ORIGINAL ARTICLE

Ultrasonography or Radiography for Suspected Pediatric Distal Forearm Fractures

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ABSTRACT

BACKGROUND

Data on whether ultrasonography for the initial diagnostic imaging of forearm fractures in children and adolescents is noninferior to radiography for subsequent physical function of the arm are limited.

METHODS

In this open-label, multicenter, noninferiority, randomized trial in Australia, we recruited participants 5 to 15 years of age who presented to the emergency department with an isolated distal forearm injury, without a clinically visible deformity, in whom further evaluation with imaging was indicated. Participants were randomly assigned to initially undergo point-of-care ultrasonography or radiography, and were then followed for 8 weeks. The primary outcome was physical function of the affected arm at 4 weeks as assessed with the use of the validated Pediatric Upper Extremity Short Patient-Reported Outcomes Measurement Information System (PROMIS) score (range, 8 to 40, with higher scores indicating better function); the noninferiority margin was 5 points.

RESULTS

A total of 270 participants were enrolled, with outcomes for 262 participants (97%) available at 4 weeks (with a window of ±3 days) as prespecified. PROMIS scores at 4 weeks in the ultrasonography group were noninferior to those in the radiography group (mean, 36.4 and 36.3 points, respectively; mean difference, 0.1 point; 95% confidence interval [CI], −1.3 to 1.4). Intention-to-treat analyses (in 266 participants with primary outcome data recorded at any time) produced similar results (mean difference, 0.1 point; 95% CI, −1.3 to 1.4). No clinically important fractures were missed, and there were no between-group differences in the occurrence of adverse events.

CONCLUSIONS

In children and adolescents with a distal forearm injury, the use of ultrasonography as the initial diagnostic imaging method was noninferior to radiography with regard to the outcome of physical function of the arm at 4 weeks. (Funded by the Emergency Medicine Foundation and others; BUCKLED Australian New Zealand Clinical Trials Registry number, ACTRN12620000637943).

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Distal forearm injuries in children and adolescents are a frequent reason for emergency department visits, with an increasing incidence worldwide.[1-3] The most common fractures in children are buckle (torus) fractures of the distal radius metaphysis, owing to the biomechanical properties of children's bones.[2,4] Buckle fractures are akin to a soft-tissue injury[5] and are amenable to management of symptoms with either a wrist splint or bandage.[6] Radiography is routinely performed as the initial imaging method for suspected fractures given the ready availability in most centers and acceptable diagnostic accuracy,[7,8] although clinician interpretation of radiographs can lead to misdiagnosis.[9-11] In 2010, the World Health Organization (WHO) determined that approximately two thirds of the world population lacked access to any diagnostic imaging.[12] Since then, ultrasonography has been increasingly adopted in low- and middle-income countries because of its relative portability and affordability.[13]

Nonrandomized studies have shown that ultrasonography performed by clinicians for the diagnosis of distal forearm fractures in children is accurate, timely, and generally preferred by children and parents to radiography as the reference standard.[5,14-16] Of note, ultrasonography does not confer any ionizing radiation, so the use of this imaging method is in keeping with the principle of maintaining radiation levels as low as reasonably achievable.[17] However, the use of ultrasonography as the initial diagnostic method has not been shown to be noninferior to radiography in terms of physical function of the arm.[18] We conducted a randomized trial of ultrasonography as compared with radiography to assess the effect of initial diagnostic imaging on patient-centered outcomes, including the medium-term physical function of the arm, in children and adolescents who presented to the emergency department with distal forearm injuries without clinically visible deformity.

Methods

Trial Design and Oversight

We conducted the Bedside Ultrasound Conducted in Kids with Distal Upper Limb Fractures in the Emergency Department (BUCKLED) trial, a multicenter, open-label, noninferiority, randomized, controlled trial, at four centers in South East Queensland, Australia. The trial centers comprised a large tertiary pediatric hospital, two large mixed academic hospitals with dedicated pediatric treatment areas within their emergency departments, and one mixed hospital without a dedicated pediatric treatment area. The protocol (available with the full text of this article at NEJM.org) was approved by the Children's Health Queensland Human Research Ethics Committee. The protocol and statistical analysis plan have been published previously.[18,19] Written informed consent was obtained from the caregivers of all the participants, and oral assent was obtained from children older than 6 years of age.

