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Collagenase injections for Dupuytren's in Australian public hospitals: a cost analysis

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Abstract

Background: Collagenase clostridium histolyticum (CCH) injection is an established alternative to surgical fasciectomy in selected patients with Dupuytren's contracture. Collagenase is currently not listed on the Pharmaceutical Benefits Scheme creating a barrier to its use in the Australian public health system. This study compares the cost of CCH delivered in an outpatient setting with a comparable surgical fasciectomy cohort, calculated retrospectively.

Methods: A retrospective audit of hospital data was conducted to determine the cost of single-digit surgical fasciectomy compared to CCH treatment delivered in an outpatient setting. Medicare Benefits Schedule coding was used to identify surgical fasciectomy patients between March 2014 and April 2015. The CCH group was prospectively followed from June 2014 to March 2016.

Results: Thirty-seven patients were successfully treated with CCH, with one patient requiring two injections. This group required less follow-up visits (4.0 outpatient clinic and 4.9 allied health) compared to the surgical group (n = *38*; 4.4 outpatient clinic and 6.1 allied health). The total cost of treatment for the CCH group was AU$2589 compared to a mean total of AU$6155 for the surgical group (AU$3574–AU$14,599)—a potential saving of AU$119,698.

Conclusion: The overall cost of CCH is substantially lower than surgical fasciectomy despite the cost of the medication (AU$1206). Additionally, CCH patients avoid a visit to the operating room thereby freeing up theatre time that is generally under pressure with long public waiting lists.

Keywords: collagenase, Dupuytren's, cost, contracture, public health

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Introduction

Dupuytren's disease is a benign fibroproliferative condition of the palmar fascia characterised by painless, progressive and irreversible contractures of the fingers and subsequent functional limitation. Until recently, fasciectomy remained the treatment of choice.[1]

Fasciectomy for Dupuytren's disease is a lengthy procedure requiring several weeks to recover motion and strength in the hand. It can vary from excision of segments of the cord through small incisions, or limited fasciectomy of the involved digits, to extensive dermofasciectomy involving skin and fascia. Complications from surgery include nerve injury leading to numbness, skin breakdown, infection and haematoma which can prolong recovery or may require revision surgery. Surgery is not a cure nor does it prevent recurrence. Reported contracture recurrence rates after surgery vary widely from 27 per cent to 80 per cent depending on the definition of recurrence.[2]

More recently, enzymatic digestion of the diseased tissue and disruption of the contracted cord has been proposed as an alternative to surgery. In a phase III trial conducted by Badalamente and colleagues,[2] collagenase clostridium histolyticum (CCH) injections were shown to be safe and effective for correction of single finger contracture with a low recurrence rate. Their protocol involved the injection of CCH into the diseased cord followed by manipulation and extension of the finger a day later. Treatment is delivered under local anaesthesia in the outpatient setting. In the USA, CCH was approved by the US Food and Drug Administration for the treatment of Dupuytren's contracture in 2010.

The widespread adoption of CCH (Xiaflex, Endo Pharmaceuticals, PA, USA) in Australia has been hampered by multiple factors. The drug has been denied coverage under the Pharmaceutical Benefits Scheme (PBS) on the basis of its reported efficacy of 50 per cent (compared to 67 per cent for surgery) and a higher recurrence rate.[2–4] Therefore, a public hospital offering the treatment has to bear the cost of the injection. As there is no specific diagnosis related group (DRG) code for chemical fasciectomy, there is no defined process for reimbursement of the activity performed at an outpatient service. Although this would seemingly be more cost-effective, it is unclear who bears the cost of the injection, as it is a medical treatment for a surgical condition.

The purpose of this paper is to compare the cost of CCH treatment in an outpatient setting in the Australian public system with single-digit fasciectomy.

Methods

We conducted a retrospective audit of hospital data to calculate the cost of surgical fasciectomy. Costings were calculated internally in collaboration with finance and compliance staff using the Medicare Benefits Schedule (MBS) code 46372 to identify patients who underwent fasciectomy over a 12-month period from March 2014 to April 2015. Only cost calculations for single-digit fasciectomy were included in order to make this cohort comparable to the CCH treatment group. The CCH cost was calculated from participants in a prospective study from June 2014 to March 2016.

The total cost for fasciectomy procedure included all hospital and operating theatre-related expenses such as: medical and surgical costs, operating theatre costs, anaesthetic staff costs, allied health costs, blood products, medical imaging, pathology, pharmacy, prosthesis costs and ward costs. All costs included direct costs and related overheads. Actual figures were obtained from the hospital cost centre in our billing department and were calculated on a cost per patient per hour basis. Overhead costs were calculated as a percentage of total lease cost on a time usage basis. Queensland Payroll assisted in providing the cost of wages of the varied health staff at an hourly rate.

