



## Clinical Trial: Open Access

## Evaluation of efficacy of Ayurvedic formulation Tulha tablets in patients suffering from menstrual irregularities

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### Abstract

The objective of the study was to evaluate efficacy of non-hormonal Ayurveda formulations (tulha tablets) in females suffering from irregular menstrual cycles. The study was an open label, non-comparative, single centre, retrospective, interventional clinical study. A total of 180 female patients between the age group of 20-45 years having complaints of irregular menstrual cycles were recruited in the study. Participants were advised to take proprietary marketed product, *viz.*, Tulha tablets containing ingredients like Hing, Shatavari, Shatpushpa, Kumari, *etc.*, in a dose of 2 tablets twice daily with water for 3 months. Monthly follow up of participants was done to assess frequency of menstrual cycle, no of days of bleeding, quantity of bleeding and associated symptoms. Participants having any serious abnormalities were excluded from the study.

Female participants of average age  $28.50 \pm 6.56$  complaining of irregular menstrual cycle over a period of  $5.50 \pm 2.80$  months were recruited. A total of 130/180 participants reported regular menstrual cycles at the end of 3 months. The frequency of the menstrual cycle improved from  $53.24 \pm 15.50$  days to  $33.23 \pm 8.24$  days at the end of 3 months. The No. of days of bleeding increased from  $1.23 \pm 0.344$  at baseline to  $2.82 \pm 1.19$  at the end of three months ( $p < 0.05$ ). Similarly, the quantity of bleeding also showed significant increase over the period of 3 months. None of the participants showed worsening in their condition. No adverse drug reaction was observed and the study products were well tolerated. Ayurvedic tablets (Tulha) were found to be effective in regularising menstrual cycles, improving overall menstrual flow. The product was also found to be safe without causing any adverse effects.

### 1. Introduction

Menstruation is an important indicator of reproductive health of women as well as pregnancy. Menstrual problems like delayed menstruation, scanty menstruation, irregular cycles are commonly observed in females in their reproductive age. According to scientific studies in India, prevalence of irregular menstruation is 35.7% in age group of 21-25 years and later it is 23.3%<sup>2</sup>. Regular menstrual cycle (counting from the first day of one menstrual period to the first day of the next cycle) is 21 to 35 days and lasts from 3 to 7 days with a volume of 5-80 ml.

Delayed periods is the most common life style disorder in women of reproductive age, resulting from stress, obesity, smoking, environmental factors. This results in adverse effects on multiple organ systems and if not treated on time, may result in PCOD/PCOS, anovulation, abnormal uterine bleeding and infertility. A variety of hormones affect the menstrual cycle. Irregular menstrual cycle is a major symptom of anovulation, hormonal imbalance and infertility. The irregularity in periods and hormonal imbalance can also lead to various chronic diseases like infertility, heart diseases and various

lifestyle disorders. Fertility problems can be experienced by women with delayed or irregular periods as irregular periods can also result in irregular or abnormal ovulation or anovulation and hormonal imbalance.

In ayurveda, Arthavkshaya is a condition described in texts like Sushruta Samhita which is characterised by delayed periods, scanty bleeding and sometimes associated with vaginal pain. "Artava" here means menstrual blood and "Kshaya" means decrease or imbalance. Management of this condition can be done using herbs, herbomineral combinations both internally as well as through administration in the vaginal route or medicated Basti and other Panchakarma treatment. Herbs like Hing (*Ferula assafoetida* : family : Umbelliferae or Apiaceae), Shatavari (*Asparagus racemosus* : family: Asparagaceae), Shatpushpa (*Pimpinella anisum*: family: Apiaceae), Kumari (*Aloe vera*: family: Asphodelaceae) are known to stimulate menstrual cycles and promote menstrual bleeding, are generally used for this purpose. Tulha Ayurvedic tablets contain these ingredients along with others and is recommended in cases of irregular and scanty menstrual cycles. The present study is a retrospective analysis of the in-clinic use of Tulha tablets in patients suffering from irregular and scanty menstrual cycles.

