






RESEARCH ARTICLE

REVISED Brace versus cast following surgical treatment of distal radial fracture: a prospective randomised study comparing quality of recovery [version 2; peer review: 2 approved]

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Abstract

Background: Immobilisation following surgical treatment of distal radial fractures (DRF) is traditionally performed with a dorsal cast splint. There is an interest in changing the rigid cast to a removable brace. This can reduce the risk for cast-corrections, complications and improve recovery of function.











The aim of the study was to compare quality of recovery (QoR) between brace and traditional cast for immobilisation during the first postoperative week.


Methods: 60 patients with American Society of Anesthesiologists (ASA) physical status 1–3, scheduled for surgical treatment of DRF under a supraclavicular block (SCB) in a day-surgery setting were randomised into two groups of immobilisation post-surgery; brace (n=30) versus traditional cast (n=30). Study objectives were: differences in self-assessed QoR using the QoR-15 questionnaire, postoperative oral oxycodone consumption, perioperative time events and unplanned healthcare contacts one week postoperatively.


Results: 54 patients, 46 females/eight males were included in the analysis; 27 with brace and 27 with traditional cast. QoR-15 median scores improved significantly from baseline/preoperative to day 7 (brace p=0.001, cast p=0.001) with no differences between the two groups. The only difference found was that patients in the brace group had significantly worse pain score 24-hours post-surgery (p=0.022). No significant differences were seen in total median oxycodone consumption the first three postoperative days. No differences were found in perioperative events or unplanned healthcare contacts.

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Any reports and responses or comments on the article can be found at the end of the article.

Conclusions: Brace appears to be a feasible option to traditional cast for immobilisation following surgical treatment of DRF. The early QoR was similar in both groups apart from more pain in the brace group the first 24 postoperative hours.

Keywords

brace, cast, distal radial fracture, immobilisation after surgery, postoperative oxycodone consumption, quality of recovery, QoR-15, removable splint.

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REVISED Amendments from Version 1

- 1) The word “sum” together with QoR-15 is removed at 14 places in the text and twice in table 3 + once in the table-lesion and once in the Figure 2-lesion. Once in Abstract/results and 13 places in the text; method (3)/results (6)/discussion (4) sections.
- 2) The word “sum” together with oxycodone consumption is changed to “total” twice in the text. Once in Abstract/results and once in the text method section.
- 3) We have expanded the description of the main study in the method section.
- 4) We have clarified in the method and discussion section that we assessed pain with the subgroup Pain in QoR-15 and the oxycodone consumption.
- 5) We have clarified the numerical difference in QoR-15 score for clinical relevance and added a reference in the discussion section.
Myles PS, Myles DB: An Updated Minimal Clinically Important Difference for the QoR-15 Scale. *Anesthesiology*. 2021; **135**(5): 934–5.
- 6) “lost to follow-up” in the result section is replaced with “not included in the analysis”.
- 7) We have added that all patients were followed-up with telephone calls in the method section.
- 8) The word “oral” has been added before oxycodone consumption at 4 places in the text. Twice in method and twice in results section.
- 9) The word “outcome” is changed to “quality of recovery” in the discussion section.
- 10) Minor spelling errors in the text has been corrected at 14 places. 7 in method section, 1 in results and 6 in discussion section.
- 11) The words “wrist functions” are changed to “more complex fractures” in the conclusion.

Any further responses from the reviewers can be found at the end of the article

Introduction

Distal radial fracture (DRF) is one of the most common fractures.¹ Fracture reduction and cast treatment is the common practice; however, if good fracture positioning cannot be achieved, open surgical correction and fixation is the most preferred option. Surgical treatment of DRF is commonly performed under either regional anaesthesia (RA) like a supraclavicular block (SCB) or general anaesthesia (GA). The currently preferred surgical treatment is volar-plate fixation followed by external cast application.² The procedure is usually associated with moderate postoperative pain, although occasionally severe. Poor postoperative pain control may interfere with rehabilitation, delay recovery and adversely affect outcomes. Achieving early pain control may help to improve patient satisfaction and functional outcomes. The cast is usually changed to a removable and adjustable brace after two weeks. Rehabilitation support from an occupational therapist is valuable in order to achieve the best final functional outcome. The use of a brace for stabilisation following DRF has now gained increased interest, and studies have shown high patient acceptance.³⁻⁵ There is, however, sparse information on the effect of the use of brace following surgical treatment of DRF in adult patients.^{6,7}

Self-assessed quality of recovery (QoR) questionnaires evaluating the postoperative course in a multi-dimensional perspective have gained increasing interest. To capture the QoR from the patients’ perspective, a variety of QoR instruments have been developed.⁸⁻¹⁴ One of these rating scales, the 40-item QoR-40, has been most extensively validated and demonstrates excellent psychometric properties. It has been translated and validated in different languages. Quality of recovery-15 (QoR-15) was developed to assess the recovery in a more simplified and user-friendly manner without reducing the quality of the instrument. It is a unidimensional measurement of QoR assessing five domains: pain, physical well-being, physical independence, psychological support and emotional state.¹⁵ Assessing perioperative interventions by means of QoR could provide a broader evaluation than merely recording the pain and analgesia consumption. Chazapis *et al* showed that QoR-15 is an acceptable and feasible outcome measure for day-surgery patients.¹⁶ Lyckner *et al* translated and culturally adapted the QoR-15 into Swedish and scores demonstrated acceptable validity, reliability and responsiveness; it can be performed in 3 minutes.¹⁷

The aim of the present study was to assess QoR and opioid consumption, following surgical treatment of distal radial fractures (DRF) comparing postoperative immobilisation with brace *versus* traditional cast, during the first postoperative week.

We hypothesised that a brace, applied directly after surgery, will give the same or better QoR as a traditional cast during the first postoperative week after surgical treatment of DRF in day surgery.

Methods

This randomised study is a part of a randomised clinical trial approved by the Gothenburg Ethical Committee (May 31 2018; registration no 214-18). It was also registered in the Sahlgrenska University Hospital GDPR (General Data Protection Regulation) database on August 28, 2018. The study was conducted in accordance with the tenets of the

1964 Declaration of Helsinki. It was retrospectively registered in clinicaltrials.gov (NCT03749174) on November 21, 2018 with explicit information about start of patient inclusion: September 3, 2018. All patients aged between 18–78 years, with American Society of Anesthesiologists (ASA) physical status 1–3 and scheduled for day surgery of a DRF between September 3, 2018, and June 15, 2020, at the Department of Anaesthesia and Intensive Care, Sahlgrenska University Hospital/Mölndal Hospital, Gothenburg, Sweden, were assessed for eligibility. Written informed consent with permission to publish was obtained from all patients before enrollment.

