RESEARCH ARTICLE

Clinical Evaluation of Three Source Drugs of *Trivrut* on *Purishaja Anaha* (Constipation): Randomized Comparative Double-blind Clinical Study

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ABSTRACT

Introduction: *Trivrut* is depicted as the best drug among *Sukhavirechana* (mild laxative). Based on the color, two varieties, *Shyama* (black) and *Aruna* (red), have been opined, where *Shyama* is said to be drastic purgative and mentioned with some side effect in classical texts of Ayurveda. *Rechaniya Dravya* (laxative drugs) is advised in *Purishaja Anaha* (constipation).

Aim: To evaluate the therapeutic efficacy of *Operculina turpethum*, *Marsdenia tenacissima*, and *Operculina petaloidea* in patients suffering from *Purishaja Anaha*.

Materials and methods: Randomized comparative double-blind study was conducted on 90 patients divided equally into three groups; 5 gm dose of root bark powder was administered for 3 days and follow-up was taken after 7 days. Result was assessed with Wilcoxon signed-rank tests for subjective parameters in single group and analysis of variance (ANOVA) followed by Dunnett's multiple comparison test for in-between groups comparison.

Results: Moderate improvement was observed in 36.67% patients in *O. petaloidea* and mild improvement was observed in 70% patients in *O. turpethum*-treated group, whereas 63.33% patients in *M. tenacissima* group showed insignificant result. In the assessment of purgative effect of the drug, *O. turpethum* and *O. petaloidea* showed better result as compared with *M. tenacissima*.

Conclusion: In all the studied parameters, *O. turpethum* showed better result.

Keywords: *Marsdenia tenacissima*, *Operculina petaloidea*, *Operculina turpethum*, Shweta Trivrut, Shyama Trivrut.

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INTRODUCTION

Trivrut is considered as the best drug among *Sukha Virechana* (mild laxative), while *Shyama Trivrut* is reported with *Ashukarita* (quick action) and advised for *Bahudosha* (vitiated *Dosha*) and *Krura Koshthi* (person with tendency of hard bowel) only.[1] It has been reported that there are 54 different combinations of *Trivrut* and its variety alone or along with different drugs and *Anupana/Sahapana* (vehicles) like milk, *Ghruta* (clarified butter), honey useful for *Virechana Karma* (laxative action).[2] *Purishaja Anaha* (constipation) is the common digestive complaint and use of *Rechaniya Dravya* (laxative drugs) is one of its treatment protocol.[3] *Operculina turpethum*, as the source drug of *Trivrut*, has been evaluated for *Virechana Karma* through clinical studies.[4] *Marsdenia tenacissima* is reported as the most commonly available market source drug of *Shweta Trivrut*.[5] *Operculina petaloidea* is considered as source drug of *Shyama Trivrut*,[6] but till date neither the root of *O. petaloidea* nor *M. tenacissima* have been evaluated scientifically for their laxative action. Therefore, a clinical study was planned to validate the efficacy of three reported source drugs of *Trivrut* (*O. turpethum, O. petaloidea,* and *M. tenacissima*) in the management of *Purishaja Anaha.*

MATERIALS AND METHODS

Patients attending the institutional outpatient department and inpatient department having the symptoms of "*Purishaja Anaha*," as described in classical texts, were selected irrespective of caste religion, occupation, and sex. The clinical trial was approved by Institutional Ethics Committee IEC PGT/7-A/Ethics/2012-2013/3552 dated 25/02/2013 and also registered in Clinical Trials Registry of India study (CTRI/2014/10/005119 dated 25/10/2014). It was a randomized, double-blind, prospective, comparative clinical trial. Patients aged between 18 and 60 years with classical symptoms of *Purishaja Anaha* and having complaints of irregular and unsatisfactory bowel motions were included in the study, whereas patients suffering from any systemic diseases like hypertension, diabetes, tuberculosis, and pregnant woman were excluded.

