

## **Efficacy of Indicated Homoeopathic Medicines in the Management of Primary Dysmenorrhoea Using VAS and WALIDD Score: A Sequential Controlled Trial**

<sup>1</sup>Dr Ravi Jain, PhD Scholar, Department of Organon of Medicine, Homoeopathy University Jaipur. Associate Professor and HOD, Department of Practice of Medicine, Faculty of Homoeopathic Science, Jayoti Vidyapeeth Women's University, Jaipur.

<sup>2</sup>Dr A N Mathur, President, Homoeopathy University, Jaipur

<sup>3</sup>Dr M P Sharma, Dean and Director, Faculty of Homoeopathic Science, Jayoti Vidyapeeth Women's University, Jaipur

<sup>4</sup>Dr Ruchi Singh, Professor, Department of Organon of Medicine, Homoeopathy University, Jaipur.

**Corresponding Author:** Dr Ravi Jain, PhD Scholar, Department of Organon of Medicine, Homoeopathy University Jaipur

**How to citation this article:** Dr Ravi Jain, Dr A N Mathur, Dr M P Sharma, Dr Ruchi Singh, "Efficacy of Indicated Homoeopathic Medicines in the Management of Primary Dysmenorrhoea Using VAS and WALIDD Score: A Sequential Controlled Trial", IJMACR- August - 2024, Volume – 7, Issue - 4, P. No. 01 – 11.

**Open Access Article:** © 2024, Dr Ravi Jain, et al. This is an open access journal and article distributed under the terms of the creative common's attribution license (<http://creativecommons.org/licenses/by/4.0>). Which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

**Type of Publication:** Original Research Article

**Conflicts of Interest:** Nil

### **Abstract**

**Background & Purpose of the study:** Painful menses or dysmenorrhoea is the most common gynaecological condition encountered by the females of reproductive age group. It is characterised by cramping pain in the lower abdomen which may radiate to back and knees. Sometimes it is also associated with symptoms like headache, nausea and vomiting, tiredness, fatigue and dizziness. The disease is so common that females keep on suffering from the given disease condition. Various research studies have been done on the given subject using 2 different groups. But homoeopathy believes that every individual is different and hence the reaction to medicines.

**Aim:** of the current study is to establish the efficacy of individualized homoeopathic medicine in cases of primary dysmenorrhoea on same person (sequential trial) using 2 scales VAS & WaLIDD.

**Objectives:** The objective of the study is to analyse the changes in the VAS WaLIDD scales in cases of Primary Dysmenorrhoea with placebo and with indicated homoeopathic medicine.

**Methodology:** The open label study was conducted at OPD/IPD of Suryansh Arogyashala Homoeopathic Hospital at Jayoti Vidyapeeth Women's University Jaipur. Rajasthan. Total 60 patients suffering from primary dysmenorrhoea were selected. The study was conducted in 2 parts. In first part Placebo was

administered to all the patients for 3 months and changes in VAS & WaLIDD score was noted. In second part Indicated homoeopathic medicine was administered to all the patients for next 3 months and changes in VAS & WaLIDD was recorded. The assessment was done every month for 6 months and at the end of the study ANOVA test was applied to compare the observations. At  $P < 0.05$  the test is considered statistically significant.

**Results:** With sample size of ( $n=60$ ), 60 cases were enrolled in the study. There was no dropout. The result was analyzed at 3 months with 3 months of placebo followup and at 6 months with months of Indicated homoeopathic medicine followup. The mean of VAS at baseline was 8.16 which remained 8.16 after 3 months of treatment with placebo  $p$  value  $p=1$ ,  $p > 0.05$ , which is not significant. With 3 months of treatment with indicated homoeopathic medicine the mean value of VAS shifted from 8.16-2.98 with  $p$  value = 0, with  $p < 0.05$ , which is statistically significant. Similarly, with WaLIDD scale the mean WaLIDD at baseline was 9.48 which after 3 months of treatment with placebo remained 9.41 with  $p$  value 0.159 which is  $p > 0.05$  hence not statistically significant. The mean WaLIDD from 9.41 after 3 months of indicated homoeopathic medicine shifted to 3.8 with  $p=0$ , the  $p < 0.05$  which is again statistically significant. Most frequently administered medicines on the basis of totality of symptoms were Pulsatilla Nigricans ( $n=12, 20\%$ ), Sepia officinalis ( $n=11, 18.33\%$ ), Nux vomica ( $n=8, 13.33\%$ ), Sulphur ( $n=6, 10\%$ ) and Belladonna ( $n=5, 8.33\%$ ) of cases.

**Conclusion:** The study demonstrates the efficacy of indicated homoeopathic medicine as compared to placebo in the management of primary dysmenorrhoea as demonstrated using VAS & WaLIDD scale in a

sequential trail which was never conducted in earlier studies.

