A measure for perioperative anxiety symptoms in patients with FUAS-treated uterine fibroids: development and validation

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\section*{ABSTRACT}
\textbf{Objective:} To develop a scale that measured the perioperative anxiety symptoms of uterine fibroids (PASM-UF) treated with focused ultrasound ablation surgery (FUAS).

\textbf{Methods:} A panel of gynecologists, nurses, and patient-reported outcome (PRO) experts created a draft of the PASM-UF scale. Women who underwent FUAS for uterine fibroids were recruited for its psychometric validation. Assessments were conducted during admission, before surgery, and at discharge. The Symptom Checklist-90 (SCL-90) was administered to assess criterion validity. We assessed the relationship between the developed PASM-UF and the SCL-90 via a correlation analysis. Cronbach’s alpha was used to assess internal consistency for reliability.

\textbf{Results:} We included five items, pain, lack of appetite, fatigue (tiredness), disturbed sleep, and anxiety, in the final version of the PASM-UF. Data were collected from 228 patients. Cronbach’s alpha was 0.745, whereas the correlation coefficient between SCL-90 and PASM-UF was 0.345 ($p < 0.001$). The total PASM-UF scores were significantly higher in patients whose SCL-90 scores were $>160$ compared to those with $<160$ ($9.85 \pm 9.07$ vs. $4.01 \pm 5.15$, $p = 0.002$). Those who did not complete the SCL-90 reported lower PASM-UF scores than those who did ($2.33 \pm 3.27$ vs. $4.67 \pm 5.09$, $p = 0.006$). Patients reported significantly lower PASM-UF scores postoperatively than preoperatively ($2.95 \pm 4.18$ vs. $3.92 \pm 4.90$, $p = 0.002$).

\textbf{Conclusions:} The PASM-UF is a valid, reliable, and sensitive scale for assessing perioperative anxiety levels among women with uterine fibroids. Statistical analysis suggests that it is also an effective instrument for scientific research.

\section*{KEY MESSAGE}
- We developed a brief scale to assess anxiety in perioperative patients with uterine fibroids. In addition, the scale monitored the anxiety levels at multiple frequencies and did not increase burden on the patients. The scale has been proven to be effective, reliable, and highly sensitive.

\section*{1. Introduction}
Uterine leiomyomata, or fibroids, the most common benign neoplasms in women of reproductive age, has a lifetime prevalence of 30–70\% \cite{1}. Clinically, patients often present with menstrual abnormalities, dysmenorrhea, pelvic pain, dyspareunia, pressure in the bladder and lower abdomen, and a foreign body sensation in the lower abdomen. Surgical management of the fibroids is currently the main choice of treatment \cite{1,2}. Previous studies found that women with fibroids experienced sadness, depression, anger, and frustration. Furthermore, their lives were significantly impacted by these symptoms \cite{3}.

Focused ultrasound ablation surgery (FUAS), a noninvasive procedure, has been used for the clinical treatment of diverse solid malignancies, including those in the pancreas, liver, kidney, bone, prostate, and breast, as well as uterine fibroids and soft-tissue sarcomas \cite{4}. Hence, it plays an increasingly important role in the treatment of symptomatic uterine fibroids \cite{5–8}. This minimally invasive procedure may effectively alleviate the symptoms of excessive menstrual bleeding, pain, and pressure \cite{2}. However, patients have limited understanding of this new technique, such as its mechanism, the surgical procedure, anesthetic approach, postoperative complications, and recovery. This may result in anxiety and depression before the operation, which may negatively impact the treatment efficacy and prognosis of the disease \cite{9}.

