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## Original Research Article

## Construction and validation of self-reporting menstrual disorder screening questionnaire for Indian population

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## ABSTRACT

**Background:** Dysmenorrhea is defined as difficulty in menstrual flow and refers to painful cramps during menstruation. There are 2 types of dysmenorrhea, primary and secondary dysmenorrhea respectively. Early diagnosis of these conditions which may be responsible for dysmenorrhea is necessary to curb the rising prevalence of infertility. There are no adequate screening questionnaires available for Indian population which can screen dysmenorrhea and differentiate primary and secondary dysmenorrhea.

**Aim and Objectives:** The objective of phase-1 of this study comprised of constructing menstrual disorder screening questionnaire and content validating the questionnaire and the objective of phase-2 was to administer the developed questionnaire on the targeted population.

**Materials and Methods:** This was a cross-sectional study in which a questionnaire was developed and content validated by experts. The expert panel was asked to validate each question on a four-point Likert scale for relevance, clarity, ease of comprehension and the question was represented in participants correct section.

**Results:** A pilot study was carried out on 31 participants. A total of 142 participants were participated in the study. Dysmenorrhea was reported by a total of 129 participants i.e. 90.85% whereas only 9.15% reported of having no pain during menstruation. Dysmenorrhea symptoms experienced only sometimes by 56 participants, but 73 participants reported to experience them with each cycle.

**Conclusion:** The questionnaire developed, and content validated in this study can be used as a self-reporting screening tool to detect menstrual abnormalities in the Indian population.

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## 1. Introduction

Dysmenorrhea is painful menstruation of sufficient magnitude to incapacitate day to day activities. The word “Dysmenorrhea” is derived from three Greek words, “Dys”, “mens” and “rhea” which means difficulty, month and flow respectively. There are 2 types of Dysmenorrhea, namely Primary and Secondary Dysmenorrhea.<sup>1</sup>

Primary dysmenorrhea is painful periods without any pelvic abnormality.<sup>1</sup> The actual prevalence of primary dysmenorrhea is difficult to identify as a small percentage of

women with dysmenorrhea took medical advice, although it affects their day to day life and performance at school/college or at work place. Most of the women don't consider it as a disorder, rather they consider it as a part of menstruation.<sup>2</sup>

A longitudinal study conducted by Sundell et al. reported that severity and prevalence of dysmenorrhea reduced in parous women; but remained the same in women who were either nulliparous or have had a miscarriage.<sup>3</sup> Duration of pain is usually 8 to 72 hours and generally begins at the onset of menstrual flow.<sup>4</sup>

There has been a close association found between the over production of uterine prostaglandins (PGs) and

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primary dysmenorrhea. PGs are derived from long-chain polyunsaturated fatty acids like arachidonic acid (found commonly in cell membrane phospholipids). PGs are one of the important components found in the intracellular matrix.<sup>2</sup>

The biological effects of PGs include a wide variety of physiological and pathological actions which includes inflammation, pain, sleep regulation and body temperature.<sup>5</sup> At the end of secretory phase, there is drop in the level of progesterone which leads to excessive contraction of the myometrium causing constriction of the uterine spiral arteries of the endometrium. This creates ischemia and necrosis of the endometrium. The shedding endometrial cells release PGs which stimulates the free nerve ending ultimately which is perceived as painful cramps in the suprapubic/abdominal region.<sup>6</sup> Some women also experience associated low back pain and pain radiating to the thighs. There is evidence that the PGs level in women in luteal phase of ovulatory cycle is higher than in the follicular phase.<sup>5</sup>

It was found through endometrial jet washings, luteal phase endometrial biopsies, and study of menstrual fluid that there is elevated levels of PGs in dysmenorrheic women as compared to non-dysmenorrheic women.<sup>2</sup> PGs i.e., PGF<sub>2a</sub> and PGE<sub>2</sub> were found to be elevated in blood circulation in women with dysmenorrhea compared with women without any symptoms during menstruation.<sup>5</sup>

