Research Article

Efficacy of Cupping Therapy and Oral Medications in the Management of Non Specific Low Back Pain-A Pilot Study

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ABSTRACT

Background: Globally, non-specific low back pain has grown to be a significant public health concern. Clinical practice guidelines on the management of NSLBP insist on the use of reassurance, physical activity, paracetamol, NSAIDs, spinal manipulation therapy, etc. NSLBP is correlated to *katishula* in Ayurveda and management includes parasurgical procedures like *Agnikarma* and *Raktamokshana*, which are practiced widely for *vatavyadhi* predominant with pain. Oral medications like *Yograja guggulu* and external applications of *Dhanwantaram taila* are commonly prescribed to relieve pain. **Objectives:** To evaluate the efficacy of *Alabu Raktamokshana* (Cupping therapy) and oral medications in Non-specific Low Back Pain (NSLBP). **Materials and Methods:** Twenty patients diagnosed with NSLBP presenting with *shoola, stambha, suptata, at kati pradesha* and who are *yogya* for *Raktamokshana* fulfilling all the inclusion and exclusion criteria were recruited. *Raktamokshana* by *Alabu* (Cupping therapy) was done on the first and 7th day, followed by internal medications such as *Yogaraja Guggulu, Erandamoola kashaya* and local application of *Dhanwantharam taila* for 14 days. VAS, VDS, SLR, Oswestry Disability Score, *Shoola, Stambha, Suptata* and Range of Movements were assessed at various time points, i.e., the 7th and 14th days from the day of enrollment. The dependent "*t*" test and the Wilcoxon match-paired test were applied to evaluate the results. **Results:** Significant results ($p<0.05$) were observed in all the assessed parameters at various time points. **Conclusion:** *Alabu raktamokshana*, along with oral medications, has given good results in the present study. Further randomised clinical trials in this aspect are necessary to provide evidence-based results.

Keywords: *Alabu raktamokshana*, Cupping therapy, Nonspecific low back pain, *Yogaraja Guggulu, Dhanwantharam taila*.

INTRODUCTION

Years of disability is the most often cause for low back pain and ranks sixth in terms of overall illness burden. Rather than being an illness in both developed and developing nations.[1] This type of low back pain is described as not being related to any identifiable, well-established pathology (such as infection, structural abnormality, cancer, osteoporosis, inflammatory disease fracture, cauda equina syndrome).[2] It can have a variety of causes and it is the most prevalent type of condition. When it is impossible to identify the patho-anatomical cause of the pain, this phrase is employed.[3] The diagnosis of non-specific pain is made in cases where the patient does not exhibit symptoms of any pathology, including osteoporosis, tumour, compression fractures, spinal canal stenosis, infections or inflammations, structural abnormalities of the spine and lumbar radiculopathy.[3] Chronic pain is referred to as pain that lasts longer than 12 weeks.[4] Female sex, middle age, sedentary lifestyles, intense physical activity, occupational overload, smoking and obesity are risk

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factors.[5] Up to 84% of people may experience low back discomfort at some point in their lives, according to some estimates. Between 11 and 12% of people indicate that their low backache has made them disabled, while about 23% of people report having chronic low back pain. In comparison to other age groups, low back pain affected more women than men and people in the 40 to 69 age range.[6] Clinical practice guidelines for the treatment of NSLBP recommend the use of paracetamol, spinal manipulation therapy, nonsteroidal anti-inflammatory medicines, muscle relaxants, weak opioids, reassurance and regular physical activity.[7] In Ayurveda, parasurgical procedures like Agnikarma and *Raktamokshana* are practiced widely for *vatavyadhi* predominant with pain.[8] Oral medications like *Yograja guggulu* and *Dhanwantaram taila* are commonly prescribed for *vatavyadhi* to relieve pain.[9,10] Hence, the purpose of this study is to evaluate the effectiveness of oral medications and *alabu* karma in the treatment of nonspecific low back pain.

Objective of the trial

To evaluate the efficacy of *Alabu Raktamokshana* (Cupping therapy) and medications in the management of Nonspecific Low Back Pain (NSLBP).

