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Diagnostic accuracy of point-of-care ultrasound in detecting clavicle fractures

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ABSTRACT

Study hypothesis: Point-of-care ultrasound (PoCUS) can be used as a non-invasive and radiation free adjunct in the triage of patients with clavicle injuries. However, the diagnostic accuracy of PoCUS performed by non-radiologists for this purpose is not yet sufficiently established.
Methods: A multicentre, prospective cohort study was conducted in 8 emergency departments (EDs) to establish the diagnostic accuracy of PoCUS of the clavicle in patients ≥4 years of age who presented with a clavicle injury. PoCUS was performed by trained emergency physicians, and results were compared with X-ray outcomes (gold standard).
Results: A total of 167 patients were included, of which 127 (76 %) patients had a fracture on X-ray, and 121 (72 %) on PoCUS. PoCUS of the clavicle had a sensitivity of 93 % (95 %CI 87–97 %), a specificity of 93 % (95 %CI 80–98 %), a negative likelihood ratio of 0.09 (95 %CI 0.04–0.14), and a positive likelihood ratio of 12.39 (95 %CI 4.17–36.82) for the presence of a clavicle fracture. Stratified based on age, specificity of PoCUS was lower in children compared to adults, whereas sensitivity was not affected. The agreement between X-ray and PoCUS for fracture displacement was substantial ($\kappa = 0.771$).
Conclusions: PoCUS of the clavicle is a useful adjunct in the triage of patients with clavicle injuries and can help to distinguish which patients need further diagnostic workup.
Trial registration number: Netherlands Trial Register, registration code: NL9236.

1. Introduction

Clavicle fractures are a common reason for Emergency Department (ED) presentation in patients from all ages [1-3]. Current standard of care is to diagnose clavicle fractures with X-ray, either through an anterior to posterior (AP) shoulder projection, or through an AP coned view [2,4-6].

Prior research has shown that although physical exam performed by experienced emergency physicians has good diagnostic accuracy for the detection of clavicle fractures without X-ray [5,6], it is not perfect. It can be difficult to distinguish clavicle fractures from other injuries, such as acromioclavicular joint injury, sternoclavicular joint injury, or rotator cuff injuries. Further, for medicolegal reasons physicians are often uncomfortable about forgoing an X-ray in patients with a clavicle injury [2,6].

However, X-ray examination generally requires the patient to attend to a hospital. Especially when travel distances are long or when resources are scarce, physicians have to decide if they want to send the patient to the ED for further diagnostic workup based on findings at physical examination. In these instances, Point-of-Care UltraSound (PoCUS) may serve as a radiation-free imaging adjunct to help decide which patients need a further workup of their injuries.

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Several smaller studies in paediatric populations have addressed the potential merit of PoCUS for this indication and report a positive effect of the use of PoCUS on diagnostic accuracy for clavicular fractures [2]. However, as children have a high remodelling potential, a missed fracture will often have limited consequences, as most fractures are treated conservatively. At present it is unknown what the diagnostic accuracy of PoCUS is for the detection of clavicular fractures in a more heterogeneous population presenting in the ED or a General Practitioner (GP) practice. Furthermore, the ability of PoCUS to estimate displacement of the clavicle fracture (as a proxy for the need for operative intervention) remains unknown [7].

Therefore, this study aimed to investigate the diagnostic accuracy of PoCUS of the clavicle performed by non-radiologists in the workup of a heterogenous population of patients presenting with clavicle injuries.

2. Methods

2.1. Study setting and study design

This multicenter prospective cohort study was performed between February 2021 and March 2022 in the ED of 8 hospitals (see Appendix A) in different areas of the Netherlands (1 trauma center, 4 teaching hospitals and 4 regional hospitals to maximize heterogeneity and minimize selection bias) to investigate the diagnostic accuracy of PoCUS of the clavicle. When patients met inclusion criteria, informed consent was obtained from the patient (when aged ≥16 years), their parents (≤12 years) or both (12–16 years of age), according to Dutch law. Thereafter a physical exam was performed as part of usual care, followed by PoCUS of the clavicle, after which an X-ray of the clavicle was performed in all patients.

