Review Article

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A CRITICAL REVIEW ON EFFICACY OF VARIOUS CLINICAL TRIALS IN THE MANAGEMENT OF AMAVATA

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ABSTRACT

In Ayurveda, it has been stated that Amavata (rheumatoid arthritis), once aggravated, is described as the disease having the highest incurable tendency among all the diseases. In modern science, it resembles rheumatoid arthritis and has been described as a crippling disease associated with severe pain, suffering, and diminished function, hence depriving the person of an optimal quality of life. This study is to assess various clinical trials that have been carried out for the management of Amavata (rheumatoid arthritis). Various clinical trials that have been conducted in various departments of different institutes have been tabulated with respect to the drugs used, their dose, mode of administration, sample size, type of study, duration of the trial, and the results obtained. After the course of treatment that varies from 15 days to 90 days, ayurvedic formulations and procedures like Kshara Basti, Vaitarana Basti, Shatyadi Kwath, Maharasnadi Kwath, Alambushadi Churna, Singhnaad Guggulu, Guduchi and Shunthi Kwath, Vatari Guggulu, Mritasanjeevana Rasa, etc. used in different trials showed highly significant ($p<0.001$), significant ($p<0.01$/ <0.05), non-significant ($p>0.01$/0.05) results in sandhi ruja, sandhi shotha, jadyata, aruchi, aalasya, sparsha ashatva, restricted range of motion and grip strength, general functional capacity, walking time, foot pressure; RA factor, ESR, CRP, DAS28 score.

Keywords: Amavata, rheumatoid arthritis, DAS 28 Score, RA factor, subjective parameters, Grip Strength, Walking time

INTRODUCTION

Amavata has great importance, as it has been described as the disease with the highest incurable tendency among all the diseases and as the most crippling disease in its modern counterpart as well. It deprives a person of performing their normal day-to-day activities and hampers their quality of life. Its prevalence is seen much more in women, with a ratio of 3:1 to that of men[1]. Amavata is a systemic disorder where, along with articular symptoms, other symptoms are also affected. In modern medicine, rheumatoid arthritis is explained as an auto-immune, musculo-skeletal disorder that leads to irreversible joint damage and systemic complications as well. Due to its chronicity, complications, incurability, and crippling nature, Amavata is considered a challenge for the physician to manage[2]. Thus, the primary aim of this article is to review various clinical trials conducted for the management of Amavata to date.

Table 1: Collections of Oral medications used in various Clinical Trials

Drug (With dose and mode of administration)	Sample size	Study Model	Duration
Group A: Rasona Pinda - 50-60 mg/kg /BW. **Group B:** Nucoxia 90 – 1 tab OD[3].	63	Randomised Control Trial	3 months and 1 month follow up
Combination of Shunthi, Guggulu, Godanti in 1:2:1 ratio respectively – 2 gm TDS[4]	47	Single Blind Clinical Study	45 Days
Group A (Trial Group): Shatyadi Kwath 20 ml BD with lukewarm water after meals. **Group B (Control Group):** Maharasnadi Kwath – 20 ml BD with lukewarm water after meals[5].	30 (15 each)	Randomised Control Trial	45 Days
Group A: Alambushadi Churna 4 tab TDS (1 Tab=500 mg Alambushadi Churna) with Singhnaad Guggulu 1 gm TDS and Shatpushpadi Taila for local application. **Group B:** Singhnaad Guggulu 1 gm TDS and Shatpushpadi Taila for local application[6].	90 (A:44 B:46)	Comparative Clinical Trial	45 Days
Combination of 1 gm Shunthi Churna and 3 gm Rasna Churna BD[7]	15	Single arm clinical study	3 months (follow up: 1 month)
GroupA: Guduchi and Shunthi Kwath (45-50 ml BD) **Group B:** Indomethacin 75 mg BD **Group C:** Guduchi and Shunthi Kwath (45-50 ml BD) with Indomethacin 75 mg BD[8].	90 (30 in each group)	Randomised Clinical Trial	3 months (follow up:1month)