MATERIAL AND METHODS

Patients who met all inclusion and exclusion criteria for *Raktamokshana* and who had classical features of *shoola, stambha, suptata*, at *kati pradesha* were recruited. Informed written consent was obtained prior to recruitment and patients who received medical care at our hospital's OPD and IPD were included in the planned study. The Institutional Ethics Committee (Protocol ID: BMK/22/RSK/01, KAHER BMK Ayurveda Mahavidyalaya, Belagavi) has provided acceptance for conducting the research. The period of data collecting was from June 2022-December 2022. Throughout the trial, the patients were monitored for any adverse events and their records were maintained in a systematic manner.

Sample size

A total of 20 patients diagnosed with non-specific low back pain and having the classical features of *shoola, stambha* and *suptata* were recruited. As it was a pilot study, 20 patients were found adequate to draw the conclusions; no specific calculation methods were used to calculate the sample size.

Inclusion criteria

Subjects with classical features of *shoola, stambha, suptata*, at *kati pradesha* of either sex and age between 20 and 70 years and who are *Yogya* for *Raktamokshana* according to classics with normal Clotting Time, Bleeding Time and Haemoglobin were included in the study.

Exclusion criteria

Patients with radiating pain from the low back to the lower limbs and who are *Ayogya* for *Raktamokshana*, including *Sarvangashopha*, *Pandu*, *Arsha*, *Udara*, *Shosha*, *Garbinishopha*, or subjects with history of spinal tuberculosis, lesion, or injury, HIV I and II, HbsAG infections, severe anaemia, or any other chronic illness (like diabetes, hypertension, etc.), pregnancy and K/C/O bleeding disorders were excluded from the study.

Screening method

In accordance with the inclusion and exclusion criteria, patients suffering from non-specific low back pain were screened. Patients who met the criteria were enrolled in the research and assignment was done in the form of consort chart (Figure 1).

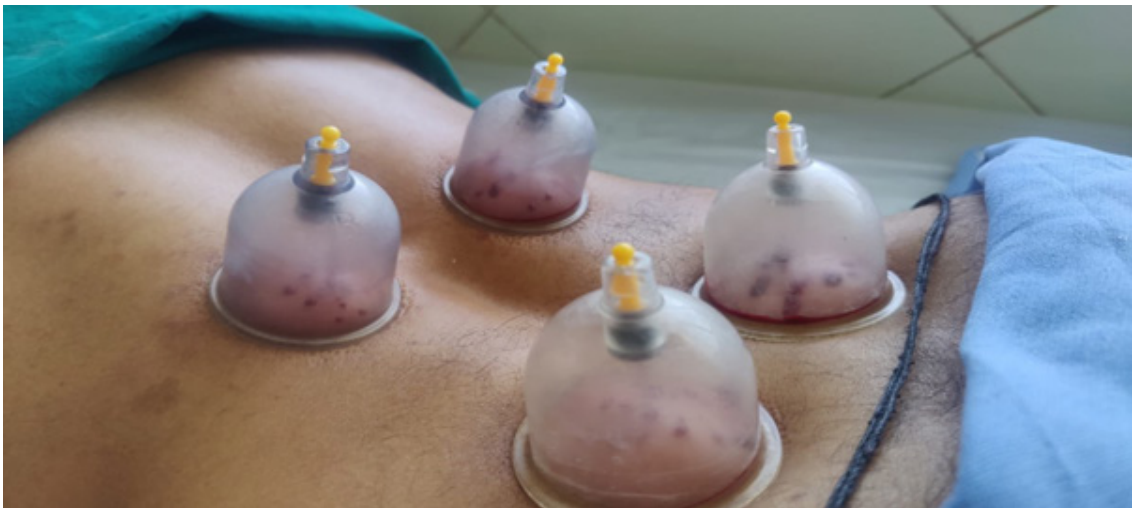
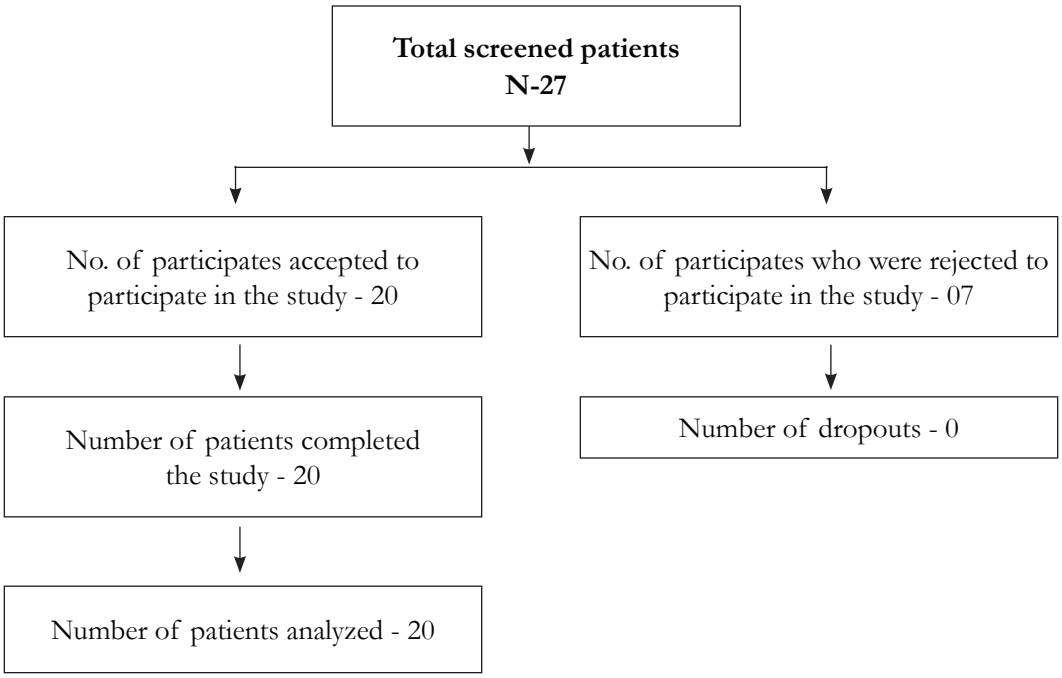


