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A CLINICAL TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF ORAL THERAPY WITH *SALLAKI* MR AND *SALLAKI* PLUS TABLET (SEQUENTIAL THERAPY) ALONG WITH TOPICAL APPLICATION OF *SALLAKI* LINIMENT IN PATIENTS WITH ACUTE MUSCULOSKELETAL SPASM WITH LOW BACKACHE

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ABSTRACT

Low back pain is a common problem affecting the major population in the world. Muscular spasms are often seen in association with low back ache. There may be many different reasons for back ache and subsequent spasm. Because there is great variability and inconsistency in the management of this condition, it warrants a simple yet powerful solution. This clinical study was planned to evaluate the efficacy of the Herbal formulations namely Tablet *Sallaki* MR along with *Sallaki* plus (Sequential therapy) and *Sallaki* Liniment, in patients of Acute Musculoskeletal Spasm associated with Low Backache. The trial was conducted at I.P.G.T and R.A., Gujarat Ayurved University, Jamnagar in the Department of Panchakarma under TRC (Technical Research Committee) project. This was an open label, interventional, single centre and non-comparative study. The treatment was done for one group consisting of 60 patients diagnosed with lower back pain and musculoskeletal spasm, prospectively, for knowing its safety and efficacy. Tab *Sallaki* MR was given for 7 days followed by Tab *Sallaki* Plus for 14 days. This was followed by *Sallaki* liniment application for 14 more days. In this study statistically highly significant results were obtained in patients of low Backache associated with musculoskeletal spasm. In efficacy parameters the relief was 48.23% in Low Backache, 66.92% in pain on Visual Analogue Scale and 61.15% in MOD Questionnaire. Almost 67% showed mild improvement with no complaints of any major side effect.

Keywords: Low back ache, *Sallaki* MR, *Sallaki* Plus, *Sallaki* Liniment, Musculoskeletal Spasm

INTRODUCTION: Low back pain (LBP) is a common problem affecting the major population in the world. It affects approximately 60–85% of adults during some point in their lives. Chronic low back pain, defined as pain symptoms persisting beyond 3 months, affects an estimated 15–45% of the population. [1] Low backache is also said to be the 2nd frequent reason for visiting a Doctor, 3rd frequent reason for surgery and 5th frequent reason for hospitalization. [2] Muscular spasms which are the involuntary and spontaneous contractions of a muscle are often seen in association with low back ache. Conditions, such as degenerative disc disease or herniated disc, may cause an acute episode of low back pain. The body

attempts to immobilize the affected area to stop pain by tightening the surrounding musculature and as a result, painful muscle spasms occur. [3]

The symptoms of low back pain may be classified by duration as acute, sub-chronic (also known as sub-acute), or chronic. The specific duration required to meet each of these is not universally agreed upon, but generally pain lasting less than six weeks is classified as acute, pain lasting six to twelve weeks is sub-chronic, and more than twelve weeks is chronic. [4] The condition may be further classified depending upon the underlying cause such as mechanical, non-mechanical or referred pain. Mechanical back pain is the most common cause of acute back pain in young people. In most episodes of low back pain, a specific underlying cause is not identified or even looked for, with the pain believed to be due to mechanical problems such as muscle or joint strain. Some low back pain is caused by damaged intervertebral discs, and the straight leg raise test is useful to identify this cause. [5] In those with chronic pain, the pain processing system may malfunction, causing large amounts of pain in response to non-serious events. [6] The management of acute nonspecific low back pain of rapid onset is characteristically with simple pain medications and the continuance of normal activity as much as the pain allows. Analgesic medications include OTC acetaminophen and aspirin, as well as prescription opioids such as codeine, oxycodone, hydrocodone, and morphine. Opioids should be used only for a short period of time and under a physician's supervision. [7] Additionally, there are many alternative medicine therapies, including the Alexander technique and herbal remedies, but there is not enough evidence to recommend them confidently.[8] Even though the prevalence of low back pain is more within our country, the treatment options are sundry and inconsistent, thereby increasing the costs and unevenness in its management. [9]

This clinical study was planned to evaluate the efficacy of the Herbal formulations namely Tablet *Sallaki* MR along with *Sallaki* plus (Sequential therapy) and *Sallaki* Liniment, in patients of Acute Musculoskeletal Spasm associated with Low Backache.