Group A: Panchsama Churna **Group B:** Eranda Paka **Group C:** Panchsama Churna and Eranda Paka both[9]	30 (10 in each group)	Comparative Clinical Study	60 Days (follow up at 15 Days)
Vatari Guggulu 1 gm with Mahaushadhi Kwath 15 ml TDS after meals[10].	30	Open Label single arm clinical trial	15 Days
Group A: Mritasanjeevani Rasa 125 mg BD **Group B:** Shunthyadi Kwath 40 ml BD **Group C:** Mritasanjeevani Rasa 125 mg BD and Shunthyadi Kwath 40 ml BD[11] both.	45 (15 in each group)	Comparative Clinical Study	45 Days (follow up :15 days)
Rasonadi Kwath 25 ml BD (6 am and 6 pm) with hot water[12]	47(but 30 completed trial)	Single arm. Prospective, open label cohort with preand post intervention analysis design	30 Days (follow up : 45 days after completion of treatment)

Table 2: Collection of Panchkarma Therapies used in various Clinical Trials

Panchakarma Therapy Given	Sample size	Study Model	Duration
Agnitundi Vati-250 mg TDS before meals followed by Kshara Basti in Yoga Basti pattern for 8 days followed by shaman aushadhi (Singhnaad Guggulu 500 mg BD and Rasnasaptak Kwath 48 ml) for 30 days[13].	15	Comparative Clinical Study	38 days , (follow up:1 month)
Group A: Rasnadi Churna Basti in Yoga Basti (course of eight therapeutic enemas), Anuvasana with Brihat Saindhavadi taila. **Group B:** Ardhamatrika Basti in Yoga Basti[14] (course of eight therapeutic enemas).	42 (21 in each group)	Double arm open labelled control clinical trial with pre-post-test study design	8 Days
Group A: Kshara Basti followed by shaman therapy (Singhnaad Guggulu 500 mg BD with Rasnasaptaka Kwath 40 ml BD). **Group B:** Vaitarana Basti in Yoga Basti (course of eight therapeutic enemas) schedule followed by shaman therapy(Singhnaad guggulu 500 mg BD with Rasnasaptaka Kwath 40 ml BD)[15].	30 (15 in each group)	Comparative Clinical Trial	45 days with 1 month follow up
Group A: Rasnasaptak Kwath 40 ml BD with lukewarm water. **Group B:** Vaitarana Basti (350 ml) for 2 times at interval of 15 days in Yoga Basti (course of eight therapeutic enemas) format and Anuvasana (therapeutic unctuous enema) with Brihat Saindhavadi Taila. **Group C:** Rasnasaptak Kwath 40 ml BD with Vaitarana Basti (350 ml) **Group D:** Leflunomide 10 mg OD[16].	56; (A-18, B16, C-05, D-17)	Open Randomized Clinical Trial	45 Days
Group A: Langhana, deepana with Chitraka churna 1.5 mg and saindhava lavana before meals, pachana (Chitrakadi vati 2 tab BD after meals), abhyanga (therapeutic oil massage) and ruksha swedana (dry sudation therapy) from 1st to 15th day. From 4th day, 1st and 2nd basti by Saindhavadi taila followed by Kshara Basti and Saindhavadi taila Anuvasana Basti (therapeutic unctuous enema) on alternate day for 8 days (once in every month consecutively for 3 months). **Group B:** Nucoxia 90 OD (at 8 pm evening time)[17].	66 (9 Dropped) Group A-29 Group B-28	Randomized Control Clinical Trial	3 Months (follow up - 1 month)

