

Emerging Clinical Output of Vanpain Capsule in Post Menopausal Female Arthritic Patients.

*¹Nailesh G. Patel and ²Madhabhai M. Patel.

¹Jodhpur National University, Jodhpur, Rajsthan-342003, India, ²Kalol Institute Of Pharmacy and Research Center, Kalol, Gujarat-382721, India.

Abstract

India is covered with the natural origin of majority of the medicinal plants. The different plants were used for various ailments including inflammation, diabetes etc. The Vanpain capsule is the formulation containing boswellic acid, l-epicatechin and diosgenin. To investigate the clinical output of the Vanpain capsule, the present study was carried out on post menopausal female arthritic patients. The study was also interpreting the different treatment potential for the arthritis in post menopausal female patients. The investigation was carried out by measurement of comparative efficacy of steroids, NSAIDs and Vanpain followers' arthritics. The determination of changes and alterations in haematological and biochemical parameters in both developing and developed phases of arthritis was measured. In post menopausal female arthritic patients, there was significant increase in ESR and RF. The patients showed brought back to near normal by the Vanpain with steroids and NSAIDs treatment. The activity of steroid worsens the situation and not shown significant reduction of RF and ESR. The progressions of diseases symptoms were critical with steroids. The Vanpain posses the significant reduction of RF and ESR when compared to the arthritic control group. In conclusion, the administration of steroid, NSAIDs and Vanpain showed significant reduction in disease progression and it could significantly normalize the haematological and biochemical abnormalities in arthritis. The Vanpain capsule found to be capable to control the symptomatic relief of arthritis in post menopausal female patients rather than steroid alone without significant adverse events.

Key Words

Rhumatoid Arthritis, ESR, RF, Menopause, Vanpain.

Introduction

The diverse culture of our country is a rich source of traditional medicines, many of which are of the plant origin. Scientific data on such plant derivative could be of clinical use¹. The available anti-inflammatory drugs (steroidal and non-steroidal) present a wide range of side effects. Therefore, many studies are being directed to find anti-inflammatory agents from natural sources. Fenugreek (*Trigonella foenum-graecum*; Fabaceae) is a plant whose seeds and leaves are used in traditional medicine. Fenugreek is known to have several pharmacological effects such as: hypoglycemic², hypocholesterolemic³, antioxidant⁴ gastroprotective activity⁵, and appetite stimulation. The acacia catechus have antipyretic, hypoglycemic, hepatoprotective, anti ulcer and digestive properties⁶. Testing reveals boswellic acids, isolated from the gum resin of *Boswellia*, in a dose-dependent manner block the synthesis of proinflammatory products,

including 5-hydroxyeicosatetraenoic acid (5-HETE) and leukotriene B₄ (LTB₄) which cause bronchoconstriction, chemotaxis, and increased vascular permeability^{7,8}. The combination of those three herbs shows activity against rheumatoid arthritis⁹. Nonsteroidal anti-inflammatory drugs (NSAIDs) can cause a disruption of glycosaminoglycan synthesis, accelerating articular damage in arthritic conditions^{10,11,12,13}. An *in vivo* animal study examined *Boswellia* extract and ketoprofen for effects on glycosaminoglycan metabolism. *Boswellia* significantly reduced the degradation of glycosaminoglycans compared to controls; whereas, ketoprofen caused a decrease in total tissue glycosaminoglycan content¹⁴. The steroids are widely used for the management of rheumatoid arthritis which is one of the auto immune, inflammatory disorders. The formulation Vanpain contains acacia catechu 50 mg, foeniculum graceum 100 mg and boswellia serrata 100 mg.

*Corresponding Author:

ptlnailesh@yahoo.co.in

Objectives of work were;

1. To investigate the potential treatment ongoing for arthritis in post menopause condition in female patients.
2. To observe the clinical output of herbal formulation Vanpain Capsule against arthritis alone and with co-administrated conventional drugs.