The highest level of PGs was observed in the first 2 days of menses, which is a characteristic feature of dysmenorrheic pain. The severity of pain, related symptoms, and levels of PGs are directly proportional to each other i.e. higher the level of PGs, higher the pain and more severe the symptoms. According to various studies, uterine activity is found to be higher in dysmenorrheic women as compared to asymptomatic women.<sup>4,6</sup>

Dysmenorrheic women were found to have greater resting or basal tone of uterus, uncoordinated uterine contractions, active intrauterine pressure and increased uterine contraction frequency. This, combined with PGs increases the cognizance of pain in women. Levels of vasopressin hormones, leukotrienes and platelet-activating factor in menstrual fluid along with PGs were found to be higher in Dysmenorrheics women. Although the action of these elements is not fully understood it is believed that they collectively facilitate pelvic pain along with arterial vasoconstriction, menorrhagia, blood clot formation, and increased uterine contractility. The symptoms observed during and before menstruation in most adolescents are physiological, psychological and emotional in nature.<sup>6</sup>

The other associated symptoms are nausea, vomiting, diarrhoea, headache, fatigue, back pain, and dizziness.<sup>7</sup> Non-Steroidal Anti-inflammatory drugs (NSAIDs) are used more often for dysmenorrhea, to reduce moderate to severe pain. Other options like Aspirin and paracetamol, thiamine, herbal remedies, topical heat (about 39°C)

Transcutaneous Electrical Nerve Stimulation (TENS), Acupressure, Vitamin E, Behavioural interventions (relaxation), Contraceptives (combined oral) are likely to reduce pain in dysmenorrhea.<sup>8,9</sup>

The most common non-pharmacological treatment is exercise participation, which is thought to reduce the severity and/or frequency of primary dysmenorrhea. Regular exercise improves some of the symptoms experienced by dysmenorrhea women like fatigue, cognitive dysfunction, mood disturbance and bloating. Role and importance of exercises as a treatment for menstrual cycle disorders have been recommended by American College of Obstetricians and Gynaecologists (ACOG) and the National Health Survey (NHS) in the UK.<sup>9</sup>

The most common gynaecological complaint in adolescent period is Primary dysmenorrhea. Menstrual pain is one of the major cause for increase in the rate of absenteeism at school/college or work.<sup>10</sup> The disabling nature of dysmenorrhea places a notable burden on the public health care system.<sup>9</sup> Despite such high prevalence and diminished quality of life, most of the women do not seek medical care for this condition. Identification and early management of dysmenorrhea is necessary to improve the quality of life of woman and increase their performance level.

Pelvic pain related to an identifiable pathological condition like endometriosis is defined as secondary Dysmenorrhea. It can be new onset of dysmenorrhea or a change in its nature (intensity, duration) over time.<sup>10</sup> It could be because of various diseases/disorders related to pelvic floor and/or uterus such as endometriosis, polycystic ovarian syndrome, pelvic inflammatory disease.

Secondary dysmenorrhea occurs after several months to years of onset of menarche. It may arise as a new symptom when women is in 30 or 40 years of age. Lower abdominal pain and cramping are the most common symptoms. The pain radiates to back and inner thigh and pain worsen as menses progresses as 24 to 48 hours of menstruation. Irregular or heavy bleeding, vaginal discharge and dyspareunia may result from secondary dysmenorrhea. It is also suggestive of an underlying pelvic pathology.

Endometriosis is defined as presence of endometrial glands and stroma in sites other than the uterine mucosa. Studies have proved that about two-third of teenage girls with chronic pelvic pain (CPP) or dysmenorrhea have endometriosis<sup>11</sup> and endometriosis was laparoscopically diagnosed in 34.2%. Studies show that endometriosis is associated with dysmenorrhea, non-menstrual chronic pelvic-abdominal muscle pain and dyspareunia.

