INTRODUCTION

Dysmenorrhea literally means painful menstruation. The definition of dysmenorrhea is severe, painful cramping in the lower abdomen just before or during the menses. Under ICD 10-CM diagnosis code of Primary Dysmenorrhea is N94. Dysmenorrhea is probably the most common complaint of gynecologic patients, affecting 75% of all women. It divided into primary and secondary type. The primary dysmenorrhea (Spasmodic) is one where there is no identifiable pelvic pathology. Secondary Dysmenorrhea (Congestive) is normally considered to be menstruation associated pain occurring in the presence of pelvic pathology. The incidence of primary dysmenorrhea of sufficient magnitude with incapacitation is about 15–20 percent. With the advent of oral contraceptives and non-steroidal anti-inflammatory drugs, there is marked relief of the symptom. The mechanism of initiation of uterine pain in primary dysmenorrhea is difficult to establish. The pain is usually cured following pregnancy and vaginal delivery. The pain is related to dyssynchronous uterine contractions and uterine hypoxia.

Research Article

ROLE OF HOMOEOPATHY IN PRIMARY DYSMENORRHOEA– A RANDOMIZED PLACEBO CONTROL TRIAL

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ABSTRACT

Background & Purpose of the study: Dysmenorrhea is a very common problem during reproductive life of women. In which primary dysmenorrhea is most common without any pathology. It affect quality of life, impairment of daily activities, absent from work and school is commonly reported. 10-20% of women with primary dysmenorrhea do not respond with NSAIDs or oral contraceptives. Therefore there is a need to explore effectiveness of alternative methods of treatment (Homoeopathy) for this condition. Objectives: The objective of the study found the role of homoeopathic treatment women suffering from primary dysmenorrhea. Methodology: This was single-blind Randomised Placebo-controlled trial conducted on Sri Ganganagar Homoeopathic Medical College Hospital and Research Institute Sriganganagar Rajasthan. Total 65 patients were enrolled that suffering from primary dysmenorrhea under the age of 25 years, randomized in two group Homoeopathy (30) and Placebo Group (35). The Visual Analogue Scale (VAS) of pain used for outcome measure, the assessment was done pre and post-treatment (after 6 Month). The duration of the study was a minimum 18 months. Homoeopathic medicine prescribed on the basis of the totality of symptoms. Nonparametric Test Mann Whitney U test applied to compare the observations. At P < 0.05 two-tailed was considered statistically significant. Results: 1 Subject dropped out and 64 subjects completed the trial. Intention to treat sample (n = 65) was analysed. After Treatment there were statistically significant reductions in pain visual analogue scale score Homoeopathy Group {median 2.0 (IQR 1.0 to 1.5)} vs. placebo group median 4.0 (IQR 3.0 to 5.0), P=0.001 i.e. P < 0.05 and before treatment there is no significant difference in visual analogue scale score in both group Homoeopathy {Median =8 (IQR 7.0 to 8.0)}, vs. Placebo {Median =8 (IQR 7.0 to 8.0)}, P = 0.7489 i.e. P > 0.05, Colocynth (n = 7, 23%), Belladonna (n = 5, 17%), Mag. Phos. and Actea Recinmosa (n = 4 each, 13%) and Pulsatilla nigricans (n = 4, 8%) were prescribed frequently. if there is no pain during menses then the quality of life is improved. Conclusion: This study shows a significant effect of homoeopathy on primary dysmenorrhea in comparison with placebo. If homoeopathic medicine prescribed on totality of symptoms of individual subjects.

INTRODUCTION

Dysmenorrhea literally means painful menstruation. The definition of dysmenorrhea is severe, painful cramping in the lower abdomen just before or during the menses. Under ICD 10-CM diagnosis code of Primary Dysmenorrhea is N94. Dysmenorrhea is probably the most common complaint of gynecologic patients, affecting 75% of all women. It divided into primary and secondary type. The primary dysmenorrhea (Spasmodic) is one where there is no identifiable pelvic pathology. Secondary Dysmenorrhea (Congestive) is normally considered to be menstruation associated pain occurring in the presence of pelvic pathology. The incidence of primary dysmenorrhea of sufficient magnitude with incapacitation is about 15–20 percent. With the advent of oral contraceptives and non-steroidal anti-inflammatory drugs, there is marked relief of the symptom. The mechanism of initiation of uterine pain in primary dysmenorrhea is difficult to establish. The pain is usually cured following pregnancy and vaginal delivery. The pain is related to dyssynchronous uterine contractions and uterine hypoxia.