The cost of surgical outpatient and hand therapy appointments were calculated in a similar fashion. The mean values of each of these items were included to estimate the total direct cost of fasciectomy itself and the cost of the outpatient clinic visits related to the surgery or CCH administration. The cost of CCH treatment included the cost of the drug and additional costs of clinic visits and hand therapy costs.

Table 1. Surgical and CCH total average costs (AU$)

	Single-digit fasciectomy		CCH injection	
	Mean cost	Range	Mean cost	Range
Theatre	$1573.30	($94.07–$3522.95)		
Theatre overheads	$764.44	($551.79–$1453.73)		
Anaesthetic staff	$529.40	($72.94–$1870.65)		
Anaesthetic overhead	$79.03	($29.72–$428.54)		
Medical and surgical	$685.08	($205.47–$1975.92)		
Medical and surgical overhead	$101.88	($45.43–$257.04)		
Ward	$102.06	($0.31–$580.91)		
Ward overhead	$46.97	($0.01–$326.90)		
Pharmacy	$162.70	($56.36–$229.38)	$1206.15	($1176.00–$2352.00) based upon 38 injections
Pharmacy overhead	$1.22	($0.01–$24.48)		
Pathology	$15.26	($0.00–$225.92)		
Pathology overhead	$0.01	($0.00–$0.02)		
Imaging	$10.97	($0.00–$208.36)		
Imaging overhead	$0.01	($0.00–$0.02)		
Mean total for theatre alone	***$4609.61***	***($2761.44–$10928.67)***		
Surgical outpatient costs	$1339.88	($606.28–$2728.26)	$1405.74	($1212.56–$1515.70)
Occupational therapist costs	$206.27	($33.65–$942.20)	$134.60	
Occupational therapy overheads (splint and odema control)			$30.00	
Overall total for care	**$6155.86**	**($3573.99–$14599.13)**	**2589.07**	**($2376.44–$3091.39)**

CCH= Collagenase clostridium histolyticum injection

The pathway for patients undergoing CCH treatment was an initial surgical consultation, a clinic visit for the injection, a subsequent visit for joint manipulation and two outpatient reviews at one and three months respectively. The hand therapy protocol was one initial consult for documentation of contracture severity and objective measurements followed by a visit immediately after manipulation for splinting and two subsequent visits for splint adjustment and finger motion exercises.

The surgical group had an initial consultation and then post-operative outpatient follow up at one week, one month and three months. Hand therapy following surgery was one initial visit for splinting and subsequent visits as needed for splint adjustment or hand range of motion. The outpatient follow-up in both groups was designed as a guideline. Ongoing subsequent surgical review or hand therapy was customised to the individual patient on an as required basis.

Results

We identified 38 patients who underwent single-digit fasciectomy during the review period. The actual total cost per patient was calculated and compared to CCH treatment (**Table 1**). The mean cost of surgery for single-digit fasciectomy was AU$4609.61 (AU$2761.44–AU$10,928.67). In terms of fasciectomy component cost, the highest was theatre, followed by medical and surgical staff and then anaesthetic staff. The cheapest variables were imaging, pathology and pharmacy.

Outpatient visits for the fasciectomy group were compared with the CCH group (**Table 2**). The single-digit fasciectomy group required a mean of 4.4 (2–9) surgical outpatient visits. The mean cost for a single surgical outpatient appointment was AU$303.14 per visit (AU$180.80–AU$4165.20) making the total mean outpatient cost AU$1339.88 (AU$606.28–AU$2728.26). The high cost in some patients was related to preoperative work-up for anaesthesia. The mean number of occupational

Table 2. Number of outpatient and hand therapy visits including costs

		Mean	Mean cost	Range
Single-digit fasciectomy	**Outpatients**	4.42 (2–9)	AU$1339.88	($606.28–$2728.26)
	Occupational therapy	6.13 (1–28)	AU$206.27	($33.65–$942.20)
CCH injection	**Outpatients**	4.00 (3–8)	AU$1405.74	($484.32–$1515.75)
	Occupational therapy	4.92 (3–16)	AU$164.60	($102.65–$756.74)

CCH= Collagenase clostridium histolyticum injection

Table 3. Cost of Dupuytren surgery for patients treated at the Gold Coast University Hospital from March 2014 to April 2015 (AU$)

	Digits affected	Number of injections	Mean	Standard deviation	Minimum	Maximum	Sum	Alternative cost of CCH injection	Saving
Total	1	38	AU$4610	AU$1905	AU$2761	AU$10,929	AU$175,165	AU$55,467	**AU$119,698**

CCH= Collagenase clostridium histolyticum injection

therapy visits was 6.13 (1–28) in the surgical group with a mean cost of AU$206.27 (AU$33.65–AU$942.20).

