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## RESEARCH

### Title: A study to verify the effect of homoeopathic preparation of viburnum opulus in centesimal potency in the management of primary dysmenorrhoea

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#### ABSTRACT:

**BACKGROUND:** As many as 90% of adolescent females and above 50% of menstruating women worldwide report suffering from it, with 10–20% of them describing their hurt as severe and distressing. The true prevalence of Primary Dysmenorrhea is not yet clearly established in India.

**OBJECTIVE:** The objective of this study is to find out the role of Viburnum Opulus in the women age group including 12-30 years suffering from Primary Dysmenorrhea with the help of Numerical Rating Scale (NRS).

**METHODOLOGY:** 32 cases of Primary Dysmenorrhea were treated with homoeopathic medicine Viburnum Opulus prescribed in centesimal potency on the basis of totality based on female menstrual complaints with the help of Numerical Rating Scale (NRS) before and after treatment.

**RESULTS:** Paired t-test was conducted on the Numerical Rating Scale Scores obtained from before and after treatment and the result showed that p value is  $< 0.05$  & the mean of the paired difference of scores was 3.438. The 95% confidence interval of the difference between the means ranged from [2.980 to 3.895];  $t(31) = 15.331$ ,  $p = 0.000$ . These results suggest that when patients received Viburnum Opulus in centesimal potency, the average scores decreases means that the patients has less impairments due to Primary Dysmenorrhea.

**CONCLUSION:** Viburnum Opulus is effective in treating cases of Primary Dysmenorrhea.

**Keywords:** *Homoeopathy, Primary Dysmenorrhoea, Viburnum Opulus, MENSTRUAL CRAMPS, CRAMP BARK.*

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**INTRODUCTION:** The term dysmenorrhoea derived from the Greek word “DYS” meaning difficulty/ painful/ abnormal, “MENO” meaning month and “RRHOEA” meaning flow.<sup>[1]</sup> Dysmenorrhoea refers to the cramps of uterine region.<sup>[2]</sup> It occurs 6 to 12 months after menarche, when ovulatory cycles are established. Duration of pain is usually 8 to 72 hours.<sup>[2]</sup> It is highly prevalent in adolescence.<sup>[2]</sup> Malaise, fatigue, nausea, vomiting, or headache is often concomitant.<sup>[2]</sup> Increased production of endometrial prostaglandin has been reported in suffering women which cause frequent uterine contractions that induce pain.<sup>[3]</sup> The objective of this study is to find out the role of Viburnum Opulus in centesimal potency in the cases of Primary Dysmenorrhoea.

## MATERIALS & METHODS

### 1. STUDY SETTING:

The study was conducted at the O.P.D. & I.P.D. of Swasthya Kalyan Homoeopathic Medical College & Research Centre, Jaipur.

**2. STUDY DURATION:** The duration of study was 12 months, out of which first 9 months was for enrolment of the patients along with regular

follow-ups, at an interval of 15 days covering at least three menstrual cycle with minimum 6 follow-ups.

**3. SELECTION OF SAMPLES:** Non randomized sampling on the basis of inclusion criteria.

**SAMPLE SIZE:** The sample size was calculated based on the t-test family and Means: Wilcoxon signed- rank test (matched pairs) and the standardized effect size in terms of standard deviation (0.5) with  $\alpha$  error probability = 0.05,  $1-\beta$  error probability (Power) = 0.8, and assuming a 10% drop-out rate. Therefore, the required sample size of this study was estimated to be 35 patients. The sample size (n) is determined by using G\*power version 3.1.9.4 software.

### 4. SELECTION CRITERIA

#### INCLUSION CRITERIA:

- New & undiagnosed cases, took treatment from other system of medicine, under control, but seeking homoeopathic treatment.
- Both married and unmarried female patient, age group between 12-30 years (both 12 & 30 years also), were included in the study.
- Patients who had a history of painful menstruation with associated symptoms.

- The Patient who gave their consent to participate in study with minimum 6 follow-ups for at least 3 menstrual cycles.