Table 3: Results of studies including Oral Medications

Study 1: Group A shows highly significant improvement in pain ($p<0.0001$), swelling, tenderness, stiffness ($p<0.001$); decrease in ESR, RA factor, CRP ($p<0.001$); improvement in grip power, foot pressure and a decrease in ama lakshanas ($p<0.001$).
Study 2: Highly significant ($p<0.001$) decrease in morning stiffness, pain at rest and motion, swelling, tenderness, muscle power, functional status, anorexia, restriction of joint movement. Non-significant improvement in ESR values.
Study 3: The control group provided better relief in most of the cardinal features like, sandhishoola (joint pain), sandhistabdhta (joint stiffness), aruchi (tastelessness), aalasya, apaka (indigestion), tenderness in joints, joint swelling and marked improvement in grip strength, foot press strength and DAS28 response criteria. While trial group provided better relief in angmarda (body ache), trishna (thirst) and jwara (fever).
Study 4: In Group A, 65% shows maximum improvement while, in group B, 50% shows minor improvement.
Study 5: Highly significant ($P<0.001$) difference from baseline to 3rd follow up in body ache, lack of enthusiasm, heaviness, indigestion, swelling of the body, pain, joint swelling, tenderness, morning stiffness; improvement in walking time, grip power, reduction in Anti-CCP. Significant improvement in thirst ($p<0.05$), appetite ($p<0.02$); RA, CRP, ESR values ($p<0.01$).
Study 6: In the intergroup comparison, group A shows improvement in gauravata (heaviness in the body), jwara (fever), apaka (indigestion) in comparison with B and C. The absence of pain was more significant in group B in comparison to other two groups. There was a mean reduction in ESR, RA and CRP values in all groups, but the intergroup comparison was not significant. On interpreting both subjective and objective criteria, trial drug shows better results in subjective parameters whereas, standard drug shows better results in objective parameters.
Study 7: Group C shows highly significant improvement ($p<0.001$) in Sandhi shoola (joint pain), shotha (swelling), raga (redness), jadyata (stiffness), sanchari vedana (migratory pain), ushna-sparshashtwa (warmth of joints), sandhi karyahani (decreased range of motion of joints), ESR values, walking time, grip strength, foot pressure and general functional capacity. Significant improvement ($p<0.05$) in RA factor, lymphocyte and ($p<0.01$) monocyte count.
Study 8: Significant improvement ($p<0.05$) in Amavata saamanya lakshanas, nidraviparyaya, sandhi ruja (joint pain), sandhi shotha (swelling of joints), sparsha asahyata (tenderness), RAPID3, foot pressure, grip strength, morning stiffness, ACR Eular score algorithm, DAS28 score. Non-significant improvement in sandhi ushnata (warmth of joints) in upper limbs, CRP, ESR, RA factor, Hb%.
Study 9: On comparing the effect of 3 therapies, Group C provided better relief than B and A in most of sign and symptoms at significant level.
Study10: Highly significant improvement in shoola (pain), shopha (swelling), stabdhta (stiffness), angmarda (bodyache), aruchi (tastelessness), alasya, apaka (indigestion), grip strength, foot pressure and functional assessment is observed after treatment and follow up. 53.3% showed mild improvement after treatment while, 63.33% showed mild improvement after follow up.