The study protocol was approved by the ethical committee of Medical Centre Leeuwarden (RTPO 1050, METC protocol number: nWMO354) and registered in the Netherlands Trial Register by registration code: NL9236. This study was conducted and reported according to the Standards for Reporting Diagnostic Accuracy (STARD) [8].

2.2. Study population

The study population consisted of a convenience sample of patients aged 4 years or older presenting with clavicle injuries to the participating EDs, for which at triage an X-ray was ordered to exclude a clavicular fracture. Excluded were patients who were referred with an already (radiologically) confirmed clavicle fracture to avoid confirmation bias, or patients in whom one of the following conditions was present: an open fracture, (suspicion of) serious time-critical accompanying injury requiring immediate intervention, a recent (<3 months) clavicle fracture at the same side and/or pain being present for more than 7 days prior to presentation.

2.3. Study measurements

PoCUS of the clavicle was performed by an ED consultant or registrar who had passed the national ED PoCUS certification program [9]. Each sonographer received additional dedicated training to perform PoCUS of the clavicle in the month prior to the start of the study, consisting of a short instruction video (≤2 min) and a presentation (circa 10 min) by a member of the study team. The instruction video and study protocol were available for reference during the study period. A PoCUS trained ED consultant or registrar was present in the ED during the study period 24/7, except for the participating regional hospitals where patients could not be included during night hours.

Transverse and coronal long-axis views of the clavicle were obtained using a linear array ultrasound probe (4–12 MHz, each hospital used their own ultrasound machine (Supplementary Table 1) scanning from medial to lateral (Fig. 1), looking for an interruption in the clavicle cortex (Fig. 2). All PoCUS images were saved and interpreted (positive, negative or inconclusive for the presence of a cortex interruption) by the physicians performing the exam at the time of the exam. If the performing ED physician visualized a fracture an ultrasound image was saved in both views and displacement was measured from cortex to corresponding cortex.

After PoCUS an X-ray of the clavicle (in two directions) was obtained as a gold standard to evaluate for the presence or absence of a clavicle fracture. Discomfort during both X-ray and PoCUS examination was scored using the Numeric Rating Scale (NRS). PoCUS outcome was compared to the formal radiology report, and radiologists were blinded for PoCUS outcome. Further treatment, after the X-ray was performed at the discretion of the treating physician, supported by local- and regional treatment protocols.

An electronic case report form (eCRF; REDCap 13.7.19), was used to collect patient and PoCUS data, including baseline demographic data, findings at physical exam, PoCUS and X-ray outcomes and final treatment of the patient. PoCUS results were compared with the gold standard, and a pre-specified subgroup analysis was performed according to the patient's age at presentation.

2.4. Outcome measures

The primary outcome was defined as the diagnostic accuracy (sensitivity, specificity and likelihood ratios) of PoCUS of the clavicle to demonstrate or exclude a fracture in patients presenting with clavicle injuries to the ED. PoCUS outcome (positive, negative or inconclusive

