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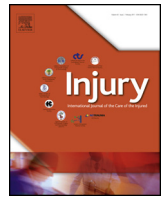
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Clinical outcomes and predictors of patient satisfaction in displaced midshaft clavicle fractures in adults: Results from a retrospective multicentre study



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ABSTRACT

Background: The optimal treatment of displaced midshaft clavicle fractures (Robinson Type 2B1 & 2B2) in adults remains controversial. Little is known about patient satisfaction with treatment for this type of injury. The purpose of this study was to compare clinical outcomes and explore predictors of patient satisfaction after nonoperative and direct-operative treatment of displaced midshaft clavicle fractures in adults.

Methods: A retrospective multicentre study was conducted. Clinical data were retrieved from electronic patient charts. A questionnaire informing on current subjective function (QuickDASH), pain levels (VAS), health-related quality of life (Eq-5D-5L), impact on employment and satisfaction with treatment results was sent to all patients. Univariate and multivariate linear regression was performed to identify predictors of satisfaction.

Results: A total of 278 patients were identified (nonoperative n = 150, direct-operative n = 128). 67% of eligible patients returned the questionnaire. Median questionnaire follow-up was 2.1 years. No differences were found between groups for QuickDASH, Eq-5D-5L or pain VAS scores. Impaired union was observed in 13.2% of nonoperative cases vs. 2.3% in the direct-operative group. Patients in the nonoperative group could resume work after a median of 30.0 days, compared to 13.5 days in the direct-operative group. Patient satisfaction was higher in the direct-operative group, 8/10 vs. 7/10 for overall treatment results respectively. Patients' rating for the level of shared decision-making was the main predictor of overall satisfaction.

Conclusion: Direct-operative management led to higher patient satisfaction, despite similar long-term patient reported outcomes with nonoperative treatment. Patients' rating for the level of shared decision-making was the main predictor of overall satisfaction. This study highlights the need to enhance communication to facilitate shared decision-making.

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Introduction

Clavicle fractures constitute approximately 2.6 to 10% of all fractures in adults and about 35% of all fractures that occur in the shoulder region. About 80% of clavicle fractures occur in the midshaft, most of which are displaced [9,10]. There is an on-going debate on whether to prefer nonoperative or operative treatment for this type of injury. Earlier work shows that 31% of non-operatively-treated patients with displaced midshaft clavicle fractures were dissatisfied with the treatment result[5]. More

recently, patient satisfaction was shown to be higher among operatively treated patients than among their nonoperatively-treated counterparts [1,12]. Little is known about the causes of these differences in satisfaction. The purpose of this study was to compare clinical outcomes and explore predictors of patient satisfaction after nonoperative and direct-operative treatment of displaced midshaft clavicle fractures in adults from a community hospital population.

Materials and methods

Design

A retrospective multicentre study was conducted in three community hospitals in the northern part of The Netherlands. The

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institutional review board issued a waiver for this study (medical ethical committee of University Medical Center Groningen, the Netherlands (2014/581)). The study was conducted in compliance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement and adhered to guidelines of good clinical practice. All patients with an acute (< 4 weeks old) displaced midshaft clavicle fracture (classified as Robinson Type 2B1 or Robinson Type 2B2[10], aged 18–65 years, and presenting between 2011 and 2014 were included. Patients with non-traumatic causes or bilateral fractures, or those mentally or physically incapable of participating in the follow-up were excluded. All medical charts and clinical notes were reviewed and the following items were retrieved: age, gender, affected side, co-injuries, treatment details, length of follow-up and complications. Inherent to the retrospective nature of the study it was chosen to define impaired union as failure of radiological union progression longer than three months, or at least two months with little or no callus observed during surgical reconstruction.

Measurements

A questionnaire was sent to all eligible patients. The shortened Disabilities of the Arm, Shoulder, and Hand (QuickDASH) score was used to assess subjective function[2]. Health-related quality of life was measured using the EuroQol group 5D tool (Eq-5D-5L)[3]. Current pain levels were assessed using a visual analogue score. Customised questions informed on patient demographics and work absenteeism. Overall satisfaction with treatment results was measured using a numerical rating scale ranging from 1 to 10, with 10 representing maximum satisfaction. Separate ratings probed into satisfaction with current shoulder function, care provided at the emergency room and level of shared decision-making. Open-ended questions were added to encourage additional comments and suggestions (see Appendix A).