1. Psychosomatic factors of tension and anxiety during adolescence; lower the pain threshold.

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2. Abnormal anatomical and functional aspect of myometrium. Uterine myometrial hyperactivity has been observed in cases with primary dysmenorrhea.\textsuperscript{1,2}

3. Imbalance in the autonomic nervous control of uterine muscle. There is overactivity of the sympathetic nerves → hypertonicity of the circular fibers of the isthmus and internal os.\textsuperscript{1,2}

4. Role of prostaglandins - In ovulatory cycles, under the action of progesterone, prostaglandins (PGF2α, PGE2) are synthesized from the secretory endometrium. Prostaglandins are released with maximum production during shedding of the endometrium. PGF2α is strong vasoconstrictor, which causes ischemia (angina) of the myometrium.\textsuperscript{1,2}

5. Role of vasopressin: There is increased vasopressin release during menstruation in women with primary dysmenorrhea. Vasopressin increases prostaglandin synthesis and also increases myometrial activity directly. It causes uterine hyperactivity and dysrhythmic contractions → ischemia and hypoxia → pain.\textsuperscript{1}

6. Endothelins causes myometrial smooth muscle contractions, specially in the endomyometrial Junction.\textsuperscript{1,2}

7. Platelet activating factor (PAF) is also associated with the etiology of dysmenorrhea as its concentration is found high. Leukotrienes and PAFs are vasoconstrictors and stimulate myometrial contractions.

Primary dysmenorrhea is predominantly confined to adolescent girls\textsuperscript{1,2,3}. The pain begins a few hours before or just with the onset of menstruation. The severity of pain usually lasts for few hours, may extend to 24 hours but seldom persists beyond 48 hours. The pain is spasmodic and confined to lower abdomen; may radiate to the back and medial aspect of thighs. Systemic discomforts like nausea, vomiting, fatigue, diarrhea, headache and tachycardia may be associated. It may be accompanied by vasomotor changes causing pallor, cold sweats and occasional fainting. Abdominal or pelvic examination does not reveal any abnormal findings.

**Aims and Objective**

**Primary objectives**

1. To determine the efficacy and significance of homoeopathic medicines in the management of primary dysmenorrhea.
2. To determine the list of medicines and the corresponding potencies frequently indicated in the management of primary dysmenorrhea
3. To observe change in quality of life at the end of treatment.

**Hypothesis**

H\textsubscript{0} (Null Hypothesis)- There is no significant difference of post VAS score in Homoeopathy and placebo group.

H\textsubscript{1} (Alternate Hypothesis)- There is significant difference of post VAS score in Homoeopathy and placebo group.

**MATERIALS AND METHODS**

**Settings and Design:** This was single blind Randomised Placebo controlled (Parallel arm) trial conducted at Gynecology and Obstetrics OPD/IPD of Sri Ganganagar Homoeopathic Medical College Hospital and Research Institute, Sri Ganganagar Rajasthan. Duration of study was 18 months. Study begins in July 2018.
**Ethical clearance:** The study protocol was approved by the Institutional Ethical Committee of Tantia University prospectively.

**Trial Registration:** The trial has been registered in ‘Clinical Trial Registry -India (CTRI)’ no. CTRI/2018/07/014949 [Registered on: 18/07/2018] Trial Registered Prospectively and

**The Universal Trial Number:** U1111-1227-0870.

**Inclusion and Exclusion Criteria**

**Inclusion criteria**

1. All the patients fulfilling case definition of Primary dysmenorrhoea.
2. Women’s age group 12 to 25 year are included in my study.
3. Patients suffering from Primary dysmenorrhoea, willing to participate and taking treatment regularly and co-operating for regular follow-up had been included.