MATERIALS AND METHODS:

The Study was an interventional, single centre, single group and non-comparative type where the masking was open label. The study was done prospectively for endpoint assessment of efficacy and safety. 60 patients having low backache and fulfilling the inclusion criteria as per the protocol was selected from the O.P.D. and I.P.D. of the Hospital. The medicines are manufactured, marketed and supplied by Gufic Biosciences Ltd., Mumbai.

Inclusion criteria:

- Age: 18-70 years
- Patients presenting with history of Acute Musculoskeletal spasm with Low Back pain due to Lumbar Spondylosis and Muscle sprains with spasm.
- Patients who are willing to take the medications as directed and willing to come for follow-ups.
- Patients who are willing to comply with the protocol requirements.
- Patients who are willing to give the written informed consent.

Exclusion criteria:

Patients with other associated spasm conditions like;

- Pain & spasm associated with fractured bone, deficits and cauda equine syndrome, history of previous surgery on the lumbar spine and spinal canal stenosis
- Pregnant and lactating women patients
- Patients with hypersensitivity to any of the ingredients of the study drug formulation
- Patients unwilling or unable to comply with the study procedures.
- Patients having the following disorders: renal failure, Bulimia, Hypo and Hyperthyroidism, Nephrotic syndrome.
- Patients having uncontrolled diabetes mellitus, or any other metabolic disorders.
- Patients that have received treatment with any investigational drug in the Preceding 4 weeks.

Laboratory Investigation

- Routine hematological including CBC, ESR, Liver Function Tests, and Renal Function Tests was carried out to assess the present status of the patient and to exclude other pathologies.

DRUGS ADMINISTRATION:

Drug: The name of drug proposed for trial along with their plan of usage (All drugs manufactured and supplied by Gufic Biosciences Ltd., Mumbai):

Drug Ingredients. (Composition): Table. 1 Tab. *Sallaki* MR

No.	***Name of Ingredient***	***Part Used***	***Quantity/tab***
01	*Boswellia serrata* (Guggulu)	Gum Resin	400 mg.
02	*Gloriosa superba (Langali)*	Seed	10 mg.

Dose and Duration: Two tablets twice a day for 7 days orally

Time of Administration: After breakfast and dinner **Anupana**: Warm water

Table. 2 Tab. *Sallaki* PLUS

No.	***Name of Ingredient***	***Part Used***	***Quantity/tab***
01	*Boswellia serrata* (Guggulu)	Gum Resin	200mg.
02	*Vitex negundo (Nirgundi)*	Whole Plant	200mg.

Dose and Duration: 2 Tablets, thrice a day for next 14 days orally

Time of Administration: After breakfast, lunch and dinner **Anupana**: Warm water

Table. 3 *Sallaki* Liniment

	Name of Ingredient	***Part Used***	***Quantity w/w***
Extract of	*Boswellia Serrata* (*Guggulu*)	Gum Resin	7.5%
Oil of	*Gaultheria franggratissima (Gandapura ka taila)*	--	20.0%
	(Mentha arvensis) Pudinah ke taila	--	5.0%
Crystals of	*(Mentha arvensis) Pudinah ke phool*	--	7.5%
	Camphora officianarum (Karpura)	--	1.0%
	Mahanarayan Taila	--	5.0%

Usage: External Application thrice a day according to the area affected for 14 days

ASSESSMENT CRITERIA: Efficacy was assessed after one week of course with *Sallaki* MR and after two weeks of course with *Sallaki* Plus. The reduction in intensity and duration of various symptoms and improvement in quality of life (QOL) was observed. Follow up was done at weekly intervals for the first three weeks. The changes in intensity of below mentioned signs and symptoms were observed: Low backache, Restriction in Movement, SLR test, MOD Questionnaire and VAS.

