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A clinical study to assess the effectiveness of Abroma Augusta mother tincture in relieving the pain intensity and quality of life in college going female students of Sangareddy with primary dysmenorrhoea using numerical rating scale

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#### Abstract

Primary dysmenorrhea is characterised by menstrual pain that does not have a known aetiology. Dysmenorrhea can interfere with daily activities and have a negative impact on a woman's quality of life. Increased prostanoids, particularly prostaglandins, produced by the cyclooxygenase pathway are likely the cause of the pathophysiology of primary dysmenorrhea. Anaerobic metabolites are produced as a result of the elevated prostaglandins, which also generate uterine contractions that reduce blood flow and activate pain receptors and cause pain.

In this study, 30 subjects presenting with primary dysmenorrhea with Abroma Augusta symptoms were randomly chosen. The variety of symptoms was used to gauge improvement both before and after therapy using visual numerical rating scale. Out of 30 cases, 16 had significantly improved, 13 had a modest improvement, and 1 had not improved at all. In this study, the efficacy of Abroma Augusta tincture in treating primary dysmenorrhea in adolescent girls is evaluated. The study that was conducted was economical, safe, and effective.

Through this study, we got a general understanding of primary dysmenorrhea and the efficacy of Abroma Augusta in reducing the severity of pain.

Keywords: Dysmenorrhoea, homoeopathy, Abroma Augusta, symptoms

#### Introduction

Sharp, sporadic, and spasmodic pain are characteristics of dysmenorrhea <sup>[1]</sup>. It is one of the most typical reasons of pelvic pain <sup>[2]</sup>. Once a regular ovulator cycle has been established, primary dysmenorrhea typically starts within the first 6–12 months after menarche <sup>[3]</sup>. Primary dysmenorrhea affects many teenagers and women who are menstruating <sup>[4]</sup>. More women suffer from dysmenorrhea than any other gynaecological condition <sup>[5]</sup>.

In an epidemiological study of an adolescent population (aged 12-17 years) klein & Litt reported a prevalence of 59.7% of dysmenorrhea <sup>[6]</sup>. The worldwide prevalence varies considerably among countries, consisting between 50% and 90%. This is partly due to the definition of dysmenorrhoea itself and/or the way this is measured <sup>[7]</sup>. One year prevalence of dysmenorrhoea was found to be 85.6% because pain is a highly subjective symptom and therefore difficult to quantify,there is a lack of consensus definition of dysmenorrhoea. In an epidemiological studies,it is difficult to compare findings with that of the other studies at a regional or an international level <sup>[8]</sup>.

The Indian drug Abroma Augusta (Ola kambal) is a drug of choice for the treatment of dysmenorrhoea. Pain is intolerable, patient becomes panic due to extreme unbearable pain. This is indicated when the blood is dark, clotted, sometimes scanty, sometimes profuse flow. This is often accompanied with leucorrhoea and hysterical spasms <sup>[9]</sup>.

An article on Dysmenorrhoea among University Health Sciences students, Northern Ethiopia- Impact & Associated factors by Teshagar Aklilu Yesuf, Nigist Assefa Eskinder Ayalew Sissay Concluded that the prevalence of dysmenorrhoea was 71.8% & the participants who were more likely to have dysmenorrhea are alcohol users,who had long menstrual cycle,flow for long duration & positive family history. They also reported that 28.6% feel depressed, 16.2% are absent from the class & 22.9% had poor personal relationship due to dysmenorrhoea & 78.2% of them practiced self medication [10].

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An article on Dysmenorrhoea among high school students & it's associated factors in Kuwai by Sharefah Al-Mutairi, Herrah Al Mutairi, Ohood Al-Mutairi, Fatima Ab dulaziz, Dara Barr, Mona Al-Enzi &Addullah Al Taras concluded that the prevalence is 85.6% & 26% of the people visited a public or private clinic for their pain & 4.1% were hospitalized. Furthermore 58.2% of the students with dysmenorrhoea missed atleast one school day&13.9% missed atleast one exam [11].

An article on a clinical study to assess the action of Pulsatilla in pain management of spasmodic dysmenorrhoea by Nirja. R concluded that, among the sample of 30 cases studied, all the 30 cases showed marked improvement in the treatment of Spasmodic dysmenorrhoea. Out of the 30 cases, 18 cases (60%) belong to age group 15-20 years of age. Students were most commonly affected (70%). Out of 30 cases, 18 (60%) were Hindus, 10 (33.33%) were Christians and 2 (6.67%) were Muslims. 11 cases (36.67%) attained FMP at 13 years. Regarding the duration of menstrual flow 15 cases (50%) had menstruation 4-5 days [12].

An article on the efficacy of the homoeopathic similimum in the treatment of the symptoms of primary dysmenorrhea in black females by Mamakiti Eunice Mokabane concluded that several research studies on the use of the homoeopathic similimum have efficacy in the treatment of various conditions. In a small pilot study at University of Johannesburg, the homoeo similimum was found to reduce primary dysmenorrhoea and ameliorate general symptoms [13].

