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Influence of postoperative immobilization on pain control of patients with distal radius fracture treated with volar locked plating: A prospective, randomized clinical trial

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ABSTRACT

Objectives: The purpose of this study was to compare the pain scores and the rates and doses of opioid use in patients undergoing volar locked plate fixation of intra-articular distal radius fractures using or not postoperative immobilization.

Methods: This was a prospective randomized controlled trial. Thirty-nine patients with distal radius fractures scheduled to receive volar plate fixation were randomly assigned to receive a short forearm splint for two weeks postoperatively or conventional bandage with early wrist mobilization. Thirty-six patients completed the follow-up. The outcome measurements included pain scores (0–10 points); rates and doses of tramadol use; DASH score; wrist range of motion; patient satisfaction; and complication rates. The last follow-up assessment was performed at 6 months.

Results: The pain scores were similar between the groups during hospital stay, as well as after hospital discharge within the first week and in subsequent assessments up to six months. The rates of tramadol use were greater in the No splint group during hospital stay, but this difference was not statistically significant (No splint = 65%; Splint = 47%; p = 0.296). Likewise, the doses of tramadol intake were higher in the No splint group during hospital stay (No splint = 218 mg; Splint = 167 mg; p = 0.273) and after discharge (2nd day: No splint = 112 mg; Splint = 75 mg; p = 0.286), with no statistically significant differences. The functional results and complication rates were similar between the groups.

Conclusions: In this study, there was a trend to a greater use of tramadol in patients who did not use immobilization and started early wrist mobilization after volar locked plating of distal radius fracture, compared with patients who were immobilized for two weeks. The pain scores were similar but may have been influenced by the unbalanced use of opioids between the groups. The functional results and complication rates were not influenced by the use of immobilization.

Level of Evidence: Therapeutic Level I.

Introduction

Volar locked plating is frequently used for the treatment of unstable extra-articular and intra-articular distal radius fractures [1,2]. Although volar plating represents a very stable method of fixation, most authors report the use of immobilization after fixation [3–6]. The reasons for its use are poorly discussed in the literature. One possible benefit is controlling the pain caused by active and involuntary movements during the early postoperative stages [7]. Another reason for using immobilization could be osteosynthesis protection during the early healing stages, which has been justified for less stable methods, such as pin fixation [8], and for more comminuted fractures.

Studies comparing early and late rehabilitation protocols after volar locked plating have shown better initial results in patients undergoing early rehabilitation, with no differences in the mid-term and long-term outcomes [3,4]. Handoll and Elliott [9] reported a systematic review showing inconclusive results regarding the use of postoperative immobilization in patients with distal radius fractures, with most of the included studies reporting the use of immobilization after plate fixation varying from two weeks to seven weeks. A recent study comparing immediate wrist mobilization with wrist immobilization for five

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weeks after volar plate fixation showed better functional results in patients undergoing immediate mobilization but no differences in pain scores [10].

Despite the lack of evidence favouring the use of immobilization after volar locked plating, it remains a current practice among orthopaedists treating distal radius fractures [11–14]. The purpose of this study was to compare the pain scores and rates and doses of opioid use after distal radius fracture fixation in patients using or not postoperative immobilization. Additional objectives included the analysis of functional results and complication rates, including loss of fracture reduction.

Methods

Study design and participants

This was a prospective, randomized clinical trial that was performed at a single tertiary health institution. Patients with intra-articular distal radius fractures who were scheduled to receive volar plate fixation were randomly assigned to receive or not receive postoperative immobilization by allocation into two groups: the Splint group or the No splint group. The local institutional ethics committee approved the study, and all patients provided informed consent to participate. The study was registered at ClinicalTrials.gov (NCT03186963). The inclusion criteria were as follows: an age over 18 years old, an intra-articular distal radius fracture (AO/OTA [15] types B or C) occurring within the prior 30 days scheduled to undergo volar locked plating, and consent to participate. The following exclusion criteria were adopted: ipsilateral upper limb concomitant fracture, dislocation or neurologic injury, previous functional deficit, pathological fracture, bilateral fracture, contraindication for surgery, and patients who were not amenable to follow-up. One of the surgeons participating in the study classified the fractures and determined the patient's eligibility for the study. After that, the study coordinator, who was not involved in patient enrolment, performed the randomization using a computerized randomization list designed with a 1:1 ratio with randomly generated block sizes.

