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Clinical Trials Study

Short arm cast is as effective as long arm cast in maintaining distal radius fractures reduction: Results of the SLA-VER noninferiority trial

Dib G *et al*. Short arm cast for DRFs

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Abstract

BACKGROUND

Distal radius fractures (DRFs) are a common challenge in orthopaedic trauma care, yet for those fractures that are treated nonoperatively, strong evidence to guide cast treatment is still lacking.

AIM

To compare the efficacy of below elbow cast (BEC) and above elbow cast (AEC) in maintaining reduction of manipulated DRFs.

METHODS

We conducted a prospective, monocentric, randomized, parallel-group, open label, blinded endpoint evaluation noninferiority trial comparing the efficacy of AEC and BEC in the nonoperative treatment of DRFs. Two-hundred-eighty patients, > 18 years of ages, diagnosed with DRFs were successfully randomized and included for analysis over a 3-year period. Noninferiority thresholds were defined as a 2 mm difference for

radial length (RL), a 3 difference for radial inclination (RI) and volar tilt (VT). Registered at Clinicaltrials.gov, NCT03468023.

RESULTS

One-hundred-forty-three patients were treated with BEC, 137 patients were treated with AEC. The mean time of immobilization was 33 d. The mean loss of RL, RI, VT were respectively 1.59 mm, 2.83°, 4.11° for BEC and 1.63 mm, 2.54°, 3.52° for AEC. The end treatment differences between BEC and AEC in RL, RI, VT loss were respectively 0.04 mm (95%CI: -0.36; 0.44), -0.29° (95%CI: -1.03; 0.45), 0.59° (95%CI: -1.39; 2.57) and they were all below the prefixed noninferiority thresholds. The rate of loss of reduction was similar.

CONCLUSION

BEC performs as well as AEC in maintaining the reduction of a manipulated DRF. Being it more comfortable to patients, BEC may be preferable for nonoperative treatment of DRFs.

Key Words: Distal radius fracture; Immobilization; Above-elbow cast; Below-elbow cast; Long arm cast; Short arm cast

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Core Tip: Currently, there is no general agreement on how best to immobilize a distal radius fracture (DRF) although classic teaching was that immobilization of the elbow would ensure better control of fracture instability. This has been recently challenged by a number of new randomized control trials (RCTs) but no one was designed as non-inferiority RCT, which is the most appropriate way to evaluate the hypothesis that

blocking the elbow is unnecessary. We devised a large population noninferiority RCT to give statistical evidence that short arm cast is equally as effective as long arm cast to treat DRFs using predetermined noninferiority thresholds.

INTRODUCTION

Distal radius fractures (DRFs) are a common clinical challenge in orthopaedic trauma care. Traditionally it was though that immobilization including the elbow would ensure better control of fracture instability, prevent loss of reduction and result in better clinical outcomes. However, long arm casts are cumbersome and treatment with lighter short arm casts is generally considered a more comfortable option for patients. Currently, there is no general agreement on how best to immobilize a DRF. Various methods have been described, but no one approach has been identified as being more effective than another[1–4]. According to the latest clinical practice guidelines from the American Academy of Orthopaedic Surgeons, released in 2009, the evidence available for and against elbow immobilization in patients treated with a cast is "inconclusive" and the choice between them is down to the clinician's judgment[5]. The hypothesis that short arm casts might perform equally as well as long arm casts in maintaining the reduction of DRFs has been tested in a number of previous studies. These superiority randomized control trials (RCTs) have not found a significant difference in outcome and risk of loss of reduction between below-elbow cast (BEC) and above-elbow cast (AEC)[6-11]. However, the absence of any significant difference in these studies does not necessarily indicate equivalence[12]. To compare the efficacy and tolerability of these two treatment approaches, we designed a noninferiority randomized trial using predefined minimal clinically important difference thresholds.

In this paper, the terms long arm cast and AEC or short arm cast and BEC are used interchangeably.

MATERIALS AND METHODS

Design

The SLA-VER trial is a prospective, monocentric, randomized, parallel-group, open label, blinded endpoint evaluation noninferiority trial (PROBE design), comparing the efficacy of BEC and AEC in maintaining reduction of manipulated DRFs. This study was approved by the local institutional review board (CE\1165CESC), conducted in

accordance with the Declaration of Helsinki and registered on ClinicalTrials.org (NCT03468023). All patients enrolled gave written informed consent.

Outcomes

The primary outcome was fracture reduction maintenance, measured as variation in radial length (RL), radial inclination (RI) and volar tilt (VT). Secondary outcomes included disability of arm, shoulder and hand (DASH) scores and short form 12 (SF-12) scores as measures of cast tolerability.

