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EFFECTIVENESS OF KATIVASTHI AND EXERCISE IN CHRONIC LOW BACK PAIN: A RANDOMIZED CONTROL STUDY

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ABSTRACT
Chronic low back pain is very common and comprises of 2 .21% in US population and 15% in working groups over the age of 30. In this study there were two groups, one was Kativasthi therapy group and another was Exercise therapy group. Both groups were continued for 10 days. Kativasthi is process specially prepared warm medicated oil kept over low back area with Masa churna (Black gram powder) paste boundary over a period of 45 minutes. An open prospective study was conducted to evaluate the effectiveness of Kativasthi (warm oil stagnation procedure) in patients of chronic low back pain. Mahanarayan taila is used in Kativasthi for 10 days after Sarvanga Snehana with Mahanarayan taila (oil massage) and Sarvanga Baspa Svedana (steam bath). 40 patients, aged 40±10.4 years were divided into two groups by a computer generated random number table. X ray of lumbo-sacral spine (antero-posterior & lateral view) was reviewed. Differences of lumbar and ridiculer pains on an analog visual scale, Modified Oswestry Disability score and distance finger ground test were assessed at 0-day & 10^{th} -day. There is significant improvement in all above parameters on 10^{th} day. It was found that Kativasthi was more effective than the conventional exercise practices.
KEYWORDS: Chronic low Back pain, Kativasthi, sarvanga snehana, sarvanga baspa swedana, Mahanarayana taila.

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INTRODUCTION

Low back pain is the main cause of work absence and disability in industrialized societies, and 10% to 50% of people with this condition experience symptoms that persist for more than 3 months[1]. Individuals who experience persisting symptoms are generally described as having chronic low back pain (CLBP), a condition that accounts for more than 80% of the resources allocated for back problems and is particularly resistant to treatment. It is extremely common and comprises of 2.21% in US population and 15% in working groups over the age of 30.One percent of the US population is chronically disabled due to CLBP[2]. Various ergonomic, educational and treatment methods have generally failed to control it. Although the exact origin of longstanding back pain is still unknown, Connective tissue remodeling as a result of emotional, behavioral and motor dysfunction and connective tissue stiffness due to fibrosis are important pathogenic mechanism leading to chronicity of pain[3]. There are few known effective treatment options for patients with CLBP, exercise is one treatment that has some degree of both clinical and research support[4]. On the other hand Alternative treatment involving external application (oil massage) is very commonly used physical therapy in CLBP. It has advantage of not causing drug induced side effects gastritis, sedation)[5,6,7]. Kativasti is a method of treatment by retaining lukewarm herbal medicated oil by special gadgets & arrangement lumbar region and effective against Lumbar Spondilysis, Low Back Pain etc[8]. There has been an extensive non-pharmacological interventional research and physical medicine research in the field of CLBP[9]. But Kativasti in particular, as a tool to treat CLBP has not been studied much. We have attempted to study the effectiveness and compliance of Kativasti in CLBP patients.

MATERIALS & METHODS

Subjects

A total of 74 patients with CLBP were diagnosed from the OPD of Ayurveda Regional Research Institute, Tadong, Gangtok, Sikkim from July 2009 to August

2010. Of these, 40 patients satisfied the inclusion criteria were recruited.

The inclusion criteria were as follow:-

(a) History of CLBP more than three months.

(b) Pain in the lumber spine with or without radiation to leg.

(c) Age between 18 to 60 years.

The Exclusion criteria were as follows:-

(a) CLBP due to organic pathology and gross structural abnormalities.

(b)The patients were suffering from chronic infection.

(c) Age above 60 years and below 18 years.

The study was approved by Institutional ethical committee of our Institute. An informed consent was obtained from all patients.

Study design

It is an open prospective randomized control study, 40 subjects who satisfied the inclusion criteria were allotted in to two groups by a computer generated random number table. X ray of lumbo-sacral spine (antero-posterior & lateral view) was reviewed. Demographic details of vital clinical data, personal, family and occupational history are documented before the starting of intervention. Out come variables were recorded at 0-Day & 7th-day. The patients of trial group were selected for Kativasthi therapy whereas the control group received physical exercise. Both the groups had equal time for treatment.