**Exclusion criteria**

1. The patients not fulfilling the case definition of Primary dysmenorrhoea.
2. Patients who require emergency medical intervention.
3. Patient without written consent.
4. Patients who not take medicine & follow up properly and not follow advice, diet and regimen.

**Sample size and Randomization:** Total 65 patient included in my study. The case registered and fullfilling the case definition of primary dysmenorrhoea allocated (randomized) in two group with the help of randomizer.org. (Simple random sampling method)

**Intervention:** Patient randomized in two group, Group 1 received Homoeopathic medicine on basis of totality of symptoms and Group 2 received placebo. In group 1 or homoeopathy group 30 patients were allocated and in group 2 (Placebo group) 35 patients were allocated. Medicine given in similar form in both the group. This study was single blind study, so patient does not know they take homoeopathic medicine or placebo.

**Outcome assessment:** In this study we follow pre and post study design. We use the Visual Analogue Score of Pain (VAS) for outcome assessment. The VAS assemset done at beginning of study and after 6 month of study.

**Statistical Analysis:** Both descriptive and inferential statistics was used. Intention to treat sample was subjected to statistical analysis. First check the normality of data with the help of Kolmogorov- Smirnove Test (K-S Test). Then appropriate statistical Mann Whitney U test (Data is Not Normally distributed) was applied. P < 0.05 and before treatment there is no significant difference in visual analogue scale score in both group Homoeopathy group [median 2.0 (IQR 1.0 to 1.5)] vs. placebo group median 4.0 (IQR 3.0 to 5.0), P=0.001 i.e. P < 0.05 and before treatment there is no significant difference in visual analogue scale score.

**RESULT AND OBSERVATION**

**Study Flow:** A total 90 patient were screened for study in which 65 included in study on basis of inclusion and exclusion criteria of our study. 25 patient are excluded during screening.

**Fig 1 Study Flow Chart**

**Sociodemographic profile of the patients (n=65):** The Maximum patient belong the age group below 20 years (n= 36, 55.33 %) and 20 to 25 years (n=29, 44.61%) (Table 1). During my study unmarried women (n=48, 73.83 %) and Married women (n= 17, 26.15%).

**Table 1 Sociodemographic Profile of study**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 20 Years</td>
<td>36</td>
<td>55.33 %</td>
</tr>
<tr>
<td>20 – 25 Years</td>
<td>29</td>
<td>44.61 %</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unmarried</td>
<td>48</td>
<td>73.83 %</td>
</tr>
<tr>
<td>Married</td>
<td>17</td>
<td>26.15 %</td>
</tr>
</tbody>
</table>

**For Pre and Post Treatment (after 6 months) study compirson use Mann Whitney U Test (Non -Parametric Test):** Intention to treat sample (n = 65) was analysed. First we use the Kolmogorov- Smirnov Test (K-S Test) to check the normality of data (Table no. 3). Data was not normally distributed so we used non-parametric Mann Whitney U-test. After Treatment there were statistically significant reductions in pain visual analogue scale score Homoeopathy Group [median 2.0 (IQR 1.0 to 1.5)] vs. placebo group median 4.0 (IQR 3.0 to 5.0), P=0.001 i.e. P < 0.05 and before treatment there is no significant difference in visual analogue scale score in both group Homoeopathy { Median =8 (IQR 7.0 to 8.0)} vs. Placebo { Median =8 (IQR 7.0 to 8.0), P = 0.7489 i.e. P > 0.05. (Table no. 2).

**Table 2 Pre and Post Mann Whitney U Test**

<table>
<thead>
<tr>
<th></th>
<th>Pre / Post VAS</th>
<th>Homoeopathic Group Mean of rank</th>
<th>Placebo Group Mean of rank</th>
<th>U Value</th>
<th>Z Score</th>
<th>Calculated P Value</th>
<th>By Mann Whitney U Test</th>
<th>At 95% Confidence interval</th>
<th>Significant</th>
<th>Hypothesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIG VAS</td>
<td>Score</td>
<td>33.3</td>
<td>31.79</td>
<td>800</td>
<td>0.31616</td>
<td>0.19696</td>
<td>0.19696</td>
<td>Significant level P value &lt; 0.05</td>
<td>Significant</td>
<td>H Accepted</td>
</tr>
<tr>
<td>Score</td>
<td>Post VAS</td>
<td>19.18</td>
<td>44.25</td>
<td>110.5</td>
<td>0.36796</td>
<td>0.1233</td>
<td>0.1233</td>
<td>Not Significant</td>
<td>Not Significant</td>
<td>H Accepted</td>
</tr>
</tbody>
</table>

