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Overtreatment of displaced midshaft clavicle fractures

A survey of hospitals in Sweden, Denmark, and Finland

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Background and purpose — The best treatment for displaced clavicle fractures has been debated for decades. Operative treatment has become more common. However, several randomized trials comparing non-operative and operative treatment have not shown any compelling evidence in favor of surgery. We identified the preferred treatment of displaced midshaft clavicle fractures at public hospitals in 3 countries in Scandinavia.

Patients and methods — A purpose-made multiple-choice questionnaire in English was sent to all public hospitals in Denmark, Sweden, and Finland. This was addressed to the orthopedic surgeon responsible for treatment of clavicle fractures, and completed questionnaires were obtained from 85 of 118 hospitals.

Results — In the 3 countries, 69 of the 85 hospitals that responded would treat displaced clavicle fractures operatively. Clear criteria for treatment allocation were used at 58 of the hospitals, with the remaining 27 using individual assessment in collaboration with the patient. Precontoured locking plates were mostly used, placed either superiorly (64/85) or anteriorly (10/85).

Interpretation — Displaced midshaft clavicle fractures are mainly treated operatively in Sweden, Denmark, and Finland. This treatment is not supported by compelling evidence.

The best treatment method for displaced clavicle fractures (Figure 1) has been debated for decades. A recent Cochrane review concluded that evidence is still limited regarding the choice of optimal treatment (Lenza et al. 2013).

Traditionally, a non-operative approach to treating all types of clavicle fractures has been the gold standard. This tradition is probably based on historical reports of non-union rates of less than 1% (Neer 1960). With non-operative treatment of displaced fractures, the clavicle unites in a malunited position, which was suggested earlier to be of radiological interest only (Neer 1960). However, starting in the 1990s, several studies began to find non-union rates considerably higher than first



Figure 1. A typical displaced midshaft fracture with a displacement of more than 1 bone width, some degree of shortening, and several inter-mediary fragments.

reported and also unsatisfactorily results following malunited fractures (Hill et al. 1997, Nowak et al. 2005, Zlowodzki et al. 2005). Several operative methods have gradually been introduced, ranging from the use of wires and external fixators to internal plating and nailing. Nowadays, precontoured locking plates and intramedullary nails are mostly used, and the results reported have been that there are few complications and high union rates (Fridberg et al. 2013). Although several randomized trials have been performed comparing non-operative and operative treatment, the evidence in favor of operative treatment is not compelling—and therefore routine operative treatment is not recommended, even though it appears to be a trend (Lenza et al. 2013, Robinson et al. 2013).

We identified how patients with displaced midshaft clavicle fractures (by more than one bone width) are treated according to surgeon preference in public hospitals in 3 Nordic countries. We also determined the radiological parameters, fracture-related parameters, and patient-related parameters used for treatment allocation.

Patients and methods

The study was questionnaire-based and cross-sectional. A

purpose-made multiple-choice questionnaire in English was sent to all public hospitals in Denmark, Sweden, and Finland. These 3 countries were chosen because their healthcare systems are comparable, and the populations of the countries do not differ substantially in terms of ethnic distribution, socio-economic status, and predisposing environmental conditions. An English-based questionnaire was used to circumvent the language differences in the 3 countries and the possible bias related to forward-backward translation. Only public hospitals were chosen, as fractures are mainly treated at these hospitals in the 3 countries. Possible hospitals were identified based on the local knowledge of the author associated with each particular country, and information from the country-specific orthopedic society. The orthopedic departments of the hospitals identified were contacted electronically. Each department was asked to identify the orthopedic surgeon responsible for clavicle fracture treatment and to have this person fill in the questionnaire. If there was no response within 4 weeks, another request was sent electronically. This was then followed by telephone contact after another 4 weeks if there was still no response.

The questionnaire was composed of 17 multiple-choice items covering 3 topics: 1) general aspects of diagnostics and patient involvement in treatment, (2) treatment allocation, including choice of treatment and parameters important for allocation (Figure 2, see Supplementary data), (3) follow-up regimes, regardless of kind of treatment. The 17 items were supplemented with 6 case reports, where the choice of non-operative or operative treatment had to be determined (Table 2).

