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Research Article

Vedistry Shallaki

Clinical Evaluation of Vedistry Shallaki + Tablets in the Management of Osteoarthritis

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Objective: To establish the efficacy and safety of Vedistry Shallaki + Tablet in the management of osteoarthritis (OA).

Method: A randomized, double blind, active controlled, single center, clinical study was carried out in 300 osteoarthritic subjects to evaluate the efficacy and safety of Vedistry Shallaki + Tablet in relieving symptoms of moderate to mild OA. The efficacy and safety of Vedistry Shallaki + Tablet administration in a dose of 1 tablet twice daily for 90 days was directly compared with the selective COX-2 inhibitor, celecoxib given in a dose of 100 mg twice daily using total Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) score, pain score, functional ability score, visual analog scale (VAS) score and Lequesne functional index values.

Results: The results of the study showed that Vedistry Shallaki + Tablet can provide significant improvement in relieving the symptoms and the pain associated with OA. Osteoarthritic subjects receiving Shallaki Plus reported statistically significant changes/decreases in their clinical symptoms and pain compared to those receiving Celecoxib. This was evident from significant changes in the total Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) score, pain score, functional ability score, visual analog scale (VAS) score and Lequesne functional index values at $P < 0.05$ level.

Conclusion: Vedistry Shallaki + Tablet promises the beneficial effects for the treatment of osteoarthritis by controlling inflammatory responses as well as the pain without any adverse effects.

Keywords: Vedistry Shallaki + Tablet, Osteoarthritis (OA), Boswellia serrata, Degenerative joint disease, Joint pain

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Introduction

Osteoarthritis (OA), the most common form of arthritis, is defined by degradation of articular cartilage, joint pain, stiffness and inflammation.**[1,2]** It affects about 10–15% of the world population, particularly adults and is one of the leading causes of physical disability and impaired quality of life in them. Although the exact etiology of OA is not fully understood, age is the strongest predictor of the development of OA. Obesity, trauma and physically demanding occupations also increase the risk of OA of the hand, knee and hip. Age associated degenerative changes, or the unusually high stress placed on the joint surfaces lead to the degradation of the joint structures causing pain, stiffness, and other OA symptoms.

Even though the number of osteoarthritic patients is surging continuously, most of the available treatment modalities can provide symptomatic relief only with no drugs that can modulate the progression of OA. The latest OA management guidelines commonly suggest non-steroidal anti-inflammatory drugs (NSAIDs) as the first choice for OA treatment.**[3]**

NSAIDs, though, are effective in controlling the inflammation and reducing the pain in affected joints caused by OA, they do not have a positive impact on the regeneration of damaged cartilage and joint structures. They also carry an elevated risk of adverse events like kidney injury, peptic ulcer disease, especially when consumed for a long period of time.**[4]** These issues of inadequate efficacy, safety and tolerability associated with NSAIDs demand the development of new agents to manage OA without adverse events.

In recent years, many ancient herbs have gained much attention as a potent anti-inflammatory, anti-arthritic and analgesic agent. The gum resin extracted from the herb Shallaki (*Boswellia serrata*) is one of these herbs. Boswellia gum resin is actively used in traditional *medicine* for thousands of years to treat ailments including musculoskeletal diseases. 3-Oacetyl-11-keto-beta-boswellic acid (AKBA), the most active component of Boswellia gum extract, has been demonstrated to be a potent inhibitor of 5-lipoxygenase (5-LOX), which is a key enzyme in the biosynthesis of leukotrienes from arachidonic acid in the cellular inflammatory cascade.**[5,6]**

Boswellia also prevents a decrease in glycosaminoglycan levels which is required for cartilage repair. NSAIDs may disrupt glycosaminoglycan synthesis, which, in turn, may accelerate cartilage damage. Non-acid section of gum has pain-relieving qualities. In a meta-analysis including seven clinical trials involving 545 patients, Boswellia and its extract were reported to have a positive effect on relieving pain, and stiffness and improving joint function. **[7]** In present clinical study, we compared efficacy and safety of Vedistry Shallaki + Tablet in a randomized, double-blind, monocentric, comparative study in individuals with mild to moderate degenerative osteoarthritis.