The current in-clinic response study is aimed to evaluate the therapeutic effect of Tulha Ayurvedic tablets in patients suffering from delayed menstrual cycle. Clinical assessment of frequency of menstrual cycle along with its duration and quantity of menstrual

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flow were evaluated from a population treated with Tulha tablets for a period of 3 months.

## 2. Materials and Methods

### 2.1 Study design

Retrospective, open labelled, single centric, non-comparative clinical study.

### 2.2 Sample size

A total of 180 participants were reviewed who had been prescribed Tulha tablets for delayed menstrual cycle for a period of 3 months.

### 2.3 Study site

Patients visiting OPD of Dhanwantari Ayurveda Centre, Pallakad,

Kerala, India, who were recommended Tulha tablets were considered for analysis in this study.

### 2.4 Details of study product

#### 2.4.1 Name of the product

Tulha Ayurvedic tablets manufactured and marketed by Gynoveda Pvt. Ltd as Ayurvedic proprietary medicine.

#### 2.4.2 Key ingredients

Shatavari, Shatpushpa, Kumari, detailed composition are in Table 1.

#### 2.4.3 Recommended dosage

2 tablets two times a day with warm water after meals for a period of 3 months (90 Days).

**Table 1: Details of ingredients of Tulha tablets along with their properties and action as per Ayurveda**

Ingredient	Rasa (taste)	Guna (properties)	Virya (potency)	Vipak (Post digestion effect)	Karma (Action)
Kumari	Katu	Alua (Aqueous extract-Usna, Ruksha)	Tikshna	Tikta	Artavajanana, Dipana, Pachana, Bhedana
Shatavari	Madhura, Tikta Madhu	Guru, Snigdha	Sheeta	Madhu	Vatahara, Rasayana, Artavajanana.
Shatapuspa	Katu, Tikta Tikta	Laghu, Tikta	Ushna	Katu	Vatahara, Pittaagnivardhini, Dipana, Artavajanana
Haritaki	Madhur, Amla, Katu, Tikta, Kashay	Ruksha	Ushna	Madhu	Vatahar, Dipan, Medhya
Dashmool	-	-	-	-	Tridoshghna
Devdaru	Tikta Katu	Laghu	Ushna	Katu	Vatahara, Asrajita
Kulatha	Kashaya	Ruksha, Laghu	Ushna	Katu	Vata-Kapha Hara, Vidhahi
Krushna Jeera	Katu	Ruksha	Ushna	Katu	Garbhashay Vishudhi, Vatanuloman
Ulatkambal	Katu Tikta	Laghu Ruksha	Ushna	Katu	Yoni Vyapad and Rajodoshhara
Gajar	Katu Tikta	Tikshna, Ruksha, Ushna	Ushna	Katu	Vidahi, Pittakar
Karpasa	Katu, Kashaya	Laghu, Tikshana	Ushna	Katu	Artavajanana, Dipana, Pachana, Bhedana
Methi	Katu Tikta	Laghu Snigdha	Ushna	Katu	Vatahara, Rakta Pitta prakopan
Rasona	Amla Varjita Pancha Rasa	Snigdha, Guru, Tikshna, Sara	Ushna	Katu	Vata-kaphahara, Vrisya, Balya, Artavapravartak, Dipana
Jyotismati	Katu, Tikta	Tikshna	Ushna	Katu	Artavajanana, Vatahara, Vedanast Hapak Dipana
Manjistha	Tikta Kashaya Madhu	Guru Rooksha	Ushna	Katu	Rakta Sanshodhan
Ashwagandha	Katu Tikta Kashay	Singha Laghu	Ushna	Katu	Yoni Rog Hara, Vandhyatva Hara, Bruhana, Garbhakar
Gokshura	Madhu	Guru, Snigdha	Sheeta	Madhur	Tridosh Hara, Basti Shodhan
Sunthi	Katu	Guru, Ruksha, Tikshna	Ushna	Madhu	Kaphagna Dipana,
Eranda	Madhura	Ushna, Guru	Ushna	Madhu	Pitta-Rakta Prakopak, Basti Rog Hara
Pippali	Katu	Laghu, Tikshna	Ushna	Madhu	Vrushya, Tridoshhara, Dipana, Pachna
Hingu	Katu	Tikshna	Ushna	Katu	Kapha-Vatashamaka, Artavajanana, Dipana, Pachana

## 2.5 Inclusion criteria

Patients between the age group of 18-40 years complaining of delayed menstrual cycles with scanty or normal menstrual flow were selected for the study.

