ASIAN JOURNAL OF PHARMACEUTICAL AND CLINICAL RESEARCH

INNOVARE ACADEMIC SCIENCES
Knowledge to Innovation

Vol 15, Issue 12, 2022

Online - 2455-3891
Print - 0974-2441

Research Article

UTERINE FIBROIDS: SYMPTOMS SEVERITY AND ITS IMPACT ON HEALTH-RELATED QUALITY OF LIFE AMONG WOMEN IN REPRODUCTIVE AGE GROUP IN NORTH KERALA

ABHILASH ANTONY V, HEERA SHENOY T*, SHIVAKUMAR, CHELLAMMA VK, HIBA HASHIM

Department of Obstetrics and Gynaecology, KMCT Medical College, Kozhikode, Kerala, India. Email: heerarprabhu@gmail.com

Received: 25 July 2022, Revised and Accepted: 30 August 2022

ABSTRACT

Objectives: This study was conducted to determine the effect of uterine fibroids (UFs) and their symptoms severity and its impact on health-related quality of life (QoL) among women in reproductive age group reporting to a teaching medical institution in the state of Kerala.

Methods: The questionnaire QoL-life quality of patients with symptomatic UF was used to assess their QoL in 104 women attending outpatient department at KMCT Medical College from March 2021 to August 2021.

Results: Mean age was 45.86. About 34.62% of cases were in Obesity I category; followed by 13.46% of Obesity II. About 33.65% had UF with corporeal location; 44.23% in cervical and 22.12% had isthmic fibroids. About 32.69% showed presence of sub-serous; 42.67% had intramural and 24.04% had submucosal fibroid. HMB followed by abdominal pain and bladder dysfunction was the presenting features.

Conclusion: There was a strong negative correlation between symptoms and the UF QoL. This shows that with the increase in symptoms; the QoL was reduced in all the overall aspects. Hence, it was concluded that UF has a profound negative impact on the overall QoL in reproductive age women.

Keywords: Uterine fibroids, Health-related quality of life, Reproductive age group.

 DOI: http://dx.doi.org/10.22159/ajpcr.2022v15i12.45970. Journal homepage: https://innovareacademics.in/journals/index.php/ajpcr

INTRODUCTION

Uterine fibroid (UF) is the most common type of tumor among women of reproductive age and increases with age [1]. Approximately half of women with fibroids have bothersome symptoms, including heavy menstrual bleeding, abdominal pain, and pressure, that negatively affect quality of life (QoL) [2]. The occurrence of fibroids is in the range of 20–40% of women in their reproductive ages and 11–19% in case of perimenopausal patients. The clinical symptoms suh as pain and lumps or irregular bleeding are severe enough in approximately 25% of women to require treatment [3]. The annual cost of UF has been estimated to total 34.4 billion USD, which is more than breast cancer, colon cancer, or ovarian cancer, though less than cardiovascular disease. According to Smailova *et al*., the assessment of the QoL scale has an independent prognostic value and can be used when choosing a treatment strategy for the patients with UF [4]. Studies have reported that the clinical symptoms of UF are inversely correlated with the various indicators of QoL such as physical activity, self-monitoring, anxiety, and concern [5]. There are negligible studies reported among women with UF and their QoL from the state of Kerala. Hence, this study was carried out to determine the effect of UFs and their symptoms severity and its impact on health-related QoL (HRQL) among women in reproductive age group reporting to a teaching medical institution in the state of Kerala.

Objectives

The objectives of the study are as follows:

1. To study the impact on fibroids on the HRQL using questionnaires
2. To study the clinical spectrum of fibroid uterus.

METHODS

Ethical clearance was obtained from the institution before the start of the study.

Study design

This was a prospective and descriptive study.

Study population

Female adult patients attending outpatient department who agreed to be a part of the study.

Study setting

The study was conducted at a tertiary care institution, KMCT Medical College.

Study duration

The duration of the study was 6 months; from March 2021 to August 2021.

Sample size N=Z×2 *SD2 *2/d^2 SD=Pooled Standard deviation obtained from the previous study=18.4 d= precision=5.

Substituting the above formula, we got a sample size of 104.