Opioid-naïve patients were included; when having a closed DRF assessed on radiographs and classified as AO 23 A-C1 (Orthopaedic Trauma Association), ≤ 17 days from trauma and scheduled for operative fixation with a locked volar-plate. Finally, maximum length-of-surgery had to be < 90 min and all surgeons used tourniquet. Exclusion criteria were: multifractures, inflammatory diseases, dementia, severe psychiatric disorder or other cognitive dysfunction, ongoing drug and alcohol abuse, known local anaesthetic allergy, pregnancy and finally, no fluency of the Swedish language.

Fracture classification was performed by an experienced orthopaedic surgeon.

In total, 142 patients were informed about the study. 22 patients declined to participate, leaving 120 patients to be included following written informed consent. The effect of anaesthetic technique was assessed in 90 patients and is presented separately elsewhere. The patients in this part of the study were randomised to different anaesthetic techniques, SCB with mepivacaine, SCB with ropivacaine or general anaesthesia. Rebound pain, difference in pain (NRS) at rest at 24-hours and further during the first three days after surgery between the short acting block (mepivacaine) and long acting block (ropivacaine), with general anaesthesia being control group was studied. 60 patients with the same anaesthetic technique (SCB with mepivacaine) from this study were randomised by the investigator, using sequentially numbered opaque envelopes, to one of two groups of immobilisation methods post-surgery: 1) traditional dorsal cast ($n = 30$); and 2) removable brace ($n = 30$), prefabricated and stabilised with volar and dorsal steel rails (Wrist lacer, Camp Scandinavia AB).

All patients followed the dedicated day-care bundle for enhanced recovery and safe discharge on the day of surgery. Perioperative care was optimised for providing rapid and effective recovery.

The QoR was measured with the QoR-15 score, (see the extended data).¹⁷ The questionnaire uses an 11-point numerical rating scale (for positive items, 0 = “none of the time” to 10 = “all of the time”; for negative items the scoring is reversed; maximum score 150). The 11-point numerical rating scale leads to a minimum score of 0 (very poor recovery) and a maximum score of 150 (excellent recovery). Question 7: “Getting support from hospital” was not useful in this study since all patients were in a day-surgery setting and followed-up with telephone calls. That reduced the maximum total score to 140 points instead of 150. The five dimensions of health were incorporated in the 14 questions (questions 1–6 and 8–15): physical comfort (questions 1–4 and 13), physical independence (questions 5 and 8), psychological support (question 6), pain (questions 11 and 12) and emotions (questions 9, 10, 14, and 15).

All patients received oral premedication, acetaminophen (1000 mg), oxycodone (5 or 10 mg; 5 mg to > 70 years and/or < 60 kg), etoricoxib (90 mg; if no contraindication) and meclizine (25 mg). All patients were given 8 mg betamethasone *intravenous* perioperatively.

All patients underwent surgical treatment with a volar-plate fixation by a senior orthopaedic surgeon and were then immobilised for two weeks with one of the two randomised immobilisation methods applied directly post-surgery. After two weeks, the patients allocated to the traditional cast had this routinely replaced with a brace. All patients obtained a SCB with a short-acting local anaesthetic agent (mepivacaine 1%, 25–30 mL) and were offered a mild sedation with propofol perioperatively. SCB was performed by an experienced anaesthesiologist with ultrasound guidance.

Patients being considered stable and adequate pain-relieved bypassed the Post-Anaesthesia Care Unit (PACU) and were transferred directly to the post-surgery ward. Patients needing monitoring stayed in the PACU until considered stable. All patients were planned to be discharged home from the step-down ward.

Patients obtained a protocol to note the type, dose and frequency of analgesic consumption at home and they all received the same postoperative pain management at discharge: oxycodone 5–10 mg and acetaminophen 1000 mg for pain control, respectively. They received a prescription of these medications to be taken *ad libitum* within a daily maximum dose of 30–40 mg oxycodone and 4000 mg of acetaminophen.

At day 2–4 postoperatively, the patients had their first appointment to the occupational therapist with following appointments scheduled at 2, 6, 12 weeks and 1 year postoperatively.

Data collection

All data were collected by the same two investigators, while patients were still in hospital and then by four follow-up telephone calls at 24, 48, 72 hours and 7 days after discharge. Patient characteristics were collected prior to start of surgery and anaesthesia. QoR-15 was performed four times (baseline/preoperatively, 24, 72 hours and 7 days post-surgery). The pain domain was used for the assessment of pain. Postoperatively, we collected oral oxycodone consumption, administered at the hospital and after discharge; the first 3 postoperative days and 7 days after surgery. We also registered perioperative time events; surgery time (including fixation with cast or brace), time the anaesthetic nurse was occupied with the patient, theatre time, unplanned admission, number of patients needing PACU stay, total time in hospital, SCB total duration time and duration time after surgery.

The primary outcome was difference in the sum median (interquartile range) and its five domains of QoR-15 score at baseline, 24 hours, 72 hours and 7 days after surgery between the two groups.

