Original Article

An open-label, prospective, multicenter, clinical study to evaluate efficacy of Ayuartis capsules in patients suffering from osteoarthritis of the knee(s)

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Abstract

Background: The management of chronic degenerative joint disorders such as osteoarthritis (OA) with ayurvedic medicines provides a safe and effective alternative. Ayurvedic medicines possess analgesic, anti-inflammatory, anti-oxidant and immunomodulator activities. **Aims:** The main aim of the study was to assess the efficacy of Ayuartis capsule in patients suffering from OA of the knee(s). **Materials and Methods:** Thirty-one patients suffering from OA knee(s) were recruited after evaluating them as per inclusion/exclusion criteria. Patients were advised to take two Ayuartis capsules twice daily orally for 90 days. Knee joint(s) pain was assessed on the Visual Analog Scale. Patients' joint pain, stiffness, and physical functions were assessed on the Western Ontario McMaster University Osteoarthritis (WOMAC) index. Quality of life (QOL) and the time required to walk 50 feet was evaluated. Patients were called for follow-up visits on every 15th day till 90 days. Adverse events and vitals were recorded at every visit. Safety laboratory investigations were done before and after the completion of trial. **Statistical Analysis:** Data describing quantitative measures are expressed as mean ± standard deviation. The comparison of variables representing categorical data was performed using pair *t*-test. **Results:** The mean joint pain reduced significantly by 53.82% on day 90. The mean WOMAC combined score, pain score, stiffness score and difficulty score reduced significantly by 50.88%, 54.96%, 58.76% and 49.02%, respectively on day 90. A significant improvement was observed in mean QOL of patients. A significant reduction in mean time required to walk 50 feet was observed. Majority of the patients had shown good overall improvement and excellent tolerability to the trial drug. **Conclusion:** Ayuartis capsule is a safe and effective medicine for the treatment of OA of the knee(s).

Keywords: Ayuartis capsules, osteoarthritis, quality of life, Visual Analog Scale, Western Ontario McMaster University Osteoarthritis

Introduction

Osteoarthritis (OA) is a chronic degenerative joint disorder characterized by destruction of the articular cartilage, subchondral bone alterations, synovitis, joint pain and tenderness, limitation of movements, occasional effusion and variable degrees of local inflammation without systemic manifestations.[1-3] The prevalence of OA increases with age, and 80% of the cases are observed after 65 years of age.[4,5] Before the age of 50, the prevalence of OA is higher in men than women. The high prevalence rates, economic cost and adverse implications on the quality of life (QOL) and health make OA as a major public health issue.[4,5]

Several factors are responsible to cause OA. Biomechanical stresses affecting the articular cartilage and subchondral bone, biochemical changes in the articular cartilage and synovial membrane, and genetic factors are all important in pathogenesis.[6,7] The synovial inflammation appears to play a minor role in most cases of OA.[6,7] Obesity is a major risk factor for the disease affecting the knee. Poor joint alignment and trauma are other causative factors.[1-3,6,7] Since there is no known cure for OA, the goals of the management of disease are to reduce abnormal stresses imposed on affected joints, restore joint alignment, strengthen muscles

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and treat pain and muscle spasm. Pain relief with the use of nonsteroidal anti-inflammatory drugs (NSAIDs), opioid analgesics and others is the first priority in most of the patients.[8-10] Although the pharmacological and surgical means are used in the management of OA,[11,12] most of these treatment options are related to the risk of side effects such as gastrointestinal,[13-15] cardiovascular,[16-18] hepatotoxicity[19] and surgical complications. Thus, patients with severe pain are likely to try alternative and complementary therapies such as Ayurveda.[20]

Ayuartis capsule is intended to be used for the management of OA and other similar joint and muscle conditions. Ayuartis capsule is a combination of 13 herbal ingredients effective in the management of arthritis [Table 1]. Almost all the ingredients of Ayuartis capsule possess anti-inflammatory activity. Few ingredients are useful as central as well as peripheral analgesic agents. Ingredients of Ayuartis capsule also possess antioxidant activity. These multiple actions of ingredients help in reducing pain, inflammation and stiffness associated with OA knee(s) and other musculoskeletal painful conditions.[20-26]

Hence, to check the hypothesis that Ayuartis capsule is effective in OA of the knee and in consideration of patient pool, geographical locations, environmental and ethnic or cultural backgrounds i.e. as per rural and urban population, a multicentre clinical study to evaluate the efficacy of Ayuartis capsule in patients suffering from OA of the knee(s) was planned.