Inclusion criteria

The following criteria were included from the study:

1. All women with symptomatic fibroid above 18 years of age
2. Written informed consent was provided.

Exclusion criteria

The following criteria were excluded from the study:

1. Age group < 18 years
2. Patient refusal to participate in the study
3. Pregnant women
4. Women in post-menopausal status.

Study procedure

Participants were explained about the study and written consent was obtained from them. Demographic data – age, parity, body weight, height, and body mass index (BMI) – were noted. A detailed medical and gynecological history was taken. Ultrasonography was done to confirm the location of fibroids.

The questionnaire QoL -life quality of patients with UF was used to assess their QoL.

Table 1: Classification of cases based on parity

Parity (gravida)	Number (n=104)	Percentage
1	44	42.31
2	48	46.15
3	12	11.54

Table 2: Classification of the patients based on their BMI score

BMI category	Number (n=104)	Percentage
Underweight	2	1.92
Normal	10	9.62
Overweight	28	26.92
Obesity I	36	34.62
Obesity II	14	13.46
Obesity III	10	9.62
Extreme obesity	4	3.85

Table 3: Distribution of fibroids according to their location

Location	Number (n=104)	Percentage
Corporeal	35	33.65
Cervical	46	44.23
Isthmic	23	22.12
Type of fibroid		
Sub-serosal	34	32.69
Intramural	45	42.67
Submucous	25	24.04

Table 4: Associated symptoms in UF. Multiple complaints were noted in these patients with UF

Symptoms	Number (n=104)	Percentage
Bladder dysfunction	46	44.23
Abdominal pain	58	55.77
Bowel disturbance	20	19.23
Dyspepsia/abdominal discomfort	10	9.62
Heavy menstrual bleeding	72	67.29

Table 5: QoL questionnaire

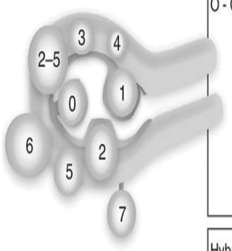
Serial number	Question	Mean	SD
1.	Concern reg fibroids	23.27	8.96
2.	Level of activity	30.92	12.34
3.	Energy/mood	31.29	10.98
4.	Self-control	21.29	5.67
5.	Anxiety	12.28	1.26
6.	Sexual function	8.9	1.24
7.	Life quality index-SUM (1-6)	130.45	12.39

QoL: Quality of life

Statistical analysis

The data were entered in Microsoft excel 2013 and cleaned. It was checked for normality of distribution using the Shapiro–Wilk test. Paired means were compared using the t-test. All p-values were considered to be statistically significant. SPSS 22.0 (IBM Analytics, New York U.S.A) was used for the analysis process.

The FIGO Fibroid classification was used as follows:



SM - Submucosal	0	Pedunculated intracavitary
	1	>50% intramural
	2	≥50% intramural
O - Other	3	Contacts endometrium; 100% intramural
	4	Intramural
	5	Subserosal ≥50% intramural
	6	Subserosal <50% intramural
	7	Subserosal pedunculated
	8	Other (specify e.g., cervical, parasitic)
Hybrid leiomyomas	2-5	Submucosal and subserosal, each with less than half the diameter in the endometrial and peritoneal cavities, respectively.

Assessing the QoL of patients with symptomatic UF: Questionnaire QoL Life quality of patients with UF

The present study used the UF Symptom and HRQL Questionnaire (UFS-QoL).

The UFS-QoL is a disease-specific questionnaire that assesses symptom severity and HRQL in patients with UFs. It consists of an 8-item symptom severity scale and 29 HRQL items comprising six 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.

The UFS-QoL is widely used to evaluate patient-reported UF symptoms and their impact on HRQL and is the only disease-specific instrument developed and validated in a population of women with UF. It was developed based on qualitative input from patients with UF; the original validation demonstrated its ability to discriminate between women with and without UF and also between varying patient-reported disease severity. Furthermore, the UFS-QoL has been shown to be highly responsive to change following treatment [5].

