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Point-of-care ultrasound-guided versus standard reduction of displaced distal radius fractures in the emergency department: a randomised controlled clinical trial

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ABSTRACT

Background During closed reduction of displaced distal radius fractures, physical examination is used to determine the need for further manipulation before radiographic confirmation and cast application. Manipulation performed under ultrasound guidance has the potential to decrease the number of reduction attempts.

Methods This multicentre randomised controlled trial was undertaken between December 2018 and July 2020 in the ED of four hospitals in the Netherlands. Patients aged ≥16 years presenting to the ED with a distal radius fracture requiring closed reduction were randomised to either point-of-care ultrasound (PoCUS)-guided or standard reduction. The primary outcome was the proportion of patients requiring more than one reduction attempt. The secondary outcomes were time to complete reduction and treatment plan at ED discharge (conservative or operative repair).

Results A total of 214 patients were screened, of which 211 patients were included for primary endpoint analysis (87% female, median age 68 years, 94% dorsal angulation, 59% intra-articular and 73% multifragmentary). In total, 105 patients were randomised to standard treatment and 106 patients to PoCUS-guided fracture reduction. In the standard treatment group, 13 patients (12%) required more than one reduction attempt, compared with 6 patients (6%) in the PoCUS group (OR 2.35, 95% CI 0.86 to 6.45). The median reduction time was 5 min in the PoCUS group (IQR 3–6) vs 3 min (IQR 2–4) in the standard reduction group (p<0.001). At ED discharge, operative repair was indicated for 17 (16%) patients in the standard group and 21 (20%) patients in the PoCUS group (OR 0.78, 95% CI 0.39 to 1.58).

Conclusion This study could not demonstrate that PoCUS-guided reduction of distal radius fractures was associated with a statistically significant decrease in the number of reduction attempts.

Trial registration number The Netherlands Trial Register (NTR7934).

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Point-of-care ultrasound (PoCUS) has been shown to be accurate for confirming cortical alignment for radius fractures.

WHAT THIS STUDY ADDS

⇒ This multicentre randomised controlled trial did not find a statistically significant improvement in the number of reduction attempts using PoCUS-guided reduction of distal radius fractures or a reduction of the proportion of patients requiring operative repair compared with standard care.

⇒ The median time to perform the reduction was slightly longer when PoCUS is used as an adjunct to closed reduction.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study did not find evidence to support the routine use of PoCUS-guided closed reduction of distal radius fractures in the ED.

INTRODUCTION

Displaced fractures of the distal radius are frequently encountered in the ED. In adults, these fractures often require closed reduction and/or operative repair, depending on fracture configuration and displacement.[1–5] Closed reduction is usually performed by applying traction followed by manual reduction of the fracture, after which a splint or cast is applied and radiography is used to confirm post-reduction alignment.[3 4] The primary goal of closed reduction is to realign the cortices of the distal radius, to minimise the need for operative repair.[4 6] The physician performing the procedure often has to rely on physical examination during the procedure to determine if cortical alignment is adequate before applying the cast. However, this assessment can be impeded by soft tissue swelling as a result of the fracture.[7]

When adequate alignment has not been obtained, additional reduction attempts may be required. Further attempts may require further use of analgesics and sedatives, and increase the length of stay in the ED.[8 9] Point-of-care ultrasound (PoCUS) could provide visual feedback during the procedure on alignment of the cortices, even before obtaining a post-reduction radiograph or cast application.[10] This could increase the likelihood of achieving

successful alignment and so reduce the need for further reduction attempts. Previous studies have shown that PoCUS has an adequate sensitivity and specificity to confirm alignment of radius fractures.[7 11–15] However, there is insufficient evidence to determine whether this translates into a higher first attempt reduction success rate.[10] The role of imaging guidance for reduction of displaced distal radius fractures is therefore a research priority for the UK National Institute for Health and Care Excellence.[16]

This multicentre randomised controlled trial aimed to investigate whether PoCUS-guided reduction can be used to improve the success rate of closed reductions of displaced distal radius fractures in adults in the ED.