Materials and Methods

The study protocol and study-related documents were reviewed and approved by the Institutional Ethics Committee (IEC) at Ayurveda Research Center, Ayurved Seva Sangh, Ganeshwadi, Nashik City - 422003, India, on November 11, 2016 and by the IEC, KVTR College of Ayurveda, Boradi Village, Tal-Shirpur, Dist.-Dhule - 425428, India, on October 14, 2016. The study was conducted in accordance with approved protocol and ASU-GCP guidelines. The clinical trial is registered on Clinical Trial Registry – India (CTRI) on June 8, 2017, vide registration number CTRI/2017/06/008790.

Sample size

The sample size calculation was based on the assumption that a sample size of 30 evaluable cases would provide an 80% power to estimate the reduction of the total Western Ontario McMaster University Osteoarthritis (WOMAC) score and Visual Analog Scale (VAS) at 5% level of significance at the end of the study.

Study design and grouping

It was a non-comparative, single-arm, prospective, open-label, multicenter clinical study.

Inclusion criteria

Male and female patients in the age group between 40 and 70 years having symptoms of OA in one or both knee joints for a minimum of 6 months and maximum of 5 years and OA confirmed by radiographs and diagnosed according to the American College of Rheumatology (ACR) classification criteria were included in the study. Individuals without any knee joint deformity and having VAS pain score > 40 mm on weight-bearing activities were included in the study. Individuals who were willing to give informed consent, ready to comply with the protocol and ready to provide regular follow-ups till study completion were included in the study. Individuals who were requiring the use of NSAIDs, acetaminophen or another analgesic agent on a regular basis (≥3 days/week) for at least 6 months before the screening visit were included.

Exclusion criteria

Individuals who refused to give informed consent were excluded from the study. Individuals having a history of rheumatoid arthritis (RA), gout, pseudogout, inflammatory arthritis, Paget's disease of bone, chronic pain syndrome, fibromyalgia or another major joint disease and individuals

Table 1: Composition of Ayuartis Capsule: Each capsule contains

Ingredients	Botanical name	Parts used	Quantity (mg)
Guggul	*Commiphora mukul* Engl.	Gum resin (Extract)	50
Ashwagandha	*Withania somnifera* Dunal.	Roots and stem (Extract)	50
Shallaki	*Boswellia serrata* Roxb.	Gum resin (Extract)	35
Motha	*Cyperus rotundus* Linn.	Rhizome	35
Prasarini	*Paederia foetida* Linn.	Roots and leaves (Extract)	30
Nirgundi	*Vitex negundo* Linn.	Leaves (Extract)	30
Kutaja	*Holarrhena antidysenterica* Wall.	Stem bark	30
Chopchini	*Smilax china* Linn.	Roots	30
Punarnava	*Boerhavia diffusa* Linn.	Whole plant	25
Gokhru	*Tribulus terrestris* Linn.	Fruit	25
Ajmoda	*Apium graveolens* Linn.	Seeds	25
Bala	*Sida cordifolia* Linn.	Roots	20
Ajwain	*Trachyspermum ammi Sprague* Linn.	Seeds	20
Methi	*Trigonella foenum-graecum* Linn.	Seeds (Extract)	10

Hard gelatin capsules shell - IP. Permitted colors are used in capsule shell. IP: Indian pharmacopeia

having a history of surgery, including arthroscopy or major trauma to the knee joint in the previous 6 months before the screening visit were excluded from the study. Individuals requiring knee arthroplasty (as per an investigator's decision) within 6 months of screening or anticipating any need for a surgical procedure on the knee joint during the study were excluded. Individuals showing signs of clinically significant active inflammation of the knee joint including redness, warmth and/or a large, bulging effusion with the loss of normal contour at the screening, and/or baseline visits were excluded. Individuals who used systemic corticosteroids within the last 2 months from screening visit or intra-articular viscosupplementation within the past 3 months or any other investigational drug within 1-month prior to randomization were excluded. Individuals having a history of major medical diseases (uncontrolled diabetes, tuberculosis, human immunodeficiency virus [HIV] and ischemic heart diseases) or surgical diseases, pregnant and lactating mothers and persons having known hypersensitivity to ingredients used in study drug were excluded from the study.