The first draft of the manuscript was written by the first author, and all the authors provided critical feedback on the manuscript and made the decision to submit the manuscript for publication. The sponsors had no influence on the design or conduct of the trial and were not involved in data collection or analysis, in the writing of the manuscript, or in the decision to submit it for publication. The authors vouch for the accuracy and completeness of the data and for the fidelity of the trial to the protocol.

Trial Population

Children and adolescents between 5 and 15 years of age who presented to the emergency department with an isolated, acute, clinically nondeformed, distal forearm injury for which imaging for a suspected fracture was indicated were eligible for enrollment. Full eligibility criteria are described in the Methods section of the Supplementary Appendix, available at NEJM.org. The consent process included a standardized informational video (https://vimeo.com/393215861). The demographic characteristics of the participants were reported by participants and parents or caregivers at enrollment.

Randomization

Randomization was conducted in a 1:1 ratio in blocks of six to eight and stratified according to site and age (5 to 9 years and 10 to 15 years of age) with the use of a Web-based central randomization service (Griffith University Randomization Service).

Initial Imaging

Ultrasonography

Participants in the ultrasonography group underwent point-of-care ultrasonography performed by a trained and credentialed emergency depart-

ment health care practitioner who was a nurse practitioner, physiotherapist, or emergency physician (details of the imaging procedures are provided in the Supplementary Appendix).[20,21] A modified six-view forearm ultrasonography protocol was followed,[5] including the recording of secondary signs.[22,23] A variety of units and probes were used across the trial settings, including cart-based machines and handheld devices. The final image from each set of scans was prospectively labeled with an overall forearm diagnosis that was as specific as possible for any cortical breach subtype.

The overall forearm diagnosis was classified according to ultrasonography findings as no fracture, buckle fracture, or other fracture. The other-fracture category consisted of any fracture that was identified as having a cortical breach, and this classification was further subclassified as an incomplete (unicortical or bicortical), a complete, or a Salter–Harris fracture. The overall diagnosis of the fracture was based on the most clinically important injury that was identified (fracture of the radius or fracture of the ulna). Participants in the ultrasonography group also underwent radiography if their injury was classified as an other-fracture type. If a participant's injury was classified as no fracture or a buckle fracture on ultrasonography, radiography was not performed unless specific indications were met (see the Supplementary Appendix).

Radiography

Participants in the radiography group underwent, at a minimum, biplanar imaging performed by a radiographer and later reported by a radiologist. Radiographs were interpreted by the treating practitioner at the time of the initial imaging with or without advice from the radiologist or local orthopedic service. Images were classified as no fracture, buckle fracture, or other fracture. The other-fracture category also included any fracture that was identified at sites in the target arm apart from the distal forearm.[18]

EXPERT PANEL CONSENSUS DIAGNOSIS

At the conclusion of the trial, a final diagnosis was determined for each participant by consensus of an expert panel that consisted of a pediatric radiologist, a pediatric orthopedic surgeon, and an emergency physician who had received pediatric fellowship training. The panelists retrospectively considered the investigations, treatment, and clinical course of each participant to determine a consensus final diagnosis.

TRIAL TREATMENTS AND PROCEDURES

All the participants received routine care, with analgesia provided as appropriate. Management principles were the same for both groups, with initial treatment standardized across the trial sites. The injuries of participants who received a diagnosis of no fracture were conservatively managed at the clinician's discretion. Participants with buckle fractures received injury management that consisted of a wrist splint, and participants with other-type fractures received intervention (manipulation or surgery) as needed and cast immobilization with outpatient referral to an orthopedic service. The orthopedic service was consulted in cases of displaced or angulated fractures.

