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Operative treatment of displaced midshaft clavicle fractures: has randomised control trial evidence changed practice patterns?

Prism Schneider,[1] Richard Bransford,[2] Edward Harvey,[3] Julie Agel[2]

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[1]Foothills Medical Centre, University of Calgary, Calgary, Alberta, Canada
[2]Orthopaedics, Harborview Medical Center, Seattle, Washington, USA
[3]Orthopaedics, Montreal General Hospital, Montreal, Quebec, Canada

Correspondence to
Julie Agel; bagel@uw.edu

ABSTRACT

Objectives To determine if level 1 evidence from a landmark trial changed practice patterns for treatment of patients with displaced midshaft clavicle fractures.

Design Retrospective cohort study.

Setting Two level 1 trauma centres.

Participants Displaced midshaft clavicle fractures.

Results 686 patients met inclusion criteria. The pretrial cohort (n=108) was 68.5% male, with a mean age of 37.7 (±13.9) years. The post-trial cohort (n=578) was 76.1% male, with a mean age of 41.9 (±12.7) years. There was nearly a 10-fold increase in the patients treated with openreduction and internal fixation (ORIF) in the post-trial cohort (34.1%) compared with the pretrial cohort (3.7%) (p<0.001). Patients in the post-trial cohort were more likely to undergo ORIF if they were <40 years (OR=2.2; 95% CI 1.53 to 3.10), if their Injury Severity Score was >9 (OR=1.6; 95% CI 0.89 to 2.99) or if they were treated at a centre that participated in the *Canadian Orthopaedic Trauma Society (COTS)* trial (OR=5.2; 95% CI 3.31 to 8.21).

Conclusions This study demonstrated a significant shift towards more frequent *ORIF* for displaced midshaft clavicle fractures following the COTS trial. Quantifying changes in practice pattern following publication of level 1 evidence is important to further our understanding of the impact large *randomised clinical trails* are having on clinical practice.

Strengths and limitations of this study

- Two level 1 trauma centers.
- Two reviewers at each site.
- Critical look at treatment pattern after publication of a randomised clinical trial (RCT).
- Retrospective nature may not account for factors that influenced treatment decisions.
- Analysis was not part of original RCT design.

INTRODUCTION

Quantifying changes in practice pattern following publication of level 1 evidence is important to further our understanding of the impact large randomised clinical trials (RCTs) are having on clinical practice. One landmark paper presenting new level 1 evidence to the orthopaedic community was an RCT on midshaft clavicle fractures. Midshaft clavicle fractures were historically treated non-operatively. Non-union rates of 1% and negligible functional consequences after conservative management had traditionally been accepted.[1 2] More recent prospective studies reported significant residual impairments in strength and function following nonoperative treatment of displaced midshaft clavicle fractures.[3 4] Significantly higher non-union rates (15%) have been also reported when compared with surgical fixation.[5 6] In 2007, members of the Canadian Orthopaedic Trauma Society (COTS) conducted an RCT comparing open reduction and internal fixation (ORIF) with non-operative management of displaced midshaft clavicle fractures.[7] The findings of this trial were improved functional outcome scores, decreased malunion rates and decreased non-union rates for ORIF compared with non-operative treatment. Two recent meta-analysis of six RCTs comparing operative versus non-operative treatment of midshaft clavicle fractures concluded that operative treatment resulted in a significantly lower non-union rate, significantly lower symptomatic malunion rate and earlier return of function with operative fixation.[8 9] Surgical fixation of displaced midshaft clavicle fractures has also been shown to be cost-effective, with a US$65 000 base case cost per quality-adjusted life-year gained for ORIF of midshaft clavicle fractures.[10]

As the field of orthopaedic surgery strives to achieve evidence-based clinical practice, we are collectively unsure if large clinical trials are changing current practice. Recently, a survey was completed by members of the Canadian Orthopaedic Association to examine the influence of major fracture clinical trials on the practice of individual orthopaedic surgeons.[11] This survey found that the COTS clavicle fixation study[7] was

perceived by most surgeons to be influential in improving patient care and 73% of respondents stated that this RCT changed their practice pattern.[11] However, to date, this perceived change in practice pattern for clavicle fractures has not been quantified.

Several studies are starting to quantify the change in orthopaedic clinical practice following published level 1 evidence. Early attempts include the distal radius acute fracture fixation trial[12] and proximal fracture of the humerus: evaluation by randomisation (PROFHER)[13] randomised control trials. A review of the English Hospital Episode Statistics demonstrated that surgeons appeared to change their practice pattern for distal radius fractures after a large randomised control trial. A survey of British Orthopaedic Surgeons demonstrated the belief that the findings of the PROFHER trial impacted surgeon treatment decisions.