Many patients experience anxiety prior to their surgery, which is referred to as preoperative or pre-surgical anxiety \cite{10}. Preoperative anxiety has been described as an adverse state of apprehension that is secondary to a patient being...
worried regarding the disease, hospitalization, planned anesthetic protocol, surgery, and the unknown [11]. Preoperative anxiety has been the focus of research for many years [12]. Several studies have shown that women undergoing surgery experience higher levels of anxiety compared to men [13]. Pain is a common symptom among women experiencing gynecological problems. Furthermore, high levels of pain and adverse psychological symptoms are common in women undergoing gynecological surgery [14]. Numerous studies demonstrated a positive correlation between anxiety and pain, and that less anxious patients felt lesser pain [15]. Thus, the assessment of individual levels of preoperative anxiety is crucial to provide the appropriate psychological interventions [16]. The Enhanced Recovery After Surgery (ERAS) Guidelines for Perioperative Care in Gynecologic/Oncology Surgery, 2019 edition, had high recommended ratings for pre-admission information, education, and consultation, which mainly aimed to alleviate the patients’ perioperative anxiety, improve their satisfaction, relieve fatigue, and promote early discharge [17]. Therefore, it is necessary to evaluate the level of anxiety and its influencing factors at different time periods, such as during surgery and recovery.

A patient-reported outcome (PRO), a measurement of any aspect of a patient’s health status, comes directly from them (without a physician or anyone else interpreting the patient’s responses) [18]. In pain or anxiety assessments, a PRO may be the only viable approach since there are no observable or measurable physical/physiological markers of the disease or treatment activity [19]. However, the commonly used PRO instruments for anxiety are relatively long [20] and require both time and staff to ensure the response rate and data quality. In both research and practical settings, a decrease in the measurement burden for potential participants may have a favorable impact on the sample size and consequently, the quality of the findings [21]. Accordingly, a scale with high sensitivity, fewer items, and high compliance is preferred for a busy surgical clinic.

Following the principle of developing a PRO measure [18], the present study aimed to develop a scale which assessed the perioperative anxiety symptoms for uterine fibroids (PASM-UF) in women. With this brief PRO instrument, changes in patients’ anxiety during the perioperative period can be evaluated multiple times. Furthermore, any psychological changes can be fed back to the medical staff promptly via an alert threshold to achieve a rapid response.

2. Materials and methods

2.1. Scale development

Based on a literature review, question sets for 13 items were prepared with particular attention to ensure that they were clear, understandable, and relevant to the subject matter [22–24]. Next, opinions from experts were obtained to determine whether the items were suitable for the measurement objective and were representative of the area to be measured [25]. The scale items were finalized by 20 experts, which included ten gynecologists, seven gynecological nurses, and three PRO experts, via a meeting. The ten gynecologists were selected based on practicing time and professional title, which included three doctors with senior professional titles and seven with intermediate titles. In addition, all had practiced for more than five years. The nurses were screened based on the length of their practice. Of these, two had practiced for more than 10 years, while the other five had practiced for more than three years. All three PRO experts had PhD degrees and rich research experience. The PASM-UF symptom items were rated on a scale from 0 (not present) to 10 (as bad as you can imagine) [26].

2.2. Psychometric validation of the scale

The subjects were women treated at a hospital, which specialized in uterine diseases in Chongqing, China, between November 2020 to June 2021 (n = 228). Individuals with high-risk pregnancies, chronic illnesses, psychiatric disorders, and communication problems were excluded at the time of enrollment. Subjects completed the PASM-UF without any intervention at admission (the first time), before surgery (the second time), and at discharge (the third time). During the recruitment, the Symptom Checklist-90 (SCL-90) was administered. The hospital made a reservation for the operation. The patients were admitted the day before the operation, and the median hospitalization time was three days. Patients received standard preoperative education at the time of their admission, conducted by a bed doctor and the nurse in charge. Subjects completed the PASM-UF thrice at intervals of more than 24 h, however, lesser than 30 h. Although patients with surgical complications were excluded, no such cases were encountered.

2.3. Ethics

This psychometric validation study was conducted at a hospital after approval was obtained from the Hospital’s Ethics Committee (approval number: 2020-003). The registration number of the China Clinical Trial Center was ChiCTR2200056735. Patients with uterine fibroids were informed of the purpose of the study, timing, and expectations. Furthermore, informed consent was obtained on a voluntary basis. This study did not involve human trials.

