A Study of Efficacy and Tolerability of Rosehip Extract (Gopo) vs. Ibuprofen (a nsaid) in Treatment of Osteoarthritis in Weight Bearing Joints

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Abstract

Introduction: Osteoarthritis is the most common form of arthritis. Osteoarthritis is a joint failure, which occurs due to pathological change in all structure joint. Aim: The aim of the study was to compare the efficacy and tolerability of Rosehip Extract and ibuprofen along with individual effect of both drugs. Material and Methods: This was an open, randomized, prospective study to compare ROSE HIP Extract and IBUPROFEN for treatment of Osteoarthritis in 100 patients. In this study two comparative groups (50 each) were taken. First group was prescribed 400 mg TDS Ibuprofen and the other group was given Rose hip extract in the form of 275 mg capsule BD. The pain assessment was done through Womac scale and visual analogue scale. The data was collected for efficacy and tolerability for both drugs at 14 days and 3 months. Result: In ibuprofen group, the mean score of pain intensity on womac scale on visit 1 was 39.2 ± 9.58 which was decreased to 11.62 ± 4.97 in the last visit. On VAS scale on visit 1 was 7.26 ± 1.426 and was decreased to 3.36 ± 1.467 at visit 3. In rosehip group. The mean score of pain intensity on WOMAC scale on visit 1 was 38.44 ± 8.45, 30.88 ± 8.068 which was decreased to 26.68 ± 8.474. The mean score of pain intensity on VAS scale on visit 1 was 7.02 ± 1.06, 5.84 ± 1 and was decreased to 4.6 ± 1.16 at the end of study. Conclusion: Ibuprofen is a better choice than rosehip because it had shown better improvement. Both rosehip and ibuprofen were well tolerated.

Keywords: Ibuprofen, Osteoarthritis, Rose hip, Womac Scale, GOPO

1. Introduction

Osteoarthritis (OA) is a chronic debilitating disease of joints. It is a joint failure, which occurs due to pathological change in all structures i.e., bone, cartilage and synovium.[1] Prevalence of knee OA was found to be 28.7% in India.[2] It commonly affects hip, knee, cervical and lumbar joints, first metatarsal phalangeal joint, base of thumb. The wrist, elbow, and ankle are usually spared. The cause include age, sex, heredity, obesity, previous knee injury etc.[1,4]

Current treatment of OA is based primarily on the use of NSAIDs (non-steroidal anti-inflammatory drugs) and other analgesics. It has been noted that drugs like Ibuprofen, celecoxib, Acetofenac are widely used for reducing symptoms.[7] Rose hip Extract is derived from seeds and shells of the fruits of Rosa canina. The main active ingredient is called GOPO (galactolipid (2S)-1,2-di-O-[(9Z,12Z,15Z)-octadeca-9,12,15-trienoyl]-3-O-β-D-galactopyranosyl glycerol).[8] It inhibits chemotaxis and chemiluminescence of peripheral blood leucocytes without any toxicity to the normal cells. [9] In contrast to NSAIDs and aspirin, rosehip do not have ulcerogenic effects, interfere with the coagulation cascade or fibrinolysis and do not inhibit platelets.[10] In the present study we compared a commonly used drug ibuprofen with Rosehip Extract for efficacy and safety in patients with osteoarthritis in weight bearing joints along with monitoring their side effects.

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2. Materials and Methods

A total number of 100 patients of Osteoarthritis from Orthopedic department of Rajindra Hospital and Government Medical College Patiala were included in this study. The study protocol was approved by institutional ethics committee. Patients of either sex in the age group of 40-60 years with confirmed diagnosis of Osteoarthritis i.e., duration of disease more than 3 months were selected. A detailed history and physical examination was done. All the patient fulfilling the inclusion and exclusion criteria were enrolled in the study.

