Presence and Impact of Uterine Fibroids in Women with Menstrual and Premenstrual Syndrome – A Statistical Analysis

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Abstract: A number of non-invasive alternatives to hysterectomy are available for treating uterine fibroids, but they may not effectively relieve all symptoms. As a result, it has become increasingly important to use patient-reported outcomes to assess the success of these alternative therapies in reducing uterine fibroid symptoms. These symptoms can range from heavy menstrual bleeding to dysmenorrhea for women who experience menstrual and premenstrual syndrome. To standardize the assessment of fibroid-related symptoms, the Uterine Fibroid Indicators and Analysis of Patient Recovery survey form (UFS-APR) was developed as a patient-recovery report analysis. The UFS APR is used to analyze womenfolk with uterine fibroids existing with menstrual and premenstrual syndrome. In our study, we had translated and validated the UFS-APR in India to examine its reliability, correctness, scope, validity and responsiveness in assessing the treatment of uterine fibroids.

Keywords: Uterine fibroids, menstrual pain, minimally invasive surgery, Medical health.

1. INTRODUCTION

Uterine fibroids, otherwise identified as uterine leiomyomata, are a typical type of noncancerous tumor that can develop in the female reproductive system. They are often found in up to 77% of hysterectomy specimens and are caused by the growth of monoclonal tumors for Serene muscle cells and fibroids in the myometrium. Fibroids that become symptomatic could consequence in abnormal uterine bleeding, pelvic pain, pressure, and even infertility or poor pregnancy. For many women, fibroids can have a substantial impression on their daily lives, with symptoms such as heavy bleeding, stomach pain, urinary urgency, and frequency, low back pain, and aching during intercourse. The study focuses on analysis women experiencing menstrual and premenstrual symptoms with or without uterine fibroids these symptoms and the analysis of the patient recovery questionnaire (UFS-APR), are the most suitable tools for assessing the effect and outcomes of fibroid therapies. Although the initial validation of the UFS-APR demonstrated its capability to differentiate between women with and without fibroids and those with differing symptoms, the current study aimed to analyze its reliability, validity, and responsiveness among women both with and without fibroids.

To take part in the study, women with fibroids had to arrange for a hysterectomy, myomectomy, or uterine embolization and undergo a routine physical examination and imaging to confirm their diagnosis. The study included women who were part of the usual control group and had no past of uterine fibroids. These women had regular menstrual cycles and a normal gynecologic examination at the time of enrolment. Women who were pregnant, physically challenged or mentally disturbed, had a life expectancy of less than a year, having any impairment that would affect in completion of the questionnaire, were not included in the study. Women who had leiomyomata were focused on and used to create the (UFS-APR) Uterine fibroid Symptom-Analysis of Patient Recovery. The questionnaire is again rechecked with a group of women with uterine fibroids as well as in healthy controls. The UFS-APR was designed to be the primary measure to evaluate the outcomes of women having uterine fibroids, and also evaluate the outcomes of women before and after surgery of the uterine fibroids. The questionnaire was also used to establish “normal” scores from patients without fibroids. The study anticipated to compare the outcomes of women having uterine fibroids and who underwent different medications to the outcomes of normal controls. This comparison would help assess the effectiveness of the therapies in treating uterine fibroids. Furthermore, The study’s goal was to give insight into the course of fibroids-related symptoms in individuals who were found to be normal at the start.

2. METHODOLOGY

A. Study Design

The research is carried out as a survey study in Hospitals, around Coimbatore, India with a self-governed and self-managed, web-based questionnaire. The questionnaire was specifically created for this study and also allowed participants to answer questions online at their convenience. By combining these two types of data, the study aimed to gather a comprehensive understanding of the research topic. The use of a web-based questionnaire also allowed us to efficiently gather data from a huge number of participants in a timely manner.

B. Questionnaire

The study collected data from both clinical routines and through a self-administered web-based questionnaire. The questionnaire consists of six sections that include Personal Details, Menstruation, Sexual Activities, physical activities, Medical illness issue after surgery, and Medication. The 'Personal details' of the participants include basic demographic characteristics. Under the 'Menstruation' section record their menstrual cycle features and the symptoms associated with Premensuration syndrome with its severity. In the 'Sexual and Physical Activities' section the participants record their comfort level during the same. The questionnaire also analysis the participants who underwent fibroid surgery and its aftereffects. For the participants who did not take the surgery alternate therapy and its impact was also recorded.