Study drug

Ayuartis capsule in an Ayurvedic proprietary medicine manufactured by the sponsor of the study, i.e. Welex Laboratories Pvt. Ltd. Ayuartis capsule contains standardized extracts of 14 herbal ingredients such as *Guggulu* (*Commiphora mukul* Engl.), *Shallaki* (*Boswellia serrata* Roxb.), *Ashwagandha* (*Withania somnifera* Dunal), *Motha* (*Cyperus rotundus* Linn.), *Prasarini* (*Paederia foetida* Linn.), *Nirgundi* (*Vitex negundo* Linn.), *Kutaja* (*Holarrhena antidysenterica* Wall), *Chopachini* (*Smilax china* Linn.), *Punarnava* (*Boerhavia diffusa Linn.*), *Gokshura* (*Tribulus terrestris* Linn.), *Ajmoda* (*Apium graveolens* Linn.), *Bala* (*Sida cordifolia* Linn.), *Ajwain* (*Trachyspermum ammi Sprague* Linn.) and *Methi* (*Trigonella foenum graecum* Linn.) in specified quantity as mentioned in Table 1.

Assessment criteria

The efficacy of Ayuartis capsule in patients suffering from OA knee (s) was evaluated by assessing knee joint pain on the basis of VAS and WOMAC index, QOL on Karnofsky and Lansky performance score and mean time to walk 50 feet on even surface. Efficacy was also assessed by considering overall changes by a patient and an investigator at the end of study. The use of rescue medicines including paracetamol or any NSAIDs was noted during each visit.

Safety of Ayuartis capsules was assessed by clinical review of all safety parameters, including the laboratory investigations (blood sugar, liver function test (LFT), renal function test (RFT), lipid profile and urine examination); adverse event (AE) and severe AE (SAE) reporting; and clinical examination including vital signs such as pulse rate, respiratory rate, body temperature and blood pressure.

Study procedures

On screening visit, written informed consent was obtained from patients for their participation in the study. Patients' clinical symptoms and medical history (if any) were noted. Demographic details were recorded and general, physical and clinical examinations were done. On screening visit, patients' knee joint(s) pain was assessed on VAS. Patients were asked to walk 50 feet on flat surface and the time required to walk 50 feet and distance between feet while walking 50 feet on even surface was recorded. Patients' X-ray (anteroposterior and lateral views) of index/selected knee was done. OA of the knee was confirmed by radiographs and diagnosed according to the ACR diagnostic criteria (clinical + radiological). Laboratory investigations such as RA test, serum uric acid, fasting blood sugar, complete blood count (CBC), erythrocyte sedimentation rate (ESR), hemoglobin (Hb%), LFT (liver function test), RFT (renal function test), lipid profile, urine routine and urine microscopic, urine pregnancy test (in female patients with child-bearing potential), serum calcium, HIV test and electrocardiogram were done.

On screening visit, a washout period of 7 days was given to patients. During washout period and whole study period (viz. 90 days + 7 days), patients were advised to refrain from local analgesics, systemic steroids, Ayurvedic drugs other than study medication, Homeopathy, Unani, Siddha drugs and nutraceuticals/food supplements for the management of OA. Patients were allowed to take tablet paracetamol (up to 2 g/day) or any standard analgesic drug in case of severe joint pain. Patients were advised to continue their usual routine diet and exercise/activity regimen, which they had been following during the entire study period.

On baseline visit (day 0), a patient was recruited in the study if he/she met all the inclusion criteria. Patients' *Prakriti* (body constitution) evaluation was done. After baseline visit, patients were asked to come for subsequent follow-up visits on days 15, 30, 45, 60, 75 and 90.

