

CLINICAL EVALUATION OF A PLANT VITEX NIGUNDO TREAT FORMULATION IN FEMALE PMS & DYSMENORRHOEA BY

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ABSTRACT: In a study group comprising 10 patients, 6 were suffering from dysmenorrhoea and 4 had premenstrual syndrome (PMS). We were applied **FEMISPAS at a dose of 1 Tablet Twice daily** before 2 days from Menstrual cycle then follow continued 3 months . At the end of the study period, all 6 patients with dysmenorrhoea were symptom-free and 4 patients with PMS were free from premenstrual symptoms. None of the patients experienced any side-effects. PMS and menstrual cramps are often referred to as primary dysmenorrhoea. This is a common gynaecological complaint for young girls and women of all menstruating age. The most common over-the-counter treatment is non-steroidal anti-inflammatory (NSAIDs), such as acetaminophen and ibuprofen or sodium naproxin commonly sold under various brand names. The failure rate of NSAID's is often 20-25%.

PLANT PROFILE :

Vitex negundo L. (Verbenaceae) is a hardy plant, flourishing mainly in the Indian subcontinent. All parts of the plant, from root to fruit and berry from possess a multitude of phytochemical secondary metabolites which impart the following isolated experiment an unprecedented variety of medicinal uses to the plant. It is interesting to note that a single plant species finds use for treatment of a wide spectrum of health disorders in traditional and folk medicine; some of which have been experimentally validated.

The plant is a component of a number of commercially available herbal formulations and has also shown potential as an effective biocontrol agent.

Employment of techniques such as cell and tissue culture would provide means of rapid propagation and conservation of the plant species and, from the point of view of phytochemistry, give scope for enhancement of the quality and quantity of the bioactive secondary metabolites occurring in the plant.

Phytochemical Constituents

Higher plants are warehouses of assorted bioactive constituents or phytochemicals which find ample use in the

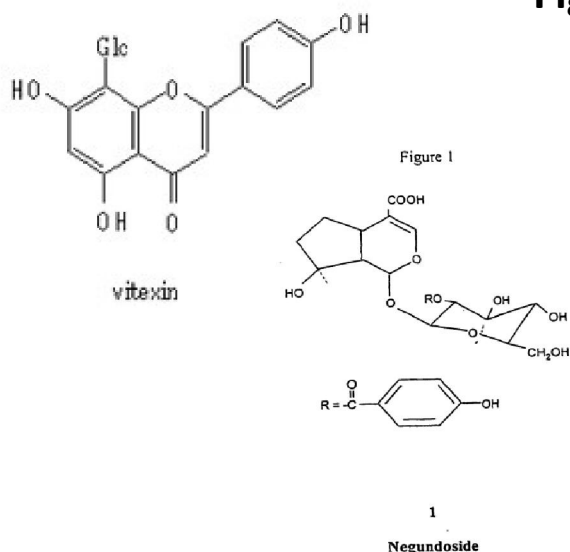
CLINICAL TRIAL

A total of 10 female worker find **Maxcure Nutravedic Ltd** between ages 23 to 35 who complained of primary dysmenorrhea were contacted 10 worker to participate and four were excluded secondary to a diagnosis of secondary dysmenorrhea.

10 were randomized 10 Of the 6 worker participants were excluded from the study analysis due to withdrawal or loss to follow-up in the Vitexin groups, 4 worker were excluded from the study analysis 2 workers were lost to follow-up and three were excluded because of discontinuation of medication or use of other pain relief drugs. In the placebo group, The final analysis was conducted on 10 participants.

There were no significant differences in any variable between reported in 93% of the workers. Both drugs effectively relieved menstrual pain compared with the placebo. show the outcomes at 2 and 3 months. There were statistically significant reductions

Fig- 1



The plant finds mention in the verses of the *Charaka Samhita* which is unarguably the most ancient and authoritative textbook of Indian Ayurveda. *Vn* has been designated as an anthelmintic (verse *Su:4-15*) and is prescribed as a vermifuge (verse *Vi:7-21*) in the exposition on the *Charaka Samhita* by Sharma . Other Ayurvedic uses of *Vn* are described by Tirtha also effective in treatment of venereal diseases and other syphilitic skin disorders. A leaf decoction with *Aloe vera* is used in cases fever with heaviness of head and dull hearing.

