



Research Article

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AN OPEN PARALLEL PRAGMATIC COMPARATIVE CLINICAL AND ANALYTICAL TRIAL ON CONVENTIONAL AND IMPROVED METHOD OF BASTI SANDHANAM

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ABSTRACT

In Classical methods the procedure of Basti sandhanam has been mentioned and the qualities of the sadhita dravya are also mentioned. In present day practice both the conventional method and electrical method of preparing Basti dravya is used in institutions. In both the methods drugs are added in order mentioned in Classics. The former procedure consumes lot of man power and the latter lacks the scientific validation. As Basti is practiced very commonly in clinical practice hence study was planned to find out the blending techniques which are scientifically analysed and standardised. 15 patients in each group were administered basti with conventional and improvised method. Study shows improvement in assessment criteria like stability, viscosity, loss on drying, pH, total solids in physicochemical analysis of improvised method of Basti sandhanam whereas in clinical study there were significant results in both objective and subjective criteria along the course of treatment in both the groups. Improvised method of Basti sandhanam is better than conventional method when compared with physicochemical properties whereas clinically both the methods have almost same effects to check the progression of diseases and provide relief to the patients.

Key words: Basti Karma, Basti sandhanam, conventional method, improvised method, Panchakarma

INTRODUCTION

Panchakarma is unique modality of treatment consists of vamana, virechana, anuvasana Basti, niruha Basti and nasya karma.¹ Out of the above five karmas, Basti is the most important constituent of panchakarma due to its multifocal effects.² According to Ayurvedic principles, niruha Basti is a procedure by which medicines in the form of suspension are directly administered to the lower gastrointestinal tract using Basti yantra.³ Niruha Basti possesses a significant place among panchakarma as it is being used for curing or mitigating vata predominant diseases.^{4,5} In classical texts we can observe elaborate descriptions on different aspects of Basti karma.

In the present day practice, the blending of Basti is generally carried out by grinding honey, lavana, sneha dravya, kalka and kwatha respectively by adding them one after another. This unidirectional grinding process consumes a lot of man power and time which has forced to seek alternative techniques of blending. It has been observed that electrically operated mixer has been in use for this purpose in various institutions, but it lacks scientific validation.

This research encompasses a clinical study of conventional and artificial methods of blending and comparing the efficacy of Basti dravya. For this purpose, a major type of ailment among rheumatic disorders, rheumatoid arthritis is selected, for which niruha Basti is considered as a prime treatment. Rheumatoid arthritis is a chronic condition that affects the people in their most active period of life. The deformities that may develop due

to this disease stands as acrippler of mankind. Hence this study is being undertaken to know the physicochemical characters of Basti dravya prepared by conventional and electrically operated mixer and also to find out any difference in their clinical effects.

MATERIALS AND METHODS

Drug preparation

Conventional method

The Basti sandhanam was done as mentioned in Astanga hridaya- Basti vidhi adhyaya, where makshika, lavana, sneha kalka and kwatha were mixed in respective order.⁷⁻⁸

For this study we took honey, saindhava lavana, madhuyashtyadi taila, shatapushpa kalka and erandamoola kwatha^{6,9}. All the ingredients were mixed in respective order in Urali (a bronze vessel) with help of a wooden stirrer till a homogenous mixture was prepared. The mixing was done unidirectional way.

The Urali used in the procedure had dimensions of 26cm diameter, 16cm height and 81cm circumference with a capacity of approx. 5000ml.

Electrical operated method

The Basti sandhanam was done as mentioned in classics in same order mentioned in an electrically operated mixture with particular time interval for adding the dravyas. (Table 1)

Specifications of Electric mixer

Wattage – 500W

Voltage – 230v

AC – 50Hz

Sturdy motor- 18000rpm

Stainless steel liquidizing jar
3 speed with incher facility
6 blades – 4 upwards +2 downwards

Good quality standard drugs were assured before doing the procedure. The drugs from same company and from same batch of medicines were used for whole procedure as not to affect the physicochemical standards.

Basti dravyas prepared by conventional and electrical mixer method were subjected to physicochemical analysis at R&D Division, Pharmacy of institute. All the parameters pertaining to the analysis were carried out and compared, and results were drawn.¹³⁻¹⁴ The quantity of drugs taken to prepare Niruha Basti was same for both Physicochemical and clinical study.

Temperature of Basti dravya

In clinical study and in physicochemical analysis, the Basti was maintained at a temperature of 99^o F to 100^o F.

