

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF VIRECHANA KARMA WITH TRIVRUT LEHYA AND TRIVRUT KWATHA BHAVITA TRIVRUT CHURNA IN THE MANAGEMENT OF AMAVATA VIS-À-VIS RHEUMATOID ARTHRITIS

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ABSTRACT

Background *Amavata* is characterized by the accumulation of *Ama* and vitiation of *Vata dosha*, with involvement of *Agni* and other *doshas* in association with *Pitta* and *Kapha*. The clinical presentation of *Amavata* includes symptoms like *Angamarda*, *Aruchi*, *Jwara*, *Gaurava* and *Sandhi shotha*, resembling the clinical features of Rheumatoid Arthritis. Among various Ayurvedic modalities, *Virechana* is known for its efficacy in eliminating *Pitta*, *Ama* and enhancing *Agni*, thereby breaking the pathogenesis of *Amavata*. *Trivrit* a potent purgative, is widely used in *Virechana* karma for its *Ama pachana* and *Dosha-shodhana* properties. **Aim:** To compare the efficacy of *Virechana Karma* with *Trivrut Lehya* followed by *Ushna Jala* as *Anupana* & *Trivrut Kwatha Bhavita Trivrut Churna* followed by *Kanji* as *Anupana* in *Amavata*. **Methodology:** The study was a comparative clinical study with pre and post-test design involving 2 groups with 20 subjects in each group.

Results: Statistically significant improvement was observed in both subjective and objective parameters after intervention. Group B shown more significant results than group A, *Trivrut kwatha bhavita Trivrut Churna* helps to attain more number of *Vegas* and *Samyak virikta Laxanas* than *Trivrut lehya*. **Conclusion:** Based on the result it can be concluded that, *Trivrut*

kwatha bahvita Trivrut churna with *Kanji Anupana* is more effective than *Trivrut Lehya* with *Ushnajala Anupana* for *Virechana* in *Amavata*.

KEYWORDS: Amavata, Rheumatoid Arthritis, *Trivrit Leha*, *Trivrit Churna*, *Virechana*, *Ama*.

INTRODUCTION

Virechana Karma is a *Shodhana* procedure, which comes under *Panchakarma*.^[1] It is indicated in multiple conditions like *Pittaja Vikara*, *Amajanya Vikara*, *Udara Roga* and *Adhmana*.^[2]

Various *Virechana Dravyas* have been described for *Virechanartha*, even after critical analysis of *Virechana Dravyas* in literature, still there is a minimal practice of disease specific formulations.

Amavata is a *Rasa Pradoshaja Vikara* caused by *Ama*, with the vitiation of *Kapha-Vata Pradhana Tridosha*. It is characterised by *Shotha* (swelling), *Vruschika Damshavath Vedana*^[3] (pain), *Stabdhatata* (stiffness) of *Sandhi*'s, *Aruchi* and *Gourava*.^[4] In contemporary science, *Amavata* can be co-related to Rheumatoid Arthritis, a poly-arthritis involving small & large diarthroidal joints of extremities symmetrically presenting with pain, swelling, morning stiffness etc.

Incidence of Rheumatoid arthritis is 11% per year and prevalence rate varies between 0.5-1% in the world.^[5]

The management of RA includes NSAIDs, Steroids and DMARDs, Monoclonal antibody therapy^[6] these will give only symptomatic relief. In this perspective we can rely upon Ayurvedic management such as *Langhana*, *Swedana*, *Deepana Pachana*, *Virechana* and *Basti*.^[7]

Virechana Karma plays an important role in the management of *Amavata*. Hence in this study *Shodhananga Snehapana* with *Shunti Dhanyaka Ghrita* was selected as it is indicated in *Amavata*^[8] for *Virechana Trivrut Lehya* and *Trivrut Kwatha Bhavitha Trivrut Churna* was selected. Because Acharya Charaka opines that *Trivrut* is *Sukha Virechaka*^[9] and *Sarva Rogahara*.^[10]

As *Trivrut Lehya* is commonly used for *Virechana* in *Tridoshaja Vyadhis* and *Trivrut Kwatha Bhavita Trivrut Churna* along with *Kanji* as *Anupana* is directly indicated in *Amavata* as a disease specific condition.^[11]

Hence, in this present study an attempt which was made to find out the efficacy of *Virechana* in *Amavata* with two different *Yogas Trivrut Lehya* with *Ushna Jala* as *Anupana* and *Trivrut Kwatha Bhavita Trivrut Churna* with *Kanji* as *Anupana*.