An article on Lifestyle & prevalence of dysmenorrhoea among Spanish female University by Elia Fernandez - Martinez Maria Dolores, Onieva- Zafara Maria Laura Parra-Fernandez concluded that the prevalence of dysmenorrhoea was of 74.8% (n=193) with a mean severity of 6.88.Our results show that 38.5% of students describe their menstrual pain as severe and 58% as moderate [14].

An article on a clinical study on effectiveness of homoeopathic management in primary dysmenorrhoea among young women by Dr.Laxmi concluded that the true incidence and prevalence are not clearly established in India due to cultural reasons, menstrual problems often get unreported but some studies has mentioned in range of 50% to 87.8%

In this study, Abroma Augusta Tinchure was given to patients of dysmenorrhea according to symptoms and the improvement is evaluated with numerical rating scale.

# **Material and Methods**

The present study was undertaken at MNR Homoeopathic Medical college and Hospital, Sangareddy, Telangana state, during the period of 2021-2022.

# Methodology Study Setting

A sample of 30 cases are randomly selected from the patients who is having dysmenorrhoea visiting our MNRHMC collegiate OPDs/IPD, peripheral OPD.

Case taking along with consent form will be taken from each and every patient

## Study design and type

Single random sampling, interventional study.

Sample size: 30 patients

**Follow up:** Cases were followed up properly for three month interval and results was assessed on the basis of clinical symptoms and changes in the Numerical rating scores.

## **Procedure**

Abroma Augusta mother tincture 10 drops in half ounce of water, 3 times a day (during dysmenorrhea) for 4 days. Improvement is assessed by Numerical rating scale before and after the study (Group with 30 cases).

#### **Selection of Tools**

MNRHMC case record format Estimation by Numerical rating scale (Using a verbal report from numeric rating scale, the intensity of primary dysmenorrhoea related pain was considered as No pain(Numerical rating scale=0),mild pain(Numerical rating scale=1-3) moderate pain(Numerical rating scale=7-10)

## Study population & Study participants

College going female students of Sangareddy district, Telangana state having primary dysmenorrhea.

Total of 30 cases are considered for the study after fulfilling the criteria of the inclusion & exclusion studies

## **Inclusion criteria**

- Age -15-25 years
- College going girls.

#### **Exclusion criteria**:

- Females with underlying pathology
- Below the age of 15 years
- Sexually transmitted diseases
- Usage of contraceptive pills

Steps for administration: After case taking of the patients presenting with the symptoms of the primary dysmenorrhoea Abroma Augusta mother tincture 10 drops in half ounce, 3 times a day for 4 days during menses with dysmenorrhea is given to 30 patients.

Outcome is assessed by Numerical rating scale before and after the treatment

## Observation and result

Table 1: Showing the results of treatment

Sr. No	Result	No. of patients	Percentage
1	Recovered	16	53.3%
2	Improved	13	43.3%
3	Not Improved	1	3.4%

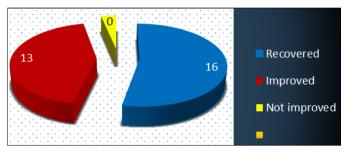


Fig 1: Results of treatment of the patient

**Table 2:** Statistical Analysis

S. No X Y d=x-y d- <sup>-</sup> d (d-d <sup>-</sup> )2						
1	6	2	4	0.9	0.81	
2	5	0	5	1.9	3.61	
3	8	6	2	1.1	1.21	
4	3	1	2			
5	4		1	1.1	1.21	
		3	4	2.1	4.41	
6	6	2	-	0.9	0.81	
7	3	0	3	0.1	0.01	
8	4	0	4	0.9	0.81	
9	5	1	4	0.9	0.81	
10	4	0	4	0.9	0.81	
11	5	0	5	1.9	3.61	
12	6	3	3	0.1	0.01	
13	3	0	3	0.1	0.01	
14	5	2	3	0.1	0.01	
15	6	0	6	2.9	8.41	
16	3	0	3	0.1	0.01	
17	4	0	4	0.9	0.81	
18	5	2	3	0.1	0.01	
19	6	0	6	2.9	8.41	
20	2	0	2	1.1	1.21	
21	3	0	3	0.1	0.01	
22	3	0	3	0.1	0.01	
23	2	2	0	3.1	9.61	
24	5	3	2	1.1	1.21	
25	2	0	2	1.1	1.21	
26	3	0	3	0.1	0.01	
27	4	1	3	0.1	0.01	
28	3	0	3	0.1	0.01	
29	6	4	2	1.1	1.21	
30	5	3	2	1.1	1.21	
30 d== 04/30 =		)		1.1	1.41	

 $d^-= 94/30 = 3.1$ 

x = Score before the treatment

y = Score after the treatment

d = Mean difference

Questions to be answered

Is there any difference between the scores taken before the treatment and after the homoeopathic treatment.

## **Null hypothesis**

There is no difference between the scores before and after the homoeopathic treatment.

