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Efficacy and safety of local application of *Vijaya* oil in the management of *Sandhivata* with special reference to Osteoarthrosis: An open-labeled single-arm clinical trial

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ABSTRACT

Background: Osteoarthrosis is the second most common rheumatologic problem in India. Symptoms of Osteoarthrosis resemble *Sandhivata* in *Ayurveda*. *Vijaya* (cannabis sativa) oil manufactured by Bombay Hemp Company is used as a topical application in patients suffering from *Sandhivata*. **Aim:** To evaluate the efficacy & safety of local application of *Vijaya* oil in patients suffering from *Sandhivata,* with special reference to Osteoarthrosis. **Materials and methods**: Present clinical study was an open-label, single-arm study for the management of *Sandhivata* aged 30-75. The oil was applied locally on the affected site for 2 months. A total of 42 eligible patients suffering from symptomatic OA were enrolled, and 40 completed the study. Patients were assessed by clinical sign and symptom score for *Sandhivata*, Visual Analog Scale for Pain (VAS), WOMAC score for pain, stiffness, and physical function difficulty, Quality of life (QOL) score, Global assessment scale (GAS), and Overall disease severity (ODS). Statistical analysis was done by the Wilcoxon test. **Results**: The result was highly significant for all the subjective parameters. **Conclusion:** The study revealed that *Vijaya* oil significantly reduced pain, and stiffness, improved quality of life, and physical functions. It could be concluded that *Vijaya* oil can be a used as safe and effective drug of choice in patients suffering from *Sandhivata*.

Key words: *Sandhivata, osteoarthrosis, WOMAC, VAS (visual analog scale), GAS, ODS.*

INTRODUCTION

Osteoarthrosis (OA) is the second most common rheumatologic problem and is the most frequent joint disease with a prevalence of 28.7% in India.[1] Osteoarthrosis is widely regarded as a spectrum of conditions that affect all joint tissues primarily affecting cartilage loss. Osteoarthrosis or Degenerative Joint Disease (DJD) is associated with the symptoms, such as pain and inflammation.[2] It is a chronic condition requiring long-term treatment.

Osteoarthrosis is a non-inflammatory joint disease characterized by degeneration of the articular cartilage, hypertrophy of bone margin, and change in the synovial membrane.[3] To signify the lack of inflammatory response, most orthopedic surgeons from Russia, France, Germany, and Europe, refer to this degenerative disease as 'osteoarthrosis'.[4] Therefore, for degenerative joint disorder osteoarthrosis is the right term to use. So, in this view, we use osteoarthrosis term instead of osteoarthritis.

With time, the patient's condition may deteriorate to end-stage arthritis requiring joint replacement surgery,

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which is quite expensive and hence is not accessible to everyone.

Correct drug and their effective administration have been a challenge in OA. Many drugs, in modern medicine have failed, either due to their ineffectiveness or their side effects. Intra-articular injections have received increased interest, but they have their own disadvantages.[5]

In *Ayurveda, Sandhigata Vata* is considered as a *Vatavyadhi* predominantly due to vitiated or imbalanced *Vata*.[6] The primary treatment for *Vatavyadhi* is *Snehana* (oleation).[7] *Vijaya* is widely used as a pain-relieving drug, but its efficacy and safety remain contentious. *Vijaya* oil manufactured and marketed by Bombay Hemp Company, Mumbai, India is an herbal topical application which can be applied locally to get desired benefit of *Snehana*. The main ingredients in the *Vijaya* oil are Hemp seed (*Vijaya seeds*) oil and hemp leaf extract. The efficacy and safety of local application of this oil were evaluated in a clinical trial of 42 patients for a duration of 2 months. The result of this trial is being presented here.

Aim and Objective

To evaluate the efficacy and safety of local application of *Vijaya* oil in the management of *Sandhivata* with special reference to osteoarthrosis.

Materials and Methods

The Ethics Committee of National Institute of Ayurveda, Jaipur, India approved the study with No. IEC/ACA/2019/2-19 on 15-10-2019. The study was registered on Clinical Trial Registry India (CTRI) vide registration number, CTRI/2020/07/026491 registered on July 10, 2020. Patients visiting the out-patient and in-patient department of *Rognidana* Department of National Institute of *Ayurveda*, Jaipur were thoroughly examined for clinical signs and symptoms of *Sandhivata*.