Table 6: Association between symptoms of fibroids with quality of life (Pearson's co efficient correlation)

Number	Question	Symptomatology				
		Bladder	Abdomen pain	Bowel	Dyspepsia	HMB
1.	Concern	−0.88	−0.76	−0.76	−0.65	−0.98
2.	Level of activity	−0.65	−0.98	−0.76	−0.76	−0.89
3.	Energy/mood	−0.89	−0.76	−0.65	−0.98	−0.75
4.	Self- control					
5.	Anxiety	−0.76	−0.89	−0.65	−0.98	−0.75
6.	Sexual function	−0.65	−0.98	−0.76	−0.65	−0.75
7.	Life quality index (all 6)	−0.76	−0.89	−0.89	−0.65	−0.98

(p=0.0001 for all the individual scores compared) There was a strong negative correlation between symptoms and the UF QoL. This shows that with increase in the symptoms; the QoL was reduced in all the aspects and also cumulatively (overall)

Question	Never	Little of the time	Some of the time	Most of the time	All of the time
Fear caused by uncertainty of commencement date and duration of menstruation					
Fear of trips and travelling					
Limitation of physical activity					
Tiredness and fatigue					
Reduction of time spent on sports or outdoor activities					
Feeling of losing control over own life					
Concern about underwear cleanliness					
Decreasing of working abilities					
Fatigue and drowsiness during a day					
Weight gain					
Observation that it is challenging to keep previous level of activity					
Disturbance of social activity					
Observation of changing of size or form of abdomen					
Concern about cleanliness of bedclothes					
Feeling of sadness, frustration					
Feeling of depression feeling of desperation, hopelessness					
Concern about own health condition					
Thorough planning of activities					
Inconvenience due to necessity to care about own look, to use special liners, tampons					
Embarrassment					
Lack of confidence for future					
Irritability					
Concern about cleanliness of clothes					
Change of size and type of clothes during menstrual period					
Feeling unconfident about health condition					
Feeling of weakness and voidness					
Reduction of sexual activity					
Need to avoid sexual contact					

RESULTS

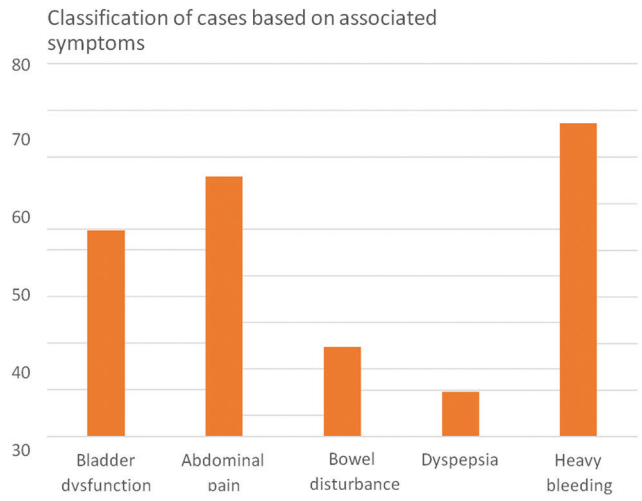
Mean age of the study participants was 45.86 (±13.25).

There were 20 (19.23%) women below 30 years; 30 (28.84%) women between 31 and 40 years of age and the remaining 54 (51.92%) women were between 41 and 50 years of age. PARITY- P 1 and P 2 went hand in hand (Table 1).

Among the total 104 cases; maximum cases were in the overweight category. About 34.62% of cases were in Obesity I category; followed by 13.46% of Obesity II; 9.62% cases had Obesity III, respectively; extreme obesity was seen with four cases and two were underweight (Table 2).

Of the total 104 cases; 35 had UF with corporeal location; 46 cervical and isthmic 23 cases. Of all the cases; 32.69% showed presence of sub-serosal UF; 42.67% had intramural and 24.04% had submucosal fibroids (Table 3).

DISCUSSION



The present study was carried out among 104 women reporting to the tertiary health center. The mean age of the study participants was 45.86 (±13.25). UF is the most common type of tumor among women of reproductive age and increases with age.

