UTERINE EMBOLIZATION FOR MANAGEMENT OF SYMPTOMATIC FIBROIDS: QUALITY-OF-LIFE IMPACT*

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Abstract OBJECTIVE: To determine the impact on the quality of life in patients with symptomatic uterine fibroids submitted to uterine artery embolization. MATERIALS AND METHODS: Forty patients with symptomatic fibroids submitted to embolization have answered a quality-of-life questionnaire before and 12 weeks after the procedure. RESULTS: Mean score for symptoms severity before the procedure was 62.07 ± 6.34 and decreased with statistical significance to 20.42 ± 3.81 after the procedure. Similarly, scores for quality of life have improved from 40.26 ± 2.98 before the procedure to 85.06 ± 2.57 after the procedure, which again was statistically significant. CONCLUSION: Uterine embolization results in evident symptoms relief and significant improvement in the quality of life of patients with symptomatic fibroids.

Keywords: Therapeutic embolization; Uterus; Leiomyoma; Quality of life; Interventional radiology.

Resumo Embolização uterina para tratamento de miomas sintomáticos: impacto na qualidade de vida.

OBJETIVO: Verificar a mudança na qualidade de vida de pacientes portadoras de miomatose uterina sintomática submetidas a tratamento por embolização. MATERIAIS E MÉTODOS: Quarenta mulheres portadoras de miomatose uterina sintomática que foram tratadas com a técnica de embolização responderam a um questionário de qualidade de vida antes e 12 semanas após o procedimento. RESULTADOS: Verificou-se que o escore médio relacionado com a gravidade dos sintomas nas 40 pacientes antes da embolização foi de 62,07 ± 6,34 e se modificou, com significância estatística após o tratamento, quando se verificou escore médio de 20,42 ± 3,81. Da mesma forma, comprovou-se a melhora na qualidade de vida pela modificação dos escores antes e depois do tratamento, o que também apresentou significância estatística, passando de 40,26 ± 2,98 para 85,06 ± 2,57. CONCLUSÃO: A embolização uterina provoca alívio evidente dos sintomas relacionados com a miomatose e proporciona melhora substancial da qualidade de vida das pacientes. *Unitermos:* Embolização terapêutica; Útero; Leiomioma; Qualidade de vida; Radiologia intervencionista.

INTRODUCTION

Uterine myomas, also called leiomyomas or fibroids, are the most common benign gynecologic tumors, and may be present in up to 40% of women in childbearing age⁽¹⁾.

Most frequently, myomatosis affects nulliparous, obese, black women, or those with family history of myomatosis or hyperestrogenic syndrome⁽²⁾.

Despite the absolutely benign nature of myomas, complaints of uncomfortable symptoms such as menorrhagia (abnormal menstrual bleeding), dysmenorrhea (painful menstruation), a felling of pressure in the pelvis, increase in the urinary frequency, pain, infertility or increase in abdominal volume and palpable pelvic mass are very frequent⁽³⁾.

Clinical presentation is variable and is particularly related to the size, location and number of myomas, but certainly myomatosis symptoms, when present, result in a remarkable impairment of the patients' quality of life.

The most frequent symptom is an abnormal uterine bleeding (menorrhagia) that usually is characterized by increased menstrual duration and blood flow volume, sometimes leading to anemia⁽⁴⁾. Generally, women complain of a progression in the intensity, that is to say, a gradual increase in the menstrual blood flow obliging them to more frequent tampon or pad changes, or even to the use of diapers during the period. It is in these circumstances where women report that they avoid leaving home, scheduling professional or social activities because of the discomfort caused by the menstruation, or in order to avoid embarrassing or upsetting situations.

Until recently, only two therapeutic modalities were available for treating symptomatic myomatosis: the surgical approach or hormone therapy.

Definitely, hysterectomy is the most commonly performed procedure for the management of myomatosis. It is estimated that myomatosis accounts for one third of almost 400,000 hysterectomies performed in the United States of America⁽⁵⁾. Despite the advantage of being definitely curative, hysterectomy is a formal surgical procedure that requires hospital stay for some days and a variable period of postoperative recovery and convalescence. Also, hysterectomy may be associated to a considerable blood loss, ureter injury, prolapse and other complications⁽⁶⁾. Besides, it eliminates any possibility of fertility, which represents a deep loss for nulliparous women.