Subjects were enrolled for the study considering the criteria of inclusion and consent was obtained from each patient in the study. The registered patients were given *Vijaya* oil for local application. Warm *Vijaya* oil was used on the affected joints for two months. Study evaluation visits were made at baseline and screened subjects were asked to visit after every 15th day i.e., visit 1 (day 0), visit 2 (day 15), visit 3 (day 30), visit 4 (day 45), visit 5 (day 60). The study was conducted in compliance with Good Clinical Practice guidelines (ICH) and the declaration of Helsinki and national regulations.

This was an open label, single arm, investigator initiated drug trial in phase-4, comparing the efficacy and safety of the drug before and after intervention, and also studying the same at every follow-up of the patient.

Diagnostic criteria

Patient with *Ayurvedic* clinical sign and symptoms of *Sandhivata* like *Sandhishula* (pain), *Shotha* (inflammation), *Stambha* (stiffness), *Sparshaasahyata* (tenderness), *Vatapuranadritisparsha* (crepitation), and *Akuncana Prasarana Vedana* (restricted range of movement due to pain), were screened in OPD and IPD of NIA, hospital. Patient enrollment began in February 2021 and the last follow-up was completed in September 2021.

Inclusion criteria

Patients of either sex between the age group of 30-75 years (both years inclusive). Patients suffering from *Sandhigata Vata* (Osteoarthrosis) and those with a history of fractures that may have occurred with a minor injury or fall. Those ready to abide by trial procedures and to give informed consent.

Exclusion criteria

Patient suffering from Osteomalacia, Tumor, Osteonecrosis, infection, and other bone-softening metabolic disorders and congenital disorders (Dysosteogenesis and Marfan's Syndrome). Patients with Leukemia, Lymphoma, Metastases (bony and other), Pathologic fractures secondary to bone metastases from cancer, Pediatric osteogenesis imperfect or Renal osteodystrophy, Malabsorption syndrome. Patients with endocrine disorders (Hyperthyroidism, hyperparathyroidism, Untreated Cushing's syndrome)

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Patients who have undergone organ transplantation and are immobilized since > 6 weeks. Patients with any other serious illness e.g., Hepatic/renal failure.

Those receiving any other treatment for osteopenia other than vitamin supplements and those requiring long term treatment of oral and/or injectable steroids or surgical intervention. Symptomatic patient with clinical evidence of Heart failure.

Patients with concurrent serious Hepatic Dysfunction (defined as AST and/or ALT > 3 times of the upper normal limit) or Renal Dysfunction (defined as S. creatinine > 1.2mg/dl), uncontrolled Pulmonary Dysfunction (asthmatic and COPD patients) or other concurrent severe disease. Patients with poorly controlled Diabetes Mellitus (HbA1c > 10%), alcoholics and/or drug abusers. Pregnant and lactating women and those with history of hypersensitivity to any of the trial drugs or their ingredients. Patients who participated in any other clinical trial during the past six (06) months. Any other condition which the Principle Investigator thinks may jeopardize the study.

Investigational Product

Vijaya oil is composed of *Vijaya* (*Cannabis sativa* Linn.) leaf extract 3% and *Vijaya* seed oil 97%. The formulation of drug was kept confidential as per the protocol of the company.

All the subjects were asked to apply *Vijaya* oil locally by following the process described in the protocol. 5-7 mL of *Vijaya* oil was used. The oil was kept at room temperature and was then applied locally to the affected area. Vigorous massage is to be avoided. The oil is applied gently over the affected area twice daily (Morning after bath and in night before going to bed). The quantity of oil depends on the size of the affected area.

Ongoing concomitant medication for concurrent chronic illnesses was permitted. Other than study drug, no other Allopathic, *Ayurvedic*, Homeopathic, Siddha, Unani drug(s) or any other traditional or folklore medicine or therapy was permitted for the said indications during study period. All the subjects were advised to continue their regular diet and exercise regimen (which they are already following) during the entire study.

Assessment criteria

The assessment was done by considering changes in the subjective parameters before and after the treatment. The primary and secondary efficacy variables were recorded, some at every visit and others, before and after treatment.

