Assessment of health-related quality of life (SF-36 QOL) in Non-specific low back pain treated by cupping therapy and medications – A Randomized controlled trial.

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Abstract

Background - Non-specific low back pain (NSLBP) is a serious health issue in developing nations, with a significant impact on patients' quality of life. These issues can be adequately measured using the Short Form Health Survey (SF-36), and the individuals' social determinants. Cupping therapy has been shown to be beneficial for controlling NSLBP and enhancing quality of life. Various physiotherapy techniques, such as Transcutaneous Electrical Nerve Stimulation (TENS), HMP (Moist hot pack) and exercise, are currently in use and widely accepted for treating NSLBP.

Objective: To compare SF36 QOL in patients treated with cupping therapy and oral medications to physiotherapy (HMP, TENS, and exercise).

Materials and Methods - The study was designed with the enrollment of 134 individuals with chronic non-specific low back pain who met the inclusion and exclusion criteria. Participants were allocated into two groups: Trail (Cupping therapy and medicines) and Standard (HMP, TENS, and Exercise therapy). The trial lasted 28 days (14 days of treatment plus two follow-ups). The SPSS 20.0 program was used with a 95% confidence interval and a significance level of $p < 0.05$.

Results – Maximum of the patients were from the age group between 31 to 40. Most of patients were doing occupation which was more of sitting at one place for a longer period. The results showed that both group treatments were significant independently (Pre and post) but non-significant when both groups were compared.

Conclusion - The study found that both groups are equally effective in improving quality of life as measured by SF 36.

Keywords - Cupping therapy, Non-specific low back pain, SF-36 QOL, Physiotherapy, Exercise.

1. Introduction

Chronic non-specific low back pain has a considerable impact on workers' life, causing them to become sad, nervous, dissatisfied, and frequently fearful of losing their jobs [1]. The prevalence of NSLBP among adults is 60% and it is significantly connected with numerous socio-demographic variables; it increases with age and is the most common musculoskeletal disorder among middle-aged persons [1,2]. Women are more likely to be impacted, as are those who engage in sedentary or physically demanding jobs, such as heavy lifting [2]. Another key consideration is the increased public and private costs associated with absence from job, insurance, and healthcare [3].

Education, reassurance, analgesic medications, non-pharmacological therapy, and prompt review comprise standard management of NSLBP [4]. The goal of management is to minimize disability and symptoms such that participation in physiotherapy and return to everyday activities are possible [4]. Patients with NSLBP may benefit from neuromuscular rehabilitation techniques such as exercise therapy, transcutaneous electrical nerve stimulation (TENS), and hot moist pack (HMP) to reduce discomfort and enhance physical function [5,6]. In order to alleviate their pain and discomfort, patients typically turn to traditional remedies [7]. In addition to Asia and Europe, wet cupping is very popular in the Middle East [7]. Wet cupping appears to be beneficial for musculoskeletal discomfort, according to rising data[7]. Formulations like *Dhanwantari taila*, *Erandamula kashaya* and *Yograja guggulu* are frequently prescribed to treat pain [8]. Therefore, using the SF-36 questionnaire, sociodemographic factors, the study was conducted to compare the two treatments in terms of patient quality of life and spine functional status in NSLBP.

2. Objective - The trial's objective was to compare the quality-of-life metrics using SF36 between patients with NSLBP receiving cupping therapy plus medication and those receiving regular physiotherapy techniques.

3. Material and Methods

3.1 Study design and setting- The research was a prospective, open-label, randomized controlled experiment with pre and post-tests. Patients with NSLBP who met the inclusion and exclusion criteria were recruited. Prior to recruitment, informed written agreement was obtained, and the proposed study comprised patients who received medical care at KLE

Ayurveda Hospital, Medical Research Center in Belagavi, and our hospital's OPD and IPD. The research has been approved by the KAHER Human Ethical Committee Belagavi (Protocol ID: KAHER/EC/21-22/250122001- H). Data collection was place between December 2022 and June 2024. Using computer- generated random number software, the participants were split into two groups at random and assigned to the control and treatment groups in a 1:1 ratio. The participants were assigned central case registration numbers based on the randomization chart. The patients' records were kept in a systematic manner throughout the course of the study, and they were monitored for any adverse results.

3.2 Sample size estimation- We recruited 134 patients who had been diagnosed with nonspecific low back pain. The sample size was determined using a 95% significance level (i.e., 1.96), and an 80% power level (i.e., 0.84). A 10% dropout rate was predicted and computed using the formula n = [(Zα/2 + Zβ) 2 × {2(ó) 2}]/(μ1 - μ2)2, which came out to be 122. To account for the 10% dropout rate, 136 patients were recruited.