Drugs and Posology

Roots of the three drugs were collected from the natural source after proper identification by taxonomist. Root barks were powdered in mechanical grinder and passed through mesh 80#. Accurately weighed fine powders of each trial drug were packed in a brown paper. Such packing for 3 days was sealed in a polyethylene bag and labeled as A, B, or C accordingly. Details of the posology are presented in Table 1.

Grouping and Sampling

Patients were randomly divided into three groups following computerized randomization[7]:

Criteria for Assessment

Diagnosis and Assessment of Purishaja Anaha

Purishaja Anaha was diagnosed with the help of proforma based on its classical signs and symptoms and scoring pattern was adopted for assessment of drugs on each symptom following previous research proforma.

Criteria for Assessment of Koshtha

Evacuation of the stool is related with the *Koshtha* (bowel tendency) of the individual; it was assessed with the help of specially designed proforma referred from previous thesis.[8] Scoring pattern for the assessment of *Koshtha* is presented in Table 2.

Criteria for the Assessment of the Effect of Drug through Virechana Karma

Special clinical research pro forma was made to assess the laxative effect as well as undesirable effects of the drug. Grades for the assessment of effect of drugs through *Virechana Karma* are presented in Table 3.

Table 1: Grouping and posology of drug

Subject	Group I	Group II	Group III
Part used	Root bark		
Form	Powder + *Sharkara* (sugar) in equal quantity with *Koshnajala* (lukewarm water 80 ml)		
Dose	5 gm		
Route	Oral		
Time	Empty stomach in the morning (*Shleshmakale Gatam*)		
Duration	3 days		
Follow-up	After 7 days		

Table 2: Scoring pattern for the assessment of *Koshtha*

Score	Type of Koshtha
0–4	*Mrudu Koshtha*
5–9	*Madhyama Koshtha*
10–14	*Krura Koshtha*

Table 3: Desirable effects of drug through *Virechana Karma*

Grades	Onset of defecation	Frequency	Consistency	Feeling
0	More than 12 hours	Absence of *Vega*	Normal	No change
1	9–12 hours	1–2 *Vega*	Loose	Unsatisfactory feeling without effort
2	5–8 hours	3–4 *Vega*	Watery	Satisfactory feeling without effort
3	Within 5 hours with urgency/ without urgency	5/>5 *Vega*	Watery with mucus	Generalized debility

Table 4: Grades for the assessment of the undesirable effects

Grades	Criteria
0	Absent of symptom
1	Presence of symptom and no need of intervention
2	Presence of symptom and need intervention

Undesirable Effects

Bhrama (giddiness), *Daha* (burning sensation), *Hrudaya-karshana* (discomfort in the heart region), *Kanthakarshana* (irritation in throat region), *Mada* (slight intoxication), *Murccha* (syncope), *Sammoha* (confusion), *Cchardi* (vomiting), and *Shula* (abdominal cramp) are the reported undesirable effects of *Shyama Trivrut*.[9] The grades for the assessment of the undesirable effects of drug mentioned in the classical texts are presented in Table 4.

Patients were also monitored for other adverse events during the study period.

Criteria for Assessment of Overall Effect of Therapy

The total effect of therapy was assessed considering the overall improvement in signs and symptoms. After the completion of treatment, percentage improvement in each patient of every symptom was calculated and average percentage was considered for final assessment. Criteria for assessment of overall effect of therapy are presented in Table 5.

Table 5: Criteria for assessment of overall effect of therapy

Criteria	Percentage
Cure	>99–100% relief
Marked improvement	>75–99% relief and feeling of well-being occasionally
Moderate improvement	>50–75% relief and feeling healthier than before
Mild improvement	>25–50% relief and feels better but not relieved completely
Unchanged	<25% relief in and no feeling of betterment

Statistical Analysis

The obtained data were analyzed statistically using GraphPad in Stat 3 version. The data were analyzed by Wilcoxon signed-rank tests for subjective parameters in single group. Analysis of variance was followed by Dunnett's multiple comparison test for in-between group comparison. A level of p-value <0.05 was considered as statistically significant; p < 0.01 or p < 0.001 were considered as highly significant.

