# Experiences with Dologran tablets in the treatment of headache with special reference to migraine

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## Abstract

Shirashool can be clinically correlated with the Migraine; which is commonly occurring vascular headache. It presents cardinal symptom of pain on one half of the head. Factors which trigger the disease include weather, missing a meal, stress, alcohol and certain types of food items. About 50% of women reported menstrual periods as a significant trigger. Additionally, allergic reactions, exposure to loud noises or certain odors, smoking, or long exposures to computer screens/televisions could lead to Migraine attacks. Present Clinical study of Dologran Tablets with respect to Shirashool (Migraine) was conducted on 30 patients irrespective of sex in the age group of 18 to 60 yrs. All the patients presented with classical features of Shriashool. The present study also includes a causation of the disease and clinical conditions considered for differential diagnosis of Shirashool found in classical texts. Dologran Tablet was administered with warm water for 30 days. Appropriate diet was advised to all the patients. Follow up was planned every 15 days till 1 month to assess if there is any recurrence of symptoms. Highly significant results were observed and improvement in cardinal symptoms of Shirashool was observed. Dologran Tablets appears to provide good clinical improvement in patients with Shirashool.

**Keywords:** Ayurved, Dologran, Migraine, Shirashool, Ardhavabhedaka.

## 1. Introduction

Ardhavabhedaka is one of the Shiroroga (disorder of head) which can be correlated with migraine having symptoms like paroxysmal unilateral (half cranial) headache sometime associated with vertigo, nausea, photophobia and phonophobia [1]. As per Acharya Sushruta Ardhavabhedaka occur due to vitiation of Tridosha (Vata – Pitta – Kapha); while Acharya Charaka had mentioned that vitiated Vata/Vata-Kapha is involved in manifestation of Ardhavabhedaka, while Acharya Vagbhatta believed that Ardhavabhedaka occurs due to vitiated Vata [2].

According to International headache society, migraine is the most common neurovascular headache and is a common disabling primary headache disorder. It is now recognized as a chronic illness, not simply as headache. Migraine headache often limited the degree to which headache sufferers could engage in regular activities.

In the global burden of disease survey 2010, it was ranked as the third most prevalent disorder and 7th highest specific cause of disability worldwide. The world health organization (WHO) ranks migraine among the world's most disabling medical illness [3]. It is three times more common in women than men.

In Ayurvedic clinical practice Pathyadi Quath, Shirshuladi Vajra Ras, Laghu Sutsekar Ras are widely used for the treatment. Hence a combination therapy was essential for better patient compliance with regards different pathogenesis. Acute toxicity studies of Dologran tablets was conducted at Bombay College of Pharmacy, Mumbai vide and was considered as completely safe to use upto 5000 mg/kg as per OECD guidelines.

**Aims and objectives:** To assess the efficacy of Dologran Tablets in the management of Shirashool (Migraine).

## 2. Materials and methods:

Sample size -30

Study duration – Follow up every 15 days till1 month

Type of study- open non comparative study

Drug Formulation: Dologran Tablets 2 bid

### Table 1: Contents of Dologran Tablets

Each film coated tablet contains :

| Sr. No | Name Of Ingredients | Qty |
|--------|--------------------|-----|
| 1 | Pathyadi kwath ext | 250mg |
| 2 | Shirsuladi Vajra Ras | 120mg |
| 3 | Godanti Bhasma | 100mg |
| 4 | Laghu Sutshekhar Ras | 100mg |

### 2.3 criteria for diagnosis:

### Table 2: Criteria for diagnosis

| Symptoms | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
|----------|---------|---------|---------|---------|---------|
| Severity of headache | Nil | Mild headache, patient is aware only if he/she pays attention to it | Moderate, but does not disturb the routine work | Severe headache can't ignore but he/she can do usual activities | Excruciating headache can't do anything |
| Frequency of Headache | Nil | >20 days | 15 days | 10 days | <5 days |
| Duration of headache | Nil | 1-3 hours /day | 3-6 hours /day | 6-12 hours/day | More than 12 hours /day |
| Nausea | Nil | occasionally | Moderate headache, can ignore at times | Severe , disturbing routine work | Severe enough, small amount of fluid regurgitating from mouth |
| Vomiting | Nil | Only if headache does not subside | Vomiting 1-2 times | Vomiting 2-3 times | Forced to take medicine to stop vomiting |
| Vertigo | Nil | Feeling of giddiness | Patient feels as if everything is revolving | Revolving signs + black outs | Unconscious |
| Aura | Nil | Last for 5 mins | Last for 15 mins | Last for 30 mins | Last for 60 mins |

### 2.4 Criteria of assessment:

The improvements in the parameters were assessed mainly on the basis of relief in the signs and symptoms of the disease. To assess the effect of therapy all the signs and symptoms were scored depending upon their severity. Scored as following gradings- 0,1,2,3…

### 2.5 Statistical analyses

Various observations made, and results obtained were computed statistically using Wilcoxon matched pairs signed-ranks test, Paired 't' test for conception to find out the significance of the values obtained and various conclusions were drawn accordingly. All the results calculated by using Online InStat GraphPad software.