OUTCOMES

The primary outcome was physical function of the arm at 4 weeks (28 days, with a window of ±3 days), as measured with the use of the Pediatric Upper Extremity Short Patient-Reported Outcomes Measurement Information System (PROMIS) tool.[24] The PROMIS tool is validated for children and adolescents 5 to 15 years of age and assesses physical function of the arm by means of an eight-item questionnaire, with each item measured on a 5-point scale (range, 8 to 40, with higher scores indicating better function). Participants completed the questionnaire by means of an online survey sent by email. A key secondary outcome was physical function of the arm at 4 weeks in participants who had initially been determined to have had buckle fractures by the expert panel. Other secondary outcomes included physical function of the arm at 1 week (7 days, with a window of ±3 days) and 8 weeks (56 days, with a window of ±3 days); satisfaction at 4 and 8 weeks (as measured by the participant and parent or caregiver with the use of a 5-point Likert scale,[5,18] with lower scores indicating greater satisfaction); pain at 1, 4, and 8 weeks (as measured with the use of the 6-point Faces Pain Scale–Revised tool,[25] with higher scores indicating greater pain); frequency of complications; frequency of radiography (initial and follow-up to 8 weeks); and the length of stay and treatment time in the emergency department (time from clinician review to discharge from the emergency department).

Table 1. Characteristics of the Participants at Baseline.*

Characteristic	Ultrasonography (N=135)	Radiography (N=135)
Male sex — no. (%)†	67 (49.6)	77 (57.0)
Age — yr	10.4±2.8	10.2±2.8
Weight — kg	43.1±17.9	41.1±17.2
Height — cm‡	146±18	144±18
Body-mass index percentile§	64.8±30.0	64.1±30.2
Right hand dominant — no. (%)	122 (90.4)	122 (90.4)
Right hand affected — no. (%)	64 (47.4)	64 (47.4)
Dominant hand affected — no. (%)	63 (46.7)	65 (48.1)
Previous forearm issue affecting physical function — no. (%)	3 (2.2)	0
Mechanism of injury — no. (%)		
Fall on outstretched hand	87 (64.4)	88 (65.2)
Strike or direct blow	25 (18.5)	21 (15.6)
Other fall	19 (14.1)	24 (17.8)
Hyperextension of wrist	3 (2.2)	0
Rotational force	1 (0.7)	2 (1.5)

* Plus–minus values are means ±SD. Percentages may not total 100 because of rounding.
† One participant in the ultrasonography group was of female sex and nonbinary gender.
‡ Height data were missing for one participant in each of the two groups.
§ The body-mass index is the weight in kilograms divided by the square of the height in meters. Values for the percentiles shown are according to World Health Organization growth reference data based on age (https://www.who.int/tools/growth-reference-data-for-5to19-years/indicators/bmi-for-age). The body-mass index could not be calculated for one participant in each of the two groups.

STATISTICAL ANALYSIS

For our calculations of the sample size, we assumed a true between-group difference in the PROMIS score of 0 at 4 weeks, with a noninferiority margin of 5 points and a standard deviation of 11.5 points.[24,26,27] The noninferiority margin of 5 points was chosen by experts from the BUCKLED trial group. We assumed that the enrollment of 300 participants would yield primary outcome data for 224 participants (112 per group) and would provide the trial 90% power with a one-sided alpha level of 0.025. Power calculations for key secondary outcomes are shown in the Methods section of the Supplementary Appendix.