Starting in 1991, a team of French doctors started the clinical utilization of uterine embolization as an alternative for treating uterine fibroids. The early results of these experiments were published in 1995

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by the prestigious journal *The Lancet*, em 1995, suggesting that this was a highly efficient method for the management of uterine myomatosis symptoms⁽⁷⁾.

Since that time, numerous clinical experiments have been reported worldwide, demonstrating the validity of this promising percutaneous procedure^(8–15).

Uterine embolization is a minimally invasive modality of interventional radiology that consists in intentionally blocking the arteries that supply blood to the fibroids, causing their ischemia and shrinkage, resulting in the resolution of their symptoms. For this purpose, a thin catheter is inserted under local anesthesia, by means of puncture of the femoral artery in the inguinal region, and, under fluoroscopic vision generated by a digital angiography apparatus, the catheter is inserted and advanced to the uterine arteries. Gelatin microspheres measuring about 500-µ is then injected through the angiographic catheter until stasis of the branches that supply blood to the fibroids⁽¹⁶⁾.

Since we started applying this technique in Brazil, in 1999, we have already treated 450 patients. Technical and clinical outcomes from this initial experiment have been previously published⁽¹⁷⁾.

The present study reports outcomes from a group of patients submitted to uterine embolization, utilizing a system for evaluation and comparison of their quality of life before and after the treatment.

MATERIALS AND METHODS

The present study evaluated data obtained from images and questionnaires answered by 40 women with symptomatic uterine myomatosis who were submitted to uterine embolization in the period between July/2004 and June/2006, in the Division of Interventional Radiology at Hospital Santa Catarina in São Paulo, SP, Brazil.

The analysis included data from women with complaints resulting from the presence of uterine fibroids who, during the preoperative clinical evaluation and the period of postoperative clinical follow-up had answered a questionnaire about quality of life related to the disease treated. The mean age of patients was 38 years (age range = 22 - 46 years). As regards the patients' race, 31 women were Caucasian, five were black, and four Asian. The patients' gestational history showed that 28 of them were multiparous, and 12 were nulliparous. Amongst the patients included in the present study, 28 reported a job or professional activity, and 12 defined their activity as "housewives". The main complaint leading to the treatment was increased menstrual bleeding, with or without anemia in 29 patients, and pain or compressive symptoms secondary to uterine increase in 11. The diagnosis of uterine myomatosis was based on data collected from the clinical history, clinical examination and pelvic magnetic resonance imaging or ultrasound. All of the pre- and postoperative image studies were performed in an ambulatorial setting in different divisions of the hospital where the patients were submitted to the treatment. All the patients presented with increased uterine volume (mean = 666 cm³, ranging between 245 cm³ and 1.930 cm³). The method included puncture of the right femoral artery, angiographic study of uterine arteries, and embolization with calibrated 500–700-µ spheres (Embosferas[®]). The procedures were documented by means of pre- and post-embolization angiographic studies (Figure 1).

All the patients remained hospitalized 24 hours for rest and observation.

At the time of the preprocedural clinical evaluation, all the patients answered a questionnaire for evaluation of their quality of life related to the presence of fibroids (Chart 1). This questionnaire was specifically developed for this purpose in the Georgetown University, Washington, USA⁽¹⁸⁾, and translated into Portuguese by a professional translator. It includes 37 questions, and is divided into two parts. The first one includes eight questions about the intensity or severity of symptoms reported by the patient. Each of these questions offer five options corresponding to intensity: "no", "little", "reasonable", "much", "very much", with a corresponding scoring from 1 to 5. The final scoring is converted into a corrected score by means of a mathematical formula. The second part of the questionnaire includes 29

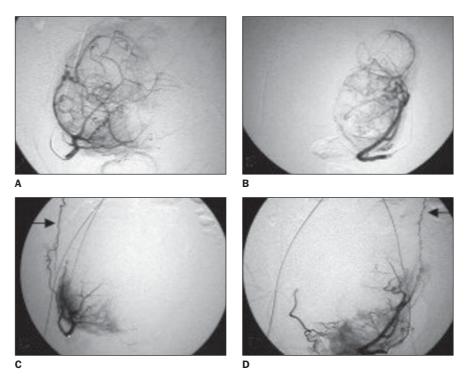


Figure 1. Standard angiographic documentation of uterine embolization procedure: **A:** Selective catheterization of right uterine artery. Intrauterine branches can be observed delimitating nodular areas. **B:** Left-sided selective catheterization with angiographic aspect similar to the right side. **C:** After embolization, disappearance of the branches that supply blood to the fibroids, with main intrauterine branches preserved. Also, a preserved right ovarian artery is observed with ascending course (arrow). **D:** After embolization, main branches and left ovarian artery are preserved (arrow).

