



ORIGINAL RESEARCH PAPER

Obstetrics & Gynaecology

“A SINGLE BLIND RANDOMIZED PLACEBO CONTROLLED TRIAL ON EFFECTIVENESS OF ABROMA RADIX Q IN RELIEVING PAIN INTENSITY & QUALITY OF LIFE IN ADOLESCENT GIRLS WITH PRIMARY DYSMENORRHOEA USING VAS SCALE”

KEY WORDS:

Dysmenorrhoea, Abroma radix Q, Placebo, VAS Scale.

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ABSTRACT

Primary Dysmenorrhea is a cycle where in the adolescent girls present with chronic pelvic pain due to excessive vasopressin, leukotrienes, prostaglandin, myometrial ischemia, uterine malformation¹. Primary dysmenorrhea may present with pain in abdomen before or during menses, associated with nausea, irritability, fatigue, headache. Abroma radix mother tincture is an homoeopathic mother tincture where its indicated for dysmenorrhoea², colicky pain in abdomen before menses. It is effective remedy in female disorders. This project helped to know the efficacy of Abroma radix and its usefulness in treating Primary dysmenorrhoea.

INTRODUCTION

Menstrual pain or dysmenorrhoea is a common complaint seen in most of the adolescent girls¹. Dysmenorrhoea will affect her day to day activities involving physical and emotional symptoms. This may also interrupt her educational & social life due to which there may be absenteeism for in which will affect her career up gradation. Usually to overcome with pain girls get habituate in seeking medical advise and NSAIDS are taken and with few self measures, which is not suggestible due to the reason on longstanding procedure the intake of NSAIDS may lead to Renal disorders, Liver disorders etc. Homoeopathic medicine brings effective and safe mode of treatment without placing patients at risk. Homoeopathic medicines will provide capacity in treating the dysmenorrhea in an effective manner with natural substances. Abroma radix is a drug prepared from the root of Abroma augusta⁸ Common name :Olat Kambal¹³ or Devil's cotton¹⁰. Introduced by Dr.S.C.Ghose. Useful in treating dysmenorrhea, it provides strength to uterus, these patients are irritable, angered easily. It has great affinity on the female Reproductive system and it regulates in maintenance of female hormones.

AIMS AND OBJECTIVES

- To verify the efficacy of Abroma radix Q in Primary Dysmenorrhoea
- To establish the improvement by follow up analysis with VAS Scale.

Need OfThe Study

Most of the girls usually have complaints of dysmenorrhoea which may interrupt there daily routine and cause depression, various mood swings may vary. Almost 50% of girls experience dysmenorrhea, and 15% severe pain which limits their daily routine⁹. Homoeopathy is the safe medicine which patients accept as an alterenative medicine over worldwide. Homoeopathic remedies are very effective in treating gynaecological diseases. In this study we have selected Abroma radix Q¹³ for treating dysmenorrhea because this remedy is having more affinity in treating uterine diseases. Its a rare indicated Indian medicine for Dysmenorrhoea where no previous studies had done & in our study we would like to prove this rare remedy, Present study will help the adolescent girls to overcome with Dysmenorrhoea and may move with whole ease.

Scope/accompanying Merits Of Research

Abroma radix¹⁴ is extracted from the root of plant. Botanical name is Abroma august. Indicated for dysmenorrhea, leucorrhoea, affinity over ovaries, uterus, vaginal mucosa. It acts as uterine tonic¹³. It helps to regulate female hormones

and maintain the levels of hormones. It regulates strength in muscles of uterus. As it has an antispasmodic quality helps to reduce pain in abdomen in menses. Hence, the remedy may be much helpful in adolescent girls.

METHODOLOGY:

Written Consent is taken from each and every patient who had participated in the study, the treatment plan had explained to each patient in their own language.

Study Setting:

A sample of 60 cases are randomly selected from patient who is having primary dysmenorrhoea visiting our MNRHMC collegiate OPDs/IPD, Case taking and consent form is taken from each and every patient and parents who had participated in this study and the treatment plan had explained to each patient in their own language.

STUDY DESIGN AND TYPE:

Single blinded, simple random sampling, Interventional study.

Sample Size: 60 patients

Procedure:

Two groups (One group with Abroma Radix Q, Another group with placebo in liquid form (14), each group with 30 cases.

Categorization of patients:

Group 1 – Abroma Radix Tincture, patient is advised to take 10 drops in 1-ounce water every half hourly at the time of dysmenorrhoea (administered for 30 patients) i.e. 30 ml is given per week.

Group 2 – Placebo in liquid form 30 ml is given, patient is advised to take 10 drops of given medicine in 1-ounce water every half hourly (administered for 30 patients). To both group dietary management is advised.

