Assessment of Risk Factors and Drug Therapy in Patients with Uterine Fibroids in a Tertiary Care Hospital

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ABSTRACT

Introduction: Uterine fibroids are the most common benign tumours, affecting most women of childbearing age. Fibroids have brought a huge public health burden to women and also brought economic losses to society. We assessed the assessment and risk factors associated with the development of female fibroids

Aim: To assess the risk factors and drug therapy in patients with uterine fibroids

Methodology: We assessed the patient details from January 2020- July 2020 who were admitted to the Department of obstetrics and gynaecology (OB-GYN) for our study. The data collected were symptoms, menstrual history and present menstrual status, past medical and medication history, obstetric history and present.

Results: Data from 65 patients who were presented to the department of obstetrics and gynaecology with uterine fibroids. The mean age was 43 ± 7.101 years. Most women presented were with dysmenorrhea (48%) and increased Abdominal pain (86%). Anaemia (77%) was found to be a predominant comorbid condition due to the increased menstrual bleeding and passage of clots (45%). The majority of the patients present with multiple myomas and intramural (45%) and anterior position is the most common. Surgical procedures of Hysterectomy were undergone in 95% of women.

Conclusions: We observed that the significant risk factors for uterine fibroid were the age factor as most women were between 30-50 years. Menstrual history of the passage of clots and dysmenorrhea were also linked. Surgical management was used in most of the patients.

Key Words: Uterine Fibroids, Age, Risk Factors, Dysmenorrhea, Menorrhagia, Parity, Infertility

INTRODUCTION

Uterine fibroid (leiomyomas or myomas) are benign monoclonal tumours of smooth muscles taking origin in the myometrium of the uterus.^{1,2,3} Uterine fibroid is most common in women during their middle and late reproductive period i.e., mostly during their childbearing age⁴ Abortion and adverse obstetric outcome are linked to fibroids.⁵ Uterine fibroid accounts for 20% of women in their childbearing age and they affect up to 70-80% of women.^{6,7} In India, the incidence is high, and it inflicts a heavy burden on women's health care system.⁸ Prevalence estimates range from 45% to 68.6% and it is underestimated because of its asymptomatic nature in women.⁹ There are many risk factors associated with the development of uterine fibroid that is important for diagnosis and rational treatment.⁵ Race and Age, Early menarche, Fer-

tility, Parity and Pregnancy, Genetic Factors, Caffeine Intake, Alcohol and Tobacco, Disease State, Dietary Intake others stress, infection and degenerative changes can also lead to the development of uterine fibroids.^{1-4,6,26} Pathophysiology on the development of fibroids is not clear, but it is believed that fibroids are raised from the overgrowth of smooth muscles and connective tissue in the uterus.¹⁰⁻¹⁴

The International Federation of Gynaecology and Obstetrics (FIGO) classification describes fibroids may be single or multiple in growth and location. These are factors that lead to determining if a fibroid causes symptoms and problems.¹⁵ Likewise, a small lesion can be symptomatic if located within the uterine cavity but when a large fibroid outside can or may go unnoticed. Management strategies are usually individualized based on the severity of the symptoms, the

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size and location of the fibroid, the patient's age and chronological proximity to menopause, and the patient's desire for future fertility. Localization, measurement, and characterization of uterine fibroid in women are essential for research into clarifying the natural history of tumours and for evaluating therapeutic responses to investigational agents and optimal selection of patients for medical therapy, non-invasive procedures, or surgery depending on an accurate assessment of the size, number, and position of myomas.^{16,17} this study aims to assess the prevailing risk factor and management in uterine fibroids.

METHODOLOGY

Research design

An observational study was carried out in 65 subjects who were admitted to the Department of obstetrics and gynaecology (OB-GYN) from January 2020 through July 2020 at Karpagam Faculty of Medical Sciences and Research, Coimbatore, India was screened for this study. This study was carried out after approval (approval number – IHEC/212/KCOP/12/2020) from Institutional Human Ethical Committee (IHEC).

