Comparative study of Diclofenic sodium and menfamic acid for treatment of Primary Dysmenorrhea.

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ABSTRACT:

Background:
The exact cause of primary dysmenorrhea remains unclear, a gathering of treatment options is accessible to improve symptoms and improve general quality of life. With documented evidence of excessive absenteeism, prolonged use of NSAIDs and poor QoL amid Dysmenorrhea in young females, an easily approachable method to manage the issues is necessary.

Objective:
To assess the effects of diclofenic sodium and mefenamic acid on the severity and systemic symptoms of primary dysmenorrhea in the young age girls of Nursing School in Karachi Pakistan.

Methodology:
This is an observational, prospective study conducted from January 2023 to August 2023, the minimum sample size was 350. Data was collected by pre-structured questionnaire including age, marital status, clinical history, family history. The severity of pain is calculated by the Verbal Multidimensional Scoring System (VMS). Analysis was performed on SPSS-22. Chi-square test was performed keeping <0.05 p value as significant.

Results:
The mean age of participants was 22.15 ±1.9 years. Participants were divided into two groups A & B. Group A prescribed Diclofenic Sodium and Group B prescribed Mefenamic Acid as pain management medicine during the menstrual cycle. The difference in the VMS pain scale after 2 months of intervention was reported as significant, Grade 0 reported 20 (5.7%) and 29 (8.2%) in Group A & B respectively indicating remarkable difference in overall pain severity after using Diclofenic as pain management medicine while slight difference was noted in menfamic acid group.

Conclusion:
The findings contribute to the understanding of pain management options for young women experiencing dysmenorrhea, highlighting the potential advantages of Diclofenic Sodium in improving their quality of life during menstruation.

Keywords:
Primary Dysmenorrhea, pain management, diclofenic sodium, menfamic acid

INTRODUCTION

Dysmenorrhea, indicated by painful menstruation, arises as one of the most prevalent gynecological issues[1]. It shows abdominal cramps located in the pelvis or hypogastric region in the menstrual cycle[2]. Dysmenorrhea is usually categorized into two distinct categories: Primary Dysmenorrhea and Secondary Dysmenorrhea[3]. Whereas the cause of primary dysmenorrhea remains mysterious[4], secondary dysmenorrhea appears from underlying pathological conditions[5].

Primary Dysmenorrhea, for most cases, contains 45 to 95% of women of reproductive age, with 2–29% lasting in severe pain. It shows severe pelvic pain and often prompts persons to get medical attention[5]. Symptoms might continue for up to 72 hours, with nausea, dizziness, fainting, diarrhoea, headaches, vomiting and fatigue [6]. Some risk factors, including smoking habits, early beginning of puberty, menorrhagia, and psychological or emotional uncertainty, have been associated with dysmenorrhea[7].

These symptoms start in the elevated levels of prostaglandins and their metabolites within the endometrium[8]. Usually emerging available at the time of menarche or within 6 to 12 months after the beginning of menstruation, the pain related to primary dysmenorrhea can last for 2-3 days[9]. This disorder significantly impacts daily life, with several individuals reporting absenteeism from school or work, leading to reduced productivity and academic performance[10]. Findings have shown that 42% of women experience decreased work efficiency, however, 17% report disappearing from work or school overall due to primary dysmenorrhea[11].

Several treatment modalities occur for primary dysmenorrhea, varying from nutritional supplements, to adapted diet plans, vitamins, and herbal remedies[12]. With these, non-steroidal anti-inflammatory drugs (NSAIDs), oral contraceptive pills, and the purpose of localized heat have demonstrated efficacy[13]. Though, it's essential to note that the consequences of NSAIDs are often short-lived and can be accompanied by adverse effects such as heartburn, diarrhea, constipation, hemolytic anemia, and renal toxicity[12].

Developing upon the treatment preferences for primary dysmenorrhea, healthcare providers may also suggest lifestyle adaptations, such as regular exercise, stress management methods, and dietary adjustments. Furthermore, alternative therapies like acupuncture, transcutaneous electrical nerve stimulation (TENS), and cognitive-behavioral therapy (CBT) have achieved a grip in managing the symptoms associated with dysmenorrhea[9,11].

In up-to-date years, there has been a collective interest in holistic approaches to the management dysmenorrhea[13], highlighting and showing the importance of a multidisciplinary method that imitates not only the physical symptoms but also the mental and emotional well-being of persons affected by this condition, mindfulness practices, relaxation techniques, and healthy diet modifications, purpose to support a inclusive framework for management dysmenorrhea and enlightening the complete quality of life [8-11,13]. Also, continuing research into the pathophysiology of dysmenorrhea and the improvement of new therapeutic means propose potential better management and treatment of the outcomes. Since pointy drug therapies to advanced non-pharmacological interventions, improvements in this area continue to raise the armamentarium current in healthcare providers and persons fraught with the trials caused by dysmenorrhea [1-6,9,11]. While the exact cause of primary dysmenorrhea stays unclear [12-14], an assembly of treatment selections is accessible to improve symptoms and progress general quality of life. Through a complete and identified approach that reports both physical and psychosocial properties, individuals affected by dysmenorrhea can discover relief and recover control over their lives. The purpose of this study is to evaluate and compare the effects of diclofenic sodium and mefenamic acid on the severity and symptoms of primary dysmenorrhea in young age girls in Karachi Pakistan.