Interventions

All patients were operated on under general anaesthesia and a brachial plexus blockade. The surgeries were performed using a standard Henry volar approach with direct visualization of the fracture fragments and volar locked plate fixation under fluoroscopic control. The acceptable alignments included a radial shortening < 5 mm, a sagittal angulation up to the neutral position, and an articular step off < 2 mm. The size of the plate and number of screws varied according to the fracture characteristics. Six experienced surgeons performed the procedures.

No splint group

The patients received a soft wrist dressing made with gauze, cotton padding and an inelastic bandage without any type of immobilization. The patients were instructed to perform light wrist movements as soon as sensitivity and motor recovery had occurred. A physiotherapist described wrist exercises to be performed at home and precautions against excessive movements or impact activities.

Splint group

The wound was dressed with gauze and cotton padding, and a plaster splint extending from the volar mid-forearm to the distal palmar crease, allowing flexion of the metacarpophalangeal joint, was applied. The patients were instructed not to remove the splint for two weeks and to perform free metacarpophalangeal and elbow movements as tolerated.

All patients received the same postoperative analgesic protocol during the hospital stay, which included 100 mg intravenous (IV) ketoprofen twice a day, 1000 mg IV dipyrone four times a day regularly, and 100 mg IV tramadol up to three times when necessary. Usually, patients were discharged from the hospital 24 h after the surgery. At home, the patients were scheduled to receive 50 mg diclofenac three times a day and 500 mg dipyrone three times a day orally for five days and 50 mg oral tramadol up to three times a day as needed. The patients were scheduled to undergo an outpatient consultation at 2 weeks postoperatively, which is when the dressing or splint, as well as the skin suture, were removed and when they were referred to a physiotherapist.

Outcomes

Pain score

Pain was measured using a visual analogue scale (VAS) with scores ranging from 0 to 10. During the hospital stay, the scale was applied at 12, 18 and 24 h postoperatively. An evaluator instructed patients on how to complete the scales. The operated limb was covered by the nursing staff with a sheet so that the evaluator was blinded on the treatment group during the contact with the patient. After discharge, the patients were instructed to complete the scale with the worst pain score on each day until the seventh postoperative day. Further assessments were performed during the outpatient consultations at two, six, twelve and twenty-four weeks.

Tramadol use

During the hospital stay, data on tramadol use were collected from the nursing records. At home, the patients completed a form registering the time and doses that were used on a daily basis until the seventh postoperative day, and this was assessed as a binary outcome. Additionally, the total daily doses among patients who required the drug were registered. The tramadol doses are presented in milligrams and in oral morphine equivalents (OME), which were calculated using a conversion rate of 0.2 for IV tramadol and a rate of 0.1 for the oral presentation [16].

Functional score and wrist range of motion (ROM)

The Disabilities of the Arm Shoulder and Hand (DASH) score was assessed at six, twelve and twenty-four weeks postoperatively. Wrist flexion-extension and forearm rotation were assessed by goniometry at two, six, twelve and twenty-four weeks. The evaluator was blinded to the treatment group.

Satisfaction scale

The patients were asked to complete a VAS at two weeks regarding their level of satisfaction within the first two weeks and at six weeks regarding the previous month.

Other assessments

Radiographs were obtained at two, six, twelve and twenty-four weeks. Wrist edema was assessed as a categorical outcome at two weeks and included the following levels: absence, mild, moderate, and severe. The following events were registered as complications: infection, implant failure, loss of reduction, non-union, and reoperation.

Sample size calculation

The minimum relevant difference for the VAS pain score was set to 2.0 points. Considering a standard deviation of 2.0 points, a power of 0.8, and a significance level of 0.05, thirty-four patients

were required for the study (seventeen in each group). We enrolled a total of thirty-nine patients, expecting a 10% loss to follow-up rate.

Statistical analysis

Student's *t*-test was used to compare means between the treatment groups when the distribution was normal, whereas the Mann-Whitney U test was used for non-normal distributions. Categorical variables were compared with the Chi-square test or Fisher's exact test according to the minimum number of observations in each group. The Spearman test was used to assess the correlation between the pain score and satisfaction level. A p value <0.05 was considered to be significant.