2.1 Inclusion Criteria
1. Age between 40-60 years
2. Both sex are eligible
3. Patients with confirmed diagnosis of OA

2.2 Exclusion Criteria
1. Major surgery of joints
2. Previous hypersensitivity to NSAIDs
3. History of renal, hepatic, cardiovascular disease or recent GIT disease
4. Blood dyscariasis, significant anemia, recent hemorrhage

After the informed consent, they were randomized and then divided into two groups of 50 each 1st group was given Tablet Ibuprofen 400 mg TDS and the 2nd group was prescribed Rosehip extract 275 mg BD in the form of capsule available in the market. The symptoms, adverse effects were monitored at 14th day and at the end of 3 months using Womac and Vas scale for each patient. The results of observations of individual patients were pooled and analyzed. Data was statistically analyzed using t test. The results were eventually tabulated and graphically represented.

3. Results

Out of one hundred subjects enrolled in the present study, 67 (67%) were female and 33 (33%) were male. In group A there were 15 (30%) males and 25 (70%) females. In group B there were 18 (36%) males and 32(64%) females. The study showed a female preponderance in patients of hypertension (Graph 1).

Graph 1. Distribution of Patients According to Gender.

The baseline pain score with Womac scale (western Ontario and McMaster Universities Osteoarthritis) and VAS (visual analogue scale) of both groups did not have any statistically significant difference.

In ibuprofen group (Table 1), the mean score of pain intensity at on womac scale on visit 1 was 39.2 ± 9.58, 20.96 ± 8.07 at visit 2 (P-value <.001) which was highly significant. It was further decreased to 11.62 ± 4.97 at visit 3 (P-value <.001) which was again highly significant. The mean score of pain intensity at on VAS scale on visit 1 was 7.26 ± 1.426, 5.1 ± 1.313 at visit 2 (P-value = .002) which was significant and further decreased to 3.36 ± 1.467 at visit 3 with P-value <.001 i.e., highly significant.

In rosehip group (Table 1), the mean score of pain intensity at on WOMAC scale on visit 1 was 38.44 ± 8.45, 30.88 ± 8.068 at visit 2 which was significant and further decreased to 26.68 ± 8.474 at visit 3 which was significant. The mean score of pain intensity at on VAS scale on visit 1 was 7.02 ± 1.06, 5.84 ± 1.13 at visit 2 with P-value = .01 showing Graph 2. Comparison of Vas score Reduction in Group A and B.
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Table 1. Intergroup comparison score of womac scale

| VISIT       | DRUG     | Mean  | SD    | P Value (T-Test) | results |
|-------------|----------|-------|-------|------------------|---------|
| VISIT 1 (DAY 0) | ROSEHIP  | 38.44 | 8.45  | >.05             | NS      |
|             | IBUPROFEN| 39.2  | 9.58  |                  |         |
| VISIT 2 (DAY 14) | ROSEHIP  | 30.88 | 8.068 | 0.01             | S       |
|             | Ibuprofen| 20.96 | 8.07  |                  |         |
| VISIT (3 MONTH) | ROSEHIP  | 26.68 | 8.474 | 0.002            | S       |
|             | Ibuprofen| 11.62 | 4.97  |                  |         |

Table 2. Intergroup comparison score of vas scale

| VISIT       | DRUG     | Mean  | SD    | P Value (T-Test) | results |
|-------------|----------|-------|-------|------------------|---------|
| VISIT 1 (DAY 0) | ROSEHIP  | 7.02  | 1.06  | >.05             | NS      |
|             | IBUPROFEN| 7.26  | 1.426 |                  |         |
| VISIT 2 (DAY 14) | ROSEHIP  | 5.84  | 1.13  | 0.01             | S       |
|             | Ibuprofen| 5.1   | 1.313 |                  |         |
| VISIT (3 MONTH) | ROSEHIP  | 4.6   | 1.16  | 0.002            | S       |
|             | Ibuprofen| 3.36  | 1.467 |                  |         |

In womac scale readings for both groups (Table 2), at visit 1 there was no significant difference in the base line pain score (p value > .05). At visit 2 there was statistically significant difference in the pain score change between the two group (p value = .195). At visit 3 the difference in the change pain score was highly significant in between both groups (p value = 0.0024) (Graph 3).

