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RESEARCH ARTICLE OPEN ACCESS

CLINICAL EVALUATION OF NITYAVIRECHANA AND TRAYODASHANGAGUGGULU FOR MANAGING KATIGRAHA (LOW BACK PAIN) IN OVERWEIGHT AND OBESE INDIVIDUALS: AN OPEN-LABEL SINGLE-ARM STUDY

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ABSTRACT

Introduction: Low back pain (LBP) refers to discomfort in the lower back. It is a common issue affecting all age groups. There is a correlation between LBP and *Katigraha* in Ayurvedic texts. According to modern science, LBP is characterized by persistent pain in the lower back. Ayurveda views LBP as a manifestation of doshic imbalance involving *Vata, Pitta*, and *Kapha.* ***Aim of the study:*** Management of *Katigraha* with *Nityavirechana*using *Gandharvahastaditaila*, Nirgundikwatha, and *Trayodashanagaguggulu.* ***Study Design****:* Open Label Single Arm Clinical Study Sample Size: 20 Intervention: *Nityavirechana* for 7 days with *Gandharvahastaditaila* (10-20ml) as per the *koshta* and *Nirgundikwatha* (50ml) early morning on an empty stomach. *Shamanaushadi* for 15 days from the 1st day of the intervention: *Trayodashanaguggulu*, two tablets (240mg each) twice daily, morning and night after food with lukewarm water. Study Duration: 15 days. ***Results:*** The statistical analysis revealed high significance with $p<0.001$ for all parameters assessed in the study. ***Conclusion:*** The present study provides insight on the use of integrative medicinal formulation in the treatment of lower back pain.

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INTRODUCTION

Ayurveda, often lauded as the "Science of Life," represents one of the most ancient holistic healing systems globally. Originating from the longstanding traditions of the Indian subcontinent, this profound healthcare and wellness system has persevered through millennia, continuously evolving and adapting to the dynamic landscape of human health (Suhail, P.2020). The term "Ayurveda" translates to "knowledge of life" in Sanskrit (Sawarkar, 2020) and offers a comprehensive and intricate comprehension of the human body, mind, and spirit. *Katigraha* is considered a *Vataja Nanatmaja vyadhi*, where *Shoola* is the main symptom due to *Vata.Vata Dosha* is considered the most significant *Tridosha*, mainly aggravated by Dhatukshaya[1] and Margavarodha[2]. Katigraha has been identified as a distinct disease entity in *Gada Nigraha*[3]. It has been classified under *VatikaNanatmajaVyadhi* in *Charaka Samhita* as *PrishtaGraha*. The term "*Kati Graha*" is formed by combining the words "Kati" and "graha."[4] The term "*kati*" denotes the lower back region[6], while "*graha*" signifies stiffness resulting from pain[7].

Katigraha is a condition characterized by the localization of aggravated *vata* in the *Kati Pradesha*, leading to pain and stiffness at the specific site[8]. Low back pain (LBP) is defined as discomfort located between the lower edge of the ribs and the buttock in the posterior aspect of the trunk[9]. In the year 2020, low back pain was a prevalent issue, impacting 619 million individuals globally. Projections suggest that this figure will increase to 843 million cases by 2050[10]. The prevalence of low back pain rises steadily with age, reaching its peak between 50 and 55 years[11]. Low back pain (LBP) exhibits a higher prevalence among women. This condition can be classified as acute (lasting less than 4 weeks), sub-chronic (lasting between 4 and 12 weeks), or chronic (lasting more than 12 weeks)[12]. Low back pain (LBP) is prevalent, affecting an estimated 60 to 85% of adults at some stage of their lives[13]. The experience of pain associated with LBP varies, ranging from an abrupt, sharp sensation to a persistent, dull ache[14]. According to the 2010 Global Burden of Disease study, lower back pain was identified as the leading cause of global disability and ranked sixth in terms of overall disease burden[15]. Even though various factors such as anxiety, stress, vitamin D deficiency. can contribute to low back pain (LBP), being overweight

and obese plays a major role in causing LBP in the modern era[16]. In the current research study, 20 patients diagnosed with low back pain (Katigraha) who fulfilled the inclusion criteria were chosen as participants. These individuals received *NityaVirechana*[17,18,19] in conjunction with *Gandharvahasthadi taila*[20] and *Nirgundi kwatha*[21] for the initial 7 days, administered in the early morning on an empty stomach, with dosages tailored based on *agni, koshta,* and *bala*.Additionally, *Trayodashanaga Guggulu*[22], a *Shamanaushadi*, was administered as two tablets twice daily for 15 days, commencing on the first day of the intervention.