**Keywords:** Primary Dysmenorrhoea, VAS, WaLIDD, ANOVA Test, P value, IBM SPSS

### Introduction

Dysmenorrhea or pain during menstruation in a female of reproductive age group sufficient in magnitude to incapacitate her day today activities. It represents the cramping pain in lower abdomen occurring just before or within few hours after the onset of menses. Other symptoms include backache, headache, nausea, vomiting, diarrhoea, fainting, etc. The symptom depends on dysmenorrhoea type. Principally dysmenorrhoea is classified into two types. Primary Dysmenorrhoea with no identifiable pelvic pathology, and Secondary Dysmenorrhoea where pelvic pathology is identified by diagnostic investigations like ultrasound. Common pelvic pathologies include Uterine fibroids, endometriosis, and Pelvic inflammatory disease.<sup>1</sup>

The probable cause of primary dysmenorrhoea is unknown, but several studies have contributed which demonstrates events like uterine contractions, and role of prostaglandins as prime cause of pain. The intensity of pain is proportional to the amount of  $PGF2\alpha$ .<sup>1</sup>

The treatment solely based on the use of NSAID's and hormonal pills. This reduces the inflammation and suppresses ovulation, as anovulatory cycles are painless, but unfortunately these medicines produce an adverse effect on the health of individual and increased risk of cancers.<sup>2</sup>

PD is commonly affecting adolescent girls between age group 18-25 years. The prevalence of primary dysmenorrhoea is 73.2%.<sup>3</sup> In previous studies the prevalence of dysmenorrhea in Rajasthan was found to be very high (81.5 % rural and 76 % urban).<sup>3</sup>

In this study Visual Analogue scale, VAS and WaLIDD scale have been used. The study has been conducted in sequential control way on same individual. Initially the VAS & WaLIDD score has been recorded followed by administration of placebo for initial 3 months and response recorded. After 3 months administration of indicated homoeopathic medicine for next 3 months with the observation recorded. The changes in VAS & WaLIDD Score have been recorded on monthly basis. The Scores of both the scales have been compared to reach at the conclusion. The data was analysed separately using SPSS software version 22, and P value calculated to establish the efficacy of Indicated homoeopathic medicine.

The study also mentions the variability factors like age of menarche, socioeconomic condition, BMI, length of menstrual cycle, locality (urban or rural), family history, and other symptoms related to menstrual cycle of the female and thus makes the data more reliable on the Homoeopathic aspect.

**Research Question:** Does Homoeopathic Medicine produce significant changes in pain and working ability in the cases of Primary dysmenorrhoea?

**Aim:** To study the Efficacy of Homoeopathic medicine by assessing the changes in the symptomatology of pain and working ability after administration of indicated Homoeopathic medicine in the management of Primary Dysmenorrhoea.

### Objectives

1. To study the efficacy of Homoeopathic medicines in the changes using Visual Analogue scale in the subsequent follow-ups in cases of Primary dysmenorrhoea.

2. To evaluate the changes using WaLIDD Scale in subsequent follow-ups in cases of Primary dysmenorrhoea.

### Hypothesis

**Null Hypothesis (H<sub>0</sub>)** Indicated Homoeopathic Medicines produce no significant changes in symptoms of pain and working ability in the management of Primary Dysmenorrhoea when assessed by VAS & WaLIDD score.

**Alternate Hypothesis (H<sub>1</sub>)** Indicated Homoeopathic Medicines produce significant changes in presenting symptoms of of pain and working ability of the patient in the management of Primary Dysmenorrhoea when assessed by VAS & WaLIDD score.

### Materials and Methods

**Settings and Design:** The study was taken at the OPD of Suryansh Arogyashala Homoeopathic Hospital at Jayoti Vidyapeeth Women's University, Jaipur. The study duration was of 18 months in which First 1 Year was for the case registration and follow up was taken for next 6 months of the last registration case. The study started in July 2022.

**Ethical clearance:** Ethical clearance was obtained from the Institutional Ethical Committee of Homoeopathy University, Jaipur. No Objection certificate was also obtained from Jayoti Vidyapeeth Women's' University for carrying out the research at University Homoeopathic Hospital Suryansh Arogyashala.

**Registration no:** The Homoeopathy University registration number for conduction of the study is **HU/2021/PhD/Reg/00100**.

**Sample size and Randomization:** Sample size was estimated using the following formula for a 2-sided t-test at  $\alpha = 0.05$  with 90% power assuming  $\delta = 10$  mm

(Christoph Gerlinger et al., 2010)<sup>4</sup>. The sample size was set at 57 which is further increased to 60 patients.