P value

• $P > 0.05$ - Not significant or not quite significant

• $P < 0.05$ – Significant

• $P < 0.01$ - Very significant

• $P < 0.001$ - Highly significant

### 2.1 Inclusion criteria-

1) Patients between age group 16-60 years
2) Having recurrent attacks of headache (mostly unilateral, variable in intensity) With or without nausea, vomiting aura and GI tract symptoms

### 2.2 Exclusion criteria:

1) Patients suffering from sinusitis, hypertension, and fever
2) Secondary headache caused by meningitis, tumor, encephalitis, cervical spondylosis, and refractive errors
3) Individuals suffering from immuno- compromised disease or on immunosuppressive drugs.
4) Pregnancy and lactation

## 3. Results:

It was observed that out of 30 patients 18 patients (60.0 %) were female &12 patients (40%)were male. The maximum number of patients 23(76.66 %)were in age group of 31 to 40 years &4 (13.33 %) patients were in age group of 21-30 years and 3 (10%) patients were in age group of 41-50 years.

Majority of patient about 22(73.33%) belongs to >6 months chronicity & 9 (30.00%) patients belongs to 3- 6 months chronicity.

88% patients were Non- vegetarian36% patients had family history of headache. 62% patients were totally dependent on allopathic medicine.

Exertion, lack of sleep, hunger (missing meals) and stress were the most important factor for aggravating migraine. Maximum patients those who were enrolled had migraine attack once a week. Maximum migraineurs complained of nausea, photophobia, phonophobia and vomiting as associated symptoms.

**Table 3: Observation on results of complains**

| Severity of headache | G0 | G1 | G2 | G3 | G4 | Total |
|---|---|---|---|---|---|---|
| Before Treatment | - | - | 6 | 21 | 3 | 30 |
| During Treatment | - | 12 | 15 | 13 | - | 30 |
| After Treatment | 21 | 8 | 1 | - | - | 30 |
| | | | | | | |
| Frequency of Headache | G0 | G1 | G2 | G3 | G4 | Total |
| Before Treatment | - | 7 | 8 | 15 | - | 30 |
| During Treatment | 8 | 15 | 7 | - | - | 30 |
| After Treatment | 23 | 6 | 1 | - | - | 30 |
| | | | | | | |
| Duration of headache | G0 | G1 | G2 | G3 | G4 | Total |
| Before Treatment | - | - | 14 | 15 | 1 | 30 |
| During Treatment | - | 16 | 14 | - | - | 30 |
| After Treatment | 2 | 22 | 6 | - | - | 30 |
| | | | | | | |
| Nausea | G0 | G1 | G2 | G3 | G4 | Total |
| Before Treatment | - | - | 8 | 20 | 2 | 30 |
| During Treatment | 6 | 14 | 10 | - | - | 30 |
| After Treatment | 19 | 11 | - | - | - | 30 |
| | | | | | | |
| Vomiting | G0 | G1 | G2 | G3 | G4 | Total |
| Before Treatment | - | 8 | 10 | 12 | - | 30 |
| During Treatment | - | 16 | 11 | 3 | - | 30 |
| After Treatment | 20 | 10 | - | - | - | 30 |
| | | | | | | |
| Vertigo | G0 | G1 | G2 | G3 | G4 | Total |
| Before Treatment | - | 5 | 10 | 15 | - | 30 |
| During Treatment | 8 | 12 | 10 | - | - | 30 |
| After Treatment | 22 | 8 | - | - | - | 30 |
| | | | | | | |
| Aura | G0 | G1 | G2 | G3 | G4 | Total |
| Before Treatment | - | 5 | 20 | 5 | - | 30 |
| During Treatment | 2 | 20 | 8 | - | - | 30 |
| After Treatment | 15 | 10 | 5 | - | - | 30 |

**3.1 Severity of headache**

After the treatment, at the end of study 21 patients were completely relieved of the symptom i.e. grade 0, while 8 were in grade 1**,** 1 in grade 2Severity of headache. After applying Wilcoxon Signed rank test shows significant result as compare to 1st visit with (p= <0.001)