Sr. no.	Group	No. of Patients
1	Control	10
2	Vanpain Treated	10
3	Steroid + NSAIDs Treated	10
4	Steroid + NSAIDs + Vanpain Treated	10

Materials and Methods

The study was conducted as observational study in the different district places of North Gujarat. The details in the form of CRF were collected by consulting the patients directly from the hospitals who are taking the steroids, NSAIDs and Vanpain Capsule for the treatment of RA. The study was conducted in accordance with the consideration of post menopause symptoms in female patients. The biochemical comparisons of the different groups were done for clinical output measurements. The translation of ICF in Gujarati and ethical review were done and approved by c-max clinical services, Ahmedabad. The written consent was taken from each patient. The patients who were already on current use of Vanpain capsule, NSAIDs and Steroid were approached for data collection.

Inclusion criteria

- Post menopausal females
- Suggestive of arthritis since last one year
- Age between 18-70 years
- Weight between 50-90 kgs.

Exclusion criteria

- Menstruated female
- Pregnant female
- Age more than 70 years
- Lactating female
- Patients with renal and hepatic failure
- Hypersensitive females with herbs
- Participated in other trials

Study design

The post menopausal female patients fall under the inclusion criteria were enrolled in the study. The assessment of biochemical parameters were done in four major groups as follows,

The doses of drugs were as follows,

Vanpain: 500 mg (2 capsules) 4 times a day for first 5 days then 1 capsule 3 times a day.

Prednisolone: 10 mg BD

Acceclofenac: 100 mg BD

Estimation of Biochemical Parameters

The vital signs, pulse rate and respiratory rate were observed at the time of clinical visits. The estimated values of ESR and RF at initial, after 1 month, after 3 month and after 6 month of the treatment were noted in CRF as assessment parameter; the other biographical parameters were monitored and noted in CRF during the whole period of treatment.

RA Factor¹⁴:

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

Erythrocyte Sedimentation Rate: (Westergren method)

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 obtained from the post menopausal female patients were expressed as mean \pm standard error of the mean. The results were analyzed by two tailed t test. The comparisons of each group fall under the different treatment were done by statistical analysis and % reductions of symptoms and conditions of diseases were calculated using software Graph Pad Prism.

Result and Discussion

The Vanpain affects on the post menopausal female more than the male and pre menopausal female. It shows time dependent significant reduction of RF and ESR values. It also recovers the high value of RF and ESR nearer to the normal healthy person. Steroid and NSAIDs treated patients have marked reduction of RF and ESR but the reduction is lesser significant than the combination of all the tree drugs. The fast recovery in post menopausal female is very difficult in RA than the others category of patients, even though the significant effect is observed in combinations of herb and conventional drugs. Present study demonstrates the anti-arthritic activity of Vanpain Capsule in post menopausal female arthritic patients. The significant reduction of ESR and RF by Vanpain Capsule nearer and identical to the combination of steroids and NSAIDs without marked side effects. The patients drop out were not observed with herbal formulation which was always

with steroids and other anti inflammatory drugs. The patient overview also suggests the symptomatic relief in the treatment with these combinations.

Conclusion

The study result suggests that the use of steroid is controversial and analgesic is less preferable for subsiding the pain. The hormonal imbalance in post menopausal female patients may be controlled by Vanpain; it recovers the RF and ESR near to normal which is prompt to be higher in diseases conditions. Vanpain Capsule acts through lipo-oxygenase pathway, so the gastric discomfort was not observed which is most frequently found with painkillers. Vanpain Capsule reduces glycosaminoglycan degradation and increases maintenance of collagen which inhibits the progress of arthritis in lower doses than conventional drugs. It also shows symptomatic relief from the post menopausal conditions of females.

Acknowledgement

The authors would like to thanks to my well wishers for providing the technical supports and guide Dr. M.M. Patel for instant support during the work. Also he would like to thanks the team of YDIK nature care product pvt. Ltd., Ahmedabad.

References

1. Gupta S S. Prospects and Perspectives of natural plants products in medicines. Indian J Pharmacol.1994,26,1-12.
2. Sharma R D, Raghuram T C and Rao N S. Effects of fenugreek seeds on blood glucose and serum lipid in type I diabetes. Eur J clin nutr, 1990, 44,301-306.
3. Ajabnoor M A and Tilmisany A K. Effect of Trigonella foenum-graecum on blood glucose levels in normal and alloxan-diabetic mice. J Ethnopharmacol, 1998, 22, 45-49.
4. El-Sokkary A M and Ghoneim M A. Effect of plants antioxidants in retarding the oxidative deterioration of Samna [Ghee]. Indian J Dairy Sci, 1951, 4, 123-128.
5. Bouaziz A. Veterinary drugs. French Demande, 1976, 20, 4-8.
6. Singh K N, Mittal R K and Barthwall K C. hypoglycemic activity of acacia catechu, acacia summa, albizzia odoratisimma seed diet in normal albino rats. Indian J Med Res, 1976, 64, 754.