OBSERVATION AND RESULTS: Total 63 patients were enrolled out of which 60 patients completed the study. Three patients were drop outs due to some personal reasons. The observations as analyzed as per various parameters are mentioned in the following tables.

Effect on efficacy parameters:

Table no. 4: Effect of therapy on Low Backache: (n=60) (Wilcoxon Signed rank test)

Low Backache		**BT**	**AT**	**Diff**	**%**	**W**	**T+**	**T-**	**P**	**Significance**
1st week	**Mean Score**	1.70	1.50	0.20	11.76	-91	0.00	-91	<.05	HS
	S.D(±)	0.561	0.748							
	S.E(±)	0.072	0.097							
3rd week	**Mean Score**	1.70	0.88	0.82	48.23	-1035	0.00	-1035	<.05	HS
	S.D(±)	0.561	0.691 0.089 0.691							
	S.E(±)	0.072	0.089							

Low Backache was reduced by 11.76% after 1st week and by 48.23% after 3rd week so after treatment the result was statistically significant.

Table no. 5: Effect on Musculoskeletal Spasm (Forward Flexion): (Wilcoxon Signed rank test)

***Katigrah* (Flexion)**		**BT**	**AT**	**Diff**	**%**	**W**	**T+**	**T-**	**P**	**Significance**
1st week	**Mean Score**	0.52	0.33	0.19	36.53	-45	0.00	-45	<.05	HS
	S.D(±)	1.097	0.774							
	S.E(±)	0.142	0.100							
	Mean Score	0.52	0.17	0.35	67.30	-45	0.00	-1035	<.05	HS

3rd week	**S.D(±)**	1.097	0.493							
	S.E(±)	0.142	0.064							

Katigrah in Forward Flexion was reduced by 36.53% after 1st week and by 67.30% after 3rd week and the result was significant.

Table no. 6: Effect on Musculoskeletal Spasm (Extension): (Wilcoxon Signed rank test)

***Katigrah* (extension)**		**BT**	**AT**	**Diff**	**%**	**W**	**T+**	**T-**	**P**	**Significance**
1st week	**Mean Score**	0.08	0.07	0.01	12.50	-1.00	0.00	-1.00	>.05	NS
	S.D(±)	0.462	0.406							
	S.E(±)	0.060	0.052							
3rd week	**Mean Score**	0.08	0.03	0.05	65.50	-3.00	0.00	-3.00	>.05	NS
	S.D(±)	0.462	0.181							
	S.E(±)	0.060	0.023							

Katigrah in extension was reduced by 12.50% after 1st week and by 65.50% after 3rd week and the result was insignificant.

Table no. 7: Effect on MOD Questionnaire :(paired 't' test)

PARAMETER	**N=60**	**Mean Score**		**Mean Diff**	**%age Change**	**SD**	**SEM**	**t**	**P**	**Significance**
		BT	**AT**							
MODQ		14.93	5.80	9.13	61.15	4.725	0.610	5.779	<0.001	HS

There is 61.15% relief in MOD Questionnaire after the completion of treatment and the value of p is <0.001 so the results was highly significant.

Table no. 8: Effect on Visual Analogue Scale: (paired't' test)

PARAMETER	**N=60**	**Mean Score**		**Mean Diff**	**% Change**	**SD**	**SEM**	**t**	**P**	**Significance**
		BT	**AT**							
VAS		4.233	1.400	2.833	66.92	1.107	0.143	10	<0.001	HS

There was 66.92% relief in Visual Analogue Scale for pain after the completion of treatment and the value of p is <0.001 so the results was highly significant.