A tincture of the root-bark provides relief from irritability of bladder and rheumatism. Jadhav and Bhutani report the Ayurvedic use of *Vn* in dysmenorrhea.

Patkar refers to the formulations described in *Anubhoga Vaidya Bhaga*, a compendium of formulations in cosmetology, in outlining the use of *Vn* leaves along with those of *Vallerian walchhi* in a notable rejuvenation treatment known as *Kayakalpa*.

PHYTOCHEMICAL CONSTITUENCY

In decade study in vitex nigundo are there more available phyto constituency there are lot in **FEMISPAS** hydroxyurs-en-oic acid]; n-hentriacontanol; β- sitosterol; hydroxybenzoic acid protocatechuic acid; oleanolic acid; flavonoids **agnuside**; casticin; vitamin-C; nishindine; gluco-nonitol; phydroxybenzoic

Table 3 shows the comparison of self-care behaviour scores between two groups before and one and two menstrual period after intervention. There was a significant difference in self-care behaviour

Between evidence-based education versus control group at the second menstrual period after intervention. The mean of dysmenorrhoea

In case the evidence based education group decreased 0.7 score in the first menstrual after intervention and 2 score in the second menstrual after intervention. (Fig1.)

Table1: Clinical Features

SYMPTOMS	FEMALE	%
Pre menstrual syndrome	10	90
Dysmenorrhoea	10	90
With Vertigo	1	60
With Nausea	1	30
With Vomit	2	40
With Backache	1	70
With Breast tenderness	1	40
With Migraine	2	30

Table 2: Effect of FEMISPAS

SYMPTOMS	FEMALE	%
Pre menstrual syndrome	10	90
Dysmenorrhoea	10	90
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With Backache	1	70
With Breast tenderness	1	40
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INTRODUCTION-:

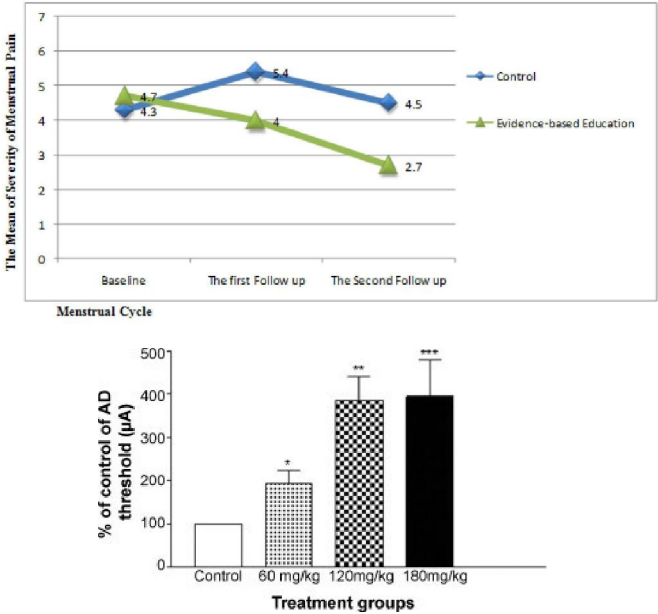
Menstrual disorders such as dysmenorrhoea and liable premenstrual syndrome are most commonly encountered in a gynaecologist's outpatient practice. In the adolescents, the problem of dysmenorrhoea is rather frequent, its incidence being between 20 to 40 percent Dysmenorrhoea was one here to fore poorly understood, its way of treatment regimens comprising psychotherapy, exercise, vitamins or surgery. However, in the last five years, research has brought about a better understanding of its path physiology, thereby enabling the physician to rationally evaluate and properly treat this disorder. Primary dysmenorrhoea without day comprises painful menstruation without significant one region pelvic pathology.

