Clinical and Experimental Obstetrics & Gynecology

Clin. Exp. Obstet. Gynecol. **2022**; 49(8): 167
https://doi.org/10.31083/j.ceog4908167

Original Research

Effect of Paracervical Block Before Ultrasound Guided High Intensity Focused Ultrasound Treatment in Uterine Fibroids and Adenomyosise

Jae-Seong Lee[1], Kye-Hwa Lee[2], Tae-Eung Kim[3,*]

[1]Aegisroen Obstetrics Gynecology Clinic, 06160 Seoul, Republic of Korea
[2]Department of Information Medicine, Asan Medical Center, 05505 Seoul, Republic of Korea
[3]Department of Obstetrics and Gynecology, Catholic University of Korea, Incheon Saint Mary's Hospital, 21431 Incheon, Republic of Korea
*Correspondence: stablers@hanmail.net (Tae-Eung Kim)

Academic Editor: Michael H. Dahan
Submitted: 17 March 2022 Revised: 5 April 2022 Accepted: 18 April 2022 Published: 19 July 2022

Abstract

Background: The purpose of this article was to evaluate the effect of paracervical block before ultrasound-guided high-intensity-focused ultrasound treatment of adenomyosis and uterine fibroids. **Methods**: This retrospective analysis examined 2173 women who received HIFU treatment for uterine fibroids and adenomyosis, among them 311 patients with paracervical block and 1862 patients without paracervical block, from February 4, 2010 to March 8, 2019. We assessed treatment time, ablation time, treatment energy and volume reduction. Paracervical block (10 cc of 2% lidocaine diluted with epinephrine 1:1 million) was performed before treatment. **Results**: When paracervical block was performed, the total treatment time was estimated to be 0.886 times (expected (–0.121)) which was statistically significantly shorter ($p < 0.0001$), ablation time was statistically significantly shorter by 0.853 times (expected (–0.159)) ($p < 0.0001$), and the total energy was statistically significantly smaller by 0.891 times (expected (–0.115)) ($p = 0.0003$). There was no significant difference in volume change between the group with and without paracervical block. However, total treatment time, ablation time, and treatment energy were all statistically significantly lower in the group treated with paracervical block. **Conclusions**: Paracervical block before USgHIFU treatment was a cost-effective method because it helped reduce the total treatment time, ablation time, and total energy.

Keywords: paracervical block; high-intensity focused ultrasound ablation; uterine fibroid; adenomyosis

1. Introduction

High-intensity focused ultrasound (HIFU) is an effective non-invasive treatment method that induces thermal ablation at a target site by using an external energy source to focus ultrasound at a specific location for various solid tumors. It is used to treat uterine fibroids and adenomyosis, which can cause various symptoms such as vaginal bleeding, dysmenorrhea, menorrhagia, and infertility [1–4].

During HIFU treatment for uterine fibroids and adenomyosis, the operator avoids general anesthesia and only uses sedatives and analgesics to allow them to still communicate with the patient and monitor the patient's response. Most patients can return to their daily activities the next day after treatment.

If sufficient analgesic suppression is not achieved through the use of only sedatives and analgesics during treatment, the pain causes the patient to move more, and the focus of the ultrasound on the tissue is not good, thus making it difficult to generate sufficient thermal energy in the tissue; as a result, the therapeutic effect decreases and the treatment time becomes longer.

Most HIFU practitioners want to relieve the patient's pain while avoiding excessive usage of sedatives and analgesics during treatment, and they want to reduce uterine nerve pain but preserve other tissues and nerve sensations.

Paracervical block is a local anesthetic procedure used in various obstetrics and gynecology procedures [5]. In the field of gynecology, it is used as a local anesthetic for minor surgeries such as dilatation and currettage (D&C), and in the field of obstetrics, it is used to relieve pain during labor. Therefore, we tried to suppress the patient's pain during the procedure through local anesthesia delivered by paracervical block prior to HIFU treatment.