7. Ammon H P, Mack T, Singh G B and Safayhi H. Inhibition of leukotriene B4 formation in rat peritoneal neutrophils by an ethanolic extract of the gum resin exudate of *Boswellia serrata*. *Planta Med*,1991,57,203-207.
8. Robertson R P. Arachidonic acid metabolites relevant to medicine. In: Braunwald E, Isselbacher K J, Petersdorf R G, et al, eds. *Harrison's Principles of Internal Medicine*. 11th ed. New York, NY. McGraw-Hill; 1987:375.
9. Vyas A, Patel N, Panchal A, Patel R, Patel M. Anti-arthritic and vascular protective effects of Fenugreek, *boswellia serrata* and acacia catechu Alone and in combinations. *Pharma science monitor*.2010; 1(2):95-111.
10. Lee K H and Spencer M R. Studies on mechanism of action of salicylates. V. Effect of salicylic acid on enzymes involved in mucopolysaccharides synthesis. *J Pharm Sci*, 1969, 58, 464-468.
11. Palmoski M J and Brandt K D. Effect of salicylate on proteoglycan metabolism in normal canine articular cartilage in vitro. *Arthritis Rheum*, 1979, 22,746-754.
12. Dekel S, Falconer J and Francis M J. The effect of anti-inflammatory drugs on glycosaminoglycan sulphation in pig cartilage. *Prostaglandins Med*, 1980,4,133-140.
13. Brandt K D and Palmoski M J. Effects of salicylates and other nonsteroidal anti-inflammatory drugs on articular cartilage. *Am J Med*, 1984, 77,65-69.
14. Reddy G K, Chandrakasan G and Dhar S C. Studies on the metabolism of glycosaminoglycans under the influence of new herbal anti-inflammatory agents. *Biochem Pharmacol*, 1989,38,3527-3534.
15. Lothar F, Thomas S, Samartzis D, Jenis L and An H. Rheumatoid arthritis: evaluation and surgical management. *The Spine Journal*, 1998, 4, 689-700.

Comparison of Disease Vs. Vanpain treated

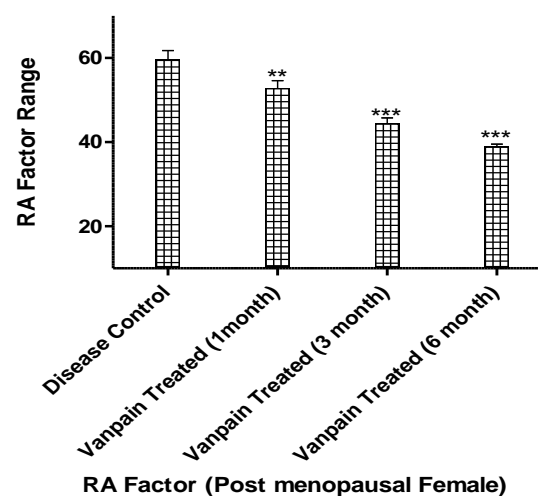


Figure 1: Data represents the effect of Vanpain on RF of post menopausal female arthritic patient. Mean ± S.E.M. n = 15. One-way ANOVA followed by t-test. ** p<0.01, *** p<0.001.

Comparison of Disease Vs. Steroid + NSAIDs treated

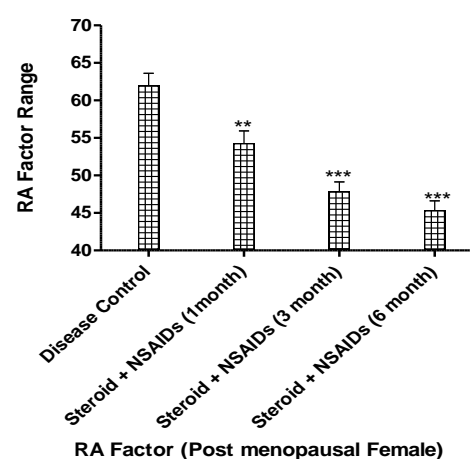


Figure 2: Data represents the effect of Steroid + NSAIDs combination on RF of post menopausal female arthritic patient. Mean ± S.E.M. n = 15. One-way ANOVA followed by t-test. ** p<0.01, *** p<0.001.