## 2.6 Exclusion criteria

Patients who have been diagnosed with PCOD, hyper or hypothyroidism, hyperprolactinemia, low AMH levels were excluded from the study. Pregnant and lactating females were also excluded from the study. Patients in menopausal transition were excluded from the study. Patients complaining of heavy menstrual bleeding and early menstrual cycles were also excluded from the study. Patients suffering from any acute or chronic medical or surgical condition requiring regular and continuous medical care and management were excluded from the study. Patients who were non compliant to the study requirement (like not taking regular medicines) were also excluded from this evaluation.

## 3. Results

### 3.1 Baseline demography

The average age of patients in the study was  $28.50 \pm 6.56$  (range 18 to 40 years). The mean weight of participants at baseline was  $58.34 \pm 8.29$  with an BMI of  $23.65 \pm 3.49$ . A total of 98 participants (54.44%) were married while 82 participants (45.55%) were unmarried. 65 participants (66.32%) of the married participants had children while 33 (33.67%) did not have any gestational history. Of the 180 patients in the study the average time since they had a history of delayed menstrual cycle was  $5.50 \pm 2.80$  months. A total of 34 patients had a history of PCOD while 66 patients had taken treatment for delayed menstrual cycle.

**Table 2: Baseline demography**

Parameter	Values
Average age	$28.50 \pm 6.56$ (range 18 to 40 years)
Average weight	$58.34 \pm 8.29$ in years
Average BMI	$23.65 \pm 3.49$ weight in kg/ht in m <sup>2</sup>
Married participants	98 (54.44%) n
Unmarried participants	82 (45.55%) n
Participants with gestation	65 (66.32%) n
Average time since delayed menstrual cycle	$5.50 \pm 2.80$ months
History of PCOD	34 (18.88%) n
History of taking treatment for delayed menstrual cycle	66 (36.66%) n

### 3.2 Assessment of effect of Tulha tablets on frequency of menstrual cycle

At baseline, *i.e.*, initial visit the mean frequency of menstrual cycle over the last 3 months was  $53.24 \pm 15.50$ . At the end of the study, *i.e.*, after 90 days the frequency is observed to be  $33.23 \pm 8.24$ . The change in frequency of menstrual cycle was found to be statistically

significant from baseline to the end of the study. A total of 130 subjects (72.22%) of 180 subjects achieved normalization of their menstrual cycle at the end of 3 months. It was also observed that 40 subjects (22.22%) had experienced a menstrual cycle after a gap of 4 months while 48 subjects (26.66%) had a menstrual cycle after a gap of 3 months. 42 subjects (23.33%) had a menstrual cycle after 2 months in the study. Table 3 provides details of frequency of menstrual cycle.

**Table 3: Assessment of frequency of menstrual cycle from baseline to 90 days**

Frequency at baseline in days	Frequency at the end of 90 days
$53.24 \pm 15.50$	$33.23 \pm 8.24$
<i>p</i> value from baseline	<i>p</i> <0.01 (highly significant)
No. of participants achieving normal menstrual cycle at 90 days	130 (72.22%)
No. of participants achieving menstruation after 4 months	40 (22.22%)
No. of participants achieving menstruation after 3 months	48 (26.66%)

### 4.3 Assessment of effect of Tulha tablets on duration of menstrual cycle

The average duration of menstrual cycle at baseline visit was  $1.23 \pm 0.34$  days which increased to  $2.82 \pm 1.19$  days at the end of 3 months of the study. This increase in the duration of menstrual flow was observed in 145 subjects while 35 subjects did not show any increase in the menstrual flow. The increase in menstrual flow was found to be statistically significant (*p*<0.05) from baseline to the end of the study (3 months). Table 4 provides details of the duration of the menstrual cycle.

