



Anti-Arthritic Effect of *Boswellia Serrata* in Arthritic Patients in a Secondary Care Hospital

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ABSTRACT

Rheumatoid arthritis (RA) is an autoimmune disease that results in a chronic, systemic inflammatory disorder that may affect many tissues and organs, but principally attacks flexible (synovial) joints. It can be a disabling and painful condition, which can lead to substantial loss of functioning and mobility if not adequately treated. Conventional medicine treats rheumatoid arthritis with steroids and other immunosuppressive medications, most of which are toxic when used long-term. Patients who are dependent on them are now likely to respond to herbal products. *Boswellia serrata* (Shallaki) is mentioned as a pain remedy in ancient Sanskrit texts dating back thousands of years. The herb is recommended in treating rheumatoid arthritis, osteoarthritis, gout, joint pain, skeletal muscle pain and back pain. B-boswellic acid, its 11-keto derivative and their acetates are the important constituents derived from the resin which are responsible for the anti-inflammatory activity of Shallaki. Shallaki improves the blood supply to the joints and restores the integrity of blood vessels destroyed by spasms. Degradation of glycosaminoglycans, which leads to articular damage and cartilage breakdown, is a common condition in patients on nonsteroidal anti-inflammatory drugs (NSAIDs). Shallaki significantly reduces the degradation of glycosaminoglycans and protects the joints. So, in this present study an attempt was made to study the anti-arthritic efficacy of the Shallaki in patients by observational study. A total 65 patients who suffered with severe rheumatic pain with joint dysfunction and clinical decline during the treatment with Shallaki capsule was examined. Rheumatoid factor (RF) and Erythrocyte sedimentation rate (ESR) were measured to evaluate the anti arthritic activity. Results of the present study revealed that the percent reduction of ESR found with Shallaki capsule is more than the combination of steroids and NSAIDs. The significant effects were observed with percent reduction of RF by Shallaki capsule then steroids and NSAIDs. The triple combination possesses quite more effects than observed with individuals. From the above data it was concluded that the Shallaki capsule possesses the ulcer protective anti-inflammatory and anti arthritic effects in patients of arthritis, whereby, it is not possible to propose a same effects by conventional steroids and NSAIDs. Shallaki capsule reduces glycosaminoglycan degradation and increases maintenance of collagen which inhibits the progress of arthritis in lower doses.

Keywords: Arthritis, *Boswellia serrata*, NSAIDs.

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INTRODUCTION

Over the past twenty years the management of RA has undergone dramatic changes, particularly in the past five years. Traditionally, RA was diagnosed late in the disease course; the symptoms were treated without addressing the underlying damaging¹. RA is an autoimmune disorder characterized by synovial proliferation and inflammation, and subsequent destruction and deformity of joints^{2,3}. The prevalence of rheumatoid arthritis worldwide is about 1-2% (2 million people) of adult population worldwide^{4,5}. Women are also three-times more likely to get RA than men. The peak incidence is between the ages of 20-40 and can lead to substantial loss of mobility due to pain and joint destruction. The disease is also systemic in that it often affects many extra-articular tissues throughout the body including the skin, blood vessels, heart, lungs, and muscles. We have tried to assess the comparative efficacy of Shallaki Capsule, steroids and NSAIDs for the treatment of RA by observational study. The questionnaires were circulated to different specialist of RA in the Tertiary care hospital in Salem District Tamilnadu and data was collected. The collected data was analyzed statistically. In general, the traditional anti-inflammatory drugs both steroidal as well as non-steroidal are mostly associated with a common list of unwanted side effects including ulceration, which are the most common and a serious problem⁶. RA has been studied extensively for a number of activities including anti-inflammatory, immunomodulatory, anti-tumor, and inflammatory bowel disease. Shallaki (*Boswellia serrata*) is mentioned as a pain remedy in ancient Sanskrit texts dating back thousands of years. The herb is recommended in treating rheumatoid arthritis, osteoarthritis, gout, joint pain, skeletal muscle pain and back pain. Extracts of *Boswellia serrata* have been clinically studied for osteoarthritis and joint function, particularly for osteoarthritis of the knee, with the research showing a slight improvement of both pain and function compared to a placebo. Positive effects of *Boswellia* in some chronic inflammatory diseases including rheumatoid arthritis, bronchial asthma, osteoarthritis, ulcerative colitis and Crohn's disease have been reported⁷. Various studies have been conducted on *Boswellia serrata* extract for its human efficacy, comparative, pharmacokinetic studies⁸⁻¹⁰. In view of its multi facet therapeutic potential as well as non-toxic nature, we envisaged to evaluate the anti-arthritis potential clinically by observation of patients.