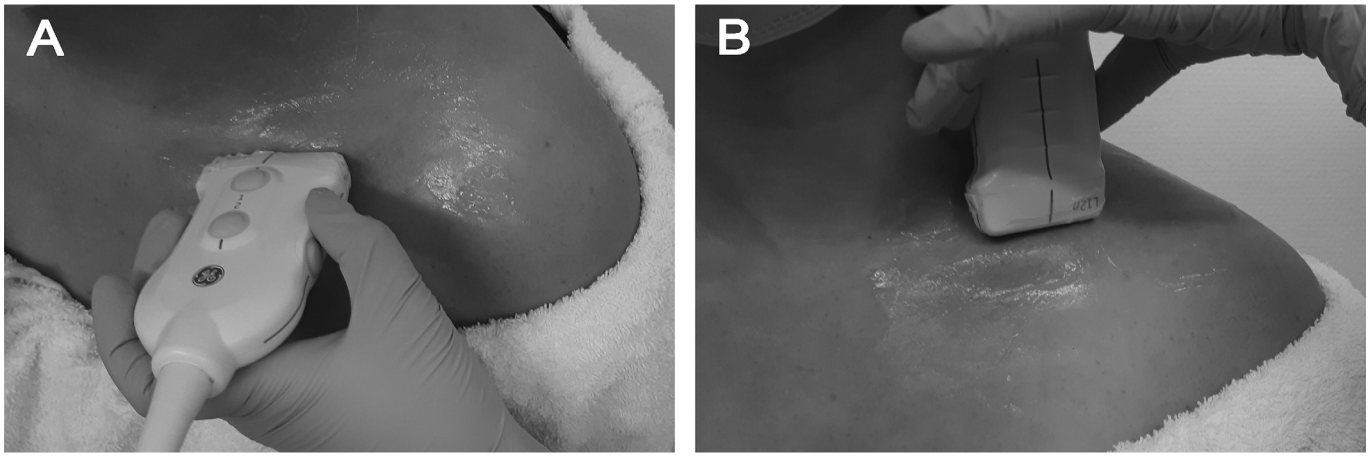

Fig. 1. PoCUS of the clavicle obtaining the transverse (A) and coronal views (B).

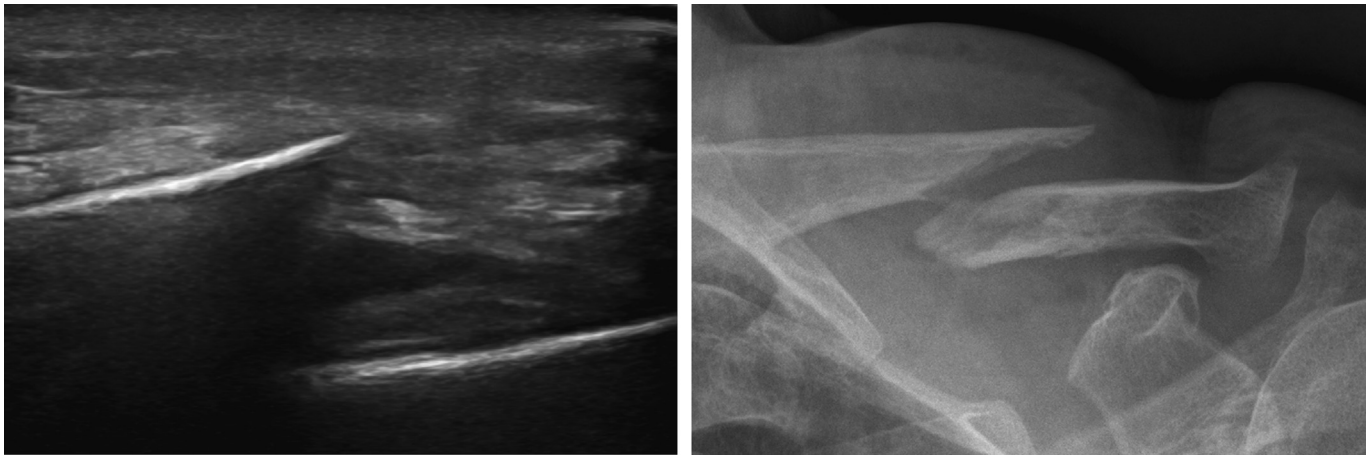

Fig. 2. PoCUS image and X-ray of a clavicle fracture.

for a clavicle fracture) served as an index test and a clavicle X-ray served as a reference test. For diagnostic accuracy analysis, inconclusive PoCUS ratings were considered as positive findings (as PoCUS is primarily used as a rule out test).