METHODOLOGY:

This is an observational, prospective study conducted at Karachi Institute of Nursing education, for the duration of 6 months, from July 2021 to January 2022. Young females of age 19-25 years, with positive history of dysmenorrhea were requested to get enrolled in the study. The sample size is calculated with the help of WHO and RaoSoft sample size calculator keeping the confidence level at 95% and margin of error at 5% and population size was determined by the total population of 18-25 years in Pakistan (n= 8.97m)* (United Nation Data of Country population), the obtained minimum sample size is 350. A consent in the language of understanding, explaining the complete design of the study, use of medicines, consultation with a gynecologist and follow-up details were signed.

Data was collected by pre-structured validated questionnaire containing three parts, part one had detailed questions about demographics including age, marital status etc. Part two obtained study-related history including clinical history, family history of

any relevant disorder or any diagnosed psychological issue, any recent traumatic incidents. Part three contains questions about diet, lifestyle, socioeconomic status, quality of life, painkillers, irregular periods, weight gain, heavy bleeding, and site of pain and associated symptoms like nausea, vomiting, diarrhea, dizziness and abdominal pain. The severity of pain is calculated by the Verbal Multidimensional Scoring System (VMS). This scale represents the degree of pain from Grade 0-Grade 3 determines none to severe pain.

Grade 0: Menstruation is not painful and daily activity is unaffected None Is required

Grade 1: Menstruation is painful but seldom inhibits the woman's normal activity. Analgesics are seldom required. Mild pain rarely affected None Rarely required

Grade 2: Daily activity affected. Analgesics are required and give relief so that absence from work or school is unusual. Moderate pain moderately affected few required

Grade 3: Activity inhibited, Poor effect of analgesics, headache, tiredness, nausea, vomiting, and diarrhea.

Data was entered, sorted and analyzed by using Statistical Package of Social Sciences (SPSS) version 22. Dependent variables were analyzed with the help of frequency, percentages, mean values, and standard deviation tests. Independent variables were analyzed with the help of frequency and mean values; however, data significance was analyzed by using a chi-square test keeping a significant P value ≤ 0.05 as a significant.

RESULT

The total sample size of this study was 350. The mean age of participants was 22.15 ±1.9 years, and the mean age of menarche was 13.48 ±0.7 years with a minimum of 12 and a maximum of 14 years. The mean duration of menses is 2.52 ±0.5 days, with a range of 2 days. After complete demographic details, and history documentation, participants were divided into two groups A & B. 175 participants were included in Group A and prescribed Diclofenic Sodium and 175 were included in Group B and prescribed Mefenamic Acid as pain management medicine during the menstrual cycle, the dosage and frequency were determined by a gynecologist.

Reported associated symptoms were documented within groups for better resolution assessment, the results indicated Irregular Periods in 5(2.0%) participants and 5(2.0%) participants in Groups A & B respectively, with a P-Value of 0.626. Weight Gain was experienced by 6(2.4%) and 11(4.39%) participants in Groups A & B respectively, with a P-Value of 0.158. Heavy Bleeding was experienced by 20(0.80%) and 21(8.4%) participants in Groups A & B respectively, with a P-value of 0.5. The highest reported associated symptom was lower abdominal pain with 56(22.4%) and 63(25.2%) participants in Group A & B respectively, with a P-Value of 0.07.

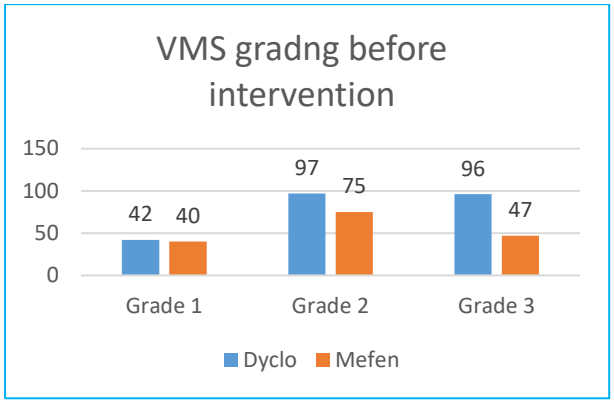
Nausea was experienced by 40(16.0%) and 23(9.2%) participants in Group A & B respectively. Diarrhea was experienced by 27(10.8%) and 51(20.4%) participants in Group A & B respectively. (Table I)

Table I: Distribution of symptoms and associated factors within Diclofenic sodium and Mefenamic group participants.