Selection Of Tools:

- MNRHMC case record format.
- VAS Scale.

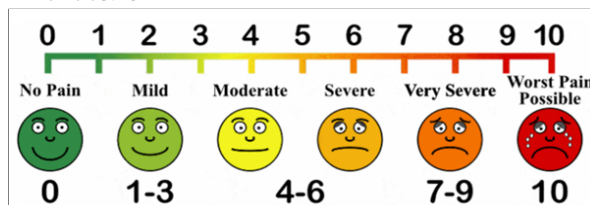


Fig no-1 VAS Scale

Quality Control And Quality Assurance

All medicines is procured from GMP certified pharmaceutical companies approved by the institutional ethical committee. Drug is acquired from standard homoeopathic pharmacy and drugs are stored as per the rules of Indian homoeopathic pharmacopoeia.

Ethical Issues

Ethical clearance has been obtained from college ethical committee before starting the study.

Inclusion Criteria:

- Age between 13-19
- Only Adolescent girl

Exclusion Criteria:

- Males.
- Age below 13 and above 19.
- Dysmenorrhoea with complications

Steps For Administration:

After case taking of patients who is presenting with symptoms of Primary dysmenorrhoea, to one group we had given Abroma Radix Q every half hourly 10 drops in half ounce of water. To another group we had given Placebo in liquid form. To both group dietary management is advised. Patient is also advised to visit OPD of collegiate hospital once in 2 wks. Improvement is assessed by changes in symptoms based upon VAS Scale before and after the study.

OBSERVATION AND RESULT:

Outcome is assessed by comparing the symptoms of primary dysmenorrhoea and VAS Scale before and after treatment. 60 Patients with primary dysmenorrhoea are included in this study. All these cases are divided into 2 groups.

Group 1 – Abroma Radix Q, patient is advised to take 10 drops in half ounce of water every half an hour daily for 4 days during menses until pain is relieved (administered for 30 patients)

Group 2 – Placebo in liquid form 30 ml is given, patient is advised to take 10 drops of given medicine in half ounce water every half an hour daily for 4 days during menses until pain is relieved (administered for 30 patients).

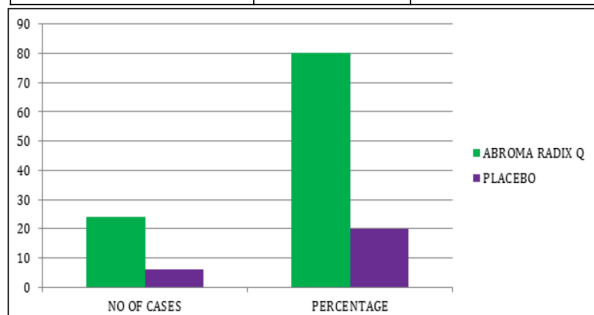
To both group dietary management is advised.

Each group contains 30 patients. All these cases are followed up for 6 months. The statistical analysis and corresponding observations are made based on the data so obtained.

The statistical analysis and correspondin

Table 1: Distribution Of Cases According To Improvement In Abroma Radix Q Group And Placebo Group

IMPROVEMENT	NO OF CASES	PERCENTAGE
ABROMA RADIX Q	24	80
PLACEBO	6	20



RESULTS:

Abroma radix Q group	
Average (x d) :	(-7)
Sample size (n) :	30
Sample SD (Sd) :	3.300993
Skewness :	0.46837
Skewnes Shape :	Potentially Symmetrical (pval=0.077)
Normality p-value :	0.4609

PLACEBO group

Average (x d) :	0.266667
Sample size (n):	30
Sample SD (Sd) :	2.333169

Group name:

Group 1 – Abroma radix Q group

Group 2 – Placebo group.

Sample average(x): Group 1 –(-7)

Group 2- 0.2667 sample size

(n): Group 1-30.

Group 2-30.

Sample σ(S): Group 1-3.300993.

Group 2- 2.333169.

Two sample t-test (Welch), using T distribution (DF=52.1882) (two-tailed) (validation)

1. H₀ Hypothesis:

Since p-value < α, H₀ Is rejected. The average of Abroma radix Q population is considered to be not equal to the average of the Placebo's Population.

In other words, the difference between the average of the Abroma radix Q and placebo population is big enough to be statistically significant.

2. P-value:

P-value equals 1.70322e-13, (p(x≤T) = 8.51610e-14). This means that the chance of type 1 error (rejecting a correct H₀) Is small: 1.703e-13 (1.7e-11%). The smaller the p-value the more it supports H₁. H₀ is rejected and H_a is accepted so, by this study we can know that Abroma radix Q is effective in treating primary dysmenorrhoea.