2.4. Data analysis

Descriptive statistics (mean and standard deviation and numbers and percentages) were provided for continuous and categorical variables, respectively. The total PASM-UF score was calculated by adding the answers to five questions. The greater the scores on each item and total score, the higher levels of anxiety or related symptoms.

Cronbach’s alpha was used to assess the internal consistency for reliability. Generally, values of >0.9, >0.8, >0.7, and <0.6 as were rated as excellent, good, acceptable, and doubtful, respectively [27]. For criterion validity, we estimated the relationship between the developed PASM-UF and SCL-90 (anchor) via a correlation analysis. For knowngroup validity, the Wilcoxon rank-sum test was conducted to
compare the PASM-UF scores between the patients with total SCL-90 score of ≥160 and those <160. An SCL-90 score of ≥160 was considered positive for psychological abnormalities [28]. To evaluate the ability of the PASM-UF to detect changes, we compared the PASM-UF scores before and after surgery via the Wilcoxon signed-rank sum test.

Statistical significance was set at \( p < 0.05 \). IBM SPSS version 18 was used for statistical analysis.

3. Results

From the 13 items summarized previously, five items, which included pain, lack of appetite, fatigue (tiredness), disturbed sleep, and anxiety, were finalized in line with the experts’ opinions.

3.1. Patient characteristics

Among the 228 patients, 185 (81.14%) were married, 151 (66.23%) had a bachelor’s degree or higher, and 178 (78.07%) worked full-time. Their mean age was 40.46 ± 6.74 years. (Table 1)

### Table 1. Demographic characteristics and descriptive information (n = 228).

| Patient information | n  | %        |
|----------------------|----|----------|
| Age (mean ± SD, 40.46 ± 6.74) |    |          |
| <40                  | 110| 48.25    |
| ≥40                  | 118| 51.75    |
| Marital status       |    |          |
| Married              | 185| 81.14    |
| Single, widowed or separated | 43| 18.86    |
| Education            |    |          |
| Primary or secondary school | 77| 33.77    |
| University or postgraduate | 151| 66.23   |
| Employment status    |    |          |
| Full time            | 178| 78.07    |
| Retired              | 3  | 1.32     |
| Unemployed           | 31 | 13.60    |
| Freelancer           | 15 | 6.58     |
| Homemaker            | 1  | 0.44     |

SD: standard deviation.

### Table 2. Internal consistency reliabilities, means and standard deviations for PASM-UF.

| Scales/items | Cronbach’s alpha | N | Min | Max | Mean | SD | Missing (%) |
|--------------|------------------|---|-----|-----|------|----|-------------|
| PASM-UF Total (Before FUAS) | 0.745 | 228 | 0   | 29  | 4.14 | 5.56 | 0           |
| Pain         | 0.827            | 228 | 0   | 7   | 0.39 | 1.21 | 0           |
| Lack of appetite | 0.732 | 228 | 0   | 5   | 0.33 | 0.97 | 0           |
| Fatigue (tiredness) | 0.813 | 228 | 0   | 9   | 0.94 | 1.73 | 0           |
| Disturbed sleep | 0.657 | 228 | 0   | 9   | 1.36 | 2.03 | 0           |
| Anxiety      | 0.721            | 228 | 0   | 8   | 1.12 | 1.72 | 0           |

Min: minimum; Max: maximum.

