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Original Research

EFFECTS AND HEALTH - RELATED QUALITY OF LIFE CHANGES AMONG PATIENTS UNDERGOING UTERINE FIBROIDS EMBOLISATION IN HUE CENTRAL HOSPITAL

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ABSTRACT

Background: *Uterine fibroids (UF) are the most common neoplasms of the female pelvis. The current treatment trend is to use noninvasive methods such as uterine fibroids embolization to reduce severe symptoms and improve the quality of life. The study's main objective was to investigate the clinical features and treatment results after 2 years of uterine fibroids embolisation to evaluate the effectiveness and improve the symptoms of uterine fibroids. The secondary objective is to evaluate changes in the quality of life and potential relationships with age, number of children, volume and number of fibroids compared to before embolism.*

Methods: *All patients with uterine fibroids had been treated with uterine fibroid embolisation therapy at Hue Central Hospital between 2012 and 2018. Study period: 02 years, since the patient received treatment. Method of the study was retrospective cross-sectional description at the time before and 2 years after treatment. Use the uterine fibroid symptom and quality of life questionnaire to collect data.*

Results: *There were twenty patients treated by Uterine fibroid embolisation. About age: 85% in the age group 30 - 50 years old; The number of patients with infertility caused by fibroids accounts for 30%; 65% of patients were in rural areas. Clinical characteristics: 50% of patients with mild anemia before treatment; 55% had 2-5 fibroids; The largest fibroids in the muscle account for 30%. Regarding treatment after 2 years, the reduction in symptoms of uterine fibroids after treatment was statistically significant, with an overall reduction of 16% (95% CI 12 to 20, P <0.01). The improvement in the health-related quality of life (HRQOL) score was 21.7% (95% CI 13.4 to 30, P <0.01). There are 3 cases, accounting for 15%, needing surgical intervention after treatment.*

Conclusions: *Treatment of uterine fibroid embolisation (UFE) has been shown to improve symptoms after 2 years, helping patients keep uterus and improving the quality of life. Uterine fibroid embolisation may be an option for patients with large, sub-serous, or sub-endometrial fibroids. Cases in the uterine muscle will be less effective.*

Keywords: *Uterine fibroid embolisation (UFE), Uterine fibroid symptom and quality of life questionnaire (UFS-QOL), Health-related quality of life (HRQOL), Symptom severity.*

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I. INTRODUCTION

Uterine fibroids (UF) are benign, smooth muscle cells tumor of the uterus. Fibroids occur in 20-40% of women of reproductive age, the most common female benign tumors [1,2]. Despite benign tumors, fibroids may lead to significant clinical symptoms such as heavy menstrual bleeding, painful menstruation, and local pressure effects (pelvic pain, urinary frequency or urgency, constipation). Symptomatic patients often seek treatment, with common therapeutics being hysterectomy or myomectomy. While a hysterectomy relieves all UF

symptoms by removing the uterus, many women are opposed to having a hysterectomy due mostly to undesirable comorbidities such as prolonged inpatient hospitalization, blood transfusion, and scarring, relatively long recovery time, and the loss of fertility [2,3].

Therefore, various minimally and noninvasive alternatives to hysterectomy that preserve the uterus have been introduced. These less-invasive alternative techniques can be cited: Since fibroids are estrogen- and progesterone-dependent tumors, pharmacological treatment can be considered. GnRH-agonists reduce the volume and symptoms of fibroids, but they are note suitable for long-term use due to significant side effects. Other pharmacological treatment options include mifepristone (a progesterone receptor antagonist) and selective progesterone receptor modulators, such as ulipristal acetate [4-6].

Minimally invasive management worldwide and in Viet Nam includes uterine artery embolization, percutaneous laser ablation, cryoablation, transvaginal uterine artery occlusion and magnetic resonance imaging-guided focused ultrasound [7-9]. Of the above, undoubtedly, the most significant innovation in the treatment of uterine fibroids is uterine fibroid embolization (UFE). Treatment with UFE has been proven to reduce symptoms safely and effectively, helping patients keep uterus and improving the quality of life [8]. This treatment has been used in Hue Center Hospital since 2012.