Intervention

Kativasthi intervention

A specific treatment module was prepared; first the patients were selected to external oil massage (sarvanga snehana) with Mahanarayan taila (Dabur company) and then moist heat fomentation (sarvang baspa swedana) of whole body and lastly the warm medicated oil *(*Mahanarayan taila*,* Dabur company) is kept over low back area with Masa churna [*Vigna mungo* (L.) Hepper] paste boundary over a period of 45 minutes. This procedure had been done in each patient for continuous 10 days. The temperature of oil inside the boundary was maintained to 40^{0}C.The oil was changed continuously to maintain the temperature.

Control intervention

The Exercise practices consist of set of physical movements (**Table 1**) for one and half hour daily for 10 days.

Outcome variables

Four important domains directly related to low back pain are: pain intensity, low-back-pain-specific disability, patient satisfaction with treatment outcome, and work disability. Data were obtained from both groups using the Visual Analog Scale (VAS)[10,11], a scale of zero to 10, with zero being no pain and 10 being the most severe. Modified Oswestry Disability[12,13] Index (ODI) Questionnaire is used to measure the stage of patient's acuity status and monitor changes on 5th day and 10th day.

ODI=the point total from each section is summed and then divided by the total number of questions answered and multiplied by 100 to create a percentage disability. The scores range from 0-100% with lower scores meaning less disability[14].

ODI = (Sum of items scored/Sum of sections answered) X 100

RESULTS

Figure 1 shows the study profile. There was no drop out in this short term treatment programme. The two groups Kativasthi and Control were similar with respect to socio-demographic and medical characteristic (**Table 2**). The baseline data for all variable were normally distributed and did not differ significantly between two groups ($p<0.05$).

There was a significant redaction of pain in both the groups after the 10days of Kativasthi and Exercise. There was also a significant increase in SLR (Straight leg rising test) in both the legs after treatment. Modified Oswestry Disability index (ODI) was changed in both the groups (**Table 3**).

The percentage of change (Pain relief, SLRR, SLRL & ODI) is more noted in Kativasthi group compared to Exercise group (Table-3)

DISCUSSION

This randomized control study on 40 patients with CLBP, who underwent a

Kativasthi therapy and Exercise therapy for 10 days showed that there was significant negative correlation in the baseline values of Pain with all domains of ODI. In this study, it has been shown that Kativasti is more effective than exercise therapy. Pain, heaviness, uneasiness and restricted of movement of the low back area is more reduced with in 10 days in Kativathi therapy in compare to Exercise therapy. Several non-pharmacological interventions including Yoga, Magnet therapy, and mindfulness based meditation, cognitive behavior modification and multidisciplinary programs have been shown to be effective in reducing pain and disability.

Mode of Action

In Kativasthi continuous warm Ayurvedic oil (i.e. Mahanarayana taila) application over the low back area for the period of 45 minutes increases the blood flow over the low back area and helps it to get the good nutrition and pain relieving bio-chemicals of the affected area. It also helps to wash out the local toxins, waste

materials and pain producing bio-chemicals from the affected area. By this process it restores the local damage of ligaments, tendons, muscles, bones and inter vertebral discs e.t.c. of that area for chronic low back pain.

Sarvanga snehana (Full body gentle massage) with Ayurvedic oil (i.e. Maha narayana taila) helps to increase the peripheral blood circulation and Sarvanga baspa swedana (full body steam bath) helps to increase the peripheral vasodilatation of the body and it helps to eliminate the bio-toxins and waste materials from the body through sweating of the whole body.

As per Ayurvedic view, taila itself is vata kafa smaka and Mahanarayana taila is effective on mainly vatavyadhi (Neuro-musculoskeletal disorders) and it is also vedana sthapaka i.e. analgesic.

In Exercise therapy, it improves the physical fitness, relaxes the muscles, improves muscle tone specially low back are and also helps to enhance the blood flow specially low back area.

CONCLUSION

This randomized control study has shown that patients with CLBP had got better result in Kativasthi therapy than Exercise therapy for the period of 10 days therapy. It should be better effective treatment if Ayurvedic Kativasti therapy for 10 days is applied along with yoga therapy for 30 days for CLBP patient.