METHODS

Study setting and study design

This multicentre randomised controlled trial was performed between December 2018 and July 2020 in the ED of four mixed (adult and children) hospitals in the Netherlands: one level 3 trauma centre (Tjongerschans Hospital), one level 2 (Medical Centre Leeuwarden (MCL)) and two level 1 trauma centres (University Medical Centre Groningen (UMCG) and Isala, Zwolle)). MCL, UMCG and Isala are teaching hospitals for ED registrars and all four hospitals have an orthopaedic surgeon on call at all times. A PoCUS-certified ED consultant or registrar was available at all times except overnight in one hospital. The trial was registered in the Netherlands Trial Register by registration code: 7934 (https://trialsearch.who.int/Trial2.aspx?TrialID=NL7934). This study was conducted and reported according to the Consolidated Standards of Reporting Trials guidelines.[17]

Patient and public involvement

Patients and the public were not involved in the design, conduct, reporting or dissemination of our research.

Study population

Patients aged ≥16 years were included if they presented with a significantly displaced distal radius fracture that required closed reduction according to the treating emergency physician or orthopaedic surgeon and a PoCUS-certified physician was on duty. Significant displacement was defined as either dorsal angulation >10° or volar angulation >20°, radial inclination <15°, radial shortening >5 mm or intra-articular incongruity >2 mm.[18 19] The exclusion criteria were: open fracture, neurovascular compromise, indication for primary operative repair, previous osteosynthesis on the same wrist and a contraindication to use ultrasound gel (eg, allergy or large wounds).

Study protocol

The treating physician reviewed the initial radiograph and assessed the indication for closed reduction. Thereafter, patients who met the inclusion criteria were informed about the study by the treating physician and received trial information. After written informed consent was obtained, patients were randomised to receive either standard reduction or PoCUS-guided reduction by envelope randomisation (1:1 ratio). All envelopes were randomised before the start of the study using an internet-based electronic randomisation program (randomizer.org) by the primary investigator. The physician and patient could not be blinded to treatment allocation.

All patients were offered either oral or intravenous analgesics (eg, paracetamol, non-steroidal anti-inflammatory drugs or opioids) at triage by the treating nurse or physician in accordance with the hospital-specific ED pain management protocols. After randomisation, a haematoma block with lidocaine was provided before the application of horizontal finger-trap traction (10 kg) for 15 min to the injured wrist (regardless of treatment allocation). Thereafter, closed fracture reduction was performed by a physician with experience in performing this procedure without the aid of real-time imaging (eg, fluoroscopy), as this is not routinely used in the ED in the Netherlands.

When the participant was randomised to PoCUS-guided reduction, PoCUS was performed by an ED consultant or registrar certified in PoCUS. The sonographers each had considerable experience having followed an ED ultrasound course, portfolio of 250 ultrasounds and passed an ultrasound examination. They also received dedicated training to perform PoCUS-guided reduction (an instruction video and presentation by the study investigator) in the month prior to study inclusions. The instruction video and study protocol were available for reference during the study period (online supplemental file 1).[20]

Dorsal and radial views of the distal end of the radius were obtained along the long axis using a linear array ultrasound probe (4–12 MHz), aiming for adequate alignment with the cortices forming as straight a line as possible with less than 3 mm step-off in both views (figure 1).[7 13] Pre-reduction and post-reduction PoCUS views were saved and reviewed retrospectively by two members of the study team. Images were judged on image quality (good enough to judge alignment) and adequacy of the PoCUS-guided reduction (less than 3 mm step-off in both views).

After reduction, a cast was applied and post-reduction radiographs obtained as a gold standard to evaluate reduction adequacy. It was at the discretion of the treating physician to decide whether the alignment on the post-reduction radiograph was adequate and whether an additional attempt or open (operative) reduction was required supported by local and regional guidelines.[21] All patients were referred to an outpatient orthopaedic trauma clinic for further treatment and follow-up. The orthopaedic surgeon reviewing the patient in clinic was blinded to treatment allocation.

