

Gynecologists' perception of High-Intensity Focused Ultrasound as a treatment for uterine leiomyomas

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자궁근종의 치료로서 고강도 집속 초음파 치료에 대한 부인과 의사의 인식에 대한 연구

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Abstract Recently, there has been an increased awareness on the use of High-Intensity Focused Ultrasound (HIFU) as a non-surgical treatment option for leiomyomas. This study aimed to assess gynecologists' perception of HIFU therapy for uterine leiomyomas in Korea. We analyzed questionnaires from 162 Korean gynecologists who provided data on 1) demographics, 2) pattern of practice with respect to leiomyomas, and 3) opinion regarding HIFU therapy for leiomyomas. Of the 162 gynecologists, 2.8 % regarded HIFU as a first-line treatment for leiomyomas. HIFU was only available at the workplace of 19 % of respondents: of these, 58 % had requested the use of HIFU. When asked about their perception of HIFU for treating leiomyomas, only 19 % of the respondents thought that it was effective. The commonest perceived complication was a delay in the adequate treatment of sarcoma (59 %), followed by bowel injury (52 %). The respondents considered HIFU to be suitable in the following circumstances: age between 40 and 49 years, those patients who no longer desired pregnancy, medium-sized (5-6 cm) leiomyomas, and up to 2 leiomyomas. The Korean gynecologists' perception of HIFU as a treatment for leiomyomas is still not favorable. Gynecologists working at hospitals where HIFU is available tended to have a higher positive perception of this treatment. In addition to research involving a large number of gynecologists from multiple countries, a study on the long-term outcomes of HIFU is needed.

요 약 최근 자궁근종에 대한 치료방법으로서 비수술적 고강도 집속 초음파 (High-Intensity Focused Ultrasound, HIFU)한 인식이 증대되고 있다. 본 논문에서는 한국에서 자궁근종의 HIFU 치료에 대한 부인과 의사들의 인식을 평가해 보고자 하였다. 우리는 162명의 한국의 부인과 의사들에게 인구통계학적 특성, 자궁근종에 대한 실제 진료의 패턴, 자궁근종의 HIFU 치료에 대한 의견에 대하여 설문지를 시행하여 분석하였다. 162명 중, 2.8 %에서 HIFU를 자궁근종의 1차 치료로 고려하였다. HIFU는 응답자의 19 %에서만 이용가능 하였고, 이중 58 %에서는 HIFU에 대한 의뢰를 경험하였다. 자궁근종 치료로서 HIFU에 대한 인식을 살펴보았을 때, 응답자의 19 %에서만 효과적이라고 답하였다. 가장 흔한 부작용으로 생각되는 것은 자궁육종의 적절한 치료가 늦어지는 것 (59 %) 이었고, 그 다음이 장 손상 (52 %) 이었다. 응답자들이 HIFU를 고려하기에 적합하다고 생각한 경우로는 연령이 40세부터 49세 사이이며, 추후 임신 계획이 없고, 중간 크기 (5-6 cm)의 자궁근종이 2개까지 일 때였다. 자궁근종 치료로서 HIFU에 대한 한국의 부인과 의사들의 인식은 여전히 호의적이지 않으며, 근무하는 병원에서 HIFU를 이용 가능할 때, HIFU에 대한 인식이 좀 더 긍정적인 경향을 보였다. 여러 나라에서 더 많은 수의 부인과 의사들을 대상으로 한 연구뿐만 아니라, HIFU의 장기적인 결과에 대한 추가적인 연구가 더 필요하다.

Keywords : Gynecology, High-Intensity Focused Ultrasound Ablation, Leiomyoma, Physicians, Surveys and Questionnaires

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1. Introduction

Uterine leiomyomas are one of the commonest benign pelvic tumors in women. It is estimated that approximately 80 % of women will develop one or more leiomyomas during their lifetime, and about 60 % are women in the reproductive age group [1,2]. According to the National Health Insurance Service of South Korea, 237,000 women in South Korea were diagnosed with leiomyomas in 2009. This increased to 293,000 women in 2013, showing a mean annual increase of 5.5 % [3].

Women with leiomyomas may experience a wide variety of symptoms depending on the size, location, and characteristics of the tumors. For example, submucosal leiomyomas may cause abnormal uterine bleeding or pregnancy complications, while large leiomyomas may cause symptoms related to their mass effect, such as urinary frequency and abdominal pain [4].

Therefore, treatment of leiomyomas should be individualized, depending on each patient's symptoms. Small asymptomatic leiomyomas found incidentally via imaging or examination, do not require treatment and close observation may be sufficient [5]. However, if symptoms are present, treatment is usually required, with the definitive treatment of uterine leiomyomas being hysterectomy or myomectomy. Such surgical methods are invasive and require general anesthesia, hospitalization, and a long recovery period.