Data analysis

Patients were classified into either nonoperative or direct-operative treatment groups. Nonoperative treatment was described as treatment of a fracture with a sling or collar-and-cuff. Patients who underwent delayed surgery after initial nonoperative treatment for a minimum of 4 weeks were recorded as non-operatively-treated patients analogue to an intention-to-treat principle. Direct-operative treatment was described as operative reduction and internal fixation (ORIF) within 4 weeks of injury. All operations were performed using locking plates. The window of 4 weeks was chosen to be inclusive of patients with an acute fracture presenting with a delay to the outpatient fracture clinic. Normally distributed continuous variables are presented as averages with

standard deviations given in brackets and were analysed using Student's *t*-test. Non-normally distributed continuous variables are presented as medians with the first and third quartiles given within brackets and analysed using the Mann-Whitney *U*-test. Categorical parameters are presented with counts and percentages given within brackets and were analysed using the chi-squared test. Predictors for satisfaction with overall treatment result were identified using a backward stepwise multivariable linear regression model. The model included all variables that showed a *p*-value < 0.25 upon univariate regression analysis. The model with the highest R^2_{Adjusted} value was retained. All analysis were conducted with SPSS v. 22.0. A *p*-value < 0.05 (two-sided) was considered to be statistically significant.

Results

Baseline characteristics

A total of 404 clavicle fractures were included, 278 (68%) of which were displaced (classified as Robinson 2B1 or 2B2). 150 (54%) were listed to the nonoperative group, 27 (18%) patients underwent delayed operative treatment. 128 (46%) patients received direct-operative treatment. 11 patients in the non-operative group and 6 patients in the direct operative group could not be contacted because they had either moved address, or were medically incapable of completing the questionnaire. Overall questionnaire response amounted to 67% (nonoperative *n* = 94, operative *n* = 81).

Median questionnaire follow-up was 2.1 years. Treatment groups were comparable in terms of baseline patient characteristics (Table 1). No open-fractures were registered. Fractures in the direct-operative group had more shortening on presentation, $28.9 \pm \text{SD}16.4$ vs. $24.7 \pm \text{SD}15.6$ ($p < 0.05$)mm respectively. Co-fractures were more prevalent in the direct-operative group, 19 (14.8%) vs. 11 (7.3%) ($p < 0.05$) respectively.

Clinical outcomes

Impaired union was registered in 20 (13.3%) patients with nonoperatively-treated fractures and three patients (2.3%) in the direct-operative group. In the non-operative group, clinically relevant malunion requiring osteotomy was reported in three cases. Refractures requiring plate fixation were reported in three conservatively treated patients. One case was complicated by a costoclavicular compression syndrome. More complications were reported in the direct-operative group ($p < 0.001$). Hardware failure necessitating re-surgery was seen in five (3.9%) operative cases. No refractures were registered. One surgery was complicated by a deep infection requiring additional surgical treatment. On

Table 1
Baseline characteristics.

| | Non-operative N = 150 | Direct-operative N = 128 | <i>p</i> -Value |
|---|-----------------------|--------------------------|-----------------|
| Age (years) ¹ | 42.4 (25.6–55.8) | 39.7 (23.6–50.4) | 0.125 |
| Male gender (%) ² | 117 (78.0) | 111 (85.9) | 0.088 |
| Comorbidities (%) ² | 12 (8.0) | 12 (9.4) | 0.684 |
| Smoker (%) ² | 29 (28.2) | 21 (24.7) | 0.594 |
| Clavicle shortening on presentation (mm) ³ | 24.7 (SD15.6) | 28.9 (SD16.4) | 0.027 |
| Fracture dominant side (%) ² | 54 (36.0) | 43 (33.6) | 0.644 |
| Polytrauma (%) ² | 11 (7.3) | 19 (14.8) | 0.044 |
| Delay from injury to surgery (days) ¹ | 64.0 (31–64) | 6.0 (2.0–10.0) | <0.001 |
| Questionnaire response (%) ² | 94 (67.6) | 81 (66.4) | 0.463 |
| Median questionnaire follow-up (days) ¹ | 768.0 (455.8–1233.8) | 798.0 (544.0–1114.0) | 0.848 |

¹ 17 patients were unavailable for follow up.