Data acquisition

A case report form was used to collect patient and procedure data, including baseline demographic data, relevant medical history (including osteoporosis), fracture characteristics, years of experience of the proceduralist in reducing displaced distal radius fractures and the treatment plan at ED discharge.

Outcome measures

The primary outcome was the proportion of patients requiring more than one reduction attempt. The secondary outcomes were the adequacy of alignment, time required to complete the reduction and the proportion of patients requiring operative repair at the time of ED discharge. Time to reduction was measured from the start of manual reduction to the start of cast application.

For the purpose of this study, one reduction attempt was defined as all reduction manoeuvres before cast application. Any reduction attempt that required removal of the cast counted as a new reduction attempt.

Sample size calculation

A single-centre pilot suggested that closed reduction of distal radius fractures was unsuccessful in 38% of the patients at the first attempt. This trial was powered to detect a 50% reduction (from 38% to 19%) in the proportion of patients requiring more than one reduction attempt with an alpha of 5% and power

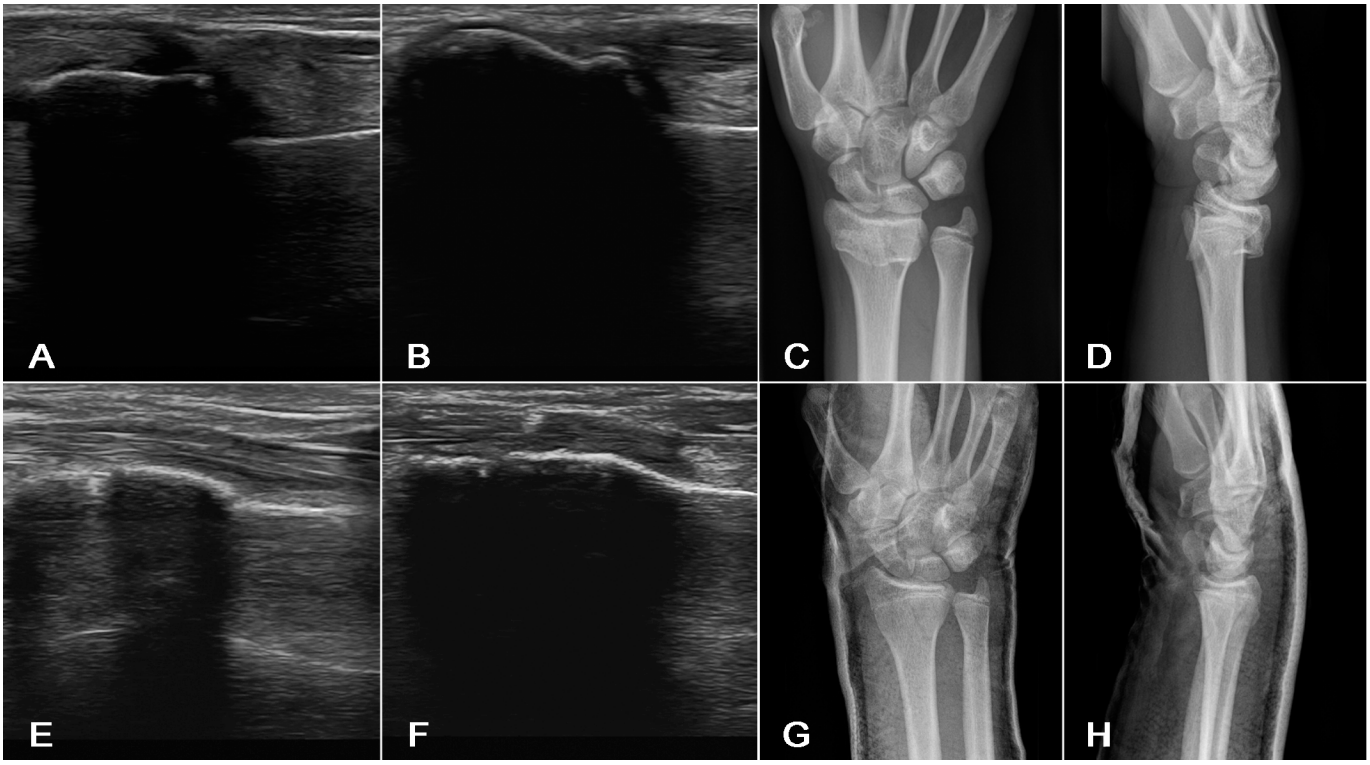

Figure 1 Ultrasound and radiographic images before and after reduction: (A) ultrasound image pre-reduction dorsal view, (B) ultrasound image pre-reduction radial view, (C,D) pre-reduction radiograph, (E) ultrasound image post-reduction dorsal view, (F) ultrasound image post-reduction radial view, (G,H) post-reduction radiograph.

of 80%.[18] To account for a 10% attrition rate, we aimed for a sample size of 214 patients.

Data analysis

Continuous variables are expressed as means with 95% CIs when normally distributed and medians with IQRs when skewed. Categorical data were presented as absolute numbers and percentages. We performed an intention-to-treat-analysis. Differences between the two treatment groups were evaluated using Mann-Whitney U test for continuous data or Fisher's exact test for binary data. A preplanned sensitivity analysis was performed on the effect of PoCUS guidance on reduction success rates by the degree of experience of the doctor performing the reduction. A two-tailed p value of <0.05 was considered statistically significant. Inter-rater agreement for PoCUS outcome was measured by the Cohen's kappa test. All analyses were performed with IBM SPSS Statistics V.23 for Windows.

