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The Efficacy of Vibrational Anesthesia in Reducing Pain and Anxiety among a Single Rod Contraceptive Implant Recipient: A single-blinded randomized controlled trial

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ABSTRACT

Objectives: To evaluate the effectiveness of vibration anesthesia in reducing pain and anxiety in the group receiving single rod contraceptive implant recipient (SRCI).

Materials and Methods: This study was a single-blinded, randomized, controlled trial. Forty-five women were randomly assigned to the experimental group and forty-five women to the control group. The control group had SRCI using the standard method. However, the experimental group received vibrational anesthesia during the implantation. The study variables were general information, the numeric rating scale, and the state-trait anxiety inventory (STAI) form Y-1 questionnaire.

Results: The median pain score of the experimental group was 2 (1-2), while that of the control group was 4 (3-4). There was a statistically significant difference ($p < 0.01$) in the pain scores. Thirty-six cases (80.0%) in the experimental group showed low anxiety levels compared to no cases in the control groups ($p < 0.01$). No adverse events were reported.

Conclusion: Vibrational anesthesia during SRCI may reduce pain and anxiety among the recipients.

Keywords: vibrational anesthesia, single rod contraceptive implant recipient, pain, anxiety.

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ประสิทธิภาพของการระงับความรู้สึกแบบสั่นสะเทือนเพื่อลดความเจ็บปวดและความวิตกกังวลในกลุ่มที่มารับบริการฝังยาคุมกำเนิดแบบแท่งเดียว: การทดลองปกปิดทางเดียวแบบสุ่มและมีกลุ่มควบคุม

น้ำผึ้ง นันทวงศ์

บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาประสิทธิภาพของการระงับความรู้สึกแบบสั่นสะเทือนเพื่อลดความเจ็บปวดและความวิตกกังวลในกลุ่มที่มารับบริการฝังยาคุมกำเนิดแบบแท่งเดียว*

วัสดุและวิธีการ: *การศึกษานี้เป็นการทดลองแบบสุ่มและมีกลุ่มควบคุมโดยปกปิดทางเดียว โดยใช้วิธีการสุ่มเข้ากลุ่มทดลอง 45 ราย และกลุ่มควบคุม 45 ราย กลุ่มควบคุมได้รับวิธีการฝังยาคุมกำเนิดแบบมาตรฐาน กลุ่มทดลองได้รับการประยุกต์ใช้การระงับความรู้สึกแบบสั่นสะเทือนระหว่างรับบริการฝังยาคุมกำเนิด ตัวแปรในการศึกษาได้แก่ ข้อมูลทั่วไป คะแนนความเจ็บปวด visual analog scale (VAS) และแบบสอบถามความวิตกกังวลขณะเผชิญ (The state-trait anxiety inventory (STAI) form Y-1)*

ผลการศึกษา: *เมื่อเปรียบเทียบระหว่างกลุ่มพบว่าค่ามัธยฐานคะแนนของความเจ็บปวดของกลุ่มทดลอง 2 (1-2) และกลุ่มควบคุม 4 (3-4) พบแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p < 0.01$) และความวิตกกังวลขณะเผชิญระดับต่ำ กลุ่มทดลอง 36 ราย (ร้อยละ 80.0) และกลุ่มควบคุม 0 ราย พบความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p < 0.01$) ไม่พบเหตุการณ์ไม่พึงประสงค์ด้วยวิธีการระงับความรู้สึกแบบสั่นสะเทือน*

สรุป: *การระงับความรู้สึกแบบสั่นสะเทือนอาจจะมีประสิทธิภาพในการลดความเจ็บปวดและความวิตกกังวลในกลุ่มที่มารับบริการฝังยาคุมกำเนิดแบบแท่งเดียว*

คำสำคัญ: *การระงับความรู้สึกแบบสั่นสะเทือนฝังยาคุมกำเนิดแบบแท่งเดียว, ความเจ็บปวด, ความวิตกกังวล*

Introduction

Due to its greater efficacy and consistency than oral contraceptives, the American College of Obstetricians and Gynecologists (ACOG) recommends long-acting reversible contraception as an effective method of birth control, particularly for adolescents[1]. It provides all women with long-term contraception and can also be used by those women, who cannot use hormonal contraception which contains estrogen. Implants are more convenient than oral contraceptives because they require no maintenance for up to three years[2]. In accordance with the universal health coverage policy of Thailand, family planning services are free, and free access to contraceptive implant services for all health rights is promoted. Services are accessible at any facility within the network of the National Health Security Office[3]. However, the Bureau of Reproductive Health has reported that only 2.4% of teenage mothers actually use contraceptive implants, whereas 55.2% of postpartum women do use them[4]. According to Inoue, women are more likely to generate negative opinions after hearing about subdermal implants from others[5]. Within the Australian setting, it is necessary to explore interventions in order to improve informed awareness of the implant's benefits and drawbacks, such as enhancing access to supportive contraceptive counseling. Additionally, further investigations should explore avenues that can be used to enhance a woman's sense of control over the device.