OBSERVATIONS

Totally, 90 patients were registered in the present study, among them 30 patients were enrolled each in groups I, II, and III, respectively. All the patients completed the treatment duration. Maximum, i.e., 38.89%, were in the age group of 31 to 40 years, 52.22% were female, habit of tea was observed in 100% of the patients, whereas habit of junk food was observed in 84.44% of the patient. *Vata-Pitta Prakriti* was present in 68.89% patients. *Mandagni* (poor digestive fire) and *Vishamagni* (irregular digestive fire) were reported in 54.44 and 45.56% patients respectively. After assessment of *Koshtha*, it was observed that 51.11% patients were having *Madhyama Koshtha* (medium formed bowel tendency), whereas 38.89% patients, were having *Krura Koshtha* (hard bowel tendency). After the assessment of the questionnaires regarding stool examination, it was observed that 93.33% patients had *Atigrathita Mala Pravritti* (hard bowel), 80% patients had *Krichhena Mala Pravritti* (painful defecation), 48.89% patients had *Alpalpa Mala Pravritti* (less amount of stool), and 47.78% patients had *Sashabda Mala Pravritti* (defecation with sound). In the chief complaints, 100% patients reported *Aniymit Purishpravartana* in all the three groups. *Udaradhmana* was chief complaint in 90%, 93.3% and 100% patients in group I, II and III respectively. In all the three group 83.3% patients had *Katiprushthashula*. *Katiprushthastambha* was observed in 60%, 66.66%, 76.66% in group I, II and III respectively.

RESULTS

After the treatment in group I, maximum improvement was noticed in *Aniymit Purishapravartana* 68.96%, *Adhmana* 59.57%, *Katiprushthashula* 20.68%, *Katiprushthastambha* 21.05%, *Udaragaurava* 54.05%, *Pindikodweshtana* 47.61%, and *Shirashula* 72.41%. In group II, maximum improvement was noticed in *Aniymit Purishapravartana* 70.31%, *Adhmana* 60.42%, *Katiprushthashula* 45%, *Katiprushthastambha* 37.04%, *Udarashula* 33.33%, *Udaragaurava* 40.48%, *Pindikodweshtana* 55%, and *Shirashula* 70.27%. In group III, maximum improvement was noticed in *Udarashula* 68.75%, followed by *Shirashula* 50%, *Adhmana* 42.85%, *Aniymit Purishapravartana* 34.92%, *Katiprushthashula* 10.52%, *Katiprushthastambha* 13.33%, *Udaragaurva* 25%, and *Pindikodweshtana* 25%.

In group I, highly significant result (p < 0.001) was observed in *Aniymit Purishapravartana*, *Udaraadhmana*, *Udaragaurava*, and *Shirashula*, whereas p < 0.01 was observed in *Sashulamalapravritti* and *Pindikodweshatana* symptoms. In group II, highly significant result (p < 0.001) was observed in *Aniymit Purishapravartana*, *Udaradhmana*, *Udaragaurava*, *Katiprushthashula*, and *Shirashula*. In group III, highly significant result (p < 0.001) was observed in *Aniymit Purishapravartana* and *Udaraadhmana*, whereas p < 0.01 was observed in *Sashulamalapravritti*, *Udaragaurava*, and *Shirashula* (Table 6). In-between groups comparison was done by applying ANOVA followed by Dunnett's multiple comparison test for elucidating the best group (Table 7).

In comparison of group I with II, highly significant result (p < 0.01) was observed in *Katishula* only. In comparison of group I with III, p < 0.001 was observed in *Aniyamita purishapravartna* symptom, whereas significant result (p < 0.05) was observed in *Udaragaurava*. In comparison between groups II and III, highly significant result (p < 0.001) was observed in *Aniyamita purishapravartna* and *Katishula*, whereas p < 0.01 was observed in *Shirashula*.