#### **EXCLUSION CRITERIA:**

- Cases with prediagnosed pelvic inflammatory disease.
- Cases with any other known cause of secondary dysmenorrhoea.
- Patient using any form of hormonal contraceptives.
- Patients with other severe systemic illness or any other auto-immune disease.
- Lactating mothers.

#### **DROP OUT:**

- The cases without proper follow up & discontinuation of treatment in between study were withdrawn from the study.
- If the patient was not benefitted from the treatment, then patient could withdraw.
- Any patient found to be uncooperative during the study.
- Any participant who wishes to withdraw her consent from participation in the study.

**5. STUDY DESIGN:** Interventional non-randomized study.

#### **6. INTERVENTION:**

**SELECTION OF MEDICINE:-** The homoeopathic medicine Viburnum Opulus was given according to the female menstrual symptoms and the complaints associated with Primary Dysmenorrhoea like headache, nausea, fatigue etc. have been confirm from Materia Medica.

**CHANGE OF REMEDY:-** In case of acute exacerbation of symptoms or a patient condition was standstill or appearance of any other acute disease condition, the medicine selected was either a continuation of preselected medicine, or one of the better-indicated medicines. Case was re-analysed to make further prescription. In case where no signs of improvement noticed, potency was raised. If no change was observed, even after the raised potency, reanalysis of the case was

done.

**DOSES AND POTENCY:-** The scale used for prescribing the medicine was centesimal only. Initially 30th potency was prescribed and then the potency was raised if there were no signs of improvement as per the need of the case. Medicine was administered orally, during or just before the periods according to menstrual pain followed by placebo for 15 days.

**REPETITION:-** Medicine was repeated depending on the frequency, intensity and duration of symptoms till perceptible changes appeared. Appearance of any change was immediately followed by placebo/change in potency depending upon the response. In case where no signs of improvement noticed, potency was raised.

**PROCUREMENT OF MEDICINE:-** The medicine was procured from the pharmacy having the Good Manufacturing Practices certificate.

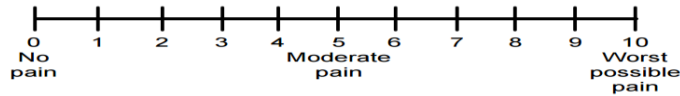
#### **ANCILLARY MEASURE<sup>[4]</sup>:-**

- Avoid oily and junk food & take nutritious diet.
- Warmth application advised during pain on painful parts to relax the muscles.
- Take iron rich food like spinach, tofu, lentils, broccoli, red meat etc.
- Increase physical activity and walk for atleast 30 minutes daily.

**RESTRICTIONS:-** Medicines of other streams restricted during the treatment. Any simple analgesics, such as aspirin & paracetamol strictly restricted during the treatment.