2. Materials and Methods

This retrospective analysis involved 2173 women who received HIFU treatment for uterine fibroids and adenomyosis, with 311 patients with paracervical block and 1862 patients without paracervical block among them, from February 4, 2010 to March 8, 2019. Uterine fibroids and adenomyosis were diagnosed through patient history, physical examination, diagnostic ultrasound (US), and magnetic resonance imaging (MRI) scans. In this study, patients with myoma of 2–12 cm with moderate to severe symptoms and patients with symptomatic focal and diffuse adenomyosis were included. However, patients with poor general condition or suspected malignancy were excluded. This study was approved by the ethics committee. Before treatment, written informed consent was obtained before every procedure from each patient after informing them of the possible effects of HIFU on pregnancy rate and treatment out-

come. All patients underwent careful bowel and skin preparation prior to HIFU treatment. The bowels were prepared to avoid adverse effects to adjacent bowel loops in the treatment field. The skin of the lower abdominal wall was shaved and degreased with 70% alcohol. The epidermal skin was degassed with a vacuum suction device. A urinary catheter that was filled with sterile saline was inserted into the bladder to control the bladder volume during the procedure. Paracervical block (10 cc of 2% lidocaine diluted with epinephrine 1:1 million) was performed before HIFU treatment, and the injected dose was 5 cc at each of the four and eight o'clock positions of the uterine cervix.

HIFU treatment was administered using a Haifu JC-Focused Ultrasound Tumor Therapeutic System (Chongqing Haifu Technology, Chongqing, China) under real-time US guidance. During HIFU treatment, the acoustic power was delivered in single exposure dot mode at an intensity of 300–400 W/cm^2 and exposure over 24 shots at one point (one sec per shot and shot intervals of three sec). It was stopped when a gray scale change appeared on the ultrasound image. After termination of treatment, the total treatment time from the first sonication shot to the last, total time of sonication, and total treatment energy were obtained.

During the procedure, intravenous conscious sedatives—including fentanyl, midazolam, and lower propofol doses (0.3–0.6 mg/kg/h by continuous infusion)—were administered, and the patient's pain, movement, and vital signs, including blood pressure, pulse, and oxygen saturation, were all monitored during treatment and for at least 12 hours after surgery. The goal of HIFU treatment was to cure at least 80% of all uterine lesions. To prevent infection and inflammation of the lesion, appropriate oral antibiotics and anti-inflammatory drugs were administered for seven days after treatment.

We evaluated the effect of paracervical block for US-gHIFU treatment by assessing treatment time, ablation time, total treatment energy, and volume reduction.

After completing the treatment, data on the total treatment time, ablation time, and total treatment energy were obtained. The effectiveness of ablation and lesion volumes were determined through ultrasound and enhanced MRI. Lesions were measured in the longitudinal (D1), anteroposterior (D2), and axial (D3) dimensions, and fibroid volume and adenomyosis volume were calculated using the following equation: $V = 0.5233 \times D1 \times D2 \times D3$ [6]. The volume reduction rate was calculated by measuring the lesion volume at pre-treatment and post-treatment 3, 6, and 12 months.

For the 2173 patients who received HIFU treatment for uterine fibroids and adenomyosis, the characteristics of the study subjects, including age, presence of absence of cesarean section, treatment indicators, and treatment progress indicators were summarized according to whether or not paracervical block was performed. Categorical variables were summarized by frequency and fraction, and comparisons were made between whether or not paracervical block was performed using the chi-square test. Continuous variables were summarized by mean, standard deviation, median, minimum, and maximum values. Student's *t*-test was used to determine if the assumption of normality was satisfied and Wilcoxon rank-sum test was used to compare whether or not the paracervical block was performed (Tables 1,2). We used SAS software, version 9.4 (SAS Institute, Inc., Cary, NC, USA) [7].

3. Results

Among the 1111 patients with uterine fibroids, 153 patients underwent paracervical block, and 46 of these cases included delivery by caesarean section. The total treatment time, ablation time, and total energy were 73.8 ± 28.86 (min, Mean ± SD), 906.89 ± 425.82 (sec, Mean ± SD), and 345078.69 ± 170781.79 (J, Mean ± SD), respectively. The mean volume before treatment was 140.1 ± 122.19 (cm^3, Mean ± SD), and the volume reduction rates after treatment were 57.41 ± 12.78 (%, Mean ± SD) at three months, 68.44 ± 11.41 (%, Mean ± SD) at six months, and 78.18 ± 12.52 (%, Mean ± SD) at 12 months. There were 958 patients without paracervical block, and 203 of these cases included delivery by caesarean section. The total treatment time, ablation time, and total energy were 85.16 ± 36.32 (min, Mean ± SD), 1138.08 ± 567.33 (sec, Mean ± SD), and 429955.35 ± 227357.43 (J, Mean ± SD), respectively. The mean volume before treatment was 174.43 ± 149.58 19 (cm^3, Mean ± SD), and the volume reduction rates after treatment were 58.09 ± 14.77 (%, Mean ± SD) at three months, 67.3 ± 15.68 (%, Mean ± SD) at six months, and 77.19 ± 12.58 (%, Mean ± SD) at 12 months (Table 1).