The study's primary goal was to analyze the cause of uterine fibroids therapy on women's symptoms and life quality. The study also aimed to establish "normal" scores for patients who did not have fibroids, which could be used to compare the results of investigational therapies. Overall, the study provides useful information about the experiences of women who have uterine fibroids and the effectiveness of various treatment options. The CVI was used to evaluate the significance and legitimacy of all questionnaire items. To revise the item's, comprehensive written feedback was provided. For relevance and clarity, 3-point scale was used to rate all the items, based on five healthcare experts and three domain professors. Following that, according to the item rated as somewhat or completely understandable or relevant, the index was evaluated. The value M = 0.68 (range 0.44-1.00), was the normal rating of the item precision and the value M=0.80 (range 0.75-1.00) was the regular rating of the items of significance. For reflecting the scale's internal steadiness, Cronbach's Alpha was used which has high in the present study examination: α=0.93 (94%, 0.90-0.94 (confidence interval)). Factors cogitate-the patient's age, the type of surgery (hysterectomy, myomectomy or uterine fibroid embolization), menstruation difficulties, Sexual difficulties, and medication undergone earlier, are gathered from medical database.

C. Study Population and Data Collection

Around 402 participants who had undergone treatment for uterine fibroids with premenstrual and menstrual symptoms between October 1, 2022 and February 27, 2023 at various Hospital in Tamilnadu, and had a gestational age of minimum 20, were identified and the data was collected. Based on the survey responses, the various test analysis was carried out.

Inclusion and Exclusion criteria:

Women who were pregnant, physically challenged or mentally disturbed, had a life expectancy of less than a year, and any impairment that would affect in completion of the questionnaire, was not included. Women within the age group of 20 to 40 with uterine fibroids and menstrual issues were considered for the study.

3. STATISTICAL DATA ANALYSIS

The analysis of data was aimed to determine the effect of treatment received by patients on various aspects of their experience. These included their overall satisfaction with the gynecologists and the surgery, whether their expectations for the surgery were met, was the symptoms were as regular and about value of life after the surgery, and the duration of their recovery after the surgery. To achieve these goals, the researchers employed four multivariable linear regressions, controlling for potential unmeasured variables such as statistical information, medication, and surgery-related variables. The regressions were performed on the four dependent variables listed in Table II. Additionally, the researchers analyzed responses to open-ended questions from patients about their treatment using content analysis to provide number of totals of the most frequent responses. To perform the statistical

analysis, IBM SPSS is used. Descriptive statistics were compared using Fisher's exact test and Welch's two sample t-test. The multivariable regressions were examined using base coefficient. In summary, the analysis of data was aimed to evaluate the potential effect of the treatment received by patients on various aspects of their experience, and the authors used a variety of statistical methods to achieve this goal.

4. RESULTS

Of the 435 women requested to contribute in the study, 420 launched the online survey and 402 completed the questionnaire. From 280 (69.7%) women, received drug treatment for fibroids and 122 (30%) underwent fibroid surgery (see Table I). Women who received medication were more likely to recover from the cause than surgery 76% of the married women suffered with uterine fibroids and they are able to manage without surgery and only through medication. Around 70% of women with uterine fibroids experienced fatigue irrespective of their therapy. Frequent urination was most common among the women who is taking medication for uterine fibroids. 24% of the unmarried women also suffered with uterine fibroids All these parameters were included as possible features in multivariate regressions to provide insight into the incidence, characteristics, and treatment options of uterine fibroids. However, it's significant to mention that every woman's experience with fibroids is unique, so it's important to discuss any concerns or symptoms with your healthcare provider.