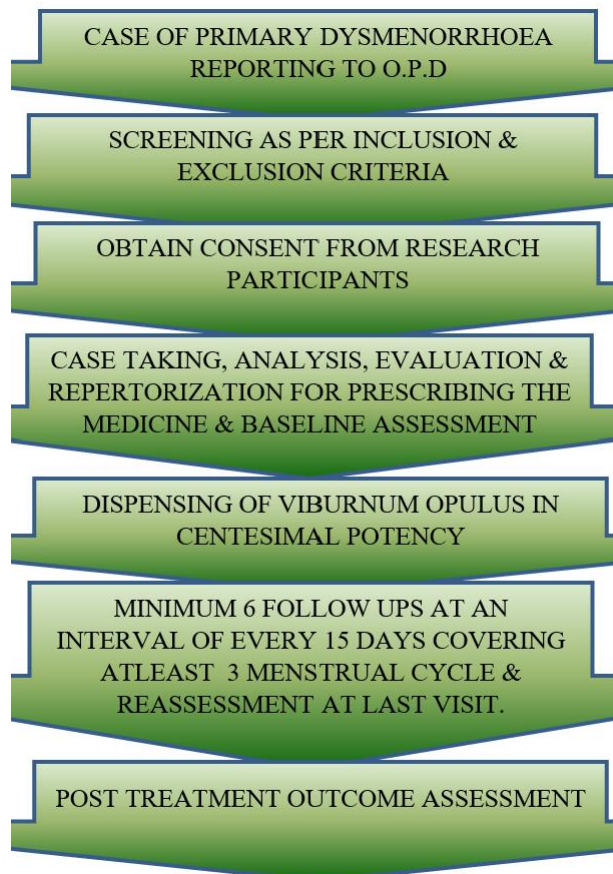
#### **7. SELECTION OF TOOLS.**

- Homoeopathic Case Taking Proforma specially designed for this study.
- RADAR 10.0 (Synthesis 9.0) was used for repertorization after proper analysis and evaluation of symptoms.
- Consent form.
- Numerical Rating Scale (NRS) (65) was used to assess the treatment outcome.

**0–10 Numeric Pain Rating Scale****Fig 4.2. Numerical Rating Scale.**<sup>(5)</sup>

The NRS cut-off point ranges on this scale are as follows:-

- Mild Pain:- 1-3
- Moderate Pain:- 4-6
- Severe Pain:- 7-10

**8. BRIEF PROCEDURE FOR CASE TAKING AND ANALYSIS:**

**9. OUTCOME ASSESSMENT:**

Parameter for analyzing the outcome/result of this study:

$P = \frac{S1 \text{ at baseline} - S1 \text{ at completion of study}}{S1 \text{ at baseline}} \times 100$

S1 at baseline

P=Percentage

S1=NRS Score

**TREATMENT OUTCOME ASSESSMENT:**

- Marked Improvement:-  $75\% \leq P < 100\%$
- Moderate Improvement:-  $50\% \leq P < 75\%$
- Mild Improvement:-  $25\% \leq P < 50\%$
- Status quo:-  $0\% \leq P < 25\%$
- Any increase in NRS score from the baseline score was counted as worse.

**10. DATA COLLECTION:**

- Data was recorded in Homoeopathic Case Taking Proforma especially designed

for this study. (Annexure-III)

- All the clinical data related to the study would be kept in the form of hard as well as soft copy.
- Data was collected after proper follow ups.

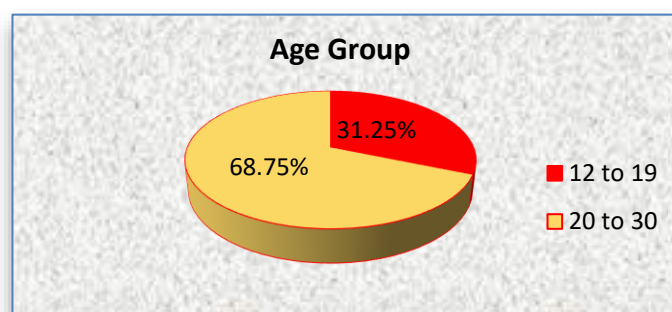
**11. DATA ANALYSIS & STATISTICAL TECHNIQUES:**

- Demographic data was presented using Descriptive Statistics i.e. mean, median, percentage, etc.
- Treatment outcome was analyzed using Paired t-test by using IBM SPSS 25.0.

**12. ETHICAL ISSUES:**

- A written consent was obtained from each participant.
- The study was approved by the Institutional Ethical Committee.

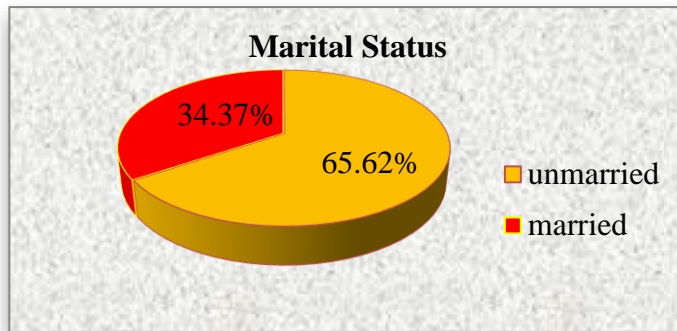
**RESULTS:** In this Interventional study, 35 patients were selected non-randomly on the basis of inclusion criteria. 03 patients were dropped-out due to irregular follow-up. Observations and statistical analysis was done on 32 patients as per protocol.