However, these alternative therapies may not relieve all symptoms of UF. Consequently, their use has generated the need for patient-reported outcomes to assess symptom reduction of UF. It has become increasingly important to evaluate the clinical success of patients who choose noninvasive treatment of fibroids. Consequently, we use the Uterine Fibroid Symptom and Health Related Quality of Life Questionnaire (UFS-QOL) to evaluate uterine fibroids' symptoms and their impact on HRQL in the women who choose the noninvasive treatment of fibroids above [3]. The study's main objective was to investigate the clinical features and treatment results after 2 years of uterine fibroids embolisation to evaluate the effectiveness and improvement of the symptoms. The secondary objective was to evaluate changes in the quality of life and potential relationships with age, number of children, volume and number of fibroids compared to before embolism.

II. MATERIALS AND METHODS

2.1. Study population

All patients having fibroids were referred for UFE in Hue Center Hospital between 2012 and 2018.

Time of study: 02 years, since patients were referred for UFE.

Inclusion criteria: patients with symptomatic, intramural uterine fibroids qualified for UFE were included in the study.

Exclusion criteria: the patients with a mental disorder, can not answer interview and lose follow-up.

2.2. Methods

A prospective cross-sectional descriptive study with convenient sample size.

Steps of study:

Step 1: Choose patients.

Step 2: Collect the information about administrative part, medical and gynecological history. Use the Uterine Fibroid Symptom and Health Related Quality of Life Questionnaire (UFS-QOL). This questionnaire was used to collect information when the patients hospitalized and UFE after 2 years.

Step 3: Evaluation of improvement of uterine fibroid symptoms and quality of life through a questionnaire of fibroids symptoms and health-related quality of life.

The Uterine Fibroid Symptom and Health Related Quality of Life Questionnaire (UFS-QOL) is a uterine fibroid specific questionnaire developed to evaluate the symptoms of uterine fibroids and their impact on HRQL. The UFS-QOL has been used in a number of studies of uterine fibroid treatment, including studies of uterine artery embolization, radiofrequency thermal ablation, magnetic-resonance-guided ultrasound surgery and treatment with medication. This instrument has demonstrated reliability and validity among women with uterine fibroids [3,10].

The UFS-QOL is a disease-specific questionnaire that assesses symptom severity and HRQL in patients with uterine fibroids [23]. It consists of an 8-item symptom severity scale and 29 HRQL items comprising 6 domains: Concern, Activities, Energy/ Mood, Control, Self consciousness, and Sexual Function. All items are scored on a 5-point Likert scale, ranging from "not at all" to "a very great deal" for symptom severity items and "none of the time" to "all of the time" for the HRQL items. Symptom severity and HRQL subscale scores are summed and transformed into a 0–100 point scale. The Symptom Severity scale and HRQL subscale scores are inversely related, with higher Symptom Severity

scores indicating greater symptoms while higher HRQL subscale scores indicate better HRQL [3].

This is a useful outcome measure, demonstrating responsiveness to treatment effects. This study aimed to evaluate the responsiveness of the UFS-QOL in a clinical study of treatment for uterine fibroids [10].

2.3. Statistical analysis

Statistical analysis was performed using the SPSS software package (SPSS 10.0.7; SPSS Corporation, Chicago, USA) and Microsoft Excel 2010. Identifier variables: quantity (n), rate (%). The percentage rate compares the difference between groups using independent-sample Student's t-tests for continuous variables and chi-square tests for categorical variables. Statistical significance was accepted at $P < 0.05$.

