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HerbClip™

FILE: ▪ Rose hip (*Rosa canina*)
▪LitoZin® / Hyben Vital®
▪Osteoarthritis

HC 100551-291

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RE: Patented Powder from Danish Rose Hip Subspecies Reduces Pain in Osteoarthritis of Knees and Hips

Winther K, Apel K, Thamsborg G. A powder made from seeds and shells of a rose-hip subspecies (*Rosa canina*) reduces symptoms of knee and hip osteoarthritis: a randomized, double-blind, placebo-controlled clinical trial. *Scand J Rheumatol*. 2005; 34:302-308.

Osteoarthritis (OA) is an inflammatory disease of the joints. Most treatments are directed against symptom control rather than against the disease itself. The typical conventional drug treatments include nonsteroidal anti-inflammatory drugs (NSAIDs, e.g., aspirin [acetylsalicylic acid]), glucocorticoids, cyclooxygenase-2 (COX-2) inhibitors, and paracetamol (acetaminophen); in some European countries, synthetic opioids (e.g., tramadol and codeine) are also widely used. These conventional pharmaceuticals can cause serious adverse side effects, as has been evidenced by recent high-profile media stories about Vioxx® and related COX-2 inhibiting pharmaceutical drugs. Scientists are searching for new compounds that can minimize pain and stiffness caused by OA and do not have serious adverse side effects.

In a previous Danish study the authors of this trial reported that a standardized dry powder from the seeds and shells of a subtype of rose-hip (*Rosa canina* subspp. Lito) reduces the migration of polymorphonucleated leucocytes.[1] These leucocytes participate in the inflammation and tissue damaged associated with OA. The authors also discovered that the study participants had less pain and stiffness during treatment. In a previous Norwegian study, end-stage patients who were scheduled for a hip or knee replacement experienced a reduction of the limitations of OA-caused flexion (freedom of movement) by about 40 percent (%), plus a reduction of pain and use of NSAIDs as a rescue medication.[2] Thus, the purpose of the present study was to fully evaluate whether the standardized rose-hip powder could alleviate symptoms and improve function of patients with OA.

Patients (38 to 92 years old) with diagnosed, symptomatic OA of the knee or hip participated in this randomized, double-blind, placebo-controlled, crossover trial. Patients (n = 94) were recruited from outpatient clinics of the Department of Rheumatology of Copenhagen University Hospital Glostrup and the Institute for Clinical Research (Vejle and Copenhagen, Denmark). Any patients who took the increasingly popular dietary supplements glucosamine sulfate and/or chondroitin sulfate or the intra-articular drugs hyaluronate or glucocorticoids during 6-weeks prior to the study were excluded.

After a 14-day run-in period patients were randomly allocated to receive placebo or a patented, standardized rose-hip powder at a total daily dose of 5 grams for 3 months. (The rose-hip powder is called LitoZin®, a.k.a. Hyben Vital®, and is manufactured and marketed by Hyben-Vital International, Langeland, Denmark.) Unlike the usual design employed in most cross-over trials, there was no wash-out period in this trial. Patients were directly crossed-over to the other treatment for 3-months. After the first 2-weeks of treatment, patients were advised to reduce their intake of analgesics other than NSAIDs, if possible. Consumption of daily analgesics was recorded in a diary. Additionally, patients were not allowed to start any new type of pain-relieving medications during the study. Symptoms of OA were assessed with a validated WOMAC (Western Ontario and McMaster Osteoarthritis Index) questionnaire.

After 3-weeks of treatment, patients taking the rose-hips had a significant reduction in joint pain ($P < 0.001$). In contrast, the patients taking placebo had no reduction. Those who responded to LitoZin treatment reported that the pain was first reduced after 2-3 weeks of treatment. Also, there was a carry-over effect — pain relief lasted for several weeks after treatment was stopped. More LitoZin-treated patients responded to treatment, although after 3-months of treatment the percentage of responders in both groups was not significantly different. Significantly more LitoZin-treated patients reduced their use of rescue medication (analgesics) ($P < 0.05$). In fact, paracetamol consumption was reduced by 40% and synthetic opioid use was significantly reduced. This reduced consumption of rescue medication by the LitoZin-treated patients may explain why the pain score after 3 months of LitoZin treatment was reduced but was not statistically different from the pain score of placebo-treated patients. Compared to placebo, 3 months of treatment with LitoZin significantly reduced stiffness, improved limitation of physical function, and improved patients' global assessment of disease severity ($P < 0.04$). The use of LitoZin was predictably quite safe; patients taking the special rose-hips powder reported similar side effects to those taking placebo.

It is interesting to note that after 3 weeks of treatment 82% of the LitoZin-treated patients reported less pain compared with 49% of the placebo-treated patients. However, the patients did not report a significant reduction in their global assessment of OA symptom severity, their limitation of physical activities, and their joint stiffness. It is generally acknowledged that pain must cease before other OA parameters can improve to a measurable level. Therefore, it is probable that pain (and possibly the side effects caused by consumption of rescue medication) had to decline before the other parameters showed significant improvement. Since the reduction in pain reported at week 3 was a

prerequisite to other improvements, it was not entirely surprising that the other parameters improved later (after 3 months of treatment).

The authors conclude that LitoZin has a beneficial effect on symptoms of knee and hip OA. They believe that the significant effect on pain was evident before 3-weeks of treatment but not after because after 3-weeks many patients reduced their use of rescue medications. It is encouraging that LitoZin had an influence on the consumption of rescue medications. The authors speculate that it is possible that a higher dose of LitoZin may have been more effective. They point out that the effect of this rose-hip preparation is species subtype specific and that LitoZin may be working through an anti-inflammatory action.

The authors did not discuss the possibility of a synergistic action between LitoZin and the conventional pharmaceutical rescue medications. Future studies might examine whether LitoZin potentiates the action of the rescue medications. The results of a recent clinical trial on LitoZin for patients with OA, published in the journal *Phytomedicine*[3], are consistent with the results of this trial (see HerbClip # 020452-283).

—Heather S. Oliff, PhD and Mark Blumenthal

References

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3. Rein E, Kharazmi A, Winther K. A herbal remedy, Hyben Vital (stand. powder of a subspecies of Rosa canina fruits); reduces pain and improves general wellbeing in patients with osteoarthritis -- a double-blind, placebo-controlled randomised trial . *Phytomed*. 2004;11:383-391.