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Research Article

A Comparative Study of Ethinyl Estradiol and Dienogest with Ethinyl Estradiol and Levonorgestrel in the Management of Spasmodic Dysmenorrhoea in Late Adolescence

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A B S T R A C T

Introduction: Spasmodic dysmenorrhoea (SD) is defined as painful menses. Dysmenorrhoea may limit the day-to-day activities of a person. Its occurrence is 63% and it is severe in 15% of the people. It requires counselling and treatment.

Aims and Objectives: To know the efficacy of ethinyl estradiol and dienogest versus ethinyl estradiol and levonorgestrel in reducing pain among women with primary dysmenorrhoea

Methodology: This was a prospective observational study done for six months among 100 females having dysmenorrhoea. They were divided into Group A (N = 50) and Group B (N = 50). The participants of Group A received ethinyl estradiol 0.03 mg/ dienogest 2 mg and those of Group B received ethinyl estradiol 0.03 mg/ levonorgestrel 0.15 mg for three consecutive menstrual cycles. After consent from the participants, their menstrual history was noted and examinations and investigations were done. Drugs were given and follow-up was done. Side effects of these drugs seen in the subjects were noted. The collected data were analysed.

Results: Most of the subjects belonged to the age group of 15-18 years in Groups A and B (80% and 84% respectively). Severe pain was more in Group A (24%) than in Group B (16%). Absence from school was 54% versus 48% in Groups A and B respectively. Menstrual irregularities were present in 42% of subjects in Group A versus 36% in Group B. Additional symptoms were present in 12% and 8% of participants in Groups A and B respectively. Anxiety was observed among 8% and 6% of adolescents in Groups A and B respectively due to pain and menstrual irregularities. Severe pain relief was observed in 100% of participants in Group A and 96% in Group B.

Conclusion: SD is common in adolescents. It reduces the quality of life of women and should be treated. It was seen in this study that dienogest is a better option for its treatment due to a significant reduction of dysmenorrhoea with minimal side effects.

Keywords: Adolescents, Primary Dysmenorrhoea, Hormonal Contraceptives

Introduction

Spasmodic dysmenorrhoea (SD) is defined as painful menses with intermittent pain predominantly in the suprapubic region and bilateral iliac fossae radiating to the lower back and thighs and associated with prostaglandins-induced vomiting and diarrhoea. Dysmenorrhoea limits daily social and educational performance and affects our day-to-day activities significantly.[1]In young girls, the occurrence of SD is around 63% and it is found to be severe in around 15%. It is a very important health problem that requires counselling and immediate treatment. 33% to 50% of adolescents with SD are school dropouts; they take leave at least one day per menstrual cycle and more leaves per cycle are seen among 7% of them. Even in developed countries, one-third of females take leave from work due to spasmodic dysmenorrhoea, with a reduction in proficiency at the workplace and hence they pose a financial burden on the country.[2,3] In a study done on women suffering from painful menstruation, half of them were found to have a limitation in their day-to-day activities.[4] Irrespective of the status and geographic distribution of the place where the adolescents are residing, they are associated with many risk factors for severe pain during menstruation, such as early menarche, lengthy cycles, menorrhagia, smoking, and siblings with spasmodic dysmenorrhoea. Newly married women using combined pills either for contraception or abnormal uterine bleeding have less severe pain during menstruation. Since there is a very high incidence of spasmodic pain during menstruation among young girls, it needs to be taken seriously. The severity of the pain and less pain tolerance of adolescents are the factors which lead to a decrease in their performance.[5,6] Therefore, this decrease in performance in terms of school absence and decreased marks due to lack of concentration are proportional to the severity of spasmodic dysmenorrhoea. The severity of SD is often measured by Visual Analog Scale (VAS), Numerical Rating Scale (NRS), and Verbal Rating Scale (VRS). Many studies have used VAS for measuring the severity of SD.[7-9] However, this scale is both time-consuming and expensive to use for large samples. NRS is easy and fast to administer and score but it is difficult to interpret. One of the most commonly used VRSs is the McGill questionnaire, which contains illustrated representations of pain at different intensity levels.

Aims and Objectives

To know the efficacy of ethinyl estradiol plus dienogest versus ethinyl estradiol plus levonorgestrel in reducing pain among women with primary dysmenorrhoea.