Assessment of Drug

In the assessment criteria of the efficacy of the drugs, it was observed that in 30% of the patients in both groups I

Table 6: Result of Wilcoxon signed-rank test on chief complaints of 30 *Purishaja Anaha* patients

Symptoms	Group I		Group II		Group III	
	W	p-value	W	p-value	W	p-value
Aniyamit purishapravartana (irregular bowel)	465	<0.001**	465	<0.001**	136	<0.001**
Udaraadhmana (bloating)	300	<0.001**	300	<0.001**	210	<0.001**
Katiprushthashula (pain in back and lumber region)	21	<0.05*	171	<0.001**	10	0.125
Katiprushthastambha (stiffness in back and lumber region)	10	0.1250	45	<0.01**	10	0.1250
Sashulamalapravritti (painful defecation)	36	<0.01**	45	<0.01**	45	<0.01**
Udaragaurava (heaviness in abdomen)	190	<0.001**	153	<0.001**	45	<0.05*
Pindikodweshtana (cramps)	55	<0.01**	66	<0.001**	21	0.031
Shirashula (headache)	190	<0.001**	325	<0.001**	78	<0.001**

W: Sum of all ranks; **Highly significant (p < 0.001), (p < 0.01); *S = Significant (p < 0.05)

Table 7: Comparison in-between the groups by ANOVA test

Parameters	p-value	Groups I–II	Groups I–III	Groups II–III
Aniyamita purishapravartna	p < 0.001**	>0.05 NS	<0.001**	<0.001**
Katishula	<0.001**	<0.01**	>0.05 NS	<0.001**
Udaragaurava	0.0215	>0.05 NS	<0.05*	>0.05 NS
Shirashula	0.0028	>0.05 NS	>0.05 NS	<0.01**

NS: Nonsignificant; **Highly significant (p < 0.001) (p < 0.01); *Significant (p < 0.05)

and II, defecation was started within 5 hours after intake of drug, whereas it was within 5 to 8 hours in 46.67% of patients of group I and 33.33% of group II. In 93.33% of the patients, defecation was started after 12 hours of medication in group III. In group I, 53.3% of the patients reported more than five *vegas*, 66.7% patients reported watery and mucus stool consistency and 46.7% patients stated general debility after evacuation, whereas it was 43.3%, 46.7%, and 60% respectively, in group II. Patients treated in group III showed presence of 1 to 2 *Vegas* in 90%, normal consistency of stool in 100%, and unsatisfied feeling in 63.33%.

Undesirable Effects

Among the list of undesirable effects reported for the *Shyama Trivrut*, it was observed that maximum 100% of the patient treated with groups I and II reported *Udarashula*. *Kanthakarshana* was observed in 53.33 and 33.3% of the patients, respectively, in groups I and II. In group III, *Chhardi* was reported in 36.67% of the patients. All the observed undesirable effects were mild and did not require any intervention. No other adverse events (AEs) other than reported undesirable effects were observed during the study period in all the treated groups.

Overall Effect of the Therapy

Moderate improvement was found in 36.67% patients treated with group II, and 26.67% patients in group I. Mild improvement was found in 70% patients in group I, 56.67% patients in group II, and 33.33% patients in group III (Table 8).

Table 8: Result of overall effect of the therapy

Improvement	Group I O. turpethum (%)	Group II O. petaloidea (%)	Group III M. tenacissima (%)
Complete remission (100%)	0	0	0
Markedly improved (>75–99%)	3.33	0	3.33
Moderately improved (>50–75%)	26.67	36.67	0
Mild improved (>25–50%)	70	56.67	33.33
Unchanged (<25%)	3.33	3.33	63.33

Follow-up

It was observed that 56.67% of patients from groups I to II got recurrence of complaints, while 93.33% of patients from group III reported recurrence of compliant after the follow-up of 7 days. After completion of the study, the blinded drugs were identified as group I—powder of *O. turpethum* root bark, group II—powder of *O. petaloidea* root bark, group III—powder of *M. tenacissima* root bark.