3.3 Inclusion criteria - The study included patients who were between the ages of 20 and 70 and who had the typical signs and symptoms of low back pain [9].

3.4 Exclusion criteria - The study excluded participants with a history of spinal tuberculosis, lesion, or injury, HIV I and II, HbsAG infections, severe anemia, or any other chronic illness (such as diabetes, hypertension, etc.), pregnancy, or known bleeding disorders. Patients with radiating pain from the low back to the lower limbs were also excluded [9].

Screening method - Patients with non-specific low back pain were screened based on the inclusion and exclusion criteria. Patients who fulfilled the requirements were assigned to the study using a consort chart (Figure 1).

3.5 Intervention- Patients who met the inclusion and exclusion criteria and gave their consent for the trial were given the intervention following clinical screening. The purpose and design of the trial were explained to the patients prior to their informed permission. On days 0 and 7, participants in the trial group received treatment with wet cupping therapy (Figure 1). It was recommended to take *Erandamoola Kashaya* (20 mL) twice a day after meals and *Yogaraj Guggulu* (250 mg) twice a day after meals. Additionally, *Dhanwantari Taila* was applied locally twice a day for a period of 14 days. The medications were procured from KLE Ayurveda Pharmacy, Belagavi, which holds GMP certification. The patients in the standard group received Transcutaneous Electrical Nerve Stimulation (TENS), HMP (Moist hot pack) for 7 days and exercise therapy for 14 days. Core Stabilization and Spinal Mobility Exercises like bridging, trunk rotation, cat - camel exercise and back extension, all were done

for 10 repetitions per day.

3.6 Outcome Measures - In this study, two validated standard questionnaires and demographic data collected at predetermined intervals were used. The Health related quality of life (HRQoL) of patients was assessed using the validated 36-item Short Form Health Survey (SF-36), which was developed for respondents aged 20 to 70. Higher scores indicate better HRQoL and the total scores of the various components can be calculated (range: 0–100). Physical functioning, physical role functioning , mental health, Social role functioning, emotional role functioning, energy and vitality, body pain and general health are the eight categories used to assess quality of life [10].

3.7 Statistical analysis - Demographic attributes were summarized using percentage. Comparison between trial group and standard group with SF 36 at different treatment time points were performed by Mann-Whitney U test. Comparison of individual group (Trial group and standard group) treatment time points with SF 36 was performed by Wilcoxon matched pairs test. All data analyses were conducted using SPSS 20.0, and any p-value below 0.05 was considered statistically significant.

4. Results

The study was completed within the specified time frame, with no adverse effects and 8 dropouts.

4.1 Subject Characteristics

Age - Patients in the trial group had an average age of 34.33 ± 6.30, compared to 33.79 ± 5.95 in the standard group. In the trial group, 53.97% were between the ages of 31 and 40, whereas 57.14% were in the regular group (Table 1).

Sex - In the trial group, 58.73% were male and 41.27% were female, while the standard group included 57.14% male and 42.86% female (Table 1).

Occupation: 23.81% of the patients were doing government job, 12.70% were doing private job, 14.29% were Housewife, 14.29% were doing business, 9.52% were doing agriculture and 25.40% were self- employed from trial group. In standard group 20.63% of the patients were doing government job, 9.52% were doing private job, 25.40% were Housewife, 11.11% were doing business, 7.94% were doing agriculture and 25.40% were self- employed (Table 1).

Marital status – 84.21% of the patients in the trial group were married and 15.79% were unmarried. In standard group 82.53% were married and 17.47% were unmarried (Table 1).

Educational status – In trial group 11.11% completed primary education, 9.52% had

secondary and 79.36% completed degree education. In standard group 7.93% completed primary, 11.11% had secondary and 80.95% completed degree education (Table 1).

4.2 Quality of life – The normality of the QOL and its component scores at different treatment durations in the Trial and Standard groups did not follow a normal distribution, hence non- parametric tests were used. The overall assessment of QOL parameters was done by SF 36 questionnaire and comparable results (Table 2) were seen in between group results assessed by Mann Whitney test in all the parameters and at different time points. Wilcoxon matched pairs test was applied to see the significance (Table 3) i.e. $p< 0.05$ in both trial and standard groups. There were significant changes i.e. $p <0.05$ observed in all the parameters of SF 36 questionnaire (Table 3) assessed at various time points (14^{th} and 28^{th} day) in both trial and standard group.