Chart 1 Quality-of-life questionnaire utilized in the present study.

QUALITY-OF-LIFE QUESTIONNAIRE RELATED TO UTERINE FIBROIDS.								
The following items correspond to common symptoms experienced by women affected by uterine fibroids. Please, consider each of these symptoms as being related to the presence of fibroids or to your menstrual cycle. Each of the questions is related to the level and intensity of anguish or discomfort you have experienced as a result of these symptoms during the last three months. There is no correct or wrong answer. Simply choose an option which best fits your symptoms that has led you to seek for the treatment (indicate by marking X on the appropriate site).								
During the last three months, what has been the level of discomfort caused by	/ No	Little	Reasonable	Much	Very much			
1. Heavy bleeding during menstruation.		2	3		5			
2. Clots in the menstrual flow.		2			5			
3. Alteration in the period duration as compared to previous periods.		2	 3		5			
4. Alteration in the interval between periods as compared to the past.		2	□ 3	4	□ 5			
5. Feeling of pressure or tension in the pelvis.		2	□ 3		□ 5			
6. Frequent necessity to urinate in the daytime.		2	□ 3		□ 5			
7. Frequent necessity to urinate at night.		2	□ 3		□ 5			
8. Feeling of fatigue.		2	□ 3		□ 5			
The questions below relate to the impact caused by the fibroids symptoms intensity on your life. Please, consider each of these questions as being exclu- sively related to the presence of fibroids during the last three months. There is no correct or wrong answer. Simply choose an option which best fits your symptoms that has led you to seek for the treatment (indicate by marking X on the appropriate site). If no option fits your experience, select "at no time" (1).								
During the last three months, with which frequency symptoms caused by fibroids	At no moment	Few times	Some times	Most of time	All the time			
9. Have caused anxiety because of the unpredictability of the amount and duration of your menstrual period?	1	2	 3	4	5			
10. Have caused preoccupation with a travel?		2	3	4	5			
11. Have affected your physical activities?		2	3	4	5			
12. Have caused tiredness?		2	3	4				
13. Have made you to reduce the amount of time spent on exercises or physical activities?		2	3	4	5			
14. Have made you feel like you were not in control of your own life?		2	3	4	5			
15. Have caused a fear that you might stain your underwear?		2	 3	4	5			
16. Have made you feel less productive?		2	 	4	5			
17. Have caused somnolence in the daytime?		2	3	4	5			
18. Have cause embarrassment because of overweight?		2	3	4	5			
19. Have made you feel difficulty in your daily activities?		2	 3	4	5			
20. Have affected your social activities?		2	3	4	5			