Among the 1062 patients with adenomyosis, 158 patients underwent paracervical block, and 43 of these cases included delivery by caesarean section. The total treatment time, ablation time, and total energy were 66.23 ± 25.69 (min, Mean ± SD), 834.28 ± 394.92 (sec, Mean ± SD), and 314000.71 ± 160284.31 (J, Mean ± SD), respectively. The mean uterine volume before treatment was 232.93 ± 137.46 (cm^3, Mean ± SD), and the volume reduction rates after treatment were 46.74 ± 10.43 (%, Mean ± SD) at three months, 59.85 ± 9.02 (%, Mean ± SD) at six months, and 60.97 ± 7.28 (%, Mean ± SD) at 12 months. There were 904 patients without paracervical block, and 216 of these cases included delivery by caesarean section. The total treatment time, ablation time, and total energy were 78.97 ± 30.66 (min, Mean ± SD), 996.87 ± 453.2 (sec, Mean ± SD), and 359569.01 ± 181129.16 (J, Mean ± SD), respectively. The mean uterine volume before treatment was 248.48 ± 146.28 (cm^3, Mean ± SD), and the volume reduction rates after treatment were 45.62 ± 15.7 (%, Mean ± SD) at three months, 51.13 ± 18.97 (%, Mean ± SD) at six months, and 59.3 ± 14.47 (%, Mean ± SD) at 12 months (Table 2).

Table 1. Characteristics of uterine fibroids research subjects according to whether paracervical block was performed.

		Total (n = 1111)	Whether paracervical block		*p*-value
			no (n = 958)	yes (n = 153)	
Age					
	20's, n (%)	54 (4.86)	50 (5.22)	4 (2.61)	0.0274(1)
	30's, n (%)	302 (27.18)	273 (28.5)	29 (18.95)	
	40's, n (%)	664 (59.77)	558 (58.25)	106 (69.28)	
	Over 50, n (%)	91 (8.19)	77 (8.04)	14 (9.15)	
Cesarean section					
	no, n (%)	862 (77.59)	755 (78.81)	107 (69.93)	0.0145(1)
	yes, n (%)	249 (22.41)	203 (21.19)	46 (30.07)	
Total treatment time (min)	Mean ± SD	83.58 ± 35.58	85.16 ± 36.32	73.8 ± 28.86	0.0009(2)
Ablation time (sec)	Mean ± SD	1105.98 ± 555.48	1138.08 ± 567.33	906.89 ± 425.82	<0.0001(2)
Total energy (J)	Mean ± SD	418171.21 ± 222254.02	429955.35 ± 227357.43	345078.69 ± 170781.79	0.0001(2)
Pre-treatment volume (cm^3)	Mean ± SD	170.79 ± 147.2478.1	174.43 ± 149.58	140.1 ± 122.19	0.0160(2)
Volume reduction rate after 3 months (%) *	Mean ± SD	58 ± 14.54	58.09 ± 14.77	57.41 ± 12.78	0.6800(3)
Volume reduction rate after 6 months (%) *	Mean ± SD	67.43 ± 15.25	67.3 ± 15.68	68.44 ± 11.41	0.5473(3)
Volume reduction rate after 12 months (%) *	Mean ± SD	77.26 ± 12.56	77.19 ± 12.58	78.18 ± 12.52	0.7416(3)

*((Volume before treatment – Volume after treatment)/Volume before treatment) *100 (1) *p*-value by Chi-square test (2) *p*-value by Wilcoxon rank sum test (3) *p*-value by *t*-test.