Table 4: Results of Studies Including Panchakarma Therapies

Study 1: Decrease in Subjective parameters (11 patients got marked relief, 3 got moderate, 1 got mild relief); improvement in objective parameters like grip strength- (9 patients got marked, 3 got moderate, 3 got mild relief), tenderness (11 got marked, 2 got moderate, 2 got mild improvement); decrease in ESR value (14- mild, 1-no improvement).
Study 2: Decrease in shoola (pain), shotha (swelling), stabdhta (stiffness); improvement in Functional Grading; Decrease in CRP and DAS28 Score.
Study 3: Sandhi shoola (joint pain) is significantly ($p<0.01$) reduced after kshara basti while, after shaman aushadhi it is highly significant ($p<0.001$)in group A. Highly significant ($p<0.001$) reduction in sandhi shotha (swelling of joints), stabdhta (stiffness), sparsh-asahatwa (tenderness), ESR value is seen after kshara basti. Highly significant ($p<0.001$) improvement in grip strength is observed after kshara basti.
Study 4: Significant decrease in mean titre value of Anti-CCP% mean ESR in A, B, C groups, but difference of mean was greater in group D. Significant reduction in CRP, RA factor, Hb% values in group A and B, while it is non- significant in group C with greater difference in group B.
Study 5: In between group comparison, Group A shows highly significant improvement in pain score ($p<0.0001$), tenderness ($p<0.005$), stiffness ($p<0.005$). swelling ($p<0.001$), DAS28 score ($p<0.001$), score based algorithm of ACR Eular 2010 criteria ($p<0.001$). Significant reduction in RA, CRP, ESR values in group A is noticed, but was non- significant ($p>0.05$) in between group comparisons.

DISCUSSION

The contents of Shatyadi Kwath have katu-tikta rasa (pungent-bitter taste) and ushna veerya (hot potency), which are essential for Amavata management, according to Chakarpani. Katu rasa (pungent taste) by the properties of shodhana (purifying), agni deepana (increases power of agni), and bhukt aahara shoshana, it destroys ama (undigested food or toxins). Its laghu guna (light property) and ushna veerya (hot potency) decrease Kapha dosha, increase salivary and gastric secretion, improve intestinal motility and lead to better absorption[18]. Singhnaad guggulu has katu-tikta rasa pradhan dravyas having agni deepana (increases appetite) and ama pachana (digests ama) properties. Parada acts as a yogavahi (carrier of properties) so, carries drug to sandhi (joints), which is the target. Both Parada and Gandhaka are rasayana (rejuvenating), so acting at the level of autoimmune antibodies, as immunomodulators, helps in alleviating free radicles. Vibhitaki, by virtue of its chedaniya (detachment of vitiated doshas) guna, relieves srotorodha (obstruction of body channels). Chitraka is deepana (enhances metabolism or digestion), shothahara (relieves swelling) and shoolahara (relieves pain). Guggulu has more affinity towards skin and joints, reaches there, and is shothahara (relieves swelling) and shoolahara (relieves pain) [13]. Due to katu-tikta rasa (pungent-bitter taste) and ushna veerya (hot potency), Rasna-Shunthi churna act as deepan-pachan (carminative-digestive), lekhan (scrapping), vishaghna and arochaka-ghna. As mandagni (diminished digestive fire) is the root cause of the disease, deepan drugs should be used [7]. While considering Guduchi-Shunthi Kwath, both (Guduchi and Shunthi) are having ushna veerya (hot potency), due to which it enters sukshma srotas (minute body channels) and removes ama. Guduchi has anti-rheumatic, anti-inflammatory and immunomodulatory properties by decreasing proinflammatory cytokines. Shunthi has an inhibitory effect on prostaglandin synthesis and leukotrine biosynthesis as well as analgesic and anti-inflammatory effect [8]. Vatari Guggulu helps suppress inflammatory mediators like TNF-α and IL-1β and decreases inflammatory symptoms. By virtue of ushna veerya (hot potency), bhedan (purgative), lekhan (scrapping), and deepana-pachan (carminative-digestive) karma helps in ama pachan and removes margavrodha (obstructing channels) [10]. In the clinical trial involving Mritasanjeevana Rasa and Shunthyadi Kwath, both of these drugs have rechak (purgative) property and act by their prabhava[11]. The active ingredients in the contents of Rasonadi Kwath are anti-inflammatory, anti-arthritic, anti-rheumatic and immune-modulators[12]. 8 out of 10 drugs of Rasnadi churna Basti have ushna veerya (hot potency), Vata-Kapha hara (alleviates Vata-Kapha doshas) guna. Dhanyamla is added, which is agni deepana (carminative), sroto shodhana (purifies body channels), bhedana (purgative) and Vata-kaphahara. In Ardhamatrika Basti, Dashmool Kasaya is used which is, Vata-Kaphahara, vedana sthapana (analgesic), shothahara (alleviates swelling). Shatpushpa kalka is there, which is laghu, deepana and Kaphahara. Madanphala kalka is there, which is Vata-kaphahara and asthapanopaga, and hence, due to its ushna and teekshna (sharp) guna, it removes vitiated doshas. Both of these basti have Brihat saindhavadi taila that contains Sarjikshara, which is amahara (removes free radicles or toxins) and Kaphahara (alleviates Kapha). Kanjika helps with bhedana, rochana, pachana, shoolahara, amahara and vibandhahara (relieves constipation). All the drugs in this taila have laghu, ushna, vyavayi (spreads quickly), teekshan, sukshma, shoolahara, and shothahara properties[19]. Vaitarana Basti acts by virtue of the action of basti karma itself as well as by its deepan (enhances metabolism or digestion), pachan (digestive), srotoshodhan (purifies body channels) and Vatashamana (pacifies Vata) karma[16]. Kshara Basti contains gomutra having katu, teekshna properties, chedana (detaches vitiated doshas), marga vivaraka, kaphashamaka, srotoshodhaka and agnideepana karma. It contains Amlika that acts on agnimandya, vibandha (constipation), stabdhgatrata (stiffness in the body), shotha (swelling), and vednashamaka (pacifies pain). Contains mishraya which is analgesic and carminative. Saindhav Lavana is shothahara, vedanahara, and destroys Amavata pathogenesis[17].