The primary outcome of the PROMIS score at 4 weeks was analyzed for the noninferiority of ultrasonography to radiography, with analyses conducted in both the per-protocol and intention-to-treat populations. The per-protocol population included participants who received initial imaging as assigned and had outcome data collected at 4 weeks (with a window of ±3 days). The intention-to-treat population included all participants with outcome data collected at any time. Prespecified subgroup analyses were conducted according to diagnostic category and age category. Post hoc analysis according to trial site was performed. The primary analysis was conducted with the use of linear regression modeling to assess the noninferiority of ultrasonography as compared with radiography, with trial-group assignment included as the main effect. Outcomes that were expected to have data that were considerably skewed or to have influential outliers were analyzed with the use of median regression. Count data were analyzed with the use of negative binomial regression. Binary data were analyzed with the use of logistic regression. Details of all the reported analyses are shown in Table S1 in the Supplementary Appendix.

Statistical analyses were performed as prespecified.[19] Missing data were not imputed, and a complete-case analysis was performed; the sensitivity analysis for the primary outcome is described in the Supplementary Appendix. For secondary outcomes and subgroup analyses, formal adjustment of confidence intervals for multiplicity was not performed, and no definitive inferences should be drawn from these findings. Analyses were performed with the use of Stata software, version 17.0 (StataCorp).

RESULTS

PARTICIPANTS

From September 1, 2020, to November 11, 2021, a total of 270 participants underwent randomization (Fig. S1) — 135 were assigned to initial ultrasonography and 135 were assigned to initial radiography. All the participants underwent the assigned initial imaging. Primary outcome data were recorded at 28 days (with a window of ±3 days) for 130 participants in the ultrasonography group and for 132 participants in the radiography group; data were recorded outside this range for an additional 3 participants in the ultrasonography group and 1 participant in the radiography group. The demographic and clinical characteristics of the participants at baseline are shown in Table 1. Diagnostic categories were

Table 2. PROMIS Scores.*

Variable	Ultrasonography		Radiography		Mean Difference (95% CI)
	No. of participants with data	Score	No. of participants with data	Score	
Primary outcome					
PROMIS score at 4 wk, per-protocol analysis	130	36.4±5.9	132	36.3±5.3	0.1 (–1.3 to 1.4)
PROMIS score at 4 wk, intention-to-treat analysis	133	36.4±5.9	133	36.3±5.3	0.1 (–1.3 to 1.4)
Secondary outcomes, per-protocol analysis					
PROMIS score at 1 wk	129	28.4±8.7	126	27.7±8.6	0.7 (–1.4 to 2.8)
PROMIS score at 8 wk	120	39.2±2.2	117	39.1±2.6	0.1 (–0.5 to 0.7)
Subgroup per-protocol analysis — PROMIS score at 4 wk†					
Diagnostic category					
No fracture	45	38.3±4.9	42	38.6±2.6	–0.3 (–2.0 to 1.4)
Buckle fracture	51	36.6±5.7	53	36.8±5.1	–0.2 (–2.3 to 1.9)
Other fracture	34	33.4±6.4	37	32.9±6.2	0.4 (–2.5 to 3.4)
Age					
5–9 yr	55	36.8±4.8	59	35.3±6.3	1.6 (–0.5 to 3.6)
10–15 yr	75	36.0±6.6	73	37.1±4.2	–1.1 (–2.9 to 0.7)

* Plus–minus values are means ±SD. The prespecified noninferiority margin was 5 points on the Pediatric Upper Extremity Short Patient-Reported Outcomes Measurement Information System (PROMIS) scale (range, 8 to 40, with higher scores indicating better function). Randomization was stratified according to trial site and participant age. Results from intention-to-treat and per-protocol analyses are reported for the primary outcome. Full per-protocol and intention-to-treat results are reported in Table S8. The per-protocol population underwent initial imaging as assigned, and outcome data were collected at 4 weeks (with a window of ±3 days). Outcome data for the intention-to-treat population were collected at any time.

† No apparent association was observed between group assignment and expert panel diagnosis of buckle fracture or no fracture (mean difference, 0.1 point; 95% CI, –2.9 to 3.1) or other fracture or no fracture (mean difference, 0.7 points; 95% CI, –2.6 to 4.0) or between group assignment and age category (mean difference, –2.7 points; 95% CI, –5.4 to 0.1).

similar in the two groups (Table S2). As prespecified, 40 participants in the ultrasonography group also underwent radiography; no participants in the radiography group underwent ultrasonography (Table S3). Management of injury in the emergency department was generally similar in the two groups (Table S4), but immobilization with a plaster cast was slightly less frequent in the ultrasonography group (in 23% of the participants) than in the radiography group (in 32%) (Table S5).