RESULTS

A total of 214 patients were screened, of whom 211 patients were randomised. Three patients had to be excluded after randomisation; one patient was unexpectedly relocated to the operating room before the reduction procedure could be performed and written informed consent was not obtained in two cases (figure 2). A total of 105 patients were randomised to the standard treatment group and 106 patients to PoCUS-guided closed reduction.

Baseline characteristics

Baseline characteristics of the study population are presented in table 1. Demographic and fracture characteristics were similar in both treatment groups, although there were slightly more patients with an associated ulnar fracture in the standard care group. The majority of reductions were performed by ED registrars (64%) or ED consultants (18%), followed by orthopaedic surgery registrars (16%) and orthopaedic surgery consultants (1%) (table 1).

PoCUS-guided reduction

After review by the study team, the pre-reduction and post-reduction PoCUS image quality was sufficient to quantify alignment in 80 of the 106 patients. Images were not saved in 20 patients and of insufficient quality to evaluate alignment in 6 patients. Agreement between the treating physician and the study team reviewers regarding adequacy of the reduction attempt (<3 mm difference between cortices) was substantial with an agreement of 66% (Cohen's kappa 0.66).

Primary outcome

More than one attempt at closed reduction was undertaken in 13 (12%) patients in the standard reduction group and 6 (6%) patients in the PoCUS group (OR 2.35, 95% CI 0.86 to 6.45) (table 2).

Sensitivity analyses

The majority of patients in whom more than one additional reduction attempt was performed had multifragmentary intra-articular fractures (n=7 in the standard group, n=4 in the PoCUS group, online supplemental table 1). Post hoc sensitivity analyses were undertaken to investigate whether fracture configuration influenced this finding. Multifragmentary intra-articular fractures were not associated with additional reduction attempts nor suboptimal radiographic alignment (online supplemental table 2). In patients with a distal radius fracture with an associated