□ 1

□ 1 □ 2

□ 2 □ 3

□ 3 □ 4

4

21. Have made you feel uncomfortable with the size of your abdomen?

22. Have caused fear that you might stain your bed linen?

□ 5

□ 5

Kisilevzky N

Chart 1 Quality-of-life question	onnaire utilized in the present study. (Continued).						
During the last three mon fibroids	ths, with which frequency symptoms caused by	At no moment	Few times	Some times	Most of time	All the tim	
23. Have made you feel sad	d, discouraged or desperate?		2	3	4	5	
24. Have made you feel de	pressed?			3	4	5	
25. Have made you "feel lik	e a wet rag"?					5	
26. Have caused preoccupa	ation with your health?						
27. Have made you to plan	your activities more carefully?						
-	thered to carry pads and additional cloths to prevent						
accidents? 29. Have made you experie	nce embarrassing situations?						
30. Have caused uncertaint	y about the future?						
31. Have caused irritation?							
32. Have caused a fear that				4	5		
33. Have affected the size of			3		5		
34. Have made you feel like			3	4	5		
35. Have made you feel tire	edness like the energy had been sucked out of you?						
36. Have caused a decrease							
37. Have made you to avoid		2	3		5		
	Calculation of quality of life related t	o the presence of	fibroids				
	1 – Calculation of the symptoms severity (higher va	alue = higher sever	ity — scale	1 to 100)			
Scale	Summation – items	Possible v	Possible options				
Symptom severity	Sum up the values obtained in 1 to 8	8; 40 32					
	Formula: Converted score = (current score - · Possib	< possible score) × le options	100				
	2 – Calculation by category and g	eneral quality of life	;				
Scale	Results summation items	Possible v	alues < e >	>	Possible	options	
Preoccupation	9 + 15 + 22 + 28 + 32	5; 25			20		
Activity	10 + 11 + 13 + 19 + 20 + 27 + 29 12 + 17 + 22 + 24 + 25 + 21 + 25		; 35 ; 35		28		
Mood/energy	12 + 17 + 23 + 24 + 25 + 31 + 35 14 + 16 + 26 + 30 + 34			28			
Self-control Embarrassment	14 + 16 + 26 + 30 + 34 18 + 21 + 33	5	20 12				
Sexuality	36 + 37	3; 15 2; 10			8		
		۲.	,				

Chart 1 Quality-of-life questionnaire utilized in the present study. (Continued)

Formula for calculation of quality of life — higher value = higher quality of life — scale 1 to 100

Score = (> possible score - current score) \times 100

29; 145

Possible options

the time

116

Total quality of life

Summation

questions about the frequency in which the fibroids symptoms affect aspects of the patients' daily lives. These questions are divided into groups corresponding to six aspects: preoccupation, activity, mood/energy, self-control, embarrassment, and sexuality. Each of these questions offers five answering options to measure frequency: "at no time", "few times", "sometimes", "most of time" and "all the time", with a corresponding scoring from 1 to 5. The final score is converted into a corrected score by means of a mathematical formula.

In the first part, the questionnaire presents the evaluation of symptoms intensity stratified from 0 to 100, meaning that 100 corresponds to the highest intensity or severity of the patients complaint. The second part evaluates the quality-of-life itself, i.e. the health condition expressed by a stratified scoring from 0 to 100, where 100 corresponds to the best level of quality-oflife in general, and for each of the specific aspects investigated by the questionnaire.

During the 12-week follow-up period following the procedure, the patients were submitted to a pelvic magnetic resonance imaging for evaluating the uterine size as compared to the similar study previously performed. Also, they were asked to, again, answer the quality-of-life questionnaire.

Data obtained from questionnaires answers as well as those concerning the uter-

Moment

n

Variable

ine volumes evaluated by magnetic resonance imaging were transcribed into a Microsoft Excel worksheet for statistical analysis. Initially, all of the variables were descriptively analyzed. As for quantitative variables, this analysis was performed through observation of minimum and maximum values, as well as calculation of median and standard deviation. As for qualitative variables, absolute and relative frequencies were calculated. The paired Student's t test was utilized for analysis of premoment x postmoment equality hypothesis; when the data normality assumption was rejected, the non-parametric Wilcoxon test was utilized. The significance level utilized for these tests was 5%.

The present study was submitted to the Committee for Ethics in Research of do Hospital Santa Catarina, whose approval (Process CEP019/06) has established that the study was conducted in compliance with the Resolution 196/96 of Conselho Nacional de Saúde (National Council of Health).

RESULTS

All of the statistical variables evaluated before and after the procedure are shown on Table 1.

Mean uterine volume measured by postembolization magnetic resonance imaging

SD

Minimum

Maximum

was 450 cm³, corresponding to a statistically significant decrease in volume of 32.5% (Figures 2 and 3).

The mean score related to symptoms intensity reported in the preprocedural quality-of-life questionnaires was 62.07. The postprocedural quality-of-life questionnaires demonstrated a statistically significant decrease in the mean score to 20.42, representing a 67.1% improvement in symptoms.

The analysis of total quality of life (health condition) related to the patients' myomatosis showed postprocedural score of 40.26, that changed substantially after the treatment, achieving 85.06. This was statistically significant, representing an improvement of 52.6% in the patients' quality of life (Figure 4).