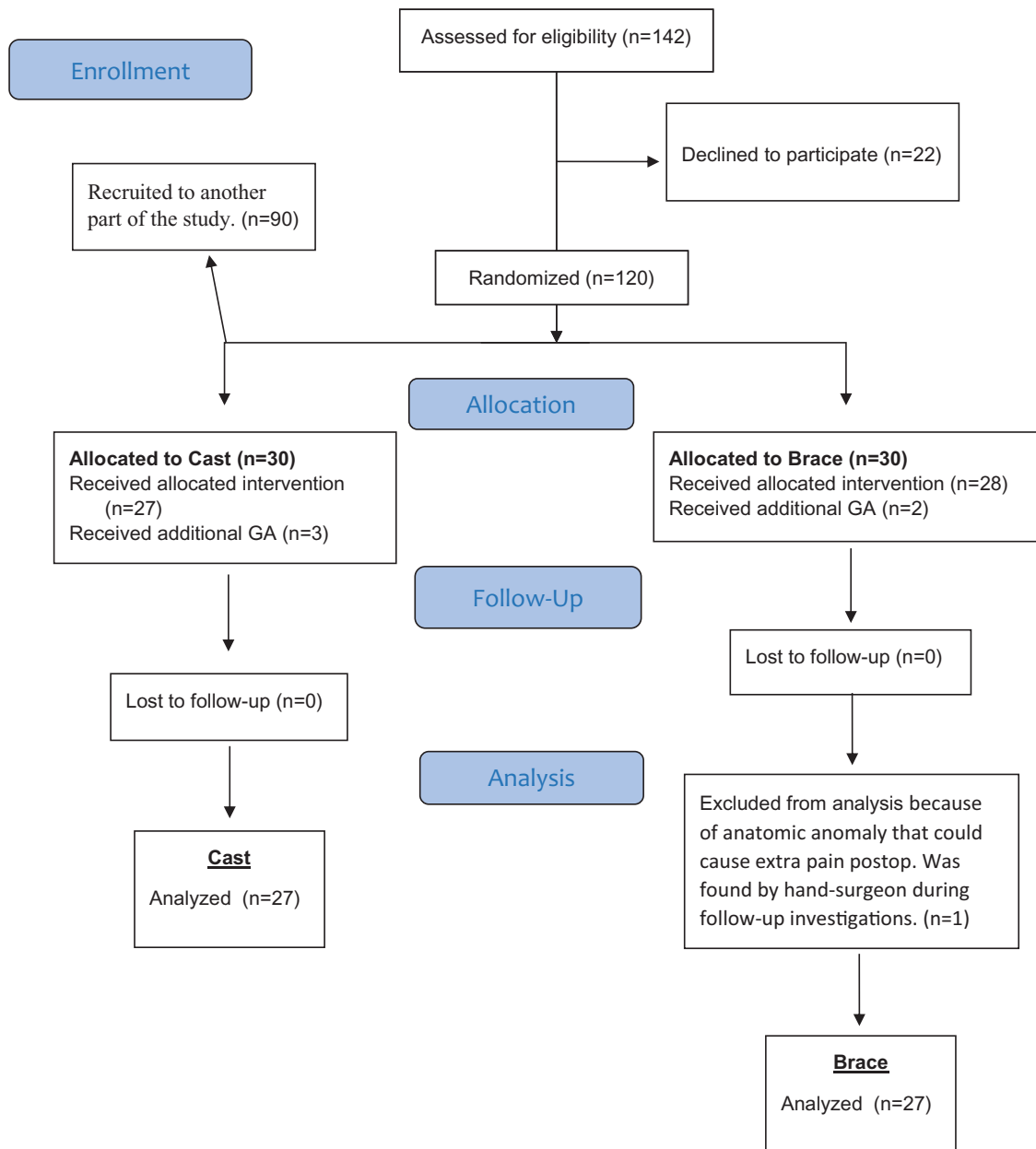


Figure 1. CONSORT Flowchart. Flow of patients through the trial. General anesthesia (GA).

The secondary outcome was the total median (interquartile range) amount of postoperative oral oxycodone consumption administered at the hospital and after discharge, the first 3 postoperative days and 7 days after surgery. Finally, perioperative time events were as described above.

Statistical analyses

Numerical data are presented as mean and standard deviation (SD) and median and quartiles for non-normally distributed data. Categorical data is presented as numbers and percent. Differences between the study groups, brace and cast, were studied with independent sample t-test for normally distributed data and Mann–Whitney U-test for skewed data. Differences in proportion were studied with a Chi-squared test. The QoR data are presented as median and interquartile range (IQR). Differences between median QoR-15 and changes in QoR-15 score between time points were analysed with non-parametric tests, Mann–Whitney U-test and Kruskal–Wallis test as applicable. A $p < 0.05$ was considered statistically significant.

Results

60 patients scheduled for surgical treatment of DRF were included in the study following informed consent. Six patients were not included in the analysis; five due to failed supraclavicular block and one because of anatomic anomaly (Figure 1).

Table 1. Patient characteristics and clinical data presented as mean (± 2 SD) or absolute number as appropriate. Classification of patients' health and comorbidity level by the American Society of Anesthesiologists (ASA) system, Body mass index (BMI), Apfel score; riskfactors (1-4) for PostOperative Nausea and Vomiting (PONV).

Characteristics	Cast (n = 27)	Brace (n = 27)	p-value
Age (years)	60 (± 10)	51 (± 17)	$p = 0.02$
Gender; female/male (no of patients)	24/3	22/5	0.44
BMI (kg m^{-2})	23 (± 2.3)	25 (± 3.5)	$p = 0.02$
Smoking; yes/no (number of patients)	3/24	4/23	0.69
Snuffing; yes/no (number of patients)	2/25	1/26	0.55
Apfel score; 1/2/3/4 (number of patients)	0/4/17/6	0/7/14/6	0.58
ASA; 1/2/3 (number of patients)	13/13/1	14/13/0	0.60
Day from injury Number of days	8.4 (± 3.1)	9.7 (± 3.6)	0.15

Table 2. Perioperative time observations. Data are presented as mean ($2 \pm \text{SD}$) or for categorical data (no; %). Post Anaesthesia Care Unit (PACU), Day Surgery (DS), Supraclavicular block (SCB).

Perioperative time events	Cast (n = 27)	Brace (n = 27)	p-value
Anaesthesia nurse time (minutes)	152 (± 46)	155 (± 47)	0.97
Theater time (minutes)	192 (± 48)	172 (± 43)	0.11
Surgery time (including plaster/orthosis) (minutes)	71 (± 21)	69 (± 20)	0.48
PACU admitted patients (number of patients, %)	4 (15%)	1 (4%)	
Unplanned Admission (number of patients, %)	2 (7.4%)	0	
Hospital time, DS patients (minutes)	501 (± 100)	503 (± 79)	0.99
SCB total duration time (hours)	4.6 (± 1.1)	4.9 (± 1.5)	0.78
SCB duration time after surgery (hours)	2.7 (± 1.0)	2.6 (± 1.5)	0.55

54 patients, 46 females and eight males with a mean age of 56 (SD ± 15) years, ASA 1–3 patients, were included in the analysis, 27 patients in each group; brace *versus* cast for immobilisation post-surgery. The mean age was lower (p = 0.02) and the mean BMI was higher (p = 0.02) in the brace group. No further differences were found in patients’ baseline characteristics (Table 1).

Time from injury and perioperative time events did not differ between the groups. The majority of patients could bypass the PACU and were transferred directly to the step-down ward. The SCB resolution-time was a mean of 2.6 hours after surgery in both groups. No further differences were seen between the groups in any perioperative time events (Table 2).

Unplanned admission and unplanned healthcare contacts after discharge

Two patients (7.4%) from the cast group were admitted overnight post-surgery, both due to social reasons. None of the patients in the brace group needed an unplanned overnight admission and neither did any patient need unplanned healthcare contacts after hospital discharge during the first postoperative week.

Quality of recovery

The median QoR-15 score was equal in the two groups at preoperative baseline assessment. Then, there were an increase in median QoR-15 score in both study groups from baseline and up to 1 week after surgery (cast p = 0.001, brace p = 0.001). No postoperative reduction in median QoR-15 score was seen. There was a slightly different pattern between the two groups and thus, the cast group had the largest increase from baseline already after 24 hours while the brace group increased slower and reached the largest increase from baseline first at 72 hours post-surgery. The median QoR-15 score did not differ between the groups one week postoperatively (Figure 2, Table 3).