5. Discussion

Non-specific low back pain is a significant health issue in modern nations, and its symptoms have an enormous negative effect on HRQoL [11]. The purpose of this study was to investigate the relationship between sociodemographic characteristics, pain severity, quality of life, and disability in people with chronic NSLBP [11]. Any healthcare system's purpose is to maximize care, which includes reducing pain and disability while improving quality of life [12]. Several studies have demonstrated that the SF-36 questionnaire, utilized in the current study, is appropriate for assessing HRQoL in NSLBP patients [12].

Quality of life (SF-36 questionnaire) – The SF 36 QOL assessment (Table 2,3) makes it possible to measure the risks, benefits, and prognosis of a specific therapeutic intervention in addition to detecting changes in health status [13]. Both groups' physical functioning improved after treatment, according to the results. Physical functioning (Table 2,3), which includes performing daily tasks around the house and other physical activities, was limited in both groups [13,14,15]. However, following therapy, activities increased as a result of decreased pain and disability [13,14,15]. In terms of the outcomes for "Role limitations due to physical health," as shown in Table 3, we found that the intervention groups progressed effectively with treatment [13,14,15]. This item evaluates the presence and severity of restrictions linked to physical capacity. Both therapies decreased pain, relaxed muscles, improved impairment, and increased physical strength [13,14,15]. Both treatment groups showed satisfactory improvements (Table 2,3) in "Role limitations due to emotional problems". Recent study highlighted the benefits of exercise i.e. it alleviates pain, improve mobility and function, and minimize chronicity, hence

lowering stress, depression, and anxiety [13,14,15].

The "social aspects" and "emotional aspects" showed the best results following both interventions. In addition to other general health measures, exercise should be a part of healthy life habits [13,14,15]. Therefore, experts have frequently recommended systematic physical activity as a preventative and therapeutic measure for a variety of illnesses [[13,14,15]. The energy/fatigue parameter showed improvement in both groups on the 14th and 28th days after therapy. According to certain research, LBP was linked to sitting time [16]. The biomechanical drawbacks of extended sitting on the lumbar spine, such as weakened lower back muscles and stiffened lumbar spines, could be the cause of this connection [16]. An age-old healing technique that has been utilized all over the world, cupping therapy is a great asset to individuals [17]. According to a recent study, cupping helped persons with persistent, non-specific low back pain by reducing their pain and functional disability [17]. Physical functioning, pain, overall health, energy, social and emotional elements, and mental health categories were all improved during the two months of exercise therapy [18].

Regarding the "general health" criteria, we found that both intervention groups made therapeutic progress that was satisfactory. This area assesses the patients' overall health perceptions. For continuous improvement, physical activity must frequently be maintained.

Due to lack of time, lack of interest, or lack of drive, patients frequently begin treatment then discontinue it [15].

Mode of action (Trial group) - Cupping therapy has equal advantages to passive stretching in terms of muscle contraction, flexibility, and pain threshold [19,20]. It is said to primarily reduce unpleasant muscle tension and increase local blood flow [19,20]. This technique improves the patient's functional state and encourages progressive muscle relaxation [19,20]. In clinical practice, the roots of *Eranda* (*Ricinus communis* Linn) are used to treat a range of diseases, including rheumatism (*Amavata*), inflammation (*Sotha*), and back pain (*Katishula*) [21]. The roots have anti-inflammatory, hepatoprotective, and free radical scavenging effects. *Yogaraja Guggulu* is effective for all sorts of *Vataja* (vitiated vata) and neurodegenerative illnesses [22].The majority of the drugs in *Dhanvantaram Tailam* have *Vatahara* characteristics, which when administered externally aid relieve pain, numbness, and swelling while also strengthening the muscles and joints [23].

Mode of action (Standard group) - Exercise therapy and other physical therapy programs have been suggested because they have been shown to be successful in lowering the severity

of low back pain, improving function and mobility, generating improvements in muscle strength and resistance, and lowering chronicity, dysfunction, and medical care particularly for chronic patients [24]. The therapeutic use of heat to the body that raises tissue temperature is known as heat treatment [25]. In order to reduce pain, heat wraps or heat packs apply low-level superficial heat that activates temperature-sensitive nerve endings called thermoreceptors [26]. These thermoreceptors then send out signals that prevent the lumbar dorsal fascia and spinal cord from processing pain signals, or nociception [25]. A higher temperature tends to promote metabolism, vasodilation, and the pace of fascial tissue stiffness reduction and accelerate healing process [25]. TENS is an affordable, secure, and easy to use "non-pharmacological" pain management method. According to earlier research, TENS reduces dorsal horn neuron sensitization, excitatory neurotransmitter release, and hyperalgesia by using opioid receptors both spinal and supraspinal [26].