¹ Data presented as median (first quartile – third quartile).

² Data presented as count (percentage).

³ Data presented as average (standard deviation).

average, 43.2% of all operatively treated patients had their hardware removed. Duration of clinical follow-up was longer in operatively treated patients, with a median of 203.0 (50.0–344.0) days vs. 50.0 (25.8–106.8) days in nonoperatively treated patients (Table 2).

Patient-reported outcomes

Patients in the direct-operative management returned to work after a median of 13.5 (5.0–35.5) days compared to 30 (6.0–44.0) days for the nonoperative group ($p < 0.001$). No differences between the groups in terms of reported subjective function, pain levels or health-related quality of life scores were observed (Table 3).

Patient satisfaction

Table III shows patients' satisfaction with different dimensions of healthcare delivery and treatment outcomes. On a numerical rating scale (NRS), patients in the direct-operative group were more satisfied with the overall treatment result, at 8.0 (7.0–9.0) vs. 7.0 (6.0–8.0) respectively ($p < 0.001$) (Table 3). Separate ratings show similar satisfaction with the care at the emergency room and cosmetic appearance of the shoulder after treatment for both groups. Higher satisfaction for the level of shared decision-making was seen in the direct-operative group, at 8.0 (7.0–9.0) vs. 7.0 (5.0–8.0) respectively. Patients' rating for current perceived function was also higher in the direct-operative group, 8.0 (7.0–9.0) vs. 7.0 (6.0–8.0) ($p < 0.01$). Table 4 reports the predictors for overall satisfaction. The P–P plot and scatterplot of standardised predicted values show that the data met the assumptions of homogeneity of variance and linearity. The explanatory model demonstrated that patients' ratings for level of shared decision-making, satisfaction with current shoulder function and male gender remained significant in predicting overall satisfaction with the treatment result ($F(3, 162) = 108.1, p < 0.01, R^2 = 0.67, R^2_{\text{Adjusted}} = 0.66$).

Discussion

In this retrospective study similar scores for subjective shoulder function, pain and health-related quality of life were found between nonoperative and direct-operative treatment of displaced midshaft clavicle fractures in adults. This notion is consistent with other studies reporting no long-term functional benefit of operative treatment[13]. Patients in the direct-operative group did have a shorter return-to-work period, in line with previous studies[1].

Among the study aims were comparing patient satisfaction and exploring predictors of satisfaction. This study confirms superior

patient satisfaction in favour of direct-operative reconstruction, as shown elsewhere[1]. In our explanatory model, patient ratings for level of shared decision-making and current shoulder function were major predictors and gender a minor predictor for overall satisfaction. Open remarks provided a clue as to why patients in the nonoperative group reported lower satisfaction with level of shared decision-making. Twenty patients stated that they did not perceive a sling as a treatment, or would have liked more information about their condition. Both statements indicate poor patient-doctor communication. Failure to communicate information about the condition and treatment options is shown to be the most important source of patient dissatisfaction[6]. Without adequate communication it is likely that patients' expectations were not met, or that unrealistic expectations could not have been corrected, resulting in dissatisfaction, especially in nonoperatively-treated patients. Surgeons should continue to explore patient perspectives and provide realistic expectations of treatment options to allow for full shared decision-making. Remarkably, return to work was not a significant predictor in our multivariate regression model. This suggests that, contrary to what has been previously suggested[12], early return to function is not the most important factor for patients in our study.

The present study suggests that patient satisfaction with overall treatment result is affected by both subjective health outcomes and patient involvement during initial presentation. Care should therefore be taken not to equate patient satisfaction directly with patient treatment preferences in a search for defining the optimal treatment strategy for this injury.

