



A Control Clinical Study to Evaluate Effect of *Trachyspermum ammi* extract on Primary Dysmenorrhoea

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ABSTRACT

Dysmenorrhoea is one of the most common gynaecological problem found in reproductive age group of woman. It tends to hamper a woman's day to day life during menstrual phase enough to drag her down from race. Primary dysmenorrhoea often symptomatically correlated with *Udavartini Yonivyapad* described in Ayurveda classics. Many effective herbal remedies have been used since long for the effective management of menstrual cramps and discomfort. In folk lore practice 'Yavani' – *Trachyspermum ammi* is used in western part of India for the same. Present study was aimed to evaluate and compare analgesic effect of *trachyspermum ammi* extract on Primary dysmenorrhoea. Where a group of 20 female subjects of reproductive age group with primary dysmenorrhoea were selected and categorized in 2 groups i.e. trial and control group. Trial group was administered with Aqueous Extract of *Trachyspermum ammi* for 3 days during menstruation whereas control group was administered with standard drug Mefenamic acid for the same duration. Evaluation was done before and after the intervention with parameters such as duration and intensity of pain, episodes of anorexia, nausea, etc. The result significantly indicates effectiveness of *Yavani* for the management of Primary dysmenorrhoea.

Keywords: *Dysmenorrhoea, Udavartini Yonivyapad, Ayurveda, Trachyspermum ammi*

Introduction

Women play important role for the development of the society. They contribute in both aspects - as a working woman and a home maker. But often some physiological problems drag her down from the race. Dysmenorrhoea is the one of the most common among them. Dysmenorrhoea is categorized into 2 types- Primary and secondary. Primary dysmenorrhoea indicates menstrual pain without any other pelvic pathology. Majority cases of dysmenorrhoea are fall under the primary dysmenorrhoea. A systematic review of studies in developing countries shows that approximate 50 % of adult women, and about 75 % of adolescents, experienced pain with menstruation. Approx. 5 - 20 % among them report severe

dysmenorrhea or menstrual cramps which prevent them from participating in their usual daily activities.¹ The prevalence is higher up to 5-15% additional in sensitive, intelligent and stressful working class women.^{2,3}

In Ayurvedic classical text *Yavani - Trachyspermum ammi* is mentioned having analgesic property.^{4,5,6,7} Since long *Yavani (Trachyspermum ammi)* is used for the treatment of dysmenorrhoea in Indian traditional practice. *Trachyspermum ammi* contains various phytochemical constituents mainly glycosides, phenolic compounds, saponins, carbohydrates, volatile oil (thymol, γ -terpinene, para-cymene, and α - and β -pinene) etc.⁸ The volatile oil mainly contain thymol which is known for having effective antispasmodic property. In regular medical practice *Trachyspermum ammi* primarily used for the ailments of gastrointestinal tract and respiratory tract. Hence this novel study was conducted to evaluate & compare efficacy of *Trachyspermum ammi* extract for the management of Primary Dysmenorrhoea in a systemic way.

Aim and Objective:

- To evaluate analgesic effect of *Trachyspermum ammi extract* on primary dysmenorrhoea
- To compare the efficacy of *Trachyspermum ammi extract* with standard medicine

Materials and Methods:

- **Subjects:** A group of 20 female subjects from reproductive age group diagnosed with Primary dysmenorrhoea were selected for the study.
- **Sample size:** 20
- **Study design:** Standard control clinical trial
- **Site for the study:** Prasuti Tantra & Streeroga department, , Khemdas Ayurved Hospital, Parul University, Vadodara

Study design:

A group of 20 female subjects diagnosed with primary dysmenorrhea were selected and randomly categorized into 2 groups Group A (Control Group) and Group B (Trial group).

Where all the subjects of control group were administered with standard drug Mefenamic acid 250 mg – three times per day orally whereas subjects of trial group were administered with aqueous extract of *Trachyspermum ammi* -5 ml with 100 ml water- three times per day orally. Intervention was given to all subjects of both group for first 3 days of menstruation.

Follow up treatment: for next 2 consecutive cycles.

Intervention

Group A – Mefenamic acid & Group B – *Yavani Arka*- Aqueous extract of *trachyspermum ammi* prepared as per Ayurved Formulary of India.⁹

Inclusion criteria:

- Subjects with age group of 14 to 45 years.
- Subjects having regular menstrual cycle.
- Subjects complaining of dysmenorrhoea at least two consecutive cycles.