Results

Participant flow

Thirty-nine patients were enrolled in the study from May 2013 to May 2016. Nineteen patients were allocated to the No splint group, and twenty patients were allocated to the Splint group. Seventeen patients in the No splint group (90%) and nineteen patients in the Splint group (95%) completed the follow-up and were included in the data analysis (Fig. 1). The mean age of the overall sample was 49.3 years, 56% were female patients, and falls represented the most common mechanism of injury (57%). AO/OTA C1 fractures were the most frequent type of fracture (44%), with the majority presenting with dorsal displacement (90%) and a mean angulation of 23.2° (Table 1). The mean time to surgery was 10.3 ± 5.2 days in the overall sample, with no statistically significant differences between the groups (No splint = 10.2 days; Splint = 10.4 days; p = 0.910).

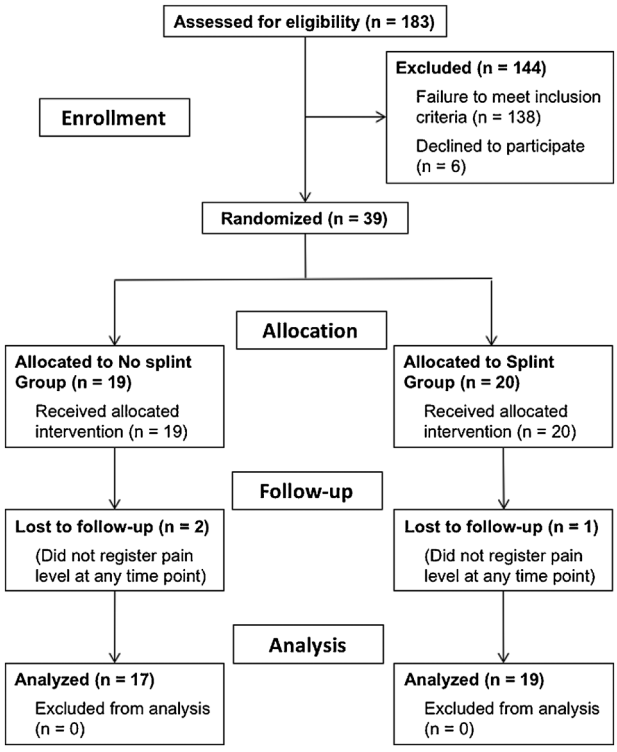

Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart of the trial enrolment and analysis.

Pain scores

No statistically significant or clinically relevant differences were observed regarding the pain scores during immobilization and in the subsequent assessments up to six months (Table 2). During the hospital stay, the maximum pain scores were observed at 18 h postoperatively (No splint = 4.5; Splint = 4.1; p = 0.678). After discharge, a progressive decline occurred from the second day, with the greatest difference between groups occurring on the fourth day (0.8 points in favour of the No splint group), but this was not a statistically significant difference (95% CI = −2.5 to 0.9; p = 0.354) (Fig. 2).

Tramadol use

During the hospital stay, there were more patients in the No splint group who required tramadol (n = 11; 65%) than in the Splint group (n = 9; 47%), but this analysis did not reach statistical significance (p = 0.296) (Table 2). Likewise, the tramadol doses utilized in the No splint group were higher than in the Splint group, with no statistically significant difference (No splint = 218 mg; Splint = 167 mg; p = 0.273). Similarly, when the overall sample was considered, the tramadol doses where higher in the No splint group, but the difference was not statistically significant (No splint = 141 mg; Splint = 79 mg; p = 0.164). At home, there were no relevant differences regarding the rate of patients who used oral tramadol during the first week (No splint = 65%; Splint = 68%; p = 0.813) (Table 2). The difference in the doses of oral tramadol was higher on the second postoperative day, with no statistical significance (No splint = 112 mg; Splint = 75 mg; p = 0.286).