6. Conclusion

The current study demonstrated that the SF-36 is a valid tool for assessing the HRQoL of patients with NSLBP. In addition, both groups' HRQoL increased considerably from baseline to 24 days. The study demonstrated the efficacy of both therapies in enhancing the parameters in SF36 QOL questionnaire. However, the outcomes of both therapies were similar.

Patient consent – The consent of the patients was taken prior to the recruitment for the participation in the study and as well as for scientific publication.

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Conflict of interest - None

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Author statement

All the authors provided their contributions in treating the patients. Dr Ramesh Killedar and Dr Pradeep Shindhe, Dr Vijay Kage 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 and review, correction of manuscript was done by Dr Pradeep Shindhe and Dr Dr Vijay Kage. Approval from all the authors was provided for the submitted manuscript.

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Table 1: Comparison of Trial group and standard group with socio-demographic data

Comparison of Trial group and standard group with Age						
Age group	Trial group	%	Standard group	%	Total	%
21-30yrs	17	26.98	16	25.40	33	26.19
31-40yrs	34	53.97	36	57.14	70	55.56
41-50yrs	12	19.05	11	17.46	23	18.25
Total	63	100.00	63	100.00	126	100.00
Comparison of Trial group and standard group with Occupation						
Occupation	Trial group	%	Standard group	%	Total	%
Government job	15	23.81	13	20.63	28	22.22
Private job	8	12.70	6	9.52	14	11.11
Housewife	9	14.29	16	25.40	25	19.84
Business	9	14.29	7	11.11	16	12.70
Agriculture	6	9.52	5	7.94	11	8.73
Self employed	16	25.40	16	25.40	32	25.40
Total	63	100.00	63	100.00	126	100.00
Comparison of Trial group and standard group with gender						
Gender	Trial group	%	Standard group	%	Total	%
Male	37	58.73	36	57.14	73	57.94
Female	26	41.27	27	42.86	53	42.06
Total	63	100.00	63	100.00	126	100.00
Comparison of Trial group and standard group with Marital status						
Marital status	Trial group	%	Standard group	%	Total	%
Married	53	84.21	52	82.53	105	83.33
Unmarried	10	15.79	11	17.47	21	16.67
Total	63	100.00	63	100.00	126	100.00
Comparison of Trial group and standard group with educational status						
Educational status	Trial group	%	Standard group	%	Total	%
Primary	07	11.11	05	07.93	12	9.52
Secondary	06	09.52	07	11.11	13	10.31
College (Degree)	50	79.36	51	80.95	101	80.15
Total	63	100.00	63	100.00	126	100.00

Table 2: Comparison of Trial group and standard group with component of Quality of life (SF-36) at different treatment time points by Mann-Whitney U test

	Time points	Trial group			Standard group			U-value	Z-value	P-value
		Mean	SD	Mean rank	Mean	SD	Mean rank			

Physical functioning	Day 0	27.54	7.67	63.37	28.25	6.17	63.63	1976.5	-0.0366	0.9708
	Day 14	57.62	7.40	62.95	58.33	6.16	64.05	1950.0	-0.1659	0.8682
	Day 28	59.60	3.15	63.50	59.60	3.15	63.50	1984.5	0.0024	0.9981
Physical role functioning	Day 0	19.05	39.58	61.50	25.40	43.88	65.50	1858.5	-0.6123	0.5403
	Day 14	99.37	5.04	63.50	99.37	5.04	63.50	1984.5	0.0024	0.9981
	Day 28	99.37	5.04	63.50	99.37	5.04	63.50	1984.5	0.0024	0.9981
Mental health	Day 0	19.05	39.58	61.50	25.40	43.88	65.50	1858.5	-0.6123	0.5403
	Day 14	99.37	5.04	63.50	99.37	5.04	63.50	1984.5	0.0024	0.9981
	Day 28	99.37	5.04	63.50	99.37	5.04	63.50	1984.5	0.0024	0.9981
Energy/ Vitality	Day 0	56.27	8.61	62.63	56.83	8.34	64.37	1930.0	-0.2635	0.7922
	Day 14	76.27	8.61	62.63	76.83	8.34	64.37	1930.0	-0.2635	0.7922
	Day 28	89.76	4.79	62.63	90.08	4.44	64.37	1930.0	-0.2635	0.7922
Emotional role functioning	Day 0	56.63	7.64	62.53	57.21	7.38	64.47	1923.5	-0.2952	0.7678
	Day 14	79.94	6.68	62.63	80.38	6.25	64.37	1930.0	-0.2635	0.7922
	Day 28	88.89	4.09	62.63	89.14	4.03	64.37	1930.0	-0.2635	0.7922
Social role functioning	Day 0	51.39	6.39	62.63	51.79	6.29	64.37	1930.0	-0.2635	0.7922
	Day 14	76.39	6.39	62.63	76.79	6.29	64.37	1930.0	-0.2635	0.7922
	Day 28	86.51	3.41	65.50	85.71	4.41	61.50	1858.5	0.6123	0.5403