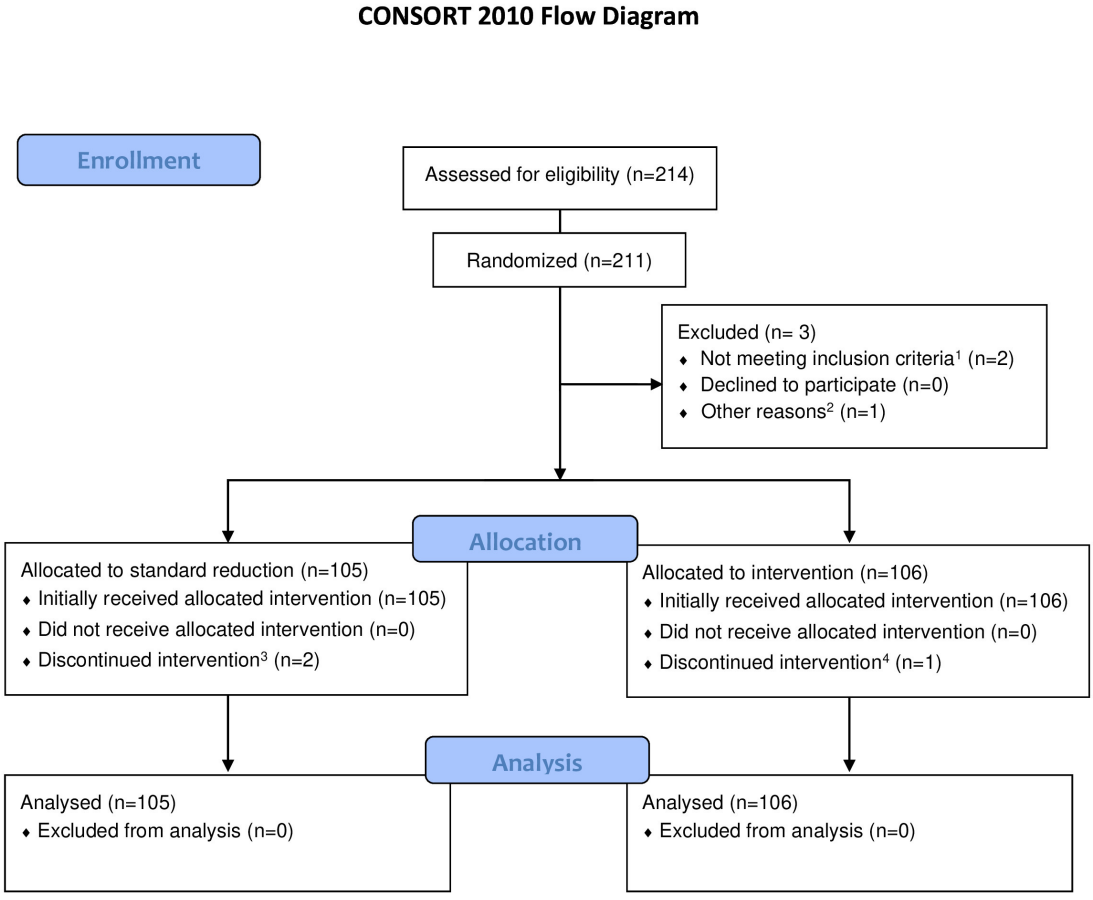

Figure 2 Patient flow chart in the ED. [1]Only verbal consent was obtained from these patients, written consent was not obtained. [2]This patient was unexpectedly relocated to the operation room before the reduction procedure could be performed. [3]The treating physician switched to point-of-care ultrasound-guided reduction after the initial standard reduction was unsuccessful. [4]The treating physician performed the second reduction attempt without point-of-care ultrasound due to unavailability of the ultrasound machine. CONSORT, Consolidated Standards of Reporting Trials.

ulnar fracture, PoCUS was associated with a significant reduction in the need for more than one reduction attempt (OR 5.60, 95% CI 1.20 to 26.14), although alignment on the radiograph obtained after the reduction attempt was similar (online supplemental table 2).

