



Long-term clinical outcome of collagenase clostridium histolyticum treatment is independent of Dupuytren Diathesis Score

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Collagenase clostridium histolyticum (CCH) is a pharmaceutical, non-surgical treatment option for Dupuytren Disease. However, recurrence is common, and predictors of treatment outcome of CCH treatment are largely unknown. In this retrospective study, we analysed the possible correlation between Abe's Dupuytren Diathesis Score (DDS) and recurrence after treatment with CCH. In a total of 74 patients, with an average follow-up of 5 years, we found an overall recurrence rate of 67% after 5y but no correlation with DDS. Sub-scale analysis indicated that the presence of knuckle pads was associated with a reduced recurrence risk. Patient satisfaction after CCH was high. Deriving from our data, there is no correlation between DDS and recurrence following CCH treatment. Therefore, at this moment, we do not advocate the use of the DDS when informing patients about recurrence rates after CCH treatment.

Level of evidence: IV: therapeutic cohort study.

Keywords: Dupuytren disease, Dupuytren contracture, collagenase clostridium histolyticum, recurrence, diathesis.

INTRODUCTION

Dupuytren disease is a benign connective tissue disease affecting the palmar fascia of the hand. The development of nodules and cords beneath the skin of the palm leads to flexion contractures of the fingers thus leading to functional impairment that can become debilitating¹⁻⁴. The aetiology of DD is largely unknown, and it is believed that both genetic and environmental factors contribute to the onset and progression of the condition. Contributing factors (may) include diabetes, liver disease, alcohol consumption, smoking and the use of anti-epileptic drugs and familial disposition^{2,5}.

Dupuytren disease has a high variability in clinical presentation and disease progression, both before and after surgery. Some patients have a limited and slowly progressive type whereas others suffer from a widespread and rapidly progressive type. The latter group of patients, who suffer from an aggressive disease type, are denoted to have a severe Dupuytren diathesis and have an increased risk for postoperative recurrence and/or disease progression. The term Dupuytren diathesis was first described by Hueston in 1963, noting early onset, positive family history, ectopic lesions and bilateral involvement as risk factors. The concept of

diathesis is widely supported but factors contributing to disease diathesis have been altered and modified after its introduction^{2,5,6}. Which factors contribute and to what extent was, among others, studied by Abe et al.⁶. In 2004, they designed a Dupuytren Diathesis Score (DDS), in which a combination of disease parameters account for a cumulative score. This score predicts the risk of recurrence and/or extension after surgery. The parameters include: early onset, bilateral hand involvement, ectopic lesions, knuckle pads, little finger surgery and radial side involvement. The degree of diathesis is considered very important in the prediction of recurrence and/or progression after treatment^{2,6}.

Dupuytren disease cannot be cured and therefore, treatment is symptomatic^{4,5,7,8}. Historically, surgery was seen as the primary treatment modality. Radical or segmental fasciectomy with excision of all Dupuytren tissue is an effective treatment but has the risk of surgical complications and is generally followed by a laborious follow-up treatment schedule with physiotherapy and splinting, thus needing high patient compliance. Furthermore, in selected cases, general health issues may preclude patients from undergoing surgery because anaesthesia is deemed too risky. Alternatively, in cases with mild flexion contractures

and limited disease, percutaneous needle fasciotomies (PNF's) can be performed^{1,3,7-10}.

Collagenase clostridium histolyticum (CCH) is a pharmaceutical, non-surgical treatment option that is conceptually analogous to PNF. The injected collagenase selectively degrades all types of collagen (except type IV) in the Dupuytren cords, thereby weakening them. Manipulation of the affected digit under local anaesthesia follows 1-2 days after injection and extension deficits can thus be improved or diminished^{1,3,9,11}. Possible complications of CCH treatment are generally mild and include local oedema, injection site pain, contusion, haematoma formation, skin rupture and resolve without treatment. Flexor tendon or pulley system injury is rare (3%) but severe and requires operative reconstruction and thorough rehabilitation. Cases of CRPS are reported but are very rare^{1,3,9,11}.

With the advent of collagenase treatment in 1996 it was noted that there was a shift in DD treatment away from open surgical interventions and toward CCH¹². Available literature shows that functional treatment outcomes between fasciectomy and collagenase are similar in specific groups, but rehabilitation and return to normal activities are much easier after collagenase¹²⁻¹⁵.