On baseline visit and every follow-up visit, patients' general and physical examinations were done. Patients' clinical symptoms (if any) were noted. Knee joint(s) pain was assessed on VAS. A patient was asked to walk 50 feet on flat surface and the time required to walk 50 feet and distance between feet while walking 50 feet on even surface was recorded. Patients' joint pain score, stiffness score and physical function score were assessed on WOMAC index. The knee(s) was examined for soft-tissue swelling/synovitis (Grade: 0 = none, 1 = mild, 2 = moderate, and 3 = severe.). On baseline visit, day 30 visit, and day 90 visit, all the patients were evaluated for their QOL on Karnofsky and Lansky performance score.

On baseline visit and every follow-up visit (except last follow-up visit), all the patients were given a high-density polyethylene container containing 80 Ayuartis capsules. Patients were advised to take two capsules twice daily orally after meals with lukewarm water for the next 30 days (60 capsules for 30 days and 20 extra capsules if follow-up was delayed maximum by 5 days). On every follow-up visit, the dispensed container was collected from the patient and the capsules were counted to check drug compliance.

On baseline visit and every follow-up visit, patients were asked for any AE or SAE occurred. The details of the incidence were documented. SAE was reported to the IEC in a SAE reporting form. Rescue medications used were recorded. All the study-related details were recorded in source documents and case record form (CRF).

On the last follow-up visit (day 90), patients' global evaluation and investigator's global evaluation for overall improvement were done. Tolerability of trial medicine was assessed by investigator and by patients at the end of the study. On final follow-up visit, laboratory investigations (viz. CBC, ESR, Hb%, LFT, RFT, lipid profile, urine routine and microscopic) were performed. After completion of 90 days of study treatment, all the patients were asked to stop trial medication and take the advice of the investigator for further treatment.

Statistical analysis

All baseline and demographic data were summarized descriptively. All continuous variables were summarized using mean, standard deviation, standard error of mean and median. All categorical variables were summarized using frequency and percentages. The primary population for this study was per-protocol population. The primary efficacy endpoint was analyzed using two-proportion test. 95% confidence interval was constructed for the proportion. All other secondary outcomes were analyzed by applying appropriate statistical (proportion test and *t*-test) tests.

Results

A total of 36 patients suffering from OA of the knee joint were screened during the study period. There were three screen failures, as they did not meet the inclusion/exclusion criteria. Of 33 enrolled patients, 2 patients dropped out from the study due to lost to follow-up. Both dropouts were not related to any adverse effect of the study drug or procedure. Total 31 patients were considered as completers for efficacy evaluation parameters. All patients who took even a single dose of the study drug were considered for safety evaluation. Among 31 patients, 5 (16.13%) were male, whereas 26 (83.87%) were female. The mean age of patients in the study was 55.19 ± 6.48 years. There were 8 (25.80%) patients aged 40–50 years, 17 (54.84%) patients aged 51–60 years, and 6 (19.35%) patients aged 61–70 years.

Among 31 patients, 12 (38.71%) had *Pitta-Kapha Prakriti*, 5 (16.13%) had *Pitta-Vata Prakriti*, 4 (12.90%) had *Kapha-Pitta Prakriti*, 3 (9.68%) had *Vata-Kapha Prakriti* and *Tridoshaja Prakriti* each, 2 (6.45%) had *Vata-Pitta Prakriti* and 1 (3.23%) had *Kapha-Vata* and *Vata Prakriti* each.

On baseline visit, the mean VAS score of knee joint pain was 76.13 ± 11.45, which reduced significantly ($P = 0.000697$) to 69.68 ± 13.54 on day 15. The mean VAS score for knee joint pain reduced significantly ($P < 0.0001$) to 61.45 ± 14.21, 56.94 ± 12.16, 52.58 ± 12.64, 44.52 ± 11.50 and 35.16 ± 12.62 at the end of 30 days, 45 days, 60 days, 75 days and at the end of the study (day 90), respectively. As compared to baseline visit, there was 8.47%, 19.31%, 25.21%, 30.93%, 41.52% and 53.82% reduction in the mean VAS score of knee joint pain at the end of 15 days, 30 days, 45 days, 60 days, 75 days and 90 days, respectively. The graphical details are shown in Figure 1 and Table 2.