All the items evaluated by the questionnaire demonstrated changes after the treatment (Figure 5).

Mean score related to "preoccupation" in the preprocedural questionnaires was 37.87. In the post procedural questionnaires this score changed to 83.5, showing a statistically significant difference, and corresponding to an improvement of 54.6% in this item.

Mean score related to "activity" in the preprocedural questionnaires was 43.53. In the postprocedural questionnaires, this score changed to 85.49, showing a statis-

Median

р

Table 1 Mean, standard deviation, minimum, maximum values and median of variables in pre- and postprocedural evaluation of 40 patients.

Mean

Uterine volume	Pre Post	40 40	666.03 449.95	418.70 289.64	245.00 168.00	1930.00 1350.00	495.00 357.50	< 0.001*
Symptoms	Pre Post	40 40	62.07 20.42	6.34 3.81	46.80 9.30	78.10 28.10	62.50 20.25	$< 0.001^{\dagger}$
Preoccupation	Pre Post	40 40	37.88 83.50	8.16 5.45	10.00 65.00	45.00 95.00	40.00 85.00	< 0.001 [†]
Activity	Pre Post	40 40	43.53 85.40	4.12 4.37	28.50 71.40	46.60 89.20	42.80 85.70	< 0.001 [†]
Mood/energy	Pre Post	40 40	44.09 85.49	3.74 4.11	28.50 71.40	46.60 89.20	46.60 85.70	< 0.001 [†]
Self-control	Pre Post	40 40	39.75 84.88	6.79 3.30	25.00 80.00	60.00 90.00	40.00 85.00	< 0.001 [†]
Embarrassment	Pre Post	40 40	36.61 85.78	6.77 8.26	16.20 58.30	41.60 91.60	41.60 91.60	< 0.001 [†]
Sexuality	Pre Post	40 40	28.44 83.75	8.00 7.05	12.50 62.50	37.50 87.50	25.00 87.50	< 0.001 [†]
Quality of life	Pre Post	40 40	40.27 85.06	2.98 2.58	33.60 76.70	44.80 8.70	40.50 85.30	< 0.001 [†]

* Descriptive level of probability of the paired t test. † Descriptive level of probability of the Wilcoxon non-parametric test. SD, standard deviation.

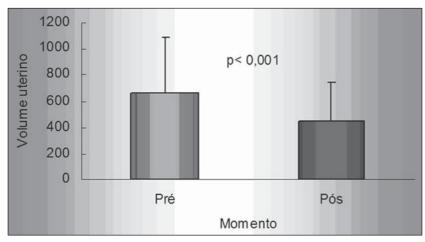


Figure 2. Statistical representation, comparing preprocedural and postprocedural uterine volumes.

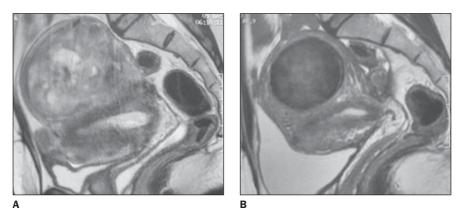


Figure 3. Pre-embolization (A) and postembolization magnetic resonance imaging (sagittal view) demonstrating complete ischemia of subserous and significant decrease in uterine volume.

tically significant difference, and corresponding to an improvement of 49% in this item.

Mean score related to "mood/energy" in the preprocedural questionnaires was 44.01. In the postprocedural questionnaires, this score changed to 85.39, showing a statistically significant difference, and corresponding to an improvement of 48.52% in this aspect.

Mean score related to "self-control" in the preprocedural questionnaires was 39.75. In the postprocedural questionnaires, this score changed to 84.87, showing a statistically significant difference, and corresponding to an improvement of 53.31% in this item.

Mean score related to "embarrassment" in the preprocedural questionnaires was 36.60. In the postprocedural questionnaires, this score changed to 85.78, showing a statistically significant difference, and corresponding to an improvement of 57.33% in this item.

Mean score related to "sexuality" in the preprocedural questionnaires was 28.43. In

the postprocedural questionnaires, this score changed to 83.55, showing a statistically significant difference, and corresponding to an improvement of 65.97%.