**OBSERVATION & RESULT:****1. AGE GROUP DISTRIBUTION**

**Fig. (a) Distribution of cases of Primary Dysmenorrhea according to Age Group.**

- In this above figure, it was observed that out of 32 patients, maximum cases was observed in the age group of **20-30** years i.e. **22 (68.75%)**, whereas minimum cases were observed in the age group of **12-19** years i.e. only **10 (31.25%)**.

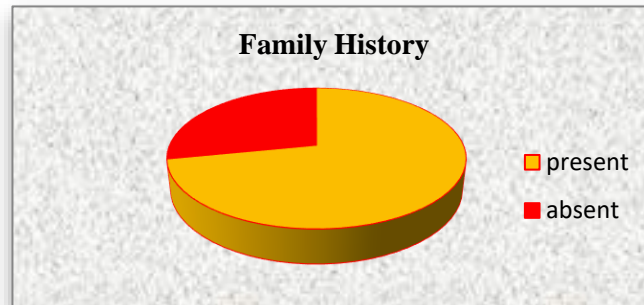
## 2. MARITAL STATUS DISTRIBUTION



**Fig. (b) Distribution of cases of Primary Dysmenorrhea according to Marital Status.**

- In the above figure, it was observed that maximum number of cases of Primary Dysmenorrhea were noticed under **unmarried females** i.e. **21 (65.62%)** and minimum cases were noticed in **married females** i.e. **11 (34.37%)**.

## 3. FAMILY HISTORY OF DYSMENORRHEA DISTRIBUTION.



**Fig. (c) Distribution of cases of Primary Dysmenorrhea according to Family History of Dysmenorrhea.**

- In this above figure, maximum cases had family history of Dysmenorrhea i.e. **23 (71.87%)** & followed by cases had no family history of Dysmenorrhea i.e. **09 (28.12%)**.

#### 4. SOCIO-ECONOMIC STATUS DISTRIBUTION.

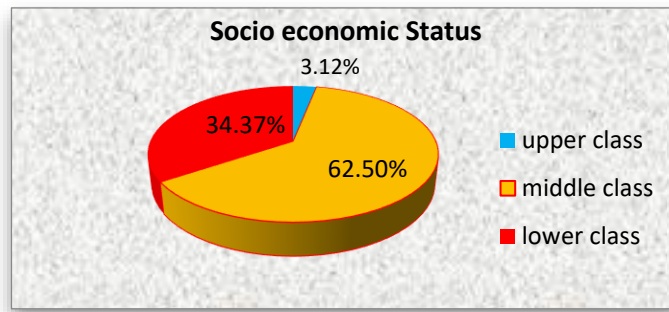


Fig. (d) Distribution of cases of Primary Dysmenorrhoea according to Socio-economic Status.

