

## DEVELOPMENT AND CONTENT VALIDATION OF AN EDUCATIONAL HANDOUT FOR WOMEN WITH UTERINE FIBROIDS

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### ABSTRACT

**Background:** Uterine fibroids (UF) are a generally overlooked public health issue that affects between 20% to 50% of women of reproductive age with symptoms such as heavy menstrual bleeding and pelvic pain. It's regarded as an estrogen-dependent illness, and studies show that regular exercise can help with hormonal imbalances. Many women with UF who visit physiotherapy clinics for the treatment of related pelvic pain are ignorant of their condition and worry that their fibroid will turn into cancer. They are unaware of the benefits of a healthy lifestyle and physical exercise, in disease management. Further health education is required among the patients to guarantee early diagnosis and improve management.

**Aim:** To develop and content validate an educational handout for women with UF.

**Method:** A pictorial handout with information about the clinical features, diagnosis, and management tips was developed. Nine experts from different disciplines namely obstetrics and gynecology (3), physiotherapy (4), nutrition and dietetics (2) participated in the content validation by filling out a 9-item questionnaire.

**Results:** The Item Level Content Validity Index (I-CVI) for individual items was calculated and ranged from 0.78 to 1.0. The Scale Level Content Validity Index (S-CVI) was found to be 0.94 (CVI score  $\geq 0.8$  is acceptable). The results imply that the content is valid. Comments from the experts reflected the need for simplifying a few medical terms used, to update the treatment

options with novel minimally-invasive techniques such as selective embolisation, to redraw images of infertility and surgery, and to add a bibliography and reference section at the end. Modifications were incorporated. Following the experts' complete agreement on the handout; it was translated into the regional language. Before being distributed to patients, this handout will be pretested on 20 women with UF.

**Conclusion:** The results indicate that the handout's content is valid. It will be distributed among women with UF who attend the gynecology department as well as physiotherapy clinics after the pretesting.

*Keywords: Content validation; Educational handout; Patient education; Uterine fibroids*

## INTRODUCTION

Uterine fibroids (UF) are pelvic tumors common among women of reproductive age. Its estimated prevalence is 20-50% with a morbidity rate of 30% [Ciavattini et al., 2013]. The etiology of UF is still unclear but it is hypothesized that estrogen dominance could be a possible mechanism behind its pathogenesis [Wong, Gold, Johnson and Lee, 2016]. It has become a global public health issue due to its prevalence, symptom severity, and overall disease burden. According to the study by Giuliani, As-Sanie and Marsh, 2021, approximately 30% of fibroid patients experience menorrhagia, pelvic pain and pressure, bloating, bowel or bladder dysfunction and weakness. Modern medical therapies have varying adverse effects and only temporarily ease symptoms or reduce the likelihood of recurrence of fibroids. According to the National Family Health Survey (NFHS) [Desai, Shukla, Nambiar and Ved, 2019], UF is one of the most likely causes of hysterectomies. Evidence suggests that UF has a negative impact on one's health-related quality of life (HRQoL) [Fernandez, Ardaens, Queval and Solignac, 2018; Laberge, Vilos, Vilos and Janiszewski, 2015; Soliman et al., 2017]. The severity of their symptoms has a psychological (anxiety and depression) and socio-professional (lower work performance and absenteeism at work) impact on their everyday lives and self-image.

A sedentary lifestyle with a poor diet and lack of exercise increases the risk for UF. Moreover, there was an increased risk of UF among women with a high BMI and obesity [Sun, Xie, Zhao and Li, 2019]. Diet and physical activity have been reported as modifiable risk factors for UF. Several observational studies have discovered an inverse relationship between physical

activity and circulating estrogen levels [Chan et al., 2007; Bertone-Johnson, Tworoger and Hankinson, 2009]. However, poor physical fitness among women raises the risk of hormonal imbalances. Furthermore, the importance of physical activities in alleviating menstruation problems and pelvic pain has been established via studies, which eventually serves to improve the patient's quality of life [Daley, 2009]. Most of the women with UF attending the clinics are unaware of their condition and worry about the possibility of malignancies from fibroids. Regardless of their clinical features and symptoms, most women believe that hysterectomy is the only treatment option. Krishnan, Ganapathy, and Parasuramanmarimuthu (2020) reported the need for health education among fibroid patients. They reported that the women have insufficient knowledge about UF and this little knowledge negatively impacts their lives. Adegbesan-Omilabu, Okunade and Gbadegesin, 2014, in their study concluded that patients have an extremely low understanding of UF and that the majority of women take over-the-counter medications to reduce the growth of fibroids.