Doctors performing the closed reductions had the same level of experience with reductions in both groups: median 2 (IQR 1–4) years in the standard group and 2 (IQR 1–5) years in the PoCUS group (p=0.635). A prespecified sensitivity analysis including only reductions performed by physicians with ≤2 years of experience (n=122; 61 in each group) yielded similar results: need for additional reduction attempt was 11% (n=7) in the standard group and 8% (n=5) in the PoCUS group (OR 1.45, 95% CI 0.43 to 4.85).

Secondary outcomes

Adequate alignment

The treating physician defined that adequate alignment on the initial post-reduction radiograph was obtained in 82 (78%) patients in the standard group and in 83 patients (78%) in the PoCUS group (OR 1.01, 95% CI 0.53 to 1.95) (table 2).

Time to reduction

The median reduction time was slightly longer in the PoCUS group: 5 min (IQR 3–6) vs 3 min (IQR 2–4) in the standard reduction group (p<0.001) (table 2).

Need for operative repair

At ED discharge, operative repair was indicated for 17 (16%) patients in the standard group and 21 (20%) patients in the PoCUS group (OR 0.78, 95% CI 0.39 to 1.58) (table 2).

DISCUSSION

This multicentre randomised controlled trial did not detect a statistically significant difference between PoCUS-guided and standard reduction in terms of first attempt success during closed reduction of distal radius fractures in the ED.

Previous studies on the effect of PoCUS on relevant clinical outcomes for patients with a displaced radius fracture requiring reduction are conflicting: a recently published review[10] advocated that PoCUS may be a helpful tool. Nevertheless, they recognised that the underlying level of evidence was low, particularly as

Table 1 Baseline participant characteristics

	Standard reduction (n=105)	PoCUS-guided reduction (n=106)
Age		
Median in years (IQR)	69 (59–79)	68 (58–79)
Sex		
Female	92 (88%)	91 (86%)
Hospital		
Medical Centre Leeuwarden	43 (41%)	46 (43%)
Tjongerschans	18 (17%)	19 (18%)
Isala	34 (32%)	21 (20%)
University Medical Centre Groningen	10 (10%)	20 (19%)
Fracture side		
Right	47 (45%)	50 (47%)
History of osteoporosis		
Yes	30 (29%)	32 (30%)
No	70 (67%)	68 (64%)
Unknown	5 (5%)	6 (6%)
Fracture characteristics		
Intra-articular	65 (62%)	60 (57%)
Ulnar involvement	72 (69%)	58 (55%)
Multifragmentary	81 (77%)	73 (69%)
Angulation		
Dorsal	98 (93%)	101 (95%)
Volar	7 (7%)	5 (5%)
Time from injury to presentation		
<24 hours	96 (91%)	95 (90%)
24–48 hours	8 (8%)	9 (8%)
>48 hours	1 (1%)	2 (2%)
Reduction proceduralist experience*		
Median in years (IQR)	2 (1–4)	2 (1–5)
Reduction proceduralist specialty		
ED registrar	70 (67%)	65 (61%)
ED consultant	16 (15%)	20 (19%)
(Orthopaedic) surgery registrar	15 (14%)	18 (17%)
(Orthopaedic) surgeon	0	1 (1%)
ED physician assistant	4 (4%)	2 (2%)

Data are presented in numbers and percentages; n (%).
*Two missing values.
IQR, Interquartile range; PoCUS, point-of-care ultrasound.

Table 2 Reduction success by treatment allocation group

	Standard reduction (n=105)	PoCUS-guided reduction (n=106)	OR (95% CI)
Reduction attempts			2.35 (0.86 to 6.45)
More than one attempt	13 (12%)	6 (6%)	
Mean (range)	1.1 (1–3)	1.1 (1–2)	
After initial reduction			1.01 (0.53 to 1.95)
Adequate alignment on radiograph	82 (78%)	83 (78%)	
Treatment plan at ED discharge			0.78 (0.39 to 1.58)
Indication for operative repair	17 (16%)	21 (20%)	
Reduction time			**P value**
Median in minutes (IQR)	3 (2–4)	5 (3–6)	<0.001
Missing	9 (9%)	0	

Data are presented in numbers and percentages (n (%)).
PoCUS, point-of-care ultrasound.

previous studies demonstrated conflicting results.[8 22 23] The present study demonstrates that the clinical benefit of PoCUS for fracture reduction may be less than anticipated based on previous studies that examined its ability to confirm cortical alignment.[7 11–15] The lack of benefit of PoCUS reported in this study may be explained by several factors.