MATERIALS AND METHODS

A clinical study was conducted with 20 subjects using an open-label, single-arm design. The sample size was selected from the *Kayachikitsa*OPD and IPD based on inclusion criteria. The drugs needed for the study, *Gandharwastadhitaila,* and *Trayodashangaguggulu*, were obtained from an authentic Ayurvedic pharmacy, and *Nirgundikwatha*. Before undertaking the study, ethical clearance was obtained from the Institutional Ethical Committee. The diagnosis was based on classical signs and symptoms of *Katigraha*, such as *Shula* (pain) and *Graha* (stiffness) in *Katipradesha*. The subjects were diagnosed as overweight and obese based on the BMI scale.

Inclusion Criteria

1. Subjects clinically diagnosed with *Katigraha.*
2. Chronic low back pain (> 3 months), tenderness, or/and numbness.
3. Patients of age between 20-60 years irrespective of gender, religion, socio-economic status.
4. Willing to sign the informed consent for study participation.
5. Subjects presenting with BMI 25-39.9wt/m^2.

Exclusion Criteria

1. Recent fractures of the spine including acute spondylolisthesis.
2. Patients having spinal tumors, and malignant diseases of the pelvis and spine.
3. Patients with infective spinal diseases including tuberculosis.
4. Recent lumbar surgery or implanted instrumentation.
5. Chronic metabolic and inflammatory pathologies including Ankylosing Spondylosis, Rheumatoid Arthritis, Psoriatic Arthritis, and Gouty Arthritis.
6. Pregnancy and lactating women.
7. Any systemic illness interfering with the study.

Diagnostic Criteria

The diagnosis was based on classical signs and symptoms of *Katigraha*, such as *Shula* (pain) and *Graha* (stiffness) in *Katipradesha*. The subjects were diagnosed as overweight and obese based on the BMI scale.

Assessment criteria

Assessment criteria include:

1. *Shula* in *Katipardesha*(Pain in lower back region)
2. *Graha*in *Katipradesha*(Stiffness in lower back region)
3. Numerical Pain Rating Scale (NPRS)-VAS
4. Body weight (in Kg)
5. BMI (in Kg/m^2)
6. Oswestry Disability Index[23] (ODI) for assessing quality of life.

Shula in Katipardesha (Pain in lower back region)

0 No pain.
1 Mild pain of bearable nature which comes occasionally.
2 Moderate pain but no difficulty in movement of joint, appears frequently and requires some relieving measures.
3 Slight difficulty in joint movements due to severe pain and requires medication.
4 Severe pain with more difficulty in moving joints, disturbing sleep and requires strong analgesics.

Graha in Katipradesha (Stiffness in lower back region)

0 No stiffness
1 Sometime for 5-10 minutes
2 Daily for 10-30 minutes
3 Daily for 30-60 minutes/more than 1hrs

Visual analog scale (VAS)

0:- No Pain
1-3:- Mild Pain
4-5:- Moderate Pain
6-7:- Severe Pain
8-9:- Very Severe Pain
10:- Excruciating Pain

Body mass index (BMI)

18.5-24.9:- Normal
25-29.9:- Overweight
30-34.9:- Obese class1
35-39.9:- Obese class2
>40:- Obese class3

Assessment schedule

In the scope of this study, two assessments were conducted in adherence to the subsequent schedule:

1. The pre-assessment was executed on the 0th day before the intervention.
2. The post-assessment was administered upon the completion of the intervention, specifically on the 15th day.

STATISTICAL METHODS

The data was inputted into Microsoft Excel and subsequently analyzed using the Statistical Package for the Social Sciences (SPSS) for Windows software. The interpretation of results was based on a statistical analysis of data derived from the assessment of 20 subjects before and after the intervention. Descriptive analysis encompassed the use of median and interquartile range, while inferential data analysis employed the Wilcoxon signed-rank test to compare scores before and after the trial. Observational data was presented in tabular form. The significance level was established at $p < 0.001$ for high statistical significance, and at $p < 0.01$ and $p < 0.05$ for statistical significance, while $p > 0.01$ indicated statistical non-significance.

Intervention: During the intervention, a regimen of *NityaVirechana* and *Shamanaushadi Trayodashanga Guggulu* was implemented for 7 days, followed by Shamanaushadi exclusively for an additional 8 days.

