QUESTIONNAIRE BASED ANALYTICAL TOOL ON UTERINE FIBROIDS

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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 and dysmenorrhea to bulk symptoms. To standardize the assessment of fibroid-related symptoms, the Uterine Fibroid Symptom and Analysis of Patient Recovery questionnaire (UFS-APR) was developed as a patient-reported outcome measure. The UFS APR is used to analyze women with and without uterine fibroids. In our study, we aimed to translate and validate the UFS-APR in India, with the goal of examining its reliability, validity, and responsiveness in assessing the treatment of uterine fibroids.

Design: Validation study.

Setting: Patients were recruited by a gynaecologist at the outpatient clinic.

Participants: Women with and without uterine fibroids.

Methods: A prospective study was carried out at multiple centers, which was non-randomized and involved women who were receiving treatment for uterine fibroids as well as those who did not have this condition. Women who had uterine fibroids were recruited when they were scheduled for treatment. At enrollment, as well as 6 and 12 months later, participants completed the UFS-APR health survey. Descriptive statistics, Cronbach's alpha, t-tests, and general linear regression models were employed to assess the internal consistency and reliability, concurrent and discriminant validity, as well as the responsiveness of the UFS-APR.

Keywords: Uterine fibroids, gynaecology, minimally invasive surgery, health-related quality of life, therapies.

INTRODUCTION

Uterine fibroids, also known as uterine leiomyomata, are a common type of noncancerous tumour 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 tumours from smooth muscle cells and fibroblasts in the myometrium. Fibroids that become symptomatic can cause abnormal uterine bleeding, pelvic pain, pressure, and even infertility or poor pregnancy outcomes. For many women, fibroids can have a significant impact on their daily lives, with symptoms such as heavy bleeding, abdominal pain, urinary urgency and frequency, low back pain, and pain during intercourse. These symptoms can lead to disruption of work productivity, sleep, and social activities. As a result, patient-reported outcome measures, such as the Uterine Fibroid Symptom and Analysis of Patient Recovery questionnaire (UFS-APR), are the most appropriate tools for assessing the impact and outcomes of fibroid therapies. Although the initial validation of the UFS-APR demonstrated its ability to distinguish between women with and without fibroids and those with varying degrees of symptoms, the current study aimed to further evaluate its reliability, validity, and responsiveness among women both with and without fibroids. To participate in the study, women with fibroids had to be scheduled for 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 normal control group and had no history of uterine fibroids. These women had regular menstrual cycles and a normal gynaecologic examination at the time of enrolment. Women who were pregnant, had cognitive or psychiatric impairment that would interfere with completing the questionnaires, had comorbidity with a life expectancy of less than one year, or were physically challenged were all excluded from the study. Focus groups of women with leiomyomata were used to create the Uterine Fibroid Symptom and Analysis of Patient Recovery questionnaire (UFS-APR). The questionnaire was verified in 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 with uterine fibroids before and after therapy. The questionnaire was also used to establish "normal" scores from patients without fibroids. The study aimed to compare the outcomes of women with uterine fibroids who underwent different therapies 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 fibroid-related symptoms in individuals who were found to be normal at the start.

The objectives of this study are:

A. To determine the change in symptoms and health-related quality of life in patients undergoing hysterectomy, myomectomy, and uterine fibroid embolization.

B. To compare the outcomes for women with uterine fibroids, both before and after therapy.

C. To validate the UFS-APR questionnaire in hysterectomy patients to determine a "normal" score for patients without a uterus.

METHODS

STUDY DESIGN:

For our research, we carried out a survey study at a single site where we collected clinical routine data along with information from a self-administered, web-based questionnaire. The questionnaire was specifically created for this study and allowed participants to answer questions online at their convenience. By combining these two types of data, we aimed to gather a comprehensive understanding of the research topic. The use of a web-based questionnaire also allowed us to efficiently collect data from a large number of participants in a timely manner.