DD is associated with recurrence and/or progression irrespective of which type of treatment was provided^{8,9}. Furthermore, (salvage) fasciectomy after earlier CCH treatment is technically more challenging and associated with higher complication risks than primary fasciectomy due to alterations in the native anatomy in the treated area^{3,9,16,17}. Therefore, prior to collagenase treatment, it is important to inform the patient of treatment success rates, recurrence rates and the more technical demanding surgical procedures that may follow recurrence after collagenase treatment¹³. In order for the treating physician to do so, knowledge regarding what factors correlate to recurrence is imperative. The prognostic value of disease diathesis in the clinical outcomes of collagenase treatment is largely unknown. Therefore, the objective of our research was to evaluate whether high Dupuytren Diathesis Scores are correlated to recurrence in Dupuytren patients treated with collagenase.

METHODS

We performed a retrospective cohort study which included patients treated with CCH treatment for DD between September 2011 and July 2014. The study was approved by the local ethics committee (S57228). Patients received injections by one of two expert

hand surgeons¹⁸ with CCH (Xiapex, Swedish Orphan Biovitrium, Solna, Sweden) at multiple sites in their Dupuytren cords according to the manufacturer's instructions. The affected digits were manipulated 2 days later under local anaesthesia in the outpatient clinic. Follow-up treatment consisted of night-time splinting for a minimum of 4 weeks and functional use of their hand.

Baseline characteristics and data regarding which digits and joints were affected were retrieved from the medical charts. All patients were sent a questionnaire (Appendix 1) to assess self-reported recurrence and satisfaction with the treatment. The questionnaire also comprised questions regarding the presence of risk factors for recurrence. From these questions, we calculated a Dupuytren diathesis score (DDS) for each patient and then correlated this score to the patient-reported outcomes. The patients from this cohort who had not reported a recurrence were invited to the outpatient clinic for a live examination of the treated digits to verify the clinical situation in these patients. Recurrence was defined as a 20 degrees increase in flexion contracture and/or a digit needing additional treatment after the CCH therapy.

Data was collected in Excel and analysed in SPSS (version 25). Baseline characteristics, self-reported recurrence and satisfaction are reported as descriptive statistics. To analyse correlations between recurrence and the DDS and its sub-scores, logistic regression analysis using the Pearson correlation coefficient and Fischer exact tests were used. Odds ratios with 95% confidence intervals were calculated to further analyse the relationship between recurrence and the DDS sub-scores. Statistical significance was set at $p \leq 0.05$.

RESULTS

Between September 2011 and July 2014, ninety-five patients were treated for their DD with CCH. Sixty-eight participated in our study, of whom 12 had bilateral hand involvement. Thus, 79 hands were eligible for analysis. Eventually, 31 patients were recalled for clinical examination as they did not self-report recurrence. Two patients, accounting for 3 hands, were lost to follow-up. Furthermore, due to incomplete questionnaire data, the total amount of hands eligible for statistical analysis in SPSS was 74 (in 64 patients), of which 40 were right and 34 were left hands. Fifty-four males were included versus 10 females and average age at inclusion was 62 years (range; 27-87y). Fifty-two cases had DD in one ray, in 21 patients 2 rays were affected and in 1 patient, 3 rays were affected. The fourth and fifth digit

Table I. — Baseline characteristics.

		number	[%]
Patients		64	
Hands		74	
	left	34	[46%]
	right	40	[54%]
Gender			
	male	54	[84%]
	female	10	[16%]
Age (average, range)		62 [range; 27-87]	
Number of affected rays			
	1	52	[70%]
	2	21	[28%]
	3	1	[1%]
Affected digits			
	2	2	[3%]
	3	5	[7%]
	3+4	4	[5%]
	3+4+5	1	[1%]
	4+5	17	[23%]
	4	20	[27%]
	5	25	[34%]
Joint involvement			
	MCP	16	[24%]
	MCP + PIP	10	[14%]
	PIP	48	[62%]

were most commonly involved. In the majority of cases (62%) there was a flexion contracture in both the PIP and the MCP joint of the affected fingers, followed by single contracture in the MCP joint (24%) and PIP joint (14%). The baseline characteristics are summarised in Table I.