### Table 3. PASM-UF scores between patients with SCL-90 ≥160 and <160, Filled SCL-90 and Not filled SCL-90 (mean SD).

| SCL-90 score | Pain       | Lack of appetite | Fatigue (tiredness) | Disturbed sleep | Anxiety | PASM-UF Total |
|--------------|------------|------------------|---------------------|----------------|---------|--------------|
| ≥160(n = 20) | 1.30(2.13) | 0.90(1.48)       | 2.30(2.49)          | 2.70(2.68)     | 2.65(2.30)| 9.85(9.07)   |
| <160(n = 157)| 0.37(1.18) | 0.31(0.99)       | 0.92(1.74)          | 1.34(2.06)     | 1.06(1.68)| 4.01(5.15)   |
| P            | 0.003      | 0.000            | 0.001               | 0.006          | <0.001  | 0.002        |
| Filled (n = 177) | 0.47(1.34) | 0.38(1.07)       | 1.08(1.88)          | 1.49(2.17)     | 1.24(1.83)| 4.67(5.99)   |
| Not filled   | 0.12(0.43) | 0.18(0.52)       | 0.45(0.94)          | 0.90(1.37)     | 0.69(1.22)| 2.33(3.27)   |
| P            | 0.094      | 0.556            | 0.034               | 0.189          | 0.046   | 0.006        |

*P*, obtained from Mann-whitney U rank-sum test.

### 3.2. Internal consistency reliability

Cronbach’s alpha was 0.745, whereas the total PASM-UF score was 4.14 ± 5.56. The highest symptom was ‘disturbed sleep,’ followed by ‘anxiety’ and ‘fatigue (tiredness).’ (Table 2)

### 3.3. Criterion validity

The total PASM-UF score was associated with the total SCL-90 score \( r = −0.345, p < .0001 \), somatization, \( r = −0.406, p < .0001 \) and psychoticism \( r = −0.321, p < .0001 \). In addition, the anxiety item in the PASM-UF was associated with the total SCL-90 score \( r = −0.384, p < .0001 \), somatization \( r = −0.371, p < .0001 \), obsessive-compulsive symptoms \( r = −0.320, p < .0001 \), depression \( r = −0.332, p < .0001 \), anxiety \( r = −0.342, p < .0001 \), and others \( r = −0.357, p < .0001 \).

### 3.4. Known-group validity

Among the 228 subjects who completed the PASM-UF, only 177 (77.63%) completed the SCL-90 scale. The total PASM-UF scores were significantly higher in patients with SCL-90 scores of ≥ 160 than in those with < 160 (9.85 ± 9.07 vs. 4.01 ± 5.15, \( p = .002 \) (Table 3).

### 3.5. Ability to detect change

The patients completed the PASM-UF at admission, before surgery, and at discharge. Their levels of anxiety were higher prior to surgery (3.92 ± 4.90) and lower at discharge (2.95 ± 4.18). Furthermore, their levels of pain were lower prior to surgery (0.31 ± 0.94) and higher at discharge (0.77 ± 1.01). Except for the item ‘lack of appetite,’ the scores on other items present significant differences between before surgery and at discharge. (Table 4)

### 3.6. Utility of the PASM-UF

Patients who did not complete the SCL-90 scale reported significantly lower individual items and total scores for the PASM-UF compare to those who completed it. (Table 3) Furthermore, anxiety scores at the second assessment (before surgery) were positively correlated with the pain scores at the third assessment (at discharge).
A 5-item PRO instrument, the PASM-UF, was designed to assess the level of perioperative anxiety and related symptoms in perioperative patients with uterine fibroids. Our study showed that this PRO-based instrument had good validity and reliability and was able to detect the changes in anxiety symptoms before and after the FUAS. Moreover, the PASM-UF was brief and understandable among patients from different ages and varied levels of education. Based on these psychometric properties, this PRO measures might be recommended for use in clinical research and practice.

As a brief instrument, the PASM-UF is especially suited for frequent assessments of perioperative anxiety levels in patients and can be sensitive to changes in anxiety levels. While all 228 (100%) patients completed the PASM-UF, only 177 (75.97%) completed the SCL-90 scale. A high proportion of patients complied with the PASM-UF, which did not increase the burden on them. Lower PASM-UF scores reported by those who did not complete the SCL-90 suggested that the use of a scale with many items, such as the SCL-90, overestimated the anxiety level of the entire population and decreased patient compliance.