Materials and methods

Study design

The present study was a randomized, double blind, mono centric, comparative, clinical study to evaluate the efficacy and safety of Vedistry Shallaki + Tablet and Celecoxib as the reference standard (purchased online) in subjects with mild to moderate degenerative osteoarthritis. Vedistry Shallaki + Tablet was supplied by Charak Pharma Ltd, Mumbai. The study was conducted at Dr. Neelam Chaturvedis' Shree Vishwadhatri Ayurved Clinic, Mumbai, India from March 2024 to August 2024. All the procedures described in this study were previously reviewed and approved by the Institutional Ethics Committee of Dr. Neelam Chaturvedi's Shree Vishwadhatri Ayurved Clinic, Mumbai, India.

A total of 450 subjects attending the medicine outpatient clinic with complaints of joint pain and swelling were evaluated through detailed medical history and comprehensive physical examinations. After thorough screening, 300 subjects meeting the inclusion criteria were included in the study. The subjects were randomly assigned to one of two treatment groups using a randomization table.

- **Group 1 (Vedistry Shallaki + Tablet):** 150 subjects received 1 Vedistry Shallaki + Tablet twice daily after meals.
- **Group 2 (Celecoxib):** 150 subjects received 100 mg of Celecoxib twice daily after meals.

The study spanned 90 days, during which the subjects were required to visit the clinic every 30 days. At each visit, vital signs, symptom scores, and clinical examination results were recorded.

Analysis of the results indicated that the maximum number of subjects experienced significant relief in Group 1, highlighting the effectiveness of Vedistry Shallaki + Tablet in managing joint pain and swelling.

The criteria used to withdraw a subject from the study were:

I) any indication of an allergic reaction to the treatment; ii) the subject developed severe symptoms that were uncontrollable with the study drugs; iii) withdrawal of consent; iv) administrative reasons, such as subject non-compliance or major protocol violation (pregnancy or alcohol consumption during the study) and v) any condition that might put the subject at undue risk.

The screening assessments were as follows: obtaining written informed consent from the subject, persistent explanation to the subjects that the subject must adhere to the instructions, recording of demographic data, detailed case history including history of general previous diseases, documentation of previous and supplementary medications and physical examination. Each subject underwent routine haematological and urine analysis. Data was collected for Liver Function Tests and Kidney Function Tests before start of the study and at the end of the study. Subjects were asked not to eat any food, except for water, for 12 to 14 hours before taking blood samples. The clinical side effects if any were recorded at each visit and discussed with the subject to know the nature, severity and frequency. Concomitant medications were monitored throughout the study. The results were analysed using a paired 't' test.

Preparation of Vedistry Shallaki + Tablet

Vedistry Shallaki + Tablet was procured from Charak Pharma Pvt. Ltd. Each tablet of Shallaki Plus contains 300 mg extract of Shallaki gum, Bhavana (trituration) with 50 mg of Shallaki and 25 mg of Pippali fruit extract.

Inclusion criteria

Male and female participants in the age group of 40–70 years, otherwise healthy, diagnosed with OA, having symptoms in accordance with that of OA and radiological findings corresponding to Kellgren-Lawrence (KL) grades I-II based on an X-ray of the knee joint and anteroposterior view on standing were enrolled in the study.

The participants had to demonstrate a VAS score ranging between 40 to 70 mm during the most painful knee movement, and Lequesne's functional index (LFI) score greater than 7 points. Other inclusion criteria were willingness to comply with the study protocol, avoid use of any analgesic medication, and attend regular follow-up visits. All the participants signed the written informed consent form.

Exclusion criteria

The participants with non-degenerative joint diseases that can interfere with the evaluation of OA (Rheumatoid arthritis, active gout, recent knee joint trauma, or joint infection), KL grade of III or higher, incapacitated or bound to wheelchair or bed and unable to carry out self-care activities and those with a history of knee or hip replacement surgery were excluded. Participants with prior treatment with corticosteroids, glucosamine, chondroitin, hyaluronate, glucocorticoids, steroids, or intra-articular corticosteroid injections within the preceding 3 months or herbal and alternative medicines within 1 month before screening, were also excluded from the study. Other exclusion criteria were the presence of chronic diseases and hypersensitivity to herbal extracts or dietary supplements.