Table no. 9: Effect on SLR test: (paired 't' test)

PARAMETER	N=60	Mean Score		Mean Diff	% Change	SD	SEM	t	P	Significance
		BT	AT							
SLR Rt. Leg		0.350	0.183	0.167	47.71	0.493	0.063	2.619	<0.05	S

There was 47.71% relief in Straight leg raising of right leg test after the completion of treatment and the value of p is <0.05 so the results is significant.

Table no. 10: Effect on SLR test: (paired't' test)

PARAMETER	N=60	Mean Score		Mean Diff	% Change	SD	SEM	t	P	Significance
		BT	AT							
SLR Lt. Leg		0.383	0.150	0.233	60.83	0.673	0.086	2.685	<0.05	S

There was 60.83% relief in Straight leg raising test of left leg after the completion of treatment and the value of p is <0.05 so the results was significant.

Percentage relief in efficacy parameters:

Fig.1: Shows the percentage improvement 1st week and after 3rd week

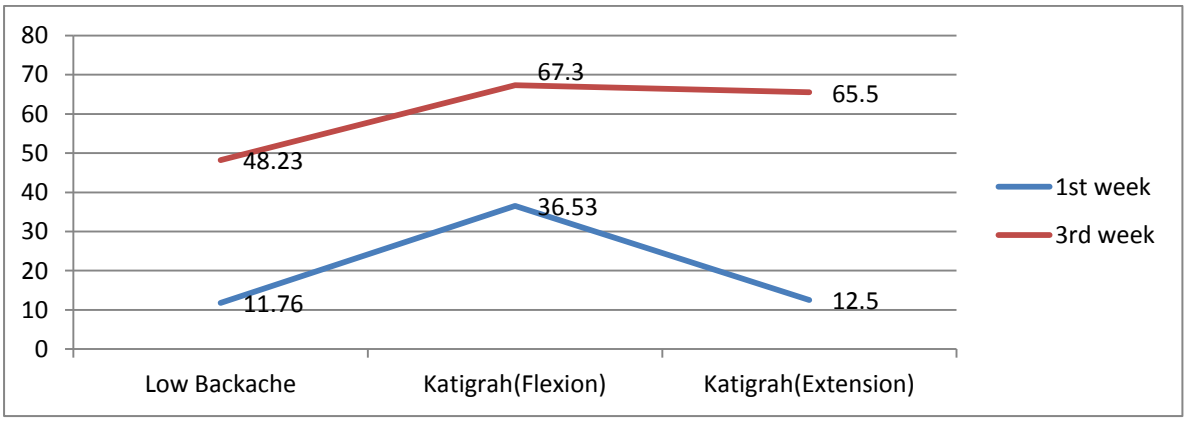

Fig.2: Shows the percentage improvement after treatment

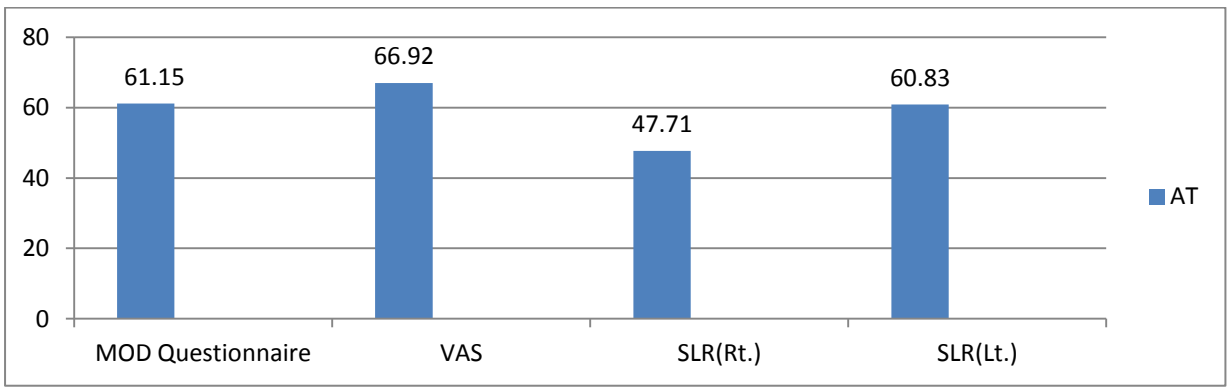

Table no. 11: Overall effect of therapy: (n=60)