Selection of patients

Diagnosed cases of Rheumatoid arthritis, attending OPD, Department of Panchakarma, and also with satisfying inclusion criteria were selected for the present study. After permission being obtained from institutional ethics committee vide IEC/09-10/08

A detailed history of all the aspects of problem, and disease was collected with the help of a structured proforma, which also includes laboratory investigation.

Diagnostic criteria

Diagnosed cases of rheumatoid arthritis i.e. R.A factor – more than 25 IU/ml.

Selection criteria

Inclusion criteria

Patients diagnosed to have Rheumatoid arthritis without major joint deformities on the basis of objective and subjective criteria.

After 6 months of onset

Patients between 20-60 years of age

Patients of both sexes

With written consent from the patient.

Exclusion criteria

Diagnosed disorders of bone and joint like osteoporosis, psoriatic arthritis, malignancy, and other disorders like rheumatic fever, connective tissue disorders, SLE, Gout, and bone marrow disorders.

Diagnosed cases of cardiovascular disorders

Other systemic diseases like DM, HTN, etc.

Niruha Basti aranhas

Null Hypothesis

Niruha Basti dravyas prepared by conventional and electrically operated mixer methods are not the same in physicochemical parameters and clinical effect.

Alternative Hypothesis

Niruha Basti dravyas prepared by conventional and electrically operated mixer methods are same in physicochemical parameters and clinical effect.

Procedure

Stage First

- Deepanam-Pachanam – To attain the agni bala and ama pachana, amrutottara kashaya and vaishwanara churnam was given to subjects for 5 to 7 days
- Snehapanam – after attaining agnibala, snehapanam was done with Gulgulu thiktakam Ghritham for 3 days to attain samyak snigdha lakshanas with proper care and concern of pathya-apathya described in classics.
- Swedanam – after snehapanam, abhyanga with Kottamchukkadi tailam & ushnambu snanam for 3 days thereafter.
- Virechanam- on 7th day after snehapanam, virechanam with 25ml of Gandharva erandam in morning at 8:30 am on empty stomach.
- Samsarjana Krama – after virechana the patient is advised to follow strict diet schedule for 3 days.

Stage Second

After attaining proper agnibala by above procedure, yoga Basti protocol is carried for consecutive 8 days with Madhutailika niruha Basti. The Yoga Basti protocol consisted of 5 Anuvāsana Basti and 3 Madhutailika Basti.

Madhutailika Niruha Basti

Madhu- 240ml

Saindhavam – 15gms

Madhuyashtyadi taila – 240ml

Shatahwa kalka – 30 gms

Erandamoolam kashyam – 480ml

960 ml of Basti dravyas was taken for the clinical study.

Anuvāsana Basti

This was done with 120ml Madhuyashtyadi tailam.

Procedure

Purvakarma

The patient was advised to take some breakfast before taking Basti procedure.

Local abhyanga with Kottamchukkadi taila & local svadana was done for 5 – 10 min.

Pradhana Karma

Basti was done in between 10:30am to 11:30am. The patient was asked to attend natural urges prior to the procedure. The prepared Basti dravyas was heated to optimal temperature before administration. Patient was asked to lie on cot of knee height in left lateral position & his left arm was kept folded under his head. A small amount of taila was smeared over the tip of Basti netra as well as the anus of the patient for lubrication. Wearing hand gloves for rectal examination is necessary. The tip of Basti netra was closed with tip of left index finger after evacuating the air and was introduced into the anal canal gently by taking all precautions as per classical references. Putaka is pressed slowly and steadily to push the medication into the rectum. Patient was asked to take deep breath during the procedure. Basti netra was withdrawn with little amount of medicine retained in it to prevent the entry of air. The patient was asked to lie in supine position till the urge of defecation occurs. The patient was allowed to evacuate bowel as urge appeared.

In case of Anuvāsana Basti, it was done between 1pm to 1:30pm after food. No local snehana & svadana is necessary.

Pascata Karma

After the patient felt proper evacuation, Luke warm water bath was advised. The patient was asked to take food after bath. Rice with green gram gruel was given to patient.

The Yoga Basti protocol consisted of 5 Anuvasana Basti and 3 Madhutailika Basti. Then the patients were observed for 5 days and then discharged. The contents of Madhutailika Basti given in drug review.

Time and Duration of Study

The duration of the study was 18 months. Each patient was admitted in hospital for about 35 days. The follow up was done twice at regular interval of 30 days.

Assessment criteria

The assessment was made using clinical parameters. The findings and results were recorded periodically after and before Basti and at the time of each follow up. (Table 2)

Apart from this, Retention time of Basti dravya is assessed by measuring the difference between the time of administration and time of expulsion of Basti dravya. The numbers of Vegas were also noted in all patients of both the categories. The samyak, ayoga and atiyoga lakshanas were also being monitored and data was collected.