Results were subjected to the statistical analysis and hypothesis were tested using Paired-T test.

# Confidence interval

The mean of Group One minus Group Two equals 3.17 .95% confidence interval of this difference: From 2.70 to 3.64.

## Intermediate values used in calculations

t = 13.7467

df = 29

Standard error of difference = 0.230

Table 3: Review of data

Group	Group One	Group Two	
Mean	4.30	1.13	
SD	1.49	1.55	
SEM	0.27	0.28	
N	30	30	

P value and statistical significance:-=

The two-tailed P value is less than 0.0001

By conventional criteria, this difference is considered to be extremely statistically significant. So we will reject the null hypothesis. By statistical analysis, the difference is considered to be extremely statistically significant, hence proved that Abroma Augusta tinchure is effective in primary dysmenorrhea.

## **Quality control and Quality Assurance**

All the medicines will be procured from the GMP certified pharmaceutical companies approved by the Institutional Ethical Committee: Drug is acquired from the standard homoeopathic pharmacy and the drugs are stored as per the rules of the Indian Homoeopathic pharmacopoeia.

#### **Ethical Issues**

Ethical clearance will be taken before the enrollment.

## Discussion

A lot of people experience pain with their periods. The medical name for period pain is dysmenorrhoea. This can be anything from dull achy crampy pain to intense pain.

Primary dysmenorrhoea is physiological. The pain usually begins when the period start but may start slightly before. The main symptom is cramp or achy pain in the abdomen. The other symptoms include feeling tired, feeling bloated, diarrhoea, headache and mood swings. Factors that make the pain even worse are heavier or irregular menstrual period, lack of exercise, psychological or stress obesity, a positive family history of dysmenorrhoea.

Use of mother tinctures are known to arrest the progress of the disease and offer instant cure and in some instances offer prompt relief. Mother tinctures contains the lowest possible potency of any particular homoeopathic preparation.

The study was conducted to know the effectiveness of Abroma Augusta mother tincture in the treatment of Primary dysmenorrhea. In this study, 35 cases of primary dysmenorrhea of age group 10-25 years were enrolled from general screening of the patients. Out of which 5 cases were dropped out, rest 30 cases completed the study with regular follow ups (n=30). Before enrolling in the study population, every patient was evaluated and diagnosed on the basis of clinical history, clinical examination and Numerical Rating scoring which is dedicatedly used for diagnosis of primary dysmenorrhoea. Improvement is assessed by the grading, paired T-test was applied for statistical analysis.

The analysis of sample size of 30 cases depicted higher preponderance of primary dysmenorrhea in age group of 16-20 years, followed by 11 cases (37%) are from the age group between 21-25.

A total of 30 cases was selected and followed up for a period of 3 month. The cases selected were between the age group of 10-25 years. The cases were diagnosed based on clinical presentation.

Based on the analysis from 30 cases of primary dysmenorrhoea, following observations are made with the comparison of all the literatures

Among 30 study participants of primary dysmenorrhoea, 27 participants are unmarried and 3 are married, maximum no. of cases are seen in unmarried female. In this study, 10% of the participants are between the age of 10-15yrs, 53% are between the age of 16-20yrs and 37% are between the age of 21-25yrs.

In this study, it is seen that, 16.7% had increased appetite and thirst, 10% had acne on face and 3.3% had constipation,

disturbed sleep, fever, stomach pain, thirstless, numbness of the legs and sour eructations.

In this study, Among the 30 cases, 13.3% had irritability and anger, 6.7% had mood swings and desires company, 10% had anxiety and becomes emotional, 3.3% becomes depressed, had timidity, aversion to life and 3.3% are fastidious, sympathetic, short tempered and losses patience. In the study, Among 30 cases, 30% had backache, 26.7% had headache, 16.7% had fatigue, 6.7% had nausea, vomiting, diarrhoea and 3.3% had heaviness of abdomen, dizziness and weakness.

In the study, it is seen that among 30 cases, 63% had cramping type of pain, 10% had pricking type of pain, 6.7% had dragging, stitching, spasmodic and throbbing type of pain. 3.3% had dull type, stabbing, twisting and squeezing type of pains.

In this study, it is seen that among 30 participants, 22 participants (73.3%) had scanty flow and 8 participants (26.7%) had profuse flow during the menses.

Improvement is assessed by Numerical rating scale, accordingly 53.3% recovered, 43.3% improved and 3.4% are not improved.

#### Conclusion

In this study 53.3% of cases recovered and 43% of cases showed improvement and only 3% cases shows no improvement thus Abroma augusta mother tinchure had proved its effectiveness in treating primary dysmenorrhea. The study only included 30 cases, thus the conclusion drawn here is suggestive and should not be considered as gospel. Therefore, more research is required before coming to a firm judgement. Finally, I expect that in the near future, additional study in this subject will be undertaken with a large sample size and a longer period of follow-up to assess the effectiveness and recurrence.

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**Declaration of patient consent:** Nil.

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Conflicts of interest: None declared.

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