They are unaware of the benefits of healthy lifestyle practices and physical exercises, in disease management. This points towards the need for health education among women to reduce the stigma associated with the condition and treatment options, encourage more women to speak with their health care providers, reinforce the demand for increased gynecological checkups and improve management by incorporating more exercises and a healthy lifestyle practices. Hence the need arises for materials as a guide for the women to educate them about their health conditions. Keeping this in mind, the current study aimed to develop and validate an educational handout for women with UF in both English and the native (Kannada) language. Its main objective was to help educate patients about the illness, symptoms, and its management.

## **METHODOLOGY**

### **Initial content generation for the handout**

The handout's initial content was developed from a comprehensive literature review of currently available educational materials for women with UF, endometriosis, and other menstrual diseases. We also looked into the epidemiology and pathology of UF, as well as the symptoms, etiology, diagnosis, and treatment of the disease. Expert input was taken into consideration when developing the material, based on their day-to-day clinical practice.

## **Handout Design**

From the literature and official websites, we gathered information about the epidemiology, prevalence, symptoms, causes, diagnosis, and treatment of UF. Discussions were held with experts (one gynecologist and one physiotherapist with at least 15 years of experience). The initial framework was developed and it was divided into seven components; introduction, symptoms, causes, diagnosis, treatment, do's and don'ts. Each item was thoroughly examined. These contents were then rendered into pictures with the help of an artist. The experts reviewed the drawings after they were completed, and any images that needed to be modified were redrawn and corrected. The criteria for selecting the pictures were set to be as similar as possible to the content while giving the least amount of distraction to the patient. After multiple modifications, the pre-final draft was prepared, which included the following sections:

**Introduction:** The section defines UF and provides an overview of its prevalence and epidemiology.

**Main content:** This section divides the major causes, symptoms, diagnosis, and management of UF into four subsections.

**Do's and Don'ts:** A section on the Dos and Don'ts was also included to convey fundamental but valuable information, particularly to women with lower literacy.

**Some tips for management:** This section is intended to give the patient a quick overview of the importance of dietary habits, physical exercise, and other lifestyle changes in managing the condition.

The hospital's and department's addresses were provided at the end in case there were any further questions.

## **Assessment of content validity**

The pre-final draft was sent to an expert panel for content validation. The validation process included two stages, the developmental and judgment quantification stage. During the development stage, three experts namely, a gynecologist, a physiotherapist, and a human physiology expert assessed the handout's relevancy and accuracy. All three experts had at least 15 years of clinical and/or academic expertise in their respective domains.

During the judgment-quantification step of content validation, both the item content and the overall instrument were validated [Lynn, 1986]. The handout and a validation form with the rating scale were sent to 9 validators. Experts in the fields of obstetrics and gynecology,

women's health, and physiotherapy were selected through their publications and contributions. One of the subject experts who participated in the development phase recommended two experts in the field of nutrition and dietetics, as well as an international expert in the field of Obstetrics and Gynecology (Table 1).

**Table 1: Characteristics of 9 participant experts**

Characteristics	Number (N=9)
Female	9
Country	India (8) New Zealand (1)
Profession	Physiotherapy (4) Obstetrics and Gynecology (3) Nutrition and Dietetics (2)
Main area of practice	Academics and research (3) Both clinics and academics and research(6)

Experts are required to have at least five years of clinical, research, or academic experience in their respective fields. All potential experts were contacted by email or phone and given their consent. Nine experts namely gynecologists (2), physiotherapists (4), dieticians (2) and an international expert in Obstetrics and Gynecology. The experts were given the handout, as well as a validation form with 9-item questionnaires for evaluating the relevance of the handout, as well as a cover letter outlining the purpose of the study and why they were chosen to participate in the validation process. A four-point Likert scale was used for the scoring. The Content Validity Index (CVI) [Davis, 1992; Polit and Beck, 2006] was used to quantify the results.

Translation and parallel back translation: Translation and parallel back translation: To enhance its usability and acceptability by the local populace, a standard method of translation into the local language was used [Beaton, Bombardier, Guillemin and Ferraz, 2000]. Following the completion of the content validity, the questionnaire was translated by three native Kannada speakers. Two non-medical English translators were blinded from the study and given the translated questionnaire to translate back to English. The final version was formulated after the translators, language experts, and gynecologists and physiotherapists evaluated the copies. This handout will be pretested among 20 women with and without UF before distributing to the patients.