In the analysis of all patients, the differences in total treatment time, ablation time, and total energy according to whether or not paracervical block was performed showed similar patterns. Treatment indicators according to whether or not paracervical block was performed were compared by adjusting for disease, age, cesarean section, and baseline volume. When paracervical block was performed compared to the case without paracervical block in uterine fibroid (n = 1111), the total treatment time was statistically significantly shorter by 0.867 times (expected (–0.134)) ($p = 0.0004$), ablation time was statistically significantly shorter by 0.797 times (expected (–0.223)) ($p < 0.0001$), and total energy was statistically significantly smaller by 0.803 times (expected (–0.214)) ($p < 0.0001$) (Table 3).

When paracervical block was performed compared to the case without paracervical block in adenomyosis (n = 1062), the total treatment time was statistically significantly shorter by 0.839 times (expected (–0.176)) ($p < 0.0001$), ablation time was statistically significantly shorter by 0.837 times (expected (–0.190)) ($p < 0.0001$), and total energy was statistically significantly smaller by 0.873 times (expected (–0.139)) ($p = 0.0026$) (Table 4).

The volume reduction rate after treatment was evaluated to be different for each disease of uterine fibroids and adenomyosis, so it was appropriate to estimate by disease. In the case of the treatment progress indicators of volume reduction rate, the difference in the volume change rate before and after myoma treatment was 1.385% compared to the case without paracervical block, and there was no statistically significant difference ($p = 0.3764$). Further, the difference in uterine volume change before and after treatment for adenomyosis was –3.714%, which was statistically significant but small ($p = 0.021$) (Table 5).

Out of the total 2173 patients, 311 underwent paracervical block before HIFU procedure, and no specific symptoms or complications were observed except for temporary palpitation in ten patients who underwent paracervical block.

4. Discussion

HIFU is an effective, non-invasive treatment method used for the treatment of uterine fibroids and adenomyosis that avoids the use of general anesthesia and only uses sedatives and analgesics during treatment to communicate with the patient and monitor the patient's response.

However, if sufficient pain suppression is not achieved with only sedatives and analgesics during treatment, the pain causes the patient to move more, and the ultrasound does not focus well on the tissue, thus making it difficult to generate sufficient thermal energy in the tissue. In addition, the treatment effect is reduced and the treatment time is prolonged.

Therefore, it is often necessary to use excessive sedatives and analgesics to relieve the patient's pain during treatment. Most operators want sufficient pain relief, but they also want to monitor the patient's condition during treatment while preserving other tissues and nerve sensations other than the uterus.

Table 2. Characteristics of adenomyosis research subjects according to whether paracervical block was performed.

		Total (n = 1062)	Whether paracervical block		*p*-value
			no (n = 904)	yes (n = 158)	
Age					
	20's, n (%)	17 (1.6)	14 (1.55)	3 (1.9)	0.0006(1)
	30's, n (%)	381 (35.88)	347 (38.38)	34 (21.52)	
	40's, n (%)	600 (56.5)	493 (54.54)	107 (67.72)	
	Over 50, n (%)	64 (6.03)	50 (5.53)	14 (8.86)	
Cesarean section					
	no, n (%)	803 (75.61)	688 (76.11)	115 (72.78)	0.3697(1)
	yes, n (%)	259 (24.39)	216 (23.89)	43 (27.22)	
Total treatment time (min)	Mean ± SD	77.07 ± 30.3	78.97 ± 30.66	66.23 ± 25.69	<0.0001(2)
Ablation time (sec)	Mean ± SD	972.57 ± 448.57	996.87 ± 453.2	834.28 ± 394.92	<0.0001(2)
Total energy (J)	Mean ± SD	352751.03 ± 178835.26	359569.01 ± 181129.16	314000.71 ± 160284.31	0.0025(2)
Pre-treatment volume (cm^3)	Mean ± SD	246.75 ± 145.33	248.48 ± 146.28	232.93 ± 137.46	0.1919(2)
Volume reduction rate after 3 months (%,) *	Mean ± SD	45.76 ± 15.14	45.62 ± 15.7	46.74 ± 10.43	0.4038(3)
Volume reduction rate after 6 months (%,)*	Mean ± SD	52 ± 18.41	51.13 ± 18.97	59.85 ± 9.02	<0.0001(3)
Volume reduction rate after 12 months (%) *	Mean ± SD	59.4 ± 14.15	59.3 ± 14.47	60.97 ± 7.28	0.3907(3)

*((Volume before treatment – Volume after treatment)/Volume before treatment) *100 (1) *p*-value by Chi-square test (2) *p*-value by Wilcoxon rank sum test (3) *p*-value by *t*-test.