#### Inclusion Criteria

- Unmarried Females with clinically diagnosed Primary Dysmenorrhoea
- Age Group: Between 18 - 25 Years
- Girls having regular menstrual cycle (length of cycle between 23-35 days days).
- Mild to Severe dysmenorrhoea for at least for 2 days during the cycle with VAS score 5-10 and WaLIDD Score 5-12 since last 3 cycles.
- Females not having any other pre-diagnosed disease condition or on any medication which can affect the action of our medicine.
- Assenting adults providing consent for the study.

#### Exclusion Criteria

- Patients developing other gynecological complaints not related to primary dysmenorrhea.
- Patients under NSAIDS for any chronic complaint which can affect the remedy response.
- Cases of mild pain during menses VAS score 1-4 and WaLIDD Score 1-4.

#### Intervention

In First 3 Months when only Placebo was given. Proper counselling was done related the complaints during the study. After 3 cycles Indicated Homoeopathic medicine was given based on the principles of Homoeopathy. In case of Acute pains Homoeopathic medicine was administered on the basis of present totality after 3 months from the enrolment of the study. Interpretation of the Indicated Homoeopathic remedy response was noted and compared in the pain and working ability using VAS and WaLIDD Score. In case of severe pain Auxiliary measures like Hot fomentation was allowed to

relieve distressing pain during the course of study and duly noted in the observations.

#### Outcome Assessment

In this study we have followed pre and post study design. Visual analogue scale and WaLIDD scale have been used. The assessment was done at every month by noting the VAS & WaLIDD at the end of every cycle. Score and the evaluation was done at the end of the study after 6 months from the available data.

#### Statistical Analysis

ANOVA test was applied using IBM SPSS software version 22. The mean values of VAS & WaLIDD Score along with p value was calculated. The data was represented in tabular form and graph was plotted to see the changes in VAS & WaLIDD for easy understanding of the changes.

#### Result and Observation

**Study Flow:** Screening of 96 patients was done. Based on inclusion and exclusion criteria and sample size 60 patients were enrolled for the study.

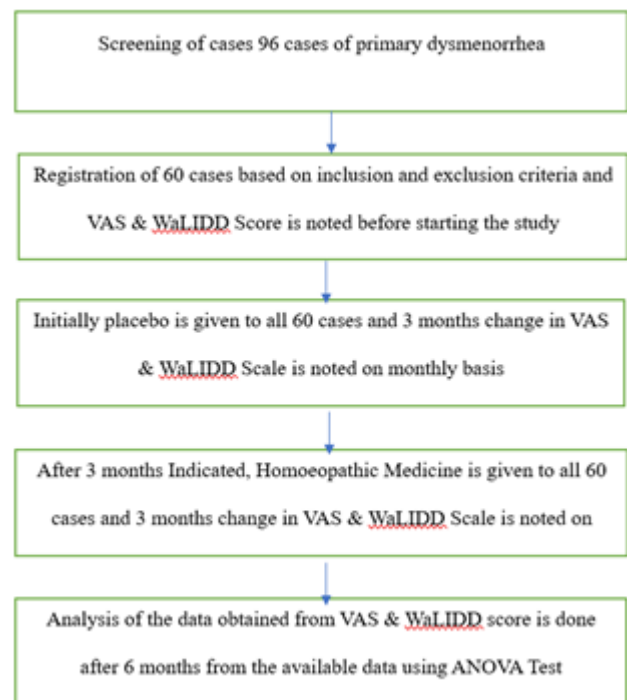


Fig. 1: Flow chart of the study protocol.

**Mean VAS at different times**

Dependent Variable	Mean± SD	95% Confidence Interval	
		Lower Bound	Upper Bound
Baseline VAS	8.1667 ±1.25	7.844	8.490
Three-month VAS	8.1667 ±1.26	7.840	8.493
Six-month VAS	2.983 ± 2.06	2.451	3.516

Table 1, Mean VAS score at different time intervals

The baseline mean VAS score was 8.166. Following three months of administering a placebo, it remained consistent at 8.1667. However, upon prescribing the indicated medicine, it decreased to 2.983.