Population

All patients admitted to the emergency room with a diagnosis of DRF were enrolled according to the following inclusion criteria: Age ≥ 18 years; Candidate for nonoperative treatment; Displaced fracture requiring manipulation. Exclusion criteria were: Skeletally immature patient (less than 18); Undisplaced fracture; Fracture requiring surgical treatment; Open fracture; Hand/wrist/forehand skin lesion on fractured limb; Vascular or neurological deficit; Bilateral fracture; Association with homolateral upper limb fracture. Patients with any medical comorbidity were included; pregnant patients or patients requiring urgent or life-saving procedures were excluded. Patients were excluded from the study (*i.e.* dropouts) if: Unable to achieve reduction after two attempts (after which surgical treatment was offered), the cast damaged or removed during treatment or consent was withdrawn[13].

Procedures

Randomization was carried out by a statistician with no involvement in the clinical care of patients. Software random allocation in blocks of 4 resulted in 353 sequentially numbered opaque sealed envelopes. When a patient was eligible for enrollment, an envelope was opened to assign the participant to a treatment group. Closed manipulation was performed under hematoma block, the forearm was immobilized in an opposite-to-dislocation position. The arm cast was a radial gutter made of plaster of

Paris (POP) left open on the volar side to allow for swelling and then circumferentially closed 5-7 d later by applying an extra layer of POP (Figure 1). BEC patients were treated with a BEC extending from the metacarpal heads to 2-4 cm from the elbow crease. AEC patients were treated with an AEC extending from the metacarpal heads to the middle third of the arm. Posteroanterior (PA) and lateral view X-rays were taken before and after manipulation at 7 and 35 d. The radial gutter was closed at the first office visit and removed at the final visit. If closed manipulation failed to achieve satisfactory reduction, patients were offered surgical treatment and excluded from the study. If reduction was lost at 7 d, patients were offered surgical treatment. These patients were still considered for analysis as subjects who did not maintain satisfactory reduction at final follow-up. Radiographic parameters were determined at each X-ray examination. RL was measured on the PA view as the distance between two lines drawn perpendicular to the radial shaft long axis: One at the tip of the radial styloid and one at the ulnar border of the radius articular surface at the central reference point, which is a point midway between the volar and dorsal ulnar corners to eliminate variation caused by dorsal angulation as described by Slutsky[14]. RI was measured on the PA view by determining the angle between a line passing through the tip of the radial styloid and the medial corner of the articular surface of the radius and a line perpendicular to the shaft of the radius. VT was measured on the lateral view by the angle between the line of the distal articular surface (passing through the two most distal points of the dorsal and volar lips of the radius) and the longitudinal axis of the radius[14,15]. Fracture stability was assessed according to Lafontaine (dorsal angulation > 20°, dorsal comminution, articular involvement, associated ulnar fracture, age > 60 years): If three or more of these criteria were present, the fracture was defined as unstable[16]. The casting technique was assessed by means of cast index and three-point index[17,18]. Reduction was considered to be maintained when the following criteria, described by Graham, were met[13]: Loss of radial length < 5 mm, radial inclination ≥ 15°, volar tilt between +15° and -20°. Given the variability of the criteria used to assess acceptability of reduction, we decided to further test the dataset against 3 other sets of

criteria (combinations of different thresholds of RL, RI, VT). All measurements were performed by three investigators, none of whom were involved in patient recruitment and all of whom were blinded to patient group assignment. Patients were stratified by age, sex, presence of osteoporosis (indirectly assessed by osteoporosis-specific drug consumption), fracture type (according to AO classification) and fracture stability (according to Lafontaine's criteria)[19]. At the final follow-up visit, patients were asked to complete DASH and SF-12 questionnaires and elbow range of movement (ROM) after cast removal was also recorded[20,21]. Protocol details have been published previously[22] and are available at https://clinicaltrials.gov/ct2/show/NCT03468023.

Statistical analysis

For the study to have 80% power to show a difference between the treatments with a two-sided type 1 error rate of 5%, we calculated that approximately 150 patients would be required for each group using a 2 mm difference in RL and a 3° difference in RI and VT as noninferiority thresholds. These estimates of minimal clinically important differences were based on previous reports of interobserver variability of up to 3° in radiographic parameter measurement and considerable deterioration of clinical outcome when shortening of RL was > 5 mm[15,23,24]. We included 53 additional patients to make up for a predicted 15% dropout rate. Since our aim was to identify the real treatment efficacy under optimal conditions, we conducted a per-protocol analysis. In noninferiority trials, both intention-to-treat and per-protocol analysis are recommended[25]. In this trial, we did not include dropouts in the final analysis, since doing so would have introduced a confounding effect of surgery. We did not use baseline differences to decide whether, and which, covariates should be used to adjust treatment effect because we assumed that, in randomized control trials, any baseline difference between the two groups is attributable to chance, and thus negligible[26]. The 95%CI was calculated for continuous variables, assuming a normal distribution. Noninferiority *t*-tests were used to compare radiological parameters, and chi-squared tests were used to compare percentages of loss of reduction between the two groups.