Table 1: Duration of time of mixing in improvised method

| Dravya | Speed 1 (Time in sec) | Speed 2 (Time in sec) | Speed 3 (Time in sec) |
|----------|-----------------------|-----------------------|-----------------------|
| Makshika | 5 | | |
| Lavana | 5 | 5 | |
| Sneha | 25 | 25 | |
| Kalka | 30 | 30 | 30 |
| Kwatha | 30 | 30 | 30 |

Table 2: Grading of Variables and their score

| Variable | Score | Symptom |
|------------------------------------|-------|--|
| Joint pain | 0 | No pain |
| | 1 | Mild pain of bearable nature comes occasionally |
| | 2 | Moderate pain but no difficulty in movement of joints appears frequently |
| | 3 | Slight difficulty in joint movement due to pain and remains throughout the day |
| | 4 | More difficulty in moving the joints, pain is severe |
| Swelling | 0 | No swelling |
| | 1 | Slight swelling |
| | 2 | Moderate swelling |
| | 3 | Severe swelling |
| Stiffness | 0 | No stiffness or stiffness lasting for 5 min |
| | 1 | Stiffness lasting for 5 min to 2 hours |
| | 2 | Stiffness lasting for 2 to 8 hours |
| | 3 | Stiffness lasting for more than 8 hours |
| Tenderness of joints | 0 | No tenderness |
| | 1 | Subjective experience of tenderness |
| | 2 | Wincing of face on pressure |
| | 3 | Wincing of face with withdrawal of affected parts on pressure |
| | 4 | Resistance to touch |
| General functional capacity | 0 | Complete ability to carry or all routine duties without handicap |
| | 1 | Frequent normal activity despite slight difficulty in joint movements |
| | 2 | Few activities are persisting but patient can take care of him/herself |
| | 3 | Few activities are persisting; patient requires an attendant to take care of him/herself |
| | 4 | Patient is totally bed ridden |
| X-ray grading | 0 | Normal finding |
| | 1 | Soft tissue swelling, juxtra-articular osteoporosis, possibly with slight narrowing of the joint space |
| | 2 | Early but definite abnormality consisting of bone erosion and distinct narrowing of the joint space |
| | 3 | Medium destructive abnormality with marked narrowing of the joint space |
| | 4 | Severe destructive abnormality. Only minor parts of the articular surface remain |
| | 5 | Mutilating lesions |

Grading of radiographic abnormalities was done in this modified Larsen Method.

Table 3: Wilcoxon Signed Rank Test

| Pair | Type | Mean Difference | Z value | p value |
|------------|--------------|-----------------|---------|---------|
| BT vs. AT | Conventional | 0.333 | -2.236 | 0.025 |
| | Electrical | 0.400 | -2.449 | 0.014 |
| BT vs. FU1 | Conventional | 1.133 | -3.314 | 0.001 |
| | Electrical | 1.000 | -3.217 | 0.001 |
| BT vs. FU2 | Conventional | 1.533 | -3.508 | 0.001 |
| | Electrical | 1.400 | -3.391 | 0.001 |

Table 4: Wilcoxon Signed Rank Test

| Pair | Type | Mean Difference | Z value | p value |
|------------|--------------|-----------------|---------|---------|
| BT vs. AT | Conventional | 0.067 | -1.000 | 0.317 |
| | Electrical | 0.133 | -1.414 | 0.157 |
| BT vs. FU1 | Conventional | 0.133 | -1.414 | 0.157 |
| | Electrical | 0.133 | -1.414 | 0.157 |
| BT vs. FU2 | Conventional | 0.867 | -2.919 | 0.004 |
| | Electrical | 0.600 | -3.000 | 0.003 |

Table 5: Wilcoxon Signed Rank Test

| Pair | Type | Mean Difference | Z value | p value |
|------------|--------------|-----------------|---------|---------|
| BT vs. AT | Conventional | 0.133 | -1.414 | 0.157 |
| | Electrical | 0.200 | -1.732 | 0.083 |
| BT vs. FU1 | Conventional | 0.467 | -2.646 | 0.008 |
| | Electrical | 0.600 | -3.000 | 0.003 |
| BT vs. FU2 | Conventional | 1.267 | -3.153 | 0.002 |
| | Electrical | 1.067 | -3.176 | 0.001 |