## RESULTS

Responses from the nine validators were collected and analysed. Two gynecologists, two dieticians, one research fellow in Obstetrics and gynecology and four physiotherapists studied the handout and rated the items in the questionnaire. The experts had a minimum experience of 3 years and a maximum ranging from 15 – 20 years in gynecology, nutrition and dietetics and physiotherapy. Five items were completely agreed upon by all validators (Q2, Q3, Q7, Q8, and Q9) whereas the remaining 4 questions (Q1, Q4, Q5, Q6) showed a mild disagreement among the validators. Item Level Content Validity Index (I-CVI) was calculated for individual items which ranged from 0.78 – 1. Scale Level Content Validity Index (S-CVI) was calculated for total items and it was found to be 0.94. S-CVI should be at least 0.80 to be considered content valid [Table 2] [(Johnson, Sandford and Tyndall, 2003; Theis and Johnson, 1995)].

**Table 2: Scale Level Content Validity Index**

Questions	Items level content validity index (I-CVI)
This handout is presented in a simple understandable language	0.89
This handout provides information to the women about uterine fibroids	1
Introduction part in handout explains about the utility and purpose of the pamphlet	1
Images presented in the handout are legible and clear	0.89
Pictorial representation of different aspects of fibroids symptoms, diagnosis, treatment) are relevant for the knowledge of a woman	0.78
Handout design is simple and clear	0.89
Do's and Don'ts are informative	1
Tips to manage the fibroid symptoms at the end of the handout are useful& informative to the women	1
This handout serves the objective of providing knowledge about the uterine fibroids to the woman	1
Scale Content Validity Index (S-CVI) = Average of I-CVI $8.46/9 = 0.94$	
Table/Fig 2: evaluate the educational material's completeness, comprehensibility, legibility, clarity, and usefulness S-CVI was found to be >0.80, indicating that the content of the educational handout is acceptable.	

Validators expressed their views to include a bibliography and important references at the end of the handout, to mention small asymptomatic fibroids do not cause any troubles and don't require any treatments, to replace the word selective embolization of myoma instead of uterine

artery embolization, to replace the image for a healthy balanced diet with Indian Council Of Medical Research (ICMR) National Institute of Nutrition -Healthy plate for the day, 2020 and to simplify a few medical terms and to redraw a few unclear pictures. These suggestions were incorporated with consensus among the subject experts and the pre-final draft was prepared.

## **DISCUSSION**

The objective of the present study was to develop and validate an educational handout for women with UF. The necessity for health education for women with UF was obvious from the literature review and the experts' clinical experience. Thus, the focus of this study was to help educate women about the UF disease and treatment options in a simple and understandable manner.

Validators from various specialties were included in this study, and their qualifications, training, experience, publications, presentations, and research interests were all taken into account while selecting the panel of experts. This was done in accordance with American Psychological Association recommendations, which emphasize the importance of considering these elements in order to make the information more authentic and useful for the target population [Hambleton, R.K et al. 1986]. After the content validation, the I –CVI was shown to be  $> 0.80$  for all items except item- 5(I-CVI= 0.78). The majority of validators recommended redrawing a few pictures, including infertility, ultrasound scanning, radiofrequency ablation, surgery, and a positive attitude. These pictures were then redrawn after discussions with the subject experts.

The validators also recommended including a bibliography at the end to help patients grasp medical terminologies, as well as a reference section to provide details of literature sources for additional reading if necessary. The handout is mainly presented as a pictorial representation with written information. Textual content with pictorial representation increases comprehension, recollection, and adherence to health education information, particularly for patients with low literacy skills, since it makes complex knowledge much easier to understand [Houts, Doak, Doak and Loscalzo, 2006]. Furthermore, the availability of handouts in the local language will increase its capacity to reach the ground level. This is consistent with prior research [Gibbs, Waters and George, 1990], which found that presenting patients with well-designed information booklets enhances their acceptability and satisfaction [Gibbs, Waters and George, 1990]. Only having female validators on the expert panel would have strengthened the validation process since they would have shared thoughts and evaluated

the content thinking from a female perspective. We made it very obvious in our educational handout that it is an adjunct that contains simplified information. A handout is not a replacement for a therapist. This is consistent with prior research, which found that handouts are not all-inclusive; they are additional guides that should be thoroughly addressed with patients to ensure that they understand its full intention [Garcia, Chismark, Mosby and Day, 2010].

The current study is a part of an ongoing cross-sectional study. The validated handout will be pretested among women with and without UF before being distributed to patients to determine whether the material content is understandable to the patients.

## **CONCLUSION**

An educational handout for women with UF has been developed and validated. Women with UF may benefit from this educational material that includes information about UF, its symptoms, causes, diagnosis, and treatment, with simple pictorial representations. After the pretesting, this handout will be distributed to women who visit both gynecology and physiotherapy clinics as resource material to educate more about the condition and the importance of physical activity and a healthy lifestyle for a better management

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