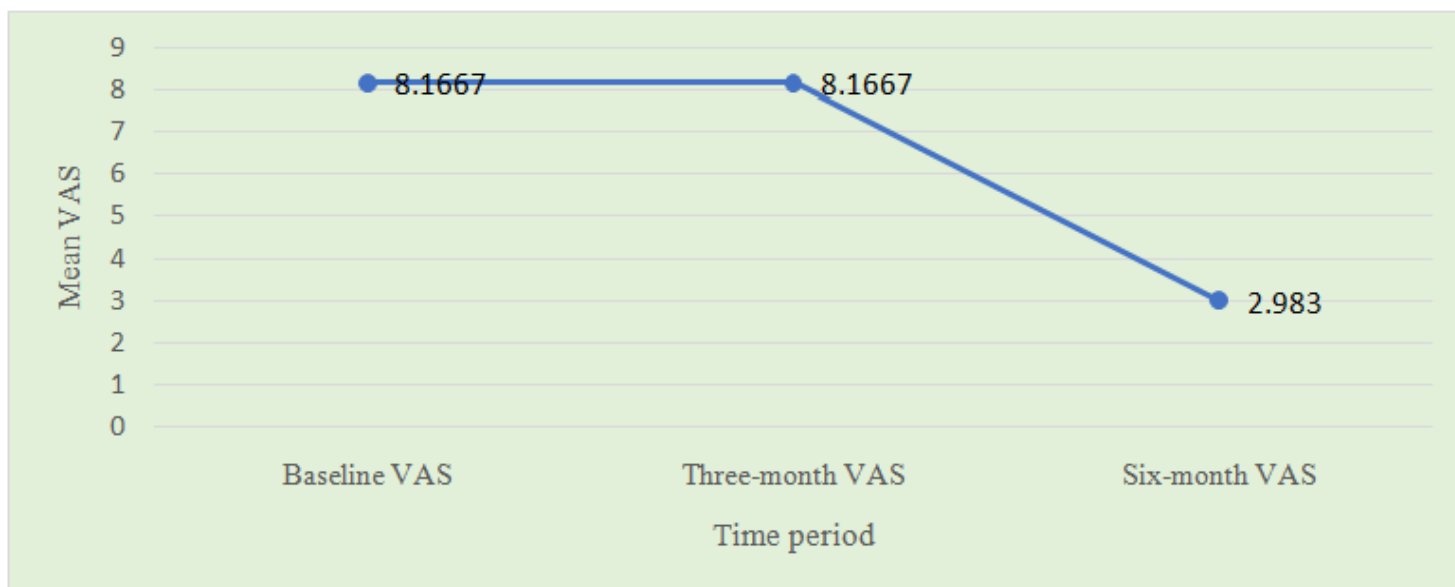


Fig. 2: Graphical representation of Mean VAS score at different time intervals

**Pairwise comparison of VAS**

Time period	Follow-up	Mean Difference	Std. Error	Sig.	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
Baseline	Three	.000	.034	1.000	-.067	.067
	Six	5.183	.309	.000	4.564	5.803
Three months	Baseline	.000	.034	1.000	-.067	.067
	Six	5.183	.309	.000	4.564	5.803
Six Month	Baseline	-5.183	.309	.000	-5.803	-4.564
	Third	-5.183	.309	.000	-5.803	-4.564

Table 2: Pairwise comparison of VAS score at different time intervals

In Pairwise comparison, there was no significant reduction when comparing the baseline VAS with the

three months p value is 1.00 which is > 0.05. However, when comparing the baseline with the VAS at six months after administering the indicated homeopathic

medicine, there was a significant reduction in pain with p value is 0.000 which is < 0.05.

A significant decrease in pain was observed when comparing the VAS at six months with the baseline, as

well as when comparing at six months with that at the third month (p < 0.05).

**Mean WaLIDD at different times**

Dependent Variable	Mean± SD	95% Confidence Interval	
		Lower Bound	Upper Bound
Baseline WaLIDD	9.483 ±1.56	9.078	9.888
Three-month WaLIDD	9.417 ±1.58	9.007	9.827
Six-month WaLIDD	3.80 ± 2.22	3.226	4.374

Table 3, Mean WaLIDD score at different times

The baseline mean WaLIDD score was 9.483. Following three months of administering a placebo, it remained consistent at 9.417. However, upon prescribing the indicated medicine, it decreased to 3.80.