Exclusion criteria

- Acute infection,
- Any pelvic pathology leading to dysmenorrhoea
- Acyclic and excessive bleeding more than 4 pads/day or more than 5 days.
- All secondary causes leading to dysmenorrhoea
- Intra Uterine Contraceptive Device induced painful bleeding

Result:

Table 1 – Comparison of mean -before and after treatment in group A (Control Group) & Group B (Trial Group)

Variables	Group	N	BT-MEAN	AT-MEAN	DIFF D	Paired t test			
						SD	SE	T	P
VAS	Group A	10	6.6000	0.5000	6.72636	0.87560	0.27689	22.031	0.000
	Group B	10	6.7000	0.4000	6.78283	0.67495	0.21344	29.517	0.000
Duration of Pain	Group A	10	3.2000	1.2000	2.33722	0.47140	0.14907	13.416	0.000
	Group B	10	3.0000	1.1000	2.30607	0.56765	0.17951	10.585	0.000
Anorexia	Group A	10	2.3000	2.1000	0.50162	0.42164	0.13333	1.500	0.168

	Group B	10	2.2000	1.0000	1.76428	0.78881	0.24944	4.811	0.001
Nausea	Group A	10	2.4000	2.1000	0.78283	0.67495	0.21344	1.406	0.193
	Group B	10	2.2000	1.0000	1.76428	0.78881	0.24944	4.811	0.001
Vomiting	Group A	10	2.0000	1.8000	0.65243	0.63246	0.20000	1.000	0.343
	Group B	10	2.2000	1.0000	1.76428	0.78881	0.24944	4.811	0.001

Table 2 – Comparison between the group A (Control Group) & Group B (Trial Group)

Variable	GROUP	N	AT-BT MEAN	SD	SE	T test	
						t	P
VAS	Group A	10	0.5000	0.70711	0.22361	0.318	0.799
	Group B	10	0.4000	0.69921	0.22111		
Duration of Pain	Group A	10	1.2000	0.42164	0.13333	0.600	0.232
	Group B	10	1.1000	0.31623	0.10000		
Anorexia	Group A	10	2.1000	0.73786	0.23333	4.714	0.002
	Group B	10	1.0000	0.00000	0.00000		
Nausea	Group A	10	2.1000	0.87560	0.27689	3.973	0.000
	Group B	10	1.0000	0.00000	0.00000		
Vomiting	Group A	10	1.8000	0.78881	0.24944	3.207	0.000
	Group B	10	1.0000	0.00000	0.00000		

In Table 1 statistical analysis reveals the mean score of Visual analogue scale- VAS heart rate before and after the treatment. In group A Mean score was 6.6000 before and after the treatment for 3 cycle it was reduced to 0.5000 with P value 0.000 (<0.001) showing highly significant result. & Group B Mean score was 6.7000 before and after the treatment for 3 cycle it was reduced to 0.4000 with P value 0.000 (<0.001) which shows highly significant result. In both group the variable duration of pain before and after treatment reveals significant result with P value 0.000 (<0.001). In group A variables - episode of anorexia,

nausea and vomiting dose not shows significant result with $P > 0.05$. In Trial group -Group B, P value of variables anorexia, nausea and vomiting shows highly significant result ($P < 0.001$).

In table 2 comparison between group A and B reveals highly significant result with variables of Anorexia, nausea and vomiting with P value 0.000 (< 0.001). Hence the result indicates that the treatment with aqueous extract of *Trachyspermum ammi* provides significant result on the variables such as VAS, duration of pain, nausea vomiting and anorexia.

Discussion:

Trachyspermum ammi (Yavani) is an herbal Ayurvedic drug which is primarily used for the management of various gastrointestinal and respiratory ailment since long. Previous studies indicates its carminative and antispasmodic properties.

Various studies has proven that *trachyspermum ammi* has pharmacological potency such as, antioxidant, antimicrobial¹⁰, antifungal¹¹, antispasmodic, antinociceptive, hypolipidemic, antihypertensive, diuretic, cytotoxic, antilithiasis, antifilarial, abortifacient, broncho-dilating, antitussive and anthelmintic efficacy.¹²

Trachyspermum ammi Seeds contains essential oil with 50% concentration of thymol as main ingredient. Thymol is a strong germicide, fungicide and anti-spasmodic.¹³ Thymol is volatile substance, hence aqueous extract was used as dosage form in present study. Aqueous extracts are easy and rapidly absorbable therefore with it can provide quick effect even with small quantity. Previous studies depicts that *trachyspermum ammi* contains various phytochemical contents such as carbohydrates, glycosides, saponins, phenolic compounds, volatile oil (thymol, γ -terpinene, para-cymene, and α - and β -pinene), protein, fat, fibre and mineral matter containing calcium, phosphorous, iron and nicotinic acid.^{14,15} The studies point out that *trachyspermum ammi* is a huge source of active components and which have huge variety of pharmacological effects; hence, it is encouraging to find its new therapeutic properties. Present study was intended to evaluate efficacy of aqueous extract of *Trachyspermum ammi* on primary dysmenorrhoea with compare to standard drug Mefenamic acid. The study indicates that *Trachyspermum ammi* can provide effective analgesic effect during the menstruation. Moreover it can provide better relief in associate gastrointestinal complaints such as nausea, vomiting & anorexia.

Trachyspermum ammi is easily available in market and its extract preparation method is feasible and cost effective. Present study on the primary dysmenorrhoea was aimed to provide an effective, feasible and economical Ayurvedic remedy, with better absorbability in smaller dosage form.

Conclusion: Administration of *trachyspermum ammi extract* in primary dysmenorrhoea reveals encouraging result on the menstrual pain. Furthermore it potentially reduce associate symptoms such as episode of nausea, vomiting & anorexia. Hence it can be an effective remedy for the management of primary dysmenorrhoea without adverse effect.

Further Studies: As the study provides positive outcome with small sample size, further study with increased sample size is continued.

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