Figure 1: Cupping therapy.

Consort Chart



Study design

A single-group, open-label clinical trial with a pre- and post-test design.

Intervention

After clinical screening, patients who fulfilled diagnostic criteria, inclusion criteria, or did not meet exclusion criteria and consented to the study were recruited. Before providing informed consent, patients were informed about the study's purpose and design. All the included patients were treated with *Alabu Raktamokshana* (Cupping Therapy) (Figure 1) on days 1 and 7. Internal medication was given, such as *Erandamoola Kashayam*, 20 mL twice daily after food and *Yogaraj Guggulu*, 250 mg twice daily after food along with local application of *Dhanwantarm Taila* twice daily for a period of 14 days. The medicines were procured from GMP-certified KLE Ayurveda Pharmacy, Belagavi. Data was collected on a regular basis and evaluated using suitable statistical methodologies.

Criteria for Assessment

Primary outcomes-Pain was assessed by VAS (Visual Analogue Scale), VDS (Verbal Descriptive Scale). Ayurveda parameters to assess the severity of disease like *Shoola, Stambha, Suptata* were assessed by standard grading from the published literature.

Secondary outcomes

The range of movements were assessed in degrees by Goniometer. The severity of pain was assessed by SLR (Straight Leg Raising Test) in degrees, the quality of life was assessed by Oswestry low back disability Score through a standard questionnaire form. All the parameters were assessed at various time points, i.e. 7th day and 14th day from the day of enrollment.[11,12] Prior to *raktamokshana*, all patients had bleeding and clotting tests as part of safety precautions.

Statistical methods

Using the Wilcoxon match-paired test, the changes in VAS, VDS, *Shoola*, *Stambha*, *Suptata* and range of motion were compared from baseline to two time points, i.e., the seventh and fourteenth days. Using the dependent "*t*" test, changes in SLR and Oswestry disability score were compared from baseline to two time points, particularly the seventh and fourteenth days. All tests were considered statistically significant at $p<0.05$, with values expressed as mean+standard deviation.

RESULTS

The study was completed by 20 patients in total; no patients dropped out. There were no adverse events during the course of the study.

Subject characteristics

Age: There were 20 patients, 9 men and 11 women. 16 patients had an average age of less than 30 and 6 patients were more than 31 years old, respectively.

Occupation: 9 of the patients were professional college students and the rest of the patients included people who worked as farmers, mechanics and other jobs.

Religion: 14 patients were Hindu and 6 patients were Muslim in the present study.