High-intensity-focused-ultrasound (HIFU) is becoming more popular due to its non-invasiveness and shorter recovery period [6]. HIFU uses ultrasound energy directed through the abdominal wall without the need for an incision [4]. The ultrasound waves are concentrated on the target, inducing thermal ablation and resultant coagulative necrosis and loss of perfusion in the focal region. This reduces the size of the leiomyoma, its symptoms, or both

[7]. Some reported adverse reactions to HIFU include vaginal secretions or bleeding, thermal injury in the abdominal skin, lower abdominal pain, lower extremity pain, and urinary retention. Rare complications include intestinal perforation, deep vein thrombosis, and neurotoxicity to the sacral plexus [8].

To date, there has not been much research on the long-term outcomes of HIFU. Therefore, many clinicians have different levels of awareness and opinions regarding this method of treatment. This study aimed to assess gynecologists' perceptions of HIFU therapy for uterine leiomyomas in South Korea.

2. Materials and methods

2.1 Development of questionnaire and survey

A survey was conducted to examine the opinion of gynecologists in South Korea on HIFU therapy. The outline of the questionnaire was developed by three investigators. An investigator developed the first draft of the questionnaire and two other investigators revised the draft. The revised draft was then circulated to all investigators. The questionnaire consisted of three sections: 1) the demographics of the responders, including gender, number of working years, and type of hospital at which they were working. 2) the pattern of practice with respect to leiomyomas, including number of leiomyoma patients encountered, type of treatment used, and methods of diagnosis of leiomyoma. 3) the perception of HIFU therapy for leiomyomas. The anticipated completion time of the questionnaire was 10 minutes.

The questionnaire was converted to web survey form and sent to all gynecologists (n = 4798) in Korea via e-mail. The e-mail was sent twice with an interval of two weeks. Two weeks after the second e-mail, the reception of responses was terminated.

2.2 Ethics

The study received Institutional Review Board (IRB) approval (B-1607-356-107) from Seoul National University Bundang Hospital, and informed consent was waived.

2.3 Statistical analysis

Data of the characteristics of gynecologists were divided into subgroups, as shown in table 1. The data of perceptions of HIFU (overall effectiveness, applicable ages of patients, feasibility for patients desiring pregnancy, treatable size of leiomyomas, and maximum treatable number of leiomyomas at one time) were also divided into subgroups, as shown in table 2. These subgroups were divided according to the response category of the questionnaire. The association between the characteristics of the gynecologists and their perception of HIFU was analyzed using Statistical Package for Social Sciences version 18.0 (IBM Corp, Armonk, NY, USA). The linear-by-linear association test was used for analyzing the association between specialists' gender, availability of HIFU in their working institution, and whether they had experience of HIFU, and their perceptions of HIFU. The Pearson's chi-squared test was used to analyze their association with feasibility for patients who desired pregnancy. To analyze the association between the type of healthcare institution and the number of new patients encountered in a week by the specialists, and their perceptions of HIFU, the one-way analysis of variance test was applied. Data under the subgroups of "others" or those with responses missing were excluded in the analysis. *P*-value <0.05 was considered statistically significant.

3. Results

3.1 Characteristics of respondents

A total of 162 gynecologists in South Korea responded to the questionnaire and were included in the study (response rate = 3.4 %). As shown in table 1, the mean period of clinical career of the specialists was 15 years. Fifty-six of the specialists worked in university hospitals, 57 at obstetrics and gynecology (OBGY) clinics, 38 at local clinics, and 11 at other sites including general hospitals. Of the 162 gynecologists, 131 dealt with leiomyoma patients and many saw more than 5-10 leiomyoma patients per week (42 gynecologists, 32%). For the treatment of these patients, excluding observation, surgery (26.4 %) and medical treatment (9.0 %) were preferred over HIFU (2.8 %). Twenty-five gynecologists (19 %) worked at institutions where HIFU was available and 14 (58 %) had experience of requesting HIFU.

3.2 Perception of HIFU therapy for uterine leiomyomas

Results regarding the perceptions of HIFU are shown in table 2. Of those who responded, 4 % thought that HIFU was very effective and 15 % thought it was effective in treating leiomyomas. More gynecologists regarded HIFU as being ineffective (19 %) or very ineffective (18 %) in treating leiomyomas. The commonest perceived complication was delay in adequate treatment of sarcoma (59 %), followed by bowel injury (52 %). The respondents considered HIFU to be suitable in the following patients: ages 40-49 years (60 gynecologists, 48 %) and those who no longer desired pregnancy (65 gynecologists, 52 %). They also responded that the most suitable size of leiomyoma for HIFU treatment was medium-sized (5 to 6 cm) (36 gynecologists, 31 %), and that the maximum treatable number of leiomyoma at a time was two leiomyomas (56 gynecologists, 48 %). The most likely therapeutic outcomes of HIFU were decreased bleeding (46 %) and size reduction (38 %).