Quantifying changes in practice pattern following publication of level 1 evidence is important to further our understanding of the impact large RCTs are having on clinical practice, duration of time required for practice patterns to change and the longevity of practice pattern changes in the treatment of displaced midshaft clavicle fractures. The aim of this study is to determine if practice patterns have changed since the RCT conducted by the COTS group in January 2007.[7] We hypothesise that there will be a significant increase in the number of displaced midshaft clavicle fractures being treated with ORIF from the time of this publication to present, when compared with treatment of displaced midshaft clavicle fractures prior to this publication. Our secondary aim is to compare practice pattern change between a trauma centre participating in enrolment for the COTS trial and a similar trauma centre not participating in this trial.

Materials and methods

Following institutional review board approval, a retrospective radiographic review was completed by fellowship trained orthopaedic surgeons at two participating level 1 trauma centres, Montreal General Hospital and Harborview Medical Center Seattle, to compare treatment patterns prior to and following the RCT published by COTS in January 2007.[7] Inclusion criteria were based on the original RCT and included patients aged 16–60 years with acute displaced (100% displaced) midshaft clavicle fractures (Arbeitsgemeinschaft für Osteosynthesefragen/Orthopedic Trauma Association (AO/OTA) 15B-1, 15B-2, 15-B3).[14] Eligible patients were identified through prospective orthopaedic trauma registries between January 2001 and December 2014 at each of the two participating centres. Demographic data collected included age, sex, Injury Severity Score (ISS), AO/OTA fracture classification, date of injury and date of treatment. Two cohorts were defined: (1) a pretrial cohort, including 2 years prior to publication (January 2001 to 30 January 2003) and (2) a post-trial cohort, including 7 years postpublication (January 2007 to December 2014), following the publication date of the COTS trial. We did not include the time period where one of the centres was actively enrolling patients into the COTS trial (February 2003 to December 2006), given the randomisation of patients to operative versus nonoperative treatment during this time period. Once included, all available radiographs were reviewed for each patient to capture any treatment group crossover.

One of the centres participated in the COTS trial; therefore, in order to avoid bias, eligible patients with displaced midshaft clavicle fractures during the trial recruitment period (beginning 31 January 2003) were excluded from both centres. All continuous data are presented as mean and SD of the mean. Subgroup analyses of treatment based on sex, age (>40 vs <40 years based on mean age of study population), additional injuries and participating site was performed. Statistical analysis used independent samples T-tests for comparing groups, with significance established at $p<0.05$. ORs were calculated for subgroup using binary logistic regression analysis of treatment based on variables including sex, age (<40 vs >40 years), ISS and pretrial and post-trial (SPSS Advanced Statistics V.22.0). Nominal variables were analysed using χ^2 tests.

Patient and public involvement

There was no patient and pubic involvement.

RESULTS

A total of 686 patients met inclusion criteria (figure 1). The pretrial cohort (n=108) was comprised of 68.5% males, with a mean age of 37.7 (±13.9) years (table 1). The post-trial cohort (n=578) was comprised of 76.1% males, with a mean age of 41.9 (±12.7) years. The mean ISS for the pretrial group was 21.3 (±13.8), compared with the postinjury cohort mean ISS of 25.1 (±13.7) (p=0.01) (table 1). There was no significant difference between groups for sex (p=0.117); however, the pretrial cohort was younger (p=0.005) compared with the post-trial cohort. There were no differences between the participating sites for age (p=0.79) or sex (p=0.80).

There was nearly a 10-fold increase in the patients treated with ORIF for displaced midshaft clavicle fractures

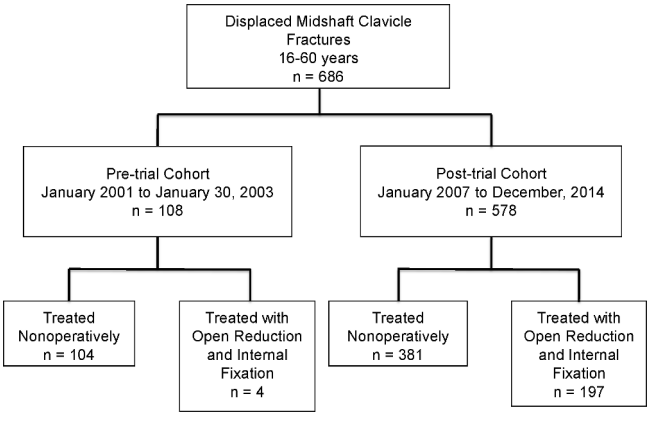

Figure 1 Study consort diagram.

