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Three-year recurrence of Dupuytren's contracture after needle fasciotomy and collagenase injection: a two-centre randomized controlled trial

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Abstract

Collagenase injection and needle fasciotomy have similar short-term outcomes in the treatment of Dupuytren's contracture. The purpose of this study was to compare the recurrence rate of these two procedures 3 years after index treatment of primary disease. We enrolled 93 patients (96 rays) from a previous two-centre randomized controlled trial. The rays that had been retreated or showed an increase in the total passive extension deficit of 30° or more compared with 3 months after treatment were regarded as recurrences. Seventeen of 40 needle fasciectomies and 12 of 36 of collagenase injections had recurred. This difference was not statistically significant. We conclude that collagenase injection and needle fasciotomy have similar 3-year recurrence rates in the treatment of Dupuytren's contracture.

Level of evidence: I

Keywords

Dupuytren's disease, needle fasciotomy, collagenase injection, randomized controlled trial, recurrence rate

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Introduction

Collagenase injection and needle fasciotomy have similar short term and one-year outcomes in the treatment of Dupuytren's contracture with predominantly metacarpophalangeal (MCP) joint contractures according to recent randomized controlled studies (Scherman et al., 2016; Stromberg et al., 2016). Collagenase injections are more expensive and cause more short-term side effects than needle fasciectomies, which conversely entail a small risk of digital nerve injury. In this study, we compared the recurrence rates at 3-years of a previous randomized controlled trial comparing needle fasciectomies with collagenase injections.

Methods

Patients and procedures

The Regional Ethical Review Board in Umeå approved the study in November 2012. Between December 2012 and November 2013, patients with primary Dupuytren's disease with palpable cords were offered participation in the study. The inclusion criteria were patients with primary Dupuytren's disease, excluding the thumb, with a palpable cord, a total passive extension deficit (TPED) between 30° and 135°, and a passive extension deficit less than 60° in the proximal interphalangeal (PIP) joint. Written informed consent was obtained from all patients. The most affected ray in the hand was randomized to either needle fasciotomy or collagenase injection. The details of the treatments and of the evaluations at 3 months and 1-year have been published previously (Scherman et al., 2016). Collagenase injections were performed as described in the Collagenase

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Option for the Reduction of Dupuytren (CORD) studies (Hurst et al., 2009) except with simultaneous treatment of MCP and PIP joints when needed. Patients returned after 24 to 72 hours (median 48 hours) for an ulnar, with or without a median, nerve block at the wrist followed by manipulation of the injected digit. There was no requirement to continue treatment until a specific contracture correction and no repeat injections were performed.

Needle fasciectomies were performed in an outpatient treatment room. After sterile preparation and minimal subdermal injection of local anaesthesia, the contracture was released under simultaneous passive extension of MCP and PIP joints using 19 gauge needles through 1 to 4 (mean 1.8) portals along the cord. No tourniquet or regional anaesthesia was used. All authors are senior consultants in hand surgery. At one centre, the second author performed all treatments with the level of expertise being 'specialist – experienced' for both treatments. At the other centre, the first author performed all the needle fasciectomies with the level 'specialist – experienced' and the third author performed all the collagenase injections with the level 'specialist – highly experienced'(Tang, 2009; Tang and Giddins, 2016).

Follow-up

Patients were asked to return 3 years after treatment, and those patients who declined were asked if they had been retreated elsewhere. In the patients who returned, the passive extension deficits were measured in each joint of the treated rays. MCP joints were measured first, and the PIP joints were subsequently measured without changing the angle of the MCP joint in order to avoid underestimating the TPED caused by dynamic defects. At one centre the Quick Disability of the Arm, Shoulder, and Hand (DASH) and Unité Rhumatologique des Affections de la Main (URAM) scores were obtained. Patients who had been retreated prior to the 3-year time point had had the same measurements performed prior to their retreatment.

Definition of recurrence

Rays that had been retreated or showed an increase in the TPED of 30° or more from the 3-months' time point were defined as recurrences.