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Table 1: Control group exercise practices

Sl.No.	Name of the Exercise	Times (Daily)
1.	Standing hamstring stretch	Two times-Morning & Evening
2.	Cat and Camel	Two times-Morning & Evening
3.	Pelvic tilt	Two times-Morning & Evening
4.	Partial curl	Two times-Morning & Evening
5.	Piriformis stretch	Two times-Morning & Evening
6.	Extension exercise	Two times-Morning & Evening
7.	Quadriceps leg raising	Two times-Morning & Evening
8.	Trunk rotation	Two times-Morning & Evening
9.	Double knee to chest	Two times-Morning & Evening
10.	Bridging	Two times-Morning & Evening
11.	Hook lying march	Two times-Morning & Evening
12.	Single knee to chest stretch	Two times-Morning & Evening
13.	Lumbar rotation	Two times-Morning & Evening
14.	Press up	Two times-Morning & Evening
15.	Curl ups	Two times-Morning & Evening

Table 2: Demographic data

Variables	Kativasti group	Control group
Number of participants	20	20
Males (M)	09	08
Females(F)	11	12
Age(mean ±SD)	49 ± 3.6	48 ±4
Education		
a) High school	M.3, F.5	M.2, F.5
b) College	M.4, F.3	M.3, F.6
c) Post Graduate	M.2, F.3	M.3, F.1
Males		
a) Working -sedentary	6	5
b) Working–non sedentary	3	3
Females		
a) Working	6	5
b) Housewives	5	7
CLBP		
<1 year	4	7
1-5 years	8	6
5-10 years	5	5
>10 years	3	2
Cause		
a)Lumbar Spondylosis(LS)	4	8
b)Prolapsed intervertebral Disc (PID)	4	3
c)LS with PID	9	5
d) Muscle spasm	3	4

Table 3: Results of all variables before & after treatment of both groups

	Kativasthi group				Exercise group			
Variables	**Pre Rx Mean ±SD**	**Post Rx Mean ±SD**	**% of change**	**P value**	**Pre Rx Mean ±SD**	**Post Rx Mean ±SD**	**% of change**	**P value**
Pain Relief	6.2±1.2	2.3±1.3	75.33	<0.001	6.3±1.4	4.2±2.3	55.33	<0.001
SLRR	57.95±20.23	76.00±16.38	31.14	<0.001	57.68±20.23	68.45±16.38	18.67	<0.001
SLRL	59.00±20.23	75.75±15.04	28.38	<0.001	59.00±20.23	68.38±20.48	21.45	<0.001
ODI	1.20±.54%	0.83±.36	25.64	<0.001	1.23±.34%	0.87±.64	24.64	<0.001

Table 4: Ingredients of Mahanarayana taila (Bhaisajyaratnavali,Vatavyadhyadhikar)[15]

Sanskrit Name	Botanical Name/English Name	Parts
Til taila	*Sesamum indicum*	32
Bilwa tvak	*Aegle marmelos*	8
Ashwagandha	*Withania somnifera*	8
Brihati	*Solanum indicum*	8
Gokshura	*Tribulus terrestris*	8
Shyonak tvak	*Oroxylum indicum*	8
Bala	*Sida cordifolia*	8
Nimba tvak	*Azadiracta indica*	8
Kantikari	*Solanum xanthocarpum*	8
Punarnava	*Boerhaavia diffusa*	8
Atibala	*Abutilon indicum*	8
Agnimantha	*Premna integrifolia*	8
Prasarini	*Clerodendrum phlomidus*	8
Patal	*Sterospermum suaveolens*	8
Gaudugdha	Cow milk	64
Satavari	*Asparagus racemosus*	64
Rasna	*Pluchea lanceolata*	1
Ashwagandha	*Withania somnifera*	1
Mishreya	*Foeniculumvulgare*	1
Devadaru	*Cedrus deodara*	1
Kustha	*Saussurea lappa*	1
Shalaparni	*Desmodium gengeticum*	1
Prishniparni	*Uraria picta*	1
Masaparni	*Teramnus labialis*	1
Mudgaparni	*Phaseolus trilobus*	1
Agaru	*Aquilaria agallocha*	1
Nagakeshar	*Mesua ferrea*	1
Saindhav lavana	Rock salt	1
Jatamansi	*Nardostachys jatamansi*	1