Nitya Virechana*:* entailed the administration of Gandharvahastaditaila (10-20ml) in conjunction with Nirgundikwatha (50ml) early in the morning (6:00 AM) on an empty stomach for 7 consecutive days.

Shamanaushadi: *TrayodashangaGuggulu* was prescribed at a dosage of two tablets twice daily, in the morning and evening after meals, with lukewarm water for 15 days commencing from the first day of the intervention.

Diet: During the initial 7-day period of *Nityavirechana*, participants were instructed to take the prescribed diet outlined in Table 1. Subsequently, they were advised to return to their regular dietary intake for the duration of the intervention.

Table 1. Table showing the diet during *Nitya virechana*

Breakfast (within 9AM-11AM)	Lunch (within 1 PM-2 PM)	Dinner (within 7 PM-8 PM)
Peya was prepared with rice and water (1:14), and cooked until a semi-solid consistency was attained.	*Yavagu* was prepared with rice, spices, and water (1:6), and cooked until a solid rice part was left.	Rice cooked with water (1:2), taken with Rasam prepared with spices.

RESULTS

The Statistical analysis done on Shola in *katipradesha* (pain in the low back region) and *Graha* on *katipradesha* (stiffness inthe low back region), VAS, Body weight, BMI and ODI scale, before and after treatmentis shown in Table 2.

Table 2. Statistical analysisdone before and after treatment

Parameters	Before treatment (Median)	After Treatment (Median)	Statistical significance (p- value)
Shula in *Katipardesha*	4	1	0.00004
Graha in *Katipardesha*	3	0	0.00004
VAS score	7	2	0.0004
Body weight	76.5	76	0.00015
BMI	28.4	27.75	0.00015
ODI score	3	2	0.00004

The values of VAS before and after treatment for each subject using a weighing scale and statistical analysis is shown in the Table 3.

Table 3. Statistical analysis of VAS before and after treatment

	Median	Inter quartile range	p-value
Before	7	7-6=1	0.0004
15th day	2	3-1=2	

Most subjects experienced significant relief from low back pain and stiffness, with highly significant results for VAS ($P < 0.001$). The values of body weight measured before and after treatment for each subject using a weighing scale and statistical analysis is shown in the Table 4.

Table 4. Statistical analysis of Body weight before and after treatment

	Median	Inter quartile range	p-value
Before	76.5	84.5-68=16.5	0.00015
15th day	76	83-67.5=15.5	

It can be noted that the intervention effectively reduced body weight by 0kg to 2kg, with highly significant results (P value <0.001). The values of BMI before treatment for the respective subjectsand statistical analysis are shown in Table 5.

Table 5. Statistical analysis of BMI before and after treatment

	Median	Inter quartile range	p-value
Before	28.4	31.6-26.7=4.9	0.00015
15th day	27.75	31.2-26.3=4.9	

The BMI showed a significant improvement after treatment, with a reduction ranging from 0 to 0.9 kg/m2, and a highly significant p-value of <0.001. The values of the ODI score before treatment and values of the ODI score after treatment and statistical analysis of respective subjects are shown in Table 6.

Table 6. Statistical analysis of ODI before and after treatment

	Median	Inter quartile range	p-value
Before	3	4-3= 1	0.00004
15th day	2	2-2=0	

The subjects in the trial showed remarkable improvement in disability scores, leading to an enhanced quality of life. The results for ODI score were highly significant with a P value of <0.001.