III. RESULTS

Of the 23 patients who received UF treatment and completed a baseline UFS-QOL, 3 patients did not complete a 2-year follow-up assessment. They did not provide a baseline UFS-QOL assessment, thus resulting in a sample of 20 patients:

Table 1: Common characteristics of fibroid patients

Characteristic	Value
Age > 30	85%
Mean age (SD)	42.5 ± 7.1
Parity: 0 ≥ 2	 30% 50%
Geography: - City - Rural-High land	 10% 90%
Hospitalizing reasons: - Menorrhagia - Pelvic pain - Severe dysmenorrhoea - Concern - Infertility	 35% 20% 10% 5% 30%

85% of patients of reproductive age with a mean age of 42.5 (± 7.1) years; nulliparity accounted for 30%; 90% lived in Rural-High land; Common reasons for admission were menorrhagia 35%, infertility 30%, only 5% of patients with concern.

Table 2: Clinical characteristics

Clinical characteristics		Before treatment		After treatment		P
		n	%	n	%	
Pressure pain		4	20.0	3	15.0	≥ 0.05
Menorrhagia		7	35.0	3	15.0	
Infertility		6	30.0	6	30.0	
Abortion		5	25.0	2	10.0	
Concern		1	5.0	0	0.0	
Total		20	100	20	100	
Level of anemia	Normal	3	15.0	5	25.0	≥ 0.05
	Mild	5	25.0	8	40.0	
	Morderate	10	50.0	6	30.0	
	Severe	2	10.0	1	5.0	
Total		20	100	20	100	

Before treatment, common symptoms were menorrhagia 35%, infertility 30% and abortion 25%; 75% of patients presented with mild and moderate anemia, severe amenia only accounted for 10%. After treatment, common symptoms were infertility 30%, pressure pain and menorrhagia 15%, severe anemia only accounted for 5% and mild/ moderate anemia took 70%. The difference was not statistically significant.

Table 3: Paraclinical characteristics

Paraclinical characteristics	Before treatment		After treatment		P
	n	%	n	%	
Fibroid Quantity					
1	6	30.0	6	30.0	≥ 0.05
2-5	11	55.0	13	65.0	
> 5	3	15.0	1	5.0	
Total	20	100	20	100	
Dominant Fibroid Volume					
< 50	3	15.0	14	70.0	≥ 0.05
50 - 100	12	60.0	5	25.0	
> 100	5	25.0	1	5.0	
Total	20	100	20	100	
Uterine Volume (cm3)					
< 100	3	15.0	5	25.0	≥ 0.05
100 – 199	6	30.0	7	35.0	
200 – 299	7	35.0	5	25.0	
> 300	4	20.0	3	15.0	
Total	20	100	20	100	

Fibroid quantity in ultrasound did not significantly change after treatment; fibroid volume decreased after uterine artery embolization, the prevalence of volume < 50 cm3 increased from 15% to 70%. Before UFE, fibroid volume of 200 – 299 cm3 accounted for 35%; after treatment, the most common fibroid volume group was 100 – 199 cm3 with 35%. The difference was not statistically significant.

80% of patients did not require supplement treatment after UFE; 3 (15%) had surgery after UFE. 1 patient was treated with Zoladex drug.

Table 4: Supplement treatment after UFE

Supplement treatment	n	%
Zoladex drug	1	5.0
Surgery (myomectomy or hysterectomy)	3	15.0
None	16	80.0
Total	**20**	**100**

Table 5. Comparison of symptom severity and quality of life scores

UFS-QOL subscale	*n (20)*	Before UFE median (25–75 percentile)	After UFE median (25–75 percentile)	Difference median (95% CI)	*P value* (Wilcoxon's test)
Symptom severity	8	43.75 (26.56–53.13)	21,88 (6,25–29,96)	25,00 (15,63 to 31,25)	<0,001
Concern	9	62.50 (41.25–88.75)	92.50 (71.25–100.00)	- 10.00 (–30.00 - 0.00)	<0.001
Activities	9	46.43 (35.71–78.57)	89.29 (67.86–100.00)	- 17.86 (–35.71–7.14)	<0.001
Energy/mood	9	60.71 (42.86–69.64)	82.14 (71.43–100.00)	- 21.43 (–32.14 –7.14)	<0.001
Control	9	65.00 (50.00–75.00)	90.00 (76.25–100.00)	- 20.00 (–30.00 –15.00)	<0.001
Self-consciousness	9	75.00 (52.08–91.67)	91.67 (77.08–100.00)	- 8.33 (–25.00 - 0.00)	<0.001
Sexual function	9	50.00 (37.50–84.38)	87.50 (62.50–100.00)	- 12.50 (–25.00 - 0.00)	<0.001
HRQOL total	8	56.90 (45.26–75.86)	87.93 (74.14–97.84)	- 17.24 (–33.62 –8.62)	<0.001