Typically, receiving contraceptive implant services can be mildly painful, but some individuals may experience significant anxiety[6]. This can also negatively impact mental health, causing psychological symptoms, such as having a phobia of needles and/or suffering other emotional consequences. Long-term consequences of needle phobia include an avoidance of healthcare facilities and a failure to comply with needle-related procedures[7]. Anxiety and depression are also possible[8]. A large body of clinical evidence has demonstrated that pain can cause psychological abnormalities that can affect behavior and mental health, with anxiety being the most prevalent abnormality that is caused by pain[9].

Vibratory anesthesia, which is widely recognized as an effective method for relieving pain and anxiety, is utilized in various healthcare settings. It is utilized when performing dermatological biopsies and injectable cosmetic treatments, as well as employed in the fields of pediatrics and dentistry[10,11]. Vibratory anesthesia is a highly efficient and widely accepted technique for distraction[12]. It is considered to be psychological in nature, since it distracts the patient and causes brain cells to transmit the vibration[13]. This muddles the perception of pain signals, leading to a "masking of pain's impact"[14].

Vibrant anesthesia has not been studied to reduce pain and anxiety in patients undergoing single-rod contraceptive implant services, which could potentially change their experiences. Therefore, the objective of this study was to evaluate the effectiveness of vibration anesthesia in reducing pain and anxiety among individuals receiving single-rod contraceptive implants.

Materials and Methods

This research was conducted at the Family Planning Unit and the Postpartum Ward of Chaiyaphum Hospital between February and July 2023. It was a single-blind randomized controlled trial (RCT) that was certified by Chaiyaphum Hospital with Ethics number 009/2023 (February 9, 2023). Additionally, the clinical trial research was registered in Thailand's Clinical Trials Registry (Thai Clinical Trials Registry: TCTR) with the registration number of TCTR20230217006. The inclusion criteria were women between 18-49 years of age, who had received single rod contraceptive implant recipient (SRCI). The exclusion criteria were the women, who had received the service of removing a SRCI and inserting a new one at the same time. Furthermore, within 6 hours before beginning the study, the volunteers should not have received any painkillers.

After obtaining written informed consent, the procedure details were disclosed to the participants and the consent forms were signed by those

volunteers, who were willing to participate in the study. It was a randomized 1:1 randomization process using the block randomization method with the block size of 5. The experimental group received 2% lidocaine without adrenaline and vibrational anesthesia to reduce pain and anxiety in the group receiving SRCI, while the control group received treatment in accordance with the standard use 2% lidocaine without adrenaline. The volunteers monitored the effectiveness of the care to reduce pain and anxiety only once and this was carried out immediately after receiving a single rod contraceptive implant. However, in order to reduce any bias that could occur, this study was masked to the evaluators, with only 1 person performing the numeric rating scale (NRS) interview and anxiety assessment form Spilberger's state anxiety inventory (STAI) formY-1 Thai version.

For this study, the researcher used a tool called the NRS to measure pain levels. The NRS uses numbers from 0 to 10 to show how much pain a person is feeling. A score of 0 means no pain, while a score of 10 means very severe pain. Patients simply had to point to the number that matched their level of pain. The Thai version of Spilberger's state anxiety inventory [STAI] form Y[15], which was created by Nonthasak et al (1991), consists of 20 items (10 positive statements and 10 negative statements). The scale, which was used for estimation, has four levels. The positive items were rated from 4 points (none) to 1 point (the most), while the negative items were scored from 1 point (the most) to 4 points (none). The total scores ranged from 20 to 80, which were interpreted comparatively. Anxiety levels were classified as low (20-40 points), moderate (41-60 points), and high (61-80 points). The reliability coefficient (C) was 0.85, encompassing the full range of scores from the lowest 20 to the highest 80. Regarding interpretation, a high overall score corresponded to high anxiety, while a low score indicated low anxiety. (Fig. 1)