Patients were selected for the study based on inclusion criteria of women aged between 25 and 60 years. The data were collected according to the questionnaire which contained information like patients age, age of menarche, geographic region, occupation, complaints of bleeding, progression, menstrual changes and duration, and other associated complaints like pain in the abdomen, intermittent spotting, vaginal discharge, bowel, bladder symptoms, and co-morbidities like hypertension, diabetes mellitus, any thyroid disorders and the family history of fibroids and complaints of primary/secondary infertility. Details on general and systemic examination for pallor, abdominal mass, per speculum for fibroid polyps and bleeding, pelvic examination for uterine size, shape, consistency and all the blood investigations with ultrasound transvaginal and transabdominal data were collected. The treatment and the management done was also included. All the information was collected from the hospital medical record data.

Statistical analysis

All the data were categorized, and they were subjected to descriptive statistical analysis using Microsoft Excel. All data were expressed as mean with standard deviation (SD) and percentage frequency.

RESULTS

Sixty-five uterine fibroid cases over 6 months were selected and the mean age of patients admitted was 43 ± 7.01 years

and the maximum no of cases were in the age group of 41-45 years of age with 31 (48%) cases (figure 1).

In this study, the mean age of menarche was 13.2 ± 1.316 in women who were presented with uterine fibroids. Most of the women were of normal body mass index (BMI) of 44 (68%) cases, overweight was of 17 (26%) and obese was of 4 (6%) cases. Almost every woman who presented with UF was associated with Anaemia 50 (77%) cases and this was due to the changes or increase in menstrual bleeding and comorbid conditions of Diabetes Mellitus 20 (31%) cases, (figure 2). Parity wise distribution the mean was found that most women had term delivery with 1.8 ± 0.67 and most of them had 2 children 41 (63%) cases (Table 1).

It was observed that nearer the fibroid to the endometrial cavity causes increased symptoms. In our study, the majority of the patients had menstrual complaints and had more than one complaint. The maximum number of cases presented with Dysmenorrhea was 31(48%). Others like Menorrhagia 25 (38%), Metrorrhagia 8(12%), Polymenorrhagia 4(6%), Amenorrhea 3 (5%) of cases were seen. In our studies, most were found still menstruating above 45 years of age. But we also found 2 cases of women with early menopause in this population. Abdominal pain was 56 (86%) cases, mass in the abdomen was 52 (80%) cases and lower back pain was 50 (77%) cases were associated with most of the women. But in this population, most of the women did not have any urinary symptoms. Only half the women in this study were presented with a passage of clots in 29 (45%) cases and whitish discharge in 10 (15%) cases. Every patient who attended with the symptoms of fibroid was undergone with abdominal ultrasonography (USG). Thus, most of the women were presented with multiple fibroids. Where most women were presented with the uterine size of fewer than 12 weeks 40 (61%) cases, and it was found that most women had multiple types of myoma and with intramural 29 (45%) cases in most women. shows the other distribution of fibroids in this study group: Subserosal 21 (45%) cases, Pedunculated 14 (22) cases, Endometrial 11 (17%) cases and Submucosal 10 (15.23%) cases. The localization of fibroids was found to be with anterior part 40 (61.538%) cases involving the most. Other locations were Posterior 33 (51%) cases, Lateral left 19 (30%) cases, Lateral right 11 (17%) cases, and Fundus 9 (14%) cases (Table- 2).

In our study, most of the patients preferred surgical management over pharmacological treatment. 92% (60 cases) of the women were prescribed the vitamin supplements like vitamin C and vitamin B complex and 90 % (58) with iron supplements (figure 3). Only one woman was given oral mifepristone 1(1.53%) cases. Almost half of the women have undergone TAH procedure 35 (53%) cases and NDVH of 22 (33.84%) cases, 2(3.07%) cases have undergone myomectomy.