On baseline visit, the mean WOMAC combined score was 62.58 ± 16.23, which reduced significantly ($P < 0.0001$) to 55.26 ± 14.76, 49.52 ± 15.11, 46.39 ± 15.07, 43.35 ± 12.66, 37.55 ± 9.83 and 30.74 ± 9.92 at the end of 15 days, 30 days, 45 days, 60 days, 75 days and 90 days, respectively. As compared to baseline visit, there was 11.70%, 20.87%, 25.87%, 30.73%, 39.99% and 50.88% reduction in the mean WOMAC combined score on day 15, day 30, day 45, day 60, day 75 and day 90 respectively. The graphical details are shown in Figure 2.

On baseline visit, the mean WOMAC pain score was 12.39 ± 3.93, which reduced significantly ($P < 0.0001$) to 11.13 ± 3.27, 9.81 ± 3.08, 9.19 ± 3.04, 8.32 ± 2.48, 7.35 ± 2.21 and 5.58 ± 2.47 at the end of 15 days, 30 days, 45 days, 60 days, 75 days and at the end of the study (day 90), respectively. There was 10.17%, 20.82%, 25.83%, 32.85%, 40.68% and 54.96% change in mean WOMAC pain score on day 15, day 30, day 45, day 60, day 75 and at the end of study (day 90) respectively. The graphical details are shown in Figure 3.

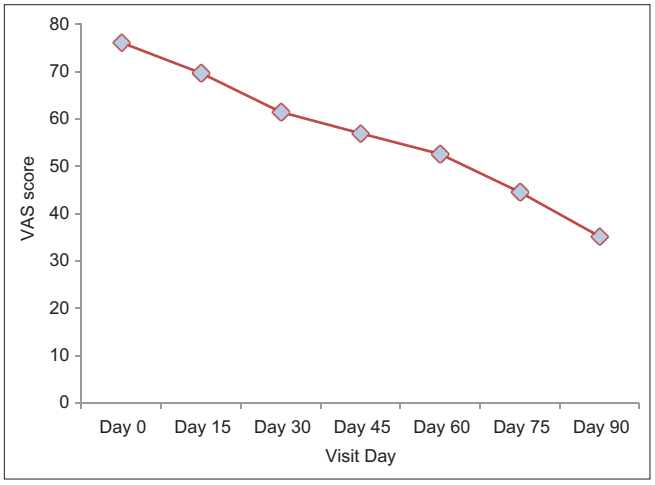

Figure 1: Effect of Ayuartis capsule on knee joint pain assessed on the Visual Analog Scale

Table 2: Effect of the study medicine on Knee Joint Pain (OA) assessed on VAS

	Baseline Visit	Day 15	Day 30	Day 45	Day 60	Day 75	Day 90
Mean±SD	76.13±11.45	69.68±13.54	61.45±14.21	56.94±12.16	52.58±12.64	44.52±11.50	35.16±12.62
P		*P*=0.000697	*P*<0.0001	*P*<0.0001	*P*<0.0001	*P*<0.0001	*P*<0.0001

On baseline visit, the mean WOMAC stiffness score was 4.39 ± 2.28 which reduced significantly ($P < 0.0001$) to 3.58 ± 2.14, 3.10 ± 1.92, 3.10 ± 1.85, 2.81 ± 1.64, 2.32 ± 1.49 and 1.81 ± 1.01 at the end of 15 days, 30 days, 45 days, 60 days, 75 days and at the end of the study (day 90) respectively. There was 18.45%, 18.45%, 29.38%, 35.99%, 47.15% and 58.76% change in the mean WOMAC stiffness score on day 15, day 30, day 45, day 60, day 75 and at the end of study (day 90), respectively. The graphical details are shown in Figure 4.

On baseline visit, the mean WOMAC difficulty score was 45.81 ± 11.09 which reduced significantly ($P < 0.0001$) to 40.55 ± 10.27, 36.61 ± 10.90, 34.10 ± 10.87, 32.23 ± 9.25, 27.87 ± 7.11 and 23.35 ± 7.19 at the end of 15 days, 30 days, 45 days, 60 days, 75 days and at the end of the study (day 90) respectively. There was 11.48%, 20.08%, 25.26%, 29.64%, 39.16% and 49.02% change in the mean WOMAC difficulty score on day 15, day 30, day 45, day 60, day 75 and at the end of study (day 90) respectively. The graphical details are shown in Figure 5.

