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> File: ■ Rose Hip (*Rosa canina*) ■ Rheumatoid Arthritis ■ Concurrent Medication

> > HC 110695-397

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RE: Rose Hip Powder Improves Rheumatoid Arthritis Disability Scores

Willich SN, Rossnagel K, Roll S, et al. Rose hip herbal remedy in patients with rheumatoid arthritis - a randomised controlled trial. *Phytomed.* 2010 Feb;17(2):87-93.

Clinical studies have examined the efficacy of rose (*Rosa canina*) hip powder in the treatment of osteoarthritis, but only a single exploratory study has assessed rose hip powder and rheumatoid arthritis (RA). ¹ This randomized, double-blind, clinical trial evaluates rose hip powder (i-flex®/LitoZin®; HybenVital ApS; Langeland, Denmark) in the treatment of RA symptoms.

Patients over the age of 18 who met the American Rheumatism Association criteria for RA were randomized using computer-generated blocks of 4 to receive either placebo or rose hip powder capsules. The patients were recruited between April 2005 and August 2006 from outpatient clinics in Berlin, Germany and Denmark. The patients took 5 g of rose hip powder per day in 2 divided doses for 6 months. The placebo had a similar taste, appearance, and smell to the rose hip capsules.

The Health Assessment Questionnaire disability index (HAQDI) was the primary outcome measure. The HAQDI is comprised of 8 subscales encompassing dressing, arising, eating, walking, reaching, gripping, hygiene, and ability to perform common activities. The degree of disability is rated on a scale of 0-3, with a higher score showing a greater degree of disability. In addition, the HAQDI uses Visual Analogue Scales (VASs) to assess the patients' pain and a global scale on a range of 0 to 100. The researchers also used the disease activity score (DAS-28) to assess swollen and tender joint counts, erythrocyte sedimentation rate (ESR) as an inflammatory marker, and the patient's self-assessment of disease activity on a scale of 0-10, with higher scores reflecting greater disease activity. The physicians evaluated disease activity on a VAS of 0-100. The researchers measured health-related quality of life (QOL) using the Short Form (SF-12) and the RA QOL questionnaires. The SF-12 has physical and mental components, with higher scores reflecting better health-related QOL. The RA QOL has 30 questions, with lower scores reflecting better outcomes. The patients continued to take their regular medications, and medication use was recorded in patient diaries and the physicians' case report forms.

At baseline, 89 patients were enrolled in the study, including 44 in the rose hip group and 45 in the placebo group. By the end of the study, 15 patients had withdrawn from the study, leaving 33 patients in the rose hip group and 41 in the placebo group. In the rose hip group, reasons for withdrawal included personal reasons (n=3), relocation (n=1), vomiting (n=1), vasculitis allergica (skin eruptions) (n=1), difficulty swallowing capsules (n=3), diarrhea (n=1), and nausea (n=1). In the placebo group, the withdrawal reasons were difficulty swallowing capsules (n=1), personal reasons (n=1), stomach problems (n=1), and ineffective treatment (n=1). The drop-outs were included in the intention to treat (ITT) analysis.

The HAQDI scores improved in the rose hip group and were significantly better than the placebo group scores at 3 and 6 months of treatment (P=0.014 and P=0.032, respectively). There were no significant differences between the groups in the HAQ patient pain and global scales. The rose hip group experienced a greater improvement in DAS-28 scores compared to the placebo group with a trend towards statistical significance (P=0.056) at 6 months. The physician's global assessments indicated a greater improvement in the rose hip group compared to the placebo group at 6 months (P=0.012). At 6 months, the SF-12 physical and RA QOL scores were also significantly better in the rose hip group compared to the placebo group (P=0.013 and P=0.043, respectively). There was not a significant difference in the SF-12 mental component scores. ESR values declined significantly in the rose hip group compared to the placebo group in both the ITT analysis and the per protocol analysis that included patients enrolled for at least 3 months (P=0.060 and P=0.045, respectively). No changes in medications were noted for either group. There were 14 adverse side effect reports in the rose hip group and 28 reports in the placebo group. In the rose hip group, 1 patient experienced a serious adverse event (vasculitis allergica), where the authors write, "it was not clear whether this event was related to the study medication as the patient was also taking a number of other medications." The authors also note the same rose hip powder has not been linked to any other serious adverse events in previous studies in osteoarthritis patients.

The authors conclude, "this study suggests some benefit of patients with RA treated with the present rose hip powder." Due to the small size of the study, the authors comment that these results should be viewed with caution. Additional studies with larger samples of patients are needed to confirm these results and provide adequate power for multivariate analysis. The authors write that dose-finding studies and research on different rose hip formulations are also needed.

-Marissa Oppel-Sutter, MS

References

1.Henson S. Review reveals therapeutic indications for rose hip. *HerbClip*. Feb 27, 2009 (No. 090384-371). Austin, TX: American Botanical Council. Review of A systematic review on the *Rosa canina* effect and efficacy profiles by Chrubasik C, Roufogalis BD, Müller-Ladner U, Chrubasik S. *Phytother Res.* 2008;22: 725-733.

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