Secondary outcomes were:

- The difference in the primary endpoint for subgroups stratified by age
- The difference in discomfort experienced during the procedure (X-ray vs PoCUS)
- The agreement between PoCUS and X-ray (gold standard) for estimating (clinically relevant) fracture displacement*

*A fracture displacement was deemed clinically relevant (i.e. potentially eligible for operative repair) when it was >20 mm [10].

2.5. Sample size calculation

Prior research in a paediatric population demonstrated a sensitivity of 95 % for PoCUS clavicle fracture detection [2]. Based on historical data of one of the participating EDs, the prevalence of clavicle fractures among patients presenting with clavicle injuries to the ED was found to be 70 %. Using the expected sensitivity of 95 %, a fracture prevalence of 70 %, an accuracy (W) of 0.05 and confidence level (Z) of 1.96, this yielded a sample size of 154 patients. To account for a 10 % attrition rate, we aimed for a sample size of 170 patients.

2.6. Data analysis

Distribution of continuous variables was tested using the Kolmogorov-Smirnov test with Lilliefors' correction. Continuous variables are expressed as an average with standard deviation (SD) when normally distributed and medians with an interquartile range (IQR) when skewed. Categorical data were presented as absolute numbers and percentages. Diagnostic accuracy measures (sensitivity, specificity, and likelihood ratios) with corresponding 95 % confidence intervals (CI) were calculated using 2×2 contingency tables. A pre-planned subgroup analysis was carried out for subgroups stratified based on age (adults/children). Differences in NRS between PoCUS and X-ray were evaluated using the Wilcoxon signed rank test. McNemar test was used to evaluate the diagnostic accuracy of the index test (PoCUS) with the gold standard (X-ray) for detection of fractures, fracture displacement and operation indication. Agreement between X-ray and PoCUS for estimating (clinically relevant) fracture displacement was measured by Cohen's kappa. A 2-tailed p-value <0.05 was considered statistically significant. All analyses were performed with IBM SPSS Statistics Premium V.24 for Windows.

3. Results

3.1. Characteristics of study subjects

During the study period 170 eCRFs were completed. After removal of duplicate entries, 168 patients remained, of which one patient had to be excluded due to violation of the inclusion criteria. A total of 167 patients were analysed. A STARD diagram of the study population is presented in Fig. 3. Baseline characteristics of the study population are presented in Table 1. The majority of patients were male (69 %) and adults (65 %). In total, 127 (76 %) patients were diagnosed with a clavicle fracture based on X-ray.

3.2. Primary outcome

PoCUS was performed in all 167 patients and was considered positive based on a visualized clavicle fracture in 120 (72 %) patients, and negative in 46 patients (Table 2). In one patient PoCUS was inconclusive because the sonographer could not reliably establish if an interruption of the clavicle cortex was present. Diagnostic accuracy measures of PoCUS to diagnose or exclude clavicle fractures are presented in Table 3. Overall diagnostic accuracy of PoCUS was not inferior to X-ray ($p = 0.146$).

PoCUS was false positive in two patients, both were described as lateral clavicle fractures without displacement by the sonographers. The only patient with an inconclusive PoCUS result did not have a fracture on X-ray. PoCUS was false negative in 9 (5 %) patients with a clavicle fracture on X-ray, all these patients were treated conservatively. Characteristics of these 9 patients are presented in Supplementary Table 2.

3.3. Secondary outcomes

3.3.1. Diagnostic accuracy stratified by age

When the subgroup of adult patients (≥18 years, $n = 109$, 65 %) was analysed separately, specificity improved to 100 % (95 % CI 89 % to 100 %), whereas sensitivity was not significantly affected 92 % (95 % CI 84 % to 97 %), thereby increasing overall diagnostic accuracy (Supplementary Tables 3, 4 and 5).

3.3.2. Pain scores

NRS pain scores were available for 160 of the 167 patients. Median [IQR] NRS, for the 160 available pain scores (no data imputation was used for the 7 missing cases), was higher during PoCUS 4 [2 - 6] compared to the NRS during X-ray 3 [1 - 6], $p < 0.001$.

