

EFFECTIVENESS OF A COLLAGEN HYDROLYSATE-BASED NUTRITIONAL SUPPLEMENT ON THE LEVEL OF JOINT PAIN, RANGE OF MOTION AND MUSCLE FUNCTION IN INDIVIDUALS WITH MILD OSTEOARTHRITIS OF THE KNEE: A RANDOMIZED CLINICAL TRIAL

Carpenter MR, McCarthy S, Kline G, Angelopoulos TJ, Rippe JM.
Rippe Health Assessment, Celebration Hospital, Orlando, FL USA
E-mail: tangelop@rippelifestyle.com

INTRODUCTION

Insoluble collagen makes up a majority of articular cartilage, and it has been theorized that new treatments should focus on improving the health of this existing joint collagen. Since collagen hydrolysate contains an abundance of the amino acids that play a role in the synthesis of collagen, which is one of the two major protein components of cartilage matrix, it may help maintain joint health. For this reason, collagen hydrolysate, a natural component of gelatine, has been suggested as a mode of treatment with minimal side effects. Therefore the purpose of this study was to evaluate the effectiveness of a collagen hydrolysate-based nutritional supplement on the level of joint pain, range of motion, and muscle function in individuals with mild arthritis of the knee.

METHODS

Study population. 250 patients with symptoms of mild OA of the knee based on criteria from the American College of Rheumatology (ACR) were randomized into the study, 126 into the collagen hydrolysate-supplemented (CH) therapy group and 124 into the placebo therapy group. Of the 250 patients 190 patients completed the study; 88 patients in the (CH) group and 102 patients in the placebo group. These 190 patients build the intention-to-treat (ITT) population for which the statistical analysis was

carried out. The rate of drop outs in the CH group is about 30%

RESULTS AND DISCUSSION

The comparisons of pain and mobility with the two questionnaires of the Knee Pain Scale, WOMAC score section B, Lequesne-Index, 50-Foot Walk Test and 6-Minute Walk Test show no differences between the therapy groups. Changes in the range of motion were evaluated with a goniometer. No significant changes were observed between groups. Muscle function was assessed with numerous measures of isokinetic leg strength, measured on a Biodex 2000 (Biodex, NY; test-retest reliability has been studied). Significant between group differences are depicted in Table 1. While these data show that CH supplementation does not impact subjective measures of pain more than placebo over a 14-week rehabilitation program, significantly greater improvements are seen in various more objective measures of joint function. Therefore further studies investigating the benefits of CH or other nutritional supplements during joint rehabilitation may have to also evaluate more objective measures of joint and muscle function in addition to evaluation of joint pain, mobility and range of motion.

ACKNOWLEDGEMENTS

This work was supported by Gelita Health Initiative, Inc.

Table 1. Isokinetic Leg Strength (mean ± SD)

| Variable | Baseline | Week 14 | Diff. basel.- week14 | p* |
|---|--------------------|-------------------|-------------------------|--------|
| Peak Torque/BW for Extension at 60°/sec | | | | |
| CH Group | 46±16.2 (n=85) | 48±15.9 (n=81) | -1.8±7.0 (n=81) | 0.0229 |
| Placebo Group | 48±14.5(n=101) | 47±14.1 (n=92) | 0.9±6.1 (n=92) | |
| Peak Torque/BW for Flexion at 60°/sec | | | | |
| CH Group | 25±9.8 (n=85) | 26±9.9 (n=81) | -1.2±5.2 (n=81) | 0.0266 |
| Placebo Group | 25±8.3 (n=101) | 25±7.4 (n=92) | 0.3±4.6 (n=92) | |
| Work/BW for Extension at 60°/sec | | | | |
| CH Group | 56±21.0 (n=85) | 59±20.9 (n=81) | -3.0±8.0 (n=81) | 0.0288 |
| Placebo Group | 58±19.0(n=101) | 58±18.6 (n=91) | 0.5±9.0 (n=91) | |
| Power for Extension at 60°/sec | | | | |
| CH Group | 74±35.6 (n=85) | 79±36.6 (n=81) | -4.7±15.7 (n=81) | 0.0162 |
| Placebo Group | 75±31.5 (n=101) | 77±31.8 (n=91) | -0.4±11.9 (n=91) | |
| Power for Flexion at 180°/sec | | | | |
| CH Group | 61±32.3 (n=86) | 69±35.8 (n=82) | -7.6±17.1 (n=82) | 0.0341 |
| Placebo Group | 64±32.3 (n=101) | 67±30.4 (n=92) | -2.8±13.9 (n=92) | |

*Mann-Whitney-U-Test ($\alpha=0.05$, two-sided) for difference between the therapy group