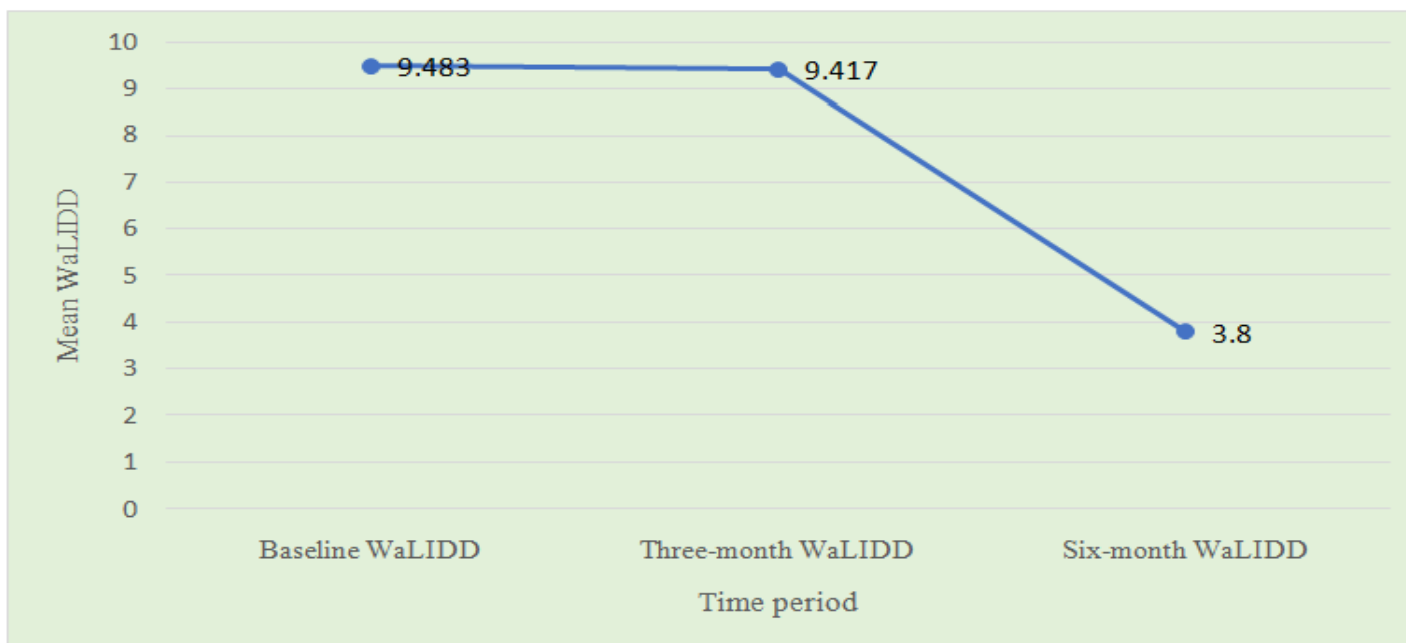


Fig. 3: Graphical representation of Mean WaLIDD score at different times.

**Pairwise comparison of WaLIDD score**

Time period	Follow-up	Mean Difference	Std. Error	Sig.	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
Baseline	Three	.067	.047	.159	-.027	.160
	Six	5.683	.335	.000	5.013	6.353

Three months	Baseline	-.067	.047	.159	-.160	.027
	Six	5.617	.333	.000	4.951	6.283
Six Month	Baseline	-5.683	.335	.000	-6.353	-5.013
	Third	-5.617	.333	.000	-6.283	-4.951

Table 4, Pairwise comparison of WaLIDD score at different time intervals.

In Pairwise comparison, there was no significant reduction when comparing the baseline WaLIDD with three months p value is 0.159 which is > 0.05. However, when comparing the baseline with the WaLIDD at six months after administering the indicated homeopathic medicine, there was a significant reduction in p value p =0.000 which is <0.05.

A significant decrease in WaLIDD was observed when comparing the WaLIDD at six months with the baseline, as well as when comparing the WaLIDD at six months with that at the third month (p < 0.05).

**Homoeopathic Medicine used in the treatment of Primary Dysmenorrhoea**

On the basis of Totality of symptoms after following homoeopathic principles, Pulsatilla was prescribed in (n=12,20%), Sepia officinalis in (n=11,18.33%) ,Nux vomica in (n=8,13.33%), Sulphur in (n=6,10%), Belladonna in (n=5,8.33%), Calcarea Carbonica and Natrum Muriaticum each in (n=4,6.67%), Phosphorus in (n=3,5%), Kali carbonica in (n=2,3.33%), and Calcarea Phosphorica, Lachesis mutus, Lycopodium clavatum, Magnesia muriatica, and Silicea terra each in (n=1,1.67%) cases.