DISCUSSION

The condition referred to as *Katigraha* is classified as a *Vataja Nanatmaja vyadhi*, characterized by pain and stiffness in the *Kati pradesh* area. Therefore, it is imperative to prioritize the management of *Vata dosha* when addressing this ailment. Pain management becomes the primary objective for *Vaidya* when treating this condition, particularly when *shoola* is the predominant symptom. The main symptoms of Shoola(pain) and Graha(stiffness) in the lower back region (Katipradesha) stem from an imbalance of the *Vata* and *Kapha doshas*. The vitiated *Apana Vayu* causes desiccation of the lubricating *SleshakaKapha* localized in the joints, resulting in laxity within the joint structures. The exacerbated *Vata* becomes seated in the region of minor joints, precipitating the onset of preliminary signs and symptoms. The *Gandharvahasthaditaila* contains *Gandharvahasthamoola* (*Ricinuscommunis*), *Yava*(*Hordeum vulgare*), Nagara (*Zingiber officinalis*), *Ksheera* (Cow milk), and *Murchitaerandataila* (Castor oil). It is having*Madhura* and *Tikta Rasa, MadhuraVipaka, UshnaVeerya, Teekshna, Sukshma* and *Picchila Guna*. Most of the ingredients in this *Gandharvahasthaditaila* have actions that balance *Vata* and *Kapha doshas*. The effects of *Gandharvahasthaditaila* can be described as *Vata-Kaphahara* (alleviating *Vata* and *Kapha*), *Vatanulomana* (maintaining the natural direction of *Vata)*[24], promoting digestion, cleansing the bowel, acting on minute channels ("srotas"), alleviating pain, improving taste, and purifying the gastrointestinal tract. Due to its hot potency and sharp-subtle properties, it penetrates into the subtle channels and cleanses them. *Nirgundi* (*Vitexnegundo* Linn.) is characterized by *tiktakatukashaya rasa pradana*, possess *lagu* and *rukshaguna, Katuvipaka,* and *Usnaveerya,* and well-known for its actions like *Vedanasthapana, Sothahara, Rasayana, Krimigna, Yakruduttejaka*, etc.[25] and is renowned for its analgesic, anti-inflammatory, rejuvenating, anti-parasitic, and hepatostimulative attributes. An *in-vitro* study has demonstrated that a sub-effective dosage of *Nirgundi*significantly augmented the anti-inflammatory efficacy of phenylbutazone and ibuprofen in experiments involving carrageenin-induced paw edema and cotton pellet granuloma models. This suggests the potential of *Nirgundi* as an adjunct therapy in conjunction with standard anti-inflammatory drugs.[26]

In the present study, *Nityavirechana* was given with *Gandarvahasthaditaila* and *Nirgundikwatha* to help in removing vitiated *doshas* from the body. These treatments are known for their actions such as *vata-kapha hara*, *srothomukavishodana, vatanulomana*, and *vedanastapana*. *Nityavirechana* not only removes morbid *doshas* from the body but also significantly reduces body weight. Most of the patients in the study had history of constipation and *vibandha* can also be considered as a symptom in *karigraha*[27], and *Nityvirechana* also helps in proper evacuation and relieving symptoms of *Vibandha*. *Trayodashangaguggulu* contains *guggulu* (Commiphoramukul) as its base and is widely used in Ayurvedic clinical practice for joint and bone-related disorders.[28] In addition to *guggulu,* it contains 13 other ingredients such as *Abha, Ashwagandha, Hapusha, Guduchi, Shatavari, Gokshura, Vriddhadaru, Rasna, Shatahva, Shati, Yavani,* and *Nagara*. *Guggulu* has properties like *snigdha, picchila, ushnaveerya, shotahara*, and *vedanasthapaka*, and is well known for managing body weight. *TrayodashangaGuggulu* also contains *Guduchi, Yavani*, and *Nagara*, which are well known for their anti-inflammatory properties. A preliminary study on *Trayodashanagaguggulu* supports the therapeutic claim of the formulation as an anti-inflammatory drug in the Ayurvedic system of

medicine. It advocates its use in inflammatory conditions.[29] As the study was planned based on the prevalence of low back pain is high in overweight and obese subjects affecting their quality of life, assessment was done for on body weight, BMI, pain scale and ODI scale for assessing QOL. As there is highly significant result in all the parameters assessed in the study, an SOP can be developed in specific condition.The study did not show drastic reduction in body weight among the subjects. However, there was a mild reduction in body weight ranging from 0 to 2 kg. This may be considered a limitation of the study. On the other hand, there was a very good reduction in the symptoms of *Katigraha*.

CONCLUSION

The present study findings are crucial in the management of Katigraha (low back pain), with a focus on not only alleviating pain and stiffness but also aiding in weight management through the use of *Nityavirechana*. The combined effect of the treatment protocol has shown promising results, offering hope for individuals struggling with *Katigraha*. This study underscores the importance of holistic approaches to addressing low back pain in the context of overweight and obesity, highlighting the potential for integrative interventions to improve both physical discomfort and weight management. The implications of this research extend beyond pain management, emphasizing the interconnectedness of various health concerns and the potential for comprehensive interventions to yield multifaceted benefits. As such, the findings provide valuable insights into the potential of integrative treatments in addressing the complex challenges associated with low back pain in the context of overweight and obesity.

Data Availability Statement: The original contributions presented in the study are included in the article; further inquiries can be directed to the corresponding author.

Author Contributions: B.D. designed the research work. V.R. and M.P. performed the research activities. R.R. analysed the data and validated. All the authors wrote the manuscript and edited the manuscript submitted. All authors have given their approval for publication.

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