Table 3. Estimated difference of index (log transformation) according to whether or not paracervical block was implemented (multivariate, total) in Uterine Fibroid.

Index	Paracervical block	Paracervical block	Estimate	SE	*p*-value*
Total N = 1111	No (n = 958)	Yes (n = 153)			
Total treatment time (min)	85.16 ± 36.32	73.8 ± 28.86	–0.134	0.038	0.0004
Ablation time (sec)	1138.08 ± 567.33	906.89 ± 425.82	–0.223	0.046	<0.0001
Total energy (J)	429955.35 ± 227357.43	345078.69 ± 170781.79	–0.214	0.050	<0.0001

*Correction factors: age, cesarean section, disease, baseline volume, SE, Standard Error.

Vaessen *et al*. [8] stated that HIFU treatment is generally uncomfortable, painful, and requires minimal movement or the absence of movement along with a synchronized breathing pattern of the patient. They reported that a moderate-to-deep sedation technique using propofol and ketamine facilitated synchronized breathing for magnetic resonance high-intensity-focused ultrasound (MR-HIFU) treatment for uterine fibroids [8].

Lee *et al*. [9] reported a comparison of the effectiveness of epidural analgesia and monitored anesthesia for pain relief during high-intensity-focused ultrasound treatment of adenomyosis.

Recently, due to the development of various drugs and deep sedation, deep sedation through sedatives has come to be preferred over paracervical block in gynecology [10]. Further, because there is bradycardia in the fetus, it is rarely used in obstetrics [11,12]. We believed that reducing pain during treatment will make the patient more comfortable and reduce the patient's movement, which will help the operator deliver better treatment in a shorter time. Therefore, we planned local anesthesia of the paracervical block before HIFU treatment.

To reduce pain for 1–2 hours during HIFU treatment, we performed paracervical block just before HIFU treatment. Paracervical block suppresses pain in the uterine plexus from the uterine body to the lower abdominal plexus, but it does not suppress pain in the ovarian plexus from the bottom of the uterus to the upper hypogastric plexus via the ovarian ligament. Therefore, it could not completely eliminate the patient's pain during HIFU treatment. However, it was considered and used as an additional method for intravenous conscious sedation during the procedure, and it was effective in reducing the pain and movement of the patient during the procedure.

Based on the results of our study, total treatment time, ablation time, and total energy in patients with paracervical block were all found to be statistically significantly smaller. When the patient's pain was relieved and the patient's movement was reduced during treatment, the treatment time was shortened and the ablation time and total en-

Table 4. Estimated difference of index (log transformation) according to whether or not paracervical block was implemented (multivariate, total) in adenomyosis.

Index	Paracervical block	Paracervical block	Estimate	SE	*p*-value*
Total N = 1062	No (n = 904)	Yes (n = 158)			
Total treatment time (min)	78.97 ± 30.66	66.23 ± 25.69	–0.176	0.033	<0.0001
Ablation time (sec)	996.87 ± 453.2	834.28 ± 394.92	–0.190	0.040	<0.0001
Total energy (J)	359569.01 ± 181129.16	314000.71 ± 160284.31	–0.139	0.046	0.0026

*Correction factors: age, cesarean section, disease, baseline volume, SE, Standard Error.

Table 5. Estimated difference in volume change rate before and after treatment according to whether or not paracervical block was performed (multivariate, total).

Disease (n)	Paracervical block (n)	Estimate	SE	*p*-value
Uterine Fibroid (n = 1111)	Yes (n = 153)	1.385	1.565	0.3764
Adenomyosis (n = 1062)	Yes (n = 158)	–3.714	1.607	0.0210

*Correction factors: age, cesarean section, disease, baseline volume, SE: Standard Error section, disease, baseline volume, SE, Standard Error.

ergy were reduced, which we believe could be attributed to the facts that the operator could focus the ultrasound more easily and that heat was generated efficiently from the tissue.