Functional scores, range of motion, satisfaction scale and other assessments

We did not find any clinically relevant difference regarding the DASH scores, wrist flexion-extension and forearm rotation in any of the assessments up to six months (Table 3). The satisfaction levels were high for both groups at two weeks (No splint = 8.7; Splint = 9.1; p = 0.972) and six weeks (No splint = 8.7; Splint = 8.5; p = 0.688). No significant correlation was observed between the satisfaction levels and pain scores (rho = -0.199; p = 0.244), and the satisfaction levels were not different between patients who used or did not use tramadol (tramadol = 8.8; no tramadol = 9.2; p = 0.395). The level of wrist edema was similar between the groups (No splint: 73% mild, 20% moderate, 7% severe; Splint: 40% mild, 47% moderate, 7% severe; p = 0.218). One patient in the No splint group presented with a loss of fracture reduction at six weeks postoperatively and underwent reoperation for plate exchange. No other relevant complications occurred.

Discussion

In this study, we did not find any difference in the pain scores of patients who used or not a plaster splint immobilization for a two-week period after distal radius volar plate fixation. However, there was a trend towards higher opioid use in patients who did not use immobilization. This is clinically relevant given the potential harms related to excessive use of opioids. In addition, this fact probably influenced the comparison of pain scores between the groups. Apparently, pain scores were similar between the groups due to a higher use of tramadol by patients in the No splint group. Although we did not reach a statistically significant difference in the analysis of tramadol use, we considered this the most relevant finding of this study.

The benefits of early mobilization after distal radius fractures fixation have been demonstrated [3,10]. On the other hand,

Table 1
Demographics and characteristics of the fractures according to the treatment group.*.

	No splint group (N = 19)	Splint group (N = 20)	Total (N = 39)
Age (years)	51.2 (16.6)	47.6 (15.1)	49.3 (15.7)
Sex (females)	11 (58%)	11 (55%)	22 (56%)
Smoking	0	4 (20%)	4 (10%)
Involvement of the dominant arm	9 (47%)	12 (60%)	21 (54%)
Mechanism of injury			
Motorcycle accident	3 (16%)	2 (10%)	5 (13%)
Car accident	1 (5%)	1 (5%)	2 (5%)
Hit by vehicle	0	2 (10%)	2 (5%)
Fall	11 (58%)	11 (55%)	22 (57%)
Fall from height	3 (16%)	3 (15%)	6 (15%)
Other	1 (5%)	1 (5%)	2 (5%)
AO/OTA Classification			
B3	0	1 (5%)	1 (3%)
C1	9 (47%)	8 (40%)	17 (44%)
C2	2 (11%)	7 (35%)	9 (23%)
C3	8 (42%)	4 (20%)	12 (31%)
Fracture with dorsal displacement	16 (84%)	19 (95%)	35 (90%)
Angulation (degrees)	24.3 (9.2)	22.1 (16.0)	23.2 (12.8)
Shortening (mm)	6.4 (3.0)	6.9 (2.9)	6.6 (2.9)
Associated distal ulna fracture	13 (68%)	9 (45%)	22 (56%)

* Continuous data are presented as means with the standard deviation in parentheses; categorical data are presented as absolute numbers with percentages in parentheses.

Table 2
Pain scores and tramadol use at multiple assessments according to the treatment group.

Parameter	No splint group* (N = 17)	Splint group* (N = 19)	Difference (95% CI) **	p value
Pain score				
12 h	3.6 (4.3)	3.9 (3.9)	−0.3 (−3.2 to 2.4)	0.575
18 h	4.5 (3.5)	4.1 (3.4)	0.4 (−1.9 to 2.8)	0.678
24 h	3.2 (2.2)	3.3 (2.1)	−0.1 (−1.6 to 1.4)	0.850
2nd day	4.0 (2.5)	4.3 (3.0)	−0.3 (−2.2 to 1.6)	0.949
3rd day	3.2 (2.2)	3.8 (2.7)	−0.6 (2.3 to 1.1)	0.836
4th day	2.9 (2.1)	3.7 (2.8)	0.8 (−2.5 to 0.9)	0.354
5th day	2.4 (1.8)	3.0 (2.7)	−0.6 (−2.2 to 1.0)	0.642
6th day	2.7 (1.6)	2.6 (2.2)	0.1 (−1.3 to 1.4)	0.911
7th day	2.2 (1.5)	2.5 (2.2)	−0.3 (−1.6 to 1.0)	0.835
2 weeks	2.4 (2.8)	2.1 (1.9)	0.3 (−1.3 to 1.9)	0.820
6 weeks	2.8 (2.0)	2.2 (2.8)	0.6 (−1.0 to 2.3)	0.204
12 weeks	0.7 (1.0)	1.8 (2.6)	−1.1 (−2.5 to 0.2)	0.425
24 weeks	1.1 (1.4)	1.7 (2.9)	−0.6 (−2.2 to 0.9)	0.832
Tramadol use				
Hospital	11 (65%)	9 (47%)	0.7 (0.4–1.3)	0.296
2nd day	8 (47%)	10 (53%)	1.1 (0.6–2.2)	0.738
3rd day	8 (47%)	9 (47%)	1.0 (0.5–2.0)	0.985
4th day	9 (53%)	7 (37%)	0.7 (0.3–1.5)	0.332
5th day	7 (41%)	8 (42%)	1.0 (0.5–2.2)	0.955
6th day	7 (41%)	8 (42%)	1.0 (0.5–2.2)	0.955
7th day	7 (41%)	7 (37%)	0.9 (0.4–2.0)	0.790

