 5-7 out of 10, which is a significant barrier to patient acceptability [2,8,9]. IUDs can be inserted for most outpatients, including nulligravida and patients with previous caesarean section [10].

Some may propose insertion of IUD in the operating theatre under general anaesthesia or procedural sedation. While this does alleviate patient anxiety and discomfort, health service cost and access to operating theatres is prohibitive for this to be routine practice [11]. Compounding these reasons, difficulty of access of operating theatres during the pandemic, and the constant requirement to keep operating theatre time as training opportunities for junior doctors, the incentive to optimise the experience of outpatient insertion of IUD is as strong as ever [11].

Several pain scales exist and can be used to quantify the pain intensity from IUD insertion including the Visual Analogue Scale (VAS), the Verbal Rating Scale (VRS) and the Numerical Rating Scale (NRS)[12]. The VAS is reliable, valid and is sensitive to subtle differences and changes in pain intensity[12]. For this reason, it is the most consistently used tool[13] and has been utilised in prior studies of discomfort associated with IUD insertion [3,5]. VAS differences of 10mm are considered clinically significant from previous studies [14,15].

Predictors of IUD insertion pain include nulliparity, remoteness from last pregnancy, dysmenorrhoea, anticipation of IUD pain and anxiety and IUD type used (levonorgestrel being more painful than copper)[3,16]. A search of the literature yielded no articles comparing brands of levonorgestrel IUDs and their associated pain at insertion.

There is currently no consensus regarding analgesic of choice during IUD insertion. Previously studied methods include oral or intravenous sedation, local anaesthetic topically or as a cervical block, oral analgesics and distraction techniques [7]. Common techniques such as NSAIDs, misoprostol, local anaesthetic gel and intrauterine instillation of local anaesthetic have been found to be ineffective [1-3, 6, 17]. Paracervical local anaesthetic injections have been suggested to be of some benefit during insertion, however the injections themselves are not

without discomfort [1]. Tramadol and naproxen have shown possible benefits in small numbers in studies exclusively investigating nulliparous women, however this was not replicated in follow up studies [2,16,17]. Further options need to be explored to improve acceptability and patient uptake.

Virtual reality (VR) is gaining momentum as a novel non-pharmacological pain relief option, and its potential role in healthcare is increasingly relevant, as technological developments have improved its accessibility [18].

VR creates an immersive virtual environment for the user [7]. It can be delivered using a range of hardware, most commonly in the form of a head mounted display with built-in headphones. It can present as an active virtual reality where participants interact with the content such as in games, or passive virtual environments such as movies. It has been suggested that active VR may have stronger analgesic properties than passive [18].

VR has demonstrated moderate benefits in acute pain management including burns, labour, dressing changes and periodontal procedures [19]. Reported side effects of VR are infrequent, mild and self-limiting. They include nausea, vomiting and eyestrain, collectively referred to as 'cybersickness' [18]. If any of these events occur, the headset can be removed with rapid resolution of symptoms.

The possible benefits of VR in pain relief and peri-procedural anxiety, combined with its minimal risks to patients, highlight the potential of this method and hence the need for further exploration of its use and cost-effectiveness in various settings [7,18,19]. Despite its initial promising results, it has been hypothesised that the effectiveness of VR is not generalisable. The benefits likely vary significantly between patient populations and indication for use, such that studies in specific settings are recommended [18].

A search of the literature for VR use in IUD insertion yielded only two research trials. One randomised controlled study performed in France with 50 patients per group found no change in perceived pain in women using VR therapy compared to those without, but rather noted the strongest predictor of pain being pre-procedure anxiety [20]. The second study performed in Scotland had directly contradicting results demonstrating an improvement in pain, anxiety and satisfaction scores in those using a VR headset compared to the control group with 40 patients in each group [21].

Research performed on other similar gynaecological procedures such as outpatient hysteroscopy disagree on whether pain scores are improved, but show promising improvements in anxiety and patient satisfaction associated with the use of VR [7, 22, 23].

The objective of this study was therefore to explore the impact of VR on patient's pain during IUD insertion in a tertiary gynaecology hospital setting in Australia. Secondary aims included the effect of VR on patient anxiety and ease of IUD insertion, while also assessing the feasibility of introducing this as an analgesic method in the outpatient gynaecological setting.

