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# Drug Utilization Study in Primary Dysmenorrhea in A Tertiary Care Teaching Hospital

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## Abstract

***Background:*** *Primary dysmenorrhea is a common gynecological disorder affecting a large number of menstruating females. Leads to disruption of activities, loss of school, and other socio-psychological issues. We in the current study tried to evaluate the drug utilization pattern, evaluation of its efficacy, and its tolerability in patients reporting to our hospital with primary dysmenorrhea.* ***Methods:*** *For selected cases, demographic data and detailed history including menstrual history, medical history, drug history, and previous history of drug reactions were documented. In menstrual history, duration of the menstrual cycle, amount of blood loss, onset, duration, and severity of dysmenorrhea, and other associated symptoms, were recorded. Investigations performed were ultrasonography, for the abdominopelvic scan to rule out pelvic pathology. The pattern of drug prescribing: The details of prescribed drug i.e., name and class of drug, dose, route, frequency of administration was recorded.* ***Results:*** *The mean age of the study population was 23.5 ± 2.5 years. primary dysmenorrhea was classified as Grade I (mild) in n=3(2.5%) cases, Grade 2 (moderate) in n=42 (35%) cases and Grade 3 (severe) in n=75 (62.5%) cases. The associated symptoms with dysmenorrhea were headache in 6.67% cases, dizziness in 8.33% cases, nausea, and vomiting in n=37.5% cases, loss of appetite in 21.67% cases, diarrhea was reported in 12.5% cases. The most prescribed drug was Mefenamic acid plus Dicyclomine in n=85(70.83%) of cases followed by Diclofenac sodium in n=18(15%) of cases.* ***Conclusion****: the occurrence of primary dysmenorrhea is very common among young adolescent females. It is associated with symptoms of headache, dizziness, nausea, vomiting leading to loss of performance in work and absenteeism from schools. The NSAIDs are the commonly prescribed medication along with antispasmodics. Tranexamic acid is added to females with heavy menstrual blood flow with clots. Most of the medication was well tolerated with mild side effects.*

***Keywords****: Dysmenorrhea, drug utilization study, NSAIDs*

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## Introduction

Primary dysmenorrhea (PD) is a common gynecological disorder characterized by painful menstruation in the absence of any underlying pelvic pathology. In the adolescence period, crampy pelvic pain occurs before the onset of menstrual periods lasting for 1-3 days. [1] The painful contractions occurring are usually felt in the lower abdomen and may radiate to the back and thigh [2, 3] The reported incidence varies from 50 – 75% in various groups leads to disruption of educational and social life, school absenteeism, and loss of working hours. [4, 5] Home remedies are commonly used methods for PD which include massage, topical heat/cooling therapy, an exercise that may be less effective. The physiological role of prostaglandins is will elucidated in the occurrence of dysmenorrhea. Pharmacological agents such as non-steroidal anti-inflammatory drugs (NSAIDs) are the main drugs for treatment. The NSAIDS such as

mefenamic acid, diclofenac, ibuprofen, flurbiprofen, ketoprofen, naproxen, piroxicam and celecoxib are used. Hormonal therapy in the form of oral contraceptive pills (OCPs) is reserved for patients with suboptimal or lack of response to NSAIDs. Other hormonal agents used are medroxyprogesterone acetate, levonorgestrel-releasing intrauterine devices, and gonadotrophin-releasing hormone analogs like leuprolide acetate. [7] Despite PD being a common problem, it is perceived as a minor health concern. Lack of adequate knowledge regarding the physiology of the menstrual cycle and the treatment available for pain and discomfort associated with menstruation among adolescent girls is responsible for their silent suffering. [8] As a result there is a considerable negative impact on the quality of life in young women and proper treatment is required. However, despite wide therapeutic options, there is no unanimity or universally accepted and standardized guidelines regarding the choice of drug therapy, criteria for selection, the dose, frequency, and duration of administration, and also for monitoring the efficacy and tolerability of the administered drug. With this background, we in the current study tried to evaluate the pattern of drug usage in primary dysmenorrhea.

## Materials and Methods

This study was conducted in the Department of Obstetrics and gynecology OPD in Prathima Institute of Medical Sciences, Naganoor, Karimnagar. Institutional Ethical approval was obtained for the study. Written consent was obtained from all the participants of the study.