The preoperative/baseline QoR-15 score showed no difference between the groups. However, the domain physical comfort was significantly lower (p = 0.048) in the cast group. The different domains in the QoR-15 questionnaire showed only minor differences between the two groups at the four time-points studied. There was a significant difference in pain-score at 24 hour-assessment when brace scored worse than cast (p = 0.022) (Figure 3, Table 3).

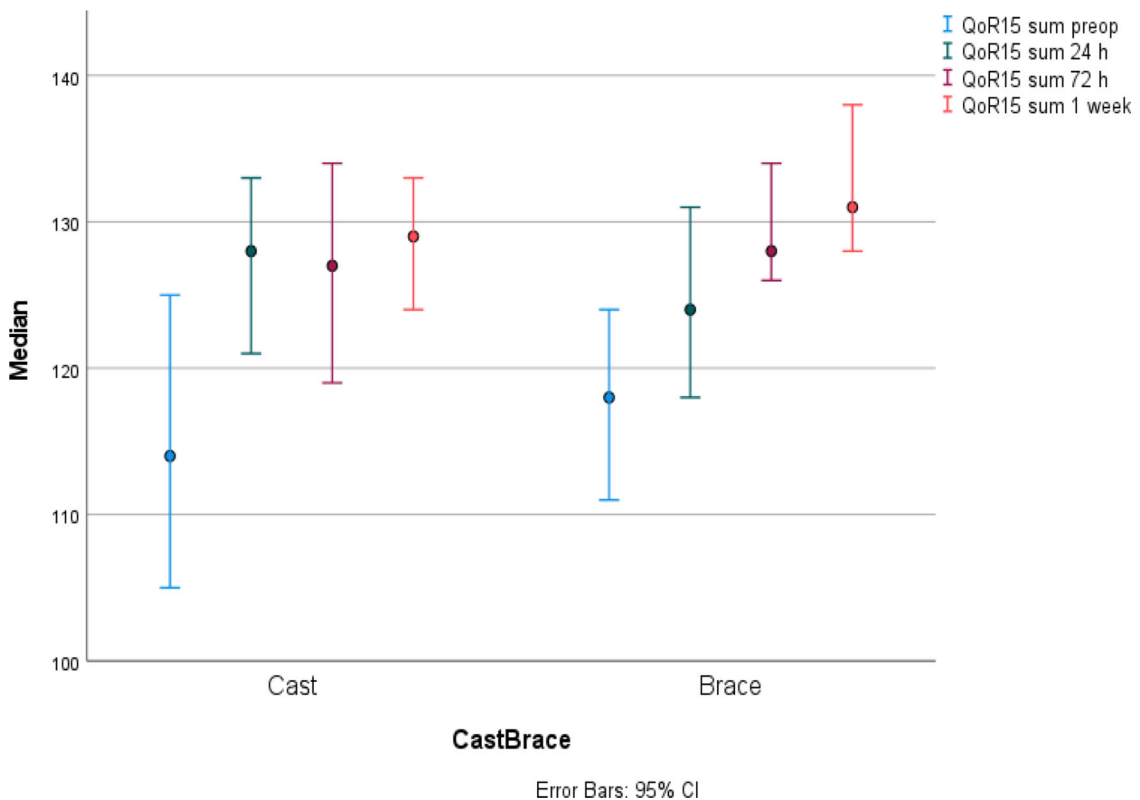


Figure 2. Quality of Recovery -15 (QoR-15) presented in median (IQR) for cast and brace groups at each time point. Maximum score possible was 140 points. Both groups showed an increase in median QoR-15 score from baseline and up to 1-week post-surgery (cast p = 0.001, brace p = 0.001).

Table 3. Quality of Recovery -15 (QoR-15) and the sum for the five different domains (with maximum score possible in parentheses) are presented in median (IQR) at the different time-points.

QoR-15 score, (max points)	Cast (n = 27)	Brace (n = 27)	p-value
Preoperative, baseline (140p) Summary score	114 (104-125)	118 (109-125)	0.34
Pain (20p)	15 (10-19)	17 (15-17)	0.19
Physical comfort (50p)	44 (39-48)	46 (44-50)	0.048
Physical Independency (20p)	15 (12-16)	16 (14-16)	0.97
Psychological support (10p)	10 (10-10)	10 (10-10)	0.53
Emotional state (40p)	33 (20-38)	32 (27-36)	0.92
Postoperative, 24 hours (140p) Summary score	128 (118-133)	124 (118-132)	0.31
Pain (20p)	18 (14-20)	15 (10-18)	0.022
Physical comfort (50p)	49 (46-50)	48 (45-50)	0.60
Physical Independency (20p)	16 (12-18)	16 (12-18)	0.99
Psychological support (10p)	10 (10-10)	10 (10-10)	0.15
Emotional state (40p)	38 (35-40)	38 (36-40)	0.79
Postoperative, 72 hours (140p) Summary score	127 (118-135)	128 (125-134)	0.72
Pain (20p)	18 (15-20)	18 (16-19)	0.97
Physical comfort (50p)	47 (44-50)	49 (46-50)	0.28
Physical Independency (20p)	15 (15-18)	17 (14-18)	0.77
Psychological support (10p)	10 (10-10)	10 (10-10)	1.0
Emotional state (40p)	38 (35-40)	38 (35-40)	0.90
Postoperative, 1 week (140p) Summary score	129 (123-134)	131 (128-138)	0.20
Pain (20p)	19 (17-20)	20 (17-20)	0.38
Physical comfort (50p)	49 (44-50)	49 (47-50)	0.52
Physical Independency (20p)	16 (14-18)	18 (15-18)	0.40
Psychological support (10p)	10 (10-10)	10 (10-10)	0.32
Emotional state (40p)	37 (32-40)	38 (36-40)	0.70

Postoperative oral oxycodone consumption

Median postoperative oral oxycodone consumption was low overall. Median consumption for both groups together was 27.7 (IQR 9-46) mg the first three postoperative days. No differences in oxycodone consumption were seen (Table 4).

Discussion

This study was initiated to assess the feasibility to use a removable brace compared with a traditional cast following surgical treatment of distal radial fracture (DRF). There are two main findings in the present study:

Firstly, supported our hypothesis, we found no significant difference in the QoR-15 score, a difference was seen in subdomain pain, noted at 24 hours, between the brace and cast groups during the first postoperative week. The numerical difference is lower than what has been shown of clinical relevance.¹⁸ The multifactorial reasons of the experienced pain have not been furthermore investigated in this study.

Secondly, we found no deterioration in the median QoR-15 score post-surgery in neither of the two groups. The postoperative median QoR-15 score increased over time from baseline until one-week post-surgery in both study groups, with no differences at any time-point assessed. This is a scarce finding since most patients usually do show impairment at 24 hours post-surgery.¹⁶ This could indicate that the preoperative QoR-15 score may not be a true baseline score.