Table 1: Comparison of changes in SLR Scores at various time points.

Comparison of different treatment time points with SLR (in degree) scores at right side by dependent 't' test							
Time points	**Mean**	**SD**	**Mean Diff.**	**SD Diff.**	**% of change**	**t-value**	***p*-value**
Baseline	71.66	9.17	–11.33	4.81	–15.81	–9.1336	0.0001*
7th day	83.03	6.48					
Baseline	71.66	9.17	–14.33	6.78	–20.00	–8.1891	0.0001*
14th day	86.02	6.31					
Comparison of different treatment time points with SLR (in degree) scores at left side by dependent 't' test							
Time points	**Mean**	**SD**	**Mean Diff.**	**SD Diff.**	**% of change**	**t-value**	***p*-value**
Baseline	72.32	9.43	–11.67	4.50	–16.13	–10.0440	0.0001*
7th day	84.04	6.31					
Baseline	72.32	9.43	–14.33	6.78	–19.82	–8.1891	0.0001*
14th day	86.69	6.18					

*p<0.05.

SLR Scores-Assessment of SLR scores of right and left lower limb from baseline to 7th and on 14th day was done with dependent '*t*' test. The mean value of SLR Right side) on baseline was 71.66 which increased to 83.03 on 7th day and 86.02 on 14th day with significant *p* value of 0.0001. The mean value of SLR (Left side) on baseline was 72.32 which increased to 84.04 on 7th day and 86.09 on 14th day with significant *p* value of 0.0001. The adopted treatment has given significant results i.e. $p<0.05$ in the SLR parameter.

Table 2: Comparison of different treatment time points with VAS and VDS scores.

Comparison of different treatment time points with VAS scores by Wilcoxon matched pairs test							
Time points	**Mean**	**SD**	**Mean Diff.**	**SD Diff.**	**% of change**	**Z-value**	***p*-value**
Baseline	6.61	1.11	3.07	0.80	46.46	3.4078	0.0007*
7th day	3.52	1.33					
Baseline	6.61	1.11	5.13	1.25	77.78	3.4079	0.0007*
14th day	1.46	1.59					
Comparison of different treatment time points with VDS scores by Wilcoxon matched pairs test							
Time points	**Mean**	**SD**	**Mean Diff.**	**SD Diff.**	**% of change**	**Z-value**	***p*-value**
Baseline	4.86	1.12	2.20	0.56	45.21	3.4078	0.0007*
7th day	2.66	0.91					
Baseline	4.86	1.12	3.87	1.06	79.45	3.4080	0.0007*
14th day	1.02	1.03					

*p<0.05.

Pain

Assessment of pain by VAS, VDS from baseline to 7th and on 14th day was done with Wilcoxon matched pairs test t. The mean value of VAS on baseline was 6.61 which decreased to 3.52 on 7th day and 1.46 on 14th day with significant *p* value of 0.0007. The mean value of VDS on baseline was 4.86 which decreased to 2.66 on 7th day and 1.02 on 14th day with significant *p* value of 0.0007. The adopted treatment has given significant results i.e. $p<0.05$ in the pain parameter assessed by VAS abd VDS.

Table 3: Comparison of different treatment time points with Oswestry Low Back Disability scores by dependent 't' test.

Time points	**Mean**	**SD**	**Mean Diff.**	**SD Diff.**	**% of change**	**t-value**	***p*-value**

Baseline	12.41	4.05	0.00	0.00	0.00	0.0000	1.0000
7th day	12.42	4.05					
Baseline	12.41	4.05	6.80	1.86	54.84	14.1643	0.0001*
14th day	5.62	3.92					

*p<0.05.

Oswestry low back disability scores-Assessment of low back disability by Oswestry questionnaire from baseline to 7th and on 14th day was done with dependent '*t*' test. The mean value of score on baseline was 12.41 which remained constant upto 7th day and reduced to 5.62 on 14th day with significant p value of 0.0001. The adopted treatment has given significant result i.e. p<0.05 on 14th day in the low back disability assessed by Oswestry questionnaire.

Table 4: Comparison of *Shoola, suptata, Stambha* parameters at various time points.