** CI, confidence interval; HRQOL, health-related quality of life; UFS-QOL, uterine fibroid symptom and quality of life questionnaire.*

After UFE, severe symptoms decreased. Quality of life scores increased.

IV. DISCUSSION

In table 1, 85% of patients treated with UFE were in reproductive age, and 30% were infertility patients. Most patients wanted to preserve infertility with minimally invasive management. The age of the patient is important for the treatment method. Limiting radical treatments such as hysterectomy in young patients who still wish to have children is very meaningful. Especially in terms of reproductive function and quality of life, patients often select alternative methods of hysterectomy such as medication, embolization, myomectomy. Only if the myoma is too big or conservative surgery is too difficult should the hysterectomy be indicated. In uterine fibroid patients, it is always necessary to consider their quality of life after treatment and the appropriate selection methods. [3,7,9].

90% of patients were from rural and high land, and only 10% from city. Most of them come from provinces such as Ha Tinh, Quang Binh and Quang Tri. That was difficult to choose preserve-uterine treatment, following up, consulting and their economic. So, some patients lost following up, and some decided to have surgery due to persistent fibroid symptoms after UFE.

The majority of fibroids were asymptomatic and required no treatment. Such fibroids were an incidental finding during gynecological or ultrasound examination and routine monitoring is sufficient. However, the presence of uterine fibroids may lead

to significant clinical symptoms. The symptoms may be associated with menstruation (heavy menstrual bleeding and painful menstruation) or local pressure effects (pelvic pain, urinary frequency or urgency, constipation). Fibroids may also be responsible for subfertility and early pregnancy loss. Table 2 shows menorrhagia 35% and infertility 35% in common symptoms. Pelvic pain, severe dysmenorrhoea or concern were seldom. This is quite suitable for the main treatment goal of the patient, which is to preserve the uterus for reproductive function, since most of the infertile cases accounted for up to 30%. In addition, menorrhagia - bleeding was also the most common symptom in patients with uterine fibroids because most women were in reproductive age

In table 2, after 2 years of UFE, the initial symptoms of fibroid reduced with different levels. Menorrhagia symptoms improved the most, from 35% down to 15% after UFE. However, infertility prevalence did not change. This proved that fertility after conservative treatment for uterine fibroids was ineffective during the 2-year study period. A longer study period is needed to evaluate the improvement in fertility. For the problem of miscarriage due to the impact of uterine fibroids, there was a good reduction after treatment with 25% before treatment to 10%. Anxiety symptoms also decreased, but not much. However, the differences in symptoms before and after treatment were not statistically significant because the number of patients observed and followed up was small, the small sample size did not reflect the possibility of post-conservative treatment for this disease. Common symptoms of uterine fibroids.

In table 2, there was no difference in the relationship between anemia before surgery and after conservative treatment of fibroids by embolization with $p > 0.05$. Before treatment, moderate anemia was the most common, accounting for 50% of anemia cases. After treatment, the most common anemia group was mild anemia in 40% of cases. With that result, there was an improvement in the degree of anemia before and after treatment. This was achieved by improving symptoms after treatment, in which the symptoms of menorrhagia - heavy bleeding were prominent. Only one case, accounting for 5%, was severe anemia after treatment. This case coincided with a case of treatment failure and subsequent conversion to radical treatment, which was a total hysterectomy.