MATERIALS AND METHODS

Source of Data: Subjects were selected from OPD and IPD of Government Ayurvedic medical college and Hospital, Mysuru and Government Hi-tech Panchakarma hospital, Mysuru. Special camps will be conducted for the purpose.

Source of Drugs: Required formulations for the study will be specifically prepared for the purpose and procured from a Good Manufacturing Practices certified Ayurveda Pharmacy.

DIAGNOSTIC CRITERIA

- Subjects having *Amavata Laxanas* like *Vruschika Damshavat Vedana, Shotha* in *Bahu Sandhi, Aruchi, Gourava*.
- 2010 ACR/EULAR classification for Rheumatoid arthritis.

(Parameters in ACR-EULAR criteria: Duration of symptoms (≥ 6 weeks), Joint distribution (0-5), Acute phase reactants (CRP and ESR) and Serology (RA Factor).

If there is Presence of ≥ 6 symptoms then it is definite RA.

1. JOINT DISTRIBUTION (0-5)

Table no. 1: Showing scoring of Joint distribution.

1 large joint	0
2-10 large joints	1
1-3 small joints (large joints not counted)	2
4-10 small joints (large joints not counted)	3
>10 joints (at least one small joint)	5

2. SYMPTOM DURATION (0-1).

Table no 2: Showing scoring of Symptom duration.

<6 weeks	0
≥ 6 weeks	1

3. ACUTE PHASE REACTANTS (0-1).

Table no 3: Showing scoring of Acute phase reactants.

Normal CRP and normal ESR	0
Abnormal CRP or abnormal ESR	1

4. Serology (0-3)

Table no. 4: Showing scoring of Serology.

Negative RA Factor	0
Low positive RA Factor	2
High positive RA Factor	3

INCLUSION CRITERIA

- Subjects fulfilling the diagnostic criteria.
- Rheumatoid arthritis with a history of more than 1 year.
(Already diagnosed and treated cases of *Amavata* vis-à-vis Rheumatoid Arthritis, who had voluntarily discontinued the treatment and will be induced after a flush out period of 7 days).
- Subjects irrespective of gender, aged between 20 to 50 years.
- Subjects who are fit for *Snehapana* and *Virechana Karma*.
- Subjects who are willing to give the consent.

EXCLUSION CRITERIA

- Subjects with other systemic disorders which interfere with the intervention.
- Rheumatoid Arthritis with deformities like swan neck deformity, Boutonniere deformity, z-shaped deformity and Rheumatic nodules.
- Pregnant & Lactating women.

LAB INVESTIGATIONS

- RA Factor
- CRP
- ESR

STUDY DESIGN: A Comparative clinical Study with Pre and Post Treatment Assessment

SAMPLING TECHNIQUE: Subjects will be made into 2 groups, using simple random technique.

SAMPLE SIZE: Total sample size consists minimum of 40 subjects, each group consisting a minimum of 20 Subjects.

STUDY DURATION: For group A and B, approximately 25 days.

Purvakarma for both the Groups A and B.

1. *DeepanaandPachana*

Vaishwanara Churna 1 to 4 grams TID before food, with *Ushna Jala* as *Anupana*, was given till attainment of *Nirama Lakshanas*

2. *Shodhananga Snehapana*, in *Arohana Krama*: with *Shunti Dhanyaka Ghrita* (3- 7 days), was given till attainment of *Samyak Snigdha Lakshanas*.