Typically, the onset of pain begins a few hours prior to or coincident with the onset of menstruation and may last from a few hours to 24 hours, occasionally persisting up to 3 days. Though its pattern is variable, it is usually characterized by sharp, colicky, supra pubic pain with radiation to the lower back and thighs. Nausea, vomiting, diarrhoea, irritability, or headaches may accompany these episodes. By research In the treatment of dysmenorrhoea and PMS, a wide spectrum of drugs is available; however, the majority of them are hormones that are known to possess untoward side-effects. Hence, the efficacy of **FEMISPAS, a non-hormonal herbal medication** was evaluated for its effect on the patho dysmenorrhoea and PMS. The composition of earlier **FEMISPAS comprises several herbal ingredients** that have a pronounced action on the female genital system. Some of the important ingredients are: Vitex Nigundo that has been proven effective in dysmenorrhoea and possesses an oestrogen-like activity that helps in healing of the inflamed endometrial during menstruation, Aloe vera that improves fertility by regulating uterine hormones and is also effective in treating menstrual dysfunction. Valerian walchii that is a known uterine stimulant & Anxiety compressor,



MATERIAL AND METHODS

The study group comprised 10 patients, of whom 6 patients had a history of dysmenorrhoea and 4 patients groups by premenstrual symptoms. The patients were diagnosed as suffering from premenstrual syndrome if their symptoms persisted for at least 3 consecutive months, if they were related to regular menstruation and if the severity disrupted their normal function. Patients who were diagnosed to be suffering from neoplasm's, malignancy or other systemic illness associated with the above disorders were excluded from the study. All the patients were administered **FEMISPAS at a dose of 1 Tablet** twice daily before 2 days of menstrual cycle for 5 days then follow up 3 months.



RESULTS & DISCUSSION

Though many factors have been implicated in the pathophysiology of Dysmenorrhea, a consistent finding appears to be an increase in myometrial activity. The aim of medical therapy in severe dysmenorrhea is to reduce uterine activity. Non-addictive analgesics are often prescribed in the treatment of dysmenorrhea. During menstruation, many women experience gastrointestinal upsets for which they are prescribed analgesics and anti-inflammatory drugs which more often than not produce gastrointestinal side-effects, apart from headache, dizziness, drowsiness and blurred vision. Other modes of treatment include antispasmodics, analgesics and amphetamine containing compound. The role of hormones (oestrogen-progesterone or contraceptive pills) as a prolonged therapeutic measure for dysmenorrhoea is itself debatable. If there are additional features, such as menorrhagia or a desire to avoid pregnancy on the part of the patient, this is perhaps justifiable. The relative benefits of symptomatic relief, especially if time has to be taken off work, has to be balanced against any potential or actual side-effects of the treatment prescribed. There may be no pathognomonic symptoms, laboratory tests, objective or physical findings present to confirm the diagnosis of PMS, which solely depends on the patient's subjective report of symptoms. A retrospective report or recall of these symptoms is insufficient, because several changes, both symptomatic and behavioural, can be attributed to menstruation, which is a repetitive occurrence in a woman's reproductive phase. Previous studies with **FEMISPAS** have shown that it has a beneficial effect in the treatment of menstrual disorders. In this study, it was observed that **FEMISPAS** taken about reduction in the symptoms of dysmenorrhoea and PMS beginning from the menstrual cycle following the commencement of treatment. Patients suffering from dysmenorrhoea reported a reduction in lower abdominal and back pain after one month of therapy and all of them were totally symptom-free after 2 to 3 months,

There is a wide range of strategies in management of primary dysmenorrhoea, but the midwives should be aware of which therapies have evidence-based support, carry a low side effect burden, and the least potential to interact with other medications. The review of trials found some evidence that NSAIDs are an effective treatment for dysmenorrhoea, though women using them need to be aware of the significant risk of adverse effects. Many dietary supplements and herbs have been proposed as being effective for primary dysmenorrhoea, including **FEMISPAS** shown to be effective treatments and there is insufficient evidence

CONCLUSION

From the above study, it is evident that **FEMISPAS** was totally effective in all patients with dysmenorrhoea and in 80% of cases with PMS. None of them experienced any adverse effects. It can be concluded that **FEMISPAS** can be used as a safe and cost-effective drug in the treatment of dysmenorrhoea and PMS.

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