#### 5. ASSOCIATED COMPLAINTS DISTRIBUTION.

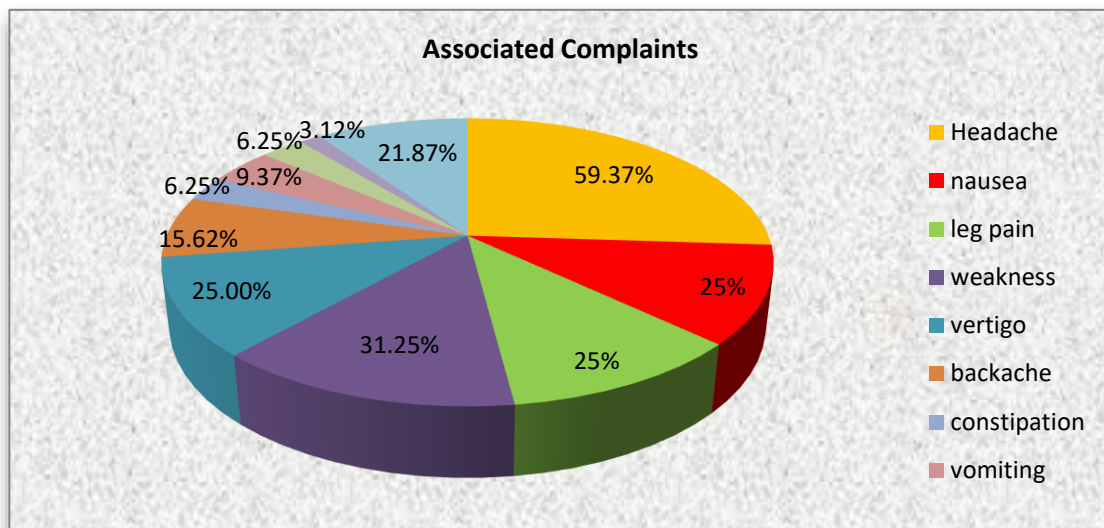
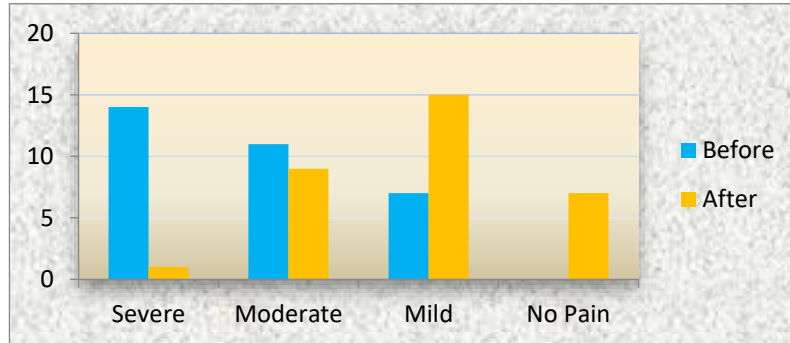


Fig. (e) Distribution of cases of Primary Dysmenorrhoea according to Associated Complaints.

In this above figure, maximum cases had associated complaints of :-

- 19 cases (59.37%) had Headache,
- 10 cases (31.25%) had Weakness,
- 08 cases (25%) had Nausea,
- 08 cases (25%) had Leg pain,
- 08 cases (25%) had Vertigo,
- 07 cases (21.87%) had Tiredness.
- 05 cases (15.62%) had Backache,
- 03 cases (9.37%) had Vomiting,
- 02 cases (6.25%) had Constipation,
- 02 cases (6.25%) had Irritability, and
- 01 CASE (3.12%) had DIARRHEA.

### 6. CASES DISTRIBUTION ACCORDING TO NUMERICAL RATING SCALE (NRS) BEFORE AND AFTER TREATMENT



**Fig. (f) Distribution of cases of Primary Dysmenorrhea according to Numerical Rating Scale (NRS) before and after treatment.**