A total of 37 patients underwent 38 CCH injections from June 2014 to March 2016. The cost of the drug in our hospital was AU$1176 per vial. At three-month follow up, a reduction in extension deficit to <5 degrees of full extension for the measured joint was achieved in 48 per cent of joints—66 per cent metacarpophalangeal (MCP) joint and 19 per cent proximal interphalangeal (PIP) joint. Mean fixed flexion deformity improved by 40 degrees and 25 degrees for MCP joint and PIP joint disease respectively. Mean active range of motion improved by 39 degrees and 18 degrees respectively. While not all patients received full correction, as is usual with all forms of treatment for Dupuytren's contracture, all but one patient was satisfied with the correction achieved. Only one patient requested a second injection for incomplete correction during the study, thereby the mean drug cost was calculated at AU$1206.15.

The CCH group of patients required a mean of 4 (3–8) visits in outpatient clinic and 4.9 (3–16) in hand therapy. Using an average estimated cost of AU$250.06 per clinic visit and AU$405.50 for the manipulation, we estimated the total cost of outpatient visits to be AU$1405.7.[4] The occupational therapy cost for the CCH group was AU$164.60 including the cost of splinting and other materials.

The overall total average cost including surgical and outpatient follow up in a single-digit fasciectomy was AU$6155.86. The overall total cost for CCH was AU$2589.07. The total average surgical cost for all 38 patients was AU$175,165.00. This reveals a potential saving of AU$119,698.00 during our one-year study period (**Table 3**). While CCH was originally indicated for use in single-finger contracture only, Verheyden has reported the safety and efficacy of one vial of CCH for treatment of contracture of two fingers thereby extending the use and possibly creating additional savings.[5]

Discussion

Fasciectomy has been the mainstay of treatment for many years with some studies supporting better efficacy and a greater mean magnitude of correction for digital contractures.[6] There continues to be much debate in the literature about the long-term outcome of CCH and its place in Dupuytren's treatment. A large systematic review by Sanjuan-Cerveró and colleagues encompassing over 50 studies and 4622 patients demonstrated a satisfactory response to CCH treatment in the short- and medium-term.[7]

Zhou and colleagues' study showed that CCH was not significantly different from fasciectomy in reducing MCP joint contractures, whereas PIP joint contractures showed slightly better reduction following limited fasciectomy.[8] As far as long-term

outcome is concerned, Peimer and colleagues' five-year data on efficacy of CCH has revealed a 47 per cent recurrence rate with CCH injections and this is comparable with reports of surgical fasciectomy.[9]

Cost-effectiveness of CCH has been studied in other countries with reports favouring injection treatment. In a prospective study on 40 patients in the UK, Mehta and colleagues reported an average cost of partial fasciectomy to be substantially higher at GBP£7115 compared to GBP£2110 in the CCH group, with a potential saving of GBP£5000 per patient. They also found that the CCH group required less physician and physiotherapist follow up.[10] In Spain, Cervero and colleagues did a comparison of 48 single or double digit fasciectomies over three years with 43 CCH injections over seven months. They demonstrated a total saving of 29–51 per cent depending on hospital admission and additional allied health requirements.[11] Likewise, another study in the USA found that treatment with one CCH injection cost 33 per cent less than fasciectomy with equivalent efficacy at six weeks regarding reduction in contracture. The total treatment cost for CCH was US$1418 and for fasciectomy US$2102.[12] Chung and colleagues undertook a cost-utility analysis comparing different treatments for Dupuytren's disease. In their model, open partial fasciectomy is not cost-effective but CCH injection is when priced less than US$945.[13]

Conclusion

Our study compares the actual cost of single-digit surgical fasciectomy in a retrospective cohort with the cost of CCH in a prospective group. Our cost calculation includes all aspects of care: medication, procedure and therapy. Our findings suggest that CCH injection treatment has a substantially lower cost when compared to surgery for management of single-digit Dupuytren's contracture. It is substantially cheaper not withstanding indirect costs to the patient for expenses related to fewer clinic visits and possible earlier recovery as suggested by fewer therapy visits. Additionally, by shifting the treatment delivery to the outpatient, CCH treatment increases the availability of theatre for other surgical procedures in a system that is already burdened by the pressures of long surgical waiting times. Our highest cost variable in our fasciectomy analysis was theatre costs.

Our study design has some weaknesses. The surgical group cost was calculated retrospectively and while we only calculated costs related to single-finger contracture, the severity of disease in the two cohorts may not be the same. It is also possible that there is an inherent bias in selecting patients with milder forms of contracture for CCH treatment. Nevertheless, the injection costs are lower than surgery. Additionally, we only report on the immediate outcome of the injection and have not reported on efficacy in the medium- to long-term.

In conclusion, our study highlights the substantially lower total cost of CCH injection for management of single-digit Dupuytrens contracture when compared with surgical fasciectomy. Even accounting for the relatively high cost of the medication, the CCH pathway is cheaper, can be delivered in the outpatients department and patients require less occupational therapy and allied services. The increased availability of operating rooms for other procedures is another vital saving to the public health service. There remains a role for surgery in patients with Dupuytren's contractures that are severe or involve multiple fingers. Our study suggests that healthcare services in Australia should consider making funding available for CCH treatment as an alternative to surgery in selected patients.

Disclosures

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