3. *Vishrama Kaala*: *Sarvanga Abhyanga* with *Brihat Saindhavadi Taila*, followed by *Bhashpa Sweda* for 3 days.

Pradhana karma

Group A: *Virechana* with *Trivrut Lehya* 40 to 80 grams based on *Koshta* and *Agni* with *Ushna Jala* as *Anupana* was given.

Group B: *Virechana* with *Trivrut Kwatha Bhavita Trivrut Churna* 12 -24 grams based on *Koshta* and *Agni* with *Kanji* as *Anupana* was given.

Paschaat Karma for both the groups A and B

Peyadi Samsarjana Krama was followed based on the type of *Shuddhi*.

ASSESSMENT SCHEDULE

Pretest - 0th Day (Before *Deepana Pachana*).

Post test - Next day of *Virechana Karma*.

Follow up - 15th day after *Virechana Karma*.

ASSESSMENT CRITERIA

For Subjective assessment *Sandhi Shoola*, *Sandhi Shotha*, *Sandhi Stabdhata* and *Aruchi* and for objective assessment RA Factor, ESR, CRP had taken, before and after the treatment.

SUBJECTIVE CRITERIA

1. *Sandhi Shoola* (Pain in joints)

Table no. 5: Showing scoring of *Sandhi shoola* laxanas.

No symptoms	0
<i>Alpa Shoola</i> on forcible movements upto 60 minutes.	1
<i>Madhyama Shoola</i> on normal movements of all affected joints upto 1-4 hours	2
<i>Teevra Shoola</i> even after rest for more than 4 hours	3

2. *Sandhi Shotha* (Swelling of joints)

Table no. 6: Showing scoring of *Sandhi shotha* laxanas.

No symptoms	0
<i>Alpashotha</i> slightly more obvious in affected in comparison with normal joint.	1
<i>Madhyama Shotha</i> covers the bony prominences of affected joints.	2
<i>Teevra Shotha</i> much elevated so that joint seems grossly deformed.	3

3. *Sandhi Stabdhatra* (Morning stiffness of joints)

Table no. 7: Showing scoring of *Sandhi stabdhata* laxanas.

No stiffness or stiffness lasting for 1 hour	0
Stiffness lasting for 1 to 2 hours	1
Stiffness lasting for 2-8 hours	2
Stiffness lasting more than 8 hours	3

4. *Aruchi*

Table no. 8: Showing scoring of *Aruchi* laxanas.

No <i>Aruchi</i>	0
Eating timely without much desire	1
Desire for food little late than normal time	2
Desire for food after a long interval than normal time or no desire at all	3

OBJECTIVE CRITERIA

- RA Factor
- ESR
- CRP

OVER ALL ASSESSMENT

Overall assessment will be based on improvement in Subjective and objective Parameters. The results were categorized as

Table no. 9: Showing overall improvement.

Complete relief	100 % improvement
Marked relief	More than 75% improvement
Moderate relief	50 -74 % improvement
Mild relief	25 -49 % improvement

STATISTICAL METHOD

The results were compared and analysed by using following statistical methods.

Table no. 10: Showing of statistical methods.

Descriptive	Non parametric	Parametric
Mean	Chi-Square test	T tests- Independent and
Standard deviation	Wilcoxon signed rank test	Paired samples
Frequency	Mann Whitney U test	Repeated measure
Percent		ANOVA

All the Statistical Operations will be done through service product for Statistical Solutions (SSPS) for Windows V 28 Software.

If Study requires, Other Statistical methods will also be incorporated.

OBSERVATIONS

In the study, approximately 65% of the subjects from both groups belonged to the age group of 41-50, indicating a higher prevalence of *Amavata* among middle-aged individuals. About (55%) of subjects exhibited *Mandagni* (55%) due to faulty dietary and lifestyle habits such as *Adhyasana* (50%) and *Vishamaashana* (50%), which are significant causative factors for the manifestation and aggravation of *Amavata*. About (55%) of subjects were found to be female, likely due to hormonal variations, particularly fluctuations in estrogen levels, which influence immune modulation and inflammation, thereby predisposing to autoimmune disorders.