Comparison of different treatment time points with *SHOOLA* scores by Wilcoxon matched pairs test						
Time points	**Mean**	**SD**	**Mean Diff.**	**% of change**	**Z-value**	***p*-value**
Baseline	2.5	0.5	1.5	59.46	3.4078	0.0007*
7th day	1.0	0.7				
Baseline	2.5	0.5	2.1	83.78	3.4081	0.0006*
14th day	0.4	0.7				
Comparison of different treatment time points with *STAMBHA* scores by Wilcoxon matched pairs test						
Time points	**Mean**	**SD**	**Mean Diff.**	**% of change**	**Z-value**	***p*-value**
Baseline	2.12	0.66	1.6	75.00	3.4078	0.0007*
7th day	0.51	0.52				
Baseline	2.12	0.66	1.9	90.62	3.4079	0.0006*
14th day	0.22	0.43				
Comparison of different treatment time points with *SUPTATA* scores by Wilcoxon matched pairs test						
Time points	**Mean**	**SD**	**Mean Diff.**	**% of change**	**Z-value**	***p*-value**
Baseline	1.73	1.02	1.3	73.08	3.2958	0.0010*
7th day	0.51	0.71				
Baseline	1.73	1.02	1.5	84.62	3.2958	0.0010*
14th day	0.32	0.61				

*p<0.05.

Shoola, Stambha and *Suptata*-Assessment of *Shoola, Stambha*, *Suptata* from baseline to 7th and on 14th day was done with by Wilcoxon matched pairs test. The mean value of *Shoola* on baseline was 2.5 which reduced to 1.0 on 7th day and 0.4 on 14th day with significant p value of 0.0007 and 0.0006 respectively. The mean value of *Stambha* on baseline was 2.12 which reduced to 0.51 on 7th day and 0.22 on 14th day with significant p value of 0.0007 and 0.0006 respectively. The mean value of *Suptata* on baseline was 1.73 which reduced to 0.51 on 7th day and 0.32 on 14th day with significant p value of 0.0010. The adopted treatment has given significant result i.e. p<0.05 on 7th and 14th day in the *Shoola, Stambha* and *Suptata* parameters.

Table 5: Comparison of Range of movements at various time points.

Comparison of different treatment time points with FLEXION scores by Wilcoxon matched pairs test						
Time points	**Mean**	**SD**	**Mean Diff.**	**% of change**	**Z-value**	***p*-value**
Baseline	1.51	0.53	1.1	72.73	3.2958	0.0010*
7th day	0.44	0.52				
Baseline	1.51	0.53	1.4	95.45	3.4091	0.0006*
14th day	0.12	0.32				
Comparison of different treatment time points with Extension scores by Wilcoxon matched pairs test						
Time points	**Mean**	**SD**	**Mean Diff.**	**% of change**	**Z-value**	***p*-value**

Baseline	0.71	0.52	0.5	72.73	2.5205	0.0117*
7th day	0.22	0.41				
Baseline	0.71	0.52	0.7	100.00	2.9341	0.0033*
14th day	0.03	0.04				

Comparison of different treatment time points with Right Lateral Flexion scores by Wilcoxon matched pairs test

Time points	Mean	SD	Mean Diff.	% of change	Z-value	*p*-value
Baseline	1.02	0.74	0.9	86.67	3.0594	0.0022*
7th day	0.11	0.42				
Baseline	1.02	0.74	1.0	100.00	3.0595	0.0022*
14th day	0.02	0.03				

Comparison of different treatment time points with Left Lateral Flexion scores by Wilcoxon matched pairs test

Time points	Mean	SD	Mean Diff.	% of change	Z-value	*p*-value
Baseline	0.94	0.64	0.5	53.85	2.3664	0.0180*
7th day	0.42	0.52				
Baseline	0.94	0.64	0.8	92.31	2.9341	0.0033*
14th day	0.12	0.32				

*p<0.05.

Range of motions

Assessment of range of motions (flexion and extension) from baseline to 7th and on 14th day was done with by Wilcoxon matched pairs test. The mean value of flexion scores on baseline was 1.51 which reduced to 0.44 on 7th day and 0.12 on 14th day with significant p value of 0.0010 and 0.0006 respectively. The mean value of extension scores on baseline was 0.71 which reduced to 0.22 on 7th day and 0.03 on 14th day with significant p value of 0.0117 and 0.0033 respectively. The mean value of Right Lateral Flexion on baseline was 1.02 which reduced to 0.11 on 7th day and 0.02 on 14th day with significant p value of 0.0022. The mean value of Left Lateral Flexion on baseline was 0.94 which reduced to 0.42 on 7th day and 0.12 on 14th day with significant p value of 0.0180 and 0.0033 respectively. The adopted treatment has given significant result i.e. p<0.05 on 7th and 14th day in the range of motion parameters.