DISCUSSION

Rechana (laxative) is the foremost pharmacological action of *Trivrut*. The drug that expels *Pakva* (formed) or *Apakva Malas* (unformed stool) after diluting them through *Adhobhaga* (anal region) is known as *Rechana* like *Trivrut*.[10] In the classical text, dose of *Trivrut* is given as 1 *Aksha*,[11] which is equated to 12 gm,[12] but this dose is reported for *Virechana Karma* which is supposed to give after proper *Snehana* (oil application) *Swedana* (hot fomentation). Therefore, for the comparative assessment of laxative action of root bark of *O. turpethum, O. petaloidea*, and *M. tenacissima* without *Snehana Swedana*, 5 gm dose per day for 3 days in the *Shleshmakale Gatam*[13] (morning 9–11 AM) was given to the clinically diagnosed patients of *Purishaja Anaha*. Demographic data showed that females were more in number than males, which support previous data.[14] Irregular dietary pattern, stress, and workload may lead to functional constipation in the age group of 31 to 40 years. Continuous standing for performance of daily domestic chores and ignorance for the natural urge could be the reason for higher incidence of constipation in housewives and labor class.[15] Maximum patients, i.e., 87.78%, were taking *Katu Rasa* (Spicy) dominant *Ahara Dravya* (dietary items). *Katu Rasa* is *Baddhavinamutrakara* (constipative, antidiuretic) and causes obstruction in passing of flatus.[16] Along with this, *Shita* (cold) and *Ruksha Guna* (dry) dominating dietary items were found as etiological factors. *Shita* and *Ruksha Guna* vitiate the *Vata Dosha* and decrease the motility of intestine by *Stambhana Karma* (checking action).[17] *Diwaswapa* (day sleep) and *Vegavidharana* (holding of natural urges) were also found as main etiological factors. *Diwaswapa* vitiates all the three *Doshas* and leads to *Agnimandya* (hampered digestion).[18] *Vegavidharana* leads to *Vatadushti*

that too specific *Apana Vatadushti*,[19] thus contributing to the *Samprapti* (pathophysiology) formation of the disease *Purishaja Anaha*. Wilcoxon singed-rank test is used to compare one sample/paired two samples.[20] *Rechana Karma* leads to increased peristaltic movement that may lead to *Antrakunjana* (colic pain).[21] *Operculina turpethum* contains saponin. Drug containing saponin is usually sternutatory and otherwise irritating to the mucus membrane,[22] which may result in abdominal cramps. Presence of calcium oxalate crystals in the root of *O. turpethum* may result in *Kanthakarshana* (throat irritation).[23] Presence of saponin and calcium oxalate crystals may be responsible for the undesirable effects. Among the undesirable effect, nausea and vomiting were observed in group III, may be because of bitterness of the drug.[24] For the assessment of the significance among the treated group, ANOVA test was applied. Highly significant result was observed in *Aniyamita purishpravartana, Katishula, Shirashula*. Patients treated with groups I and II showed near about equal effect; therefore, the result of its comparison was found insignificant, whereas differences in the results of group III with groups I and II were statistically significant. *Trivrut* and *Shyama Trivrut* have the properties like *Ushna* (hot), *Tikshna* (sharp). *Shyama Trivrut* possesses *Ashukarita*, which may get quickly circulated into large and small capillaries of the body. It pervades all over the body by virtue of its *Ushna* and *Tikshna* qualities. The accumulated *Doshas* gets liquefied and break up into small pieces at cellular level. Because of its above-mentioned *Guna*, it detaches and liquefies the *Malas*. *Trivrut* (*O. turpethum*) after ingestion mixes with HCl in stomach and forms turpethic acid and glucose. To neutralize the turpethic acid, some amount of chloride will release from interstitial compartment and mixes with it. Then it enters into circulation and comes to stomach; again it mixes with acid and releases chloride to neutralize it. Finally, it increases the peristalsis and leads to purgation. It means after ingestion it would not act directly on intestine, which may not lead to loss.[25] Thus increased peristalsis may result in abdominal pain during treatment. Result of this clinical trial is also supported by comparative screening of intestinal transit time in swice albino mice.[26]