Methodology

This was a prospective observational study which was conducted at Mamata Medical College, Telangana in the Department of Obstetrics and Gynaecology, for a period of six months from July 2022 to December 2022 among 100 otherwise healthy women aged 13-21 years having dysmenorrhoea, after obtaining ethical approval from the Institutional Ethics Committee. The subjects who fulfilled the inclusion criteria (adolescents aged 13-21 years, girls with spasmodic dysmenorrhoea, and who had given consent to participate in the study) and the exclusion criteria (adolescents less than 13 years and more than 21 years, girls with congestive dysmenorrhoea, and who did not give consent for the study) were selected for the study. They were divided into two groups: Group A (N = 50) received ethinyl estradiol 0.03 mg/ dienogest 2 mg and Group B (N = 50) received ethinyl estradiol 0.03 mg/ levonorgestrel 0.15 mg for three consecutive menstrual cycles. After obtaining informed consent, menstrual history regarding pain (premenstrual/ during menstruation/ post menstrual) and duration of bleeding was noted. We divided them into mild, moderate, and severe. Women documented their pain as experienced by them during their cycle before consuming analgesics. They recorded their menstrual calendar in a diary in their own language along with the details of bleeding and pain, which were provided to the researcher.

Figure 1 shows a scale-type survey (working ability, location, intensity, days of pain, dysmenorrhoea [WaLIDD] score) which integrated features of dysmenorrhoea such as 1) a number of anatomical pain locations (no part of the body, lower abdomen, lumbar region, lower limbs, inguinal region), 2) Wong-Baker pain range (does not hurt, hurts a little, hurts a little more, hurts even more, hurts a lot, hurts a lot more), 3) number of days of pain during menstruation (0, 1-2, 3-4, ≥ 5), and 4) frequency of disabling pain to perform their activities (never, almost never, almost always, always). Each tool's variable provided a specific score between 0 and 3, and the final score ranged from 0 to 12 points. Figure 2 shows a universal pain assessment tool with a pictorial depiction that was used where ever applicable. General examination, gynaecological examination and relevant investigations were done where ever applicable. Group A women were treated with EE/ DNG combination and Group B women were treated with EE/ LNG combination of drugs cyclically for three consecutive months. Follow-up was done for three months to look for improvement in their presenting complaints of pain. Side effects were also noted. Data collected were analysed with appropriate statistical methods.

Results

A total of 100 adolescents who presented with dysmenorrhoea were analysed. The demographic factors like socioeconomic status, literacy rate, and location where they were residing (urban or rural) were equally distributed among both groups.

Working Ability	Location	Intensity (Wong-Baker)	Days of Pain
0: None	0: None	0: Does not hurt	0: 0
1: Almost never	1: 1 site	1: Hurts a little bit	1: 1-2
2: Almost always	2: 2 -3 sites	2: Hurts a little more – hurts even more	2: 3-4
3: Always	3: 4 sites	3: Hurts a whole lot - hurts worst	3: ≥ 5

Figure 1.Wong-Baker Score

Notes: Score 0: without dysmenorrhea, 1-4: mild dysmenorrhea, 5-7: moderate dysmenorrhea, 8-12: severe dysmenorrhea. Wong-Baker scale was reclassified to adjust a four-level scale.

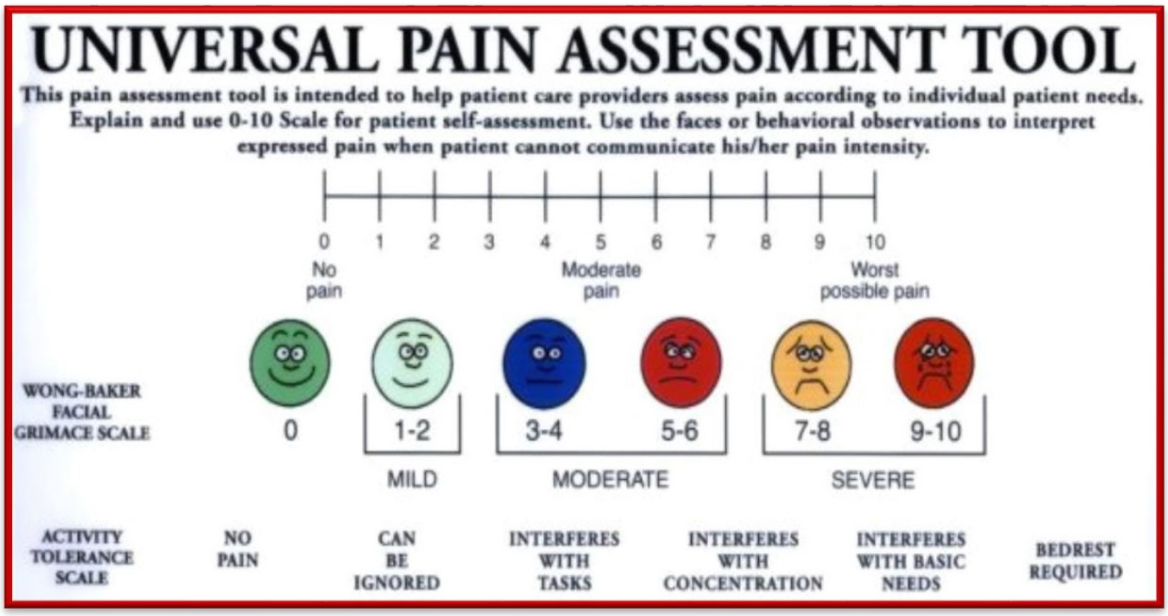

Figure 2.Universal Pain Assessment Tool[10]