Comparison of Disease Vs. Steroid + NSAIDs + Vanpain treated

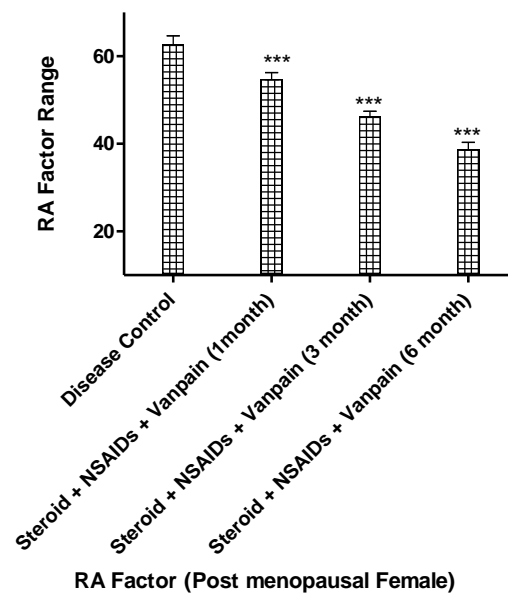


Figure 3: Data represents the effect of Steroid + NSAIDs + Vanpain combination RF of post menopausal female arthritic patient. Mean ± S.E.M. n = 15. One-way ANOVA followed by t-test. ** p≤0.01, *** p≤0.001.

Comparison between different group (Post menopausal Female)

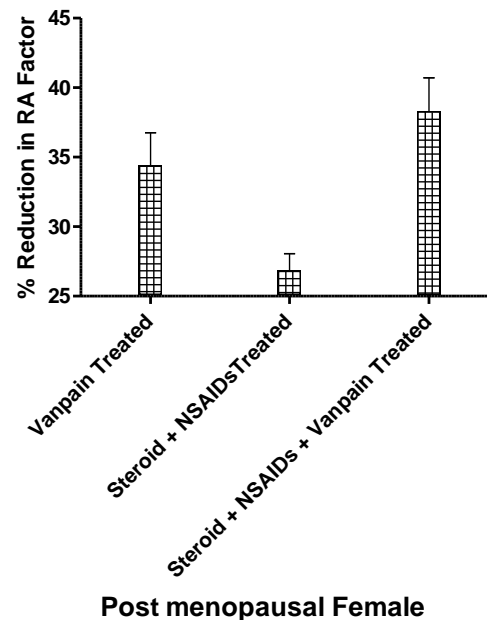


Figure 4: Data represents the comparisons between different groups of post menopausal female arthritic patient. Mean ± S.E.M. n = 15. One-way ANOVA followed by t-test.

Comparison of Disease Vs. Vanpain treated

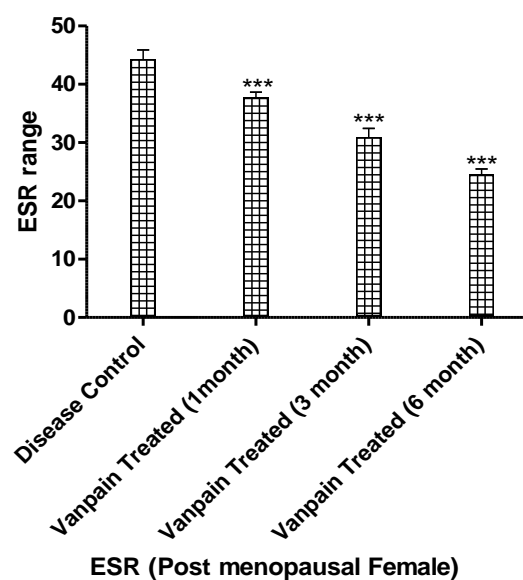


Figure 5: Data represents the effect of Vanpain on ESR of post menopausal female arthritic patient. Mean ± S.E.M. n = 15. One-way ANOVA followed by t-test. *** p≤0.001.