DASH and SF-12 scores between BEC and AEC groups were compared using superiority t tests. All variables included in the analysis were complete, with no missing data. Analyses were performed using SAS 9.4.

RESULTS

Between March 2017 and February 2020, 353 eligible patients were enrolled in the trial. Of these, 180 patients were randomly assigned to treatment group A (BEC), and 173 patients were randomly assigned to treatment group B (AEC). In group A, 29 patients dropped out of the study, and 8 patients did not complete follow-up. In group B, 25 patients dropped out from the study, and 11 patients did not complete follow-up (Figure 2). Dropouts (and dropout reasons) were similar between the groups. A total of 280 patients (143 in group A and 137 in group B) completed the study and were included in the analysis. The study groups were similar with respect to age, sex, osteoporosis, type of fracture (AO classification) and stability of fracture, as shown in Table 1. Cast index and three-point index were homogeneous between the groups (χ^2 = 1.72, P = 0.19 and χ^2 = 0.06, P = 0.79, respectively). Randomization resulted in two well-balanced study groups. The mean time of immobilization was 33 d (95%CI: 31.88; 34.10) for BEC patients and 32.6 d (95%CI: 31.5; 33.63) for AEC patients. Nine patients treated with BEC and 10 patients treated with AEC lost reduction at 7 d. Seven were treated surgically, and 2 continued nonoperative treatment in BEC group; 7 were treated surgically, and 3 continued nonoperative treatment in AEC group. Upon removal of cast at final follow-up, the mean loss of RL was -1.59 mm for BEC *vs* -1.63 mm for AEC (between-group difference: 0.04 mm; 95%CI: -0.36; 0.44); the mean loss of RI was -2.83° in BEC *vs* -2.54° in AEC (between-group difference: -0.29°; 95%CI: -1.03; 0.45); the mean loss of VT was 4.11° in BEC *vs* 3.52° in AEC (between-group difference: 0.59°; 95%CI: -1.39; 2.57). Differences in loss of RL, RI and VT during treatment between the groups reached statistical significance when tested for noninferiority (P < 0.0001 for RL, P < 0.0001 for RI and P = 0.0087 for VT), and all differences were below the prefixed thresholds outlined above. Differences between the final and baseline radiographic

parameters are reported in Table 2. According to Graham's criteria, 99 out of 143 patients (69%) treated with BEC maintained satisfactory reduction as opposed to 106 out of 137 patients (77%) treated with AEC. This difference was not significant ($P = 0.12$, see Table 3). Considering that the percentage of fractures labelled as "maintained" varies according to the criteria of acceptability of reduction used, we tested a further 3 sets of criteria as described above. In all cases, no statistically significant difference was observed (66% maintained in BEC *vs* 74% in AEC for type 2, 61% maintained in BEC *vs* 62% in AEC for type 3, 62% maintained in BEC *vs* 61% in AEC for type 4; see Table 3). DASH score, SF-12 [physical component summary (PCS) and mental component summary (MCS)] scores and elbow ROM were collected for 122 out of 280 patients: 55 (38%) patients in group A and 67 (49%) patients in group B. DASH score for BEC patients was 59 (95%CI: 53.8; 64.2) and 59.9 (95%CI: 55.6; 64.3) for AEC patients; the mean PCS and MCS scores were 34.9 (95%CI: 32.9; 36.9) and 43.6 (95%CI: 40.5; 46.8), respectively, for BEC patients and 36.6 (95%CI: 34.9; 38.2) and 41.8 (95%CI: 39.1; 44.5) for AEC patients. No difference was observed between patient groups. Subgroup analysis for dominant side fracture did not change the result. Regarding elbow ROM, BEC patients exhibited a mean flexion of 123.6° (95%CI: 117.1; 130.1), a mean extension of 6.7° (95%CI: 2.5; 10.8), a mean pronation of 69.5° (95%CI: 63.8; 75.3) and a mean supination of 52.5° (95%CI: 45.6; 59.3). AEC patients had similar ROM, with a mean flexion of 123.9° (95%CI: 118.9; 128.9), a mean extension of 5.5° (95%CI: 1.4; 9.5), a mean pronation of 72.1° (95%CI: 66.4; 77.9), and a mean supination of 52.9° (95%CI: 45.5; 60.3). Again, no difference was observed between the groups.