Table 6: Wilcoxon Signed Rank Test

| Pair | Type | Mean Difference | Z value | p value |
|------------|--------------|-----------------|---------|---------|
| BT vs. AT | Conventional | 0.067 | -1.000 | 0.317 |
| | Electrical | 0.200 | -1.732 | 0.083 |
| BT vs. FU1 | Conventional | 0.733 | -2.810 | 0.005 |
| | Electrical | 0.667 | -2.887 | 0.004 |
| BT vs. FU2 | Conventional | 1.267 | -3.272 | 0.001 |
| | Electrical | 1.067 | -3.358 | 0.001 |

Table 7: Wilcoxon Signed Rank Test

| Pair | Type | Mean Difference | Z value | p value |
|------------|--------------|-----------------|---------|---------|
| BT vs. AT | Conventional | 0.200 | -1.732 | 0.083 |
| | Electrical | 0.333 | -2.236 | 0.025 |
| BT vs. FU1 | Conventional | 0.533 | -2.828 | 0.005 |
| | Electrical | 0.667 | -3.162 | 0.002 |
| BT vs. FU2 | Conventional | 0.800 | -3.464 | 0.001 |
| | Electrical | 0.933 | -3.300 | 0.001 |

Table 8: Paired Sample t - test

| Pair | Type | Mean Difference | t value | p value |
|------------|--------------|-----------------|---------|---------|
| BT vs. AT | Conventional | 18.100 | 3.114 | 0.008 |
| | Electrical | 69.233 | 6.581 | 0.000 |
| BT vs. FU1 | Conventional | 34.513 | 4.225 | 0.001 |
| | Electrical | 95.753 | 9.150 | 0.000 |
| BT vs. FU2 | Conventional | 55.447 | 7.485 | 0.000 |
| | Electrical | 112.913 | 10.162 | 0.000 |

Table 9: Paired Sample t - test

| Pair | Type | Mean Difference | t value | p value |
|------------|--------------|-----------------|---------|---------|
| BT vs. AT | Conventional | 10.267 | 1.869 | 0.083 |
| | Electrical | 1.867 | 2.041 | 0.061 |
| BT vs. FU1 | Conventional | 25.267 | 3.294 | 0.005 |
| | Electrical | 14.267 | 5.684 | 0.000 |
| BT vs. FU2 | Conventional | 40.667 | 6.641 | 0.000 |
| | Electrical | 24.533 | 9.186 | 0.000 |

Table 10: Wilcoxon Signed Rank Test

| Pair | Type | Mean Difference | Z value | p value |
|------------|--------------|-----------------|---------|---------|
| BT vs. AT | Conventional | 0.593 | -3.433 | 0.001 |
| | Electrical | 0.627 | -3.417 | 0.001 |
| BT vs. FU1 | Conventional | 0.240 | -1.890 | 0.059 |
| | Electrical | 0.207 | -2.025 | 0.043 |
| BT vs. FU2 | Conventional | -0.247 | -2.052 | 0.040 |
| | Electrical | -0.313 | -2.305 | 0.021 |

Table 11: Wilcoxon Signed Rank Test

| Pair | Type | Mean Difference | Z value | p value |
|------------|--------------|-----------------|---------|---------|
| BT vs. AT | Conventional | 0.000 | 0.000 | 1.000 |
| | Electrical | 0.000 | 0.000 | 1.000 |
| BT vs. FU1 | Conventional | 0.133 | -1.414 | 0.157 |
| | Electrical | 0.133 | -1.414 | 0.157 |
| BT vs. FU2 | Conventional | 0.400 | -2.449 | 0.14 |
| | Electrical | 0.400 | -2.449 | 0.14 |

Table 12: Paired sample t - test

| Pair | Type | Mean Difference | t value | p value |
|------------|--------------|-----------------|---------|---------|
| BT vs. AT | Conventional | -3.667 | -1.719 | 0.108 |
| | Electrical | -1.467 | -1.976 | 0.068 |
| BT vs. FU1 | Conventional | -8.000 | -2.197 | 0.045 |
| | Electrical | -8.267 | -2.806 | 0.014 |
| BT vs. FU2 | Conventional | -17.400 | -5.444 | 0.000 |
| | Electrical | -16.933 | -6.994 | 0.000 |

Table 13: Paired Sample t - test

| Pair | Type | Mean Difference | t value | p value |
|------------|--------------|-----------------|---------|---------|
| BT vs. AT | Conventional | -1.600 | -2.423 | 0.030 |
| | Electrically | -1.400 | -2.585 | 0.022 |
| BT vs. FU1 | Conventional | -2.333 | -2.767 | 0.015 |
| | Electrical | -1.667 | -3.136 | 0.007 |
| BT vs. FU2 | Conventional | -4.733 | -4.330 | 0.001 |
| | Electrical | -5.067 | -9.906 | 0.000 |