**To Check the Normogorov distribution of data Use Kolmogorov- Smirnov Test (K-S Test)**

<table>
<thead>
<tr>
<th>Table 3 K –S test for Normality</th>
<th><strong>Mean</strong></th>
<th><strong>Median</strong></th>
<th><strong>SD</strong></th>
<th><strong>Skewness</strong></th>
<th><strong>Kurtosis</strong></th>
<th><strong>K-S test Value (D)</strong></th>
<th><strong>Calculated P Value by K-S Confidence interval</strong></th>
<th><strong>At 95%</strong></th>
<th><strong>Hypothesis</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Homoeopathy Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre VAS</td>
<td>1.77</td>
<td>1.30</td>
<td>0.46</td>
<td>-0.77</td>
<td>-0.09</td>
<td>0.00001</td>
<td></td>
<td>Significant level P value &lt; 0.05</td>
<td>Not Normal</td>
</tr>
<tr>
<td>Placebo</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre VAS</td>
<td>2.015</td>
<td>1.70</td>
<td>0.39</td>
<td>0.35</td>
<td>0.10</td>
<td>0.00001</td>
<td></td>
<td>Significant level P value &lt; 0.05</td>
<td>Normal</td>
</tr>
<tr>
<td>Pre VAS</td>
<td>1.7941</td>
<td>1.30</td>
<td>0.40</td>
<td>-0.32</td>
<td>0.13</td>
<td>0.00001</td>
<td></td>
<td>Significant level P value &lt; 0.05</td>
<td>Normal</td>
</tr>
</tbody>
</table>

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Homoeopathic Medicine and corresponding potency used during treatment: As per the totality of symptoms at baseline Colocynth \( (n = 7, \ 23\%); \ Belladona \ (n = 5, \ 17\%); \ Mag. \ Phos. \ and \ Actea \ Recimosa \ (n = 4 \ each, \ 13\%) \) and Pulsatilla nigricans \( (n = 4, \ 8\%) \) were prescribed frequently (Table no. 4). In 19 cases we used 30 Potency and 11 cases 200 potency.

Table 4 Homoeopathic Medicine and corresponding potency used during treatment

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Name of Medicine</th>
<th>No. of patient</th>
<th>%</th>
<th>Potency 30</th>
<th>Potency 200</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Actea Recimosa</td>
<td>4</td>
<td>13.32</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>Belladona</td>
<td>5</td>
<td>16.65</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>Colocynth</td>
<td>7</td>
<td>23.32</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>Chamomila M.</td>
<td>3</td>
<td>9.99</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>Gelsimium Semi.</td>
<td>1</td>
<td>3.33</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>Kali Carb.</td>
<td>1</td>
<td>3.33</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>7</td>
<td>Mag. Phos.</td>
<td>4</td>
<td>13.32</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>8</td>
<td>Pulsatilla P.</td>
<td>3</td>
<td>9.99</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>Sepia. O.</td>
<td>2</td>
<td>6.66</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Box and Whisker Plot of Pre and Post VAS Comparision of both group

**DISCUSSION**

Compared to baseline and Placebo group there is significant reduction in Visual analouge Pain score after 6 months of treatment. Homoeopathic medicine prescribed on basis of totality of symptoms and individualization. As per the totality 9 medicine used during study in which colocynth is most common medicine prescribed during study. My study show that primary dysmenorrhoea is more common in unmarried womens below the age group of 20 years.

**CONCLUSION**

Homoeopathic medicine was not only reduce the suffering but also improve the quality of life of patient with dysmenorrhoea. This study show a significant role of homoeopathic medicine in primary dysmenorrhoea in comparison with placebo. If homoeopathic medicine prescribed on basis of totality of symptoms and individualization.

**Conflict of interest- None declared**

**References**

10. ICD 10 CM, International Classification of disease by CDC and WHO.