Methods

Recruitment

In this single-centre randomised control trial, patients attending for IUD insertion in the

outpatient gynaecology clinic were screened for eligibility. Patients were eligible if aged 18 years and over and able to provide written informed consent. Patients were excluded if they had contraindications to IUD insertion, a history of epilepsy or vestibular disorders contraindicating VR use, an inability to consent, or if they had taken prescription pain relief prior to the procedure (simple analgesia was permitted).

Patients were randomised on the day of IUD insertion in the outpatient clinic to either the intervention group (addition of VR to standard care) or control group (standard care). A computerised random sequence was generated with allocations then placed in sequentially numbered opaque envelopes by a blinded third party, which were opened only once participants were enrolled to the study by the researcher, who was not otherwise involved in the patient's care. Participants were not paid for their participation. Given the nature of the intervention, blinding was not possible.

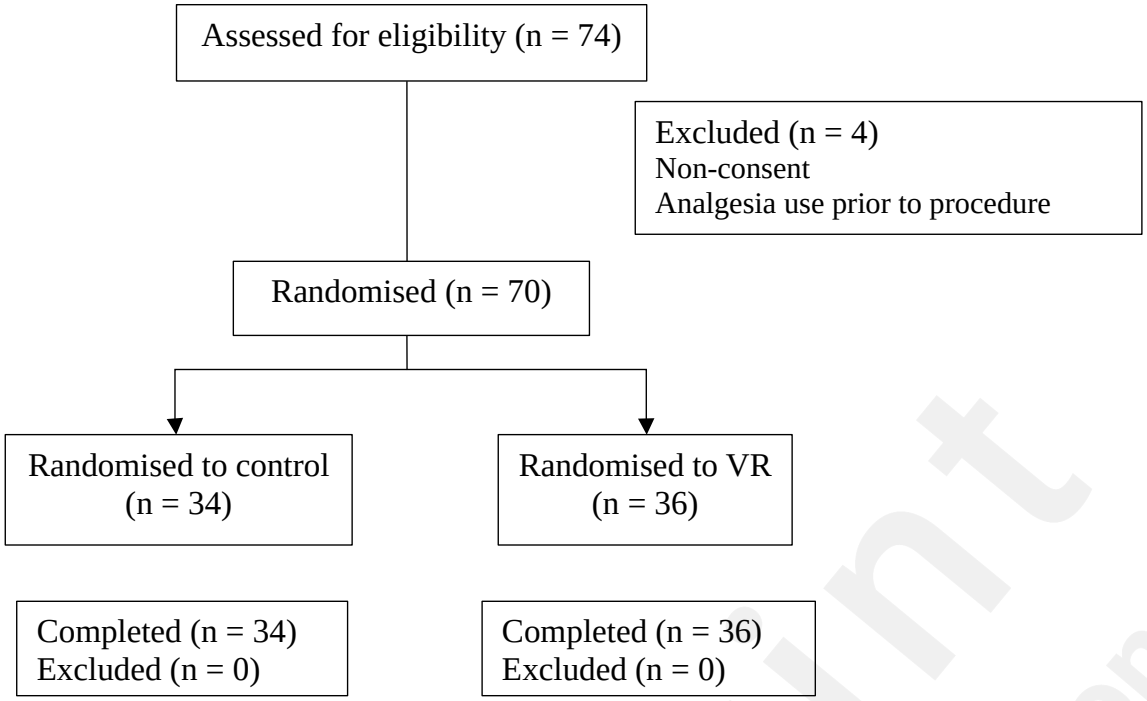
Participant flow has been described in Figure 1.

Virtual reality digital content was delivered via smartphone and headset during IUD insertion procedure. The content provided a relaxing 3-dimensional interactive environment of seals swimming with some gentle classical music. Standard care included occasional use of a lignocaine spray to the cervix according to clinician preference and this was therefore recorded as part of the data collection.

Patient demographic information was collected. In addition, patients were asked to complete a VAS of their anxiety prior to the procedure, their pain and anxiety during the procedure, as well as a questionnaire on their satisfaction, recommendations and side effects after the procedure. The time required for IUD insertion, clinician reported ease of insertion on a scale of 1 to 5, and number of attempts required for successful IUD insertion were also reported.