RESULTS

EFFECT ON SANDHI SHOOLA

Before treatment, all 20 subjects (100%) in both groups complained of *Sandhishoola* (joint pain), among which 16 subjects (80%) in Group A and 15 subjects (75%) in Group B had moderate to severe pain.

After treatment, 18 subjects (90%) in Group A and 19 subjects (95%) in Group B showed marked reduction in joint pain intensity.

Phytoconstituents of *Trivrut* Scopoletin inhibits prostaglandin, bradykinins and other pain inducing chemicals, acts on modulation pathway and reduces pain perception and *Kanji* contains lactic acid, probiotics which supports gut health, reduce inflammation caused by dysbiosis of gut hence pain reduces.

EFFECT ON SANDHI SHOTHA

Before treatment, all 20 subjects (100%) had *Sandhishotha*, among which 18 subjects (90%) in Group A and 17 subjects (85%) in Group B presented with moderate to severe swelling.

After treatment, 16 subjects (80%) in Group A and 18 subjects (90%) in Group B showed marked reduction in swelling of affected joints.

Scopoletin, Betulin, Sterols of *Trivrut* acts as Anti-inflammatory thus helps in reducing swelling of joints by inhibiting pro- inflammatory enzymes, scavenges free radicals, reducing oxidative process which improves micro circulation thereby reduces edema and lactic acids of *Kanji* reduce oxidative stress and improves circulation.

EFFECT ON SANDHI STABDHATA

Before treatment, 17 subjects (85%) in Group A and 16 subjects (80%) in Group B complained of *Sandhi Stabhata* and restricted movement.

After treatment, 19 subjects (95%) in Group A and 20 subjects (100%) in Group B showed marked reduction in stiffness with improved joint mobility

β -turpethins and scopoletins of *Trivrit* may contribute to muscle relaxation through their anti-inflammatory and analgesic properties, helping alleviate muscle stiffness. Lactic acid and vanillic acids of *Kanji* reduce inflammation and oxidative stress thus helps to relieve stiffness of joints.

EFFECT ON ARUCHI

Before treatment, 18 subjects (90%) in Group A and 17 subjects (85%) in Group B complained of *Aruchi* associated with *Agnimandya*.

After treatment, 17 subjects (85%) in Group A and 20 subjects (100%) in Group B showed marked improvement in appetite and digestive capacity.

Trivrut's purgative properties will improve digestive health, potentially addressing underlying

causes of tastelessness *Kanji's* fermented nature will improve gut health, reducing microbial imbalances contributing to *Aruchi*.

EFFECT ON RA FACTOR

Before treatment, mean RA Factor was 19.9 IU/mL in Group A and 21.7 IU/mL in Group B.

After treatment, levels decreased to 14.2 IU/mL in Group A and 14.7 IU/mL in Group B, showing 28.9% and 32.3% reduction respectively.

Decrease in RA Factor signifies suppression of autoimmune activity and inflammation, achieved through *Ama Pachana* and immunomodulatory effects of *Trivrut*.

EFFECT ON C - REACTIVE PROTEIN

Before treatment, CRP levels were 7.2 mg/L in Group A and 7.5 mg/L in Group B. After treatment, CRP reduced to 6.2 mg/L in Group A and 5.2 mg/L in Group B, showing 13.9% and 30.2% reduction respectively.

Betulin inhibits pro-inflammatory cytokines thus reducing inflammation, antioxidant properties mitigate oxidative stress, contributing to reduced CRP levels. *Kanji's* antioxidants, polyphenols help to decrease inflammation, boosts immunity which may help in reducing CRP levels.

EFFECT ON ESR

Before treatment, mean ESR was 42.9 mm/hr in Group A and 47.8 mm/hr in Group B. After treatment, ESR reduced to 39.6 mm/hr in Group A and 36.9 mm/hr in Group B, showing a 7.7% and 22.8% reduction respectively.