Efficacy and safety evaluation

The efficacy assessments of stiffness, pains, and physical function were analyzed using the WOMAC, VAS score, and LFI questionnaire data on day 0, day 30, day 60, and day 90, which is a standard duration for osteoarthritis studies.**[8-10]**

The Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index is a valid questionnaire that assesses knee pain, stiffness, and physical function. The test questions record scores on a scale of 0-4 corresponding to: None (0), Mild (1), Moderate (2), Severe (3), and Extreme (4). The total WOMAC score ranges from 0 to 96, with higher scores indicating worse pain, stiffness, and functional limitations. The visual analog scale (VAS) is a validated, subjective measure for acute and chronic pain. A score of 0 is indicative of 'no pain' whereas a score of 10 represents 'severe pain'. LFI can be used to assess effectiveness of therapeutic intervention for OA of knee. There are three sections for index viz. pain or discomfort, maximum distance walked & activity of daily living.

The criteria for LFI are described as follows: none (0), mild (1–4), moderate (5–7), severe (8–10), very severe (11–13) and ≥ 14 extremely severe. **[11]** Appropriate statistical tools were employed to compare the baseline values of these parameters with those at the end of treatment (EOT).

Safety of the Vedistry Shallaki + Tablet was assessed through i) measuring vital signs and clinical examination at every visit and ii) laboratory evaluations at baseline and after treatment completion measuring different parameters like total white blood cell count (TC), erythrocyte sedimentation rate (ESR); iii) Liver function test (LFT), including serum albumin, total bilirubin, serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT) and iv) renal function tests (RFT), including blood urea and serum creatinine.

Vital signs were measured at each visit and a heamogram, LFT and RFT were measured prior to treatment and at the end of the treatment period (90 days).

None of the enrolled subjects had an abnormal medical history. No physical abnormalities were detected during the screening or study visit.

Results

After the initial screening, a total of 300 subjects fulfilling the inclusion criteria were enrolled in the study and randomized. Of these, 272 subjects completed the study, with 28 subjects dropping out due to personal or family issues.

Baseline characteristics

The subject flowchart of the study, including the number of subjects and the interventions received by each group (Vedistry Shallaki + Tablet group and Celecoxib group), is shown in Fig. 1.

The baseline characteristics of the subjects prior to the intervention in the Vedistry Shallaki + Tablet and Celecoxib groups are compiled in Table 1. No significant differences between the groups were observed in terms of baseline characteristics, such as age, weight, height, and body mass index (BMI). Other characteristics, including gender, pulse rate, respiration rate, temperature, systolic blood pressure, and diastolic blood pressure, were also very similar in both groups.

The Vedistry Shallaki + Tablet group consisted of 60 males and 90 females, while the Celecoxib group included 59 males and 91 females. The total WOMAC score, pain score, functional ability score, VAS score, and Lequesne Functional Index **(**LFI**)** were almost identical between the two groups at baseline (as summarized in Table 2).

A paired t-test was used to measure the changes from baseline within each group, while the Mann-Whitney U test was used to compare the mean differences between the two treatment groups. No significant difference in the severity of osteoarthritis (OA) at baseline was found between the two groups, as measured by the total WOMAC score (P = 0.924), pain score (P = 0.672), functional ability score (P = 0.814), VAS score (P = 0.655), and LFI (P = 0.848).

After the initial screening, a total of 300 subjects, who met the inclusion criteria, were enrolled in the study and randomized. Of these, 272 subjects completed the study, with 28 subjects dropping out due to personal or family issues.