PRIMARY OUTCOME

The mean (±SD) PROMIS score at the 4-week follow-up in the per-protocol population was 36.4±5.9 points in the ultrasonography group and 36.3±5.3 points in the radiography group (mean difference, 0.1 point; 95% confidence interval [CI], –1.3 to 1.4) (Table 2 and Fig. 1). These findings indicate that ultrasonography was noninferior to radiography, because the lower boundary of the 95% confidence interval was higher than the noninferiority margin of –5 points. Findings of the intention-to-treat analysis were similar to those of the per-protocol analysis (mean difference, 0.1 point; 95% CI, –1.3 to 1.4). Findings were robust after sensitivity analyses (Table S6). The primary outcome did not appear to be influenced by the probe frequency or the practitioner who performed the ultrasonography (Table S7).

SECONDARY OUTCOMES

Ultrasonography appeared to be similar to radiography with respect to the PROMIS score at follow-up at 1 week (mean difference, 0.7 points; 95% CI, –1.4 to 2.8) and 8 weeks (mean difference, 0.1 point; 95% CI, –0.5 to 0.7) in the per-protocol population. Ultrasonography also appeared to be similar to radiography in subgroup

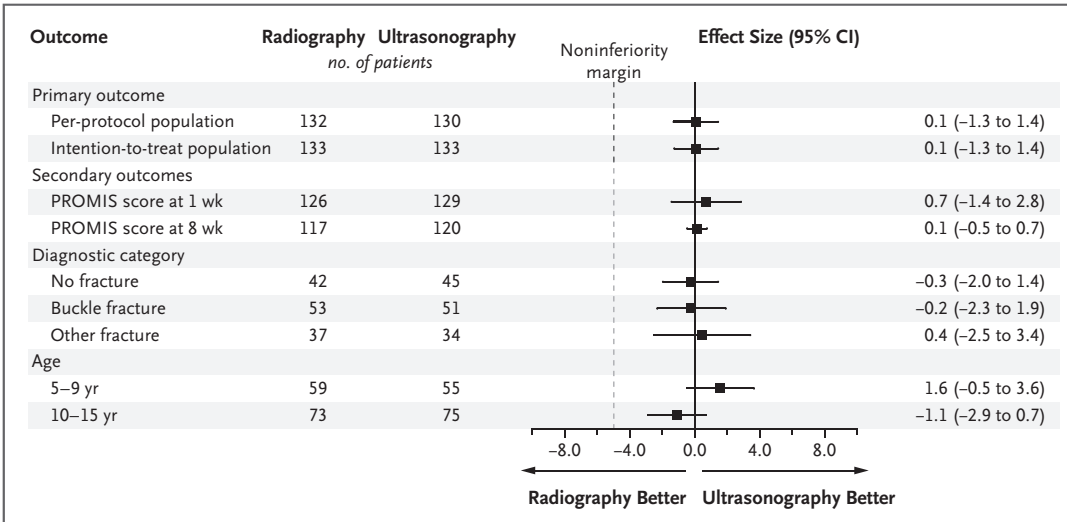

Figure 1. PROMIS Scores at 4 Weeks.

Children and adolescents with forearm injuries were randomly assigned to initially undergo point-of-care ultrasonography or radiography. The primary outcome was physical function of the affected arm at 4 weeks as assessed with the use of the validated Pediatric Upper Extremity Short Patient-Reported Outcomes Measurement Information System (PROMIS; scores range from 8 to 40, with higher scores indicating better function); the noninferiority margin was 5 points.

analyses according to diagnostic category and age category (Table 2 and Fig. S2) and trial site (Table S8). The remaining secondary outcomes were assessed in the intention-to-treat population.