Sterols inhibit pro-inflammatory cytokines, reducing inflammation and ESR. Sterols may regulate immune responses, impacting ESR levels.

Antioxidants and polyphenols of kanji may decrease inflammation, helps in reducing ESR.

OVERALL RESULTS

Comparative analysis of the overall effect of the treatments in both the groups was done by statistically with Mann witney u test and Wilcoxon matched pair test. The test shows that the treatment is statistically not significant in Group A when compared to Group B. Group A overall result is 56.71 % and Group B overall result is 67.58 %.

As per statistiacal analysis eventhough both *Trivrut leha* and *Trivrut churna* is having *Amavatahara* action, *Agnideepaka* properties of *Kanji* and *Ruksha Virechaka* property of *Trivrut Churna* was able to show significant results than *Trivrut leha*.

DISCUSSION

VEGIKI SHUDDHI

Group A: Among 20 subjects, 10 had *Pravara*, 5 had *Madhyama* and 5 had *Avara Shuddhi*

Group B: Among 20 subjects, 12 had *Pravara*, 5 had *Madhyama* and 3 had *Avara Shuddhi*

Over all subjects: Total 22 subjects attain *Pravara*, 10 *Madhyama* and 8 *Avara Shuddhi*

Trivrut churna along with *kanji* was able to bring more *Vegas* compare to *Trivrut leha* due to its *Ruksha, Ushna and Tikshna* properties.

ANTIKI SHUDDHI

Among 40 subjects, all subjects attained *Antiki Shuddhi (Kaphante Rechanam)*.

TIME OF INITIATION AND CESSETION OF VEGAS

In group A *Vegas* get started after 2-3 hrs of ingestion of *Trivrut leha* and it lasts for 6-8 hours.

In group B *Vegas* get started after 1-2 hrs of ingestion of *Trivrut churna* and lasts for 8-10 hours.

In group B initiation of *Vegas* is earlier compare to group A, cessation of *Vegas* also late in group B, which helps to attain more *Vegas* and proper therapeutic effect.

SAMYAKA VIRECHANA LAKSHANAS (LAKSHANIKA SHUDDHI)

A. Srotovishuddi: Achieved in 30 subjects and absent in 10 subjects.

Virechana Dravya is having *Ushna guna* which helps in *Deepana, Pachana, Vilayana* of doshas and decrease *Vata* and *Kapha*. *Teekshna Guna* does *Daha, Paka of dosha, Sukshma guna* helps to relieve *Strotosanga* thus eliminates toxins from it.

B. Indriya Samprasada: Achieved in 31 subjects and absent in 9 subjects.

Virechana drugs having *Vyavayi* and *Vikashi* gunas which pervade through the whole body and reaches small *Srotasas* due to *Sukshma Guna*. *Virechana* drugs circulates all over the body and does *Dosha-sanghata* by its *Virya* by this *Indriya Prasannata* will occur.

C. Laghuta: Achieved in 39 subjects and absent in 1 subject.

Laghuta will be attained by *Sroto shodhana* and *Dosha nirharana*.

D. Agnideepthi: Achieved in 25 subjects and absent in 5 subjects.

Virechana leads to *Gunatah* and *karmatah vriddhi* of *Agni* by vitiated *Dosha* elimination, by this *Agni vriddhi* and *Anamayatva* can be achieved.

E. Anamayatva: Achieved in most of the subjects.

Causative factors of disease will get eliminate through *Virechana karma* and *Doshas* will attain *Nirama avastha* and *Agni vriddhi* will also occur which lead to *Anamayatva*.

F. Vit, Pitta, Kapha and Anila Prapti: Present in all 40 subjects.

First 2-3 *Vegas* of *Mala* (formed or unformed) after that *Drava mala* and at the end mucoid slimy stools, *Kaphanta Rechanam* was achieved in all the subjects.