The study is limited by its retrospective design. Patients in the direct-operative group had significantly more shortening of fractures and more co-injuries than patients in the nonoperative group. This was expected, as both parameters are considered relative indications for surgery in our practice. The effect of underreporting is probably minor, as the reported complication rates and outcomes are consistent with other studies. We were forced to group delayed union and nonunion together leading to an impaired union rate of 13.2% in the nonoperative group compared to 2.3% in the operative group. This is similar to a meta-analysis reporting 15% and 2% respectively[14]. Despite the design, both treatment groups were of comparable size and demographic characteristics, reflecting the current lack of consensus on management of this injury. We achieved a fair response rate of 67% across both treatment groups, comparable to other retrospective clavicle fracture populations [1,8]. We were unable to ascertain patient satisfaction among non-responders. We however predict the influence of non-response to be limited, as non-responders were represented in proportions equal to responders in the treatment groups, had equal time to questionnaire follow-up and were comparable in terms of patient baseline characteristics. Due

Table 2
Technical outcomes.

| | Non-operative N = 150 | Direct-operative N = 128 | p-Value |
|--|-----------------------|--------------------------|---------|
| Length of clinical follow up (days) ¹ | 50.0 (25.8–106.8) | 203.0 (50.0–344.0) | <0.001 |
| Any type of complications (%) ² | 28 (18.7) | 70 (54.7) | <0.001 |
| -Impaired union (%) ² | 20 (13.2) | 3 (2.3) | 0.024 |
| -Refracture (%) ² | 3 (2.0) | – | – |
| -Malunion (%) ² | 3 (2.0) | – | – |
| -Neurovascular compression (%) ² | 1 (3.7) | – | – |
| -Hardware failure (%) ² | – | 5 (3.9) | – |
| -Hardware removal (%) ² | 9 (33.3) | 58 (45.3) | 0.227 |
| -Wound infection (%) ² | – | 1 (<1) | – |

[#] Each patients could experience multiple complications.

¹ Data presented as median (first quartile – third quartile).

² Data presented as count (percentage).

Table 3
Patient reported outcomes and satisfaction.

| | | Non-operative N = 150 | Direct-operative N = 128 | p-Value |
|---------------------------|--|-----------------------|--------------------------|---------|
| Patient reported outcomes | Current average pain (VAS) | 0.0 (10.0–1.4) | 0.0 (0.0–2.0) | 0.428 |
| | Current subjective function (QuickDASH) | 2.3 (0.0–14.2) | 2.3 (0.0–9.1) | 0.640 |
| | Health Related Quality of Life (Eq-5D-5L) | 100.0 (83.0–100.0) | 100.0 (87.4–100.0) | 0.287 |
| | Return to work (days) | 13.5 (5.0–35.5) | 30 (6.0–44.0) | <0.001 |
| Patient satisfaction | Overall satisfaction treatment result (NRS 1–10) | 7.0 (6.0–8.0) | 8.0 (7.0–9.0) | <0.001 |
| | Treatment at the ED (NRS 1–10) | 8.0 (7.0–9.0) | 8.0 (7.0–9.0) | 0.483 |
| | Shared decision making (NRS 1–10) | 7.0 (5.0–8.0) | 8.0 (7.0–9.0) | <0.001 |
| | Current shoulder function (NRS 1–10) | 7.0 (6.0–8.0) | 8.0 (7.0–9.0) | 0.003 |
| | Cosmetic appearance (NRS 1–10) | 7.0 (5.0–9.0) | 8.0 (6.0–9.0) | 0.323 |

All data presented as median (first quartile – third quartile)

Table 4
Univariate and multivariate linear regression analysis for predictors of overall satisfaction.