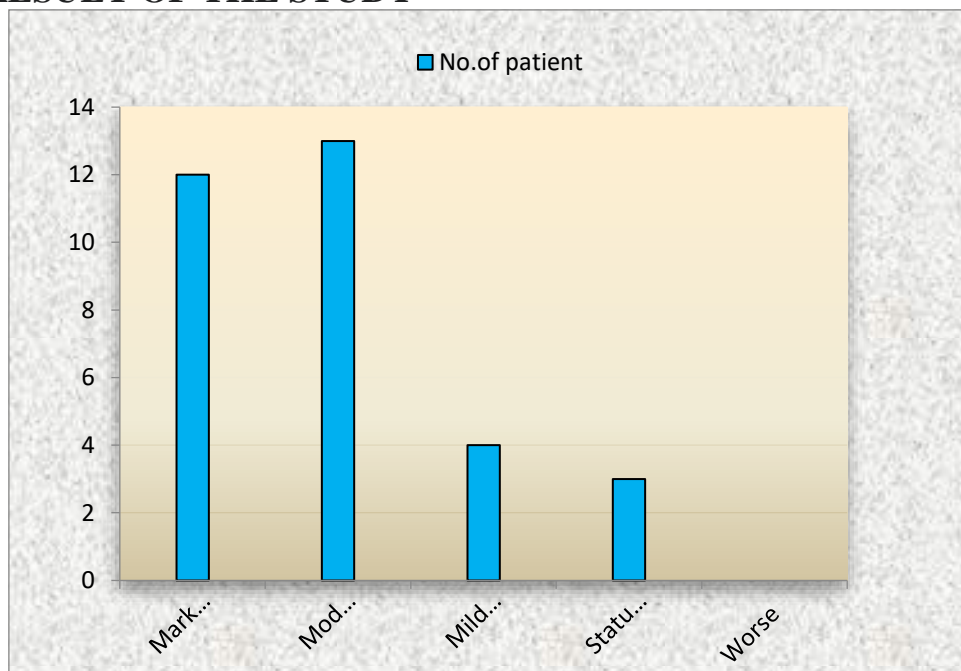
In this above figure, the baseline assessment according to the Pre-NRS Score, before treatment was:-

- 14 (43.75%) cases reported with severe pain,
- 11 (34.37%) cases reported with moderate pain; and
- 07 (21.87%) cases with mild pain at the baseline.

Re-assessment was done at last visit by using Post-NRS Score, the pain was markedly reduce i.e. the patient those who had severe pain shifted to the moderate and mild pain, i.e :-

- only 01 case (3.12%) reported with severe pain,
- 09 cases (28.12%) reported with moderate pain,
- 15 (46.87%) cases reported with mild pain, &
- 07 (21.87%) cases reported with no pain.

### 7. RESULT OF THE STUDY



**FIG. (G) RESULT OF THE STUDY**



- In this above figure, a total of 32 patients were assessed before and after treatment, using Numerical Rating Scale (NRS). 12 patients (37.5%) showed Marked Improvement, 13 patients (40.62%) showed Moderate Improvement, 04 patients (12.5%) showed Mild Improvement, 03 patients (9.37%) were at Status Quo, and 0 patient (00%) showed worsening of symptoms.

## DISCUSSION:

The interventional study was aimed to ascertain the effectiveness of homoeopathic medicine *Viburnum Opulus* in centesimal potency in the cases of Primary Dysmenorrhea. A total of 35 cases were enrolled in this study, out of which 03 cases were dropped-out due to irregular follow-up.

This study has shown encouraging results with homoeopathic treatment in cases of Primary Dysmenorrhea by *Viburnum Opulus* in centesimal potency which is evident by the mean of NRS Score before and after the treatment i.e. 5.84 & 2.41 respectively, as well as by the statistically significant difference ( $p = .000$ ).

A brief attention to observations obtained post- statistical analysis done on 32 cases of present study are as follows:-

### AGE GROUP DISTRIBUTION

- In Figure 5.1, it was observed that out of 32 patients maximum cases was observed in the Age group of 20-30 years ( $n=22$ ;

68.75%), whereas minimum cases were observed in the age group of 12-19 years ( $n=10$ ; 31.25%). A study conducted by Hu Z, et al<sup>[6]</sup> in China found that the maximum cases was observed in the age group of younger than 20 years ( $n=1284$ ; 67.6%), whereas minimum cases was observed in the age group of 20 years or older ( $n=616$ ; 32.4%).

- **Inference:** In present study, observation shows that maximum affected group was young female adults and minimum affected group was adolescents which is not similar to previous study.<sup>[6]</sup> The result may vary from previous study that shows Primary Dysmenorrhea present more in young adolescents.<sup>[2]</sup> It may be due to the

sample size of the study which was too small for interpretation of the age group.