**3.2 Frequency of Headache**

After the treatment, at the end of study 23 patients were completely relieved of the symptom i.e. grade 0, while 6 were in grade 1, 1 in grade 2 frequency of headache. After applying Wilcoxon Signed rank test shows significant result as compare to 1st visit with (p= <0.001)

**3.3 Nausea**

After the treatment, at the end of study 19 patients were completely relieved of the symptom i.e. Grade 0, while 11were in Grade 1 Nausea. After applying Wilcoxon Signed rank test shows significant result as compare to 1st visit with (p= <0.001)

**3.4 Vomiting**

After the treatment, at the end of study 20 patients were completely relieved of the symptom i.e. Grade 0, while 10 was in Grade 1 vomiting. After applying Wilcoxon Signed rank test shows significant result as compare to 1st visit with (p= <0.001)

**3.5 Vertigo**

After the treatment, at the end of study 22patients were completely relieved of the symptom i.e. grade 0, while 8 were in grade 1vertigo After applying Wilcoxon Signed rank test shows significant result as compare to 1st visit with (p= <0.001)

**3.6 Aura**

After the treatment, at the end of study 15 patients were completely relieved of the symptom i.e. Grade 0, while 10were in grade 1 & 5 in grade 2 aura. After applying Wilcoxon Signed rank test shows significant result as compare to 1st visit with (p= <0.001)

## 3.7 Overall assessment of therapy:

1) Markedly Improved: - 66% patients got markedly improvement in overall symptoms
2) Moderate Improvement: - 30% patients got moderately improvement in overall symptoms
3) Mild Improvement: - 4% patients got mild improvement in overall symptoms
4) No signs of any toxicity was observed

## 4. Discussion:

Ingredients of Dologran tablets are useful for different pathologies of migraine. The probable mode of action for different ingredients is as follows:

### 4.1 Probable mode of action of Laghu Sutashekhara Rasa 10-12:

Ushna Virya (66.67%), Katu Rasa (40%) and Tikta Rasa (20%) have Deepana - Pachana Karma, which causes amapachana and thus provides proper metabolism and ultimately balances the Agni. Snigdha Guna (28.57%), Madhura Vipaka (66.67%) and Madhura Rasa (20%) having the property Ushna Virya (85.18%), Katu Rasa (34.69%) and Tikta Rasa (28.57%) have Deepana - Pachana Karma, which causes Amapachana and thus provides proper metabolism and ultimately balances the Agni.

Ushna Virya (85.18%) has Deepana - Pachana, Virechana, Vilayana property, which softens and liquefies the morbid doshas which are ultimately expelled out due to Virechaka Karma. Laghu Guna (35.48%) and Tikshna Guna (27.42%) have Sroto-shodhaka property, which helps in expelling the morbid doshas. These Guna also have the property of Urdhavabhaga-doshaharatva, which breaks the Samprapti at Prasaravastha, where Vata alone or Kapha along with Vata causes Urdhavagapravriti of vitiated doshas.

### 4.2 Probable mode of action of Pathyadi Quath Extract:

This formulation is a multidrug combination and is indicated specially in *Shiroroga* in *Shrangdhara Samhita*. It contains 67% *Dravya* with *Ushna Virya* (hot potency) and *Madhura Vipaka* (sweet post digestion effect) 43% drugs are *Tridoshaghna* (all three *Dosha* pacification). So by all virtues cited above, it normalizes the vitiated *Vata-Kapha Dosha*. In addition, *Pathyadi* decoction contains drugs such as *Guduchi [Tinospora cordifolia* (willd.)], *Nimba [Azadiracta indica* Linn.], and *Haridra [Curcuma longa* Linn.] possessing *Rakta prasadaka* (blood purifier) property that may normalize vitiated *Rakta Dhatu* (oxygen carrying capacity of blood). Drugs such as *Guduchi [Tinospora cordifolia* (willd.)] and *Amalaki [Embelica officinalis* Gaertn.] have *Dipana* (appetizing) property. Thes drugs will normalize *Ama* (by product toxins after digestion), as *Ama* gets decreased it may subside *Ajirna* (Indigestion).

It is reported that most of the drugs of *Pathyadi* decoction also possess analgesic, anti-inflammatory, a nervine tonic property which might have helped to reduce pain.

## 5. Conclusion

*Shirashool* is *vaat kapha pradhana shiroroga*, the symptoms complex of which very well correlate to that of Migraine. The clinical study in which consists 30 patients after treatment 66% patients got markedly improvement in symptoms; the study has shown highly significant results in the management of *Shirashool*. In my opinion Dologran tablets are valuable additions in the treatment of migrainous headache especially of unknown etiology.

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