On baseline visit, the mean QOL score of patients assessed on the Karnofsky and Lansky performance score was 59.03 ± 3.96, which improved significantly ($P = 0.000561$) to 62.90 ± 5.88 on day 30. The mean QOL score improved significantly ($P < 0.0001$) to 69.68 ± 6.57 and 78.39 ± 7.35 on day 60 and day 90 respectively. From baseline visit, there was 6.55%, 18.04% and 32.79% change in the mean QOL score at the end of 30 days, 60 days and 90 days respectively. The graphical details are shown in Figure 6.

The assessment of time required to walk 50-feet distance was done on every visit. At baseline visit, the mean time required to walk 50-feet distance was 23.10 ± 3.87 seconds which reduced significantly ($P < 0.0001$) to 21.45 ± 3.71, 20.55 ± 3.08, 20.23 ± 3.10, 19.55 ± 2.98, 18.84 ± 3.06 and 17.55 ± 2.68 seconds at the end of 15 days, 30 days, 45 days, 60 days, 75 days and at the end of the study (day 90) respectively. From baseline visit, there was 7.14%, 11.04%, 12.42%, 15.36%, 18.44% and 24.03% change in mean time required to walk 50-feet distance on day 15, day 30, day 45, day 60, day 75

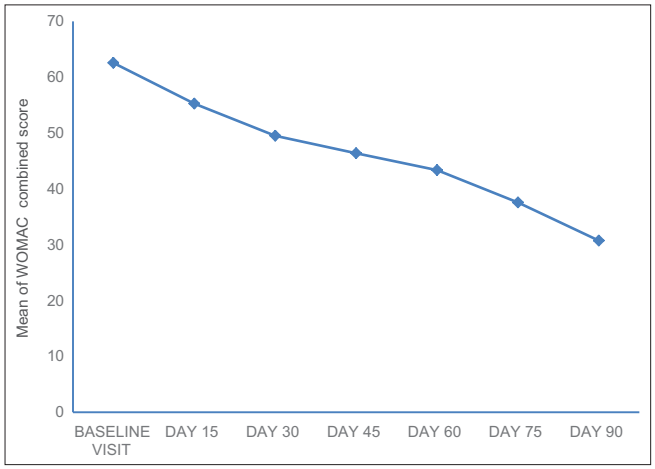

Figure 2: Effect of Ayuartis capsule on the Western Ontario McMaster University Osteoarthritis index (combined score)

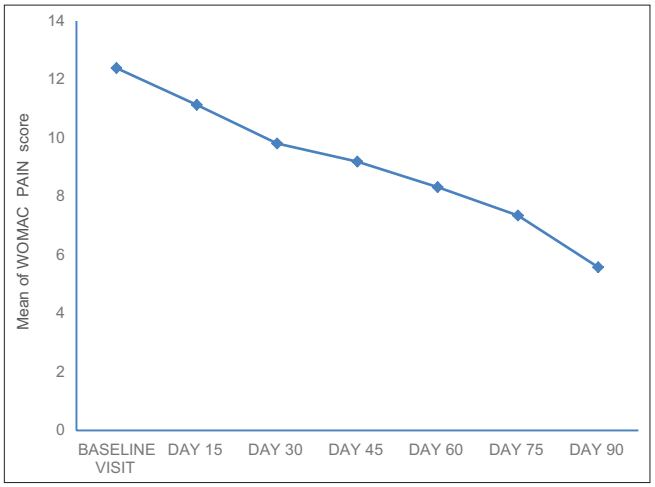

Figure 3: Effect of Ayuartis capsule on the Western Ontario McMaster University Osteoarthritis index (pain score)

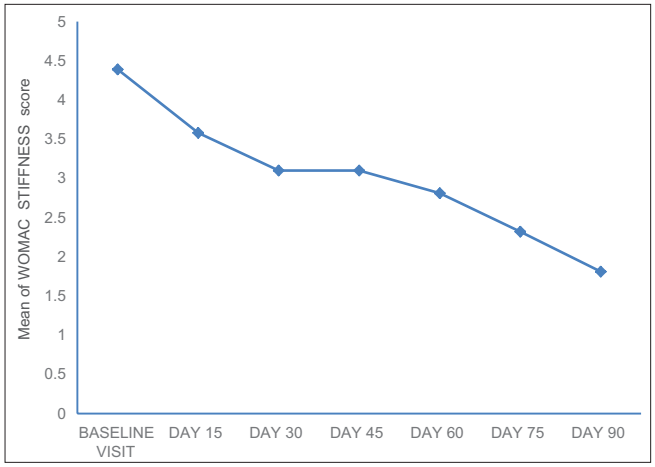

Figure 4: Effect of Ayuartis capsule on the Western Ontario McMaster University Osteoarthritis index (stiffness score)