PROBABLE MODE OF ACTION OF TRIVRUT LEHA WITH USHNAJALA IN AMAVATA

Intake of *Trivrit Leha* with *Ushnajala Anupana*

Ushna jala anupana will helps to enhance the action of *Trivrut leha* as well as it is itself acts as *Rechaka* by increasing peristalsis.

(*Ushna Jala* is mentioned as having the properties of *Sneha Jeerna*, *Shleshma Bhinna*, and *Maruta Anulomya* due to its *ushna* and *sara gunas*, which helps in *Vatashleshma Upashamana*).



Trivrit's phytoconstituents act synergistically:

Turpethin → purgative

Scopoletin & Sterols → Anti-inflammatory

Saponins → Immunomodulatory

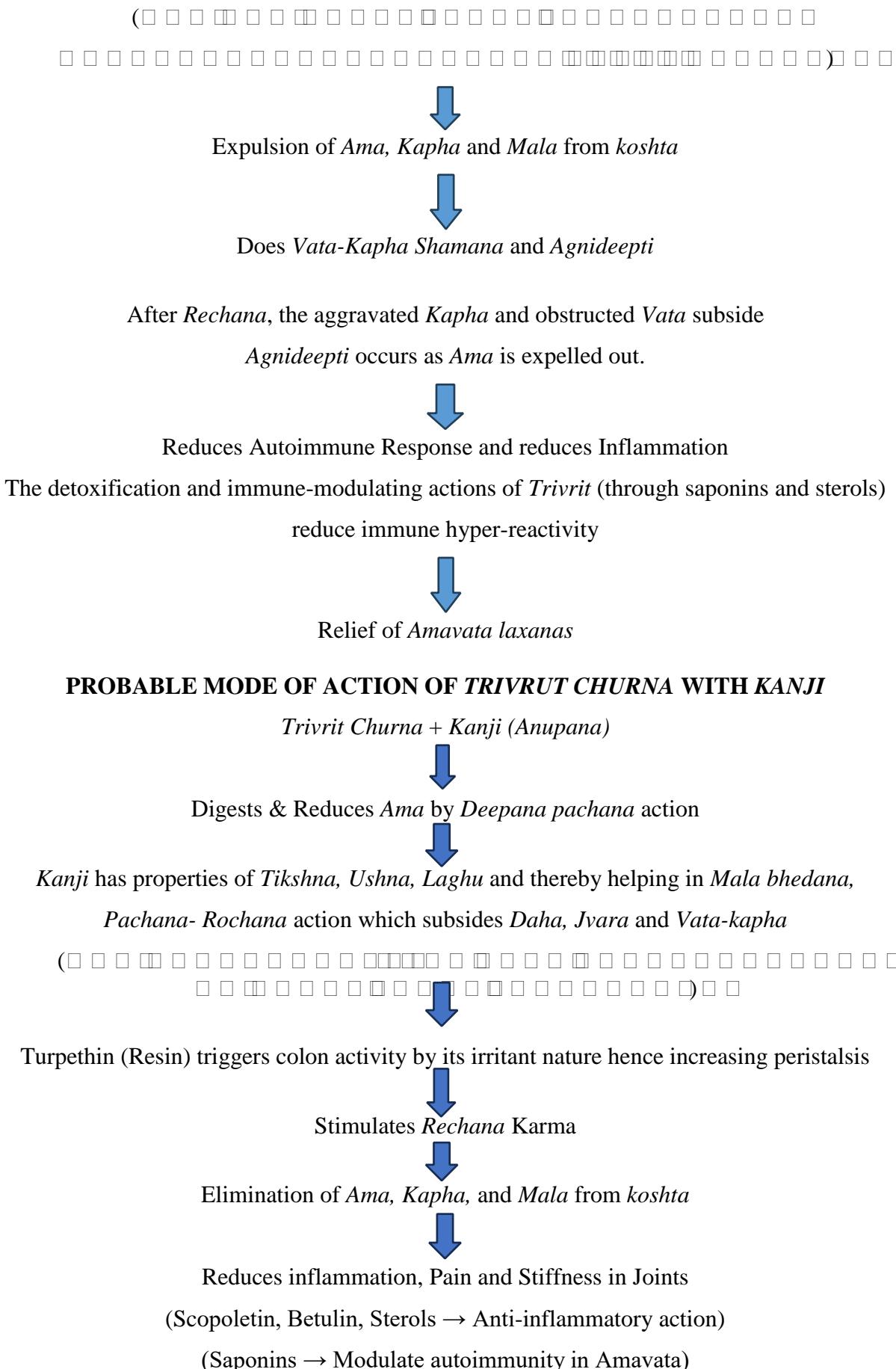


Acts on *Apana Vata* in *pakvashaya* and induce *Anuloma gati* of *Vata*



Initiates *Rechana*

Ushna jala and the *Rechana* nature of *Trivrit* stimulate *Apana Vata* by increased peristalsis, ensuring its *Anuloma gati*



DISCUSSION ON SUBJECTIVE AND OBJECTIVE ASSESSMENT

In subjective criteria, Group B demonstrated 100% improvement in *Stabdhat* ($P<0.0002$) and *Aruchi* ($P<0.0002$), 95% improvement in *Shotha* ($P<0.0019$), and 92% improvement in *Sandhi-shula* ($P<0.0003$). In comparison, Group A showed 96% improvement in *Stabdhat* ($P<0.0008$), 85% in *Aruchi* ($P<0.0021$), 77% in *Shotha* ($P<0.0045$), and 87% in *Sandhi Shula* ($P<0.0012$).

In the objective parameters, Group A showed improvement of 22.8% in ESR ($P<0.0321$), 30% in CRP ($P<0.0156$), and 32% in RA factor ($P<0.0082$), whereas Group B demonstrated greater improvement 27.7% in ESR ($P<0.0102$), 33% in CRP ($P<0.0058$) and 38% in RA factor ($P<0.0031$) indicating statistically significant results across most parameters.