QUESTIONNAIRE:

The study collected data from both clinical routine and a self-administered web-based questionnaire. Women who had surgery pain were asked detailed questions about their experiences during and after the procedure. Open-ended questions were also included in the questionnaire, allowing women to describe their experiences in their own words. The study enrolled premenopausal women aged 30 to 50 who were willing to provide written informed consent and could speak and read English. At the time of enrollment, women in the normal control group had no history of uterine fibroids, a normal gynecologic examination, and regular menstrual cycles. Women were excluded from the study if they were pregnant, had cognitive or psychiatric impairment that would make completing questionnaires difficult, had comorbidity with a life expectancy of less than one year, or were physically challenged. The study's primary goal was to assess the impact of uterine fibroid therapy on women's symptoms and quality of life. Patient-reported outcome measures, which are regarded as the most appropriate tools for measuring the impact and outcomes of interventions, were used to achieve this goal. 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 Content Validity Index (CVI) was used to assess the relevance and validity of all questionnaire items. Six healthcare professionals and experts (four gynecologists and two healthcare domain professors) rated all items on a 3-point Likert scale for relevance and clarity and provided comprehensive written feedback that was used to revise the items. Following that, an index was computed that reflected the number of experts who rated an item as somewhat or completely understandable or relevant. The average rating of item clarity was M=0.68 (range 0.44–1.00), and the average rating of relevance was M=0.80 (range 0.75–1.00). . Although the scale is divided into four subscales (‘Menstruation’, ‘Sexual Activities’, ‘Medical illness issue after surgery’, ‘Physical discomfort’), it is recommended to interpret the short version only with regard to the overall satisfaction. Cronbach’s Alpha, reflecting the scale’s internal consistency, was high in the current study: α=0.93 (94% confidence interval 0.90–0.94). Variables reflecting the age of the patient, the type of surgery (hysterectomy, myomectomy or uterine fibroid embolization), menstruation difficulties, Sexual difficulties, and medication undergone earlier, were taken from clinical routine data.

STUDY POPULATION AND DATA COLLECTION:-

All women who had a undergone treatment for uterine fibroids between October 1, 2022 and February 27, 2023 at various Women’s Hospital in Coimbatore, and who had a gestational age

of at least 20, were identified from the hospital's database. Hospitals were approached by a letter including a vanity URL of google form and women were asked to fill out the self administered questionnaire. Based on the survey responses, the various test analysis was carried out.

DATA ANALYSIS:-

The data analysis aimed to determine the impact of the treatment received by patients on various aspects of their experience. These included their overall satisfaction with the gynaecologists and the surgery, whether their expectations for the surgery were met, the change in symptoms and health-related quality of life, and the duration of their recovery after the surgery. To achieve these goals, the researchers employed four multivariable linear regressions, controlling for potential confounding factors such as demographic information, medication, and surgery-related variables. The regressions were performed on the four dependent variables listed above. Additionally, the researchers analysed responses to open-ended questions from patients about their treatment using content analysis to provide counts of the most frequent responses.To perform the statistical analysis, the researchers used R 4.2.3. Descriptive statistics were compared using Fisher's exact test or Welch's two-sample t-test. The multivariable regressions were conducted using base R. In summary, the data analysis aimed to estimate the potential impact of the treatment received by patients on various aspects of their experience, and the researchers used a variety of statistical methods to achieve this goal.

RESULTS:-

DESCRIPTIVE STATISTICS:-

Of the 246 women invited to participate in the study, 96 launched the online survey and 21 completed the questionnaire. Of these 21 women,12 (67%) received drug treatment for fibroids and 9 (33%) underwent fibroid surgery (see Table 1). Women who received medication were more likely to recover from the cause than surgery. In addition, about two-thirds of women (67.6%) recovered well by year 1–2, and the average age of women showed good recovery after hysterectomy. All of these variables were added as potential confounders in subsequent multivariate regressions. These descriptive statistics provide insight into the incidence, characteristics, and treatment options of uterine fibroids. However, it's important to note that every woman's experience with fibroids is unique, so it's important to discuss any concerns or symptoms with your healthcare provider.

MULTIVARIABLE REGRESSIONS:-

Table 2 presents results from three models representing multivariable regression on menstruation, After surgery and medication. Based on the survey, the "better" treatment option for uterine fibroids is highly dependent on the individual patient's unique situation, including the size and location of the fibroids, the severity of symptoms, the patient's age and overall health, and the patient's desire for future fertility. The blood flow- cause heavy menstrual bleeding, which can lead to anaemia if left untreated In some cases, surgery to remove the fibroids may be recommended to alleviate heavy bleeding and prevent anaemia. Alternatively, medication or other non-surgical options may be recommended to help manage heavy bleeding and prevent anaemia. And the 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 the Getting sufficient sleep is mostly not satisfied with the patients those 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 three outcomes.