Table I: Demographics and selected surgery related variables of women with uterine fibroids (n=402)

FEATURES	SURGERY (n=122)	NO SURGERY (n=280)	TOTAL (n=402)	X^2 or t	p
	n %	n %	n %		
AGE-MEAN (SD)	39.4 (2.85)	27.2 (3.24)	34.8 (2.9)	3.04	0.002
FEMALE Married Unmarried	 90(73.7) 32(26.2)	 215(76.7) 65 (23.2)	 305(75.87) 97(24.1)	 17.04	 <0.001
MENSTRUATION CYCLE Heavy Bleeding Lengthy Periods	 66(54) 48(39.3)	 88(31.4) 53(18.9)	 154 (38.3) 101 (25.1)	 21.45	 <0.001
SEXUAL ACTIVITIES Lack of Sexual Desire	 26(21.3)	 38 (13.5)	 64 (15.96)	 3.83	 0.015
PHYSICAL ACTIVITIES Frequent Urination Difficulty In Walking Anxious About Travel Fatigue	 67(55) 23(19) 24(19.6) 86(70.5)	 194(70) 42(15) 128(45.7) 202 (72.1)	 261 (64.9) 65 (16.2) 152 (37.8) 288 (71.6)	 4.83	 0.002

Table II presents results from three models representing multivariable regression on surgery with medication and only medication. Based on the survey, the "better" treatment option for uterine fibroids is highly reliant on on the individual patient's unique situation, together with the size and location of the fibroids, the severity of symptoms, the patient's age and overall health, and the patient's longing for upcoming fertility

The blood flow- causes hefty menstrual bleeding, which would lead to anemia if left untreated. In some cases, surgery to remove the fibroids may be recommended to alleviate heavy bleeding and prevent anemia. Alternatively,

medication or other non-surgical options may be recommended to help manage heavy bleeding and prevent anemia. And urination and pelvic pain are mostly occurring during the fibroids grow near or press on the bladder or ureters (the tubes that carry urine from the kidneys to the bladder). In some cases, surgery to remove the fibroids may be recommended to alleviate the pressure on the bladder or ureters and relieve urinary symptoms

Alternatively, medication or other non-surgical options may be recommended to help manage urinary symptoms and pelvic pain. And getting sufficient sleep is mostly not satisfied with the patients who are in need of surgery. Overall, the quality of life of patients Surgical and non-surgical treatment options can both be effective in improving symptoms and quality of life, but the surgical treatment did not show a statistically significant difference with regard to any of these two outcomes.

Table II: Multivariable regression investigation on the association between surgery and medication characteristics

	Surgery with medication		Only Medication	
	beta	p	Beta	p
Blood flow	0.03 [0.001, -0.05]	0.01	0.25[0.06,0.01]	0.01
Urination	0.26 [0.06,0.01]	0.25	0.11[0.01, -0.04]	0.6
Pelvic pain	0.04 [0.00, -0.05]	0.03	0.06[0.39,0.35]	4.43
Satisfied sleep	0.08 [0.00, -0.05]	0.08	0.25[0.06,0.01]	0.09

5. SPECIFIC QUESTIONS REGARDING UTERINE FIBROIDS TREATMENT

An overall positive picture was disclosed by descriptive statistics of specific questions posed about surgical and non-surgical treatment options for uterine fibroid in Table III. All women who experienced surgery stated that they either would have preferred (30%) non-surgery methods if the their oewn body cooperates with them.

More importantly, 122 (30%) women who had done surgery and 280 (69.6%) women who had not done surgery and used only medication to cure would desire this procedure if they were in a situation to have another surgery in the future. According to their health status, many women who responded to open-ended questions about the surgery technique characterized their general experience as both positive and negative (n=122). As a result, the recovery time for a patient who has undergone surgery for uterine fibroids can vary depending on the type of surgery performed, the size and location of the fibroids, and the patient's overall health. However here (67%), patients can expect to spend several weeks recovering after surgery when compared 82 % of women who were under medication recovered within a short time.

Table III: Results from specific questions regarding the surgery for uterine fibroids

	SURGERY	NON SURGERY
Assessment of the view	n=122 n(30%)	n=280 n(69.6%)
Does your Menstruation cycle is normal?	68 (55%)	178(64%)
Made you feel self-conscious of weight gain?	96(78%)	45(16%)
Are you completely Recovered for it?	81(67%)	230(82%)
Made you feel sad, discouraged or hopeless?	76(62%)	115(41%)
Are you satisfied with your sleep(no)?	65(53%)	220(79%)
Caused you to feel drowsiness or sleepiness during the day?	74(61%)	167(60%)
Feeling tightness or pressure in your pelvic area	105(86%)	167 (59%)

Overall, recovery from surgery for uterine fibroids can take several weeks, but Based on the survey (30%) most patients are able to return to their normal activities within 4-6 weeks by following all post-surgery instructions from the

doctor and regular checkup. It is possible for a patient (60%) to require additional surgery in the future, but there are steps that patients can take to reduce the risk of needing additional surgery, such as maintaining a healthy lifestyle and attending regular follow-up appointments with their healthcare provider.

