

Management of uterine fibroid with Siddha herbomineral formulation *Nandhi mezhugu* - A Case report

Case Report

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Abstract

The Siddha system of medicine finds a significant place among the traditional health care systems worldwide. This system offers tremendous clinical outcomes in treating certain disease conditions that are complicated and surgically intervened by contemporary medical systems. Fibroid uterus, which is a pressing global concern, can be well managed with Siddha medicines. The Siddha classical text *Siddha vaithya thirattu* indicates that the classical herbomineral Siddha formulation - *Nandhi Mezhugu* for the management of *Karuppai vippuruthi* (Uterine fibroid). The present case report presents a 48-year-old female with complaints of excessive bleeding in menstrual time (6 to 7 pads/day), dysmenorrhea, feeling of fullness in lower abdomen, frequent urination, low back pain, pain in upper and lower limbs and constipation. She visited the Reproductive and Child Health OPD, Siddha Central Research Institute, Chennai-106, in the month of December 2017. Her ultra-sonogram (USG)-abdomen revealed the confirmatory diagnosis of Uterine fibroid. The patient was treated with Siddha traditional medicine *Nandhi mezhugu* twice a day with palm jiggery. The treatment consisted of 7 days and a gap of 7 days for a period of 6 Months. During treatment, she was showing signs of improvement in her symptoms of menstrual flow and pelvic pain normalized after 4 months. The follow up USG abdomen revealed the successful outcome with absence of fibroid. The present case report supports the use of traditional herbal medicines in the management of Uterine fibroid.

Keywords: Fibroid uterus, Traditional medicine, Natural medicine, Non-surgical method, Nonmalignant uterine tumor, AYUSH.

Introduction

Uterine fibroid is a common problem in about 30% of women in child bearing age between 30-45 years. (1) They are benign tumors derived from smooth muscle tissue usually called as myomas, leiomyomas and fibromas. Based on their location, they are classified as myometrial, Submucosal, subserosal and Pedunculated fibroids. Myometrial fibroids grow along the uterine wall. Sub mucosal fibroids develop in the interior surface of the uterus. Sub serosal fibroids grow on the uterine wall. Pedunculated fibroids are generally seen growing outside of the uterine wall by a stalk-like growth called a peduncle. (1,2)

Fibroids may be of varying size, single or multiple and can be detected through Trans-vaginal ultrasound technology. The symptoms of fibroids are low back pain, dysmenorrhea, excessive menstrual bleeding and pelvic pain, feeling full in the lower

abdomen, frequent urination, pain during sex, infertility etc.(3) Although the exact cause of uterine fibroids are unknown, women who are overweight for their height or if their menarche began before the age of ten are at greater risk. Since it is presumed that their growth depends on estrogens. Fibroids are rarely found before puberty and they generally cease to grow after menopause due to hypoestrogenic conditions. (4). Due to the local pressure effects of fibroids, it ranks as a major reason for approximately one-third of all hysterectomies or about 20,000 Hysterectomies per year. (5,6) In Siddha system of medicine, the symptoms of *Karppa Vippuruthi* as mentioned in classical Siddha text *Yugi vaithya chintamani*, Such as abdominal distension, lower abdominal pain, weight loss, proliferation of uterine tissue with blood clots which gives a mass like structure producing symptoms similar to rolling of foetus during pregnancy, constipation, headache and ulceration of the uterus closely resemble with those of fibroid uterus etc. (7) Though conventional system of medicine usually offers surgical interventions like myomectomy and hysterectomy, Siddha system offers a wide array of herbal and herbomineral formulations such as *Rasa ghandi mezhugu*, *Chittira moola kuligai*, *Vankumari legium*, *Navamani Chendooram*, *Lavana gunathy Thyalam* etc that are non-surgical and effective clinically. But only

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very few scientific documentations of these ancient medicines are currently available. In this scenario, *Nandhi Mezhugu*, a herbo mineral formulation is one such common cost-effective Siddha medicare for *Karupai Vippuruthi*.

Apart from myomectomy and hysterectomy, a non-surgical option of uterine artery embolization (UAE) is available recently. But the affordability and accessibility of this procedure for a common Indian woman is questionable due to its high cost. Therefore, it is high time to explore the possibility of management of fibroids (a benign tumour) using traditional medicines. With this background, the present case study was carried out with a *Siddha* Herbomineral formulation *Nandhi mezhugu* as indicated in *Siddha vaithya thirattu* a medicinal compendium of *Siddha* and the results were noteworthy. (8)

Case History

The present case is a 48-year-old female with complaints of excessive bleeding in menstrual time-6 to 7 pads/day, Dysmenorrhea, feeling of fullness in lower abdomen, frequent urination, low back pain, Pain in upper and lower limbs and constipation She visited the Reproductive and Child Health OPD, Siddha Central Research Institute, Chennai-106, in the month of December 2017. History revealed that she was suffering from complaints of uterine fibroid since past one year. Abdominal examination revealed general tympany with dull note heard on all four quadrants and was bloated. Her other systemic examinations were normal. Her ultra sonogram (USG)-abdomen revealed the confirmatory diagnosis of uterine fibroid. On history taking there was no relevant family history regarding her medical condition. She reported to have the habit of increased carbohydrate and fats in her diet. On her visit to RCH OPD, SCRI, she reported her last menstrual period (LMP) as on 09- 11-2017. The impression in USG Abdomen was presented with anterior wall fibroid which was taken on 12/12/2017. On physical examination her *Nadi* was found to be *Azhal iyyam* her weight was 62kg, pulse rate 76 beats/minute and BP was 120/80mmHg. On pelvic examination her uterus felt larger than normal.