Statistical analyses

A sample size calculation was performed before the initial study based on the difference and standard deviations seen for reductions of TPED at 6 weeks in a previous comparison between needle fasciotomy and limited fasciectomy (van Rijssen et al., 2006). The power analysis suggested we needed to treat 86 rays to demonstrate 80% power and a 5% 2-tailed type I error rate. Cross tables were used to compare the treatment groups. Categorical data were analysed with the chi-square test. Several outcome measures were not normally distributed according to the Kolmogorov–Smirnov test, and quantitative data were analysed using the Mann–Whitney U-test. Data are presented as median and interquartile ranges (IQRs). Significance was set at a p-value <0.05.

Results

Demographics

Ninety-six rays in 93 patients were included in the initial study. Forty-six rays treated with needle fasciotomy and 40 rays treated with collagenase injections remained for analyses at 3 months. The groups were similar regarding age, sex, treated sides, and affected finger. At 3 years, 40 patients who had had needle fasciectomies and 36 patients who had had collagenase injections were available for re-evaluation or had been retreated during the observation time. One patient from each group had died.

Recurrence and re-treatment rates at 3 years

There was no significant difference in the recurrence rate between the two treatment groups at the 3-year follow-up (Table 1). Neither was there a significant difference in the retreatment rate. Of the 11 patients with retreated needle fasciectomies, eight had surgery, two had a repeated needle fasciotomy, and one had a collagenase injection. Of the four patients with retreated collagenase injections, three had surgery and one had a needle fasciotomy. The mean time to retreatment was 19 months in the needle fasciotomy group and 24 months in the collagenase group.

Table 1. Retreatment rate and recurrence rate 3 years after index treatment.

	Needle fasciotomy	Collagenase	*P*
Recurrence rate at 36 months	17/40	12/36	0.65
Retreatment rate	11/45	4/35	0.09

Digital motion ranges at 3 years

The passive extension deficits before treatment and at the different time points for each joint and the TPED are presented in Table 2. At 3 years, the remaining rays had an increase in TPED of 5° in the needle fasciotomy group and 16° in the collagenase group, as compared with the 3 months measurements ($p = 0.08$). The total extension deficits were 15° in the needle fasciotomy group and 28° in the collagenase group ($p = 0.05$). The reduction of TPED in the remaining rays at the 3-year follow-up compared with before treatment was significantly greater in the needle fasciotomy group.

Patient reported outcomes

The median QuickDASH score before treatment was 20 (IQR 23) in the needle fasciotomy group ($n = 25$) and 15 (IQR 20) in the collagenase group ($n = 23$). At 3 years, the QuickDASH score was 1 (IQR 7) in the needle fasciotomy group ($n = 18$) and 5 (IQR 14) in the collagenase group ($n = 19$). The median URAM scores before treatment were 16 (IQR 14) in the needle fasciotomy group and 10 (IQR 13) in the collagenase group. At 3 years the scores were 1 (IQR 5) in the needle fasciotomy group and 3 (IQR 8) in the collagenase group. The differences in scores between the groups were not significantly different.

Discussion

We found no significant difference in recurrence rates between needle fasciotomy and collagenase injections in this study. Van Rijssen and Werker (2006) found a 65% recurrence rate for needle fasciectomies at 33 months using a similar definition of recurrence as in our study, but from an immediate postoperative time point. We chose to have the 3-months' time point as our reference point due to possible differences or uncertainty of the immediate postoperative measurements given the different anaesthesia methods used for the two treatments. If using the same time points as van Rijssen and Werker (2006) on our material the recurrence rates

Table 2. Extension deficits.