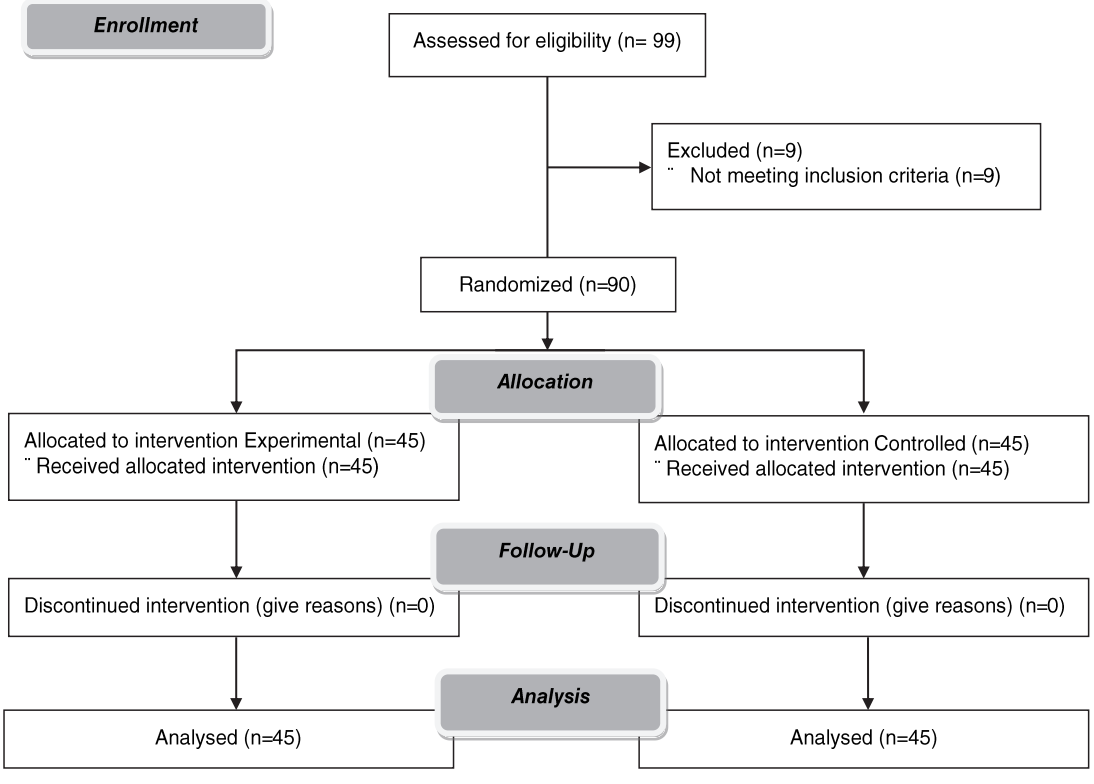

Fig. 1. The consort flow chart of randomization.

Vibrational anesthesia device (VAD) of application filed by Blaine Labs Inc. S/N:65373-009969 is a medical innovation created by medical professionals, which was approved for safety by the Food and Drug Administration (FDA) of the United States (USA) and is shown in Fig. 2. This device has been extensively examined in diverse research domains like cosmetic medicine and dentistry, while its effectiveness has been documented in international journals[11].

The manner in which it is utilized is as follows: 1. clean the VAD with a cotton ball moistened with disinfectant alcohol (70% ethyl alcohol), 2. Place the vibrational anesthesia device 2 inches under a sterile drape, as shown in Fig. 3., 3. Pressing and holding down this tool is necessary during and after usage. Pressing the pause button is the way to stop working. Vibration equipment will be used in this experiment for two periods: before the anesthetic injection and throughout the implantation process, 4. wipe the VAD with a cotton ball, which has been moistened with disinfectant alcohol (70% ethyl alcohol), and 5. finally, keep the VAD in the toolbox.

The experimental group was treated with a contraceptive implant using vibration anesthesia for 5-10 minutes, whereby the operative physician placed the VAD about 2 inches from the implant area, starting from the beginning of the contraceptive implant process until the end as shown in Fig. 2-4.

Fig. 2. The vibrational anesthesia device from Blaine Labs

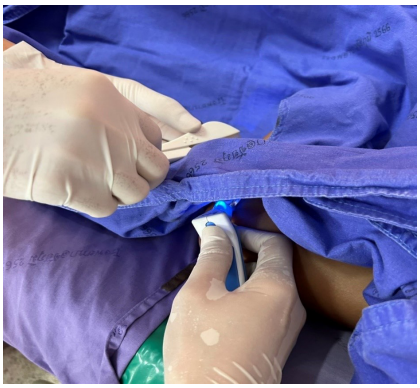

Fig. 3. Demonstrating the process of SRCI by placing the device under a sterile drape.