In Denmark and Finland, the questionnaires were collected from April 2012 to November 2012, and in Sweden from November 2013 to March 2014. The responses to the questionnaire were collected from 88 of 118 hospitals (giving a response rate of 75%). 3 of the 88 hospitals that responded did not treat acute clavicle fractures and were excluded, leaving 85 for further analysis. Inclusion of hospitals across the 3 countries was: 42/59 in Sweden (3 excluded because they did not treat acute clavicle fractures), 21/21 in Denmark and 25/38 in Finland.

In order to relate the answers from the questionnaires to reality, we extracted data on all patients with a clavicle fracture who were primarily treated surgically and registered in the Danish Fracture Database from October 2012 to the end of December 2013. The patients were grouped according to the anatomical site of the fracture and data related to need for and type of secondary surgical intervention was extracted.

Statistics

All variables were categorical and are presented as numbers and frequencies. The differences between the 3 countries or between cases were analyzed using the chi-squared test.

Table 1. Factors important for allocation of operative treatment at the 80 hospitals that could consider operative treatment based on specific risk factors. Values are number of hospitals

	The factor is a significant criterion for treating operatively at the specific hospital:	
	Yes	No
Fracture displacement by more than 1 bone width	80	0
Fracture shortening by more than 20 mm	71	9
Presence of one or more larger intermediary fragments	57	23
Presence of profound fracture angulation without displacement	19	61
Patient age	20	60
Smoking habits	20	60
Alcohol abuse	54	26
Severe comorbidity (ASA 3 or more)	63	17

Results

In the 3 countries, 69 of the 85 hospitals preferred to treat displaced clavicle fractures operatively. There were no statistically significant differences between countries regarding treatment preferences ($p = 0.3$). Clear criteria for treatment allocation were used in 58 of the hospitals, with the remaining 27 using individual assessments in collaboration with the patient. A valid set of written instructions for treating displaced mid-shaft clavicle fractures was used in 44 of the 85 hospitals.

Factors important for allocation of operative treatment

At 5 hospitals, fracture characteristics such as displacement (of greater than one bone width), 1 or more intermediary fragments, or shortening (> 20 mm) were not relevant in relation to choice of treatment, as all the fractures were treated non-operatively. In the remaining 80 hospitals, degree of displacement, shortening, and fragmentation were the most important factors used for treatment allocation (Table 1).

Differences in non-operative treatment regimes

Patients allocated to non-operative treatment were initially treated with a simple sling (60 of the 85 hospitals) or figure-of-8 bandage (7 of the 85 hospitals). In the remaining 18 hospitals, either a simple sling or the figure-of-8 bandage was used based on an individual assessment. Details of the assessment were not provided. Patients who had been treated non-operatively and experienced profound daily pain, and who had no signs of healing, would be offered operative treatment within the first 3 months post-injury at 31 hospitals. At 31 other hospitals, operative treatment would be offered 3–6 months after injury whereas the remaining hospitals would wait for at least 6 months before giving any treatment.

Differences in operative treatment regimes

Precontoured locking plates, placed either superiorly (64/85

Table 2. Preferred treatment of 6 various hypothetical patient cases according to different centers. Values are number of hospitals

	Sweden		The preferred treatment of centers across				all centers	
	Operative	Non-op.	Denmark	Finland	Operative	Non-op.	Operative	Non-op.
Case 1: 30-year-old male, active cyclist. ASA grade 1. High level of daily function. Radiograph shows a midshaft clavicle fracture displaced by approx. 1½ bone width without significant shortening or intermediary fragments.	21	18	8	13	14	11	43	42
Case 2: 32-year-old woman, mother of 3 children. ASA grade 1. Normal level of daily function, does not do sports. Radiograph: same as case 1.	9	30	8	13	3	22	20	65
Case 3: Same woman as case 2. Radiograph shows a midshaft clavicle fracture displaced by approx. 1½ bone width, and approx. 2 cm of shortening and 2 intermediary fragments.	30	9	16	5	19	6	65	20
Case 4 (Figure 1): 62-year-old man. ASA grade 2 (medically treated hypertension). Normal level of daily function. Fell in the garden. Radiograph: same as case 3.	26	13	17	4	11	14	54	31
Case 5 (Figure 1): 62-year-old active woman. ASA grade 2 (medically treated hypertension). High level of daily function. Plays badminton 3 times weekly. Radiograph: same as case 3.	28	11	16	5	17	8	61	24
Case 6 (Figure 1): 62-year-old woman. ASA grade 3 (mild COLD and previous AMI x 2). Smoking daily. Mild impairment of daily function. Lives alone in own home, and manages most daily activities herself. Radiograph: same as case 3.	9	30	8	13	23	2	40	45

ASA grade: American Society of Anaesthesiologists Physical Status Classification System; COLD: chronic obstructive lung disease; AMI: acute myocardial infarction.

hospitals) or anteriorly (10/85 hospitals), were most frequently used. Reconstruction plates (7/85 hospitals) and other implants (e.g. nails/rods; 4/85 hospitals) were used less often.