Comparison of Disease Vs. Steroid + NSAIDs treated

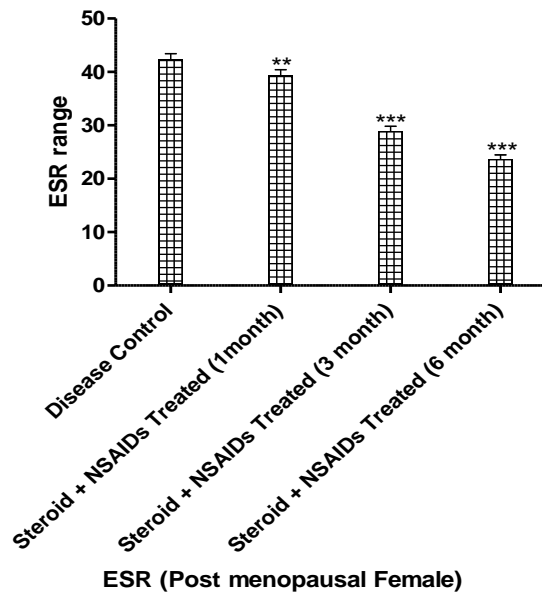


Figure 6: Data represents the effect of Steroid + NSAIDs combination on ESR of post menopausal female arthritic patient. Mean ± S.E.M. n = 15. One-way ANOVA followed by t-test. ** p≤0.01, *** p≤0.001.

Comparison of Disease Vs. Steroid + NSAIDs+Vanpain treated

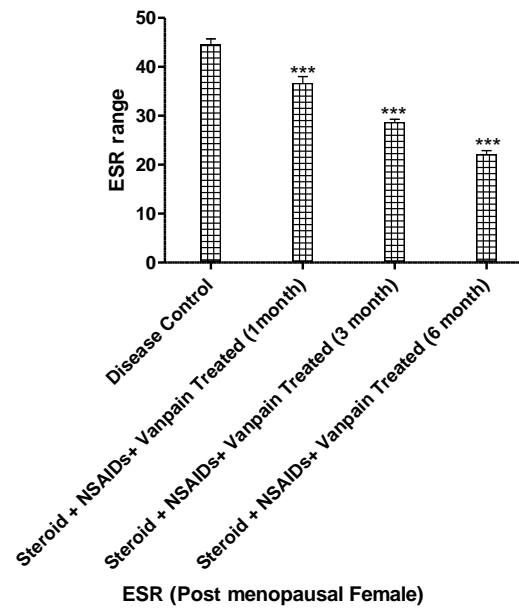


Figure 7: Data represents the effect of Steroid + NSAIDs + Vanpain combination on ESR of post menopausal female arthritic patient. Mean ± S.E.M. n = 15. One-way ANOVA followed by t-test. *** p≤0.001.

Comparison between different group

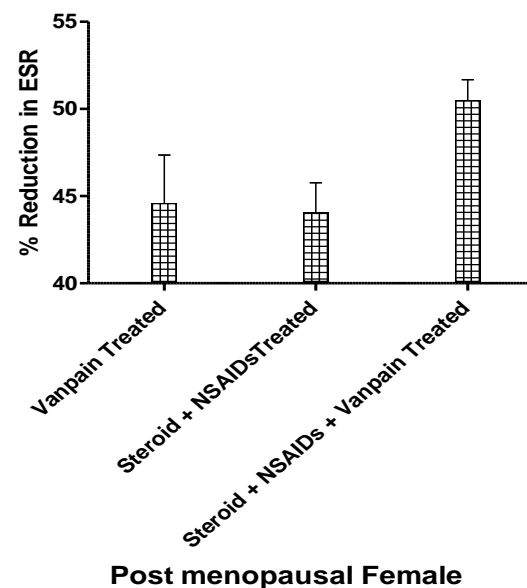


Figure 8: Data represents the comparisons between different groups of post menopausal female arthritic patient..Mean ± S.E.M. n = 15. One-way ANOVA followed by t-test.