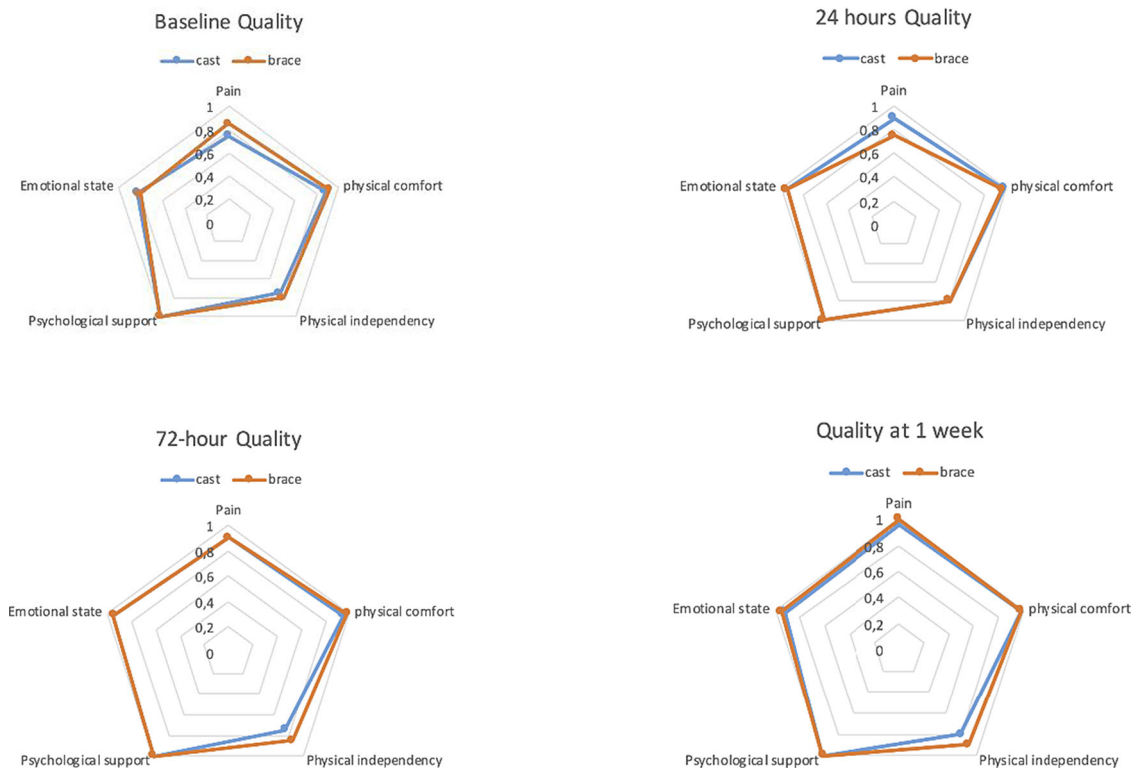


Figure 3. The Spider-chart shows the five domains median scores put in perspective of each domains max-score between groups over time.

Table 4. Postoperative oral oxycodone consumption in mg presented in median (IQR) at different time-points.

Postoperative oral Oxycodone consumption in mg	Cast (n = 27)	Brace (n = 27)	p-value
Step-down ward	5 (0-5)	5 (5-5)	0.66
Discharge - 24 h	5 (0-10)	10 (10-20)	0.08
24 - 48 h	5 (0-10)	5 (0-20)	1.0
48 - 72 h	0 (0-10)	0 (0-10)	1.0
Sum oxycodone day 0-3	15 (5-40)	35 (15-50)	0.27
Day 7	0 (0-0)	0 (0-0)	0.47
Sum oxycodone day 0-3+7	20 (5-40)	35 (15-50)	0.27

Focusing on individual items of the scores, the results indicated that patients were tired, anxious and in pain 24 hours prior to surgery. Further, all the patients in the present study had their trauma in average 9 days prior to surgery and some of them had been treated conservatively without success. These circumstances may not provide an ideal baseline for assessing recovery following surgery and could explain the impaired QoR-15 baseline scores; however, it may still constitute a baseline for comparison. This can thus explain the result that we found no postoperative deterioration in the median QoR-15 score at 24 hours post-surgery, merely a continuous improvement. Chazapis *et al.* had similar result in their study assessing orthopaedic patients scheduled for day surgery (DS).¹⁶

Both study groups had a SCB with a short-acting local anaesthetic agent (mepivacaine) as part of a multi-modal analgesia concept, reducing the risk for rebound pain after discharge.¹⁹ Oral pain therapy was started before surgery, where all patients had acetaminophen, etoricoxib, oxycodone given preoperatively and 8 mg betamethasone given *intravenously* perioperatively as a part of the multi-modal analgesic treatment. Thus, the difference in early pain is possibly related to the brace. The numerically higher oxycodone consumption, though not statistically significant, may at least partly be

associated to oxycodone dosage, adjusted to age and BMI, since patients with brace were both significantly younger and had higher BMI. No further differences were seen in the patients' self-assessed QoR or oxycodone consumption.

Day surgery (DS) continues to grow as a field of perioperative care and now also subacute surgeries, like fractures, are performed as day surgery. None of the patients in the present study required hospital admission. Two patients were however admitted of social reasons, not related to recovery. There were no unplanned healthcare contacts during the first postoperative week and therefore, this study confirms the feasibility of scheduling surgical treatment of DRF as a day surgery procedure. The immobilisation techniques hardly impact day surgery planning, nor may it affect theatre times. Although we found no time gain in the brace-group, we speculate that using a brace should reduce time in theatre as we avoid the time for cast construction. Every intervention that could facilitate a rapid, safe and effective patient turnover is of importance.

The ability to resume normal activities of daily living after surgery and anaesthesia is an important indicator of a high quality of perioperative care. Most patients' QoR-15 scores had returned to their preoperative values and exceeded them after 24 hours. This randomised study suggests that measurement of QoR-15 before surgery, (but not on the day of surgery), and 48 h postoperatively could provide a useful and feasible assessment of patient-reported quality of recovery after day case orthopaedic surgery.¹⁶

Strengths and limitations

This study had a prospective randomised clinical design that minimised the risk of confounding factors. It was a single-centre design without any loss to follow-up reducing the risk of selection and information bias and also warrants generalisability of this study. Only two investigators collected the data ensuring consistency and high standard of data collection.

However, there are some limitations to this study. All results must be assessed remembering the fact that no sample size calculation was made for this particular study. The study is a part of a larger study assessing anaesthetic techniques and the sample size calculation was made for that study.

The aim of QoR-15 was to assess QoR following anaesthesia and surgery and not to assess QoR following different immobilisation techniques. The sensitivity of the QoR-15 instrument may have been too low for this intervention and a potential ceiling effect must be acknowledged. Moreover, the trial was not blinded to any of the anaesthesia/surgery staff, nor to the study nurse and nor to the patient. We excluded patients with poor Swedish comprehension and severe pre-existing medical conditions. We cannot disregard the fact, that a nurse repeatedly calling the patients to ask for their health status during the first postoperative week could contribute to a therapeutic effect.