The average time of follow-up was 57 months (range; 43-77mo). Recurrence after CCH treatment was observed in 53 (67%) cases. In 6 cases (8%), treatment was unsuccessful and no improvement of the flexion contracture was reported (Table II). When asked for satisfaction, 42 cases (57%) indicated that they were satisfied with the obtained treatment effect and 62% of cases (n = 46) indicated that they would want to have the same treatment again should they be given the option. Of the 6 cases in which no initial treatment effect was observed, 1 patient underwent repeat CCH treatment of 1 of the 2 treated digits within the period of our follow up, with satisfactory results.

In the case of recurrent disease (n = 53), 31 patients (58%) were treated expectantly and did not have an additional treatment within our follow-up period. Nine

Table II. — Recurrence and follow-up.

	Average number of months	range
Follow-up	57	[43-7]
	N	[%]
Recurrence	53	[67%]
		[% of recurrences]
conservative	31	[58%]
collagenase	9	[17%]
surgery	15	[28%]
No initial treatment effect	6	[8%]
Satisfied	42	[57%]
	46	[62%]
Time to repeat collagenase	35	[4-51]
Time to surgery	30	[7-28]

Table III. — Cross tabulation DDS and recurrence.

	DDS			Total
	DDS ≤ 4	DDS > 4		
Recurrence				
Yes	38	15	53	
No	14	7	21	
Total	52	22	74	

patients (17%) underwent repeat CCH treatment, and 15 patients (28%) underwent surgery. One patient who underwent repeat CCH treatment eventually progressed to needing surgery. The average time between initial and repeat CCH treatment was 35 months (range; 4-51) and the average time between initial CCH treatment and surgery was 30 months (range; 7-58).

For further analyses of DDS and recurrence, cases were categorised by severity into Group A, having a DDS of ≤4 (n = 52) and Group B, having a DDS of >4 (n = 22) (Table III). In Group A, there were 38 recurrences (73%) and in Group B there were 15 recurrences (68%). The Pearson correlation coefficient for DDS and recurrence was 0.412, indicating that there was no significant relationship between the two. The Fischer exact test confirms that there was no significant correlation between DDS and recurrence after CCH treatment (p = 0.36). We then analysed whether the sub-scales of the DDS separately influenced the risk of recurrent disease by calculating odds ratios (Table IV). From our data we could derive that, within our dataset, the presence of knuckle pads was significantly associated with a reduced risk of recurrence. Contrarily, little finger treatment and plantar fibrosis show a trend toward increased risk of recurrence.

Table IV. — Odds ratios per DDS subscale.

DDS subscale	Odds ratio	CI	p-value
Bilateral disease	0.53	[0,101-2,806]	0.46
Little finger treatment	3.12	[0,744-13,105]	0.12
Early onset disease	2.16	[0,560-8,326]	0.26
Plantar fibrosis	3.07	[0,355-26,625]	0.31
Knuckle pads	0.14	[0,21-0,970]	0.05
Radial side involvement	0.93	[0,227-3,771]	0.91
CI: confidence interval.			

DISCUSSION

The goal of this study was to investigate whether a high DDS correlates to high recurrence rates after CCH treatment for Dupuytren Disease. Treated patients were therefore categorised into high and low DDS groups. We found no correlation between DDS and recurrence.

Factors influencing recurrence in DD have been studied in the past and conflicting reports have been noted^{2,5,10,13,15}. For example, in our study, the presence of knuckle pads seemed to give a reduced risk of recurrence after collagenase treatment with an odds ratio of 0.14. Contrarily, in the study of Dolmans et al.⁵, the presence of knuckle pads was denoted to be a feature predominantly associated with a high genetic risk score for recurrent disease. Furthermore, in his original article, Abe et al. mentioned that the presence of knuckle pads has a strong influence on DD recurrence and extension⁶. Additionally, Hindocha et al. found that the presence of knuckle pads increased the risk of recurrent disease². Deriving from our analysis, little finger involvement and plantar fibrosis predilect recurrence in patients treated with CCH. It has been noted earlier that ulnar digits are more refractory from treatment^{11,15}. Also, some researchers have found no correlation whatsoever between recurrence and diathesis features¹⁵.