Table 1. Characteristics of gynecologists who responded (n = 162 if not specified)

Characteristic	n	(%)
Sex		
Male	110	(68)
Female	52	(32)
Period of clinical career in years (mean±SD %)	15 ± 9	
Type of health care institution		
Local clinic	38	(23)
OBGY clinic	57	(35)
University hospital	56	(35)
Others (General hospital)	11	(7)
Number of new patients diagnosed with leiomyoma in a week (n = 131)		
≤ 5	35	(27)
> 5 to ≤ 10	42	(32)
> 10 to ≤ 20	34	(26)
>20 to ≤ 30	15	(11)
> 30	5	(4)
Method of treatment (mean±SD %)		
Medical treatment	9.0 ± 12.3	
HIFU	2.8 ± 8.9	
Radiofrequency myolysis	1.4 ± 8.3	
Operation	26.4 ± 20.7	
Observation	58.1 ± 25.2	
Other	2.2 ± 9.5	
Availability of HIFU in working institution (n = 131)		
Yes	25	(19)
No	102	(78)
Unknown	4	(3)
Type of HIFU in available institution (n = 24)		
MR - guided HIFU	9	(38)
US - guided HIFU	15	(62)
Department in charge of HIFU (n = 24)		
OBGY	15	(63)
Radiology	8	(33)
Joint treatment	1	(4)
Experience of requesting HIFU (n = 24)		
Yes	14	(58)
No	10	(42)

OBGY, Obstetrics and Gynecology; SD, standard deviation; HIFU, High-Intensity Focused Ultrasound; MR, magnetic resonance; US, ultrasound

Table 2. Gynecologists' perceptions of High-Intensity Focused Ultrasound as a treatment for leiomyomas

Questions and responses	n	(%)
Overall effectiveness of HIFU (n = 124)		
Very effective	5	(4)
Effective	19	(15)
Neutral	47	(38)
Ineffective	24	(19)
Very ineffective	23	(18)

Other	7	(6)
Potential complication[†] (n = 131)		
Skin burn	38	(29)
Edema	5	(4)
Fever	23	(18)
Pain	40	(31)
Deep vein thrombosis	18	(14)
Bowel injury	68	(52)
Persistent neuropathy	15	(11)
Emergency hysterectomy	34	(26)
Delay in adequate treatment of sarcoma	77	(59)
Other	22	(17)
Applicable ages (years) (n = 124)		
20-29	7	(6)
30-39	19	(15)
40-49	60	(48)
50-59	6	(5)
Regardless of age	20	(16)
Other	12	(10)
Feasibility for patients desiring pregnancy (n = 124)		
Yes	28	(23)
No	65	(52)
Unknown	31	(25)
Treatable size of leiomyoma for HIFU (cm) (n = 117)		
≤ 4	18	(15)
> 4 to ≤ 5	15	(13)
> 5 to ≤ 6	36	(31)
> 6 to ≤ 7	22	(19)
≥ 8	26	(22)
Most expected therapeutic outcome (n = 117)		
Size reduction	44	(38)
Bleeding reduction	54	(46)
Pain relief	11	(9)
Other	8	(7)
Maximum treatable number of leiomyoma at one time (n = 117)		
1	32	(27)
2	56	(48)
≥ 3	29	(25)

[†]Multiple responses were allowed. HIFU, High-Intensity Focused Ultrasound

3.3 Association of characteristics with perception of HIFU therapy

The association between the characteristics of the respondents and their perceptions of HIFU was analyzed. There was no association between the gender of the specialists or the type of health care institution in which they worked and the perceptions of HIFU. There was also no association between the number of leiomyoma patients encountered in a week and the perception of HIFU (data not shown). However, the availability of HIFU in the workplace of the specialist and their actual experience of requesting HIFU were associated with the

Table 3. Association between the characteristics of the gynecologists and their perceptions of High-Intensity Focused Ultrasound therapy for uterine leiomyomas[†].