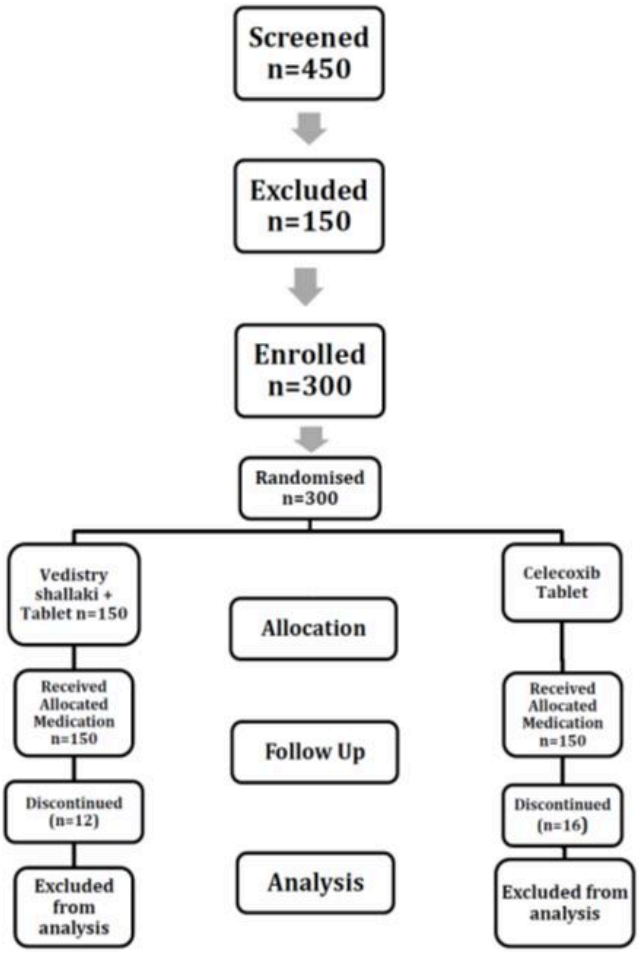

Figure 1: Subject flowchart

Table 1: Comparison of baseline characteristics for the variable under investigation in Vedistry Shallaki + Tablet and Celecoxib groups.

SN	Item		Vedistry Shallaki + Tablet (n=150)	Celecoxib (n=150)
1.	Age (years)		54.6 ± 10.22	53.4 ± 10.26
2.	Gender [n (%)]	Male	60 (40%)	55 (36.67%)
		Female	90 (60%)	95 (63.33%)
3.	Weight (kg)		64.3 ± 12.18	63.8 ± 18.14
4.	Height (cm)		157.3 ± 10.17	156.2 ± 13.48
5.	BMI (kg/m²)		27.38 ± 5.16	27.22 ± 6.28
6.	Pulse (beat/min)		77.3 ± 6.73	78.2 ± 5.89
7.	Respiratory rate (/min)		20.5 ± 2.20	21.0 ± 2.57
8.	Temperature (°F)		97.7 ± 1.15	97.8 ± 0.94
9.	Systolic BP (mmHg)		122.7 ± 10.22	121.5 ± 8.68
10.	Diastolic BP (mmHg)		81.0 ± 7.45	79.7 ± 5.61

WOMAC index

Table 2 presents data comparing the treatment effect on the total **WOMAC score**, pain score, functional ability score, **VAS score**, and **Lequesne's Functional Index** between the **Vedistry Shallaki + Tablet** and **Celecoxib** groups. The analysis was conducted using the mean changes from baseline to days 30, 60, and 90 (treatment end). In the **Vedistry Shallaki + Tablet** group, significant improvements were observed in the total WOMAC score ($P < 0.001$), pain score ($P < 0.001$), functional ability score ($P < 0.001$), VAS score ($P < 0.001$), and Lequesne's Functional Index ($P < 0.001$) by the end of treatment. The **Celecoxib** group also showed improvements; however, these changes were less consistent and of smaller magnitude compared to the Shallaki Plus group. Specifically, the percentage change in the **total WOMAC score** was 49.70% in the Shallaki Plus group versus 15.54% in the Celecoxib group, while the **pain score** improved by 54.30% in the Shallaki Plus group and 22.30% in the Celecoxib group. The **VAS score** showed a mean percentage change of 49.70% for the Shallaki Plus group compared to 30.64% for the Celecoxib group, and for the **Lequesne's Functional Index**, the changes were 32.06% and 20.53%, respectively. The **functional ability score** increased by 48.54% in the Shallaki Plus group, whereas the Celecoxib group showed a 12.75% improvement. At **day 30**, there were no significant differences in the changes between the two groups. However, at **day 60**, highly significant differences were observed between the groups in the **total WOMAC score**($P = 0.006$ and $P = 0.0001$), **Pain score** ($P = 0.018$ and $P = 0.0001$), and **functional ability score** ($P = 0.016$ and $P = 0.0001$).