In table 3, The volume of fibroids on ultrasound decreased significantly after treatment. Before treatment, most uterine fibroids from 50-100 cm2 accounted for 60%, large volumes over 100 cm2 accounted for 25%. After treatment, 70% of uterine fibroids were less than 50 cm2, only 5% of fibroids were above 100 cm2. This demonstrates how effective the treatment for uterine fibroid embolism is, significantly reducing the volume of fibroids after 2 years of treatment. Therefore, it helps reduce uterine fibroids' symptoms, especially menorrhagia - bleeding and symptoms caused by compression. However, because the sample size was small, the stated difference was not statistically significant.

In table 3, overall uterine volume decreased sequentially after treatment of uterine fibroids by UFE after 2 years. Before UFE, the uterine volume above 300 cm3 accounted for 20%. After UFE, it reduced to 15%; The uterine volume from 100-300 cm3 decreased by 5% after UFE and the volume below 100 cm3 increased from 15% to 25%. Thus, the treatment effect was clearly demonstrated by reducing the overall uterine volume after treatment of uterine fibroids by UFE. Unfortunately, because of the small sample size, the difference was not statistically significant. According to the study of Jha et al. (2000), large uterine volume before UFE treatment is known to be a poor prognostic factor. This is related to the fact that the large uterine volume before UFE means that the embolic particles need to be transferred to larger areas [11]. This finding is similar to the findings of Chung et al., which showed that the smaller the number of fibroids and the smaller the overall diameter of the fibroids, the greater the likelihood of a response to UFE [3].

Table 4 shows 3 cases requiring surgical intervention after UFE, approximately 15%. In addition, 1 case (5%) received additional medical treatment. Thus, the failure to treat uterine fibroids is related to many causes. The most important and prominent cause was the problem of patient selection. For patients with large uterine fibroids or multiple fibroids (diffuse fibroids), adenomyosis, if indicated for embolization therapy, the possibility of success was very low. In a meeting between Kröncke and X-ray experts, a symptomatic uterine fibroid indicates uterine artery embolization. UFE represents an alternative to surgical and medication-based procedures and fibroid treatment using focused ultrasound, regardless of the size and number of the fibroids or previous surgery. The basis for the choice of therapy should be the aim of the treatment as well as the patient's desire.

Success criteria for UFE are primarily on the improvement or complete disappearance of fibroid-related symptoms indicated by the patient, and less on the volume reduction of a dominant fibroid or the entire uterus after treatment [10]. The failure rate of the UFE method in our study compared to other authors' results was similar.

Table 5 showed for the first time that improvements in symptom severity and HRQOL after UFE, assessed by a validated disease-specific questionnaire, were significant and similar at before versus after UFE 2 years, indicating the stability of clinical improvement after UFE over time. The symptom severity score decrease from 43.75 (26.56–53.13) down 25.00 (15.63 to 31.25). Smith et al. (2004) presented a study in which the UFS-QOL was used in a patient population of similar size. However, the questionnaire pertaining to the patient's pretreatment condition was administered retrospectively together with the post-treatment questionnaire at the end of a follow-up period ranging from 6 to 57.5 months, which limits the quality of their results considerably because of a possible recall bias as well as non-uniformity of follow-up data [10]. In a randomized trial comparing two embolic agents for UFE, Spies et al. presented 3-month clinical follow-up results of 100 patients assessed by the UFS-QOL. They showed a mean reduction in the symptom severity score of 26.8–39.2 (±24) and a mean increase in the HRQOL total score of 23.1–36 (±23–25) (Spies et al., 2004) [11]. The mean changes in both scores in their study reflecting the dimensions of improvement in both parameters are comparable with our results with the exception that baseline values for symptom severity were lower and HRQOL total scores higher in our study, resulting in even lower symptom severity scores and higher HRQOL total scores for both follow-up groups after treatment. In a recent multicentre study using the Fibroid Registry for Outcomes Data (FIBROID) and the UFS-QOL as the outcome measure, similar results regarding reduction in symptom severity and improvement of health HRQOL total scores were reported for 6 and 12 months after UFE [12].

V. CONCLUSION

Treatment of uterine artery embolisation (UA) has been shown to improve symptoms after 2 years, helping patients keep uterus and improving the quality of life.

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