MATERIALS AND METHOD

The study was conducted as observational study in the patients of the tertiary care hospital in Salem District who are taking the steroids, NSAIDs and Shallaki capsule for the treatment of

RA. The comparisons of this different group for anti arthritic effect were done. The written consent was taken from each patient. A total of 80 patients were selected for the study and the demographic data including in-patient number, name, age, sex, address, date of admission, date of discharge and complete medical history was recorded. The drug details which includes name of the drug, dosage, duration of therapy, route of drug administration, previous medication history were recorded. The patients were divided into 4 groups each consist of 20 patients. The first group served as control and the second group treated with Shallaki capsule 125 mg twice a day and third group treated with Prednisolone 10 mg BD and Aceclofenac 100 mg BD and the fourth group treated with Shallaki, prednisolone and aceclofenac.

Inclusion criteria

Patients of either sex having age group between 20-70 years and weight between 50-90 kgs with Rheumatoid and/or osteoarthritis were included for the study.

Exclusion criteria

Patient having age above 70 years, pregnant or lactating women or patient with renal or hepatic failure was excluded from the study. The patients, who were simultaneously participated in other trials, were also excluded from the study.

Estimation of Biochemical Parameters

The biochemical data RA factor and ESR of patient were collected and noted in CRF at initiation of treatment, after 1 month, after 3 month and after 6 month of the treatment. The other biographical parameters were monitored and noted in CRF during the whole period of treatment.

RA Factor¹¹

Rheumatoid arthritis is an autoimmune disorder, where auto antibodies are produced against self-antigen (IgG). These autoantibodies are termed as Rheumatoid factors (RF), which are immunoglobulins of predominantly IgM class, which combines with Fc portion of Immunoglobulin IgG molecules. RF is present in sera of 80 % cases of Rheumatoid Arthritis. RA test antigen consists of polystyrene latex particles coated with specially modified preparation of human gammaglobulin (IgG) in order to avoid non-specific agglutination. The suspension of coated latex particles agglutinate visible when mixed with serum containing Rheumatoid factor.

Blood sampling and Serum separation

Un-haemolysed sample of blood was collected. The blood was allowed to clot at room temperature 37°C and centrifuged at 5000 rpm for 10 minutes at 4° C to separate the serum and subjected to biochemical estimation. In rheumatoid arthritis, diagnostically useful auto antibodies termed as “Rheumatoid factor” (RF) can be detected which are immunoglobulins of the class

IgG, IgA, IgM and IgE. Particularly, IgM class RF with specificity to human IgG (Fc) is the most useful prognostic marker of RA. The clinical significance of RF determination consists in differentiation between rheumatoid arthritis, in which RF of modified IgM class have been demonstrated in the serum. Agglutination test is most frequently used because of its greater sensitivity and simplicity.

Reagent

Rhelax RF reagent:

A uniform suspension of polystyrene latex particles coated with suitable modified Fc fraction of IgG. The reagent is standardized to detect ≈ 10 IU/ml of RF or more.

Positive control: Reactive with the Rhelax RF reagent.

Negative control: Non - reactive with the Rhelax RF reagent.

Semi-quantitative method

The serial dilutions of the serum sample positive were prepared in 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 and so on by using isotonic solutions. Each dilution was pipetted out onto separate reaction circles. One drop of Rhelax latex reagent was added to each drop of diluted serum sample on the slide. The sample and the latex reagent was mixed uniformly over the entire circle and the agglutination was observed. Agglutination in the highest serum dilution corresponds to the approximate amount of rheumatoid factor in IU/ml present in the test specimen.

Erythrocyte Sedimentation Rate: (Westergren method)¹²

A sample of blood from each group was obtained and mixed with 3.8% sodium citrate in proportion of four parts blood to one part of citrate solution. The mixing of blood was done by rotating the samples gently between the palms of hands. The blood was sucked slowly up to the mark zero in the Westergren's tube. The tube was set up right in the Westergren stand, taking care that no blood escapes. The tube was fixed with the help of screws cap. At the end of one hour the upper level of red cell column was read which would indicate mm of clear plasma. From the height of sedimentation in mm at the end of two hour ESR was calculated.

Statistical analysis

Data was expressed as mean \pm standard error of the mean. The results were analyzed by two tailed t test. The comparisons of each group were done by statistical analysis and % reductions of diseases were calculated using software Graph Pad Prism.