At **day 90**, significant differences were noted in the **VAS score** ($P = 0.009$ and $P = 0.0001$) and **Lequesne's Functional Index** ($P = 0.031$ and $P = 0.045$), with the Shallaki Plus group consistently showing greater improvement compared to the Celecoxib group.

Table 2: Treatment effect of Vedistry Shallaki + Tablet and Reference (Celecoxib) group as measured at baseline, day 30, day 60 and day 90.

Parameters	Vedistry Shallaki + Tablet (n=150)	Celecoxib (n=150)	p-value
Total WOMAC Score			
Baseline	0.59 ± 0.10	0.60 ± 0.10	
30th Day	0.53 ± 0.08 (10.17% change)	0.57 ± 0.08 (5.00% change)	P < 0.001*
60th Day	0.43 ± 0.05 (27.12% change)	0.54 ± 0.05 (10.01% change)	P < 0.001*
90th Day	0.30 ± 0.02 (49.15% change)	0.51 ± 0.02 (15.02% change)	P < 0.001*
Pain Score			
Baseline	0.61 ± 0.11	0.62 ± 0.10	
30th Day	0.50 ± 0.07 (18.03% change)	0.57 ± 0.09 (8.06% change)	P < 0.005*
60th Day	0.42 ± 0.06 (31.15% change)	0.54 ± 0.09 (12.90% change)	P < 0.001*
90th Day	0.29 ± 0.03 (52.46% change)	0.49 ± 0.10 (20.97% change)	P < 0.001*
Functional Ability Score			
Baseline	0.56 ± 0.11	0.59 ± 0.09	
30th Day	0.52 ± 0.10 (7.14% change)	0.57 ± 0.08 (3.39% change)	P < 0.003*
60th Day	0.42 ± 0.05 (25.00% change)	0.53 ± 0.08 (10.17% change)	P < 0.001*
90th Day	0.29 ± 0.02 (48.21% change)	0.52 ± 0.08 (11.86% change)	P < 0.003*
VAS Score			
Baseline	59.22 ± 6.90	59.15 ± 8.09	
30th Day	51.95 ± 7.51 (12.28% change)	52.58 ± 5.99 (11.11% change)	P < 0.001*
60th Day	38.82 ± 8.05 (34.45% change)	47.52 ± 4.41 (19.66% change)	P < 0.001*
90th Day	28.64 ± 3.32 (51.64% change)	40.75 ± 5.99 (31.11% change)	P < 0.001*
Lequesne Functional Index			
Baseline	13.32 ± 2.96	14.28 ± 2.57	
30th Day	12.24 ± 2.26 (8.11% change)	13.31 ± 2.43 (6.79% change)	P < 0.006*
60th Day	10.41 ± 1.34 (21.85% change)	12.19 ± 2.30 (4.64% change)	P < 0.001*
90th Day	9.49 ± 1.62 (28.75% change)	11.26 ± 2.32 (21.15% change)	P < 0.001*

Note:

- *P < 0.05* indicates statistically significant differences.
- The percentages reflect the mean percentage changes from baseline.

Biochemical Parameters

The results of biochemical parameters of blood and urine tests are listed in Table 3. These parameters remained within normal ranges throughout the study duration. The general health condition of the subjects in both treatment groups did not show any significant change or an abnormal health issue requiring medical consultation or treatment. All laboratory test results were within normal range in both treatment groups even after end of treatment.

Table 3: Summary of mean change from baseline to end of treatment in biochemical parameters.