Table 1 Demographic data for pretrial and post-trial cohorts presented as mean and SD

Demographic variable	Pretrial cohort (n=111)	Post-trial cohort (n=578)	P value
Age, years	37.7 (13.9)	41.9 (12.7)	0.005
Sex, male (%)	74 (68.5%)	440 (76.1%)	0.117
Injury Severity Score	21.3 (13.8)	25.1 (13.7)	0.01

Table 2 OR for factors predictive of open reduction and internal fixation in the post-trial cohort

Predictive factor	OR	95% CI
Sex, male	1.0	0.92 to 1.11
Age ≤40 years	2.2	1.53 to 3.10
Injury Severity Score >9 (n=581)	1.6	0.89 to 2.99
Treatment at Clavicle RCT participating centre	5.2	3.31 to 8.21

RCT, randomised controlled trial.

from the pretrial cohort (3.7%) to the post-trial cohort (34.1%) (p<0.001). There was an increased number of clavicle fracture referrals to orthopaedic surgeons from 108 patients from 2001 to 2003 (average of 50 patients per year) prior to the COTS trial, compared with 578 from 2007 to 2014 (average of 72 patients per year) following the COTS publication (figure 2). There was a significant increase in the number of clavicle fractures treated with ORIF in 2007 compared with 2001–2003 (p<0.001).

For patients in the post-trial cohort, the odds of undergoing ORIF was increased if their age was <40 years (OR=2.2; 95% CI 1.53 to 3.10), or if their ISS was >9 (OR=1.6; 95% CI 0.89 to 2.99), indicating an injury in addition to the clavicle fracture; however, there was no increased likelihood of surgical treatment based on sex (OR=1.0; 95% CI 0.92 to 1.11) (table 2). Patients with midshaft clavicle fractures who presented to the hospital with investigators who participated in the COTS trial were more likely to be treated with ORIF, as 66% of patients with displaced clavicles underwent ORIF at the participating study centre compared with 27.2% in the post-trial cohort (OR=5.2; 95% CI 3.31 to 8.21).

Discussion

Quantifying changes in practice pattern following publication of level 1 evidence is important to further our understanding of the impact large RCTs are having on clinical practice, duration of time required for practice patterns to change and the longevity of adopted changes. Since the publication of the COTS trial, there have been additional RCTs in this area; however, the time of publication of the COTS trial was selected as a discreet point in time to allow comparison of practice patterns before and after the trial. This single study was also chosen, as the COTS trial was reported as being influential in improving patient care.[11] Our study demonstrated a significant practice pattern shift in two level 1 trauma centres towards more frequent treatment with ORIF for displaced midshaft clavicle fractures meeting the criteria outlined in the COTS trial. While we cannot draw a direct correlation to the COTS trial and our findings; both these centres were well aware of the trials findings and other supporting literature. This study is not meant to be a definitive measure of adoption of medical evidence, but rather a study to determine if clinicians act on current level 1 evidence. This study suggests that clinicians likely do not wait for publication of clinical practice guidelines, but rather change their practice according to high-quality RCT results. This may indicate that clinicians value the time, energy and expense required to complete a high-quality RCT.

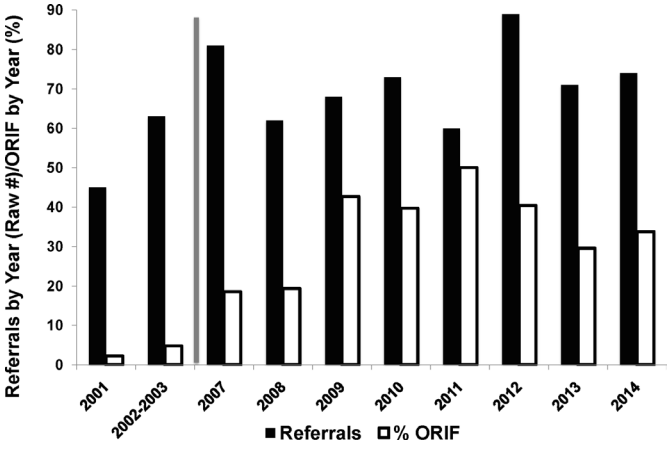

Figure 2 Number of referrals by year and percentage treated by open reduction and internal fixation (ORIF). Grey line indicates pretrial cohort versus post-trial cohort.