Non-menstrual CPP is present mostly throughout the month or only during a particular time in the cycle i.e. during ovulation.<sup>12</sup> Associated symptoms seen in some women which may or may not be related to endometriosis are dysuria, dyschezia and other chronic musculoskeletal

conditions.<sup>13</sup>

Polycystic Ovary Syndrome (PCOS) is arguably the most regular hormonal disorder observed in women of reproductive age and is most often the cause of infertility in women due to anovulation.<sup>14</sup> Tabassum K in 2014 stated that the prevalence of PCOS in India is 4.8% in 15–24 Year age group, 4.4% in 25–34-year age group and 0.8% in 35–44 year age group. According to the study the highest PCOS prevalence was in the early reproductive age and was found to decrease as the age advances.<sup>15</sup>

Pelvic inflammatory disease (PID) is caused by infection of the upper female genital tract and is often asymptomatic.<sup>16</sup> Pelvic inflammatory disorder is the main cause of infertility in India i.e. about 64% of women are known to have menstrual abnormalities.<sup>17</sup> The prevalence of self-reported lifetime PID in women aged from 18 to 44 years is 4.4%.<sup>18</sup> A single bout of PID significantly increases the risk of infertility and subsequent episodes increases it rapidly. Approximately 1% of women who have PID conceive with an ectopic pregnancy, about 20% become infertile and 40% develop chronic pain.<sup>16</sup> There is a wide spectrum of symptoms in PID. viz., peri-appendicitis, subclinical endometritis to frank salpingitis, peri hepatitis, and pelvic peritonitis. Women come with a history of abnormal vaginal discharge, adnexal tenderness and fever which requires cervical smear studies or laparoscopy for the diagnosis.<sup>19</sup>

As there is an increase in the prevalence of PCOD, Endometriosis, PID etc., early diagnosis is vital to limit the infertility issues. Till date, No questionnaire is available for Indian population which can screen dysmenorrhea at an early stage and differentiate between primary and secondary dysmenorrhea.

A questionnaire which can be easily administered by health care professionals leading to the early diagnosis and management of primary and secondary dysmenorrhea is necessary the need of the day. Therefore, a screening questionnaire which is specific and sensitive to Indian unmarried population is required to identify females to differentiate between primary and secondary dysmenorrhea or risk of developing dysmenorrhea and refer them to higher centers in an attempt to reduce the prevalence of infertility.

## 2. Materials and Methods

The objective of this study comprised of construction of menstrual disorder screening questionnaire and content validation of the questionnaire and administration of the developed questionnaire to the predefined set of participants

Ethical clearance was obtained from the Ethical committee of the College of Physiotherapy, Dayananda Sagar University, Bangalore.

The below mentioned sequence was followed.

Questionnaire Construction, Item-Development, and Initial item reduction

The first step in the questionnaire construction procedure involved a focus groups comprising the researchers including a gynaecologist for the identification of appropriate, specific, and sensitive questions related to dysmenorrhea to be included in the item pool.

The three researchers performed the review of literature related to primary and secondary dysmenorrhea independently. After careful consideration appropriate items were identified from the literature related to dysmenorrhea. The items thus generated formed the initial item pool for the questionnaire. We identified a total of 28 questions which were related to menstrual cycle and related symptoms like duration of the cycle, bleeding patterns, pain severity, etc. Item reduction was then carried out by the researchers from the initial item pool. After careful examination, and removal of duplicates and ambiguous items, 23 questions were finally retained. Further, questions related to the demographic data were added to the questionnaire. The 23 questions thus finalised were grouped into 5 different domains namely, Demographic data, Menstrual details, pain assessment, associated symptoms, and inter-course related information.