Table 1.Distribution of Adolescents according to Their Age (N = 100)

S. No.	Age-wise Distribution (Years)	First Group (A) (N = 50) n (%)	Second Group (B) (N = 50) n (%)
1.	< 15	2 (4)	1 (2)
2.	15-18	40 (80)	42 (84)
3.	> 18	8 (16)	7 (14)
Total		50 (100)	50 (100)

Table 2.Distribution as per the Severity of Pain at the Time of Enrollment using Wong-Baker Scale (N = 100)

S. No.	Pain Severity	Group A (N = 50) n (%)	Group B (N = 50) n (%)
1.	Mild	8 (16)	10 (20)
2.	Moderate	30 (60)	32 (64)
3.	Severe	12 (24)	8 (16)
Total		50 (100)	50 (100)

Table 3.Distribution as per the Impact of Pain on Quality of Life (N = 100)

S. No.	Quality of Life	Group A (N = 50) n (%)	Group B (N = 50) n (%)
1.	Absence from school	27 (54)	24 (48)
2.	Abstinence from work	42 (84)	40 (80)
3.	Devoid of outdoor games	48 (96)	50 (100)

Table 4.Distribution according to Clinical Presentation (N = 100)

S. No.	Clinical Presentation	Group A (N = 50) n (%)	Group B (N = 50) n (%)
1.	Pain	50 (100)	50 (100)
2.	Menstrual irregularities	21 (42)	18 (36)
3.	Headache, nausea, vomiting, diarrhoea	6 (12)	4 (8)
4.	Psychological symptoms (anxiety)	4 (8)	3 (6)

Table 5.Severity of Pain after Three Months of Medication (N = 100)

S. No.	Pain Severity	Group A (N = 50) n (%)	Group B (N = 50) n (%)
1.	Mild	2 (4)	4 (8)
2.	Moderate	6 (12)	10 (20)
3.	Severe	Nil	2 (4)

Table 6.Complaints During the Course of Study (N = 100)

S. No.	Complaints	Group A (N = 50) n (%)	Group B (N = 50) n (%)
1.	Nausea, vomiting	2 (4)	3 (6)
2.	Breakthrough bleeding	Nil	4 (8)
3.	Compliance (missed pill)	Nil	2 (4)

Table 1 shows that most adolescents were 15-18 years of age in Groups A and B (80% and 84% respectively). Girls above 18 years of age were also almost equally distributed among both groups (16% vs 14%). Only a few of them were less than 15 years of age. Since they have immature hypothalamic-pituitary-ovarian axis and anovulatory cycles, they very rarely present with dysmenorrhoea.

Table 2 depicts the severity of pain on enrollment in the study. Mild, moderate and severe pain was present in 16%, 60%, and 24% of patients respectively in Group A whereas, it was present in 20%, 64% and 16% of participants respectively in Group B. Adolescents with severe pain were more in Group A (24%) as compared to Group B (16%).

Table 3 shows the effect of pain on the quality of life of participants. Absence from school was observed in both groups (54% in Group A and 48% in Group B). More than three-fourths of the girls could not do even moderate work at home in both groups (84% and 80% in Group A and Group B respectively). None of them could go outdoors and play in Group B while only 4% of the subjects of Group A were able to play outside.

Table 4 depicts the clinical presentation of participants. All of them presented with pain in both groups. Menstrual irregularities were present in 42% and 36% of subjects in Groups A and B respectively. Additional symptoms like headache, nausea, vomiting, and diarrhoea were present in 12% and 8% of the patients in Group A and Group B respectively. Anxiety was observed in 8% and 6% of adolescents in both groups due to pain and menstrual irregularities.

Table 5 shows the pain relief among the subjects after using medications. All of them were using painkillers. Along with these, Group A received daily oral administration of EE 0.03 mg/ DNG 2 mg and Group B received daily oral administration of EE 0.03 mg/ LNG 0.15 mg for three consecutive menstrual cycles. Severe pain relief was seen

in 100% of participants in Group A as compared to 96% of participants in Group B. Moderate and mild pain was also relieved significantly in Group A as compared to Group B.