Author	Year	Sample size	Study population	Prevalence
Laughlin *et al.* [6]	2009	n=4.271	Women in the first trimester of pregnancy	10.7
Chen *et al.* [7]	2001	n=3.174	Women aged 17–44 years undergoing tubal sterilization	10.0
Borgfeldt and Andolf [8]	2000	n=335	Asymptomatic women aged 25–40 years	5.4
Marino *et al.* [9]	2004	n=341	Premenopausal women	21.4
Baird *et al.* [10]	2003	n=1.364	Premenopausal women	10–15% in Caucasian women 30–40% in African women

The following table compares other studies in terms of fibroids and parity:

Study	Parity and prevalence
Munusamy *et al.* [11]	Nulliparous=27 (27%), Multiparous=73 (73%)
Mishra *et al.* [12]	Nulliparous and Primipara=18 (18%), Multipara=64 (64%)
Subramaniyam *et al.* [13]	Nulliparous=14 (10.2%) 1=16 (11.6%), 2=78 (56.9%) 3 or more=29 (21.1%)

This research shows that the chances of developing fibroids were more among those with high BMI scores [14]. It was perceived that uterine myomas are most common (BMI> 30 kg/m^2) in obese women. Body weight of 70 kg or more denotes a nearly threefold augmented risk of incidence of fibroids compared with a body weight of 50 kg. Raised BMI has a more influence on the risk of the incidence of fibroids after the age of 18, if it is higher than 20 kg/m^2. Its supreme effect has been seen between 27.5 kg/m^2 and 29.9 kg/m^2 [15,16]. Parallel results were noticed in another study that, the higher BMI shows a significant association with UFs.

Padubidri and Daftary [17] and Kulkarni *et al*. [18] reported intramural leiomyoma as the most common variety. About 4% of cases were located in cervix as per the study by Mishra *et al.*; and also by Ibrar *et al.* (3%) [19].

In this study, most common encountered symptom was heavy menstrual bleeding (44.23%) followed by abdominal pain (55.77%). Least reported was dyspepsia (9.62%) and bowel disturbance (19.23%). Khyade reported that 30% of her study subjects had symptomatic fibroids who presented with metrorrhagia [20]. Coming to Shagufta's study in Pakistani women from Peshawar, 75% of women presented with HMB and anemia and often present with pressure symptoms [21]. Other symptoms include bowel dysfunction, urinary frequency and urgency, urinary retention, low back pain, constipation, and dyspareunia [22]. UFs may be associated with infertility and experts recommend that women with infertility be evaluated for fibroids, with potential removal if the tumors have a submucosal component Therefore, fibroids in pregnant women warrant additional maternal and fetal surveillance. In the postpartum period, women with fibroids have an increased risk of postpartum hemorrhage secondary to an increased risk of uterine atony [23]. The risk of malignancy for UFs is very low; the prevalence of leiomyosarcoma is estimated at about one in 400 (0.25%) women undergoing surgery for fibroids [24] (Table 4). Because the natural course of fibroids involves growth and regression, enlarging fibroids are not an indication for removal [25].

In the present study, the mean value of the level of activity was the highest and sexual function was the least; followed by anxiety. The following table enlists studies which highlighted the negative effect of UFs on the different dimensions of a women's QoL scale (Tables 5 and 6).

Author and year	Study design
Carlson *et al*. [26]	A prospective and cohort study of women
Rowe *et al*. [27]	Design: Retrospective (n=294); women with leiomyoma
Kjerulff *et al*. [28]	625 cases with leiomyoma
Scialli and Levi [29]	Prospective open-label feasibility study of
Spies *et al*. [30]	uterine fibroid outcomes (n=30) 110 women with fibroid and 29 without fibroid
Pron *et al*. [31]	538 women undergoing urinary artery embolism, Design: Multicenter,-prospective single-arm clinical treatment trial of 555 women with uterine fibroids
Kuppermann *et al*. [32]	31 women with surgery and 32 with medical intervention for uterine fibroid 68 supracervical and 67 total abdominal hysterectomy

All of these studies showed that different aspects of QoL are compromised in cases of UF. We observed a strong negative correlation between symptoms and the UF QoL. This shows that with increase in the symptoms; the QoL was reduced in all the aspects and also cumulatively (overall). This was similar to reports of two other international studies by Harding *et al.* [25] and Coyne *et al*. [5]. The QoL scale cannot just serve as a tool to assess the present condition of these patients but can be the hall mark for evaluation of the treatment outcomes among these women.

