

Research Article

Evaluating the potential for cone beam CT to improve the suspected scaphoid fracture pathway: InSPECTED: A single-centre feasibility study

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ABSTRACT

Background: The suspected scaphoid fracture remains a diagnostic conundrum with over-treatment a common risk-averse strategy. Cross-sectional imaging remains the gold standard with MRI recommended but CT used by some because of easier access or limited MRI availability. The aim of this feasibility study was to evaluate whether cone beam computed tomography (CBCT) could support early diagnosis, or exclusion, of scaphoid fractures.

Methods: Patients with a suspected scaphoid were recruited fracture between March and July 2020. All underwent a 4-view X-ray. If this examination was normal, they were immediately referred for a CBCT scan of the wrist. Those with a normal scan were discharged to research follow-up at 2 and 6-weeks.

Results: 68 participants were recruited, 55 had a normal or equivocal X-ray and underwent CBCT. Nine additional radiocarpal fractures (16.2%) were demonstrated on CBCT, the remainder were discharged to research follow-up. Based on the 2-week and 6-week follow up three patients (4.4%) were referred for MRI to investigate persistent symptoms with no bony injuries identified.

Conclusions: CBCT scans enabled a rapid pathway for the diagnosis or exclusion of scaphoid fractures, identifying other fractures and facilitating early treatment. The rapid pathway also enabled those with no bony injury to start rehabilitation, suggesting that patients

can be safely discharged with safety-net advice following a CBCT scan.

RÉSUMÉ

Contexte: La suspicion d'une fracture du scaphoïde reste une énigme diagnostique, le surtraitement étant une stratégie courante d'aversion au risque. L'imagerie transversale reste l'étalon-or, l'IRM étant recommandée mais la TDM étant utilisée par certains en raison d'un accès plus facile ou d'une disponibilité limitée de l'IRM. L'objectif de cette étude de faisabilité était d'évaluer si la tomographie à faisceau conique (CBCT) pouvait contribuer au diagnostic précoce, ou à l'exclusion, des fractures du scaphoïde.

Méthodologie: Des patients présentant une suspicion de fracture du scaphoïde ont été recrutés entre mars et juillet 2020. Tous ont subi une radiographie à quatre vues. Si cet examen était normal, ils ont été immédiatement orientés vers un scanner CBCT du poignet. Ceux dont l'examen était normal ont été renvoyés pour un suivi de recherche à deux et six semaines.

Résultats: Soixante-huit participants ont été recrutés, 55 avaient une radiographie normale ou équivoque et ont subi un CBCT. Neuf fractures radiocarpiales supplémentaires (16,2 %) ont été mises en évidence par CBCT, les autres ont été renvoyés au suivi de recherche. Sur la base du suivi à deux et six semaines, trois patients (4,4 %) ont été

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Competing interests: Carestream Health Inc supplied the CBCT scanner. All authors declare no conflict of interest.

Ethical approval: The study had ethical approval (REF: 20/EM/0012) prior to commencement and was registered as a clinical trial (ISTR12548470).

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orientés vers une IRM pour examiner des symptômes persistants sans qu'aucune lésion osseuse ne soit identifiée.

Conclusions: Les scanners CBCT ont permis un parcours rapide pour le diagnostic ou l'exclusion des fractures du scaphoïde, en identifiant

Keywords: Scaphoid; Carpal bones; Fractures; Cone-beam computed tomography; X-ray

Introduction

Management of the suspected scaphoid fracture remains a diagnostic conundrum, with most organisations requiring multiple hospital attendances and repeated investigations [1]. Given the poor sensitivity of clinical assessment, imaging remains critical in the confirmation, or exclusion, of a bony injury. As a result patients are managed proactively even if no fracture is identified, resulting in over-treatment with weeks of potentially unnecessary immobilisation and multiple hospital appointments [2,3]. This strategy is only effective if a fracture is considered on initial assessment [4]. Although X-ray is still the standard initial investigation for suspected fractures in England the National Institute for Health and Care Excellence (NICE) published guidance in 2016 for the diagnosis and management of such injuries, recommending that immediate MRI should be considered [5].