Parameters	Vedistry Shallaki + Tablet (n=150)		Celecoxib (n=150)		% Change
	Day 0	Day 90	Day 0	Day 90	
Albumin (g/dl)	4.21 ± 0.32	4.40 ± 0.21	4.22 ± 0.38	4.16 ± 0.31	−4.51%
Total Bilirubin (mg/dl)	0.56 ± 0.18	1.28 ± 0.11	0.62 ± 0.14	1.35 ± 0.09	1.35 ± 0.09
SGOT (U/L)	18.95 ± 3.77	19.2 ± 0.12	20.17 ± 3.98	21.03 ± 3.54	−1.32%
SGPT (U/L)	23.92 ± 7.80	23.34 ± 4.72	24.41 ± 7.82	23.89 ± 3.65	2.42%
Uric Acid (mg/dl)	5.2 ± 0.85	5.56 ± 1.12	5.4 ± 0.75	5.8 ± 1.4	−6.92%
Total Protein (g/dl)	6.80 ± 0.4	6.98 ± 0.8	7.3 ± 0.5	7.5 ± 0.6	−2.65%
BUN (mg/dl)	15.85 ± 5.18	12.51 ± 5.1	14.76 ± 4.8	12.95 ± 4.3	21.07%
Creatinine (mg/dl)	0.94 ± 0.12	0.85 ± 0.01	0.83 ± 0.15	0.78 ± 0.02	9.57%
Leucocyte Count (cells/cumm)	9280.95 ± 2414.92	9085 ± 3725.16	9658.33 ± 1412.91	9108.94 ± 2129.16	2.11%
ESR (mm)	24.28 ± 12.90	18.3 ± 10.12	22.83 ± 13.90	19.73 ± 10.17	24.63%
hs-CRP (mg/L)	1.30 ± 0.40	0.03 ± 0.01	1.19 ± 0.69	0.03 ± 0.01	97.69%

Discussion

Unwanted gastrointestinal and cardiovascular adverse events caused by current arthritis therapies using NSAIDs and COX-2 inhibitors underline the need of new anti-arthritic therapies. *Shallaki* or Boswellia resin has been effectively used in traditional Ayurvedic medicine to treat osteoarthritis since long without any serious adverse events.

This study compared efficacy and safety of *Shallaki* with the reference standard (100 mg of Celecoxib) in managing osteoarthritis symptoms. *Shallaki* resin is shown to have analgesic, anti-inflammatory, and antiarthritic properties. The key constituents of *Shallaki* are volatile oil (4-8%), acid resin (56-65%) and gum (20-36%). The triterpenoids are the active constituents and are collectively called boswellic acids. The gum resin of B. serrata usually contains 43% boswellic acids, which contain a combination of six major constituents, mainly 3 acetyl, 11 keto, boswellic acids (AKBA), which help to preserve the structural integrity of joint cartilage and maintain a healthy immune mediator cascade at a cellular level,**[12]** which is active against pain and inflammation by inhibiting leukotriene synthesis. Specifically, it inhibits the activity of the enzyme 5 lipoxygenase through a non-redox reaction in OA. **[13]** *Shallaki* resin also acts as COX-2 inhibitor and reduces the pain and inflammation without affecting the gastric mucosa. It soothes the joints and also helps treat levels of synovial fluid, making the entire structure lubricated and easy to rotate or to move. **[14]**

Another study conducted using an in vivo mice model showed that AKBA inhibits activation of NF-κB.**[15]** Boswellic acid reduces cartilage loss, osteophyte formation, and synovitis in a mice model study and provides evidence to implicate inhibition of both IL-1β and TLR signaling as potential mechanisms mediating this protective effect.**[16]** The *Boswellia serrata* extract (BSE) has been claimed to decrease the glycosaminoglycan degradation, which helps to keep the cartilage in good condition, which might be responsible for the recovery of the patients with OA and might stop the progression of this condition. The BSE is effective on the production of antibodies and cell-mediated immunity as well as inhibits human leukocyte elastase. This could be of help in autoimmune disorders like rheumatoid arthritis.**[17,8]**

The improvement in OA patients such as joint space, subarticular sclerosis, synovial effusion, articular erosion and osteophytes after treatment with *Shallaki* capsule.**[18]** This significant improvement in radiological findings was due to the anti-inflammatory activity of *B. serrata* resin. It soothes the joints and also helps treat levels of synovial fluid, making the entire structure lubricated and easy to rotate or to move.