Siddha Management

The trial drug *Nandhi mezhugu* is indicated for *karupai vipurudhi* (uterine fibroid) in Siddha text *Siddha vaithya thirattu*. The drug *Nandhi mezhugu* is a herbomineral formulation with 62 ingredients comprising of 35 herbs, 5 animal sources and 22 mineral ingredients. The dosage as per textual evidence is 250 mg twice a day for 7 days and a gap of 7 days as per the literature for a period of 6 months. During treatment, she was showing signs of improvement in her symptoms of menstrual flow and pelvic pain normalized after 4 months.

Results and Discussion

The uniqueness of this case report is to document the first-line clinical evidence on the drug *Nandhi*

mezhugu for the effective management of fibroids to improve the quality of life without surgical intervention. The present case had a chief complaints of dysmenorrhoea, excessive menstrual bleeding and the treatment goals were aimed at correcting the complaints and symptoms of fibroid. The treatment was continued for 6 months and the patient was followed up once in two weeks. There were no specific complaints and also no adverse reaction observed. As the patient was closer to menopause, she had other pre-menopausal complaint such as altered mood and sleep hot flashes. After treatment period, there was significant reduction of excessive menstrual bleeding (6-7pads/day) reduced to normal flow (2-3pads/day). The other complaints of dysmenorrhea, feeling of fullness in lower abdomen, frequent urination, low back pain, pain in upper and lower limbs and constipation also reduced remarkably. There was no reported adverse reaction. The results of prognosis before and after treatment have been graded based on assessment tool and subjective cross-examination and tabulated as below (Table-1). The impression of USG-Abdomen revealed the good prognosis of the treatment (Table-2).

Table 1: Results of symptomatic improvements before and after treatment

S.No	Parameters of Fibroid	Before treatment (Day-1)	After treatment (3 months)	After treatment (6 months)
1	Excessive bleedind	6-7 pads/day	4 pads/day	3-4 pads /day
2	Pelvic pain	VAS-8	VAS-2	No pain
3	Abdominal bloating	Present	No bloating	No bloating
4	Weight	64Kg	62 Kg	Maintained
5	Low back pain	VAS-8	VAS-3	No pain
6	Pain in upper and lower limbs	VAS-8	VAS-3	No pain
7	Frequent urination	Present	Reduced	Normal
8	Constipation	Present	Absent	No constipation

Table 2 : USG findings Before and After treatment

Parameters	Before treatment (13.12.2017)	After treatment (19.08.2018)
Fibroid Size (cm)	1.4x1.6 cm in	No fibroid
Uterus size (cm)	8.4x4.2x5.1	7.6x4.3x4.6

The Siddha pharmacology lies its basis on humoral theory in which any alteration in Tri- humours *Vatham*, *Pitham* and *Kabam* would result in diseases and exhibits specific symptoms according to the degree of its variation. The risk factors like obesity, high fat diet, hyper estrogenic state, increased body mass index, poly cystic ovarian disease and the involvement of various growth factor is very much suggestive of association of a *Kabam* (Fluid component) and *Amam* (buildup of toxic by-products of digestion). This state

blocks the energy channels of Pitham which is responsible for metabolic activities and balance of hormones. Hence the channels involved with steroidogenesis, folliculogenesis which are responsible for normal uterine and ovarian function are altered resulting in the abnormal growth in Uterus. Alteration in Kabam and Pitham inturn affects vatham as all trihumours are interconnected. The altered vatham affects the dasa vayus especially abana vayu(down regulating force) causing excessive bleeding, bloating, constipation, headache and pelvic pains which are the predominant symptoms of Uterine fibroid.(9) The given traditional herbomineral compound has been designed in such a way to target the altered humours which has been validated through the trial results.

Moreover, the trial drug *Nandhi mezhugu* has 53 ingredients which are a combination of herbal and Herbo mineral compounds and is clinically effective for various ailments including cancers. Though it has no clinical study documented till now, the safety of this formulation has been established on scientific grounds. A preclinical safety study by Lakshmi Kantham T et al 2017 showed that in sub-acute toxicity study (56 days) and in sub-chronic toxicity study (180 days) the high dose recovery and recovery control groups showed no treatment-related abnormalities at the high dose levels such as 90 and 110 mg/kg body weight in rats respectively.(10) Biochemical, hematological parameters, gross pathology and histopathology of the rats were also normal post treatment. ICP-OES detection of heavy metals in animal tissue samples in sub-chronic toxicity study (high dose group) were analyzed and found to have heavy metals within permissible limits. Similarly, sub-acute and sub-chronic toxicity studies showed no mortality and no treatment-related toxicity signs. Hence, the scientific validation of the safety of *Nandhi mezhugu* has also been proven by the toxicity studies. (10)

Conclusion

The Siddha system of medicine contains numerous collections of herbal / Herbo mineral formulations. These formulations are found to be time tested but require scientific evidence for its lucidity in this contemporary world. *Nandhi mezhugu*, certainly prove as a ray of hope for the treatment fibroid. Though it is a widely used Siddha formulation for chronic ailments and for the treatment of benign and malignant tumors, the present case study has validated its

effectiveness in the management of uterine fibroids. The results of the present study necessitate a large-scale clinical trial so that these formulations can have global attention. This may aid cost effective and safer therapeutic measure for the treatment of uterine fibroids.

Ethical approval

All ethical considerations were followed and informed consent was obtained from the patient. Case report was prepared according to CARE guidelines.

Conflict of interest

There is no conflict of interest.

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