DISCUSSION:

As we know "Health is wealth" and every adolescent girl will be suffering with menstrual pain & captivated in performing their regular routine due to primary dysmenorrhoea. Prime aim of physician is to give initial relief to the patient, to reduce the intensity of pain and improve the quality of life.

In this research 60 cases of primary dysmenorrhoea are taken among adolescent girls. Among 60 cases, 30 cases are under treatment of Abroma radix Q and other 30 cases are given placebo in liquid form. All the cases are taken between the age group of 13 – 19 years and only adolescent girls are included. Males & girls with other medical illnesses are excluded in this research.

This study included patients with age group between 13 – 19 years. According to this study, out of 30 cases of Abroma radix Q, 24 cases were improved, 4 cases persist as same and 2 cases were aggravated. And out of 30 cases of placebo, 6 cases were improved, 16 cases persist as same and 8 cases were aggravated. It was known that Abroma radix Q is effective in treating Primary dysmenorrhoea.

CONCLUSION:

In Abroma radix Q group ,out of 30 cases, 24 cases were improved ,4 cases Persist as same before and after treatment and 2 cases got aggravated than before treatment and in placebo group out of 30 cases 6 cases were improved, 16

cases persist as same before and after treatment and 8 cases got aggravated.

So more number of cases were improved in *Abroma radix Q* group than placebo group so it is known that that *Abroma radix Q* is effective in treating Primary dysmenorrhoea.

REFERENCES:

1. Hiralal Konar. DC Dutta' Textbook of Gynecology. 7th edition, New Central BookAgency (P) Ltd, Kolkata, 2016, 146-147
2. Howkins & Bourne. Shaws Textbook Of Gynaecology. 16th Edition, Reed Elsevier India Private Limited, New Delhi, 2015, 471-473.
3. Richa Saxena. Bedside Obstetrics & Gynaecology. Second Edition, Jypee Brothers Medical Publishers (P) Ltd, New Delhi, 2014, 1013.
4. Willium Boericke, New Manual Of Homoeopathic Materia Medica & Repertory, Augmented Edition. Indian books & periodicals publishers New Delhi, December 2015, 1455.
5. Dr. Kedarnath Naik. Handbook of Homoeopathic Therapeutics On Obstetrics and Gynaecology. 2nd impression of first edition .B. Jain Publishers (P) LTD, Noida UP, 2016, 26
6. Henry N Guernsey. Key Notes to the Materia Medica, Reprint Edition: 2003. Mayur Jain Indian books & periodicals publishers New Delhi, 147.
7. Dr Shrikant Kulkarni, Gynaecology & Obsteric Therapeutics, B Jain Publishers (P) LTD, USA, 2008.
8. Kamal Kansal, The Handbook of Homoeopathic Mother Tinctures, Second Edition. Indian books & periodicals publishers New Delhi, Feb 2016, 1
9. <https://hpathy.com/materia-medica/Indian-homoeopathic-drugs>. November, 3, 2021
10. <https://homoemart.com/products/abroma-radix-homoeopathy-mother-tincture>, October 4, 2021
11. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). *Arthritis Care Res (Hoboken)*. 2011;63 Suppl 11:240-52. doi: 10.1002/acr.20543, Pubmed
12. Witt CM, Ludtke R, Willich SN. Homeopathic treatment of patients with dysmenorrhea: a prospective observational study with 2 years follow-up. *Arch Gynecol Obstet*. 2009;280(4):603-11. doi: 10.1007/s00404-009-0988-1. [PubMed] [CrossRef] [Google Scholar]
13. <https://homeoresearch.blogspot.com/2014/03/female-disorders-24.html?m=1>, Nov 4, 2021
14. <https://homeoresearch.com/indian-homoeopathic-medicines-for-women-diseases/Nov-5-2021>
15. Pernoll's, B. & *Handbook of Obstetrics and Gynecology 10th Edition*. Mc Graw Hill Medical Publishing Company. Page 465.
16. *Williams Gynecology-by John O. Schorge, MD, Joseph Schaffer, Mdetc*, McGraw-Hill Medical Publishing Company. Ch. 8 and 11.
17. Singh Yogesh kumar, Fundamental of research Methodology, New age International publisher, Daryaganj, New delhi. Page 323.
18. Kothari CR, Research Methodology, 2nd revised edition, New age International publisher, Daryaganj, New delhi. Page 414
19. Sakineh Mohammad Alizadeh Charandabi, Mohammad Hossein Biglu, and Khatereh Yousefi Rad, Iran Red Crescent Med J. 2016 Sep -Effect of Homeopathy on Pain Intensity and Quality Of Life of Students With Primary Dysmenorrhoea: A Randomized Controlled Trial.
20. Roger P. Smith, Dysmenorrhoea and Menorrhagia, A Clinician's Guide. First Edition, 2018, Springer Publishers.