SRCI: single rod contraceptive implant recipient

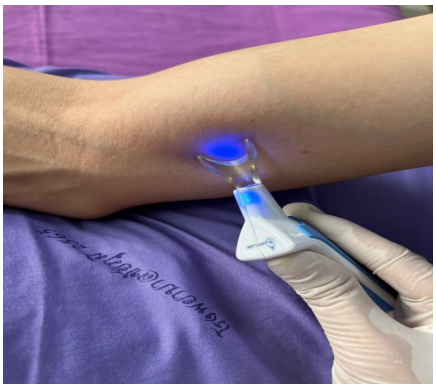

Fig. 4. Demonstrating the positioning of the device by pressing and holding it on the patient's skin.

The number of samples was calculated based on a study by Mapaisankit et al[16], which employed the formular of randomized controlled trial for continuous data. The mean in the treatment group = 3, the mean in control group = 2.4, the standard deviation (SD) in the treatment group = 1, the SD in the control group = 1 with the power of 80% and with an alpha level of 0.05. The calculated sample size was determined to be 45 patients for each group.

Statistical analysis was conducted on all the data using the STATA 10.1 program. Descriptive statistics: mean and standard deviations for continuous data that was normally distributed, median and interquartile range (IQR) for continuous data that was not normally distributed, and frequencies and percentages for categorical data were calculated. The chi-square test or the Fisher exact test was used to compare the experimental group and the control group with regard to the categorical data, while the independent t-test and the Mann-Whitney-U test were employed to compare the quantitative variables that were not normally distributed.

Results

Baseline characteristics between the standard contraceptive implant group and the dermal vibration application group are shown in Table 1. There were no significant differences.

Table 1. The Baseline characteristics.

Variables	Controlled (n = 45)	Experimental (n = 45)	p value
Age (years) (median, IQR)	27 (24-33)	28 (24-32)	0.96[a]
BMI (kg/m^2) (median, IQR)	25.05 (21.27-27.79)	24.3 (20.95-26.57)	0.27[a]
Underlying disease (n, %)			0.27[b]
- No	39 (86.67)	35 (77.78)	
- Yes	6 (13.33)	10 (22.22)	
Marital status (n, %)			0.76[c]
- Married	30 (66.67)	33 (73.33)	
- Divorced	3 (6.67)	2 (4.44)	
- Separated	1 (2.22)	2 (4.44)	
- Single	11 (24.44)	8 (17.78)	
Highest educational level (n%)			0.97[c]
- Primary school	1 (2.22)	1 (2.22)	
- Junior high school	4 (8.89)	5 (11.11)	
- High school	14 (31.11)	12 (26.67)	
- Diploma /associate	15 (33.33)	17 (37.78)	
- Bachelor's degree	11 (24.44)	10 (22.22)	
Income (median, IQR)	12,000 (9,000-20,000)	15,000 (10,000-20,000)	0.23[a]
Gravida (n, %)			0.21[c]
0	6 (13.33)	8 (17.78)	
1	20 (44.44)	23 (51.11)	
2	15 (33.33)	14 (31.11)	
3	4 (8.89)	0 (0)	
Use of contraception (n, %)			0.20[b]
- Never	18 (40.0)	24 (53.33)	
- Have used	27 (60.0)	21 (46.67)	

BMI: body mass index, IQR: interquartile range.

[a] Wilcoxon rank sum test, [b] chi square, [c] Fisher's exact test, significant $p < 0.05$*

A comparison of the pain severity scores between the standard contraceptive implantation group and the dermal vibration application group is shown in Tables 2 and 3. For the single-blinded group, the median pain scores of the experimental group were 2[1-2], and those of the control group were 4[3-4]. There was a statistically significant difference ($p < 0.01$) in the pain scores. Thirty-six cases (80.0%) in the experimental group showed low anxiety levels compared to none in the control groups ($p < 0.01$). Furthermore, no adverse events were reported.

Table 2. A comparison of the pain scores between the group that had received the standard single rod contraceptive implant recipient recipient services and those who had undergone vibration anesthesia.

Pain scores	Controlled (n = 45)	Experimental (n = 45)	p value
0	0 (0)	1 (2.22)	< 0.001[b]
1	3 (6.67)	19 (42.22)	
2	3 (6.67)	18 (40.0)	
3	12 (26.67)	4 (8.89)	
4	19 (42.22)	3 (6.67)	
5	8 (17.78)	0 (0)	
median (IQR)	4 (3-4)	2 (1-2)	< 0.001[a]

IQR: interquartile range

[a] Wilcoxon rank sum test, [b] Fisher's exact test, significant $p < 0.05$*

Table 3. A comparison of the anxiety levels between the group that had received the standard single rod contraceptive implant recipient single rod contraceptive implant recipient services and those who had undergone vibration anesthesia.