1. Maximum active pain on body weight-bearing activity (e.g., walking) was recorded on a horizontal 10cm VAS (anchored at 0 for absent pain and 10 for maximum pain).
2. A validated modified version of the WOMAC questionnaire suitable for Indian patients and available in several Indian languages was used. Patients provided categorical answers for scoring (none = 0, mild = 1, moderate = 2, severe = 3, extreme = 4) and the maximum score (of 24 questions) was 96.
3. Clinical sign and symptom score of *Sandhivata* were as recorded before and at the end of the treatment. These included clinical signs and symptoms of *Sandhivata* which were *Sandhishula* (pain), *Shotha* (inflammation), *Stambha* (stiffness), *Sparshaasahyata* (tenderness), *Vatapuranadriti Sparsha* (crepitation), *Akuncana Prasarana Vedana* (restricted range of movement due to pain).
4. Several secondary efficacy variables included the WHO Quality of life score. A questionnaire was made consisting of 10 questions. Each question was scored accordingly from 1-4 numbers.
5. Assessment of Safety of the product assessed by the physician and subject on the global assessment scale (GAS).
6. Assessment of change in Overall Disease Severity (ODS) Score i.e., treatment success (Scoring symptoms) was also done.

Patients were questioned at every visit for common drug related symptoms as per a predetermined checklist and encouraged to add any other symptom

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they considered as a drug-related side effect. At the end of study, no adverse events were found.

Statistical analysis

Wilcoxon test was used to evaluate the efficacy of *Vijaya* oil for non-parametric data GraphPad prism software. The value was considered significant at the levels of P<0.0001.

OBSERVATIONS

Out of 42 registered patients, 40 completed the study. Two patients dropped out as they didn't complete the follow-up. The maximum number of patients were in the age group of 46-60 years of age (60%), female (70%), and had weight in the range 71-80 kg (40%).

RESULTS

In finding the difference between mean change from baseline to completion in primary and secondary efficacy variables by treatment, *Vijaya* oil showed highly significant results. Significant relief was seen in the WOMAC score (Table 1) before and after the treatment.

Moreover, VAS, QOL, GAS, and ODS scales also showed significant improvement at the end of the trial (Table 2). Clinical sign and symptom scores consisting of classical signs and symptoms of *Sandhivata* mentioned in *Ayurvedic* texts also showed a remarkable improvement (Table 3).

Table 1: WOMAC score- pain, stiffness and physical function

SN	% Average	Visit I	Visit VI	Difference of the average	% relief	p-value	Results
1.	Pain	84.7	18	13.35	79	<0.0001	HS
2.	Stiffness	68.4	9.3	4.725	86	<0.0001	HS
3.	Physical function	83.2	29.1	36.775	65	<0.0001	HS

*HS- Highly Significant

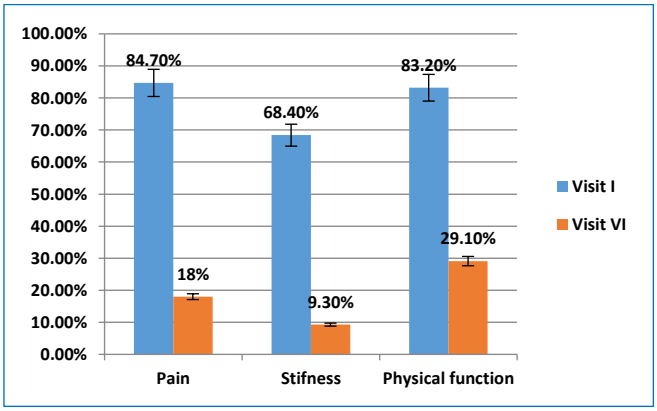

Chart 1: Percentage prevalence of WOMAC score- pain, stiffness, and physical function.

It was observed that, there was a significant decrease of 79%, 86% and 65% observed in mean values at all-time points when compared to baseline visits for WOMAC score-pain, stiffness and physical function respectively which imply that the test product was efficacious in providing significant improvement in WOMAC score of the subjects with regular use.

Table 2: Percentage Average of VAS, QOL, GAS, and ODS.