***Inclusion criteria***

1. Patients diagnosed with PD aged 12 – 30 years
2. With regular menstrual cycles
3. With at least 4 painful menstrual periods
4. Willing to participate in the study voluntarily

***Exclusion criteria***

1. Allergy to NSAIDs
2. OCP within 6 months/IUD inserted within 3 months of study
3. patients with pelvic pathology
4. patients with a history of gastritis
5. Not as per the inclusion criteria

For selected cases, demographic data and detailed history including menstrual history, medical history, drug history, and previous history of drug reactions were documented. In menstrual history, duration of the menstrual cycle, amount of blood loss, onset, duration and severity of dysmenorrhea, and other associated symptoms, were recorded. Investigations performed were ultrasonography, for the abdominopelvic scan to rule out pelvic pathology. The pattern of drug prescribing: The details of prescribed drug *i.e.,* name and class of drug, dose, route, frequency of administration was recorded. Their efficacy and tolerability were monitored, assessed, and compared. The efficacy of the prescribed drugs was assessed by pain intensity (PI) and pain relief (PR) scores during the first three days of the menstrual cycle. The subjects were followed up during treatment for three consecutive menstrual cycles. During each visit, patients were assessed for clinical relief based on the PI and PR scores and also monitored for any adverse effects. Statistical analysis was done using SPSS version 21 on windows format descriptive statistics, namely mean and standard deviation for quantitative variables. Wherever necessary, the results were depicted in the form of percentages with tables and graphs. The Chi-square test was used to find the significance of study parameters on a categorical scale between two or more groups.

## Results

Based on the inclusion and exclusion criteria n=120 cases were studied in the period of this study. The age group 13 – 20 years constituted n=40(33%) cases and age group 21 – 25 years were n=36(33%) patients and age group 26 – 30 years were n=24(20%) cases and age group 31 – 35 were n=20(17%) of cases depicted in figure 1.

The mean age of the study population was 23.5 ± 2.5 years. Of the total number of cases n=101(84.16%) were belonging to urban areas and n=19(15.83%) was belonging to rural areas. Based on the socioeconomic status majority 65% of the cases were belonging to the middle class and 26.67% were belonging to the lower class and 8.33% were belonging to the upper class. History of Primary dysmenorrhea was absent in 40% of cases of the study and positive

history was found in 60% cases with a history of a mother with PD was in 33.33% cases and 26.67% had a sister with a history of primary dysmenorrhea.

**Figure 1**: Age-wise distribution of cases

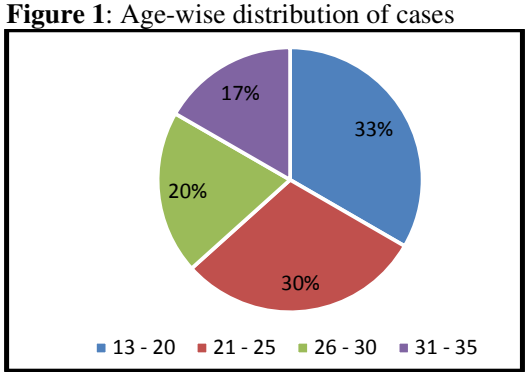



**Table 1**: Comparison of family history of PD with dysmenorrhea severity

| Dysmenorrhea severity | Family history of PD | |
|---|---|---|
| | Present | Absent |
| Mild | 0 | 0 |
| Moderate | 38 | 32 |
| Severe | 34 | 16 |
| Total | 72 | 48 |

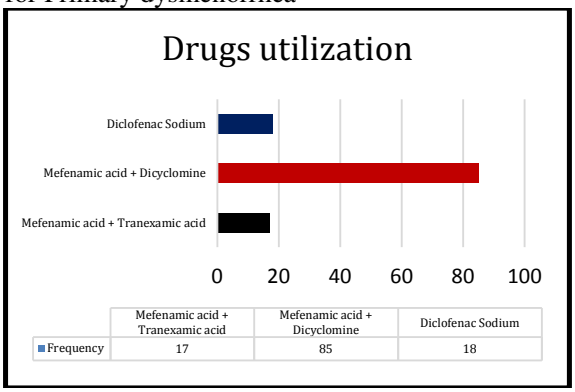
Based on the subjective response to the amount of blood loss in each menstrual cycle little blood loss was reported by 1.67% Moderate blood loss was reported by n=78(65%) of cases followed by heavy loss by n=21(17.5%) and heavy with clots was reported by n=19(15.83%) cases of the study. The mean duration of dysmenorrhea experienced by the cases in the study was 4.1 ± 1.9 years depicted in table 2.

**Table 2:** Duration of experiencing monthly dysmenorrhea in years

| Duration of experiencing monthly dysmenorrhea (years) | Number of subjects (n=120) |
|---|---|
| < 1 | 15 |
| 1-3 | 62 |
| > 4 | 43 |
| Total | 120 |
| Mean ± SD | 4.1 ± 1.9 |

In this study based on a verbal multidimensional scoring system the primary dysmenorrhea was classified as Grade I (mild) in n=3(2.5%) cases, Grade 2 (moderate) in n=42 (35%) cases, and Grade 3 (severe) in n=75 (62.5%) cases. The associated symptoms with dysmenorrhea were headache in 6.67% cases, dizziness in 8.33% cases, nausea, and vomiting in n=37.5% cases, loss of appetite in 21.67% cases, diarrhea was reported in 12.5% cases. The most prescribed drug was Mefenamic acid plus Dicyclomine in n=85(70.83%) of cases followed by Diclofenac sodium in n=18(15%) of cases and Mefenamic acid and Tranexamic acid in n=17(14.16%) cases of the study depicted in figure 2.