The study was approved by Monash Health Ethics Committee, Clayton, Victoria, Australia. Ethics Approval Reference number 80700, Monash health reference number RES-21-0000-690A. Australia and New Zealand Clinical Trial Registry: ACTRN12622000088741p.

Figure 1. CONSORT diagram of participant inclusion and exclusion



Statistical analysis

Statistical analyses were conducted in SPSS 25. Significance was defined as a *P*-value less than .05. Two-tailed t-tests were performed for group-wide comparisons.

Power calculations

For our power calculation we assumed an equal standard deviation of 14mm in VAS pain scores between groups based on previous studies of VAS pain scores in women with chronic pelvic pain. To achieve 80% of detecting a 10mm difference between groups with a type 1 error rate of 0.05, we required a sample size of 31 in each group. Accounting for a compliance rate of 90% we aimed for a sample size of 70 participants.

Results

Of the 70 patients enrolled in the study, there were 34 in the control group and 36 in the VR intervention group. Their baseline characteristics are outlined in Table 1.

There was no significant difference in maximal intraprocedural pain scores with the use of VR headsets (Table 2). Similarly, pre-procedural and intra-procedural anxiety scores did not significantly differ (Table 2).

The use of VR headsets also did not appear to have a significant impact on the IUD insertion process as clinician reported ease of insertion, time to insertion and number of insertion attempts did not differ (Table 3).

Satisfaction with use of VR headsets was overall high (mean 7.3 out of 10, SD 2.99) and recommendation scores for use of VR headsets were also high (mean 8.35 out of 10, SD 2.24). Satisfaction and recommendation were highly correlated and a high satisfaction score was weakly associated with lower intraprocedural anxiety scores (r = 0.33, *P*=.06).

Pre-procedural anxiety was significantly correlated with intra-procedural anxiety (P <.001). Overall, anxiety was the most significant predictor of pain during insertion (P = .001). Higher pain was also a significant predictor of increased procedural time (P <.001).

Subgroup analysis was performed to isolate the patients who most benefit from VR. Responders to VR with pain scores of less than or equal to 5 were compared with non-responders (those with pain scores greater than 5). The characteristics of these groups were markedly different with significantly lower pre-procedural and intra-procedural anxiety in the responders than non-responders (P < .05).

There were no significant adverse effects experienced with the use of the intervention, with only one patient reporting nausea after IUD insertion.

Table 1. Baseline population characteristics

	Control (n = 34)	VR (n = 36)
Age (mean ± SD)	34 ± 6	36 ± 7
BMI	30 ± 8	31 ± 7
Gravida	2	2
Parity	2	2
Previous vaginal deliveries	1 ± 1	1 ± 1
Time since last vaginal birth in years (IQR)	1.5 (0.21 – 3.25)	0.58 (0.19 – 4)
Previous cervical instrumentation %(n)	32% (11)	14% (5)
Anatomical distortions	18% (6)	17% (6)
Prior IUD	29% (10)	42% (15)
Previous VR use	9% (3)	30% (11)
Use of analgesic spray	32% (11)	28% (10)
Indication for IUD - Contraception - Anormal bleeding - Both	 94% (32) 0% (0) 6% (2)	 75% (27) 14% (5) 6% (2)
Mental health history	15% (5)	17% (6)
Chronic pain history	0% (0)	14% (5)

Table 2. Patient pain and anxiety outcomes

mean ± SD	Control (n = 34)	VR (n = 36)	P value
Pain score	4.3 ± 3.2	5.5 ± 3.2	.15
Anxiety prior to procedure	4.2 ± 2.8	4.6 ± 3.1	.56
Anxiety during procedure	4.8 ± 3.5	4.0 ± 3.0	.37

Table 3. Effect of VR use on IUD insertion

mean ± SD	Control (n = 34)	VR (n = 36)	*P* value
Number of attempts to successfully insert IUD	1.09 ± 0.59	0.94 ± 0.65	.73
Clinician reported ease of insertion (1-5)	2.75 ± 1.48	2.75 ± 1.63	.41
Time for insertion (min:sec)	12:06 ± 0:04	12:06 ± 0:02	.61

Discussion

Despite the many benefits of IUDs, patient discomfort is a significant barrier to accessing outpatient insertion [2,4]. There is little evidence and no clear consensus on the best methods of addressing this discomfort without this being performed under a general anaesthesia, which itself presents costs and risks [11].