Overall, Group B exhibited superior therapeutic efficacy. This may be due to the abrasive and mucosa-stimulating nature of *Trivrut kwatha bhavita Trivrut Churna* which increases the intestinal absorptive surface area by irritating the mucosal layer, thereby facilitating faster and more effective *Vega* initiation. *Kanji*, being *Sandhana Kalpa* with *Amla rasa*, *Laghu guna*, *Vata-kaphahara*, *Deepana* and *Pachana* properties acts as a *Vibandhahara* and enhances *Shodana*. As a fermented probiotic preparation containing lactic and acetic acids, *Kanji* aids in *Mala Bhedhana* and *Amapachana* promotes healthy gut flora, regulates bowel movement and increases peristalsis, thereby supporting effective *Virechana* and the patients were symptoms free for the duration of 6 to 8 months after *Virechana* devoid of any oral medications for pain management.

CONCLUSION

As *Virechana karma* is best to eliminate the *Adhoga Amashayagata* and *Pakwashaya Samsrista Doshas* Hence, in the present clinical study, *Virechana Karma* was performed to evaluate its efficacy using *Trivrut Leha* and *Trivrut Kwatha Bhavita Trivrut Churna* as purgative agents.

It is observed that Group B exhibited more *Vega*, effective expulsion of *Ama* and *Samsrista Doshas* and a more pronounced *Samanya Virechana*, contributing to better *Vyadhi Nyantranā* than group A. *Trivrut Leha* is *mridu* and *brimhana shodhana* it is helpful in mild *Ama Avastha*, It supports digestion, prevents further *Ama* accumulation, nourishes the body and maintains joint health to prevent disease progression. In contrast, *Trivrut Churna* is a

potent purgative helps in *Amavata* when Ama is significant, its strong detoxifying and purgative action helps to eliminate toxins, reduce inflammation and quickly relieve pain, stiffness and swelling.

In this study, *Trivrut churna* with *Kanji Anupana* was more effective than *Trivrut Leha* with *Ushnajala* for *Virechana* in *Amavata*.

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