Conclusion

We found brace, applied directly after surgery, to be a feasible option to traditional cast for immobilisation following surgical treatment of DRF. There was no difference in quality of recovery, assessed by QoR-15, during the first postoperative week, between brace and cast. The effects of brace immobilisation on more protracted recovery and more complex fractures needs further studies.

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Data availability

Underlying data

OSF: Underlying data for 'Brace *versus* cast following surgical treatment of distal radial fracture: a prospective randomised study comparing quality of recovery', <https://doi.org/10.17605/OSF.IO/KJC2N>.²⁰

This project contains the following underlying data: pain scores, oxycodone consumption and QoR15 scores
Data are available under the terms of the [Creative Commons Attribution 4.0 International license](https://creativecommons.org/licenses/by/4.0/) (CC BY 4.0).

Reporting guidelines

OSF: CONSORT checklist for 'Brace *versus* cast following surgical treatment of distal radial fracture: a prospective randomised study comparing quality of recovery', <https://doi.org/10.17605/OSF.IO/KJC2N>.²⁰

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Consent

Written informed consent for publication of the patients' details was obtained from the patients

Authors' contributions

Study design: JJ, BN, JK, IS, JB

Study registration: BN, IS

Patients recruitment: IS

Manuscript editing and approval: all authors.

Data interpretation: JJ, BN, JK, IS, JB

Statistical analysis: JJ

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Version 2

Reviewer Report 11 February 2022

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Jakob Walldén 

Department of Surgical and Perioperative Sciences, Anaesthesiology and Intensive Care Medicine (Sundsvall), Umeå University, Sundsvall, Sweden

The authors have addressed the issues raised in the peer review report and have made changes and clarifications in the manuscript. I have no further questions to this well-written manuscript.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Anesthesiology, postop-recovery

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 31 January 2022

<https://doi.org/10.5256/f1000research.120605.r121451>

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Robert Gvozdencovic 

Department of Orthopedic Surgery, Hand Surgery Unit, Copenhagen University Hospital Gentofte, Hellerup, Denmark

I am happy with the answers and comments provided by the corresponding author of this paper. All my questions and suggestions have been profoundly answered, and accordingly, some changes has been added in the manuscript. I have no further comments on this work.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Hand Surgery.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 17 January 2022

<https://doi.org/10.5256/f1000research.55272.r118393>

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Robert Gvozdencovic 

Department of Orthopedic Surgery, Hand Surgery Unit, Copenhagen University Hospital Gentofte, Hellerup, Denmark

Dear authors, thank you for this submission. Your paper is of high evidence level, well-designed, well-written and easy to read. Nevertheless, I have some comments and questions:

- Despite a good study-design, there might be a potential bias if any differences in fracture-complexity patterns between the groups existed. What if the cast group, for instance, had more complex fracture patterns? Please explain this in details, if only AO 23 A-C1 were included.
- Does that possibly mean that the results of this study can only have clinical relevance for this particular distal radius fracture pattern? Your conclusion is definitely not in accordance to this assumption. If relevant, correct the conclusion accordingly.
- So, the question is if the brace can also be safely used for more complex distal radius patterns? Add, eventually how many percent of this particular fracture pattern is generally present among all distal radius fracture needing surgery.
- Why this study used only one PROM and not others where minimally important clinical difference (MICD) is existing in the literature (DASH)? If you used them, than the proper sample analysis before the study probably could be foretaken.
- The use of sum median for both the QoR-scores and for opioid use is confusing and make the results not clear.
- The flowchart needs to be corrected in accordance to the text where you claim that 5 patients did not show up on the follow-up.

- There were not statistically significant difference for the postoperative pain in disfavor of brace. Could this be clinically relevant?
- Mention the eventual cost difference between brace and the cast, if it exists. In some part of the world this question is not insignificant.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Yes

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Hand Surgery.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 23 Jan 2022

Irén Sellbrant, Institute of Clinical Science, Sahlgrenska Academy, University of Gothenburg, Sahlgrenska University Hospital, Gothenburg, Sweden

Reviewer 2 (Robert Gvozdencovic)

Dear authors, thank you for this submission. Your paper is of high evidence level, well-designed, well-written and easy to read. Nevertheless, I have some comments and questions:

Despite a good study-design, there might be a potential bias if any differences in fracture-complexity patterns between the groups existed. What if the cast group, for instance, had more complex fracture patterns? Please explain this in details, if only AO

23 A-C1 were included.*Authors Comments:*

Thank you for this constructive concern. We have made sure from the start that there was no inclusion bias. We have included AO 23, A, B and C1 fractures. These subgroups cover the common distal radius fractures. These fractures are common in this age group, and it is important to be able to make general conclusions. We decided from the very start to exclude C2 and C3 fractures, as they are different type(s) of fracture(s) and call for much more extensive and different treatment. We are therefore confident that there are no major differences in fracture-complexity patterns between the groups. We would also like to mention that this is a prospective randomized study and accordingly, the randomization would take care of minor differences and level out the risk of different cofounders in the different groups. In other words, we have included and randomized fractures of similar complexity levels.

This is a prospective randomized study following the inclusion criteria described in the Methods section. Taken together, 6 patients were excluded from analysis, none of these were fracture/surgery related factors while 5 were excluded due to failed block and 1 due to an anatomic deviation.

Does that possibly mean that the results of this study can only have clinical relevance for this particular distal radius fracture pattern? Your conclusion is definitely not in accordance to this assumption. If relevant, correct the conclusion accordingly.

Authors Comments:

There is only limited information about the use of brace as early immobilisation following open reposition and fixation of distal radius fracture in literature and this is one of the main reasons why this study was performed. As mentioned above, this study included AO 23 A, B and C1 fractures. These are the common distal radius fractures in this age group. There is a high volume, and these fractures are a relatively homogenous group of patients and thus seemingly adequate for inclusion to a randomised study. However, we agree that it is not possible to provide robust comments on the generalisation of the findings. Further studies are needed to confirm its safe use, especially in relation to more complex and complicated fractures (C 2 and C3) as mentioned in the conclusion.

So, the question is if the brace can also be safely used for more complex distal radius patterns? Add, eventually how many percent of this particular fracture pattern is generally present among all distal radius fracture needing surgery.

Authors Comments:

Distal radius fracture (DRF) is one of the most common fractures, with an annual incidence of approximately 25000/year in Sweden. Data from the Swedish fracture register shows that approximately 20.6% of acute DRF undergo surgical fixation primarily and 5.5% secondary surgical fixation. We are aware of that need for open reposition and surgical fixation increases with fracture complexity. We included up to C1 fractures as described above. We do not have explicit national percentage of surgical need for the group studied, but it is without doubt the most common fractures.