CONCLUSION

Operculina turpethum and *O. petaloidea* showed better result in frequency, time of defecation, consistency, and feeling after defecation, whereas improvement was maximum in *O. turpethum*. *Marsdenia tenacissima* had no effect on frequency, time of defecation, consistency, and feeling after defecation. In all the studied parameters, *O. turpethum* has showed better results.

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हिंदी सारांश

पुरिषज आनाह (मलविबद्ध) पर त्रिवृत के तीन वनस्पति स्त्रोतों का चिकित्सकीय मूल्यांकनः यादृच्छिक रूप से तुलनात्मक डबल ब्लाइंड चिकित्सकीय अध्ययन

¹रसिका कोल्हे, ²रबिनारायण आचार्य

परिचयः त्रिवृत को अग्र्य द्रव्यों मे सुखाविरेचक कहा गया है। रंगो के आधार पर त्रिवृत के दो प्रकार जैसे श्याम और अरुण बताये गए है, जिसमें, श्याम त्रिवृत को तीव्र रेचक कहा गया है तथा इसके उपयोग से होने वाले संभावित दुष्परिणाम भी आयुर्वेद शास्त्रों में वर्णित है। पुरिषज आनाह (मलविबद्ध) में, रेचनीय द्रव्यों के प्रयोग की सलाह दी गयी है।

उद्देश्यः त्रिवृत के वनस्पति स्रोत; ओपेर्कुलिना टर्पेथम, मार्सडेनिया टेनासिसीमा तथा ओपेर्कुलिना पेटलॉयडी, के चिकित्सकीय प्रभाव का, पुरिषज आनाह से पीड़ित रोगियों में मूल्यांकन करना।

साधन एवं विधिः समान रूप से तीन समूहों में विभाजित नब्बे रोगियों में यादृच्छिकृत तुलनात्मक डबल ब्लाइंड अध्ययन किया गया; तीन दिन तक रोगियों को जड़ की छाल का पांच ग्राम चूर्ण दिया गया तथा सात दिन बाद उन रोगियों का पुनः परिक्षण किया गया। एकल समूह में व्यक्तिपरक मापदंडो के लिए विल्कोक्सन साइन रैंक टेस्ट का एवं विभाजित वर्गों के बिच तुलनात्मक अध्ययन के लिए एनोव्हा टेस्ट का उपयोग, औषधी द्रव्यों के परिणामो के आकलन के लिए किया गया।

परिणामः ओपेर्कुलिना पेटलॉयडी दिए गए 36.67% रोगियों में औसत दर्जे का सुधार देखा गया और ओपेर्कुलिना टर्पेथम दिए गए 70% रोगियों में हल्का सा सुधार पाया गया जबकि मार्सडेनिया टेनासिसीमा के 63.33% रोगियों में सांख्यिकीय रूप से महत्वहीन परिणाम पाया गया। दवा के रेचनीय प्रभाव के आकलन में, ओपेर्कुलिना टर्पेथम और ओपेर्कुलिना पेटलॉयडी द्वारा मार्सडेनिया टेनासिसीमा की तुलना में बेहतर परिणाम प्रेक्षित हुआ।

निष्कर्षः सभी मानक अध्ययन में, ओपेर्कुलिना टर्पेथम बेहतर प्रेक्षित हुआ।

कुंजी शब्दः मार्सडेनिया टेनासिसीमा, ओपेर्कुलिना पेटलॉयडी, ओपेर्कुलिना टर्पेथम, श्वेत त्रिवृत, श्याम त्रिवृत, ओपेर्कुलिना टर्पेथम, श्वेत त्रिवृत, श्याम त्रिवृत