DISCUSSION

SLR can identify nerve root compression or tension, making it a useful tool for neurodynamic evaluation.[13] The benefits of cupping therapy on muscle contraction, flexibility and pain threshold are comparable to those of passive stretching. [14] It is believed to primarily relieve the uncomfortable muscle tension and boost local blood circulation. The disruption of blood flow and congestion, as well as the halting of inflammatory extravasations (the escaping of physiological fluids like blood from the tissues), are some of the suggested modes of action for cupping therapy.[14,15] Others have suggested that cupping may have an impact on the autonomic nervous system and aid with pain management (Tables 1-3). It also promotes local tissue angiogenesis, enhance granulation, repair the capillary endothelial cell and improves microcirculation.[14,15] This procedure restores the patient's functional condition and promotes progressive muscular relaxation.[14,15] The study conducted on cupping therapy among nurses in china showed reduction of VAS scores from 2.53 to 1.88 after 4 weeks, but in our study the VAS score were reduced earlier and within less period.[16] Cupping therapy along with oral medicines might have reduced the VAS scores within less period. The study conducted with dry cupping on non-specific low back pain showed reduction in VAS from 4.68 to 2.39 after 4 weeks of treatment and during follow up.[17] In the present study the VAS parameter reduced earlier which may be due to administration of both i.e. cupping therapy and oral medications. The oswestry disability index was 17 during baseline which reduced to 10.28 after treatment (4 weeks) and follow up, in the present study it was reduced earlier.

Alabu Raktamokshana aids in improving the flow of new blood to the troubled lumbar region. As a result, it serves as a form of localised *Shodhana* (Purification) therapy that cleanses the blood vessels (*Rakta Vaha Srotas*) and Rasa.[12] Bloodletting removes the *Avarana* (covering/obstruction) of *Kapha Dosha* (humor) over *Vyana Vayu* in *Margavaranajanya Samprapti* (Obstructed Pathogenesis), which aids in the restoration of *Prakrit Rasa-Rakta Samvahana* (normalcy of blood flow) and offers nutritional support to the affected areas,

alleviating symptoms like *shoola, stambha* and *suptata* (12) (Tables 1 and 4).

In clinical practice, the roots of *Eranda* (*Ricinus communis* Linn) are used to cure a variety of conditions, including rheumatism (*Amavata*), inflammation (*Sotha*), back pain (*Katishula*), etc. Its roots possess anti-inflammatory, hepatoprotective and free radical-scavenging properties.[18] According to a phytochemical analysis, *Eranda* contains flavonoids, tannins, alkaloids and saponins.[19] Flavonoids and tannins have been found to have analgesic and anti-inflammatory properties.[19] Tannins are also said to have strong anti-edematous and cyclooxygenase-1 inhibitory effects. Thus, flavonoids, tannins, alkaloids and saponins may all contribute to the extracts' anti-inflammatory effects.[19] The pilot study conducted on *gradrasi* by using *ghati yantra raktamokshana* showed that the mean score of *ruja* (pain) was 2.55 on baseline which got reduced to 0.75 after 20 days of treatment. *Stambha* scores were 2.55 initially which got reduced to 0.75 after treatment. SLR was 36 initially which increased to 80 after treatment.[20] In the present study the *Shoola/ruja*, *Stambha* and SLR got reduced earlier than the previous study which may be due to addition of oral medicines with cupping therapy.