Table 14: Paired Sample t - test

| Pair | Type | Mean Difference | t value | p value |
|------------|--------------|-----------------|---------|---------|
| BT vs. AT | Conventional | 1.467 | 1.319 | 0.208 |
| | Electrical | 6.533 | 1.725 | 0.106 |
| BT vs. FU1 | Conventional | 4.600 | 1.503 | 0.155 |
| | Electrical | 10.133 | 2.002 | 0.065 |
| BT vs. FU2 | Conventional | 14.400 | 4.714 | 0.000 |
| | Electrical | 34.200 | 6.065 | 0.000 |

Table 15: Mann – Whitney U Test

| Parameters | Mean Difference | Z - value | p - value |
|------------------------|-----------------|-----------|-----------|
| Loss on Drying | -15.823 | -2.627 | 0.009 |
| Total Ash | -0.430 | -2.627 | 0.009 |
| Specific Gravity | -0.019 | -2.627 | 0.009 |
| pH | -0.068 | -2.635 | 0.008 |
| Acidity | 0.000 | 0.000 | 1.000 |
| Fat Content | -0.405 | -1.576 | 0.115 |
| Viscosity | 1.000 | -3.000 | 0.003 |
| Total Solids | -1.373 | -2.635 | 0.008 |
| Total Dissolved Solids | -2.800 | -2.635 | 0.008 |
| Total Plate Count | -106.250 | -2.627 | 0.009 |
| Total Fungal Count | -20.500 | -1.576 | 0.115 |
| Pathogens | 0.000 | 0.000 | 1.000 |
| Cadmium (Cd) | -0.002 | -1.985 | 0.047 |
| Sugar | 0.000 | 0.000 | 1.000 |
| Chloride | 0.000 | 0.000 | 1.000 |
| Sulphate | 0.000 | 0.000 | 1.000 |

RESULTS

Joint pain

The results within the group were assessed by using Wilcoxon Signed Rank test. The mean changes in the Conventional Group and Electrically operated group before treatment and after treatment, before treatment and first follow up and between before treatment and second follow up are statistically significant in both the groups. The p-value BT (Before treatment) & AT (After treatment) was 0.025 and 0.014, BT & FU1 (First follow up) was 0.001 in both the groups and that between BT & FU2 (Second floor up) was 0.001 in both the groups. (Table 3)

Joint Swelling

The results within the group were assessed by using Wilcoxon Signed Rank test. The mean changes in the Conventional Group and Electrically operated group BT & AT, BT & FU1 were not statistically significant in both the groups where as it showed significant results in BT & FU2. The p-value BT & AT was 0.317 and 0.157, BT & FU1 was 0.157 in both the groups and that between BT & FU2 was 0.004 & 0.003 in the two groups respectively. (Table 4)

Tenderness

The mean changes in the conventional group and electrically operated group BT & AT was not statistically significant in both the groups where as it showed significant results in BT & FU1 and BT & FU2. The p-value BT & AT was 0.157 and 0.083, BT & FU1 was 0.008 and 0.003 and that between BT & FU2 was 0.002 & 0.001 in the two groups respectively. (Table 5)

Stiffness

The mean changes in the conventional group and electrically operated group BT & AT was not statistically significant in both the groups where as it showed significant results in BT & FU1 and BT & FU2. The p-value BT & AT was 0.317 and 0.083, BT & FU1 was 0.005 and 0.004 and that between BT & FU2 was 0.001 in the two groups respectively. (Table 6)

General Functional Capacity

The mean changes in the conventional group and electrically operated group before treatment and after treatment is not statistically significant, before treatment and first follow up and between before treatment and second follow up are statistically significant in both the groups. The p-value before treatment and after treatment was 0.083 & 0.025, before treatment and first follow up was 0.005 & 0.002 and that between before treatment and second follow up was 0.001 in both the groups respectively. (Table 7)

RA Factor

The mean changes in the conventional group and electrically operated group before treatment and after treatment, before treatment and first follow up and between before treatment and second follow up are statistically significant in both the groups. The p-value before treatment and after treatment was 0.008 & 0.000, before treatment and first follow up was 0.001 & 0.000 and that between before treatment and second follow up was 0.000 in both the groups respectively. (Table 8)

ESR

The mean changes in the conventional group and electrically operated group before treatment and after treatment were not significant, before treatment and first follow up and between before treatment and second follow up are statistically significant in both the groups. The p-value before treatment and after treatment was 0.083 & 0.061, before treatment and first

follow up was 0.005 & 0.000 and that between before treatment and second follow up was 0.000 in both the groups respectively. (Table 9)