**Table 4: Assessment of duration of menstrual flow per cycle: baseline to 90 days**

Average duration at baseline in days	Average duration at the end of 90 days
$1.23 \pm 0.34$	$2.82 \pm 1.19$
<i>p</i> value from baseline	<i>p</i> <0.05 (significant)
No. of participants achieving increase in menstrual flow	145 (80.55%)

### 3.4 Assessment of effect of Tulha tablets on quantity of menstrual cycle

The average quantity of bleeding per cycle at the baseline visit was  $1.09 \pm 0.34$ , which increased to  $1.95 \pm 0.24$  at the end of 90 days. There was a statistically significant difference as compared to baseline visit. The average number of pad (s) changed per day was calculated by dividing the total number of pads used with the number of bleeding days per cycle. The amount of menstrual bleeding was then graded, *viz.*, 0 = spotting (no pad used), 1 = scanty (up to 1 pad used/day), 2 = moderate (for 1-2 pads used/day) and 3 = excessive (for 2-4 pads used/day). Table 5 provides details.

**Table 5: Assessment of quantity of menstrual bleeding baseline to 90 days**

Average quantity at baseline in days	Average quantity at the end of 90 days
1.09 ± 0.34	1.95 ± 0.24
<i>p</i> value from baseline	<i>p</i> <0.05 (Significant)

### 3.5 Assessment of adverse effects

None of the patients experienced any adverse drug reaction due to the consumption of tulha tablets in a dose of 2 tablets twice daily over a period of 3 months. The vitals assessment of pulse, respiration rate, blood pressure and temperature also did not show any significant difference and the levels were within normal range throughout the study period.

## 4. Discussion

Ayurveda descriptions of uterine and menstrual pathology are very scientific and relevant in the current situations as well. The description of Artava-kshaya in Ayurveda, can be correlated with delayed periods, which has been described as deficiency or loss of artava, artava does not appear in time or is delayed, is scanty and does not last for three days. Pain in vagina also can be seen. As per ayurveda this Artavakshaya can be due to obstructive (margavarodha) pathology or due to degenerative (dhatukshaya) pathology. While the obstructive pathology is commonly observed and is attributed to Kapha dosha in Ayurveda the degenerative pathology is usually related to Vata dosha. The former is usually observed in clinical practice where conditions like obesity, lifestyle, sedentary lifestyle, food habits along with the use of contraceptives leads to obstruction

of natural flow of menstrual blood leading to delayed and scanty cycles.

Management of this delayed menstrual cycle and scanty menstrual cycle involves the use of medications in the form of herbs and methods which are primarily Ushna, Tikshna and Laghu. These quality attributes help to remove the obstructive pathology caused due to Kapha, Meda and Kleda and thus bring about normal menstrual flow. These herbs also are mentioned to be Artavajanana/ Artavavridhikar means those which stimulate or promote menstruation. Herbs like Hing, Jyotismati, Erand, *etc.*, have these properties in abundance.

Tulha tablets as Ayurvedic proprietary medicine is a combination of ingredients like Kumari, Shatavari, Shatapuspa, Hinga, *etc.*, which possess these properties and action. Tulha tablets are a combination of herbs that are Agneya (hot in potency) and Artavavridhikar dravyas along with Grabhashay Shodhak dravyas (herbs that help to cleanse the uterus). Ayurveda explains these herbs as Ratkasodhak (blood purifiers) and Sothahar (anti-inflammatory). A detailed review of all the ingredients of Tulha tablets is provided in Table 1.

## 5. Conclusion

The present study concludes that Tulha tablets are effective in the management of delayed menstrual cycles. Tulha tablets not only help to regularize the menstrual cycle but also help to increase menstrual flow duration and quantity. Tulha tablets are safe and do not produce any adverse effects. Controlled, randomized studies on larger populations need to be carried out to establish the efficacy.

## Conflict of interest

The authors declare no conflicts of interest relevant to this article.

## Citation

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