DISCUSSION

Noninferiority tests are the most appropriate way to evaluate the hypothesis that BEC and AEC have similar efficacy. They are based on minimal clinically important thresholds that are established *a priori* by drawing on empirical assumptions. When observed between-treatment differences fall below these thresholds, treatments can be considered equivalent. Statistical superiority tests, for example, the percentage of

fractures that maintained reduction *vs* the percentage that lost reduction, can be misleading since they tell us nothing about equivalence[12]. Therefore, in the current study, we analysed both dichotomic variables (*i.e.*, percentage of reduction maintenance) and continuous variables (*i.e.*, radiographic radial parameters) for which noninferiority thresholds could be predetermined. By employing a noninferiority design, the current study shows that the efficacy of BEC in maintaining the reduction of manipulated DRFs is similar to that of AEC. According to our model, when clinicians have to choose between using BEC or AEC to immobilize a DRF, the maximum predictable outcome difference between the two treatments does not exceed 2 mm in terms of radial length loss and 3° in terms of radial inclination and volar tilt loss. Maintenance of reduction of DRFs is more likely to depend on factors other than length of cast used, for example, patient age, stability or type of fracture. SLA-VER has some limitations that warrant discussion. Quality of reduction was not assessed and could have potentially influenced the difference between BEC and AEC. Given that no computerized tomography was carried out, we may not have accurately measured every articular gap, and it is possible that its prevalence might be different between the study groups. However, our approach is consistent with general clinical practice. Furthermore, we limited our investigation to radiological outcomes only and did not include clinical outcome measures. SLA-VER aimed only at ascertaining whether the type of casting used affects the likelihood of fracture maintenance. A large amount of data about factors associated with loss of reduction risk and clinical outcome have already been published[16,27-39]. Only a small number of patients completed the DASH and SF-12 questionnaires and received elbow ROM measurements, even though this was a secondary study endpoint. Our data did not reveal a clear difference in patient comfort between BEC and AEC and this remained true even after subgroup analysis of dominant side fractures. Surprisingly, elbow range of motion was not affected by the type of cast as one would have expected. One explanation could be that the time of immobilization may have been too short to result in significant elbow stiffness or that the absence of elbow injury might have contributed to preserving joint mobility. This

finding is also reported by Okamura *et al*[11]. Finally, it may be that DASH scores are not the most appropriate way to assess cast comfort. Bong *et al*[7] found better DASH scores in below-elbow splints, although to a lesser degree than expected, suggesting that DASH might not be able to specifically address the comfort level of the two constructs. Furthermore, Caruso *et al*[10] did not find any difference in DASH scores between BEC and AEC at 4 wk follow-up but reported a significant difference in favour of BEC using the Mayo Elbow score. Similarly, Park *et al*[8] did not find any difference in DASH score between BEC and AEC, although they found a correlation with the dominant side and a higher incidence of shoulder pain in the latter group. Nevertheless, BEC is broadly considered more comfortable and preferable than AEC[8].

CONCLUSION

Data from this trial lead us to conclude that BEC performs as well as AEC in maintaining reduction of a manipulated DRF. When clinicians have to choose between BEC and AEC, the maximum predictable difference does not exceed 2 mm in terms of radial length loss and 3° in terms of radial inclination and volar tilt loss. We recommend BEC over AEC for its non-inferior performance and better tolerability.

ARTICLE HIGHLIGHTS

Research background

Distal radius fractures (DRFs) treatment is a common challenge in orthopaedic trauma care. Uncertainty exists on how best to immobilize a DRF.

Research motivation

The necessity of blocking the elbow when immobilizing a DRF is still a matter of debate.

Research objectives

To test the hypothesis that blocking the elbow is not necessary and that a below arm cast (BEC) performs equally as well as an above elbow cast (AEC).

Research methods

Noninferiority randomized clinical trial conducted on 280 patients diagnosed with a DRF managed nonsurgically. Loss of reduction was evaluated considering variation in radiographic parameters [radial length (RL), radial inclination (RI), volar tilt (VT)].

Research results

Rates of loss of reduction were similar between BEC and AEC. Variation of radiographic parameters (RL, RI, VT) is similar between BEC adn AEC and falls within the predetermined noninferiority thresholds.

Research conclusions

BEC performs equally as well as AEC in maintaining reduction of a manipulated DRF.

Research perspectives

Further large population randomized control trials and meta-analyses are required to confirm the hypothesis the BEC should become the option of choice for DRFs treatment.

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