Hemoglobin

The mean changes in the conventional group and electrically operated group before treatment and after treatment, before treatment and first follow up and between before treatment and second follow up are not statistically significant in both the groups but the p-value here represents decrease in Hb just after the treatment. This The p-value before treatment and after treatment was 0.001 in both the groups, before treatment and first follow up was 0.059 & 0.043 and that between before treatment and second follow up was 0.040 & 0.021 in both the groups respectively. (Table 10)

X – Ray Grading

The mean changes in the conventional group and electrically operated group before treatment and after treatment, before treatment and first follow up and between before treatment and second follow up are not statistically significant in both the groups. The p-value before treatment and after treatment was 1.000, before treatment and first follow up was 0.157 and that between before treatment and second follow up was 0.14 in both the groups respectively. (Table 11)

Grip Power

The results within the group were assessed by using Paired t test. The mean changes in the conventional group and electrically operated group BT & AT was not statistically significant in both the groups where as it showed significant results in BT & FU1 and BT & FU2. The p-value BT & AT was 0.108 and 0.068, BT & FU1 was 0.045 and 0.014 and that between BT & FU2 was 0.000 in the two groups respectively. (Table 12)

Foot Pressure on Weighing Machine

The mean changes in the conventional group and electrically operated group before treatment and after treatment, before treatment and first follow up and between before treatment and second follow up are statistically significant in both the groups. The p-value BT & AT was 0.030 and 0.022, BT & FU1 was 0.015 and 0.007 and that between BT & FU2 was 0.001 and 0.000 in the two groups respectively. (Table 13)

Time Taken to Walk 50 Feet

The results within the group were assessed by using Paired t test. The mean changes in the conventional group and electrically operated group BT & AT, BT & FU1 were not statistically significant in both the groups where as it showed significant results in BT & FU2. The p-value BT & AT was 0.208 and 0.106, BT & FU1 was 0.155 & 0.065 and that between BT & FU2 was 0.000 in the both groups respectively. (Table 14)

Physicochemical parameters

The results within the group were assessed by using Mann Whitney U Test. The mean loss on drying was 39.54 & 55.36 in conventional and electrically operated mixer method with standard deviation of 0.285 & 2.325 respectively with mean difference of -15.823 and p-value of 0.009. The mean of total ash was 1.19 & 1.62 in conventional and electrically operated mixer method with standard deviation of 0.010 & 0.026 respectively with mean difference of -0.430 and p-value of 0.009. The mean Specific gravity was 1.0735 & 1.0926 in conventional and electrically operated mixer method with standard deviation of 0.001 & 0.002 respectively with mean difference of -0.019 and p-value of 0.009. The mean pH was

4.43 & 4.50 in conventional and electrically operated mixer method with standard deviation of 0.010 & 0.029 respectively with mean difference of -0.068 and p-value of 0.008. The mean acidity was 0.40 in both conventional and electrically operated mixer method with p-value 1.000. The mean Fat content was 3.72 & 4.13 in conventional and electrically operated mixer method with standard deviation of 0.020 & 0.507 respectively with mean difference of -0.405 and p-value of 0.115. The mean Viscosity was 42 & 41 in conventional and electrically operated mixer method respectively with mean difference of 1.000 and p-value of 0.003. The mean Total solid was 48.74 & 50.11 in conventional and electrically operated mixer method with standard deviation of 0.010 & 0.135 respectively with mean difference of -1.373 and p-value of 0.008. The mean Total dissolved solids was 45.47 & 48.27 in conventional and electrically operated mixer method with standard deviation of 0.020 & 0.498 respectively with mean difference of -2.800 and p-value of 0.008. The mean Total plate count was 16 & 122 in conventional and electrically operated mixer method with standard deviation of 1.000 & 86.754 respectively with mean difference of -106.25 and p-value of 0.009. The mean Total fungal count was 21 & 42 in conventional and electrically operated mixer method with standard deviation of 2.000 & 27.143 respectively with mean difference of -20.500 and p-value of 0.115. The mean Cadmium was 0.0060 & 0.0081 in conventional and electrically operated mixer method with standard deviation of 0.002 & 0.001 respectively with mean difference of -0.002 and p-value of 0.047. There is no mean difference in values of pathogens, sugar, chloride and sulphate with p-value of 1.000. (Table 15)

DISCUSSION

The statistical analysis showed significant results in both Conventional and Electrically Operated method after treatment, first follow up and also during the second follow up. There was gradual reduction of pain in patients, Tenderness, RA Factor, General functional capacity, ESR, Grip power, Foot pressure on weighing scale and Time taken to walk 50 feet of both the groups. Gradual improvement in joint movements was seen due to reduced pain. So erandamoola Niruha Basti prepared by both the methods is effective in all these parameters.