RESULTS AND DISCUSSION

In our present study we had selected 60 patients from the ward of orthopaedics in the period of six months from November 2014 to April 2015. They were divided into 3 groups each consist of 20. They are classified in according to their gender and age. The data shows that 38 (63.33%) patients were males, and 22 (36.67%) patients were females. The age groups were divided into 10year breakups. The average age of the arthritic patients in the hospital was found to be 56.5 ± 11.70 Yrs. Anti arthritic activity by reduction of RF is shown in Figure 1 and the reduction in erythrocyte sedimentation rate was presented in Figure 2. The data shows that the shallki treated group shows significant reduction of RF after 3 months and ESR after 1 month compare to disease control. The combination of steroid and NSAIDs shows significant reduction of RF and ESR after 1 month. The combination of steroid, NSAIDs and Shallaki has marked Anti arthritic effects after initiation of treatment. The Shallaki treated patient shows less significant reoccurrences of symptoms of RA as compare to steroid and NSAIDs treated male. The Shallaki treated patients do not posses significant alteration in the weight during the treatment duration. The comparisons of each group with the different treatment have done by considering the % reduction of RF and ESR. The potential reduction and recovery found after the completion of treatment is observed and analyzed. In male patient the % reduction of RF is found in increasing order of Shallaki alone, steroid and NSAIDs, and Shallaki, steroid and NSAIDs respectively. Steroid and NSAIDs combination do not shows marked reduction of ESR while it is found maximum in the three drug combinations. Present study demonstrates the anti-arthritic activity of Shallaki Capsule in male arthritic patients. The significant reduction of ESR and RF by Shallaki Capsule better than the combination of steroids and NSAIDs without marked side effects was observed in the study which confirms the anti arthritic effects.

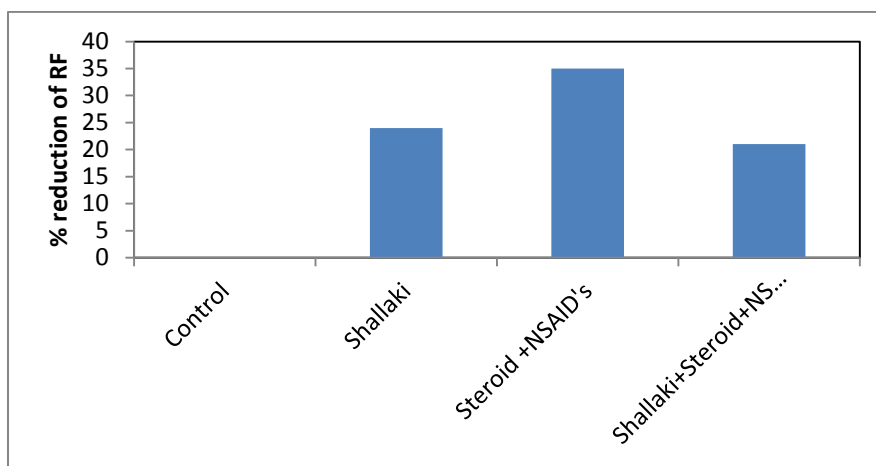


Figure 1: The % reduction of Rheumatoid Factor

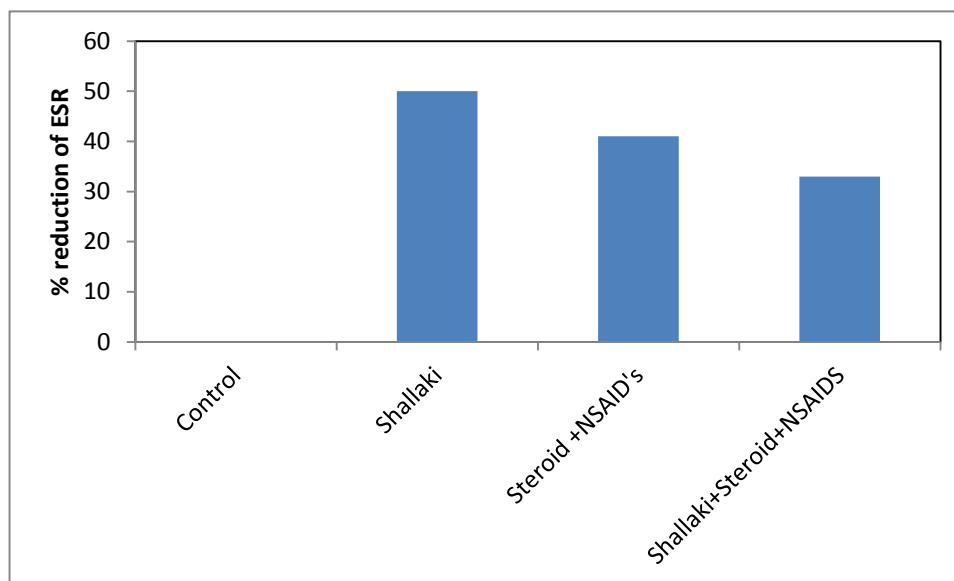


Figure 2: The % reduction of Erythrocyte Sedimentation Rate

CONCLUSION

The study result suggests that the use of steroid and analgesic is less preferable than Shallaki capsule. Steroid poses the adverse effects if used when the level of estrogen is fall in the post menopausal stage. The Shallaki recovers the RF and ESR near to normal which is prompt to be higher in diseases conditions. Shallaki capsule acts through lipo-oxygenase pathway, so the gastric discomfort was not observed which is most frequently found with painkillers. Shallaki capsule reduces glycosaminoglycan degradation and increases maintenance of collagen which inhibits the progress of arthritis in lower doses than conventional drugs.

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