CONCLUSION

- Mean age of the study participants was 45.86 (±13.25)
- More cases with multi gravida were present in the study
- About 34.62% of cases were in Obesity I category; followed by 13.46% of Obesity II; 9.62% cases had Obesity III and underweight, respectively; extreme obesity was seen with 3.85% cases and 1.92% were underweight
- About 33.65% had UF with corporeal location; 44.23% in cervical and 22.12% had isthmic. Of all the cases, 32.69% showed presence of subserosal UF; 42.67% had intramural; and 24.04% had submucosal fibroid
- Most common associated symptoms were of heavy bleeding; then abdominal pain, followed by bladder dysfunction. Least was that of dyspepsia
- There was a strong negative correlation between symptoms and the UF QoL. This shows that with increase in the symptoms, the QoL was reduced in all the aspects and also cumulatively (overall). Hence, UF can affect overall QoL.

ACKNOWLEDGMENTS

The authors would like to thank the Department of Obstetrics and Gynaecology, KMCT Medical College for their cooperation and support and all the patients without whom this study might not have been materialized.

AUTHOR' CONTRIBUTION

Dr. Abhilash has finalized the draft and guarantor, Dr. Heera has prepared the conceptual framework, and Dr Chellamma designing of draft, and Dr Shivakumar has helped in data analysis, Dr. Abhilash and Dr. Hiba were involved in data collection and have done manuscript writing.

CONFLICTS OF INTEREST

None Declared.

AUTHOR'S FUNDING

None.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee and Institutional Research Committee of KMCT Medical College, Kozhikode.

REFERENCES

1. Manyonda I, Belli AM, Lumsden MA, Moss J, McKinnon W, Middleton LJ, *et al*. Uterine-artery embolization or myomectomy for uterine fibroids. N Engl J Med 2020;383:440-51.
2. Drayer SM, Catherino WH. Prevalence, morbidity, and current medical management of uterine leiomyomas. Int J Gynecol Obstet 2015;131:117-22. doi: 10.1016/j.ijgo.2015.04.051
3. Parker WH. Etiology, symptomatology, and diagnosis of uterine myomas. Fertil Steril 2007;87:725-36.
4. Smailova LK, Iskakov SS, Tuletova AS, Shegenov GA, Kasenova DA. Assessing the quality of life of patients with symptomatic uterine fibroid. Syst Rev Pharm 2020;11:176-82.
5. Coyne KS, Margolis MK, Bradley LD, Guido R, Maxwell GL, Spies JB. Further validation of the uterine fibroid symptom and quality-of-life questionnaire. Value Health 2012;15:135-42. doi: 10.1016/j.jval.2011.07.007
6. Laughlin SK, Baird DD, Savitz DA, Herring AH, Hartmann KE. Prevalence of uterine leiomyomas in the first trimester of pregnancy: An ultrasound-screening study. Obstet Gynecol 2009;113:630-5.
7. Chen CR, Buck GM, Courey NG, Perez KM, Wactawski-Wende J. Risk factors for uterine fibroids among women undergoing tubal sterilization. Am J Epidemiol 2001;153:20-6.
8. Borgfeldt C, Andolf E. Transvaginal ultrasonographic findings in the uterus and the endometrium: Low prevalence of leiomyoma in a random sample of women age 25-40 years. Acta Obstet Gynecol Scand 2000;79:202-7.
9. Marino JL, Eskenazi B, Warner M, Samuels S, Vercellini P,