Parent- or caregiver-reported satisfaction, as assessed with the use of the 5-point Likert scale, appeared to be greater in the ultrasonography group than in the radiography group at follow-up at 4 weeks (mean difference, −0.19 points; 95% CI, −0.37 to −0.01) (Table 3) and 8 weeks (mean difference, −0.20 points; 95% CI, −0.35 to −0.06) (Table S9). Participant-reported satisfaction at 4 weeks did not differ substantially between the two groups but appeared to be greater in the ultrasonography group than in the radiography group at 8 weeks (mean difference, −0.17 points; 95% CI, −0.33 to −0.01). No notable difference between the groups was seen in participant-reported pain at 1 week, 4 weeks, or 8 weeks. Participants in the ultrasonography group were observed to have shorter length of stay in the emergency department (median difference, 15 minutes; 95% CI, 1 to 29) and shorter treatment time (median difference, 28 minutes; 95% CI, 17 to 40) than participants in the radiography group(Table 3). Participants in the ultrasonography group had missed fewer days of school at 4 weeks (median difference, 0.5 days; 95% CI, 0.1 to 0.9).

At initial presentation, 122 radiographic films were obtained in the ultrasonography group as compared with 375 in the radiography group (rate ratio, 0.33; 95% CI, 0.27 to 0.40) (Table S9). There was no substantial difference between the groups in the number of follow-up radiography films obtained up to week 8 (167 in the ultrasonography group and 183 in the radiography group; rate ratio, 0.91; 95% CI, 0.48 to 1.73).

SAFETY AND ADVERSE EVENTS

There were no significant between-group differences in the frequency of adverse events or unplanned returns to the emergency department (Table S10). One participant in each group reinjured the initially injured arm in a fall, which led to a change in treatment, and a splint was replaced by a cast at 1 week in one participant in the radiography group owing to persistent pain (Table S11). Five participants in the ultrasonography group and eight in the radiography group had unplanned returns to the emergency department (odds ratio, 0.61; 95% CI, 0.19 to 1.92; P=0.40).

DISCUSSION

Our findings show that point-of-care ultrasonography may be used as an initial diagnostic

Table 3. Additional Secondary Outcomes.*

Outcome	Ultrasonography (N=135)	Radiography (N=135)	Point Estimate (95% CI)
Satisfaction at 4 wk†			
Participant-reported	1.57±0.83	1.72±0.92	−0.15 (−0.36 to 0.06)
Parent- or caregiver-reported	1.33±0.60	1.52±0.85	−0.19 (−0.37 to −0.01)
Pain at 4 wk†	0.9±1.7	0.8±1.5	0.10 (−0.28 to 0.48)
Treatment duration (IQR) — min‡			
Triage to emergency department discharge	109 (85 to 144)	125 (103 to 157)	−15 (−29 to −1)
Clinical review to emergency department discharge	70 (44 to 107)	98 (77 to 129)	−28 (−40 to −17)
Frequency of radiographic imaging§			
At initial presentation	0.90±1.54	2.78±0.91	0.33 (0.27 to 0.40)
Follow-up ≤8 wk	1.24±2.53	1.36±2.43	0.91 (0.48 to 1.73)

* Plus–minus values are means ±SD. No computed tomography scans were performed in the ultrasonography group; two were performed in the radiography group. Two participants in the ultrasonography group and none in the radiography group underwent magnetic resonance imaging. Data in the ultrasonography group were missing on participant- and parent- or caregiver-reported satisfaction in two participants and on pain in two participants. Data in the radiography group were missing on participant- and parent- or caregiver-reported satisfaction in three participants and on pain in two participants. Satisfaction and pain were analyzed with the use of linear regressions, treatment duration was analyzed with the use of median regression, and imaging was analyzed with the use of negative binomial regression. The full secondary outcome analysis is shown in Table S9. IQR denotes interquartile range.