Since a 0–10 numerical rating scale has been used routinely for pain assessment in surgical practice, the 0–10 scale of the PASM-UF is familiar to the respondents. Moreover, digital scores can be easily integrated into modern presentation models (e.g., Internet, smart phones, web-based clinic portals). Furthermore, this flexibility allows patients to report the severity and disturbance of their symptoms in real time, whether they are in the clinic or at home [29]. Since the anxiety item of the PASM-UF was related with most items of the SCL-90 scale, the PASM-UF could be deemed highly sensitive to the measurement of anxiety.

The positive association between the preoperative anxiety score and postoperative pain suggested that reduced preoperative anxiety levels enhanced post-surgical recovery. With the PASM-UF, highly anxious patients can be identified prior to their surgery. Furthermore, interventions for reducing anxiety can be implemented for this vulnerable group.

Compared to previously reported gynecological patients, the incidence of anxiety was higher in the present cohort. There is significant uncertainty in the literature regarding when an upcoming surgical procedure affects a patient's anxiety level. However, the results of this study suggest that anxiety levels may already be elevated prior to admission [15]. Another study demonstrated that there was an insignificant difference in perioperative psychological distress between patients who underwent surgery for malignant and benign diseases [30]. Meanwhile, uterine fibroids have been shown to impair quality of life to a greater extent than other chronic conditions, such as asthma, gastroesophageal reflux, and irritable bowel syndrome [31]. Moreover, a study found that the anxiety levels in patients with uterine fibroids were significantly higher than compared to the normal population [32]. However, there are no specific questions regarding the measurement of perioperative anxiety in patients with uterine fibroids. Scales, such as the SCL-90, State-Trait Anxiety Inventory (STAI), Hospital Anxiety and Depression Scale (HADS), Self-Rating Anxiety Scale (SAS), and Beck Anxiety Inventory (BAI), are commonly used to measure anxiety. Furthermore, they contain many items (90, 40, 14, 20, and 21 items respectively), and their measurement time varies. Except for the STAI, whose recall period is ‘at present,’ the recall periods of the others are one week or longer. Therefore, they are unsuitable for frequent perioperative assessments. Additionally, they all contain more than ten items, which may burden both the patients and clinicians, especially when multiple assessments are required to describe the dramatic change in symptoms during surgical recovery. Thus, it is clear that the PASM-UF, with fewer items and lower difficulty, is a potential trend.

This study has some limitations. First, the correlation between the PASM-UF and SCL-90 was not particularly high. This was probably since the SCL-90 was suitable for psychological measurement of the normal population, while PASM-UF was suitable for patients with uterine fibroids during the perioperative period. Second, this study was conducted in a single hospital with a specific target population. Hence, interpreting our results to the entire population of patients with uterine fibroids may require further research with heterogeneous patients.

In conclusion, the PASM-UF developed in this study for assessing the perioperative anxiety levels in patients with uterine fibroids is feasible. In addition, statistical analysis suggests that it is also an effective instrument for scientific research.

Table 4. PASM-UF scores before FUAS vs. at discharge (mean SD).

|                | Pain       | Lack of appetite | Fatigue (tiredness) | Disturbed sleep | Anxiety  | PASM-UF Total |
|----------------|------------|------------------|---------------------|-----------------|-----------|---------------|
| Before FUAS    | 0.31(0.94) | 0.31(3.78)       | 0.95(1.63)          | 1.31(1.91)      | 1.07(1.57) | 3.92(4.90)    |
| At discharge   | 0.77(1.01) | 0.36(3.98)       | 0.61(1.15)          | 0.90(1.34)      | 0.31(3.74) | 2.95(4.18)    |
| Z              | −5.658a    | −2.07a           | −2.978b             | −2.698b         | −7.138b   | −3.125b       |
| P              | <0.001     | 0.836            | 0.003               | 0.007           | <0.001    | 0.002         |

aBased on negative rank.
bBased on positive rank.
P, obtained from Wilcoxon signed rank sum test.
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