

Efficacy Of Indicated Homoeopathic Medicine in The Management Of Primary Dysmenorrhoea Using VAS & WaLIDD SCORE: A Sequential Controlled Trial

Dr Ravi Jain¹, Dr A N Mathur², Dr M P Sharma³, Dr Ruchi Singh⁴, Dr Sonia Tuteja⁵

¹*Dr Ravi Jain, PhD Scholar, Department of Organon of Medicine, Homoeopathy University Jaipur.

²Dr A N Mathur, President, Homoeopathy University, Jaipur

³Dr M P Sharma, Dean & Director, Faculty of Homoeopathic Science, Jayoti Vidyapeeth Women's University, Jaipur

⁴Dr Ruchi Singh, Professor, Department of Organon of Medicine, Homoeopathy University, Jaipur.

⁵Dr Sonia Tuteja, Professor, Department of Homoeopathic Materia Medica, Homoeopathy University, Jaipur.

*Corresponding Author: Dr Ravi Jain,

*PhD Scholar, Department of Organon of Medicine, Homoeopathy University Jaipur. Email: ravij0000@gmail.com,

KEYWORDS

PD-Primary
Dysmenorrhoea, VAS,
WaLIDD, ANOVA
Test, P value, IBM
SPSS

ABSTRACT

Background: Dysmenorrhoea is a common gynaecological condition encountered by the females of reproductive age group characterised by cramping pain in the lower abdomen radiating to back and knees. Sometimes also associated with headache, nausea and vomiting, tiredness, fatigue and dizziness.

Objectives: The objective of the study is to establish to efficacy of indicated homoeopathic medicine over placebo in cases of primary dysmenorrhoea using VAS & WaLIDD scales. **Methodology:** An open label study conducted on 60 patients. The data was collected in 2 parts of 3 months each. In first part Placebo was administered to all the patients & in second indicated homoeopathic medicine was prescribed. Changes in VAS & WaLIDD score was noted on monthly basis. ANOVA test was applied to compare the observations.

Results: The mean of VAS at baseline 8.16 remained 8.16 after 3 months of treatment with placebo $p=1$ ($p>0.05$), not significant. After 3 months with indicated homoeopathic medicine VAS 8.16 shifted to 2.98 p value = 0 ($p<0.05$), statistically significant. Similarly, WaLIDD at baseline 9.48 with placebo remained 9.41, p value 0.159 ($p>0.05$) not statistically significant. With indicated homoeopathic medicine mean WaLIDD from 9.41 shifted to 3.8 $p=0$, ($p<0.05$) statistically significant. Frequently administered medicines were *Pulsatilla nigricans*, *Sepia officinalis*, *Nux vomica*, *Sulphur* and *Belladonna*.

Conclusion: The study demonstrates the efficacy of indicated homoeopathic medicine over placebo in the management of primary dysmenorrhoea using VAS & WaLIDD score in a sequential trail.

Introduction

Dysmenorrhea or painful 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.¹

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 α .¹

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.²

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

In the present 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 on monthly basis 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 Scores of both the scales have been compared to reach at the conclusion. The data was analysed separately using ANOVA Test on SPSS software version 22, and P value calculated to establish the efficacy of Indicated homoeopathic medicine.

The study also mentions the variables such as age of menarche, socioeconomic condition, BMI, length of menstrual cycle, 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 by the changes using Visual Analogue scale in the subsequent follow-ups in cases of primary dysmenorrhoea.
2. To study the changes using WaLIDD scale in subsequent follow-ups in cases of primary dysmenorrhoea.

Hypothesis:

Null Hypothesis (H₀) 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 (H₁) Indicated homoeopathic medicine produce significant changes in presenting symptoms 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 University Homoeopathy Hospital at Jayoti Vidyapeeth Women's University, Jaipur. The study duration was of **18 months** from July 2022 to Dec 2023. Where **first 1 Year was for the case registration and follow up was taken for next 6 months** of the last registration case.

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

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 57 which was 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).
- Moderate 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.
- Females providing consent for the study.

Exclusion Criteria

- Patients developing other gynecological complaints not related to primary dysmenorrhoea.
- 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 only Placebo was given. Proper counseling was done related the complaints during the study. After 3 months indicated homoeopathic medicine was given based on the principles of homoeopathy. Interpretation of response was noted and compared in the pain and working ability using VAS and WaLIDD Score.