DISCUSSION

Our current study shows the profiles of 65 South Indian women who were admitted for the management of uterine fibroids. Most women presented were during their childbearing age of 30- 45 years. More than 20% of women over 30 years harbour fibroids. The incidence of fibroids was not the monopoly of nulliparous or sterile but was high in parous women.^{18,19} These results associate with our study that almost every woman was parous (96%). The majority of the women reported heavy menstrual bleeding with cramps (dysmenorrhea), mass in the abdomen, lower back, or abdominal pain in our present study. But in comparison with other studies, a study done in Bombay mentioned most women were presented with menorrhagia and then with dysmenorrhea.^{19,20} Association of the passage of clot was also found in 45% of the women. It can be considered as the risk factor for the development of fibroid in women.

In this study, 76% of the women were associated with anaemia and all such patients had undergone a blood transfusion, and few had a history of blood transfusion (13%). It is consistent with results from a study done in Sikkim women subjects.²¹ The other comorbid conditions which we observed were Diabetes (30%), thyroid disorder- hypothyroidism (21%), hypertension and most of them were associated with ovarian cyst (20%) they all were on the treatment. These results correlate with the study by Okolo S et al.,²² This can be the risk factor in the development of uterine fibroids. The other symptoms like frequent urination, burning micturition and constipation were found in the least number of patients and we could not find any other pressure symptoms or nerve compression in any patients.

A bodyweight of 70 kg or more represents a nearly three-fold increased risk of incidence of fibroids compared with a body weight of 50 kg.²³ But these results do not correlate with our study, as most women were of normal BMI. This parameter was not correlated with a few other pieces of works of literature.

Mapping of uterine myoma is more precise with transvaginal USG than hysteroscopy. Thus, in this study, all women had undergone a USG scan as the conformational test for the presence of fibroids. Most myomas had a size of 12–24-week (62%) size of the gravid uterus in our study. This explains the fact that the uterus becomes an abdominal organ approximately at 12 years of age. Also, one important consideration in this regard is the lack of awareness of study subjects regarding myomas and ignorance of increased menstrual flow. An observation in the form of a questionnaire-based interview among the study subjects could have been done to resolve and conclude accurately on this issue.²⁴ In this present study the most women were presented with multiple myomas with intramural (44%) being the most common. This is consistent with different kinds of literature. Most fibroids

are asymptomatic and are accidentally diagnosed.^[4,21] Most fibroids are asymptomatic and are accidentally diagnosed. Symptoms are common in submucosal fibroids and subserous fibroids. Submucosal manifestations are more common as menstrual abnormalities, while subserosal manifestations are abdominal masses or compression symptoms.^{6,9,18,19,23}

The use of oral contraceptives for a long duration reduces the risk by 31% when used for 10 years.^{6,23} The symptoms like menorrhagia, tranexamic acid plays a major role in increasing the quality of life of women by reducing the impairment in social activities and overall burden.²⁵ Symptom intensity decreased significantly with the intervention in both the operated and non-operated populations. Surgical treatment was indicated for most patients, usually taking place within 3 months. In our study, most of the women were under surgical treatment (95%) as the management of uterine fibroids. Uterine leiomyoma is the single most common indication for hysterectomy. Surgery has been the mainstay of treatment and various minimally invasive procedures have been developed in addition to hysterectomy and myomectomy. The formation of new myomas after the conservative therapy remains the main problem. Although medications that manipulate the concentration of steroids hormones are effective, their side effects limit their long-term use. Due to the presence of the anaemia condition all patients were prescribed iron supplements. All women have been prescribed vitamin supplements and iron supplements for further treatment.

Most commonly women are asymptomatic but once the development of the symptoms it affects the quality of life, daily activities, often experience troubling symptoms and diminish in their sex life. Thus, this makes women experience a lot of difficulty in their daily life.²² The lifestyle changes can also be a factor for the presence of the fibroid in women. Women who consume red meat increased caffeine consumption and tobacco use are found to possess an elevated risk of uterine fibroid.¹² However, due to the retrospective nature of our study, we were not able to acquire data on quality of life and this was the limitation.