SN	% Average	Visit I	Visit VI	Difference in the average	% relief	P value	Results
1.	VAS	88.5	22	6.65	75	<0.0001	HS
2.	QOL	38.2	86.8	19.45	56	<0.0001	HS
3.	GAS	23.2	17.8	0.375	23	<0.0001	HS
4.	ODS	80	13.1	2.675	84	<0.0001	HS

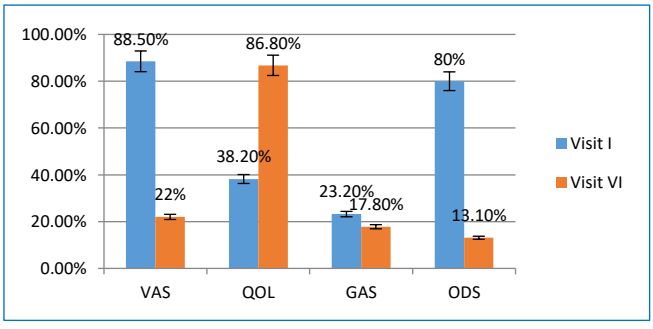

Chart 2: Percentage prevalence of VAS, QOL, GAS, and ODS score

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There was a significant increase of 56% observed in the mean values at all-time points when compared to baseline which implies that the test product was efficacious in improving the quality of life of the patients as per QOL score with regular use.

Moreover, there was a significant relief seen with the reduction of 75%, 23%, and 84% in VAS, GAS, and ODS scores respectively.

Table 3: Clinical sign and symptom score of *Sandhivata*

SN	% Average	Visit I	Visit VI	Difference of the average	% relief	p-value	Results
1.	*Sandhishula* - pain	92.5	11.6	2.425	87	<0.0001	HS
2.	*Shotha* - inflammation	79.1	11.6	2.025	85	<0.0001	HS
3.	*Stambha* - stiffness	90	10.8	2.375	88	<0.0001	HS
4.	*Sparshaasahyata* - tenderness	85.8	10.8	2.25	87	<0.0001	HS
5.	*Vatapurana driti Sparsha* - crepitation	87.5	13.3	2.22	85	<0.0001	HS
6.	*Akuncana Prasarana Vedana* - restricted range of movement due to pain	89.1	14.1	2.25	84	<0.0001	HS

There was a significant decrease of 87%, 85%, 88%, 87%, 85%, 84% observed in mean values at all-time points when compared to baseline which implies that the test product was efficacious in providing significant improvement in *Sandhishula* (pain), *Shotha* (inflammation), *Stambha* (stiffness), *Sparshaasahyata* (tenderness), *Vatapuranadriti Sparsha* (crepitation) and *Akuncana Prasarana Vedana* (restricted range of movement due to pain) with regular use.

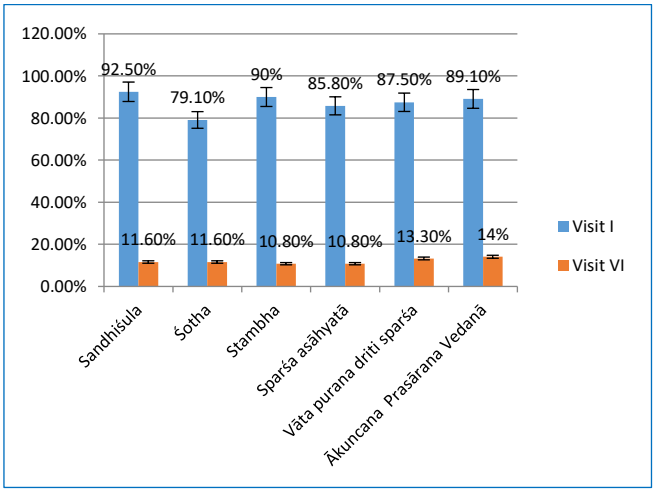

Chart 3: Percentage prevalence of Clinical sign and symptom score of *Sandhivata*

Discussion

The study was conducted to evaluate the efficacy and safety of local application of *Vijaya* oil in patients suffering from *Sandhivata* with special reference to osteoarthrosis. After the evaluation of inclusion / exclusion criteria, subjects with clinical sign and symptoms of *Sandhivata* were recruited into the study for a period of two months with six visits at an interval of 15 days.

Conventional therapies for OA have limited effectiveness and toxicities associated with suitable drugs thus often limiting utilization, leaving much facing surgery or chronic often debilitating, pain, muscle weakness, lack of stamina, and loss of function.[8] Massage therapy and certain other complementary and alternative medicine (CAM) interventions are being utilized by OA sufferers, and represent attractive, potentially effective options to manage pain.[9] Topical administration of drugs could be a practical alternative to oral delivery, not least because they avoid first-pass metabolism, are associated with a lower rate of systemic adverse events, and allow direct application over the target areas.[10] Topical formulations should be easy and acceptable to use, but important need to be able to penetrate the skin and permeate to the target areas in quantities sufficient to exert a therapeutic effect. Topical analgesics are often used in acute and chronic painful conditions, delivering non-steroidal anti-