Gavoni N, *et al*. Uterine leiomyoma and menstrual cycle characteristics in a population-based cohort study. Hum Reprod 2004;19:2350-5.
10. Baird DD, Dunson DB, Hill MC, Cousins D, Schectman JM. High cumulative incidence of uterine leiomyoma in black and white women: Ultrasound evidence. Am J Obstet Gynecol 2003;188:100-7.
11. Munusamy MM, Sheelaa WG, Lakshmi VP. Clinical presentation and prevalence of uterine fibroids: A 3-year study in 3-decade rural South Indian women. Int J Reprod Contracept Obstet Gynecol 2017;6:5596.
12. Mishra A, Mishra P, Kumar BN, Pandey T, Pandey M, Chaturvedi RK. Clinicopathological correlation of leiomyoma in a tertiary care centre: A retrospective study. J Med Sci Clin Res 2018;6:205-10.
13. Subramaniyam NK, Vanaja K, Chadeve A, Modapu D, Dumpala AJ, Gudise BR, *et al*. Prevalence of risk factors for uterine fibroids at tertiary care teaching hospital: A cross-sectional study. J Young Pharm 2020;12:86-9.
14. Flake GP, Andersen J, Dixon D. Etiology and pathogenesis of uterine leiomyomas: A review. Environ Health Perspect 2003;111:1037-54.
15. Lobel MK, Somasundaram P, Morton CC. The genetic heterogeneity of uterine leiomyomata. Obstet Gynecol Clin North Am 2006;33:13-39.
16. Marshall LM, Spiegelman D, Manson JE, Goldman MB, Barbieri RL, Stampfer MJ, *et al*. Risk of uterine leiomyomata among premenopausal women in relation to body size and cigarette smoking. Epidemiology 1998;9:511-7.
17. Padubidri VG, Daftary S. Shaw's Textbook of Gynecology. 16th ed. India: Elsevier; 2014. p. 596.
18. Kulkarni MR, Dutta I, Dutta DK. Clinicopathological study of uterine leiomyomas: A multicentric study in rural population. J Obstet Gynecol India 2016;66:412-6.
19. Ibrar F, Raiz S, Dawood NS, Jabeen A. Frequency of fibroid uterus in multipara women in a tertiary care centre in Rawalpindi. J Ayub Med Coll Abbottabad 2010;22:155-7.
20. Khyade RL. A study of menstrual disturbance in cases of fibroid uterus. Int J Reprod Contracept Obstet Gynecol 2017;6:2494-7.
21. Shaheen S, Naheed T, Sadaf F, Rahim R. Menorrhagia due to fibroids and its management. JSOGP 2013;3:231-5.
22. Carranza-Mamane B, Havelock J, Hemmings R, Reproductive Endocrinology and Infertility Committee; Special Contributor. The management of uterine fibroids in women with otherwise unexplained infertility. J Obstet Gynaecol Can 2015;37:277-85.
23. Klatsky PC, Tran ND, Caughey AB, Fujimoto VY. Fibroids and reproductive outcomes: A systematic literature review from conception to delivery. Am J Obstet Gynecol 2008;198:357-66.
24. Knight J, Falcone T. Tissue extraction by morcellation: A clinical dilemma. J Minim Invasive Gynecol 2014;21:319-20.
25. Harding G, Coyne KS, Thompson CL, Spies JB. The responsiveness of the uterine fibroid symptom and health-related quality of life questionnaire (UFS-QOL). Health Qual Life Outcomes 2008;6:99.
26. Carlson KJ, Miller BA, Fowler FJ Jr. The Maine women's health study: I. Outcomes of hysterectomy. Obstet Gynecol 1994;83:556-65.
27. Rowe MK, Kanouse DE, Mittman BS, Bernstein SJ. Quality of life among women undergoing hysterectomies. Obstet Gynecol 1999;93:915-21.
28. Kjerulff KH, Langenberg PW, Rhodes JC, Harvey LA, Guzinski GM, Stolley PD. Effectiveness of hysterectomy. Obstet Gynecol 2000;95:319-26.
29. Scialli AR, Levi AJ. Intermittent leuprolide acetate for the nonsurgical management of women with leiomyomata uteri. Fertil Steril 2000;74:540-6.
30. Spies JB, Warren EH, Mathias SD, Walsh SM, Roth AR, Pentecost MJ. Uterine fibroid embolization: Measurement of health-related quality of life before and after therapy. J Vasc Interv Radiol 1999;10:1293-303.
31. Pron G, Bennett J, Common A, Wall J, Asch M, Sniderman K, *et al* The Ontario uterine fibroid embolization trial. Part 2. Uterine fibroid reduction and symptom relief after uterine artery embolization for fibroids. Fertil Steril 2003;79:120-7.
32. Kuppermann M, Varner RE, Summitt RL Jr., Learman LA, Ireland C, Vittinghoff E, *et al*. Effect of hysterectomy vs medical treatment on health-related quality of life and sexual functioning: The medicine or surgery (Ms) randomized trial. JAMA 2004;291:1447-55.