However, we managed to find statistics for DRF classified to AO 23 C1-3, registered at

Sahlgrenska Universityhospital/Mölnåls hospital from 2012-2021, see below.
C2 and C3, the more complex fractures that not are a part of this study, seems to be 39% of all DRF that needs surgery. That leaves 61% to be the patients in our study.

DRF class	% of all DRF	% needs surgery
C1	12.1	41.8
C2	7.6	71.1
C3	5.5	84.8

Why this study used only one PROM and not others where minimally important clinical difference (MICD) is existing in the literature (DASH)? If you used them, then the proper sample analysis before the study probably could be foretaken.

Authors Comments:

The aim of the study was to assess the quality of recovery with the use of a multi-dimensional validated questionnaire constructed by the Australian group, where Paul Myles is the senior researcher. This quality of recovery questionnaire, which was used in the present study has previously been assessed as an effective scale for studying the recovery following surgery/anesthesia and it includes 5 main domains. And this was the main purpose of the study. It would of course have been of interest to also gain insight to patient reported outcomes, using PROM questionnaire, however, DASH is not optimally suited for evaluation of the early phase following surgery.

“Myles et al. defined in a study 2016 updated in 2021, the size of the minimum clinically meaningful difference to the patient. They recommend the value to be 6.0 and the largest difference between the groups that we noted in this study was 4.0. It is, however, important to know that a significant difference in QoR-points doesn't necessary have to be of clinical value.”

The use of sum median for both the QoR-scores and for opioid use is confusing and make the results not clear. *Authors Comments:* The sum was used to describe that the total score for all 14 questions were analyzed/compared over the time-point studied and between groups. Likewise, the sum describes the **total** amount of opioid use for the 3 postoperative days studied. We have **amended** the text accordingly. Please see the revised manuscript.

The flowchart needs to be corrected in accordance to the text where you claim that 5 patients did not show up on the follow-up.

Authors Comments:

Thank you for important comment; 6 patients **were not included in the analysis** and this is unfortunately described as lost for follow-up in the text. These 6 patients are excluded in the flow chart adequately and the description of exclusion is now corrected in the result section. The wording is, however, incorrect and is now **amended** accordingly.

There were not statistically significant difference for the postoperative pain in disfavor of brace. Could this be clinically relevant?

Authors Comments:

There was a statistically significant difference in QoR pain domain scores at 24 hours postop. The

numerical difference of at least 6 has by the score developers, however, shown a clinically relevant difference in domain scores. We found merely a numerical difference of 4. Moreover, we did not see any differences in need for opioid analgesics. This has been further clarified in the method as well as the discussion sections.

Myles PS, Myles DB, Galagher W, Chew C, MacDonald N, Dennis A. Minimal Clinically Important Difference for Three Quality of Recovery Scales. *Anesthesiology*. 2016;125(1):39-45.

Myles PS, Myles DB. An Updated Minimal Clinically Important Difference for the QoR-15 Scale. *Anesthesiology*. 2021;135(5):934-5. **Mention the eventual cost difference between brace and the cast, if it exists. In some part of the world this question is not insignificant.**

Authors Comments:

We agree that the impact of cost associated to a new intervention must be acknowledged. The direct cost associated to the brace is higher as compared to a cast. However, at our department we routinely apply a brace following the initial 2-week period with cast. The brace applied direct after surgery in this study can thus be used throughout the period. Thus, the net direct cost would not be increased, but possibly decreased. Moreover, the resources for a cast application, and its eventual corrections, will reduce the total cost. It should be acknowledged that all patients were called for a follow-up interview at 4 occasions, enabling patients to raise questions.

Competing Interests: No competing interests were disclosed.

Reviewer Report 03 June 2021

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Jakob Walldén

Department of Surgical and Perioperative Sciences, Anaesthesiology and Intensive Care Medicine (Sundsvall), Umeå University, Sundsvall, Sweden

It is a well written and structured manuscript evaluating postoperative quality of recovery (QoR) after surgical treatment of distal radius fracture under peripheral blockade. The authors compare immobilization with dorsal splint cast vs. removable brace and as main outcome measures uses self accessed QoR, opioid consumption. The study is an analysis of a subgroup in the RADAR-study (NCT03749174) and the randomization procedure is clearly pre-defined. Underlying data is accessible. The reporting follows CONSORT and statistical methods are appropriate. They find no main differences and concluded that brace is a feasible option. Conclusions are clear and justified.

However, I have some concerns with the study that needs to be addressed:

1. The study is a sub-analysis of two out of four arms in the RADAR-study, according to the registration in clinical trials. Please expand the description of the main study in the methods

section and justify the decision for this sub-analysis as a separate manuscript. Further, how was the quality of recovery in the two other intervention arms? Please comment.

2 The main outcome measure (QoR-15) is not mentioned in the clinical trial registration. Why? Please explain and also confirm that you had ethical approval to use the QoR-15 as your evaluation tool and that the approval was dated before the inclusion of patients in this prospective study.

3. Pain assessment with NRS is one of two primary outcome variables in the predefined protocol according to www.clinicaltrials.gov. It is described in the methods section, but results not reported in the manuscript. Please explain/revise.

4. Further, why was the occupational therapist evaluation on the 3rd day not included in the analysis? Please explain/discuss.

5. The use of "sum" in the variables might be confusing for the readers of the paper. The QoR-15 score **is** the sum of all domains and you do not need to add "sum". Please revise all section in the manuscript. For the variable opioid consumption, it is better to use "Total" instead of "sum" (ex: Table 4).

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Yes

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Anesthesiology, postop-recovery

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 16 Nov 2021

Irén Sellbrant, Institute of Clinical Science, Sahlgrenska Academy, University of Gothenburg, Sahlgrenska University Hospital, Gothenburg, Sweden

Reviewer Comments:

Reviewer 1 (Jakob Walldén)

It is a well written and structured manuscript evaluating postoperative quality of recovery (QoR) after surgical treatment of distal radius fracture under peripheral blockade. The authors compare immobilization with dorsal splint cast vs. removable brace and as main outcome measures uses self-accessed QoR, opioid consumption. The study is an analysis of a subgroup in the RADAR-study (NCT03749174) and the randomization procedure is clearly pre-defined. Underlying data is accessible. The reporting follows CONSORT and statistical methods are appropriate. They find no main differences and concluded that brace is a feasible option. Conclusions are clear and justified.

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1. The study is a sub-analysis of two out of four arms in the RADAR-study, according to the registration in clinical trials. Please expand the description of the main study in the methods section and justify the decision for this sub-analysis as a separate manuscript.

Authors Comments:

The main RADAR-study was performed to assess different anaesthetic techniques and their impact on postoperative pain (NRS) and opioid consumption during the first 3 postoperative days.