Outcome Assessment: In this study pre and post study design has been used. Visual analogue scale and WaLIDD scale have been used. The assessment was done at every month by noting the VAS & WaLIDD score at the end of every cycle. Score analysis 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.

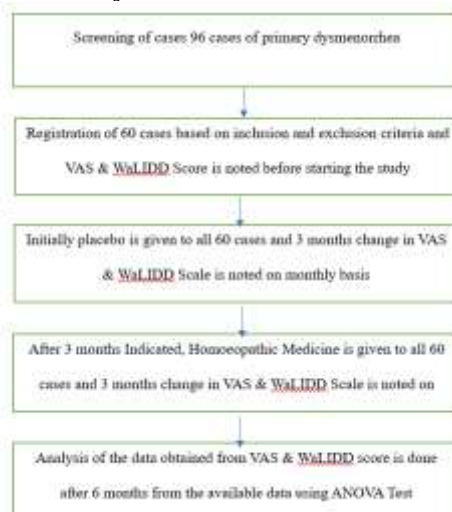


Fig 1. Flow chart of the study protocol.

Mean VAS at different times:

Table 1, Mean VAS score at different time intervals

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

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.

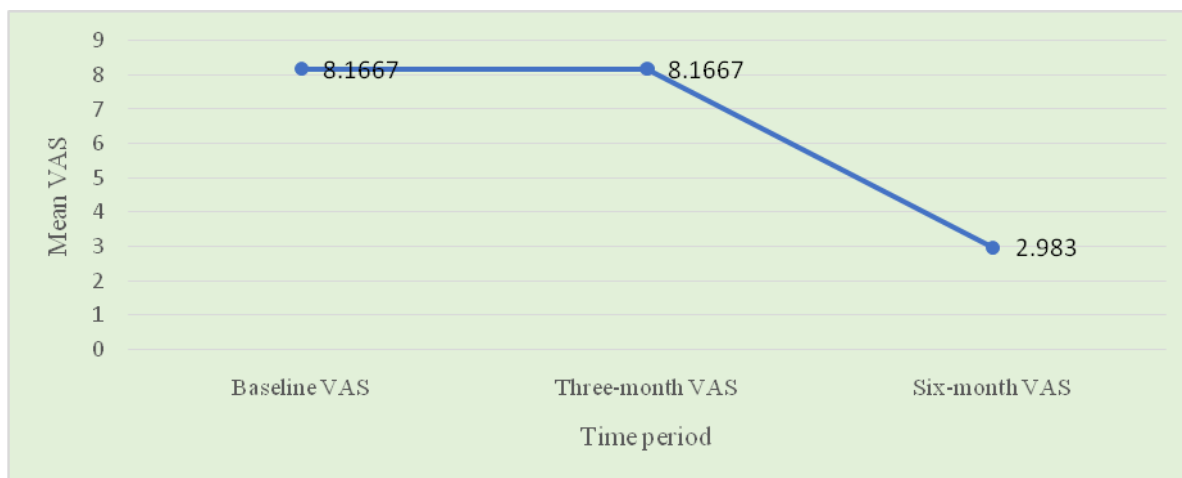


Fig:2 Graphical representation of Mean VAS score at different time intervals
Pairwise comparison of VAS

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

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

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

Table 3, Mean WaLIDD score 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

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.



Fig3: Graphical representation of Mean WaLIDD score at different times.

Pairwise comparison of WaLIDD score:

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

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

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.