Access to cross sectional imaging remains challenging [1]. This is despite research confirming the positive clinical and economic impact of early MRI [6,7]. An alternative option for 3D visualisation of the wrist is CT, with multiple studies confirming the high sensitivity and specificity [8-12]. However, despite the greater availability of CT in terms of operational hours and shorter scan times [13], the competing pressures are significant, particularly in relation to patient acuity [14]. An evolving technology in the musculoskeletal field is cone-beam extremity CT (CBCT) which provides a similar cross-sectional imaging capability but with a smaller footprint, lower patient dose and reduced cost [15]. CBCT has been shown to be effective in the identification of foreign bodies [16] and radiocarpal injuries [15,17-19] with high sensitivity and specificity [20].

This single-centre study investigated the feasibility of using CBCT in a streamlined scaphoid pathway. The aim was to develop evidence to support service planning as well as to provide data to support future research trial design. The study had ethical approval (REF: 20/EM/0012) prior to commencement and was registered as a clinical trial (ISRCT12548470).

Materials and methods

Study design and setting

A prospective observational cohort study of a convenience sample of patients presenting with a history of trauma resulting in a suspected scaphoid fracture in a single UK NHS organisation. The study centre has three hospital sites with a

d'autres fractures et en facilitant un traitement précoce. Ce parcours rapide a également permis à ceux qui n'avaient pas de lésion osseuse de commencer une rééducation, ce qui suggère que les patients peuvent être libérés en toute sécurité avec des conseils de sécurité après un examen CBCT.

catchment population of 530,000 people and emergency care provision through two consultant-led emergency departments (ED) and an urgent treatment centre (UTC). A single CBCT scanner (OnSight, Carestream Health) was located at the central hospital site, with patients referred from the other ED or UTC if they require a scan. Changes to service pathways for suspected scaphoid fracture including same day, or next day, CBCT had been implemented six-months previously.

Participants and recruitment

A pragmatic target sample of 130 participants was set prior to the study based on average ED scaphoid X-rays attendances of 100 per month and an expected attrition rate of 35%, as reported in other similar studies [21]. The inclusion criteria were patients over the age of 18 presenting with a wrist injury suspicious for a scaphoid fracture (mechanism and tenderness at either the anatomical snuff box, scaphoid tubercle or on axial loading) requiring X-ray from triage or at clinician review. Patients were excluded if they had sustained other injuries, were unable, or unwilling, to have a CBCT scan and be followed up by a researcher, including completion of questionnaires.

Patients were recruited from 4th March to 30th June 2020 and followed up for 6 weeks (last follow up completed 11th August 2020). The majority of patients were recruited by the doctor or emergency nurse practitioner (ENP) managing their care, with the research team recruiting the remainder at the CBCT scan attendance. Patients who chose to participate in the study provided written consent, which included agreement to share routinely collected hospital data about their ED attendance. Patients without CBCT confirmed fracture were followed up virtually via telephone by the research team with an understanding that ED consultant review, MRI scan and/or physiotherapy referral may be organised if symptoms persist (continued pain or analgesia use). With the permission of the patient, reasons for declining to participate were recorded to inform the design of a future multicentre study.

Data sources and variables

In line with local protocol, all participants with a suspected scaphoid fracture had a four-view X-ray series performed, with CBCT referral if the X-ray was normal or equivocal, as per standard care. Patients with a confirmed fracture on imaging