* Continuous data are presented as means with the standard deviations in parentheses. Categorical data are presented as absolute numbers with percentages in parentheses.
** The values are given as the difference between the means of the continuous variables in parentheses or as the relative risk with respect to tramadol use, with the 95% CI in parentheses.

postoperative immobilization has been used empirically to contribute with analgesia, despite the lack of studies proving this effect. Few studies have evaluated the influence of pain in early rehabilitation periods and its influence on increased opioid dependence. A reduction in opioid intake could be a relevant reason for the use of postoperative immobilization. In our study, the difference in the rates of opioid use was not statistically significant but was clinically relevant during hospital stay (65% of patients without immobilization required tramadol compared to 47% of patients with immobilization), as well as were the doses used, which were 30% greater in patients who did not use a splint compared to those who were immobilized (218 mg vs. 167 mg). Additionally, after hospital discharge there was a trend to the use of greater doses of tramadol in patients who did not use immobilization. Although the statistical power was insufficient to show a statistical difference, our data pointed to a greater need for opioid use in patients who did not use immobilization. A reduction in the need for opioids would justify the use of postoperative immobilization. To our knowledge, these aspects of postoperative immobilization were not previously reported.

Regarding the functional recovery, the results of previous studies have been controversial regarding the influence of postoperative immobilization [3,4,8–10,17]. Our data showed no differences between the parameters of the groups, including the DASH score and wrist ROM, which were expected to be similar considering the short time that immobilization was used in our study. Lozano-Calderon et al. did not find significant differences

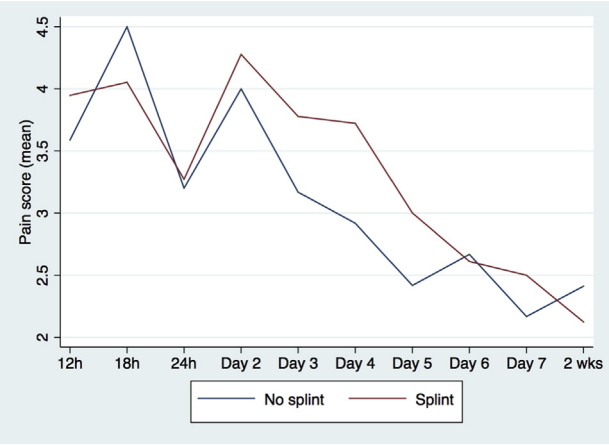

Fig. 2. Pain scores during hospital stay and up to two weeks after discharge, according to the treatment group.

between patients using a splint for 7 days and those using one for 45 days [4]. In contrast, Brehmer and Husband evaluated patients in earlier stages and demonstrated a faster functional recovery of patients who used immobilization for shorter periods [3]. Similarly, Quadlbauer et al. demonstrated better initial functional results in patients who did not use immobilization than in patients who were immobilized for 4 weeks [10]. In our study, patients used immobilization for only two weeks since the main objective was the evaluation of pain scores during its use. We did not find any benefit or functional impairment related to the use of immobilization as soon after its withdrawal and in the subsequent evaluations. Thus, according to our data, a two-week period of immobilization has no relevant influence on the functional recovery of distal radius fractures after volar plate fixation. The waiting time for surgery may also influence the results, since fractures operated with more than 15 days may present difficult fracture reduction and impaired results. Additionally, a greater surgical manipulation may interfere with postoperative pain levels. In our study, we included fractures occurring up to 30 days due to the significant frequency that these cases are treated in our service. In practical terms, the mean time to surgery was less than 15 days in the overall sample, with no difference between the groups, and did not influence the results.