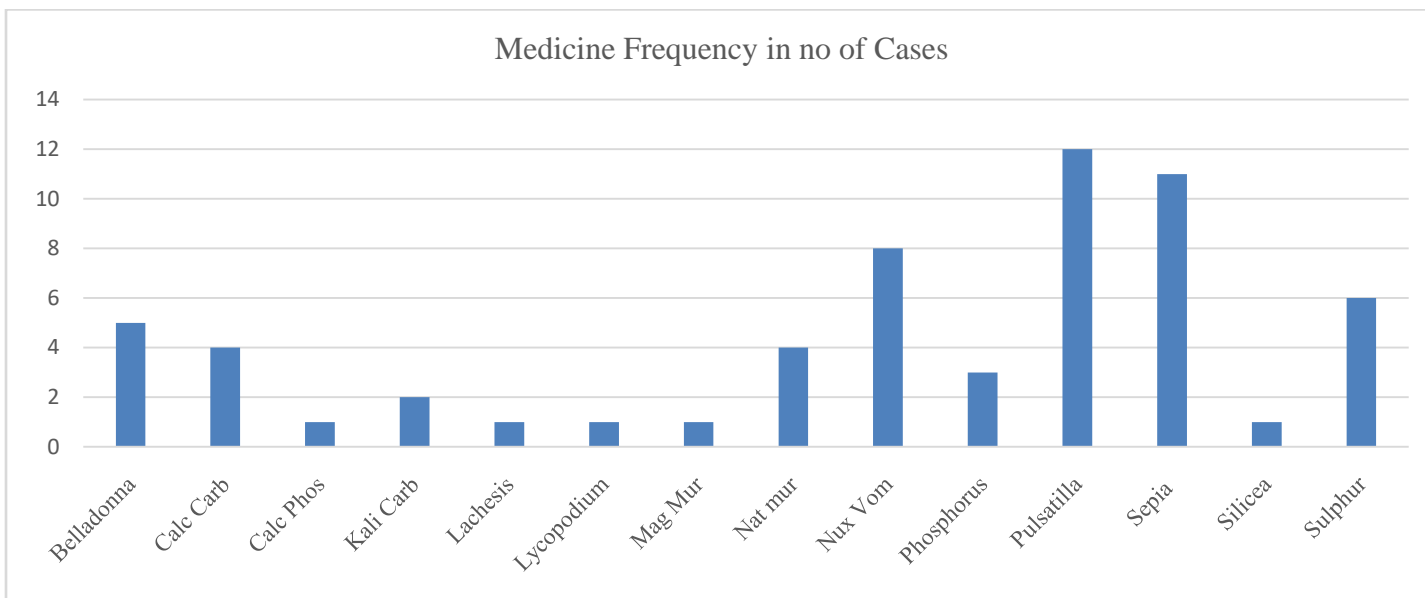


Fig. 4: Frequency of medicines administered during the course of treatment.

Degree of improvement after indicated Homoeopathic medicine

At the end of the study after indicated homoeopathic medicine. Marked improvement was shown in (n=24,40%), Moderate improvement in (n=25,41.67%),

Mild improvement in (n=7,11.67%) , 2 (3.33 %) cases each showed either no change in symptoms status Quo

or their symptoms got worse at the end of the study.

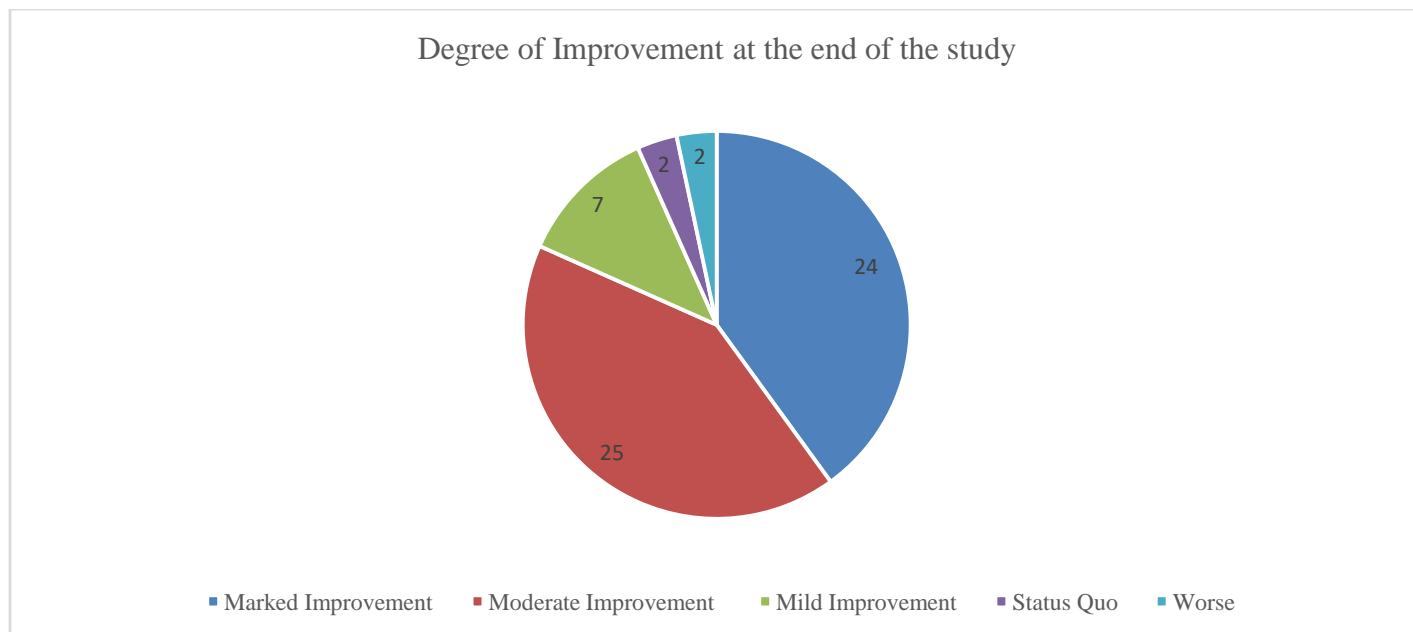


Fig. 5: Degree of improvement after administration of indicated homeopathic medicine