	Availability of HIFU at institution					Actual experience of HIFU				
	No		Yes		p-value	No		Yes		p-value
	n	(%)	n	(%)		n	(%)	n	(%)	
Overall effectiveness					0.002					0.016
All responses	92	(100)	23	(100)		9	(100)	14	(100)	
Very effective	2	(2)	3	(13)		0	(0)	3	(21)	
Effective	13	(14)	6	(26)		1	(11)	5	(36)	
Neutral	37	(40)	10	(43)		5	(56)	5	(36)	
Ineffective	18	(20)	3	(13)		2	(22)	1	(7)	
Very ineffective	22	(24)	1	(4)		1	(11)	0	(0)	
Applicable ages (years)					0.502					0.617
All responses	72	(100)	18	(100)		7	(100)	11	(100)	
20-29	5	(7)	2	(11)		0	(0)	2	(18)	
30-39	15	(21)	3	(17)		2	(29)	1	(9)	
40-49	46	(64)	13	(72)		5	(71)	8	(73)	
50-59	6	(8)	0	(0)		0	(0)	0	(0)	
Feasibility for patients desiring pregnancy					<0.001					0.043
All responses	71	(100)	18	(100)		8	(100)	10	(100)	
No	55	(77)	6	(33)		5	(63)	1	(10)	
Yes	16	(23)	12	(67)		3	(38)	9	(90)	
Treatable size of leiomyoma					0.006					0.400
All responses	90	(100)	23	(100)		9	(100)	14	(100)	
≤4 cm	16	(18)	0	(0)		0	(0)	0	(0)	
>4 to ≤5 cm	12	(13)	3	(13)		0	(0)	3	(21)	
>5 to ≤6 cm	29	(32)	6	(26)		5	(56)	1	(7)	
>6 to ≤7 cm	17	(19)	4	(17)		2	(22)	2	(14)	
≥8 cm	16	(18)	10	(43)		2	(22)	8	(57)	
Maximum treatable number of leiomyomas					0.223					0.470
All responses	90	(100)	23	(100)		9	(100)	14	(100)	
1	28	(31)	4	(17)		2	(22)	2	(14)	
2	41	(46)	12	(52)		5	(56)	7	(50)	
≥3	21	(23)	7	(30)		2	(22)	5	(36)	

[†]Missing responses and those who answered "other" were excluded from the analysis
HIFU, High-Intensity Focused Ultrasound

perception of HIFU (Table 3). Specifically, gynecologists who worked in institutions where HIFU therapy was available or who had an actual experience of requesting HIFU tended to think that it was effective (P -value 0.002 and 0.016, respectively). In addition, they also thought that HIFU therapy could be applied to women who desired pregnancy and in those with large leiomyomas.

4. Discussion

In this study, we demonstrated that the majority of

gynecologists in Korea considered HIFU ineffective. In fact, most of the gynecologists were working at institutions where HIFU was unavailable. The availability of HIFU at the institution and having had an actual experience of treating a patient with HIFU were associated with a more positive perception regarding its effectiveness. Furthermore, the gynecologists who had experience of using HIFU therapy on a patient were more likely to consider that HIFU therapy could be applied to women who desire pregnancy, even though the current Korean Society of Obstetrics and Gynecology guideline for the practice of HIFU states that this is a

relative contraindication [9].

To date there have been no studies focusing on the perception of the physicians of HIFU as a treatment for uterine leiomyomas or for any other gynecologic diseases. Some previous studies have focused on the patients' perceptions of the efficacy of HIFU in resolving their symptoms related to uterine leiomyomas. Gizzo et al. reported that the mean symptom severity score (SSS-QOL), answered through the Uterine Fibroid Symptom and Health-Related Quality of Life questionnaire (UFS-QOL), decreased from 56.3 to 31.0 within a 6-month follow-up period [10]. In a more recent study, they also demonstrated that the SSS-QOL improved significantly from 56.5 at baseline to 40.6 at two years post-treatment [11]. Despite the current data available showing positive feedback from the patients regarding HIFU as a treatment for uterine leiomyomas, the perception of gynecologists in Korea is negative. Moreover, it would be interesting to investigate the perception of HIFU as a treatment for leiomyomas amongst gynecologists worldwide, and whether the availability or an actual experience of HIFU affects this insight.

The main limitation of our study is the small sample size, and the strength of its representativeness of the gynecologists in Korea can be questioned. Furthermore, the relationship between the positive perception of HIFU and the existence of having experience of HIFU cannot be established; therefore it is not necessarily true that having an actual experience leads to a more positive view. In previous studies related to HIFU, many have focused on the adverse reactions [8], reduction rates [10], and pregnancy outcomes [12] after the HIFU procedure. However, there have not been any reports on the perceptions of the physicians of HIFU, which may be related to the frequency of HIFU being performed in treating leiomyomas. Notably, this study is the first to focus on this aspect.

5. Conclusion

Although the results of this study have shown that the perception of HIFU as a treatment for leiomyomas is still not favorable amongst Korean gynecologists, they have also shown that at places where HIFU is available and actually practiced, the perception tends to be more positive overall.

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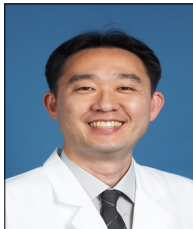
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