Table 6 shows the complaints of respondents during the course of medication. Nausea and vomiting were present only in 4% of Group A adolescents and there was no breakthrough bleeding since compliance was very good among them. On the contrary, nausea and vomiting, breakthrough bleeding, and missed pills were seen among 6%, 8% and 4% of the adolescent girls respectively in Group B.

Discussion

A total of 100 adolescents who presented with dysmenorrhoea were analysed in this study. It was seen that most of the adolescents belonged to the age group of 15-18 years in both groups. Our observations are similar to another article that showed a prevalence of around 89.5%.[11] Likewise, a study conducted in Hong Kong showed that the occurrence of spasmodic pain among similar age group adolescents was between 23.4% and 89.5%.[12] There were variations in these figures most probably due to the difference in the sample and the absence of a universal definition for spasmodic dysmenorrhoea. The disparity in methods of collecting data could be another reason for this difference.[13]

On enrollment in the study, mild, moderate and severe pain was experienced by 16%, 60% and 24% of the participants respectively in Group A and 20%, 64% and 16% respectively in Group B. Adolescents with severe pain were more in Group A (24%) as compared to Group B (16%). In the present study, almost two-thirds of the adolescents (82%) expressed their pain during menstruation as severe or moderate, which is similar to the statistics in the study done by Burnett et al.[4] This shows that spasmodic pain during menstruation is still a burning health issue and adolescents in all parts of the world feel severe or moderate dysmenorrhoea, which definitely has a bad impact on their quality of life.

In the present article, a significant difference was observed in the quality of life among adolescents with spasmodic dysmenorrhoea in relation to pain/ discomfort, which is comparable to the observations made in some of the articles in the literature, where dysmenorrhoea was experienced by many adolescents and they reported it to be the most troubling factor. Thus it is proved that this pain is highly responsible for the poor quality of their life.[14] We observed that our sample size consisted of young girls who attended higher school and college. Their quality of life definitely deteriorated in terms of social participation in their sports and college day activities. The pain also decreased their attendance in school, further leading to a less score in their exams and at times failure too.[15]

In studies done by Vannuccini et al.[16] in 2017, they stated that women with spasmodic pain during menstruation had abnormal uterine bleeding (AUB), especially menorrhagia irrespective of age group. Thus we need to keep in mind the pathological gynaecological conditions like AUB – L i.e. leiomyomas, AUB – A i.e. adenomyosis, and other uterine disorders classified in the PALM-COEIN group which present with heavy menstrual bleeding that affects women of reproductive age group and perimenopausal women. This is not similar to the present study because we included only adolescents.

Many contraceptive pill studies have included small sample sizes, limited comparative data, and the inclusion of multiple treatment regimens. The body of evidence suggests that any combination of oral oestrogen-progestin contraceptive pills is likely to reduce dysmenorrhoea. A meta-analysis of trials comparing oestrogen-progestin contraceptive pills with placebo reported treatment benefit (pooled OR: 2.01, 95% CI: 1.32-3.08, seven trials).[17] The meta-analysis also concluded that pain relief was similar for pills with oestrogen doses ≤ 0.03 mg and > 0.03 mg, and there was no clear difference in efficacy among the different pill preparations. Lower dose formulations (eg, 20 mcg of ethinyl estradiol) also appear to be effective at reducing pain.[18] While trials have reported better relief of menstrual symptoms with extended or continuous dosing compared with cyclic administration, all regimens appear to be effective for symptom relief.[19] In our study, though both groups experienced a significant reduction in pain, it was more so with the EE/ DNG group.

With regards to the complaints of participants during the course of medication, the above studies [17-19] also showed minimal side effects and good compliance with the oral pills similar to that seen in our study.

Conclusion

Spasmodic dysmenorrhoea is a frequent gynaecological abnormality encountered especially in the adolescent age, which may be ignored or underestimated due to illiteracy, low socioeconomic status, misbeliefs and lack of awareness, causing a delay in management in certain cases. The severe pain and heavy menstrual bleeding experienced due to this condition adversely impact the quality of life of people such as causing a decrease in concentration at work and college. Its management is done by relieving pain through the use of oral medications like antispasmodics or combined oral contraceptive pills. Though both ethinyl estradiol plus dienogest and ethinyl estradiol plus levonorgestrel are very effective treatment modalities in the treatment of primary dysmenorrhoea in late adolescents, dienogest is a better option due to the significant reduction of dysmenorrhoea caused by it with minimal side effects.

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