### Discussion

In the treatment of primary dysmenorrhoea the VAS & WaLIDD scores were compared to baseline with 3 months followup (3 months treatment with placebo), and after 6 months (3 months treatment with indicated medicine). There was marked change in the VAS & WaLIDD values with indicated homeopathic medicines in comparison to placebo. A significant reduction in pain was observed when comparing the VAS at six months with the baseline, as well as when comparing the VAS at six months with that at the third month ( $p < 0.05$ ). Similarly, A significant decrease in WaLIDD was observed when comparing the WaLIDD at six months with the baseline, as well as when comparing the WaLIDD at six months with that at the third month ( $p < 0.05$ ). According to totality of symptoms a total of 14 homeopathic medicines were prescribed during the study with a predominance of Pulsatilla nigricans. The study also demonstrated the relationship with other

parameters like family history, BMI, Miasm, age of menarche, duration of menses and many other related factors.

### Conclusion

In cases of Primary Dysmenorrhea, the Efficacy of Indicated Homoeopathic medicine was established using the mean values obtained from Visual Analogue Scale and WaLIDD score. The pain intensity (VAS) and the working ability, locations affected, intensity and duration of pain (WaLIDD score) showed a marked improvement with indicated homeopathic medicine when the data of the starting date and end of the study was compared. Thus, we can say homoeopathic medicines are effective in the management of primary dysmenorrhea as assessed by VAS and WaIDD scale in comparison to placebo when the study was conducted in sequential manner on the same person.



## References

1. Dutta DC. Textbook of Gynecology including contraception. 7th ed. Kolkata India: Jaypee Brothers Medical Publishers (P) Ltd: 2016.
2. Marjoribanks J, Ayeleke RO, Farquhar C, Proctor M, Cochrane Gynaecology and Fertility Group. Nonsteroidal anti-inflammatory drugs for dysmenorrhoea. Cochrane database of systematic reviews. 1996 Sep 1;2015(7).
3. Iacovides S, Avidon I, Baker FC. What we know about primary dysmenorrhea today: a critical review. *Hum Reprod Update*. 2015 Nov-Dec;21(6):762-78. doi: 10.1093/humupd/dmv039. Epub 2015 Sep 7. PMID: 26346058.
4. Gerlinger C, Schumacher U, Faustmann T, Colligs A, Schmitz H, Seitz C. Defining a minimal clinically important difference for endometriosis-associated pelvic pain measured on a visual analog scale: analyses of two placebo-controlled, randomized trials. *Health and quality of life outcomes*. 2010 Dec;8:1-7.
5. Mohamad Bakro R, Farrukh MJ, Rajagopal M, Kristina SA, Ramatillah DL, Ming LC, Paneerselvam GS, Hadi MA. Assessment of prevalence, knowledge and health-related practices of dysmenorrhea among Malaysian women in Kuala Lumpur: a cross-sectional survey. *Annals of Medicine*. 2023 Dec 12;55(2):2281655.
6. Dr. Barkha Devi, Ms Sonam Zangmu Sherpa, Ms Prerna Karki, Ms Nazung Lepcha, Ms Sujen Cintury, Ms Narmaya Chettri. Prevalence Of Dysmenorrhea And Factors Associated With Its Intensity And Duration Among Female Students. *kuey [Internet]*. 2024 Mar. 30 [cited 2024 Apr. 22];30(3):943-55.
7. Systematic review of prevalence of primary dysmenorrhea in India:Source: Banikarim C, Chacko MR, Kelder SH. "Prevalence and impact of dysmenorrhea on Hispanic female adolescents." *Arch Pediatr Adolesc Med*. 2000 Jul;154(7):1226-9. DOI: 10.1001/archpedi.154.7.1226.
8. Sinha S, Mittal S, Latha GS, Ali MA. A cross-sectional study depicting prevalence of primary dysmenorrhea in adolescent females of Hyderabad: A major urban center of South India. *National Journal of Physiology, Pharmacy and Pharmacology*. 2022;12(11):1778-84.
9. Swaroopa H, Arunachalam R, Prem A. Prevalence of primary dysmenorrhea among adolescent girls in Rajasthan Sirohi District-A cross sectional study. *Indian Journal of Natural Sciences*.;12(69):35905-10.
10. Rathod NK, Gohil JT. Prevalence of Primary Dysmenorrhea and Menstruation Related Issues Among Young Female Students with Hearing Impairment: An Institutional Based Cross Sectional Study.
11. Ju H, Jones M. Mishra G. The prevalence and risk factors of dysmenorrhea. *Epidemiologic review*. 2013 Nov 26;36(1):104-13. doi: 10.1093/epirev/mxt009.
12. Jeffocate N Principles of Gynaecology 17th edition . New Delhi India: Jaypee Brothers Medical Publishers (P) Ltd: 2008.
13. Midilli TS, Yasar E, Baysal E. Dysmenorrhea characteristics of female students of health school and affecting factors and their knowledge and use of complementary and alternative medicine methods. *Holistic nursing practice*. 2015 Jul 01;29(4):194-204. doi: 10.1097/HNP.000000000000091.