DISCUSSION

Since the publication of the first scientific study on uterine embolization in 1995, much has been learned about this theme. The huge amount of papers published and studies presented in international congresses in the last ten years constitute unequivocal scientific evidence that uterine embolization is an effective and safe method for treating symptomatic fibroids, representing a dominant therapy for symptomatic myomatosis. Up to the present moment, it is estimated that more than 200,000 patients have already been treated worldwide by means of uterine embolization.

Besides being safe and effective in the management of myomatosis symptoms, the method has already proved to present some additional advantages.

Considering that this is a minimally invasive, percutaneous method performed under local anesthesia, it allows a rapid clinical recuperation and quick recovery of normal daily activities of the patients. A study developed in Canada and published in 2003, including more than 550 women, demonstrated that 82% of patients submitted to uterine embolization have a single-day hospital stay⁽¹⁹⁾.

Another study developed in the United States of America and published in 2004

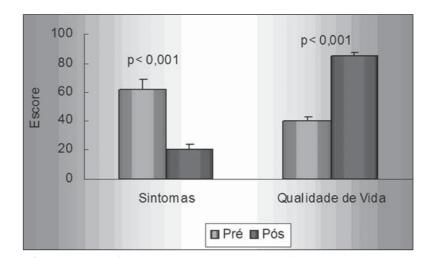


Figure 4. Representation of mean scores and standard deviation of preprocedural and postprocedural symptoms and quality of life.

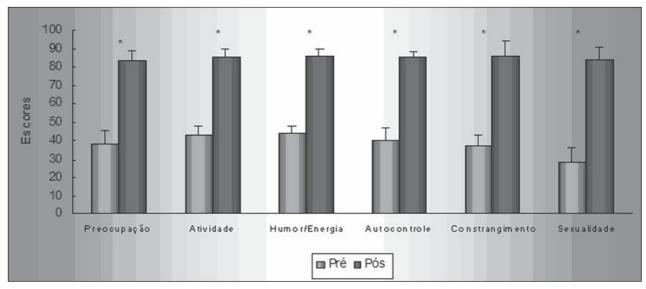


Figure 5. Representation of mean scores and standard deviation of preprocedural and postprocedural preoccupation, activity, mood/energy, self-control, embarrassment and sexuality. (*) p < 0.001.

reported that 94% of patients submitted to uterine embolization lost less than ten working days, and that about 90% of women fully recovered their activities within two - three weeks following the procedure⁽²⁰⁾.

Uterine embolization advantages become more evident in a comparison between results from hysterectomy and uterine embolization. A randomized study developed in Spain, comparing results from hysterectomy and uterine embolization, has evidenced that embolization results in shorter hospital stay, quicker clinical recovery, and lower incidence of complications⁽²¹⁾.

Besides the mentioned advantages, the embolization impact on the patients' quality of life must be taken into consideration. The questionnaire utilized in the present study was based on a survey involving both healthy women and other affected by symptomatic myomatosis. So, the idea was to create a simple tool for evaluating the impairment to the quality of life from the point-of-view of the patients. This study is the first to report the application of this type of questionnaire to Brazilian women. Besides being evident *per se*, the results are very similar to those presented by international studies.

A North-American study involving has shown a 35% improvement in symptoms and quality of life in 64 patients⁽²²⁾.

The largest multicentric study ever developed in the world including more than 2 thousand patients submitted to uterine embolization has demonstrated that the symptoms intensity score evaluated by the quality-of-life changed from 59 before the procedure to 20 after the treatment. The same study has shown that the patients' quality of life improved from 47 to 87 points⁽²³⁾.

Uterine embolization benefits and advantages are translated into a very high rate of satisfaction reported by patients submitted to this treatment. A recently published Dutch study has shown that, 36% of 158 women submitted to embolization declared to be "satisfied", and 57% "very satisfied" with this modality of treatment⁽²⁴⁾.

CONCLUSION

Uterine embolization is a minimally invasive and effective method for alleviating the uncomfortable symptoms caused by fibroids. The utilization of a quality-of-life questionnaire has resulted in a simple and effective tool for demonstrating the improvement in symptoms and in quality of life as a whole.

Uterine embolization becomes a highly significant method for treating women who wish to preserve their uteri, or those who need to quickly recover their normal activities after the treatment.

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