Levels of anxiety	Controlled (n = 45)	Experimental (n = 45)	p value
Anxiety			< 0.001[b]
- Low	0 (0)	36 (80.0)	
- Moderate	44 (97.78)	9 (20.0)	
- High	1 (2.22)	0 (0)	
mean ± SD	50.62 ± 4.59	35.26 ± 5.66	< 0.001[a]

SD: standard deviation

[a] student t- test, [b] Fisher's exact test, significant $p < 0.05$*

Discussion

Birth control implants are highly effective and suitable for women regardless of age or pregnancy history. This includes those women, who have never been pregnant, have been infected with HIV, have recently undergone an abortion, or who are undertaking breastfeeding to limit pregnancy[17]. They are 100 times more effective than the injections and pills, which are commonly used, and are 360 times[17] more effective than using condoms. Consequently, under the universal health coverage policy, family planning services are freely available in Thailand[3]. However, despite these advantages, the Bureau of Reproductive Health found that only 2.4% of teenage mothers were found to be using birth control implants, with 55.23%[4] opting for birth control pills postpartum.

Jacobstein et al[17] recommended that in order to encourage women to consider birth control implants, the women should be provided with informed choice, counseling, anticipatory guidance, the management of side effects, prompt removal services, and follow-up appointments. Counseling and effective management of any side effects are particularly crucial in facilitating the women's decision making processes regarding their treatment options.

This study placed emphasis on the importance of thoughtful counseling to aid clients in selecting methods, discussing their characteristics, and in dispelling myths and misconceptions, as well as in providing anticipatory guidance regarding the common side effects of implants[17], such as mood changes, headaches[18], and localized pain at the implant area[19], all of which are crucial. Research has shown that pain contributes to mental disorders, and affects behaviors and the mind, with anxiety being a common disorder that is associated with pain. Local pain at the insertion site is a typical complication, which occurs in approximately 2% to 3% of cases and is typically resolved by the end of the 3rd month[20]. Efforts to mitigate insertion pain, such as using ethyl chloride spray[16], have been explored and do show promise. Additionally, techniques like vibrating sensation (dermal vibration) have been recognized as effective treatments for pain and anxiety.

This study aimed at investigating the effectiveness of vibrational anesthesia in alleviating pain and anxiety among individuals receiving a single-rod contraceptive implant. The results of the study revealed that there had been a significant difference in median pain scores between the experimental group 2[1-2] and the control group 4[3-4], with a p value < 0.01. However, a lack of prior research on its use exists, specifically in individuals, who have undergone birth control implant services, which complicates the process of making direct comparisons with similar studies. Nevertheless, vibrational anesthesia has demonstrated efficacy in other fields, such as reducing patient discomfort during cosmetic botulinum toxin injections[21]. This finding aligned with previous dental studies, which have shown the effectiveness of vibrational instruments for pain control[22,23]. Vibrational anesthesia, which is considered a distraction technique, is widely accepted[12] and highly effective. These operate within the psychological realm, in which the vibrating devices distract the patients and cause confusion with regard to transmitting pain signals within the brain[13]. This phenomenon leads to a "masking of pain effects"[14] and contributes to its efficacy in pain management.

The study revealed a significant difference in anxiety levels between the experimental group, in which anxiety was low in 36 cases (80.0%), and in the control group in which no cases of common anxiety were reported ($p < 0.01$). It's important to note that fear and anxiety may influence the intensity of pain. Research has indicated that heightened patient anxiety may exacerbate both the duration and severity of pain[24].

The strength of the study was to evaluate the results of using a non-invasive device to reduce pain and anxiety in those receiving single-rod contraceptive implants. Using 80% power, the sample size was determined, and the pain and anxiety questions were asked to a single assessor after the patient's visit. Yet, our study had some limitations. First due to the nature of this study, subjects could not be blinded. Volunteers were able to feel the vibrations, which is why this happens. Although vibration is very effective in reducing pain, many factors are involved, and more studies need to be conducted in order to determine the effectiveness of vibration in pain control. This stems from the fact that these devices run on batteries. Over time, the frequency and intensity of vibration may change for each patient. Moreover, in this study, data on anxiety scores was not collected before the experiment.

Furthermore, different operators may choose to use various vibrational tools. In addition, future studies should focus on coverage that will offer women opportunities to gain access to SRCI, which should cover informed choice, counseling, anticipatory

guidance, the management of side-effects, prompt removal services, and follow-up appointments.

Conclusion

Vibrational anesthesia was a safe and effective method for contraceptive implant services. It significantly reduced pain and anxiety. No adverse events were reported

Acknowledgments

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Potential conflicts of interest

The authors declare no conflicts of interest.

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