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inflammatory drugs (NSAIDs) such as ibuprofen, diclofenac, and acetylsalicylic acid directly to the site of injury to relieve pain. They can be particularly useful in the management of osteoarthritis (OA), a chronic condition where a regular intake of oral NSAIDs to control painful flares may be associated with systemic adverse events, especially in the older population that typically suffers from OA.[11]

Bhanga (Vijaya) has been neglected earlier due to its psychoactive effect. But interestingly, *Bhanga* leaves and other parts have both psychoactive and physiological effects only when consumed, but there are no psychoactive effects on topical application. Also, seeds do not have psychoactive element (THC).[12]

Earlier the transdermal administration of CBD, via gel application, has been tested on a rat on a complete Freund's adjuvant-induced monoarthritic knee joint model.[13] In this study, CBD was found to demonstrate therapeutic potential for the relief of arthritic pain-related behavior and to exert an anti-inflammation effect without any evident high-brain-center psychoactive effects. The transdermal administration of CBD has also been observed to provide better absorption than the oral administration route in the same arthritic model.[14]

Vijaya oil contains *Bhanga* (*Vijaya*) seeds extract and *Bhanga* seed oil. *Vijaya* has been considered as *Vatadoshahara, Vedanaprashaman* (Pain reliever).[15] *Sandhivata* is a *Vatavyadhi*, the best treatment for which is *Snehana* (Oleation). *Vijaya* oil manufactured and marketed by Bombay Hemp Company, India is a herbal topical application that can be applied locally to get desired benefit of *Snehana* (Oleation). *Snigdha* (unctuous), *Guru* (heavy), and *Mridu* (soft) properties, of *Vijaya* oil; which are opposite to the properties of *Vata*; can reduce the provoked *Vata*; hence relieving pain, inflammation, and other signs and symptoms of *Sandhivata*.

Probable mode of action of the drug

There was a significant reduction in the parameters used to analyze pain and other symptoms of the disease. WOMAC scores showed relief of 79%, 86%, and 65% in pain, stiffness, and physical function. The VAS score for pain also depicted a relief of 75%. The WHO QOL index showed an increase from 38.2% to 86.8%, conveying that using the oil has greatly improved the quality of life of the patients. The results of other parameters also proved a significant improvement in disease condition, the effect in clinical sign and symptom score of OA, was also worth noticing, showing a reduction in *Sandhishula* (pain), *Shotha* (inflammation), *Stambha* (stiffness), *Sparshaasahyata* (tenderness), *Vatapuranadriti Sparsha* (crepitation), and *Akuncana Prasarana Vedana* (restricted range of movement due to pain) at the end of the treatment. These classical parameters showed a significant improvement proving the effectiveness of *Vijaya* oil in the context of *Ayurvedic* diagnostic criteria too. The GAS scale shed a relief of 23%, whereas, ODS with 84 %.

It was observed that there was an improvement in the patient's daily activities, like earlier there was difficulty in exercise, walking, climbing upstairs, doing *s*, etc., before the beginning of the study, but with the regular application of oil, there was a notable enhancement in these day-to-day movements.

The probable mode of action, in significant improvement in pain might be due to the *Vatahara* (balancing *Vatadosha*) properties of *Vijaya.* Being *Vyavayi* [16] (Potent in action) and analgesic in nature, *Vijaya* helps in instant pain reduction. Probably due to its potency of creating pleasurable effects, it helps in achieving a feeling of accomplishment of the mind's objects by creating a state of euphoria thus, helped in reducing unpleasant pain, and improving restricted movements and physical function. Recent research reports the significant analgesic activity of Cannabis in cancer pain is due to the presence of phytoconstituents like tetra-hydrocannabinol (THC) and Cannabidiol (CBD).[17]

CONCLUSION

After the successful completion of the trial, it can be concluded that *Vijaya* oil has proved effective in reducing pain, stiffness, crepitation, and other clinical sign and symptoms of OA. It has helped in the improvement of patients' daily activities like, walking,

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climbing upstairs, exercising, etc. There was no product-related AE/SAE or local intolerance of clinical significance. The test products were safe and well tolerated by the study population. Hence, *Vijaya* oil can be adopted as a safe and effective remedy in the management of *Sandhivata* (OA).

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