First, our study cohort reflects the large variation of distal radius fractures in the ED in terms of angulation, displacement, comminution and involvement of the articular surface. Patients with certain fracture types may benefit more from PoCUS than others, and it is possible that certain subgroups (eg, patients with isolated extra-articular fractures) may benefit from PoCUS-guided reduction.

Second, the potential benefit of PoCUS-guided reduction may have been impacted by the variable level of experience with musculoskeletal ultrasound of the ED consultant or registrar that provided PoCUS guidance. Although all ED consultants and registrars received dedicated PoCUS training, in some patients, adequate images were not obtained (or not saved), and inadequate PoCUS interpretation by the sonographer may have compromised the value of PoCUS in this study. This is reflected by the kappa value representing substantial but not perfect agreement between the physician and the study team reviewers, which suggests room for improvement in PoCUS training. However, this reflects how PoCUS is likely to be used in routine clinical practice where few physicians performing reductions will be PoCUS specialists.

Third, in four patients (all with multifragmentary fractures), we found near-perfect alignment on PoCUS image review, but the post-reduction radiograph showed displacement. It is likely that during cast application, alignment as seen on PoCUS was lost due to movement.

Finally, the lack of effect may be attributed to a type II statistical error, as unsuccessful standard reduction attempts were less prevalent than anticipated (23% vs 38%). We can therefore not exclude a small effect that was not detectable with the current sample size. However, as the proportion of patients who obtained adequate alignment after the first reduction attempt in both groups was equal (78% vs 78%, OR 1.01 (95% CI 0.53 to 1.95)), it is not likely that a larger sample size would have resulted in a significant (and clinically relevant in terms of number needed to treat) effect on the number of reduction attempts required to obtain adequate alignment.[2]

As anticipated, we found that the median reduction time was slightly longer (2 min) when PoCUS was used during the reduction attempt. This small difference is unlikely to significantly impact the overall length of stay in the ED, but does suggest a small additional burden on allocation of clinician time. This did not include the time taken to find, clean, set up and return the ultrasound machine.

Our study has several limitations. First, our primary endpoint was the need for more than one reduction attempt, which was a decision left to the treating physician who was necessarily unblinded to the treatment allocation group. Although alignment is easier and more objective to quantify, the primary outcome we selected is more clinically relevant. Nonetheless, we do recognise that the number of reduction attempts may have been biased by the decision of the treating physician to do no further reduction attempt but to opt for operative repair. However, as the alignment on the post-reduction radiograph was similar in both

groups, we do not think this potential bias has influenced our results significantly. Second, based on a presumed 62% success rate of the initial reduction attempt, our study may have been underpowered to detect the prespecified 19% absolute difference in primary endpoint. Finally, time to closed reduction was not registered in nine patients which may have biased results, as all of these patients were in the standard treatment group.

The findings of this trial suggest there is a limited role for PoCUS to guide the reduction of distal radius fractures in the ED, although we cannot exclude a small benefit or a benefit in specific subgroups, such as those with excessive swelling of the wrist that limits physical examination during the procedure.

Twitter Brigitta (Britt) YM van der Kolk @Britt_NL and Ewoud ter Avest @ewoudteravest

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Disclaimer The SGO had no involvement in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval This study involves human participants and was approved by the Ethical Committee of Medical Centre Leeuwarden (RTPO 1050, METC protocol number: nWMO336). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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