### 2.1. Content validation

A content-validation form was framed and was circulated as google form via email to the experts specialized in women's health or health care professionals who have published research articles on dysmenorrhea after taking their consent. The form was sent to 30 experts out of which 9 (8 females and 1 male) replied within the stipulated time. Among them 3 were practicing gynaecologists, 1 Professor of community medicine, 2 general physicians and 3 women's health physiotherapists. The experts were requested to validate each question using 4-point Likert scale for relevance of the question to the study, clarity of the question, language comprehension, representativeness of questions under each section and the appropriateness of the allocation of the given question to the respective section. The responses received from the experts were scrutinized and the content validation index was calculated for each item. Items scoring less than 0.7 were reframed and resent to the experts and finalized.

A pilot study was carried out with 31 students drawn from Dayananda Sagar University in Bangalore, India. Participants were explained and informed consent was taken prior to the study participation. The aim of the pilot study was to check the feasibility in the administration of the questionnaire related to the student's ability to comprehend the instructions and items of the questionnaire and to assess for any difficulty in choosing response categories. Modifications were made in the questionnaire based on the feedback collected from the participants. to facilitate the readability and comprehensibility of the questions The data collected was analysed.

## 2.2. Study design: A survey

Sample size: the sample size for the phase-2 study was calculated as participants to variables ratio of 5: 1 (five participants per variable i.e., 5 participants x 'n' items). Hence, 5 participants is to 23 questions from the final questionnaire was calculated to 115 participants. Permissions were obtained from respective authorities. Students from Dayananda Sagar Pre-University College, College of Nursing, Dayananda Sagar University, and College of Physiotherapy, Dayananda Sagar University were recruited in the study. The questionnaire was shared to their respective email or WhatsApp. We invited 159 females to participate in the field testing of the initial item questionnaire, out of whom 17 did not meet the study criteria, 1(0.06%) student was married, and 16 (10.06%) students were not Indians by origin. The data collected was subjected to statistical analysis.

Descriptive statistics were used to find the mean and standard deviation for demographic variables and outcome variables. Microsoft excel, and word was used to generate graphs and tables.

## 3. Results

The age of the subjects is given in the table below. The mean age of participants was 19.16 with a standard deviation (SD) of 1.76. (Table 1)

**Table 1:** Regularity of periods

Regularity of periods	No of respondents	% of respondents
Irregular	41	28.87
Regular	93	65.49
Unpredictable	8	5.63
Total	142	100.00

**Table 2:** Dysmenorrhea

Dysmenorrhea	No of respondents	% of respondents
No	13	9.15
Yes	73	51.41
Sometimes	56	39.44
Total	142	100.00

**Table 3:** Type of pain

Type of pain	No of respondents	% of respondents
Cramping	85	65.89
Dull aching	27	20.93
Piercing/stabbing	11	8.53
Throbbing	6	4.65
Total	129	100.00

## 4. Discussion

We attempted to come up with a self-reporting menstrual disorder screening questionnaire for Indian average population the average age of the study population was 19.16±1.76 years. It was convincing that the average age of the participants was appropriate in the current context since it is supported by literature that secondary dysmenorrhea develops after a period of around 3 years post-menarche. The average age of menarche was found to be 13.27 years with a standard deviation of 1.27 years. The highest percentage i.e. 32.39% of the participants attained menarche at the age of 13 years and small percent of them (4.23%) reported to have attained menarche at 16 years of age. So, in our study 26.6% (n=37) of the participants reported pubertal age less than 12 years, which could be a risk factor for developing dysmenorrhea which was in line with the studies done by Kural M et al. and George N et al.<sup>1,20</sup>

Normal menstrual cycle was reported by majority of the participants (65.67%), while shorter menstrual cycle was reported by 14.08% participants and longer menstrual cycle was reported by (7.04%) of them. However, 11.27% participants reported that their menstrual cycles were too irregular to generalise the cycle duration. This was in line with the research findings of Dasharathy et al., where they reported that the average number of days the woman had bleeding during menstrual cycle is 5 days, with the heaviest flow during the first 3 days of the cycle.