Sr. No.	Overall Effect	No. of patients	Percentage (%)
1.	Marked Improvement (>75%)	2	3.00%
2.	Moderate Improvement (51 – 74%)	3	5.00%
3.	Mild Improvement (26 -50%)	40	67.00%
4.	Unchanged (<25%)	15	25.00%

DISCUSSION: As far as the modern modalities are concerned, the conservative treatment of Low Backache associated with Acute Musculoskeletal Spasm consists of use of Non-steroidal anti-inflammatory drugs along with Muscle Relaxant. A major component of a safe and effective therapy for low backache, often overlooked, is the use of plant extract. Several plant extracts have been shown to improve quality of life in patients suffering from low backache. The treatment of this condition requires herbs that will systemically and locally reduce inflammation as well as causes the relaxation of Para spinal muscle due to which pain occurs. When Tab. *Sallaki* MR and *Sallaki* Plus were given orally and *Sallaki* liniment applied locally the herbs relaxed the Para spinal muscles and provided relief in pain.

Among the drugs used in the study, *Boswellia* has got immense evidences in Analgesic and anti-inflammatory activities. Observed benefits of *Boswellia serrata* includes reduction of joint swelling, increased mobility, steroid sparing action, less morning stiffness, improved grip strength and general improvement in quality of life. [10] *Vitex negundo* is also known to produce anti-inflammatory and Analgesic activity. A constituent isolated from *Vitex negundo* exhibits significant anti-inflammatory activity against acute inflammations. [11] *Langali* is having *Kapha Vata hara* properties *Gloriosa superba L.* (Liliaceae) seeds, known as "*kalihari*" (Hindi), were phytochemically investigated for colchicine (well known for gout treatment) and other related alkaloid content. [12] This is known to have very effective anti-inflammatory and analgesic effect. It is also known to be a good muscle relaxant. In *Vangsena Samhita,* use of *Mahanarayana taila* is described in *Vatavyadhi prakarana*. Use of *Narayana taila* and *Mahanarayana taila* in the form of *Paana*, *Abhyanjana* and *Basti* in *Antravriddhi Chikitsa* is also explained there.[13] Thus *Mahanarayana Taila* is having potent *vatahara* property which helps in reducing the musculoskeletal spasm occurring due to the *vata* vitiation in that area. Camphor is used traditionally for treating arthritis pain and rheumatism. It explains the *vata hara* property of the drug. *Gandhapura* has got a miraculous activity on pain relief that it is used extensively in pain relief oils. Several researchers have claimed that Mint would be potential tool to cure many diseases or can be used as an adjuvant therapy. On basis of its phytochemical studies, it has been found that it contains different types of flavonoids, polyphenols, essential oil that may be responsible for its antioxidant

and inflammatory activities. If any herb claimed to be anti-inflammatory or antioxidant then, it may have radio protective activity. [14]

CONCLUSION: From the study conducted, it can be concluded that the highly significant reduction in pain in visual analogue scale and musculoskeletal spasm on MOD Questionnaires showed the effectiveness of the combined formulation of local application of *Sallaki* Liniment and oral intake of *Sallaki* MR and *Sallaki* Plus tablets. This formulation showed anti-inflammatory, analgesic and muscle relaxant effects of the combined drug administration i.e. local as well as oral. Overall, it can be concluded that the *Sallaki* MR and *Sallaki* Plus tablets and *Sallaki* Liniment have potency to cure the pain and musculoskeletal spasm related with various musculoskeletal disorders; particularly it was found effective in cases of Low Backache associated with acute musculoskeletal spasm. Not only that, this combination of formulation is easy to use and convenient to take without having any fear for any adverse effect, thus ensures excellent patient compliance.

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