| | | Univariate result | | | Multivariate result [‡] | |
|---------------------------|-------------------------------------|-------------------|--------|---------|----------------------------------|---------|
| | | R ² | B | p-Value | Beta | p-Value |
| Patient characteristics | Age | 0.007 | 0.038 | 0.278 | | |
| | Gender | 0.044 | 0.210 | 0.006 | 0.107 | 0.022 |
| | Comorbidities | 0.003 | 0.051 | 0.506 | | |
| | Physical demanding work | 0.000 | 0.021 | 0.793 | | |
| | Level of education | 0.002 | 0.048 | 0.538 | | |
| Treatment effects | Length of questionnaire follow up | 0.002 | 0.040 | 0.607 | | |
| | Length of clinical follow up | 0.001 | –0.025 | 0.745 | | |
| | Work absenteeism | 0.030 | –0.173 | 0.029 | | |
| | Impaired union | 0.031 | –0.176 | 0.021 | | |
| | Complications | 0.004 | 0.066 | 0.391 | | |
| Fracture characteristics | Delay from injury to surgery | 0.074 | –0.271 | 0.011 | | |
| | Clavicle shortening on presentation | 0.027 | –0.166 | 0.040 | | |
| | Fracture at dominant side | 0.002 | 0.042 | 0.586 | | |
| Patient reported outcomes | Polytrauma | 0.004 | –0.065 | 0.398 | | |
| | Current function (qDASH) | 0.101 | –0.319 | <0.001 | | |
| | HrQoL (Eq-5D-5L) | 0.052 | 0.227 | 0.003 | | |
| Patient satisfaction | Current average pain (VAS) | 0.042 | –0.204 | 0.008 | | |
| | Satisfaction ED | 0.107 | 0.327 | <0.001 | | |
| | Satisfaction shared decision | 0.538 | 0.734 | <0.001 | 0.518 | <0.001 |
| | Satisfaction cosmetic | 0.286 | 0.535 | <0.001 | | |
| | Satisfaction current function | 0.463 | 0.681 | <0.001 | 0.391 | <0.001 |
| | | | | | R ² = 0.67 | |
| | | | | | R ² Adjusted = 0.66 | |
| | | | | | F(3, 162) = 108.1 | |
| | | | | | p < 0.001 | |

[‡] Items with p-values < 0.25 upon univariate analysis were retrained for the multivariable analysis.

to lacking statistical power, no effort was made to stratify results according to fracture type or timing of surgery. Larger studies should address these issues.

In this study only a subset of variables were used to explore patient satisfaction. Donabedian suggests that satisfaction with medical care be classified under three categories: structure, which refers to material resources (e.g. facilities, equipment and personnel); process, which refers to the act of giving and receiving care (e.g. empathy, information given); and outcome, referring to the effects on the health of care given of the receiver (e.g. union, complications, subjective function) [4]. Previous studies in musculoskeletal care have illustrated that all categories may impact satisfaction. Elsewhere, it was shown that spending time with patients and conveying empathy seem to be important for the patient experience[11]. Also non-patient-surgeon factors like outpatient clinic waiting times may influence overall satisfaction[7]. Future studies should expand on factors potentially influencing patient satisfaction after treatment for displaced midshaft clavicle fractures.

Conclusion

Direct-operative management of displaced midshaft clavicle fractures led to higher patient satisfaction, despite similar long-term patient-reported outcomes with nonoperative treatment. Patients' rating for level of shared decision-making was found to be the main predictor of overall satisfaction. This study highlights the need to enhance communication to facilitate shared decision-making.

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Conflict of interests

The authors state that no conflicts of interest, financially or otherwise, exist.

Appendix A. Custom-made questionnaire.

Patient characteristics.

1. What is your highest educational level?

No education.
 Primary school.
 Secondary school.
 Intermediate vocational education (MBO).
 University or Professional Education (HBO).
 University (WO).

2. Are you left- or right-handed?

Right.
 Left.

3. Did you smoke at the time of injury?

No.
 Yes.

4. Did you participate in sports before your injury?

No.
 Yes.

Pain

5. Could you grade your current average pain around your shoulder as you experienced it in the last week?

No pain at all

Unbearable pain

Satisfaction

Please rate your satisfaction with the items stated below, varying from 1 (very dissatisfied) to 10 (very satisfied)

1. Treatment at the Emergency Room 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

2. Involvement in treatment decision 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

3. Current shoulder function on the same side of the injury 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

4. Cosmetic appearance (bump/scar) 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

5. Overall satisfaction with treatment result 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

6. What went well in the treatment of your broken collarbone?

7. What could have been better in the treatment of your broken collarbone?

Impact on employment

1. What work did you do at the time of injury?

2. How many days were you unable to work due to your broken collarbone? (number) _____ days not worked

If you did not have any paid labour, please count the number of days that you were unable to do voluntary work or activities around your house.

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