Case reports (Table 2)

2 cases illustrate the difference in treatment of the same fracture (a simple one, displaced by 1 bone width)—a 30-year-old sports-active male (case 1) and a mother of 3 (case 2) of similar age. The preference for treatment was different between 2 such cases ($p < 0.001$). Comparison of preferred treatment of a simple fracture and preferred treatment of a more complex fracture, as illustrated in the same younger person (case 2 and case 3), also showed a statistically significant difference ($p < 0.001$). The preferred treatment of a complex fracture in older healthy individuals with a normal level of function (case 4) or a high level of function (case 5) was similar ($p = 0.3$). Increased co-morbidity and an active smoking status lowered the preference of treating operatively across Hospitals of Denmark and Sweden (case 6 compared to case 5) ($p < 0.001$). In Finland, the choice of treatment was similar to that in case 5 ($p = 0.08$).

Table 3. Data from the Danish Fracture Database (DFDB) linking primary treatment of clavicle fractures to secondary intervention. Time period: October 2012 to end of December 2013

	No. of primary treated clavicle fracture	No. of secondary interventions
Medial clavicle fractures	7	1
Midshaft clavicle fractures	287	42
Lateral clavicle fractures	64	13
Total	358	56 ^a

^a The 56 secondary interventions were due to: soft tissue pain/irritation ($n = 30$), secondary fracture dislocation ($n = 13$), non-union ($n = 5$), deep infection ($n = 5$), suboptimal osteosynthesis ($n = 2$), and a secondary fracture ($n = 1$).

Data from the Danish Fracture Database (Table 3)

358 clavicle fractures were treated surgically and registered in the database throughout the given time period. 56 patients had to undergo a secondary surgical intervention.

Discussion

This survey of 3 Nordic countries showed that, based on the surgeons' preferences, patients with displaced midshaft clavicle fractures are mainly treated operatively with a locking plate; more than 80% of all hospitals in Sweden, Denmark, and Finland prefer this approach. However, such an approach does not appear to be justified by available evidence—as a recent randomized study on 200 patients provided results that did not support routine operative intervention (Robinson et al. 2013). That report indicated that the only difference in outcome between operative and non-operative treatment was the higher number of non-unions in the non-operative group, with a number-needed-to-treat analysis revealing that 6 had to undergo surgery to prevent 1 non-union. The corresponding number in another study was 8, indicating that an unselective operative approach leads to a large number of patients undergoing unnecessary surgery, as they would have uneventful healing regardless of treatment (Murray et al. 2013). Based on these results, it appears that there is a discrepancy between what is written in the literature and surgeons' preferred treatment—with a risk of overtreatment taking place in Sweden, Denmark, and Finland.

More and more authors argue that the key to optimal treatment of patients with midshaft clavicle fractures is to identify prognostic factors that result in non-union, and primarily treating these patients operatively (Virtanen et al. 2012, Murray et al. 2013, Robinson et al. 2013). Our survey revealed that the degree of displacement, shortening, and fragmentation were the most important factors used by the clinician to allocate treatment. Comorbidity and alcohol abuse also appeared to be important as contraindications for operative treatment, whereas age did not appear to be important (Table 1). A recent review of predictors associated with non-union after midshaft clavicle fractures revealed that the literature on this subject is quite sparse and heterogeneous (Jørgensen et al. 2014). Based on our review and the existing literature, it appears that displacement is the single most reliable factor, with limited but not compelling evidence supporting shortening, age, and fragmentation as predictors of non-union. However, this information is of little use in daily practice, as the literature also shows that an unselective operative approach to all displaced fractures would lead to overtreatment (Murray et al. 2013, Robinson et al. 2013). Our results also revealed that in most hospitals, smoking was not an important factor when allocating treatment. A recent prospective study investigating 941 adults with displaced midshaft clavicle fractures revealed that smoking was the strongest risk factor for non-union, with an odds ratio of 4 compared to non-smokers (Murray et al. 2013). Again, there appears to be a discrepancy between the use of risk factors in daily practice and in the literature. With only slightly more than half of the hospitals that responded using valid written instructions, it seems that there is a need for an evidence-based algorithm/set of instructions for treatment allocation.