CONCLUSION

Considering all the data from various clinical trials regarding the treatment of Amavata, it can be said that the management of Amavata in Ayurveda is a better alternative to the modern therapy. It can be concluded that for sandhi shoola (pain), sandhishotha (swelling), sparsha asahatva (tenderness), jadyata (stiffness); Rasona pinda, (a combination of Shunthi, Godanti, and Guggulu), Maharasnadi Kwath, kshara basti with Singhnaad Guggulu and Rasnasaptak Kwath, Alambushadi Churna, (Shunthi and Rasna Churna), (Panchsama Churna with Eranda paka), (Mritasanjeevan Rasa and Shunthyadi Kwath), and Rasonadi Kwath can be used. Considering grip strength, walking time, functional capacity and foot pressure; Rasona Pinda, Rasnadi Churna Basti, Kshara Basti, (Shunthi and Rasna Churna), (Guduchi and Shunthi Kwath), (Panchsama Churna with Eranda Paka), Rasonadi Kwath can be used. On ESR; Rasona Pinda, Kshara Basti with Singhnaad Guggulu and Rasnasaptak Kwath, (Shunthi and Rasna Churna) and (Panchsama Churna with Eranda Paka) have significant effect. On CRP; Rasona Pinda, Rasnadi Churna Basti, (Shunthi, and Rasna Churna) have significant effect on them. On RA factor; Rasona Pinda, (Shunthi and Rasna Churna), Rasnasaptak Kwath, Kshara Basti, (Panchsama Churna with Eranda Paka).While, Vatari Guggulu with Mahaushadhi Kwath, Kshara Basti and Maharasnadi Kwath shows improvement in the DAS28 score. Angmarda, aruchi, trishna, aalasya, gauravata and jwara can be improved by combination of Shunthi, Godanti, and Guggulu, Shatyadi Kwath, (Shunthi and Rasna Churna), (Guduchi and Shunthi Kwath), Vatari Guggulu with Mahaushadhi Kwath and Rasonadi Kwath. Restricted range

of motion can be decreased by combination of Shunthi, Godanti and Guggulu, (Panchsama Churna with Eranda Paka).

Thus, different therapies, including basti karma and various oral formulations, show highly significant/significant results in various parameters and, hence, improve the patient's quality of life and, hence, the prognosis.

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