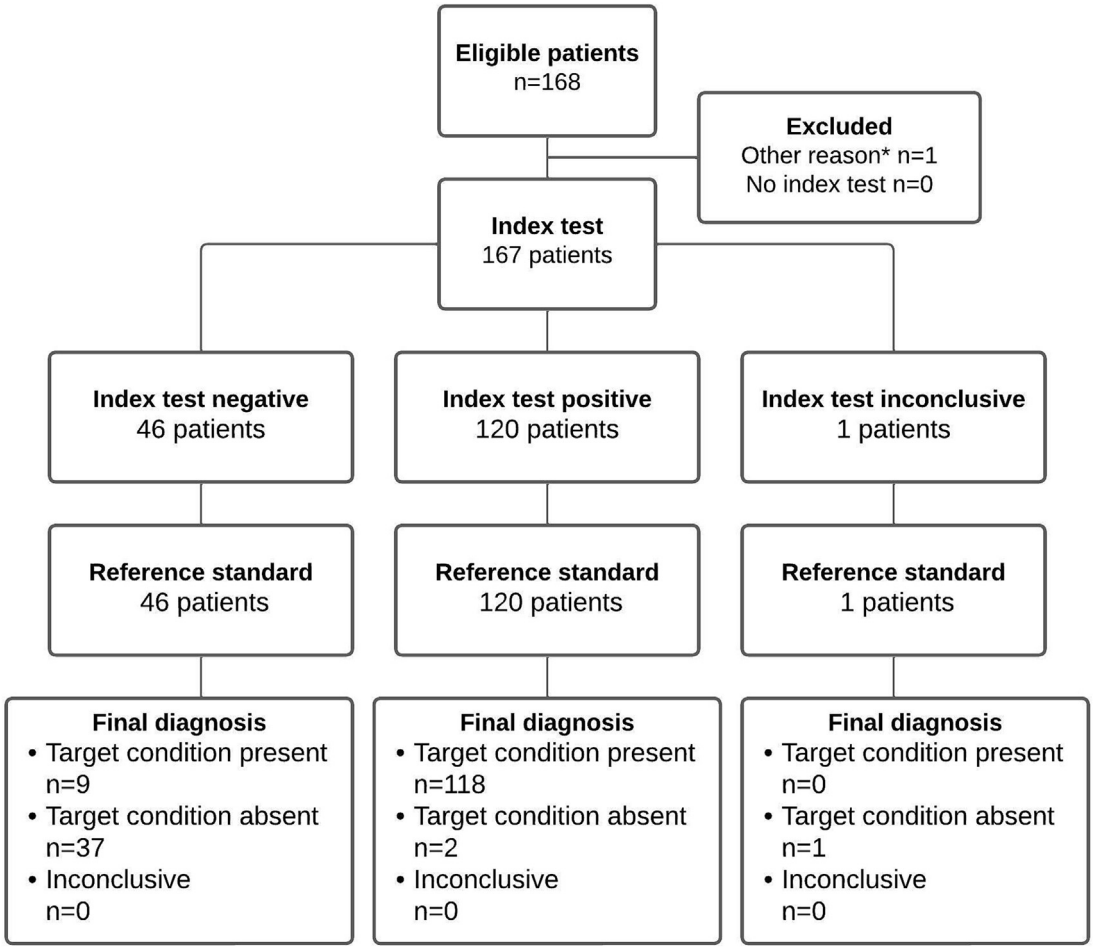

Fig. 3. STARD flow diagram. Index test: PoCUS (Point-of-care Ultrasound), reference test: X-ray.
*1 patient was excluded because of violation of the inclusion criteria: serious time-critical accompanying injury requiring immediate intervention.