AKBA helps preserve structural integrity of the joint cartilage and maintains a healthy immune mediator cascade at a cellular level. *Shallaki* improves blood supply to joints and restores integrity of vessels obliterated by spasm of internal damage.**[19]**

Vedistry Shallaki + Tablet also contains 25 mg of *Pippali* fruit extract. *Pippali* contains piperine which is known to enhance the bioavailability and efficacy of medicinal herbs. This ensures efficient absorption and utilization of *Shallaki* extract to give maximum benefits.**[20]**

Overall effect of therapy

In this randomized, double blind, active controlled, mono-centric, comparative and clinical study Vedistry Shallaki + Tablet was found to be effective against the reference standard in subjects with mild to moderate OA. The comparative efficacy was shown by the change from baseline in the total WOMAC score, pain score, functional ability score, VAS score and LF index for the 90 days of treatment (Table 2). The comparative safety was shown by the result that there was no statistically significant difference in the various biochemical parameters between the two groups (Table 3).

In this clinical study, the effects of Vedistry Shallaki + Tablet containing 300 mg mg of Shallaki resin on OA were assessed and the results showed that there were reductions in all WOMAC studies in both treatment groups. Compared to baseline, the reduction in total WOMAC scores in the two treatment groups was statistically significant ($P < 0.05$) however, the reduction of these values was not statistically significant in the reference standard i.e. Celecoxib treatment group. Furthermore, the within-group analysis, i.e. differences among subjects in the same group, showed that Vedistry Shallaki + Tablet intervention had more positive effects on the total WOMAC score, pain score, functional ability score, VAS score and LF index in OA subjects. However, the reference sample was also found to reduce the total WOMAC score, pain score, functional ability score, VAS score and LF index over a 90 days period of the study, but the reduction was very minimal (Table 2).

In case of the efficacy parameter, Shallaki Plus showed significant improvement ($P < 0.001$) in the total WOMAC score throughout this study and there was no significant difference between the two groups at the initial stage of the study.

Moreover, total WOMAC score after taking Vedistry Shallaki + Tablet for 30-90 days decreased by 11-50% from baseline. It could be combined effects of natural phytonutrients present in Shallaki resin. As per study results, VAS scores were significantly lower in the subjects treated with Shallaki Plus than in those treated with the reference standard in 90 days. These findings indicate that Shallaki may decrease pain and discomfort of OA and improve general condition and quality of daily life of patients. OA is a chronic condition that progresses slowly and decreases quality of life, herbal supplements like Shallaki Plus can provide an effective solution with no major side effects. Though both Shallaki Plus and reference standard treatment lead to reduction in hsCRP as 98% (Table 3), but the reduction in hsCRP during the Shallaki Plus treatment was well associated with a reduction in the total WOMAC scores indicate that symptom improvement may have been due to an anti-inflammatory effect of the Shallaki. The outcomes of this study shows that Vedistry Shallaki + Tablet are capable of providing significant improvement in relieving the OA symptoms like pain and stiffness.

Conclusion

Vedistry Shallaki + Tablet is an Ayurvedic formulation containing *Shallaki* or Boswellia resin and Piperine. This randomized, double blind, active controlled and mono centric clinical study evaluated the efficacy and safety of Vedistry Shallaki + Tablet administered for 90 days in subjects with mild to moderate OA and compared its efficacy with Celecoxib. Vedistry Shallaki + Tablet was significantly effective in decreasing the total WOMAC score, pain score, functional ability score, VAS score and LF index values at $P < 0.05$ level with no adverse events. All these findings suggest that Vedistry Shallaki + Tablet is a safe and effective natural formulation with a promising therapeutic utility in the treatment of osteoarthritis.

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