CONCLUSION

We found that the significant risk factors for fibroid development were the age as most women were between 30-50 years and the majority of women had comorbid conditions. Menstrual history of the passage of clots and dysmenorrhea were also considered as the risk in the development of fibroids in women. Contrary to popular opinion, the prevalence of fibroids in parous women is extremely high, even though these tumours are more common in women with low parity or sterile women. Most of the patients were treated surgically. Fibroids are often asymptomatic and do not need medication; however, often extreme symptoms such as men-

orrhagia, dysmenorrhea, and pressure symptoms occur, necessitating treatment.

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Author's contribution:

The authors confirm contribution to the research as follows: Study concept and the design by Priya Mary and Solomon Preetha, data collection and manuscript draft preparation by Padhilahouse Sruthi and Raveendranath Archana, data analysis and interpretation of result by Priya Mary, Padhilahouse Sruthi and Raveendranath Archana and the research was guided by Sellappan Mohan. All the authors have reviewed the result and approved the final version of the manuscript.

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Table 1: Demographics, Symptoms and Risk Factors (n=65) AOM- Age of Menarche

Conditions	No of Cases (N)
PATIENT DEMOGRAPHIC AND OBSTRECTIC DATA (n = 65)	
Age (years) mean± SD	43.7 ± 7.101
AOM (years) mean ± SD	13.2 ± 1.316
BMI (n, %)	
Normal	44(68%)
Overweight	17 (26%)

Table 1: (Continued)

Conditions	No of Cases (N)
Obese	4 (6%)
PRESENT MENSTRUAL CHANGES	
Dysmenorrhea	31 (48%)
Menorrhagia	25 (39%)
Metrorrhagia	8 (12%)
Polymenorrhagia	4 (6%)
Amenorrhea	3 (5%)
Menopause	2 (3%)
OTHERS	
Mass in abdomen	52 (80%)
Abdomen pain	56 (86%)
Passage of clots	29 (45%)
White discharge	10 (15%)
PARITY, mean $\pm$ SD	
Term delivery	1.8 $\pm$ 0.67
Abortion	0.35 $\pm$ 0.651
Death of child	0.169 $\pm$ 0.456
NO OF CHILDERN	
1	15 (23%)
2	41 (63%)
3	7 (11%)

Table 2 Uterine Myomas Characterization According to USG and Pelvis Study (n=65)

CONDITIONS SIZE	NO. OF CASES (n)
Less than 12 weeks	22 (34%)
12- 24 weeks	40 (61%)
More than 24 weeks	3 (5%)
TYPE OF FIBROID	
Intramural	29 (45%)
Subserosal	21 (32%)
Pedunculated	14 (22%)
Endometrial	11 (17%)
Submucosal	10 (15%)
LOCALIZATION OF FIBROIDS	
Anterior	40 (62%)
Posterior	33 (51%)
Lateral left	19 (29%)
Lateral right	11 (17%)
Fundus	9 (14%)

Figure 1: Age wise distribution among the study population (n=65).

Figure 3: Pharmacological Treatment in Uterine fibroids (n=65).

Figure 2: Medical history (n= 65).

Ethical committee clearance certificate

INSTITUTIONAL HUMAN ETHICS COMMITTEE
(DCGI Reg.No.ECR/668/Inst/TN/2014)
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Ethical clearance certificate

Ref No: IHEC/212/KCOP /12/2020

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Title of project: Assessment of risk factors and drug therapy in patients with uterine fibroids in a tertiary care hospital.

Principal Investigator: Mrs. Mary Priya, Assistant Professor, Department of Pharmacy Practice, Karpagam College of Pharmacy, Coimbatore.

Co investigator: Dr.Preetha Solomon, Assistant Professor, Department of OBG, KFMSR.

Date considered: 18.12.2020

Decision of the Committee: Approved

Validity of ethical clearance: One year

The Institutional Human Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and informed consent, and asks to be provided a copy of the first report.

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