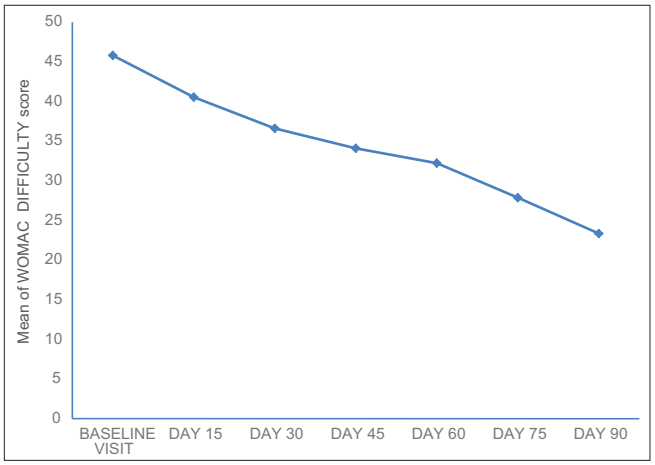

Figure 5: Effect of Ayuartis capsule on the Western Ontario McMaster University Osteoarthritis index (difficulty score)

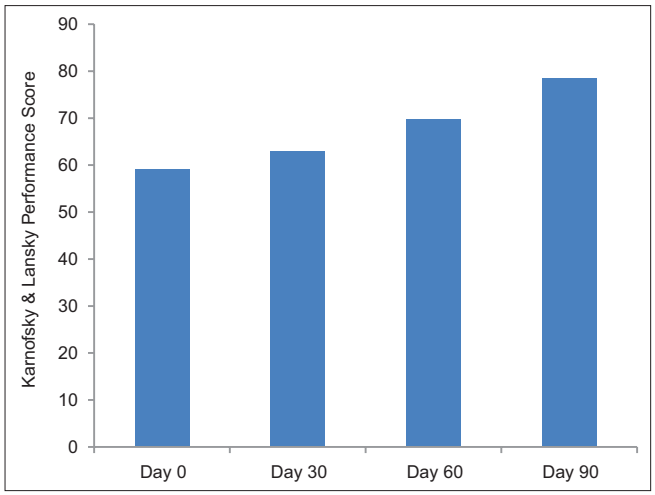

Figure 6: Assessment of quality of life on Karnofsky and Lansky performance scale

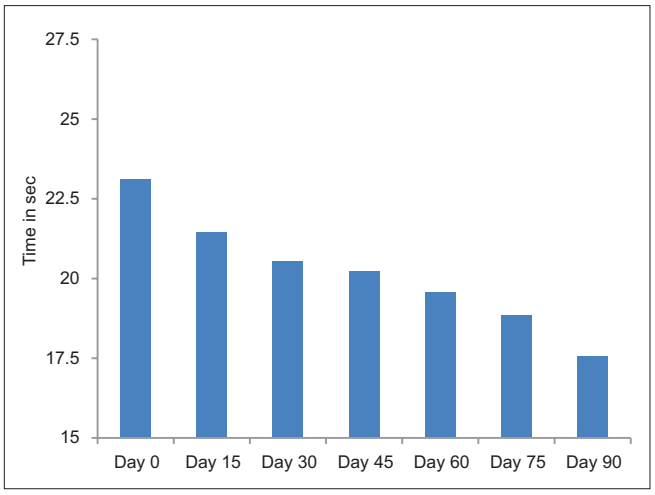

Figure 7: Assessment of time to walk 50 feet on even surface

and day 90 respectively. The graphical details are shown in Figure 7.

As per global assessment for overall improvement assessed by patients, 74.19% of patients showed minimal to much improvement, 22.58% showed very much improvement and 3.23% had no change in OA condition. As per global assessment for overall improvement assessed by the investigator, 74.19% of patients showed minimal to much improvement, 22.58% showed very much improvement and 3.23% had no change in OA condition at the end of the study.

