Effect of Synofit Premium in Patients with refractory Low Back Pain

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Abstract

Purpose The effect of Synofit Premium (liquid Green-lipped mussel, Bio-Curcumin and Blackcurrant leaf) has previously been studied in human subjects with low back pain, knee osteoarthritis and fibromyalgia. The aim of the current study is to further investigate the effect of Synofit Premium as nutritional supplement in a larger number of subjects with refractory low back pain.

Methods During 2016, 156 patients with low back pain were treated with Synofit Premium for 3 months. At the follow-up after 6 weeks and 3 months, Pain VAS, the Dallas Questionnaire, adherence to therapy, satisfaction, efficacy, reduction in NSAID and analgesic use, and side effects were recorded.

Results 85 subjects met the inclusion criteria. Using Synofit Premium resulted in a significant improvement of Pain VAS within the first 6 weeks ($p = 0.0006$). This improvement lasted for 3 months. Three Dallas Questionnaire symptoms, concerning daily life, were significantly improved within 6 weeks and lasted for 3 months. Adherence to therapy was 'fair' to 'good', satisfaction was 'little' to 'average', efficacy was 'moderate' to 'good', and except for transient diarrhea in 2/85 and difficulty with capsule swallowing in 3/85 subjects, there were no adverse events reported. Finally, the need for pain-relief drugs was significantly reduced at 6 weeks ($p = 0.0024$) and lasted for 3 months.

Conclusion In this study, supplementation with Synofit Premium showed significant improvement in subjects with low back pain.

Aim of the study

To investigate the effect of supplementation with Synofit Premium in human subjects with refractory low back pain.

Materials & Methods

Study description
The study is a retrospective observational study. Each participant received 2-3 Synofit Premium Capsules per day during 3 months.

Study methods
Subjects completed questionnaires after 6 weeks and 3 months of supplementation. The Pain VAS, Dallas Questionnaire, adherence to therapy, satisfaction, efficacy, and reduction in analgesic use were recorded before Synofit use and at follow-up. Also, side effects of supplementation were recorded.

Study participants
Medical records of 156 subjects were reviewed at the Rheumatology department of the Erasme hospital in Brussels, Belgium.
Inclusion criteria: low back pain for more than 3 months with medical imaging showing osteoarthritis, and unresponsive to current therapy.
Exclusion criteria: sensitivity for ingredients of Synofit Premium.

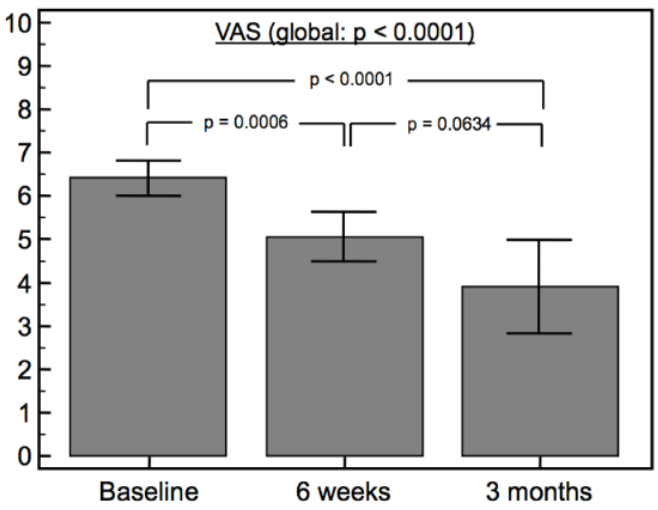
Statistical analysis
The scaled variables (from 0 to 10 or from 0 to 3) were compared using non-parametric tests because their distribution was non-Gaussian, except for age, which was expressed as mean ± standard deviation. The binary variables were compared using the Chi^2 test. $P < 0.05$ was considered significant.