Yogaraja Guggulu is useful in all types of *Vataja* (vitiated *vata*) and neurodegenerative disorders. The excessive *jalamsha* (fluid) and *aama* (toxins) that have accumulated in the joints are scraped away by *guggulu* due to its *lekhana* (scraping) function.[21,22] *Ushna guna* (hot potency) aids in re-establishing the balance of the vitiated *vata*. Most of the medications in this combination have *vata-shamaka* effects (Tables 4 and 5). Additionally, these medications function as *vedana stapaka* (reduces pain), *nadi balya* (strengthening nerves), *shulashamaka* (Pain relieving) and *shothahara* (reduces swelling), which is crucial for encouraging symptomatic alleviation in vatavyadhi.[21,22] *Yogaraj Guggulu* boosts *Agni* (metabolic fire), *Bala* (physical strength) *and* aids in the treatment of *Aamvata* (rheumatic disorders) and a variety of *Sandhi-Majjagata* issues.[23] In clinical practice for *Kshata* (Injury) and *Vatavikara* (Diseases caused by *vata*), there is widespread usage of *Dhanwantharam* thaila. The majority of the medications in *Dhanvantaram Tailam* have *Vatahara* properties and when externally applied, they help reduce pain, numbness and swelling. It strengthens the muscles and joints.[24] By giving tissues the right nutrition, it promotes muscle strength, improves muscle tone there increases the range of motions (Table 5).[24] *Bala* or *Cordifolia* extract reduces inflammation and pain by interfering with the cyclooxygenase system. The present pilot study guides the clinician to manage the pain immediately, later proper planning of basti and other local procedures can give better clinical outcomes for longer duration of pain relief. The study paves the way for conduction of larger samples with assessment of other clinical variables to produced evidence based results and helps the society at large.

Strengths of the study-The study mainly concentrates on immediate reduction of low back pain by adopting cupping therapy and oral medications which increases the range of motions and provide relief. The standard assessment and statistical parameters are considered form the published indexed journal makes the treatment outcome strong and reliable.

Limitations of the study-The study is a pilot in nature with inclusion of less samples to draw the conclusions. Follow up period of longer duration would fetch more accuracy in the pain parameter.

CONCLUSION

Nonspecific low back pain in the modern era can be considered a significant health concern that has a direct impact on sickness absence, work absenteeism and the quality of patient life. The pilot study that was conducted has shown significant results in all the assessed parameters. The present protocol can be utilized for the continuation of the study with a larger sample size and randomised clinical trials can be planned to compare the efficacy of the results.

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Nil.

CONFLICTS OF INTEREST

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTION

All the authors provided their contributions in treating the patients. Dr Ramesh Killedar, Dr Kartik KV and Dr Harishankar involved in the collection of data. Analysis, interpretation of the data was done by all the authors. Manuscript drafting was done by Dr Ramesh Killedar, Dr Kartik KV, Dr Harishankar P V and review, correction of manuscript was done by Dr Pradeep Shindhe and Dr Vijay Kage. Approval from all the authors was provided for the submitted manuscript.

ABBREVIATIONS

NSLBP: Nonspecific low back pain; **NSAID:** Non steroidal Anti-inflammatory drugs; **VAS:** Visual Analogue Scale; **VDS:** Verbal Descriptive Scale; **SLR:** Straight Leg Raising Test.

SUMMARY

Non-Specific LBP (NSLBP) is characterized as tension, pain and/or stiffness in the lower back of unknown aetiology, with joint, disc and connective tissue involvement possibly contributing to symptoms. It is estimated that up to 84% of adults experience LBP at some point in their lives. Management includes of education and reassurance, analgesic medications, non-pharmacological therapy and regular review. In *Ayurveda*, Non-specific low back pain can be linked to *vata vyadhi* cluster disorders, including *Katigraha, Gridrasi* and *Khalli*, with common symptoms such as *Shoola/Ruja* (pain), *Stambha* (stiffness) and *Suptata*. The management of pain can be classed as *Aatyayeka chikitsa* (urgent care) and it includes *Agnikarma/Raktamokshana* as a treatment. *Alabu* is especially useful for symptoms such as *Suptata, Kandu, Sthambha, shoola* and *avagadatara rakta dosha* conditions. Formulations such as *Yogaraja guggulu, Dhanawantari taila* and *Erandamula kashaya* are traditionally used to treat *Vatavyadhi*. As a result, a pilot study was conducted with *Alabu Raktamokshana* (Cupping therapy), and oral medications in the treatment of non-specific low back pain. Encouraging results were obtained in all assessed parameters (*Shoola, Stambha, Suptata* and range of movements). Hence, the above treatments can be utilized for the management of NSLBP.

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