Collagenase clostridium histolyticum (Xiapex®) versus percutaneous needle fasciotomy for Dupuytren’s contracture in proximal interphalangeal joints. An independent, open-label, randomized controlled trial

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Background: Collagenase clostridium histolyticum injection (CI), a new minimal invasive procedure for Dupuytren's contracture (DC), emerged in 2009-2011 with promising results. Head-to-head comparison with other active treatments has not been performed as of today. We hypothesized that CI would show better long-term results.

Purpose / Aim of Study: To compare percutaneous needle fasciotomy (PNF) to CI with Xiapex®.

Materials and Methods: The study was performed as a single-center, independent, open-label, Randomized Controlled Trial. 50 patients with isolated proximal interphalangeal (PIP) joint DC (≥20 degrees) were enrolled. Patients received either CI according to the manufacturer guideline or our center standardized PNF treatment. Patients were followed for 2 years. Primary outcome was clinical improvement, defined as a reduction in contracture by 50% or more relative to baseline. Several secondary outcomes were evaluated, including change in PIP-joint passive extension deficit (PED), patient satisfaction and Disability of Arm, Shoulder and Hand questionnaire score.

Findings / Results: Clinical improvement was achieved in 8% in the CI-group and 32% in the PNF-group at 2 year follow-up (p=0.05). Secondary clinical outcome parameters and DASH-scores did not differ significantly. Patient satisfaction at 2 years was poorer in the CI group with a median numerical rating scale score (0 worst, 10 best) of 1 vs. 7 in the PNF group (p=0.04). A higher complication rate was found in the CI group.

Conclusions: We conclude that CI offers no advantages over PNF in isolated PIP-joint DC. This is the first head-to-head comparison and the first independent RCT of CI to another active treatment procedure. Confirmation from other independent studies are needed.

No conflicts of interest reported