	Needle fasciotomy	Collagenase	*p*
MCP – degrees, median (IQR)			
Before	55 (25), *n* = 46	55 (24), *n* = 40	0.87
3 months	0 (10), *n* = 46	0 (15), *n* = 40	0.73
12 months	0 (10), *n* = 42	5 (10), *n* = 39	0.18
At retreatment	20 (25), *n* = 11	45 (15), *n* = 4	0.04
36 months	0 (19), *n* = 29	10 (22), *n* = 32	0.07
PIP – degrees, median (IQR)			
Before	25 (28), *n* = 25	18 (15), *n* = 16	0.24
3 months	20 (28), *n* = 25	15 (15), *n* = 16	0.44
12 months	25 (25), *n* = 23	20 (20), *n* = 15	0.36
At retreatment	40 (45), *n* = 11	0 (23), *n* = 4	0.08
36 months	5 (30), *n* = 29	15 (20), *n* = 32	0.40
TPED – degrees, median (IQR)			
Before	65 (36), *n* = 46	60 (19), *n* = 40	0.18
3 months	15 (23), *n* = 46	12 (24), *n* = 40	0.60
12 months	18 (30), *n* = 42	15 (20), *n* = 39	0.90
At retreatment	50 (20), *n* = 11	48 (35), *n* = 4	0.85
36 months	15 (35), *n* = 29	28 (26), *n* = 32	0.05
Reduction of TPED – %, median (IQR)			
Immediately after	82 (29), *n* = 46	96 (20), *n* = 40	0.01
3 months	79 (29), *n* = 46	78 (31), *n* = 40	0.94
12 months	77 (30), *n* = 42	75 (30), *n* = 39	0.73
36 months	75 (62), *n* = 29	51 (58), *n* = 32	0.02

MCP: metacarpophalangeal; IQR: interquartile range; PIP: proximal interphalangeal; TPED: total passive extension deficit.

would be 45% for needle fasciectomies and 44% for collagenase injections. The TPED before treatment was 62°, which was also similar to ours and also does not explain the difference observed between the studies. In our study, we treated predominantly MCP joint contractures.

One possible explanation for the higher recurrence rate found by van Rijssen and Werker (2006) could be that they had more PIP contractures in their study, but they did not report involvement of different joints separately. Van Rijssen and Werker (2006) found the retreatment rate to be 42%, with an average time to retreatment of 23 months after needle fasciotomy. Foucher et al. (2003) reported a reoperation rate of 24% in a study of 100 patients at 3.2 years after treatment with needle fasciotomy. In our study the retreatment rate for needle fasciectomies was 24%, with an average time to retreatment of 19 months.

The 3-year recurrence rate reported for collagenase treatment in the CORDLESS study (Peimer et al., 2013) was 35%. In that study, recurrence was defined as an increased contracture of at least 20° compared to day 30 in successfully treated joints (<5°) in the presence of a palpable cord. MCP and PIP joints were treated and analysed separately for recurrence. The retreatment rate was 7% compared with 10% in our study. If using a minimum of a 20° increase (regardless of a palpable cord or not) from the 3-months' time point in our study, the recurrence rates would be 48% for needle fasciectomies and 53% for collagenase injections; and if comparing with immediately after treatment it would be 50% for needle fasciectomies and 69% for collagenase injections. For the partially corrected joints in the CORDLESS study, 50% of patients had an increase of 20° or more at 3 years. It is not clear how many joints had an increase in contracture of 20° or more, but were found not to have a palpable cord.

Several studies have shown that PIP joint contractures do worse and recur sooner than MCP joint contractures after both collagenase treatment and needle fasciotomy (Bryan and Ghorbal, 1988; Cheng et al., 2008; Hansen et al., 2017; Peimer et al., 2013; Rowley et al., 1984). The proportion of PIP joint contractures was low in our material. We could not find any correlation between PIP joint involvement and recurrence rate. In a recently published study on isolated PIP joint contractures (Skov et al., 2017), clinical improvement, defined as a reduction of 50% or more of the baseline contracture, was maintained in 7% of the collagenase treated rays and in 29% of the needle fasciectomies 2 years after treatment. In our study, 49% of the needle fasciectomies and 47% of the collagenase injections maintained a 50% or more reduction of their initial contractures at 3 years.

There are limitations to our study. The study population was relatively small and initially powered to detect differences in TPEDs after treatment based on the assumption that collagenase injections and limited fasciectomies have comparable results and not for dichotomized recurrence rates. Although not statistically significant, more needle fasciectomies had been retreated prior to the assessment at 36 months, thus making comparisons between the groups regarding the remaining contractures at 36 months difficult. We performed all treatments and follow-ups in a non-blinded fashion, so there is a potential for both influence by experience and technique as well as measurement bias. We conclude from our study that that collagenase injection and needle fasciotomy have similar 3-year recurrence rates in the treatment of Dupuytren's contracture.

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Details of informed consent Written informed consent was obtained from all patients before entering this study.

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