Concerning treatment regimes, use of the simple sling exceeds use of the figure-of-8 bandage when treating non-operatively. This is in line with the results of the few studies that have compared these 2 modalities, as the simple sling appears to provide better patient satisfaction and better pain relief (Andersen et al. 1987, Ersen et al. 2015). Concerning operative treatment, the precontoured locking plates are mostly preferred in these 3 Nordic countries. This approach is generally accepted and supported by several studies that have shown advantages of locking plates over non-locking plates—both biomechanically and clinically (Pai et al. 2009, Eden et al. 2012).

Delayed union and non-union are not uncommon after non-operative treatment of displaced midshaft fractures (Robinson et al. 2004, Murray et al. 2013), and they are often treated operatively as they often result in pain and limitations of daily living. One-third of the hospitals wait at least 6 months (6 months is by many a threshold of defining an unhealed fracture as a non-union) before treating patients with pain and no signs of healing. Another one-third of the hospitals treat these patients within the first 3 months (the period when normal healing would be expected). The optimal threshold is definitely arbitrary, but waiting 6 months or more seems unacceptable for a person who is unable to work or to perform normal activities of daily living. However, patients with a low workload and few restrictions in their daily function could wait a minimum of 6 months, as earlier studies have demonstrated a 90% healing rate at 6 months in those with an unhealed fracture at 3 months of follow-up (Robinson et al. 2004).

Although more than 80% of all hospitals preferred operative treatment to non-operative treatment, the final allocation appeared to be individualized and based on judgement of risk factors, as the case reports revealed that the treatment varied greatly according to fracture complexity and level of daily activities and function (Table 2). The hospitals appeared to be more likely to treat operatively if a person had a higher level of daily function than individuals with a normal level of daily function. The beneficial effect of treating people with a high level of daily activity has not been investigated, but it seems rational and has been advocated by some studies (Canadian Orthopaedic Trauma Society 2007). The case reports also revealed that a more complex fracture (displacement with intermediary fragments and shortening) considerably enhances the chance of having surgery irrespective of age, daily function, smoking status, or considerable comorbidity. The evidence supporting operative treatment of complex fractures is not compelling, though a prospective study found that displacement (no bony contact) and/or comminution is a great predictor of consistent symptoms in terms of pain at rest and lack of full recovery after 10 years (Nowak et al. 2004). The non-union rate of these complex midshaft fractures treated non-operatively has recently been reported to be as high as 29% (Ban and Troelsen 2016). With such a high non-union rate and the profound symptoms related to these fractures, it

could be argued that patients with these fractures should be treated operatively. However, most of these patients would probably heal uneventfully with non-operative treatment and the number needed to treat—or in this case harm—would still be unacceptably high, when related to reported adverse events associated with operative treatment (9% infection rate, 14% skin and nerve problems, and 8% implant irritation resulting in implant removal (Lenza et al. 2013)). Furthermore, data from the Danish Fracture Database indicate that every sixth patient with a clavicle fracture who is primarily treated operatively needs to undergo a secondary operative intervention (Table 3). Thus, the results of our survey, with reported preferences of treating complex fractures operatively ranging from 47% to 76%, still indicate that overtreatment takes place in these countries.

The results of our survey should be interpreted with caution, as they come from a purpose-made questionnaire that had not been tested regarding reliability or validity, and have been based on a single surgeon's response from each hospital. The answer could possibly reflect his/her own preferences and not the overall preference of the department, potentially introducing information bias. Furthermore, the preferences reported do not necessarily reflect the true clinical practice, and thereby the real surgical frequency. Another concern regarding this study was the possible selection bias related to the identification of hospitals and the response rate of 75%. Despite the obvious limitations of this kind of study, the discrepancy between surgeons' preferences and what is found in the existing literature is a concern regarding potential overtreatment. An evidence-based algorithm/model for treating these fractures is desirable in order to optimize treatment.

Supplementary data

Figure 2 is available on the Acta Orthopaedica website (www.actaorthop.org), identification number 9304.

IB and AT designed the study and the purpose-made questionnaire. IB, JN, and KV were responsible for identifying and contacting centers in their respective countries. IB performed the analysis and prepared the manuscript. All the authors took part in revision and approval of the final manuscript.

No competing interests declared

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