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. (Table 3).All women who experienced a surgery stated that they either would have preferred (55%) non-surgery methods method if the particular individual body cooperates with them. Only two of their partners (5.1%) felt that surgery was the method they would have chosen.

TABLE 1: Demographics and selected surgery related variables of women with uterine fibroids (n=21)

	BEFORE SURGERY	**AFTER SURGERY**	**P***
	n=9	n=12	
Age(years)[a]	1(8)	6(5)	0.054
Nationality			
Indian	2(7)	5(6)	0.465
Civil Status			
Single[b]	4(5)	3(8)	0.476
Married	3(6)	4(7)	0.358
Causes			
Blood flow	5(4)	2(9)	0.397
Urination	6(3)	1(10)	0.035
Blood clot	3(8)	4(5)	0.476
Less Production	5(6)	2(7)	0.663
Fatique	6(5)	1(8)	0.0453
Weight Loss	1(10)	6(3)	0.526
Pelvic pain	7(2)	0(11)	0.0411

**p* values reflect the test for differences between the two groups, conducting Fisher's exact test (in case of frequencies) or Welch's two sample *t* test (in case of mean values)
[a]Mean (SD) [b]Single, widowed, divorced or 'other'

More importantly, 8 (67%) women who had done surgery and 5 (55%) women who had not done surgery and used only medication to cure would prefer this procedure if they were 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 overall experience as both positive and negative (n=12). The overall surgery and condition experience was noted by 8 out of the 12 women who would like to undergo a surgical procedure (in the event of a potential subsequent surgery). Of all women who would like to have a surgery method (in case of a possible next surgery) (n=8) mentioned the overall surgery and condition experience (n=12). 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 (55%), patients can expect to spend several weeks recovering after surgery.

TABLE 2: Results from multivariable regression analysis on the association between surgery and medication characteristics (n=21)

	Menstruation		After surgery		Medication	
	beta	p	beta	p	beta	p
Blood flow	0.19[0.03, -0.01]	0.19	0.03[0.001, -0.05]	0.01	0.25[0.06,0.01]	**<0.01**
Urination	**0.51[0.2,0.2]**	<0.01	0.26[0.06,0.01]	6.48	0.11[0.01, -0.04]	0.6
Pelvic pain	0.15[0.02, -0.02]	0.6	0.04[0.00, -0.05]	0.36	**0.06[0.39,0.35]**	4.43
Satisfied sleep	0.20[0.04, -0.009]	<0.01	**0.08[0.00, -0.05]**	0.08	0.25[0.06,0.01]	0.09

bold values indicate statistically significant effects

TABLE 3: Results from specific questions regarding the surgery for uterine fibroids

	SURGERY	**NON SURGERY**
Assessment of the view	n=9 n(%)	n=12 n(%)
Does your Menstruation cycle is normal?	5(55%)	8(67%)
Feeling fatigued(Feeling overtired, with low energy)	9(100%)	10(83%)
Made you feel self conscious of weight gain?	7(78%)	2(17%)

Are you completely Recovered for it?	6(67%)	10(83%)
Made you feel sad, discouraged or hopeless?	6(67%)	5(42%)
Are you satisfied with your sleep(no)?	5(55%)	9(75%)
Caused you to feel drowsy or sleepy during the day?	7(78%)	7(58%)
Feeling tightness or pressure in your pelvic area	8(89%)	7(58%)

Overall, recovery from surgery for uterine fibroids can take several weeks, but Based on the survey (40%) 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.

DISCUSSION:-

The hypothesis testing is performed on a statistical sample to present evidence of the plausibility of the null hypothesis. Measurements and analyses 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 for the incidence of uterine fibroids between medications and surgical, 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 gynaecologist 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. The p-value is calculated 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 fail to reject the null hypothesis and conclude that there is no significant association between medication and surgery for the incidence 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.).Percentage of patients who experienced side effects from medication. Median and range of medication cost.

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 can be calculated using statistical software such as Excel, SPSS, or R. These statistics can provide 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.

CONCLUSION

Therefore ,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 support the measurement properties of the UFS-APR for assessing fibroid-related symptoms and analysis of recovery in women with uterine fibroids.

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