6. DISCUSSION

The hypothesis testing is performed on a numerical sample to present evidence of the possibility of the null hypothesis. Measurements and investigations are conducted on a random sample of the population to test a theory. First, we need to define the research question and the hypothesis. Let's say our research question is "Is there a significant association between the incidence of uterine fibroids and analysis of recovery from the medication or surgical treatments?" The null hypothesis is that there is no significant association between the incidence of uterine fibroids between medications and surgery, while the alternative hypothesis is that there is a significant association between the two. We can distribute the survey to women aged 18 and above who have visited a gynecologist in the last six months. To ensure statistical power, sample of data is collected from the participants. We can then calculate the odds ratio and the Fisher exact test to determine if there is a significant association between medication and surgical for the incidence of uterine fibroids.

The Fisher exact test is a statistical test used to determine if there is a significant association between two categorical variables. In this case, the categorical variables are medication and surgical for the incidence of uterine fibroids. p-value is measured using the exact probability distribution of the test statistic under the null hypothesis. To calculate the odds ratio: The odds ratio is a measure of the strength of association between two categorical variables. It is calculated as (ad)/(bc), where a, b, c, and d are the numbers of participants in each cell of the contingency table. If the odds ratio is greater than 1, it suggests that there is a positive association between the two variables

To calculate the Fisher exact test: The Fisher exact test is used to calculate the p-value for the association between the two categorical variables. The test calculates the probability of observing the observed data or more extreme data if the null hypothesis is true. In this case, the null hypothesis is that there is no significant association between medications and surgical for the incidence of uterine fibroids. The test calculates the p-value as the sum of the probabilities of all contingency tables that are more extreme than the observed contingency table. The p-value ranges from 0 to 1, with a p-value less than 0.05 indicating statistical significance. Interpret the results: If the p-value is less than 0.05, we reject the null hypothesis and conclude that there is a significant association between medication and surgery for the incidence of uterine fibroids.

If the p-value is greater than 0.05, we be unsuccessful to discard the null hypothesis and conclude that there is no important association between medication and surgery for the occurrence of uterine fibroids. Multivariable regression is a statistical technique that is commonly used to analyze the relationships between multiple variables. In the context of uterine fibroids, multivariable regression can be used to identify the factors that are associated with the development or progression of fibroids. There are several types of multivariable regression techniques that can be used, including linear regression, logistic regression, and Cox regression. The choice of technique depends on the type of outcome variable and the research question being addressed. A multivariable regression analysis can be used to model the relationship between multiple independent variables (such as medication and surgical interventions) and a dependent variable (such as the presence or severity of uterine fibroids). Overall, multivariable regression analysis can provide valuable insights into the factors that may contribute to the presence or severity of uterine fibroids. These insights can be used to inform clinical decision-making and guide future research in this area. In summary, Descriptive statistics can be used to summarize and describe the characteristics of a dataset. In the case of uterine fibroids, descriptive statistics can be used to summarize the distribution of data related to medication and surgical interventions.

Medication: Mean and standard deviation of the duration of medication usage. Frequency distribution of the types of medication used (e.g. GnRH agonists, progestins, etc.).

Surgical interventions: Mean and standard deviation of the duration of hospital stay, Frequency distribution of the types of surgical interventions used (e.g. myomectomy, hysterectomy, etc.). Percentage of patients who experienced complications during or after surgery. Median and range of surgical cost.

Descriptive statistics have provided important insights into the characteristics of medication and surgical interventions for uterine fibroids, which can be used to inform clinical decision making and future research.

7. CONCLUSION

The analysis of recovery of the Uterine Fibroids for the people who have done surgical or non-surgical treatments have the significant association between them. The results influence the measurement properties of the UFS-APR for evaluating fibroid-related symptoms and analysis of recovery in womenfolk with uterine fibroids.

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