3.3.3. Fracture displacement

X-ray demonstrated a fracture displacement in 100 patients, whereas PoCUS identified displacement in 104 patients (Supplementary Table 6). Seven patients with fracture displacement on X-ray had a negative PoCUS for displacement, all were treated conservatively, whereas 11 patients showed displacement on PoCUS but not on X-ray. Agreement between X-ray and PoCUS for the presence of any displacement of the clavicle fracture was substantial (Cohen's kappa $\kappa = 0.771$, $p < 0.001$). Agreement dropped when only clinically significant displacement (potentially eligible for operative repair) was considered (Cohen's kappa $\kappa = 0.609$, $p < 0.001$). Overall, PoCUS was not inferior to X-ray for diagnosing fracture displacement ($p = 0.481$).

Table 1
Baseline participant characteristics and ED treatment.

	$n = 167$
Age	
Age (median) [IQR]	30 [15–54]
Adults (≥18 years)	109 (65 %)
Sex	
Female	52 (31 %)
Side	
Left	85 (51 %)
Physical exam	
Skin tenting	1 (1 %)
Anatomical location fracture	
Medial	6 (4 %)
Midshaft	101 (61 %)
Lateral	20 (12 %)
No fracture	40 (24 %)
Treatment after ED discharge	
Conservative treatment	103 (62 %)
Planned for operative repair	24 (14 %)
No fracture	40 (24 %)

Data are presented in numbers and percentages; n (%). IQR: Interquartile range.

4. Discussion

This multicenter prospective cohort study found that PoCUS of the clavicle is a useful diagnostic adjunct in the triage of patients with clavicle injuries. As a single rule-out test, it missed only 7 % of the fractures, none of these required an operative intervention.

The sensitivity of PoCUS in this study was high: only 9 patients had a false negative PoCUS exam, and all were treated conservatively with an immobilizing sling. In two patients the anatomical localization of the

Table 2
Performance of PoCUS in relation to gold standard (X-ray) for diagnosing a clavicle fracture

	X-ray positive	X-ray negative	Total
PoCUS positive	118	3*	121*
PoCUS negative	9	37	46
Total	127	40	167

* *In 1 patient* PoCUS findings were inconclusive. This patient was considered positive in the statistical analyses. *PoCUS: Point-of-care Ultrasound.*

Table 3
Diagnostic accuracy of PoCUS for diagnosing a clavicle fracture

Statistics	
Sensitivity (95 % CI)	93 % (87 % - 97 %)
Specificity (95 % CI)	93 % (80 % - 98 %)
Positive likelihood ratio (95 % CI)	12.39 (4.17–36.82)
Negative likelihood ratio (95 % CI)	0.08 (0.04–0.14)

PoCUS: Point-of-care Ultrasound. CI: confidence interval.

fracture may have explained the false negative findings, as lateral fractures can be confused with the acromioclavicular joint. Specificity of PoCUS was also high, and a high level of agreement was present between PoCUS and X-ray for the presence of fracture displacement. When only clinically relevant fracture displacement was considered (>2 cm) kappa values dropped. Although this may have been the result of measurement and/or interpretation errors, positive PoCUS with displacement should therefore prompt further evaluation with X-ray to confirm the presence of a fracture and to obtain information about the fracture configuration in order to be able to establish a treatment plan.

After stratification for age, specificity of PoCUS was lower in children compared to adults. However, specificity as reported was in line with several previous studies conducted predominantly in paediatric populations (74–98 %) [2-4,11,12]. The lower specificity in children can be related to the presence of growth plates, that can be mistaken for fractures. Alternatively, it can be a reflection of the fact that that PoCUS is sometimes more challenging in young (uncooperative) children.

One of the merits of this study was that the accuracy as reported was obtained by non-expert sonographers. Although ED consultants and registrars that performed the PoCUS examinations in this study were all certified to use PoCUS (with a broad range in experience years), they had received limited extra training in PoCUS of the clavicle, reflecting real-world clinical practice. However, it is important to realise that PoCUS test performance is operator dependent and more experienced operators will likely exhibit a higher diagnostic accuracy [13]. The good diagnostic performance came at a small price: in contrast to previous studies [2,4], PoCUS was perceived to be more painful than X-ray, which could be explained by the application of direct pressure on the fracture with the ultrasound probe. Although statistically significant, the clinical relevance of a 1-point difference in NRS score can be debated [14,15].