Variables		Diclofenic Sodium	Mefenamic Acid	P-Value
Irregular Periods	Yes	5 (2.0%)	5 (2.0%)	0.626
	No	120 (48.0%)	120 (48.0%)	
Weight gain	Yes	6 (2.4%)	11 (4.39%)	0.158
	No	119 (47.5%)	114 (45.6%)	
Heavy Bleeding	Yes	20 (0.80%)	21 (8.4%)	0.5
	No	105 (42.0%)	104 (41.6%)	
Site of pain	Lower Abdomen	56 (22.4%)	63 (25.2%)	0.846
	Flank	16 (6.4%)	14 (5.60%)	
	Thigh	6 (2.4%)	5 (2.0%)	
	Back	47 (18.8%)	43 (17.2%)	
Absenteeism	Yes	12 (4.8%)	15 (6.0%)	0.34
	No	113 (45.2%)	110 (44.0%)	
Associated symptoms	Nausea	40 (16.0%)	23 (9.2%)	0.015
	Vomiting	13 (5.2%)	13 (5.2%)	
	Diarrhea	27 (10.8%)	51 (20.4%)	
	Dizziness	6 (2.4%)	9 (3.59%)	
	Abdominal pain	9 (3.59%)	10 (4.0%)	
	None	9 (3.59%)	8 (3.2%)	
	More than two of the symptoms	21 (8.4%)	11 (4.39%)	

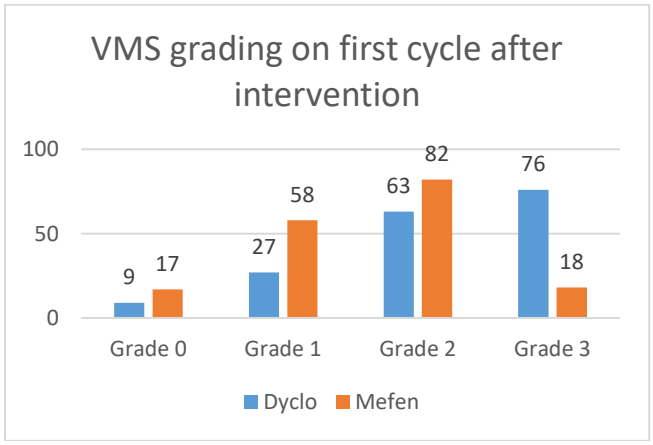
The pain grading was assessed by the Verbal Multidimensional Scoring System. Before the study, none of the participants were in Grade 0. 82 (23.4%) participants were in Grade 1 out of which 42 (12%) were administered with diclofenac sodium and 40 (11.4%) were administered with Mefenamic acid. In Grade 2 there were 172 (49.1%) participants out of which 97 (27.7%) were administered with diclofenac sodium and 75(21.4%) were administered with Mefenamic acid. In Grade 3 there were 96 (27.4%) participants out of which 47 (13.4%) were administered with diclofenac sodium and 49 (14%) were administered with mefenamic acid. (Fig I)

Fig I: Verbal multidimensional scoring system distribution before medicines in study participants.



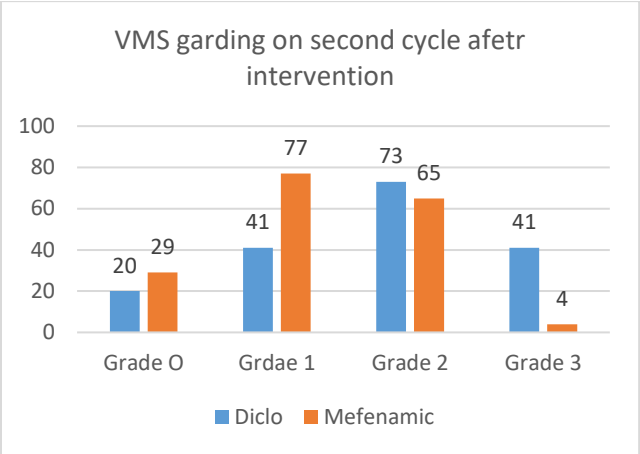
The difference in the VMS pain scale was significant on the first cycle of using medicines, Grade 0 reported 9 (2.5%) and 17 (4.8%) in Group A & B respectively. Grades 1 to 3 indicated differences in numbers as well, reporting patients with severe pain to moderate and mild pain, while participants reporting moderate to mild pain changed after taking meds. However, the higher amount of participants indicating pain settlements are from group B Mefenamic acid. (Fig II)

Fig II: Distribution of verbal multidimensional pain score on first month of medicines in study participants.