Recurrence was self-reported by our patients in this study which leaves room for different opinions and observations. For those who refrained from returning their questionnaire and were followed-up with a clinical examination, recurrence was defined as the presence of a palpable cord associated with 20 degrees or more of joint contracture compared to the baseline level. The latter definition of recurrence is commonly applied in clinical studies^{1,2,9,11,13,19}. We found an overall (both self-reported and measured) recurrence rate of 67% after almost 5 years (57 months), which is comparable to other studies^{1,19}. Early efficacy and safety studies showed success rates of 51 - 89% at 30 days^{3,4,10,11}. Short-term recurrence rates vary from 0%¹¹⁻

67% at 1 year follow up,¹ and 83% at 2-year follow up¹⁰. One-, two- and three-year recurrence rates after CCH treatment were reported to be 3%, 20% and 35% respectively by Hentz and colleagues⁹. At 3-year, Nordenskjöld et al.¹³ report maintenance of treatment result in two-thirds of their study population and thus suggest recurrence in 33%. They report a recurrence of >20 degrees contracture in 15% of treated MCP joints and 23% of PIP joints. Peimer et al.¹⁹ report a 5-year recurrence rate of 47% (39% in MCP and 66% in PIP joints respectively) and they state that the majority of recurrences had occurred in the first 3 years following treatment. Long-term outcome studies are scarce and sample size is limited, however, Watt and colleagues¹⁷ report 8-year follow up of CCH treatment in eight patients. Both patients treated for PIP contracture (100%) and 4 of 6 (67%) patients treated for MCP joint contracture had developed a recurrence. Our 5-year recurrence rate fits well into these priorly reported data. Additionally, we found a reoperation rate in 20% of our total study population, which is comparable to previously reported rates as well^{6,8}.

Also, treatment efficacy of CCH has been compared to other treatment modalities. Skov et al.¹⁰ compared 2-year treatment outcomes between CCH and PNF and found better outcomes in the PNF group in terms of maintenance of clinical improvement (32% PNF vs 8% CCH) and complications. Van Rijssen et al.¹⁵ compared treatment outcomes of limited fasciectomy with PNF at 5-year follow-up and found an 85% recurrence in the PNF group versus 21% in the fasciectomy group. They found that recurrence in the PNF group occurred sooner than recurrence in the fasciectomy group. Furthermore, they state that, in line with our observations, no diathesis characteristics were of influence on recurrence. Both van Rijssen and Skov report high percentages of recurrence following PNF. Taking this into account, our numbers suggest that there is no inferiority in treatment outcome of CCH compared to PNF and is a reasonable treatment to offer to patients suffering from DD. Generally, one might conclude that mid-term recurrence is lower after

(limited) fasciectomy, but both PNF and CCH are associated with lower risk of complications and have the great advantage of easy rehabilitation and return to activities of daily living^{7,17}.

We observed unsuccessful initial treatment in 8% of cases. Reasons for failure of cord rupture include incorrect injection technique or site, inactive substance injection and patient-related factors³. Other studies report success rates varying from 51-92% in early measurements to 85% after 30 days^{3,4,11,17,19}. These numbers may vary depending on the definition of success rate. The fact that we used self-reported outcome rather than goniometric measures may explain this difference as we did not use pre-defined cut-off points.

We did not observe significant differences in recurrence between MCP or PIP joints. It has been reported, however, that collagenase treatment has different efficacy in MCP and PIP joints. In part, this might be attributed to joint stiffness, collateral ligament and/or volar plate contraction in long existing PIP flexion contractures. Generally, it is reported that MCP joints respond more favourably than do PIP joints^{3,8,9,17}. Hansen et.al.¹ specifically studied differences between MCP and PIP joints and report that collagenase treatment is more effective and shows fewer recurrences in MCP joints compared to PIP joints at 1 year follow-up. This observation is supported by other authors^{7,11,19}. As stated, although MCP and PIP comparisons were not part of our primary analyses, at 5-year follow up, recurrence rates for MCP, PIP and combined contractures were similar in our dataset.

It is noted that treatment with collagenase is more efficacious in joints mild to moderately affected compared to those which are severely affected. Some authors suggest that when planning to treat with CCH, it may be worthwhile to perform early intervention and thus maximise treatment efficacy^{3,11,13,17}. Our study did not analyse this feature as we did not dispose of standardised measurement data. Rather, our data consisted of (self)observations and not clinical measurements. We do believe however that this feature can be important to take into account when informing the patient regarding treatment prognosis.