The findings of this study have important clinical implications. First, our findings demonstrate that PoCUS can be utilized as a diagnostic adjunct in patients presenting with a clavicle injury. When PoCUS of the clavicle is negative for a fracture or when a fracture without displacement was present, an X-ray can safely be omitted as none of the patients without fracture displacement on PoCUS needed surgical treatment. This is important in the ED environment, as it reduces resource use (with likely a positive impact on throughput times and costs). However, our findings may even have more implications for the primary- or prehospital care setting, where PoCUS can help to decide which patients need to be referred to the ED for further workup of their injuries.

This study has several limitations. First, the study population was comprised of a convenience sample of patients attending the ED. Patients referred directly to the radiology department by their general practitioner were not included in this study, including these patients would likely have affected fracture incidence which could have affected diagnostic accuracy. Additionally, a PoCUS trained ED consultant or registrar was not available 24/7 in regional hospitals, therefore patients could not be included during night hours. Although unlikely, this may have resulted in selection bias. Second, diagnostic accuracy for PoCUS was determined as a stand-alone test. Some patients had fracture displacement that was obvious on physical exam alone. For these patients the diagnostic merit of PoCUS is obviously limited. Third, the amount of fracture displacement could not always be established reliably on PoCUS. Several physicians commented that it was difficult to perform PoCUS in lean patients or in patients with severe fracture displacement due to loss of skin contact with the ultrasound probe, and others said it was difficult to measure displacement in multifragmented fractures. Finally, X-ray was used as a gold standard in this study, consistent with standard care in the Netherlands. Nonetheless, previous studies performed in paediatric populations have found that PoCUS has a higher accuracy for clavicle fractures than X-ray [11,16]. Noteworthy, in 2 patients a fracture was seen on PoCUS, but (in first instance) not on X-ray. In one of them the midshaft clavicle fracture was seen on X-ray after second review by the radiologist contacted based on the PoCUS findings. In the other patient the medial clavicle fracture was not seen on X-ray, but was confirmed on computed tomography (CT) scan of the cervical spine. This underlines that PoCUS has the potential to be more sensitive than X-ray. However, using CT as a gold standard alternative was not acceptable due to the much higher radiation exposure.

5. Conclusion

PoCUS of the clavicle is a useful adjunct in the triage of patients with clavicle injuries and can help to distinguish which patients need further diagnostic workup.

Patient consent for publication

Not required.

CRediT authorship contribution statement

Svenja L. Haak: Writing – original draft, Visualization, Validation, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Hendrika Vos:** Writing – original draft, Resources, Methodology, Investigation, Data curation, Conceptualization. **Marion G. Borgstede:** Writing – review & editing, Resources, Investigation. **Annemieke E. Boendermaker:** Writing – review & editing, Resources, Investigation. **Vincent Rietveld:** Writing – review & editing, Resources, Investigation. **Tineke Kroon:** Writing – review & editing, Resources, Investigation. **Arthur Rosendaal:** Writing – review & editing, Resources, Investigation. **Heleen Lameijer:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Jan C. Ter Maaten:** Writing – review & editing, Resources. **Renate Stolmeijer:** Writing – review & editing, Resources, Methodology, Investigation, Formal analysis, Conceptualization. **Ewoud ter Avest:** Writing – review & editing, Resources, Methodology, Investigation, Formal analysis, Conceptualization.

Data availability

Data are available upon reasonable request. The research protocol and database are available upon request. Requests can be sent to SL Haak (s.l.haak@umcg.nl). Reuse is permitted after consultation.

Declaration of competing interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajem.2024.11.008.

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