None of the patients who completed the trial required rescue medication during the study period.

Adverse effects

Of 33 enrolled patients, 27 were reported to have AEs. There were total 51 AEs such as abdominal discomfort, fever, cough, rhinitis, pain in the abdomen, constipation, headache, body ache, dyspepsia, loose motion and hyperacidity during the trial. Among 51 AEs, 37 were unrelated, 9 were probably related, 2 were possibly related, whereas 3 were unlikely related to the study drug. Dyspepsia, hyperacidity, loose motion and burning sensation at the epigastric region were the probable AEs reported due to study product. Symptomatic treatment was given to resolve AEs and no interruption of the study drug or procedure was required to resolve these AEs.

At baseline visit and at the end of the study, the mean values of most of the laboratory parameters were within normal limits. At baseline visit, the mean serum calcium (mg/dl) was 8.03 ± 2.03, which increased significantly to 9.64 ± 1.07 ($P = 0.0266$) on day 90. The mean serum uric acid (mg/dl) was 6.64 ± 2.34 at baseline visit, which reduced significantly to 4.84 ± 1.33 ($P = 0.0018$) at the end of the study, i. e., 90 days. However, these changes were within the normal limits. No significant changes in any of the vital parameters (viz. heart rate, respiratory rate, body temperature and blood pressure) were observed during and at the end of the trial.

Discussion

The present clinical study was conducted at multicentre in consideration with patient pool and geographical locations i.e. rural and urban population to evaluate efficacy of Ayuartis capsule in patients suffering from OA of knee. Subjects were advised to take two capsules twice daily orally after meals with lukewarm water for the next 90 days. After baseline visit, subjects were called for follow-up visits on day 15, 30, 45, 60, 75 and 90 to assess primary and secondary objectives, adverse events and drug compliance. Ninety-day treatment with Ayuartis capsule significantly decreased the mean joint pain score (assessed on VAS), mean WOMAC combined score, mean WOMAC pain score, mean WOMAC stiffness score, and mean WOMAC difficulty score at the end of the study. None of the patients needed rescue medicine (NSAIDs or paracetamol) for pain management during the study period. The mean time in seconds to walk 50-feet distance among patients reduced significantly at the end of the trial. Furthermore, the QOL of patients improved significantly at the end of the study.

Most of the patients had shown very much improvement to much improvement as per the assessment of the overall improvement done by the physician and by the patient himself/herself. None of the patients reported worsening of any sign or symptom of OA knee joint during and at the end of the study. These findings suggest that Ayuartis capsule is effective in reducing joint pain and joint stiffness and improving flexibility of joints in patients suffering from OA of the knee(s). It was observed from the results of the present clinical study that the synergistic effect of the herbs present in the formulation has contributed to the overall anti-inflammatory and analgesic activities of the formulation.[20,26]

In the present clinical study, 27 patients reported to have AEs. Most of the AEs were unrelated to the study drug. Symptomatic treatment was given to resolve AEs and no interruption of the study drug or procedure was required to resolve these AEs.

In the present study, the mean values of most of the laboratory parameters were within the normal limits. Although a significant

decrease in the serum uric acid levels and a significant increase in the serum calcium levels were observed, the changed values were within the normal limits. No significant changes in any of the vital parameters (viz. heart rate, respiratory rate, body temperature and blood pressure) were observed during and at the end of the trial. Taken together, these observations demonstrate that Ayuartis capsule is effective to be used in patients with OA.

Although in the present clinical study, the sample size on which the drug has been tested was enough to show a statistically significant effect, a randomized, comparative, double-blind, multicentric clinical study with a large sample size to evaluate the efficacy and safety of "Ayuartis capsule" is indicated.

Conclusion

Three months of treatment with Ayuartis capsule showed a significant reduction in joint pain and joint stiffness in the cases of OA of the knee joint. Furthermore, a significant improvement in time to walk 50 feet distance on even surface in patients suffering from OA of the knee(s) was suggestive of significant efficacy of Ayuartis capsule. Thus, the present study concluded that Ayuartis capsule is an effective treatment option for the management of OA.

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Conflicts of interest

There are no conflicts of interest.

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