Haridra	*Curcuma longa*	1
Daruharidra	*Curcuma zedoaria*	1
Shailja	*Permelia perlata*	1
Chandan	*Santalum album*	1
Puskar mool	*Inula racemosa*	1
Ela	*Elettaria cardamomum*	1
Manjistha	*Rubia cordifolia*	1
Yastimadhu	*Glycyrrhiza glabra*	1
Tagar	*Valeriana wallichii*	1
Mustaka	*Cyperus rotundus*	1
Tejpatra	*Cinnamomum tamala*	1
Rishabhaka	*Microstylis walichii*	1
Bhringaraj	*Eclipta alba*	1
Jiwak	*Microstyllis muscifera*	1
Satavari	*Asparagus racemosus*	1
Kakoli	*Lillium polyphylum*	1
Kshir kakoli	*Fritillaria roylie*	1
Riddhi	*Habenaria intermedia*	1
Vriddhi	*Habenaria intermedia*	1
Tagar	*Valeriana wallichii*	1
Hapusha	*Juniperus communis*	1
Vacha	*Acorus calamus*	1
Palash	*Butea monosperma*	1
Sthauneya	*Substitute tarcus leaccatta*	1
Punarnava shewta	*Boerhaavia diffusa*	1
Choraka	*Angelica gluca*	1
Kapoor	Camphor	0.5
Kumkuma	*Crocus sativus*	0.5

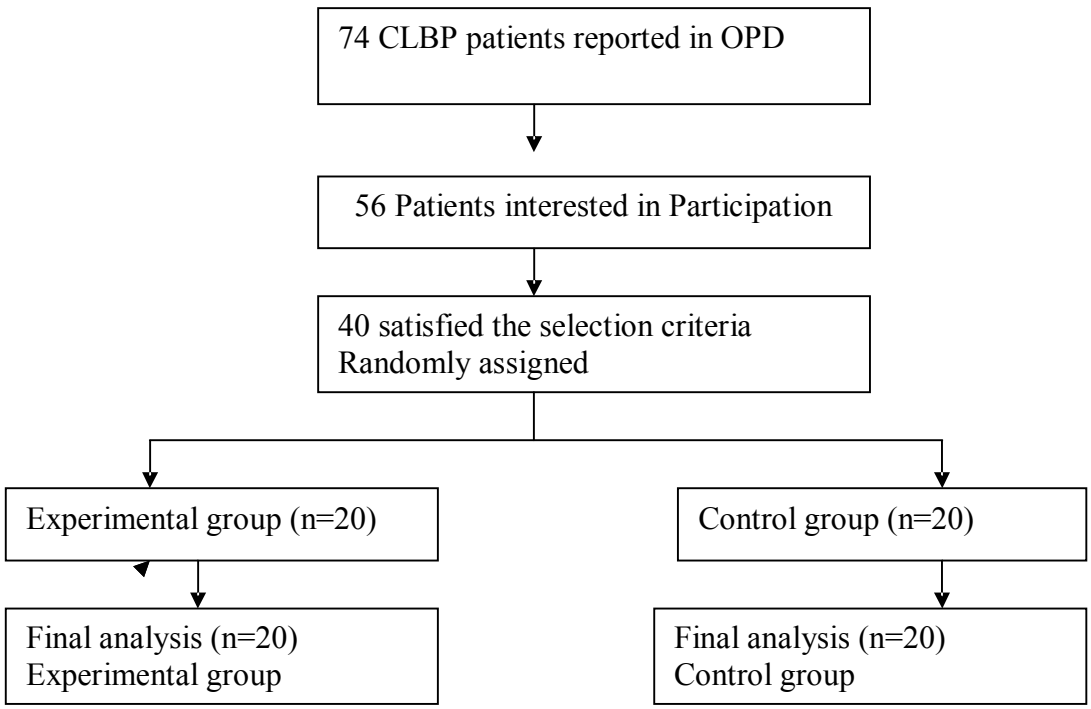

Figure 1: Trial Profile

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