In vas scale for both groups, at visit 1 there was no significant their difference in the base line pain score (p value > .05) At visit 2 there was statistically significant difference in

Tolerability of Ibuprofen

| Adverse effect | No. of Patient |
|----------------|----------------|
| Abdominal pain | 5              |
| Constipation   | 2              |
| Diarrhea       | 3              |
| Dyspepsia      | 18             |
| Epigastric pain| 10             |
| Flatulence     | 1              |
| Heart burn     | 12             |
| Indigestion    | 10             |
| Nausea         | 5              |
| Vomiting       | 1              |

Tolerability of Rosehip

| Adverse effects | No. of Patient |
|-----------------|----------------|
| Increased voiding| 1              |
| diarrhea        | 5              |
| nausea          | 6              |
| Constipation    | 4              |
| Acid regurgitation| 1             |
| heartburn       | 4              |
| Flushing and redness | 1            |
4. Discussion

Our study showed female preponderance of the disease. This result of the present study was consistent to a meta-analysis conducted by Srikanth et al., in 2005 in which results demonstrated the presence of sex differences in OA prevalence and incidence, with females generally at a higher risk.[11]

Considering the efficacy, the number of patients showing improvement in different parameters was significant in both the groups taking ibuprofen and rosehip. The degree of pain score improvement was more in group treated with ibuprofen.

The improvement in Functional status of both the drugs was observed by calculating their respective mean scores at visit 1, 2 and 3 in different parameters like pain score (VAS), for pain intensity were found to be significant in both the groups .Baumgartner et al in 1996 conducted a metacentric investigator blind parallel group study and compared the efficacy and tolerability of Ibuprofen and Diclofenac Sodium for 21 days. They observed that there was 80% improvement in overall assessment in the Ibuprofen group (p = 0.002).[12] Other studies have also shown that pain was significantly reduced in patient taking ibuprofen.[13,14]

Warlhom in 2003 conducted a double blind randomized clinical trial between rosehip and placebo in 100 patients. It was concluded that rosehip showed alleviation of pain in patients of OA. It was also noticed that rosehip also improves the hip flexion. Other studies also supported a moderate decrease in pain intensity with roasehip treatment. [15, 16]

However, in a study conducted by Winther et al., showed no improvement after 15 days of treatment which was inconsistent with this study results[17].

The efficacy of Ibuprofen and rosehip was compared by difference in patients improved by visit and the mean change i.e., improvement in mean score. The improvement of pain scores in patients improved by visit 3 was more in ibuprofen treated group.

It was analyzed that the pain score on VAS and WOMAC was decreased significantly in Ibuprofen group as compared to rosehip group. No patient in either group had any serious systemic side effects warranting discontinuation of therapy because of exclusion of patients having contraindication to study drugs and thus both the drugs have favorable systemic tolerance and safety profile. Treatment related adverse events were mostly mild in both groups and the drugs were well tolerated.

5. Conclusion

It was also concluded that ibupfen is superior to rosehip as it produced improvement in different parameters to more extent. Both Ibupfen and rosehip were effective in controlling pain in osteoarthritis with each drug showing significant changes in different parameters. Both the drugs were well tolerated and systemically safe. Both rosehip and Ibupfen are useful drugs in the treatment of osteoarthritis, but ibuprofen is a better choice than rosehip because of its action that it had shown better improvement. Rosehip has better safety profile than Ibuprofen. Rosehip extract can be used as an additional supplement for reducing Nsaids use in OA patients. However, further studies are required involving larger number of patients for effect in disease progression with rosehip as is hypothesized by many authors.

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