Enhancing patient comfort during initial postoperative stages could represent another benefit from the use of postoperative immobilization. Conversely, some patients experience more discomfort related to the use of immobilization when performing basic daily activities. We assessed the satisfaction levels at 2 and 6 weeks to evaluate these subjective perceptions and did not find any relevant difference. Also, the satisfaction levels were not associated with pain scores during hospitalization or with opioid use, nor the level of wrist edema was affected by the use of immobilization. One patient in the No splint group presented with loss of fracture reduction, while there were no cases with this type of complication in the Splint group. Although this is a clinically relevant finding, the frequency of this event was low, and we cannot establish any causal relationship between the absence of immobilization and the occurrence of loss of reduction. The previous studies reporting immediate wrist mobilization after volar plate fixation have not found complications, including loss of fracture reduction, associated with early wrist mobilization [9,10,18].

This study had some limitations. The sample size was set to test differences greater than or equal to 2 points on the pain scores according to the visual analogue scale. Although we found a clinically relevant difference in the use of opioids, this difference was not statistically significant. Thus, we cannot make a definitive recommendation on the influence of postoperative immobilization on opioid intake. The small sample size also prevented us to normalize pain scores according to opioid use. The psychological benefits of immobilization for patient comfort and confidence were indirectly measured, with no use of any specific questionnaire for this purpose. The use of an anxiety scale evaluating the subjective perceptions of patients could have provided meaningful clinical data. Lower self-efficacy beliefs and anxiety and depression disorders have been associated with greater postoperative pain and less than ideal satisfaction with pain control after fracture fixation [19]. A subgroup analysis of patients presenting with those disorders could have identified the benefits of immobilization in a specific set of patients. Future research is needed to confirm the findings of this study. The influence of immobilization on analgesics use, considering the basal levels of opioid use and baseline anxiety scores, is an important point to be further explored.

In conclusion, this study showed a tendency towards a greater opioid use in patients who did not use immobilization and started early wrist mobilization after distal radius fracture fixation, compared with those who used a volar plaster splint for two weeks. The pain scores were similar between the groups, but this finding may have been influenced by the greater intake of opioids by patients who did not use immobilization. Functional results were not influenced by the use of immobilization.

Table 3
DASH score and wrist range of motion at the progressive postoperative assessments according to the treatment group.[*].

Parameter	No splint group (N = 17)	Splint group (N = 19)	Difference (95% CI) [**]	p value
DASH				
6 weeks	32.6 (22.3)	36.5 (19.3)	−3.9 (−18.0 to 10.2)	0.375
3 months	12.2 (13.4)	20.4 (16.6)	−8.2 (−18.9 to 2.5)	0.105
6 months	10.4 (11.8)	14.5 (20.5)	−4.1 (−15.8 to 7.6)	0.754
Flexion-extension (degrees)				
2 weeks	40.8 (18.8)	44.2 (37.4)	−3.4 (−28.2 to 21.4)	0.780
6 weeks	69.0 (19.4)	67.1 (36.5)	1.9 (−19.6 to 23.5)	0.855
3 months	87.1 (26.3)	92.4 (34.6)	−5.3 (−26.8 to 16.2)	0.619
6 months	114.1 (32.5)	108.9 (29.4)	5.2 (−16.1 to 26.5)	0.621
Forearm rotation (degrees)				
2 weeks	109.2 (35.9)	111.2 (49.9)	−2.0 (−38.2 to 34.3)	0.911
6 weeks	141.0 (29.0)	152.7 (27.3)	−11.7 (−32.2 to 8.9)	0.210
3 months	163.2 (34.2)	157.9 (21.0)	5.3 (−14.5 to 25.1)	0.195
6 months	170.0 (17.5)	165.8 (17.3)	4.2 (−7.8 to 16.2)	0.233

[*] Data are presented as means with standard deviations in parentheses.
[**] Difference between the means with 95% confidence intervals in parentheses.

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Conflict of interest

None.

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