As VR grows in its implementation in the healthcare space, several studies have recently been published on its use in outpatient gynaecological procedures. The existing body of evidence relating directly to IUD insertion is scant and contradictory, with the study by Benazzouz *et al*. directly contradicting the evidence from Oz *et al.* [20,21]. This therefore highlights the need for further studies on the topic.

This study is the first one to evaluate the use of VR for IUD insertion in an Australian setting. Its prospective design and randomisation are strengths and add to the sparse body of literature and hopefully will contribute to the debate regarding use of VR in outpatient gynaecological procedures. We enrolled a representative sample of individuals who would be seen for IUDs in an Australian tertiary hospital context. Other strengths include real life, broad inclusion criteria.

Although we found no significant difference in anxiety or pain with the use of VR headsets for IUD insertion, this does not exclude their usefulness in other gynaecological procedures or in other aspects of the patient experience.

Interestingly, despite pain and anxiety scores not significantly differing between the two groups, the VR headsets may have other benefits. Firstly, satisfaction and recommendation for the VR headsets was overall very high demonstrating patient appreciation of these devices. Secondly, patients were provided with the opportunity to comment on their experience and those that did were overwhelmingly positive. Patients particularly highlighted that they appreciated the distraction provided by the headsets, with one patient reporting the distraction was helpful for anxiety, while others stated the distraction helped them to forget about the procedure. Although difficult to quantify, this implies further benefits which may improve acceptability of outpatient IUD insertion despite the lack of improvement in pain scores. It is additionally possible that further optimisations in the VR system may result in a different result.

The VR intervention was effective and well received in a subpopulation, particularly those with elevated anxiety. This study was practically oriented and therefore purposefully limited the data instruments that were collected. In turn this limited our ability to more deeply understand

which subpopulations might benefit from this intervention, and equally, those that would not. This would be an important area for future studies.

Limitations

Although the intent of randomisation is to produce confounder balance, there were apparent differences. The indications for IUD numerically differed between groups and the VR group appeared to have had fewer individuals who had previously undergone cervical instrumentation and more individuals with chronic pain. These may have affected the self-assessment of subjective experiences such as pain, anxiety and satisfaction. Baseline characteristics in both groups were compared across a wide spectrum of patient factors, however it is also possible that other potential unmeasured confounders may impact on subjective reporting such as an unmeasured history of substance use.

Further factors which may have influenced results include technological characteristics of the selected headset, and as VR is a behavioural technique, the therapeutic alliance between practitioner and patient.

This was a single-centre study with multiple operators so results may not apply to other operators or populations however, the outcomes observed are plausible and concordant with other data. Due to the nature of this VR intervention, blinding of both clinicians and patients was not feasible which increases the possibility of introduction of biases. Finally, despite a formal power calculation, we cannot exclude the possibility that this study was underpowered.

Conclusions and future directions

Importantly, this study found that the most significant predictor of pain was patient anxiety, consistent with Bennazouz and coworkers and the broader VR literature [20]. This also predicted the patients who would benefit from VR use with reduced pain scores. This implies that efforts should be focused on managing patient anxiety prior to IUD insertion as a method of alleviating patient pain and there may be a role for VR in the anxiety-reducing pre-procedural setting. Ultimately, the goal to facilitate timely, more tolerable outpatient IUD insertions remains a clinical and research priority.

Acknowledgments

Nil

Conflicts of interest

Author Dr Paul Leong is a co-founder of Smileyscope pty ltd.
The virtual reality headset was provided by Smileyscope pty ltd.
No financial funding was received for this study.

Abbreviations

VR: virtual reality
IUD: intrauterine device
VAS: visual analogue scale

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Supplementary Files

Study Protocol.
URL: http://asset.jmir.pub/assets/7b7032816f3d35f10f5e9556cfb90600.pdf

CONSORT (or other) checklists

CONSORT Checklist.
URL: http://asset.jmir.pub/assets/eeebe1a6deee689d6182028c6417935e.pdf