† Lower scores denote higher satisfaction (on the 5-point Likert scale) and less pain (on the 6-point Faces Pain Scale–Revised). Point estimates are presented as mean differences.

‡ Point estimates are presented as median differences.

§ Point estimates are presented as rate ratios.

test for distal forearm injury in pediatric patients, with radiography reserved for features suggestive of a diagnosis that leads to cast immobilization and follow-up. We observed that initial ultrasonography reduced the number of participants who would have undergone radiography at their initial emergency department presentation, particularly among participants whose injuries were diagnosed as no fracture or a buckle fracture. The two groups had radiography performed a similar number of times in the follow-up period. This approach was safe and efficient; no important fractures were missed with the use of ultrasonography, and it led to a shorter treatment time and shorter length of stay in the emergency department. The present trial showed that ultrasonography can be implemented in existing hospital systems.

A diverse group of health care practitioners, including physicians, nurse practitioners, and physiotherapists, were trained to use ultrasonography in this trial.[28,29] A broad range of ultrasonography machines and probes were used, including cart-based and handheld devices. Although the quality of imaging may be reduced when linear probes with a frequency range less than 10 MHz are used, probe frequency was not associated with the primary outcome. Although this trial primarily involved children and adolescents who presented to the emergency departments at tertiary pediatric and mixed centers, given the range of practitioners who were trained and the equipment that was used, these findings could probably be replicated in settings outside the hospital, such as prehospital services, urgent care centers, general practice offices, or sports medicine clinics.

Given the training and resource requirements associated with ultrasonography as compared with the current availability of radiography, the cost-effectiveness of an ultrasonography-first approach to the diagnosis of pediatric forearm injuries should be investigated before being implemented in emergency department settings. The implementation of ultrasonography for the prospective diagnosis of clinically nonangulated distal forearm injuries in children might be better suited to centers where radiography is less

available or more costly. Implementation of this approach in rural and remote centers may reduce the need for centers to call in radiographers after hours or for patients to travel long distances to undergo imaging.[30] In addition, this approach may be useful in low- and middle-income countries given the paucity of radiography infrastructure in those locations[12] and the increasing affordability of ultrasonography.[13,31]

The strengths of this randomized trial include the incorporation of a variety of health care practitioners, ultrasonography machines, and hospital settings. The trial was sufficiently powered to determine noninferiority with respect to physical function of the arm, which is an important patient-centered outcome and an extension of previous studies that showed diagnostic accuracy as a primary outcome.[14-16] Protocol adherence was very high in this trial, and attrition among participants was very low (<1.5% in the intention-to-treat population). Participants were largely representative of the broader population of children 5 to 15 years of age who are affected by forearm fractures, a factor that suggests the findings have good generalizability (Table S12). In addition, the use of an expert panel for consensus diagnosis was a robust means of determining the final injury diagnosis, given the inherent issues with using radiography alone as the reference standard.[9-11]

A potential limitation of our trial was that differences in subsequent therapeutic interventions may have influenced the primary outcome separately from the initial diagnostic method. However, initial management according to diagnostic category, rates of follow-up reviews and imaging, and duration of immobilization were similar in the two groups. Other limitations included the participation of a small number of sites, with health care practitioners who were trained by a single emergency physician in emergency department hospital settings. Because the PROMIS tool was not validated for use in children younger than 5 years of age, children in that age group were excluded from this trial; however, children younger than 5 years of age may also benefit from the use of ultrasonography because that age group has a high incidence of buckle fractures.[32,33] Although no differences were observed between the groups in the occurrence of adverse events, participants were not followed long-term for rare complications.

The present randomized trial examined the feasibility, safety, acceptability, and timeliness of using an ultrasonography-first approach to the diagnosis of clinically nonangulated distal forearm injury in children and adolescents who presented to the emergency department. Ultrasonography was noninferior to radiography in the outcome of physical function of the arm at 4 weeks, with no between-group differences in the occurrence of adverse events.

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