Oligomenorrhea was reported by 8.45% participants whereas menorrhagia was reported by 10.56% of them. Oligomenorrhea is often related to PCOS and menorrhagia with endometriosis, so it is important to screen such females for the above mentioned conditions. The report of the review article by Parasar et al., stated that endometriosis is associated with intermenstrual bleeding and chronic pelvic pain which may be persistent without menstrual periods.<sup>13</sup>

Dysmenorrhea has a very high prevalence in south India.<sup>3,21</sup> According to a study by NS George it was seen that the prevalence of dysmenorrhea in adolescent girls was found to be 62.70%, among which 12% had mild pain, 33% had moderate pain and 17.6% had severe pain during menstruation. In our study we have seen that 90.85% participants complained of dysmenorrhea among which 39.44% reported symptoms occasionally whereas 51.41% participants reported to experience them with each cycle. Pain being the most concerned symptom was reported by 20.16% subjects as mild, 50.39% as moderate, and 29.46% as severe. The experience of moderate to severe pain during the menstrual periods could be one of the reasons of absenteeism at college among these individuals. In a study it was reported that about 48% of the adolescent girls had limitation of daily activities during menstruation. Proper management and education of this is needed to increase the productivity of the women at work. Matthew et al reported

that 99.6% have abdominal pain, 48% girls experienced pain radiating to the thighs and legs, while low back ache was seen in 39.6%<sup>22</sup> which was contradictory to our results as 35.77% complained of abdominal pain, 28.85% low back pain and 14.62% participants complained of pain radiating to thighs. A few participants (34.75%) complained of experiencing pain at a specific site while a significant percent of them (65.25%) complained of pain at multiple sites. Majority of the participants (68.99%) reported pain for 1-2 days during menstruation, which is higher than that reported by Omidvar et al., in their study, The same study also reported that 23.2% of the dysmenorrhea girls experienced pain for 2-3 days which is more than that (17.83%) reported by us.<sup>21</sup>

Endometriosis symptoms include dysuria, dysmenorrhea, dyschezia, dyspareunia and chronic pelvic pain. In a study conducted by Mohan et al., it was reported that the most common complaint of women with endometriosis apart from infertility was chronic pelvic pain and dysmenorrhea which were experienced by 56.4% and 34.5%<sup>23</sup> women respectively. In the current study we have seen that dysmenorrhea is prevalent among 50.41% of the participants (n=142).

Pelvic inflammatory disease (PID) is usually seen in young women who are sexually active.<sup>19</sup> A small percentage of participants in our study disclosed to be sexually active (n=13). Symptoms in women with clinically suspected PID include intermenstrual bleeding, abnormal discharge, urinary frequency, postcoital bleeding, low back pain and abdominal pain.<sup>24</sup> Abnormal vaginal discharge was reported by 11 (7.75%) participants, while increase in frequency of urination was reported by 28 (19.72%) participants. Out of the 13 sexually active participants 2 (15.38%) complained of post-coital bleeding. However, due to social stigma associated with pre marital sex in India, the reliability of the response of the participants to the questions related to intercourse may be arguable.

The limitation of this study was the lack of follow up of women at risk of secondary dysmenorrhea who were referred to higher centres. We may not be assertive at this juncture in stating the number of them clinically diagnosed as secondary dysmenorrhea among those identified through screening using the menstrual disorder screening questionnaire

The future scope of this study is to establish the reliability, sensitivity, and specificity of the questionnaire in a larger population and substantiating the results with clinical diagnosis and that established through standard procedures.

## 5. Conclusion

The questionnaire can be easily administered by any healthcare professional for screening of dysmenorrhea which in turn may lead to the early diagnosis and

management of dysmenorrhea. This questionnaire is found to be effective and can be used to differentiate between primary and secondary dysmenorrhea in Indian women.

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None.

## 7. Conflict of Interest

None.

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