This study also demonstrated that the study-participating centres might more readily adopt clinical practice changes in accordance with evidence-based findings. Mahan *et al*,[15] 2012 demonstrated that surgeons participating in RCTs are able to change their practice patterns based on the best available evidence, which is similar to our finding that patients with displaced midshaft clavicle fractures who presented to a participating study centre, were more likely to be treated with ORIF following publication of the COTS trial. Similarly, prescribing practices for managing myocardial infarction among RCT investigators were more in agreement with peer-reviewed results than non-investigator physicians.[16] The current study also demonstrated practice changes within the first year following publication of the COTS RCT, which is in agreement with the decrease in the number of surgically treated Achilles tendons reported within 5 months following the Achilles tendon RCT.[17] Therefore, research-oriented surgeons may be more receptive to clinical practice change based on evidence-based recommendations.[18]

Our study identified younger age and increased ISS as factors, which may have contributed to decision-making

for recommending treatment with ORIF. The mean age of patients treated with ORIF in the pretrial cohort was significantly younger, which may be due to a patient selection bias towards perceived clinical improvement for younger patients prior to publication of the COTS trial. Certainly selection bias would be evidenced in any interpretation of a study that is prosurgical procedure. Surgeons would be more likely to adopt evidence that expands surgical indications. Both participating centres are level 1 trauma centres, therefore there was also likely an increased bias towards surgical fixation of clavicle fractures in patients with multiple injuries. The post-trial cohort had a significantly higher mean ISS; however, this study also demonstrated that there was a significant increase in annual referral of clavicle fractures from 50 to 72 patients per year, suggesting knowledge translation of level 1 evidence to referring physicians. The cause of this increase is difficult to pinpoint but may be word of mouth from training staff in the facilities involved.

Surgeons report a willingness to adopt evidence-based recommendations provided clinical trial results are compelling and the study methodology is robust.[18] Practice variation likely reflects a complex combination of surgeon experience, patient selection bias, geographical differences and lack of dissemination of recommendations based on level 1 evidence. For example, 35% of Australian orthopaedic surgeons surveyed in 2011 reported treating clavicle fractures with ORIF,[19] which is in agreement with the current study post-trial cohort ORIF rate of 34.1%. However, it is unknown if the Australian reported rate for surgical fixation is a shift towards ORIF following recent prospective study recommendations, or a pre-existing geographical bias. A 2016 review of clavicle fracture repair in Sweden between 2001 and 2012 showed an increased rate of clavicle fixation from 2.5% in 2001 to 12.1% in 2012 with the increases in rate starting between 2005 and 2006; before the COTS results were published[20] but not before the body of literature leading to the study was publicised. The current study found a significant change in practice in response to recommended operative treatment for displaced midshaft clavicle fractures; however, there may not have been the same change observed if the recommendation was for non-operative treatment. This study supports continued well-designed and executed RCTs and further research into successful knowledge translation, in order to provide evidence-based fracture care including monitoring for 'surgical indication drift', where treatment is over employed. If we cannot prove that a change in practice occurs after the publication of well-designed clinical trials, then there is no reason to support these trials.

The limitations of this study include that this was a retrospective review and some patients could have gone elsewhere for further treatment. Union rate and functional outcomes are not reported because the primary outcome of this study was to report incidence of surgical fixation of displaced midshaft clavicle fractures before and after a landmark RCT. Reasons for referral rates of displaced midshaft clavicle fractures from primary care physicians or emergency room physicians to orthopaedic surgeons were not possible to report; however, this may be a contributing factor following dissemination of the improved functional outcomes demonstrating in the COTS study. A confounding factor that may have impacted the study findings was the increased ISS in the poststudy cohort, which may have influenced the decision to operate on these patients. Despite these limitations, this study demonstrated the need for understanding knowledge translation into clinical practice.

CONCLUSION

This study demonstrated an increase in surgical treatment of displaced midshaft clavicle fractures following publication of a level 1 RCT, which demonstrated significant improvement in functional outcomes (Disability for Arm, Shoulder, and Hand (DASH) and Constant Scores), union rates, time to union and patient satisfaction with ORIF.[7] Centres that participate in RCTs were also more likely to adopt practice changes in accordance with the published level 1 evidence.

Contributors EH and JA conceived the study. EH, JA, PS and RB interpreted the data and results and drafted the manuscript. JA, PS and RB collected, organised, analysed the data and performed statistical analyses. All authors critically revised the manuscript for intellectual content. All authors read and approved the final manuscript.

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