**Figure 2:** Showing the drug utilization pattern for Primary dysmenorrhea




The side effects of the medication were studied in cases of the study the most common side effect reported was diarrhea 26.67% of cases especially with mefenamic acid plus dicyclomine medication followed by dizziness in 20.83%, followed by nausea in 20% of cases and epigastric pain in 6.67% cases the distribution of side effects in various drug groups is depicted in Table 3.

**Table 3:** Side effects to medication

| *Side effects* | *Mefenamic acid + Tranexamic acid n=17* | *Mefenamic acid + Dicyclomine n=85* | *Diclofenac Sodium n=18* | *Total (%)* |
|---|---|---|---|---|
| *Diarrhea* | 4 | 28 | 0 | 32 (26.67) |
| *Nausea* | 5 | 11 | 8 | 24 (20.0) |
| *Dizziness* | 3 | 17 | 5 | 25 (20.83) |
| *Headache* | 10 | 6 | 0 | 16 (13.33) |
| *Epigastric pain* | 1 | 3 | 5 | 08 (6.67) |

## Discussion

In the present prospective study, the pattern of drug prescribing in primary dysmenorrhea was observed their efficacy and tolerability were compared. Though PD is more common in adolescents, in our study only 33% of study subjects belonged to the adolescent group, probably because of lack of awareness regarding existing medical treatment for dysmenorrhea, the practice of non-pharmacological methods, and prevalence of self-medication practice in them. [10-12] The socioeconomic status of study

subjects as assessed by Kuppuswamy socioeconomic scale. [9] The majority of the subjects 65% of the cases were belonging to the middle class and 26.67% were belonging to the lower class. The observation that the majority of subjects were from the lower-middle group is in accordance that PD is high in the lower socioeconomic population. [12] In the current study, Moderate blood loss was reported by n=78(65%) of cases followed by heavy loss by n=21(17.5%), and heavy with clots was reported by n=19(15.83%) cases of the study. The mean duration of dysmenorrhea experienced by the cases in the study was 4.1 ± 1.9 years. In this study based on a verbal multidimensional scoring system the primary dysmenorrhea was classified as Grade I (mild) in n=3(2.5%) cases, Grade 2 (moderate) in n=42 (35%) cases, and Grade 3 (severe) in n=75 (62.5%) **cases.** The most prescribed drug was Mefenamic acid plus Dicyclomine in n=85(70.83%) of cases followed by Diclofenac sodium in n=18(15%) of cases and Mefenamic acid and Tranexamic acid in n=17(14.16%) cases. The combination of tranexamic acid with mefenamic acid was prescribed to subjects with a history of heavy bleeding or bleeding with clots. The usage of mefenamic acid and dicyclomine combination was also highest in the study by Ramya S et al., [7] they reported this combination was prescribed in 72% of the cases in their study. In similar studies by Marjoribanks J et al., [14] and Feng X et al., [15] mefenamic acid, is the widely used and preferred drug in primary dysmenorrhea. No patient in this study was prescribed oral contraceptive pills which are usually reserved for the cases in which NSAIDs alone are not sufficient to produce clinically accepted relief and OCPs are considered for those who require contraception in addition to pain relief. [7, 16] The study found that the severity of dysmenorrhea did not influence the prescription pattern of the drugs. In most of the cases, the drugs were prescribed using brand names although few prescriptions with generic names were also found. There was a description of the pattern, frequency of use of the drug was found in prescriptions. The important side effects of these medications were diarrhea 26.67% cases especially with mefenamic acid plus dicyclomine medication followed by dizziness in 20.83%, followed by nausea in 20% of cases, and epigastric pain in 6.67% cases. All the side effects were self-limiting and did not require any additional treatment or discontinuation of medications. Similar observations have also been reported by studies in this field with varying incidences of side effects. [17, 18]

## Conclusion

The present study within its limitations concluded that the occurrence of primary dysmenorrhea is very common among young adolescent females. It is associated with symptoms of headache, dizziness, nausea, vomiting leading to loss of performance in work and absenteeism from schools. The NSAIDs are the commonly prescribed medication along with antispasmodics. Tranexamic acid is added to females with heavy menstrual blood flow with clots. Most of the medication was well tolerated with mild side effects.

***Conflict of Interest*: None**
***Source of support*: Nil**
***Ethical Permission*: Obtained**

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