14. Hahnemann S The chronic disease, their peculiar nature and Homoeopathic care 6th impression 2010 B Jain Publication
15. Hahnemann S. Organon of Medicine. 6th ed. New Delhi: B. Jain Publishers (Pvt.) Ltd.; 2007.
16. Allen J H, The Chronic Miasm Volume I & II. B Jain publication, 5th impression 2009
17. Close S. The Genius of Homoeopathy Lectures & Essays on Homoeopathic Philosophy, BJain Publication 8th impression 2011
18. Singh P, Chatterjee N, Singh PK. Role Of Homoeopathy In Primary Dysmenorrhoea—A Randomized Placebo Control Trial.
19. Ghosh S, Ravindra RK, Modak A, Maiti S, Nath A, Koley M, Saha S. Efficacy of individualized homeopathic medicines in primary dysmenorrhea: a double-blind, randomized, placebo-controlled, clinical trial. *Journal of Complementary and Integrative Medicine*. 2023 Mar 14;20(1):258-67.
20. Jain L, Nayak C, Sharma MB, Gehlot K. Effectiveness of Individualised Homoeopathic Medicines versus Conventional Treatment in the Management of Primary Dysmenorrhoea in Young Unmarried Females: A Randomised, Open-Label, Clinical Study. *Homœopathic Links*. 2021 Jun;34(02):093-9.
21. Charandabi SM, Biglu MH, Rad KY. Effect of homeopathy on pain intensity and quality of life of students with primary dysmenorrhea: a randomized controlled trial. *Iranian Red Crescent Medical Journal*. 2016 Sep;18(9).
22. Adil R, Zaigham U. Prevalence of primary dysmenorrhoea and its effect on instrumental activities of daily living among females from Pakistan. *Physiotherapy Quarterly*. 2021 Oct 1;29(4):65-9
23. Witt CM, Lüdtke R, Willich SN. Homeopathic treatment of patients with dysmenorrhea: a prospective observational study with 2 years follow-up. *Arch Gynecol Obstet*. 2009 Oct;280(4):603-11. doi: 10.1007/s00404-009-0988-1. Epub 2009 Feb 20. PMID: 19229544.
24. Boericke W. Pocket Manual of Homoeopathic Materia Medica with Indian Medicines & Repertory. 9th revised & enlarged ed. New Delhi: B. Jain Publishers (Pvt.) Ltd.; 2015
25. Hering C. The Guiding symptoms of our Materia Medica. New Delhi: B. Jain Publishers (P) Ltd., 2010.
26. Kaur, N. P., Mahajan, A. D., & Jadhav, A. B. (2020). A Clinical Study of Miasmatic Predominance in the Management of Cases of Dysmenorrhoea in the Age Group of 15-35 Years. *International Journal of Health Sciences and Research*, 10(4), 82. Retrieved from [www.ijhsr.org](http://www.ijhsr.org)
27. Lawrence AS, Ezhilarasi T. A Clinical study to assess the effectiveness of Actaea racemosa 30 C and 200 C in cases of primary dysmenorrhea in young females.
28. Rifati W, Sudiarti T. A family history as dominant factors associated with dysmenorrhea among adolescents. *Journal of Health and Medical Sciences*. 2020 Mar 10;3(1).
29. Donayeva A, Amanzholkyzy A, Nurgaliyeva R, Gubasheva G, Abdelazim I, Samaha II. The relation between primary dysmenorrhea in adolescents and body mass index. *Menopause Review/Przegląd Menopauzalny*. 2023 Sep 1;22(1).

30. Hahnemann S. Organon of medicine. B.Jain publishers; 2002.
31. George A, Bhaduri A. Dysmenorrhea among adolescent girls – symptoms experienced during menstruation. Health Promotion Educ 2002;17:4.
32. Agarwal A, Agarwal AK. Menstrual Problems and Anxiety. J Ravishankar Uni 1999;11:43-9.
33. Allen HC. Keynotes and Characteristics with Comparison of some of the leading remedies of the Materia Medica with Bowel nosodes. 8th ed. B. Jain Publishers (P) Ltd., New Delhi: 2003.
34. IBM SPSS software version 22
35. Radar Computer software by Software 10.0