Physicochemical parameters

The mean loss on drying was 39.54 with a standard deviation of 0.285 in conventional method which was seen to be raised by 55.36 with a standard deviation of 2.325 with mean difference of -15.823 and p-value 0.009. Increase in loss on drying indicates that the electrically operated mixer sample has a greater volatility, because of which there is higher concentration of drugs in electrical method which in turn contributes to greater bio availability and absorption of Basti dravya. The presence of mineral content indicates the minerals like sodium, potassium, calcium etc. In regarding Basti dravya the action potential at the microvilli in intestine is generated by these minerals. So the increased mineral content in electrically operated method indicates more action potential for absorption of Basti dravya compared to conventional method. As specific gravity indicates the density and concentration of molecules in a substance the increase in specific gravity of electrically operated Basti dravya suggests the higher density of molecules available for exchange and absorption. In this way, the electrically operated method has more effect and bioavailability in colon. The mean acidity was 0.40 in both the methods. As the mean difference is zero and p-value 1.000. This shows there was no difference of acidity in both the solutions with 5% NaOH at 0.4ml. So this conveys that the Basti dravya is acidic in nature and acidic solution is

essential for the action in colon. The mean pH was 4.43 with a standard deviation of 0.010 in conventional method which was seen to be raised by 4.50 with a standard deviation of 0.029 with mean difference of -0.068 and p-value 0.008. Though the pH is statistically significant in electrically operated method, there is no much difference in the actual pH of both the solutions as both are acidic in nature. The pH of colon is 5.5-7. When acidic solution is introduced to a neutral medium there is electrical potential generated and rapid exchange takes place by diffusion osmosis till the whole medium attains the neutral state in the colon. So proper favorable pH is important for absorption and also evacuation of Basti dravya. The mean fat content was 3.72 with a standard deviation of 0.020 in conventional method which was seen to be raised by 4.13 with a standard deviation of 0.507 with mean difference of -0.405 and p value 0.115. This signifies the proper mixing of oil and uniformity of fatty acids in emulsion of electrically operated method due to high rpm of the mixer and also due to the cutting qualities of the blade. The decrease in fat content may be due to instant formation of layers in conventional type when the samples are drawn. The mean Viscosity was 42 in conventional method and 41 in electrically operated method with zero standard deviation and mean difference 1.000 with p- value 0.003. As viscosity is resistance to flow, higher the viscosity lesser the area covered by the flow of Basti in colon for absorption. This indicates that the electrically operated mixer method Basti dravya has lesser viscosity because of small molecules and also decrease of inter molecular force of different ingredients of Basti and will cover up more area for absorption and assimilation in colon than conventional method. The mean total solids were 48.74 with a standard deviation of 0.010 in conventional method which was seen to be raised by 50.11 with a standard deviation of 0.135 with mean difference of -1.373 and p-value 0.008. Total solids refer to volatile and fixed solids which are in suspended and dissolved form. The increase in the total solids in electrical method indicates they are better dissolved and kalka is suspended in solution uniformly than manual method of mixing due to high speed and intermittent flow produced in mixer due to the cutting blades thus forming a better quality of emulsion. The mean total solids were 45.47 with a standard deviation of 0.020 in conventional method which was seen to be raised by 48.27 with a standard deviation of 0.498 with mean difference of -2.800 and p-value 0.008. Total dissolved solids are the combined content of all organic and inorganic substances in liquid. Here Basti dravya prepared by electrically operated method having more dissolved solids because of proper mixing produced by shear force and speed in mixer. The results of microbial analysis of both the samples shows platelet count and fungal count within normal limits & in both the samples the test for all the pathogens in liquid were carried out and was found to be absent. This indicates the safety and standard of drugs as well as the final product of Basti. Heavy metals like Lead, Arsenic, Cadmium & Mercury were analyzed in both the samples for presence and quantity. In both the samples the analysis proved that heavy metals were within the prescribed limits thus assuring the standard and safety of the drugs used. Chemical tests showed the presence of sugars, chlorides and sulphates in both the samples which are the contents of honey and rock salt in the Basti dravya.