The RADAR-study arms assessing the impact of immobilization techniques was aimed to compare traditional cast with a flexible brace already as early fixation, directly post-surgery. Our interest was to assess whether the brace could improve the day case perioperative course, speeding up the perioperative time events and reducing early postoperative discomfort commonly associated to the cast fixation. The occupational therapist, also PhD-student, had the goal to assess the effects on the rehabilitation, need for unplanned visits due to cast issues and the functional outcome for up to 12-month post-surgery.

Further, how was the quality of recovery in the two other intervention arms? Please comment.

Authors Comments:

The main object for the "main RADAR-study" was pain and opioid requirement, assessing the risk for rebound pain following block resolution and subsequent increased need for opioid analgesic during the intermediate postoperative course. The study aims were impact of the pain 24 hours post-surgery and during the first 3 postoperative days and opioid requirement during the same period, PONV/PDNI, time events, time to discharge and unplanned health contacts. We did unfortunately not focus on the quality of recovery

in that part of the study.

2. The main outcome measure (QoR-15) is not mentioned in the clinical trial registration. Why?

Please explain and also confirm that you had ethical approval to use the QoR-15 as your evaluation tool and that the approval was dated before the inclusion of patients in this prospective study.

Authors Comments:

The ethical review protocol was approved May 31st 2018 (as described in the method section) and contains QoR-15, The Clinical trial Registration was unfortunately not fully aligned with the ethical application, but is now updated accordingly clinicaltrials.gov (NCT03749174).

3. Pain assessment with NRS is one of two primary outcome variables in the predefined protocol according to www.clinicaltrials.gov. It is described in the methods section, but results not reported in the manuscript. Please explain/revise.

Authors Comments:

The primary of this part of the study was the QoR-15 questionnaire, time events during the perioperative course and the opioid consumption. We assessed pain in this subgroup by the QoR questions that showed a pain difference at 24 hours in favor for the traditional cast.

4. Further, why was the occupational therapist evaluation on the 3rd day not included in the analysis? Please explain/discuss.

Authors Comments:

The occupational therapist follow-up is still not completed (partly because of the COVID-19 Pandemic) and will commence up to 12 months' post-surgery. The more in depth assessment of wrist function will hopefully, although delayed, be performed by the occupational therapists during coming autumn and winter.

5. The use of "sum" in the variables might be confusing for the readers of the paper. The QoR-15 score is the sum of all domains and you do not need to add "sum". Please revise all section in the manuscript. For the variable opioid consumption, it is better to use "Total" instead of "sum" (ex: Table 4).

Authors Comments:

Corrected accordingly.

Competing Interests: No competing interests were disclosed

Author Response 23 Jan 2022

Irén Sellbrant, Institute of Clinical Science, Sahlgrenska Academy, University of

Gothenburg, Sahlgrenska University Hospital, Gothenburg, Sweden

Reviewer 1 (Jakob Walldén)

It is a well written and structured manuscript evaluating postoperative quality of recovery (QoR) after surgical treatment of distal radius fracture under peripheral blockade. The authors compare immobilization with dorsal splint cast vs. removable brace and as main outcome measures uses self-accessed QoR, opioid consumption. The study is an analysis of a subgroup in the RADAR-study (NCT03749174) and the randomization procedure is clearly pre-defined. Underlying data is accessible. The reporting follows CONSORT and statistical methods are appropriate. They find no main differences and concluded that brace is a feasible option. Conclusions are clear and justified. However, I have some concerns with the study that needs to be addressed:

1. The study is a sub-analysis of two out of four arms in the RADAR-study, according to the registration in clinical trials. Please expand the description of the main study in the methods section and justify the decision for this sub-analysis as a separate manuscript.

Authors Comments:

The main RADAR-study was performed to assess different anaesthetic techniques and their impact on postoperative pain (NRS) and opioid consumption during the first 3 postoperative days. The main RADAD-study is now further clarified in the method section and aligned to the Clinical Trial registration.

The RADAR-study arms assessing the impact of immobilization techniques was aimed to compare traditional cast with a flexible brace already as early fixation, directly post-surgery. This is a separate intervention. Our hypothesis was that brace fixation direct after surgery could improve the day case perioperative course, speeding up the perioperative time events and reducing early postoperative discomfort commonly associated to the cast fixation and facilitate activities of daily living. The occupational therapist, also PhD-student, had the goal to assess the effects on the rehabilitation, need for unplanned visits due to cast issues and the functional outcome for up to 12-month post-surgery.

Further, how was the quality of recovery in the two other intervention arms? Please comment.

Authors Comments:

The object for the "main RADAR-study" was pain and opioid requirement, assessing the risk for rebound pain following block resolution and subsequent increased need for opioid analgesic during the intermediate postoperative course. The study aims were impact of the pain 24-hours post-surgery and during the first 3 postoperative days and opioid requirement during the same period, PONV/PDND, time events, time to discharge and unplanned health contacts. We did unfortunately not focus on the quality of recovery in that part of the study.

2. The main outcome measure (QoR-15) is not mentioned in the clinical trial registration. Why? Please explain and also confirm that you had ethical approval to

use the QoR-15 as your evaluation tool and that the approval was dated before the inclusion of patients in this prospective study.

Authors Comments:

The ethical review protocol was approved May 31:st 2018 (as described in the method section) and contains QoR-15. The Clinical trials Registration was not fully aligned with the ethical application, but is now updated accordingly clinicaltrials.gov (NCT03749174).

3. Pain assessment with NRS is one of two primary outcome variables in the predefined protocol according to www.clinicaltrials.gov. It is described in the methods section, but results not reported in the manuscript. Please explain/revise.

Authors Comments:

The primary of this part of the study was the QoR-15 questionnaire, time events during the perioperative course and the opioid consumption. We assessed pain in this subgroup by the QoR questions that showed a pain difference at 24 hours in favor for the traditional cast. However, the numerical difference was less than what has been shown as a clinical relevant difference by Myles et al. (references). This is now clarified in the method as well as in the discussion section.

4. Further, why was the occupational therapist evaluation on the 3rd day not included in the analysis? Please explain/discuss.

Authors Comments:

The occupational therapist follow-up is still not completed (partly because of the Covid-Pandemic) and will commence up to 12 months' post-surgery. The more in-depth assessment of wrist function will hopefully, although, delayed be performed by the occupational therapists during coming autumn and winter.

5. The use of "sum" in the variables might be confusing for the readers of the paper. The QoR-15 score is the sum of all domains and you do not need to add "sum". Please revise all section in the manuscript. For the variable opioid consumption, it is better to use "Total" instead of "sum" (ex: Table 4).

Authors Comments:

Corrected accordingly.

Competing Interests: No competing interests were disclosed.

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