### MARITAL STATUS DISTRIBUTION

- In Figure 5.2, it was observed that unmarried females ( $n=21$ ; 65.62%) were more affected than married females ( $n=11$ ; 34.37%).

- **Inference:** In present study, observation shows that unmarried females are more affected than married females. A Study by Calis KA, et al<sup>[7]</sup> stated that nulliparity is a risk factor of Primary Dysmenorrhea. Thus, the result correlates with present study.<sup>[7]</sup>

### FAMILY HISTORY DISTRIBUTION

- In Figure 5.3, it was observed that maximum cases had family history of Dysmenorrhea ( $n=23$ ; 71.87%); and cases which had no family history of Dysmenorrhea ( $n=09$ ; 28.12%). A study conducted by Omidvar S, et al<sup>[8]</sup> found that a considerable percentage of the selected subjects mentioned to have a positive family history of menstrual pain ( $n=622$ ; 64.5%), and cases that had no family history of menstrual pain was ( $n=342$ ; 35.5%).

- **Inference:** In present study, observation shows that maximum cases had positive family history of Dysmenorrhea, had greater chance of having the same problem, & it shows strong relation with family history which is similar to above study.<sup>[8]</sup>

### SOCIO-ECONOMIC STATUS

- In Figure 5.4, it was observed that maximum females were from middle socio-economic group ( $n=20$ ; 62.5%), followed by lower class ( $n=11$ ; 34.37%) and upper class ( $n=1$ ; 3.12%). A study<sup>[8]</sup> by Omidvar S, et al found that more than half of the participants belonged to medium ( $n=529$ , 52.9%) SES (socio economic status) followed by low

(n=367; 36.7%) SES and high (n=104, 10.4%) SES.

• **Inference:** In present study, observation shows that maximum cases were from middle socio-economic group then from lower & higher which is similar to the above study. Females of middle socio-economic group approaching towards westernization, being more prone for unhealthy food habits, sleep deprivation, physical inactivity and stress emerging from the competition for education and jobs; may be responsible for the Primary dysmenorrhea.

### ASSOCIATED COMPLAINTS DISTRIBUTION

• In Figure 5.5, it was observed that maximum cases had associated complaint of Headache (n=19; 59.37%) & other associated complaints were Nausea (n=08;25%); Leg pain (n=08;25%); Weakness (n=10;31.25%);Vertigo (n=08;25%); Tiredness (n=07;21.87%); Backache (n=05;15.62%); Constipation (n=02;6.25%); Vomiting (n=03;9.37%); Irritability (n=02;6.25%) and Diarrhea (n=01;3.12%).

• A Previous study<sup>[9]</sup> conducted by Alsaleem MA found the symptoms experienced by the respondents during menstruation, these symptoms are changes in appetite (n=106; 53.8%), nausea (n=90; 45.7%), and bloating (n=85; 43.1%), diarrhea/constipation/both (n=48; 24.4%), vomiting (n=47; 23.9%), indigestion and heartburn (n=40; 20.3%), low back pain (n=107; 54.3%), headache (n=58; 24.4%), dizziness (n=83; 42.1%), tiredness (n=48; 24.4%).

• A study<sup>[10]</sup> conducted by Mool Raj Kural, Naziya Nagori Noor & Anjali Patil found that majority of girls (91%) have reported PMS even in the absence of Dysmenorrhea only 9% of the girls didn't report any such symptom. Majority of them (64%) have reported multiple symptoms like Breast pain (16.3%), Irritability (42.9%), Fatigue (23.4%), Dizziness (17.7%), Leg Cramps (40.4%), Anxiety (10.3%), Nausea (5.0%)

• **Inference:** In present study, observation

shows associated complaints such as headache, nausea, vomiting, diarrhea/constipation, backache, irritability and tiredness are almost similar to the above studies. It shows that women suffering with Primary Dysmenorrhoea are presented with either one or more associated complaints during menstruation.