Body pain	Day 0	47.50	11.51	62.63	48.21	11.33	64.37	1930.0	-0.2635	0.7922
	Day 14	70.00	11.51	62.63	70.71	11.33	64.37	1930.0	-0.2635	0.7922
	Day 28	98.21	6.13	63.00	98.57	5.53	64.00	1953.0	-0.1513	0.8798
General health	Day 0	70.10	6.54	63.00	70.48	5.90	64.00	1953.0	-0.1513	0.8798
	Day 14	83.94	0.50	63.50	83.94	0.50	63.50	1984.5	0.0024	0.9981
	Day 28	91.81	1.51	63.50	91.81	1.51	63.50	1984.5	0.0024	0.9981

Table 3: Comparison of different treatment time points with component of Quality of life (SF-36) in Trial group and standard group by Wilcoxon matched pairs test

Parameters	Group	Changes from	Mean change	% of change	Z-value	P-value
Physical functioning	Trial group	Day 0 to Day 14	30.08	109.22	6.9009	0.0001*
		Day 0 to Day 28	32.06	116.43	6.9011	0.0001*
	Standard group	Day 0 to Day 14	30.08	106.46	6.9009	0.0001*
		Day 0 to Day 28	31.35	110.96	6.9010	0.0001*
Physical role functioning	Trial group	Day 0 to Day 14	30.08	109.22	6.2146	0.0001*
		Day 0 to Day 28	32.06	116.43	6.2148	0.0001*
	Standard group	Day 0 to Day 14	30.08	106.46	6.0206	0.0001*
		Day 0 to Day 28	31.35	110.96	6.0207	0.0001*
Mental health	Trial group	Day 0 to Day 14	80.32	421.67	6.2146	0.0001*
		Day 0 to Day 28	80.32	421.67	6.2146	0.0001*
	Standard group	Day 0 to Day 14	73.97	291.25	5.9683	0.0001*
		Day 0 to Day 28	73.97	291.25	5.9683	0.0001*
Energy/ Vitality	Trial group	Day 0 to Day 14	80.32	421.67	6.2146	0.0001*

		Day 0 to Day 28	80.32	421.67	6.2146	0.0001 *
	Standard group	Day 0 to Day 14	73.97	291.25	5.9683	0.0001 *
		Day 0 to Day 28	73.97	291.25	5.9683	0.0001 *
Emotional role functioning	Trial group	Day 0 to Day 14	23.30	41.14	6.0009	0.0001 *
		Day 0 to Day 28	32.25	56.95	6.0010	0.0001 *
	Standard group	Day 0 to Day 14	23.17	40.51	6.0009	0.0001 *
		Day 0 to Day 28	31.94	55.83	6.0010	0.0001 *
Social role functioning	Trial group	Day 0 to Day 14	25.00	48.65	6.0009	0.0001 *
		Day 0 to Day 28	35.12	68.34	6.0010	0.0001 *
	Standard group	Day 0 to Day 14	25.00	48.28	6.0009	0.0001 *
		Day 0 to Day 28	33.93	65.52	6.0010	0.0001 *
Bodily Pain	Trial group	Day 0 to Day 14	22.50	47.37	6.0009	0.0001 *
		Day 0 to Day 28	50.71	106.77	6.0010	0.0001 *
	Standard group	Day 0 to Day 14	22.50	46.67	6.0009	0.0001 *
		Day 0 to Day 28	50.36	104.44	6.0010	0.0001 *
General Health	Trial group	Day 0 to Day 14	22.50	47.37	6.0009	0.0001 *
		Day 0 to Day 28	50.71	106.77	6.0010	0.0001 *
	Standard group	Day 0 to Day 14	22.50	46.67	6.0009	0.0001 *
		Day 0 to Day 28	50.36	104.44	6.0010	0.0001 *

Fig. 01. – CONSORT flow diagram of the study