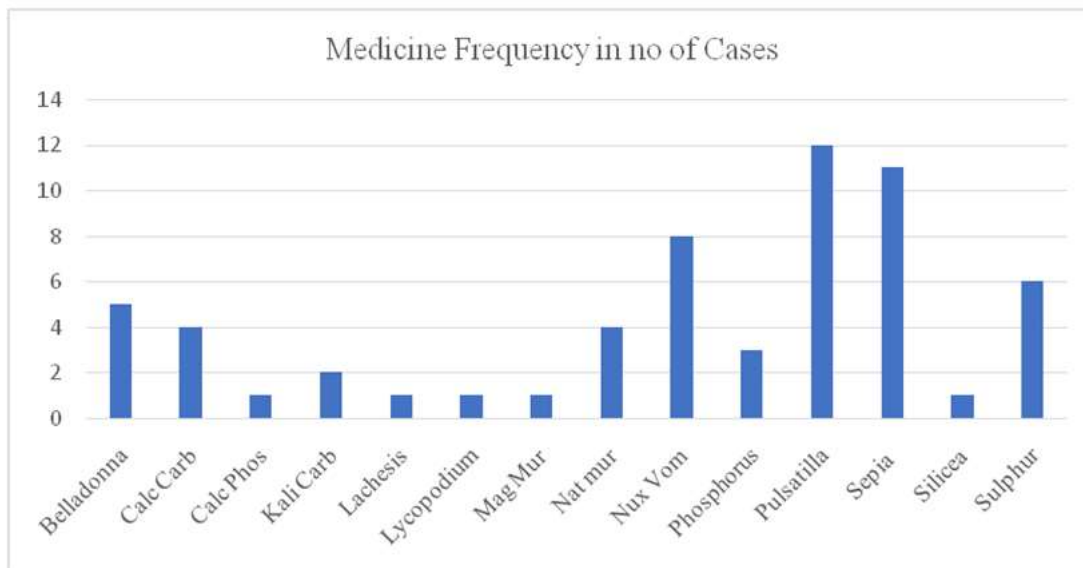


Fig:4 Frequency of medicines administered during the course of treatment.

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.

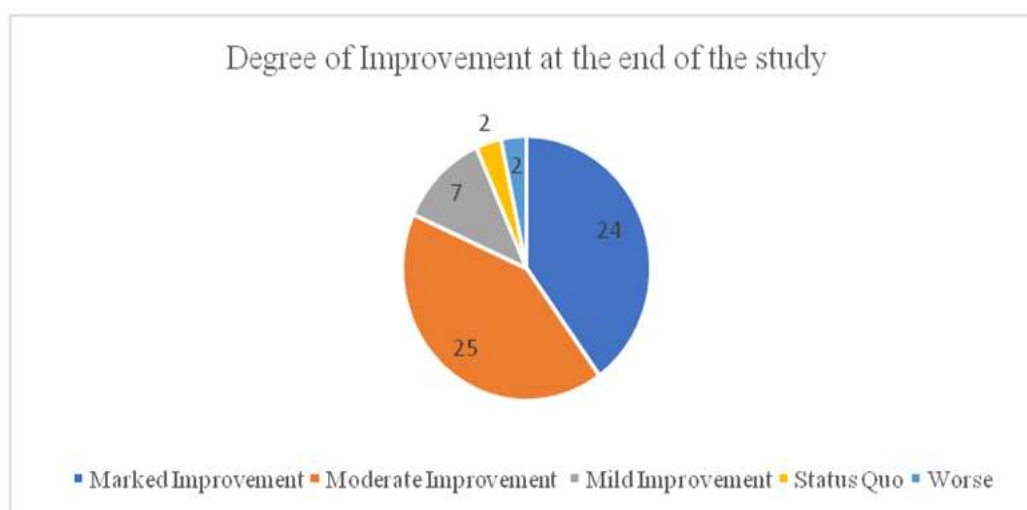


Fig 5, Degree of improvement after administration of indicated homoeopathic medicine

DISCUSSION

In the treatment of primary dysmenorrhoea the VAS & WaLIDD scores were compared to baseline with 3 months follow-up (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 VAS 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 homoeopathic medicine over placebo when the data of the starting date and end of the study was compared. Thus, we can say homoeopathic medicines are effective in comparison to placebo in the management of primary dysmenorrhoea as assessed by VAS and WaLIDD score when the study was conducted in sequential manner on the same individual.

Conflict of Interest ; Not any.

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 Purna Karki, Ms Nazung Lepcha, Ms SujenCintury, 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. Available from: <https://kuey.net/manuscript/index.php/kuey/article/view/1405>.
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 PediatrAdolesc 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. @article{Sultan2012AdolescentD, title={Adolescent dysmenorrhea.}, author={Charles Sultan and Laura Gaspari and Françoise Paris}, journal={Endocrine development}, year={2012}, volume={22}, pages={ 171-80 }, url={https://api.semanticscholar.org/CorpusID:27237714} }
13. Jeffocate N Principles of Gynaecology 17th edition . New Delhi India: Jaypee Brothers Medical Publishers (P) Ltd: 2008.
14. 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.0000000000000091.
15. Hahnemann S The chronic disease, their peculiar nature and Homoeopathic care 6th impression 2010 BJainPublication 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

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