In our study, 28% of patients with recurrence proceeded to surgical interventions to treat their DD. This is in line with previous work, in which surgical intervention following CCH treatments is reported to be between 26-44%^{2,19}. As in our series, patients sometimes opt for repeat collagenase treatment. Peimer et al.¹⁹ reported rates of 30% which is slightly higher than our observed 17%. Performing fasciectomy following CCH

does carry increased risk of complication as a result from altered local anatomy and obliteration of tissue planes resulting from scarring¹⁶. However, results of this procedure were reported to be comparable to those of primary fasciectomy in a small group¹⁶. Histological examination of excised tissue after CCH treatment and recurrent DD after primary fasciectomy could not distinguish any difference in the scar tissue that had formed¹⁴.

Even though patient satisfaction is correlated to recurrence^{13,15}, we found a relatively high self-reported satisfaction (57%). High patient satisfaction after CCH is broadly reported among existing literature and lies between 66%-81%. Also, a majority of patients indicate that they would undergo repeat CCH treatment when offered, which is in line with our results as well^{1,9,13}.

The study that we performed does have several weaknesses, owing to its design. First, it was conducted retrospectively. Furthermore, we let patients self-report the treatment outcomes using a non-validated questionnaire. This did not allow for measurement data but rather for observational data, that was later combined with observational data retrieved by a researcher who invited the non-responders to our outpatient clinic. We do believe however, that in current times, patient reported measures and satisfaction are important indicators of how physicians should conduct their clinical practise. For example, even though, recurrence rates at 5-year were relatively high, so was patient satisfaction. Deriving from this, CCH treatment should be a realistic option to be offered to patients who may benefit. The study was performed in a single centre set up and the sample size was considered moderate.

Our data do not demonstrate any correlation between DDS and recurrence following CCH treatment. Therefore, we would not advocate to use the DDS when informing patients about recurrence rates after collagenase treatment, but rather take into account other factors that might be of prognostic value, such as pre-treatment contracture severity, and the type of affected joint in order to manage patient expectations. In general, patient satisfaction following CCH treatment is high and rehabilitation and return to normal activities is short. Recurrence is often inevitable and this should be explained as patient-dependent rather than a treatment-dependent phenomenon.

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Appendix 1. — Questionnaire

Question 1:

Which hand was treated with collagenase?

- Left
- Right
- Both hands

Question 2:

Which digits were treated per hand?

LEFT:

- None
- Thumb
- Index
- Middle
- Ring
- Little

RIGHT:

- None
- Thumb
- Index
- Middle
- Ring
- Little

Question 3:

Did you have prior treatment for Dupuytren Disease on the affected hand?

- No
- Yes – if yes, please specify what type of treatment:
 - Open fasciectomy
 - Percutaneous needle fasciotomy
 - Collagenase injection
 - Other: _____

– if yes, please specify which fingers were treated:

LEFT:

- None
- Thumb
- Index
- Middle
- Ring
- Little

RIGHT:

- None
- Thumb
- Index
- Middle
- Ring
- Little

Question 4:

What is your dexterity?

- Left
- Right
- Ambidextrous

Question 5:

Are you satisfied with the collagenase treatment outcome?

- No
- Yes

Question 6:

Did you reach full extension of the finger(s) treated with collagenase?

- No
- Yes

Question 7:

Have you maintained extension of the finger(s) treated with collagenase?

- No
- Yes

Question 8:

Would you choose to have the same treatment again?

- No
- Yes

Question 9:

Are your hands or fingers painful at rest?

- No
- Yes

Question 10:

Are your hands or fingers painful during activities?

- No
- Yes

Question 11:

Did you undergo treatment for Dupuytren disease after you had had collagenase treatment of the affected fingers?

- No
- Yes – if yes, please specify what type of treatment:
 - Open fasciectomy
 - Percutaneous needle fasciotomy

Collagenase injection

Other: _____

– if yes, please specify which fingers were treated:

LEFT:

- None
- Thumb
- Index
- Middle
- Ring
- Little

RIGHT:

- None
- Thumb
- Index
- Middle
- Ring
- Little

Question 12:

At what age did you first develop Dupuytren Disease?

- <50y
- >50y

Question 13:

Do you suffer any of the below-listed conditions?

- Knuckle pads (well-defined thickening of the skin on the dorsal side of the fingers)
- Ledderhose disease (fibrous nodules on the sole of the foot)
- Peyronie's disease (hardened, cord-like lesions on the penis)

Question 14:

Have you ever suffered from Dupuytren Disease in the thumb or the index finger?

- No
- Yes

Question 15

Have you ever suffered from Dupuytren Disease in the little finger?

- No
- Yes-> if yes AND you were treated on this little finger, did you have a recurrence after treatment?
 - No
 - Yes