5. Conclusions

Paracervical block cannot be performed for women who never had sexual intercourse or if the cervix is not well exposed. However, since the procedure is safe, simple, short and cost effective, we believe that paracervical block can be helpful for HIFU treatment while reducing the excessive use of intravenous sedatives.

We hope that there will be well-designed, large-scale prospective studies in the future extending this work.

Author Contributions

JSL and TEK designed the research study. JSL performed the research. TEK provided help and advice on the research and KHL analyzed the data. JSL and TEK wrote the manuscript. All authors contributed to the editorial changes to the manuscript. All authors read and approved the final manuscript.

Ethics Approval and Consent to Participate

This study was approved by the Institutional Review Board of Incheon Christian Hospital (Approval number: 2012-01) and all procedures performed in studies involving human participants were conducted in accordance with the ethical standards of the institutional review board and with the 1964 Helsinki declaration and its later amendments or comp ethical approval.

Acknowledgment

We would like to thank the Seoul National University College of Medicine Medical Research Cooperation Center for support in the statistical analysis.

Funding

This research received no external funding.

Conflict of Interest

The authors declare no conflict of interest.

References

[1] Wang W, Wang Y, Tang J. Safety and Efficacy of High Intensity Focused Ultrasound Ablation Therapy for Adenomyosis. Academic Radiology. 2009; 16: 1416–1423.

[2] Wang W, Wang Y, Wang T, Wang J, Wang L, Tang J. Safety and efficacy of us-guided high-intensity focused ultrasound for treatment of submucosal fibroids. European Radiology. 2012; 22: 2553–2558.

[3] Zhou M, Chen J-Y, Tang L-D, Chen WZ, Wang ZB. Ultrasound-guided high-intensity focused ultrasound ablation for adenomyosis: the clinical experience of a sing center. Fertility and Sterility. 2011; 95: 900–905.

[4] Lee J, Hong G, Lee K, Song J, Kim T. Safety and Efficacy of Ultrasound-Guided High-Intensity Focused Ultrasound Treatment for Uterine Fibroids and Adenomyosis. Ultrasound in Medicine & Biology. 2019; 45: 3214–3221.

[5] Van Praagh IG, Povey WG. The use of paracervical block anesthesia for dilatation and gurettage. Canadian Medical Association Journal. 1966; 94: 267–268.

[6] Kroencke TJ, Scheurig C, Kluner C, Taupitz M, Schnorr J, Hamm B. Uterine Fibroids: Contrast-enhanced MR Angiography to Predict Ovarian Artery Supply—Initial Experience. Radiology. 2006; 241: 181–189.

[7] Statistical Analysis Software. Users' Guide Statistics Version 9.4. SAS Institute Inc. 2013. Available at https://support.sas.com/en/software/visual-analytics-support.html (Accessed: 8 February 2022).

[8] Vaessen HHB, Knuttel FM, van Breugel JMM, Ikink ME, Dieleman JM, van den Bosch MAAJ, et al. Moderate-to-deep sedation technique, using propofol and ketamine, allowing synchronised breathing for magnetic resonance high-intensity focused ultrasound (MR-HIFU) treatment for uterine fibroids: a pilot study. Journal of Therapeutic Ultrasound. 2017; 5: 8.

[9] Lee C, Lee JY, Ro S, Choi S, Moon JY. Comparison of effectiveness of epidural analgesia and monitored anesthesia care for

high-intensity focused ultrasound treatment of adenomyosis. International Journal of Hyperthermia. 2018; 35: 617–625.

[10] Sahay N, Agarwal M, Bara M, Raj N, Bhushan D. Deep sedation or paracervical block for daycare gynecological procedures: a prospective, comparative study. Gynecology and Minimally Invasive Therapy. 2019; 8: 160.

[11] Freeman RK, Gutierrez NA, Ray ML, Stovall D, Paul RH, Hon EH. Fetal cardiac response to paracervical block anesthesia. American Journal of Obstetrics and Gynecology. 1972; 113: 583–591.

[12] Asling JH, Shnider SM, Margolis AJ, Wilkinson GL, Way EL. Paracervical block anesthesia in obstetrics. American Journal of Obstetrics and Gynecology. 1970; 107: 626–634.