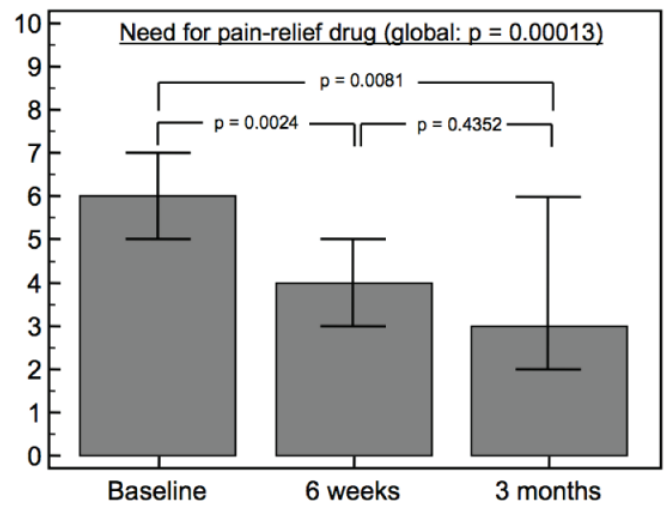
Results

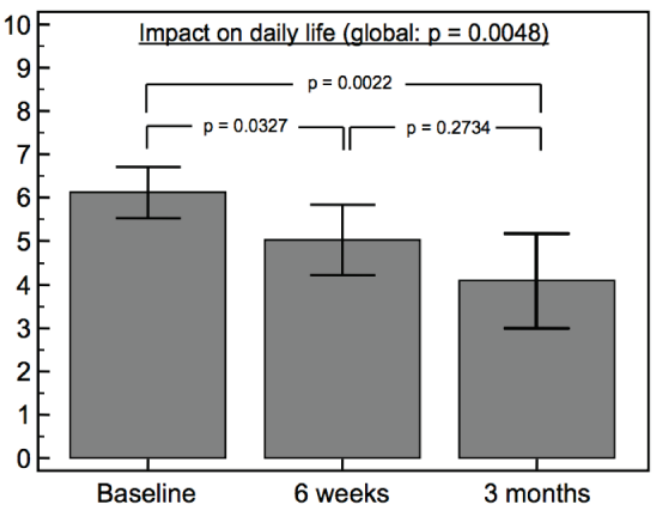
Patient characteristics
85 subjects met the inclusion criteria, with a mean age of 69 ± 3 years. There were 24 men and 61 women. 61 records were evaluable at 6 weeks and 17 at 3 months. The median duration of low back pain was 54 months (IQR: 12 to 120 months).

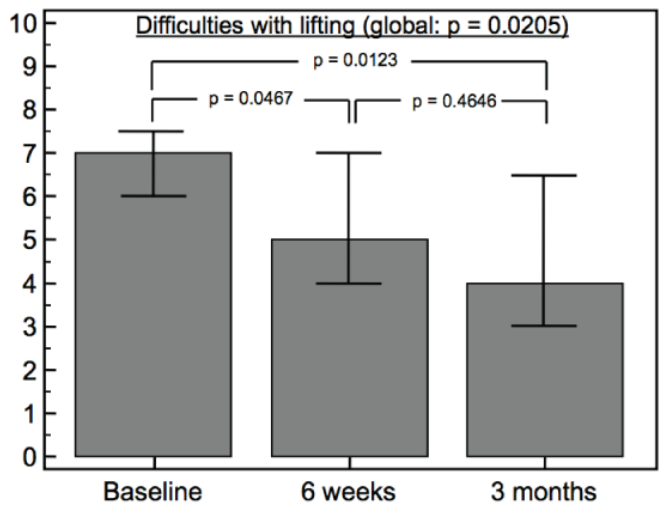
Side effects
There were no serious adverse events observed during this study.
Reported side effects were: slight transient diarrhea (2x), difficulty with capsule swallowing (3x).

Clinical evaluation
Adherence to therapy reached 2.5 (between 'fair' and 'good') at 6 weeks and remained at 2.7 after 3 months. Satisfaction was between 1 ('little') and 2 ('average') at 6 weeks and had improved somewhat more at 3 months. The efficacy was reported to be between 1 ('moderate') and 2 ('good') at 6 weeks and had improved somewhat more at 3 months.









Conclusions & Discussion

In this retrospective study, supplementation with Synofit Premium in subjects with chronic low back pain resulted in a significant improvement of Pain VAS ($p < 0.0001$), need for analgesics ($p = 0.0081$), impact on daily life ($p = 0.0022$) and difficulties with lifting ($p = 0.0123$) within 3 months. At 6 weeks, this improvement was significant already. Therefore, Synofit Premium has shown again to be a valuable alternative for subjects with refractory low back pain.