The similar difference in the VMS pain scale after 2 months of intervention was reported as significant (0.014), Grade 0 reported 20 (5.7%) and 29 (8.2%) in Group A & B respectively. Grades 1 reported 41 (11.7%) and 77 (22%), Group 2 reported 73 (20.8%) and 65 (18.5%) and Group 3 reported 41 (11.7%) and 4 (1.1%) indicating remarkable difference in overall pain severity after using Diclofenic as pain management medicine while slight difference was noted in menfamic acid group. (Fig III)

Fig III: Distribution of verbal multidimensional pain score on second month of medicines in study participants after taking Diclofenic sodium (Group A) and Mefenamic acid (Group B).



DISCUSSION:

The study associated the effectiveness of Diclofenic Sodium and Mefenamic Acid as pain relief drugs for primary dysmenorrhea. The Sociodemographic information, including age, age of menarche, and mean duration of menstruation, was quite recorded. Participants of the study were divided into two groups, A and B, with each group giving besides Diclofenic Sodium or Mefenamic Acid as guided by a gynaecologist. The reported associated symptoms inside the groups revealed interesting findings. While there were no significant differences in irregular periods, weight gain, or heavy bleeding between the two groups, lower abdominal pain was the most reported associated symptom, in contrast with the systematic review reporting pain management and quality of life [15-17]. However, the statistical analysis showed no significant difference between the groups about lower abdominal pain, showing the importance of objective measures in evaluating pain severity.

In this study Absenteeism from the institution due to dysmenorrhea was reported by 4.8% of the study participants using Diclofenic Sodium and 6.0% using Mefenamic Acid. A study that was conducted in Nigeria presented that females experiencing severe dysmenorrhea were reported 4 times more likely to show school absenteeism (OR: 4.2, CI:1.7–9.9 and P = 0.001). Respondents of the study stated the response that the convenience of analgesic drugs in schools might play a key role in avoiding school absenteeism [18-20].

Heavy bleeding was demonstrated in 0.80% of study participants taking Diclofenic Sodium and 8.4% consuming Mefenamic Acid, with no statistically significant p-value of 0.5. Subsequently these findings, a study conducted in India stated that Diclofenic did

better than Mefenamic Acid in conditions of controlling excessive menstrual bleeding [16]. The change in the rates of heavy bleeding between this study and the study conducted in India may be affected by numerous factors, including changes in the study populations, methods, and possibly regional or sociodemographic differences. Mainly, nausea was significantly more prevalent in the Diclofenic Sodium group distinguished from the Mefenamic Acid group ($p = 0.015$), representative of possible differences in side effects or satisfactoriness between the two medicines. The separation of symptoms and associated factors within the Diclofenic Sodium and Mefenamic Acid, main detail indicated the observed trends [21-23].

The Verbal Multidimensional Scoring System was applied to assess pain grading, presenting that no one of the participants was in Grade 0 before the study. After the administration of drugs, a significant fall in pain severity was noted in both A and B groups, with a higher in the proportionality of participants in the Mefenamic Acid group updating pain settlement. The division of verbal multidimensional pain scores ended the first and second months and understood the trends, emphasizing the significant impact of both medicines on decreasing pain levels[24]. Associations with the occurrence of dysmenorrhea in Lahore and other studies in Pakistan strengthened the consistency of findings related to the mean age of females suffering from primary dysmenorrhea [25-26]. The study gives an appreciated understanding of the sociodemographic characteristics, associated symptoms, and pain relief effectiveness of Diclofenic Sodium and Mefenamic Acid in the background of primary dysmenorrhea. The supposed differences in nausea and the disparity in pain reduction relating to the two drug groups protected other investigations and considerations in medical decision-making[27].

Comparations with other studies in Lahore and Pakistan show the prevalence and sociodemographic characteristics of primary dysmenorrhea in the targeted population [28-32]. Disparities in age of menarche and menses duration may be influenced by other environmental factors. Nevertheless, the study shows valuable understanding, detailed limitations should be acknowledged. The research of the study relies on self-reporting of symptoms, which may lead to recall bias. Moreover, the short period of the study may not include long-term effects or differences in pain-relieving over several menstrual cycles. The potential study might consider the long term effects, side effects, and patient fulfilment with these drugs. Moreover, objective measures of pain, such as hormonal analyses or ultrasound, might enhance the validity of pain measurements.

CONCLUSION:

The study provides evidence supporting the effectiveness of Diclofenic Sodium over Mefenamic Acid in releasing primary dysmenorrhea symptoms. The findings pay to the understanding of pain management selections for young women suffering from dysmenorrhea, highlighting the possible advantages of Diclofenic Sodium in refining their quality of life during menstruation.

Declaration(s):

- Authors declare no conflict of interest, any financial or otherwise benefit was not provided to authors.
- Priori informed consent was taken from study participants.
- Confidentiality was ensured by PI.

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