### NRS BEFORE AND AFTER TREATMENT

• In Figure 5.6, it was observed that at the baseline cases reported with Severe pain (n=14; 43.75%), Moderate pain (n=11; 34.37%) & Mild pain (n=07; 21.87%). At Re-assessment on last visit, cases markedly reduce from severe pain (n=1; 3.12%) & cases in moderate pain (n=09; 28.12%), mild pain (n=15; 46.87%), and no pain was reported by (07; 21.87%) cases.

• **Inference:** Marked decrease in post score of Primary Dysmenorrhoea indicates effectiveness of *Viburnum Opulus* when used homoeopathically in centesimal potency.

### RESULT OF THE STUDY

• In Figure 5.7 maximum cases showed moderate improvement (n=13; 40.62%), followed by marked improvement (n=12; 37.5%), mild improvement (n=04; 12.5%), status quo (n=03; 9.37%) and zero patient shows any worsening of symptoms.

• Also in Table 5.3, the result of paired t-test was given. The result shows that p value is < 0.05; which is statistically significant.

• **Inference:** The treatment result has shown maximum improvement in Primary Dysmenorrhoea. Pain was markedly improved in **37.5%** of cases & moderate relief in **40.62%** of cases. Only **9.37%** of cases had no change. The associated symptoms like nausea, vomiting, vertigo, headache, leg pain, irritability, constipation, and tiredness were also improved. It justifies that homoeopathic medicine *Viburnum Opulus* if, given in centesimal potency have definite action or is effective in the cases of

- Primary dysmenorrhea and pre-menstrual complaints.

### CONCLUSION:

Dysmenorrhoea is a major problem representing the leading cause of school absenteeism and interference with daily activities due to severity of pain as mentioned in the previous studies also. Females with long menstrual cycles, scanty flow, positive family history for dysmenorrhea and alcohol consumption are more likely to experience dysmenorrhea.

The study was aimed to verify the role of *Viburnum Opulus* which was used for dispensing in centesimal scale only, (previously which was experimented as mother tinctures and decimal scale in other studies); for the purpose of managing the cases of Primary Dysmenorrhea. It was concluded after observing 32 patients of Primary Dysmenorrhoea by assessing their treatment outcome through Numerical Rating Scale (NRS) used for assessing the intensity of pain.

Cases were selected on the basis of inclusion and exclusion criteria. Out of 32 cases, maximum cases were found in the age group of 20-30 years. In Primary Dysmenorrhea unmarried females were more affected than married females. Primary Dysmenorrhea is associated with positive family history of Dysmenorrhea. This study has illuminated the impact of *Viburnum Opulus* in Primary Dysmenorrhoea. Compared to baseline, Post-NRS Score of participants decrease significantly over 3 menstrual cycles. This is evident by the decrease in NRS score post medication when compared to the baseline score (Pre-medication).

**STRENGTHS OF THE STUDY:** The methodological strength of study was the interventional design, the subjects can be quick to conduct with regard to enrolling patients, reviewing patient records, comparison of NRS before and after treatment, treatment by single, simple medicine in minimum dose based on menstrual symptoms, in not only reducing the

painful menses but also improvement in the associated complaints present with primary dysmenorrhea as well as psychological well-being of patients without any medicinal adverse effects.

**LIMITATIONS:** The main problem with small studies is interpretation of results. The sample size was too small in study, so generalizing the result & conclusions of this study need to be done very cautiously. So, the findings of this study warrant further evaluation using better study designs with large sample size.

### PROPOSED AREA FOR FUTURE RESEARCH:

The role of homoeopathic medicine *Viburnum Opulus* in Primary Dysmenorrhoea could not be significantly proved in such a small sample size and for very less period of time. Longer study duration with large sample size can reveal a better understanding of these aspects in future. Further explorations by adequately powered randomized controlled trials and comparative study with standard treatment are desirable to arrive at a further and potential validation in the treatment of Primary Dysmenorrhoea.

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**CONFLICT OF INTEREST:** There has been no conflict of interest, the manuscript have been approved by an Ethical Committee.

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