Basti sandhanam

The stability of Basti dravya is related to emulsification capacity along with viscosity due to Honey which facilitates dispersion and the role of kalka as wetting agents. The mixers, whisks or churns involve agitating the ingredients and containing vessel would provide a continuous movement in all parts of the liquid. In a mixer, stable product was getting formed may be due to the

cutter blade is used which do not create movement like centrifuge but intermittent flow in which particles are wetted with the continuous phase and simultaneously get dispersed in the whole media, at the same time high shear rate reduces viscosity of the dispersed phase able to produce its fine subdivision. The interactions are complex in formation of multiphase emulsion. An increase in temperature decreases interfacial tension as well as viscosity. One would therefore predict and it is usually true that emulsification is favored by increase in temperature. The most important influence that temperature has on an emulsion is inversion. The temperature at which the inversion occurs depends on emulsifier concentration and is called phase inversion temperature (PIT). This type of inversion can occur during the formation of emulsions, since they are generally prepared at relatively high temperature and are then allowed to cool to at room temperature. So formed emulsions are generally considered quite stable due to finely dispersed internal phase. It can be seen that there is a slight rise in temperature in mixer where as it is not seen in conventional method. In conventional method, it is difficult to apply the uniform speed and force. And also it is difficult to attain a perfect homogenous state as the mixing method, time and man power may differ from person to person because of which the conventionally prepared Basti dravya disperses in to different layers immediately. The physicochemical properties of Basti dravya depends on the quality of drugs and the method of mixing. The physicochemical properties contribute the action of Basti dravya by influencing the qualities of Basti in generating the action potential for absorption in the colon. In Basti sandhanam, Kashaya forms the external phase whereas Taila forms the internal phase with Kalka acting as dispersing agent by reducing the surface tension at the interphase and honey being hydrophilic in nature having affinity towards water acts as emulsion stabilizing agent. The Basti being a homogenous mixture of makshika, saindhava, sneha, kalka and kwatha. The unidirectional mixing method imparts an action potential in the solution, helps in breaking down of larger molecules. Saindhava consisting of maximum portion of Sodium chloride is readily absorbed in the colon and generates action potential at the microvilli by producing the osmotic gradient. This helps in absorption of monosaccharides, amino acids and short chain fatty acids and medium chain fatty acids present in madhu and sneha by the action of bacterial flora in colon. Madhu is having yogavahi property⁸ and thus has catalyst action. Honey is amphiphilic in nature and contains hydrocarbon and cerotic acid, which combine with K⁺ ion to form an emulsifying agent. This gives a stable emulsion.

Honey is also essential because it acts as a prebiotic for the bifidobacteria present in gastrointestinal tract which are responsible for the absorption of drugs administered through rectal route. Kashaya is a hypertonic solution consisting of water as the major content and the active principles of drugs owing to the method of preparation. This hypertonicity is responsible for the passive absorption of Basti. The kalka acts as a buffer for the homogenous solution of Basti and facilitates in generating the intraluminal pressure which helps in absorption of Basti dravya and at the same time also stimulates the defecation reflex by stimulating the autonomic nervous system which in turn release catecholamines. So kalka also acts as a catalyst for action of Basti dravya and for the expulsion after the probable action. In the mixer method the ingredients are mixed in high speed with cutting action of the blade which provides intermittent flow and dispersion of molecules in whole media which denotes the proper mixing of external and internal phase, better dispersion of kalka in the solution thus forming a more stable Basti dravya than the conventional method. Apart from the physicochemical parameters, Basti preparation by electrical method have added

advantages of less man power, more hygiene and easy to prepare and requiring less time than conventional method. Therefore, Basti dravya prepared by electrically operated mixer method is a better preparation than conventional method because of its high stability, low viscosity, high fat content, better dissolved and suspended solids and a low specific gravity as all these parameters contribute to the qualities of dravya in action in colon. But as far as clinical study is concerned there is no much significant difference in improving the subjective and objective parameters & both are having similar effect clinically and also the Basti prepared by electrically operated method appears slight whitish in colour which indicates scattering of light equally. This shows that the interfaces are properly blend forming a homogenous Basti. Considering all the above facts, it leads the way to think that these physicochemical properties may constitute the Virya of Basti dravya, as any changes in these physicochemical qualities will alter the action potential. As action of Basti is totally dependent on the Virya, the proper proportion and standards of these physicochemical properties will render the maximum effect.¹⁰⁻¹⁵

CONCLUSION

Study concludes that statistical significance results were noted in the assessment criteria like stability, viscosity, loss on drying, pH, total solids etc in physicochemical analysis of improvised method of Basti sandhanam where as in clinical study there were significant results in both objective and subjective criteria along the course of treatment in both the groups. Thus, improvised method of Basti sandhanam is better than conventional method when compared with physicochemical properties whereas clinically both the methods have almost same effects to check the progression of diseases and provide relief to the patients.

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