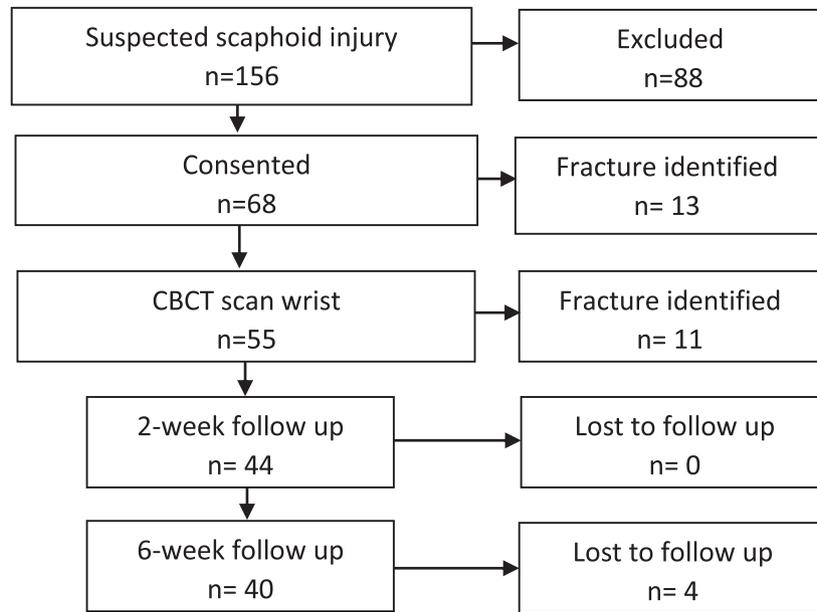


Fig. 1. Recruitment flow chart.

(X-ray or CBCT), were referred to the relevant hospital clinic and data collection ceased. Patients with a negative CBCT were discharged with a removable wrist splint and virtual follow up (2 and 6 weeks) by the research team, with oversight and any subsequent clinical decision-making in conjunction with the principal investigator.

Data was collected from the ED notes, electronic health records and radiology information system, including any related unplanned attendance at ED, other hospital clinic or imaging. Study questionnaires were completed by the patient at initial attendance recording pre-injury (baseline) and post-injury status. During follow-up telephone calls, the relevant study questionnaire was completed. If a patient did not respond to the first telephone call, 2 further attempts were made to contact the patient, and then a final letter was sent giving instruction on how to seek advice if symptoms were not improving. Data was initially recorded on case report forms (CRF) relevant to that episode, and then transcribed onto the EDGE research management system (University of Southampton, UK) using the participants unique study ID number. All missing data was recorded as an empty cell. Data validation was performed by the research team at regular intervals with queries checked against source data.

The primary outcome measure for this study was the number of hospital attendances related to suspected scaphoid fracture. Reported secondary outcome measures include the number of patients presenting at ED with suspected scaphoid fracture, fracture prevalence (including injury demographics such as time of presentation, clinical symptoms and fracture type if appropriate), and recruitment rate.

The Improving the Scaphoid Pathway with Extremity CT in the Emergency Department (InSPECTED) study team included a patient representative (with history of scaphoid fractures). They contributed to the research protocol and

commented on patient-facing materials including the information sheet, consent form and dissemination materials, such as an infographic summarising the study findings for participants and members of the public.

Statistical methods

For the purposes of the study, the primary endpoint was defined as confirmation of scaphoid (or other) fracture on imaging examination and the secondary end point as definitive exclusion of scaphoid (or other) fracture on imaging examinations and follow up review. The reported diagnosis is based on final imaging outcome with double reporting of all examinations by two independent consultant musculoskeletal radiologists.

Data for all outcome measures has been managed in Microsoft Excel® (Microsoft Corporation, Washington USA) and summarised using appropriate descriptive statistics. Further analysis used IBM SPSS statistics v27.0.

Results

Within the study timeframe 156 patients were deemed to have symptoms consistent with a scaphoid fracture requiring imaging investigation. Of these, 68 provided written consent to research follow-up and data collection (Fig. 1). The remainder included patients who were not approached for recruitment due to availability of staff trained in good clinical practice (n=34), declined participation (n=8) or lacked capacity (n=5). The other 43 patients did not meet the inclusion criteria (commonly due to additional injuries). Participants were predominately female (n=41; 60.3%) with a mean age of 41 years (S.D. ± 15.5). No specific attendance pattern was evident with greatest attendance on Mondays (n=13) and least on Thursdays and Fridays (each n=7).

Table 1

Fractures diagnosed on X-ray and cone beam CT (CBCT).

	Fractures diagnosed n (%)		
	X-ray	CBCT	Total
Radius +/- ulna	6 (8.8)	2 (2.9)	8 (11.8)
Isolated carpal bone	7 (10.3)	6 (8.8)	13 (19.1)
Scaphoid	7 (10.3)	1 (1.5)	8 (11.8)
Trapezium	-	5 (7.4)	5 (7.4)
Isolated metacarpal	-	1 (1.5)	1 (1.5)
Multiple fractures	-	2 (2.9)*	2 (2.9)
Total (% of attendees)	13 (19.1)	11 (16.2)	24 (35.3)

*1 patient had radial, capitate and metacarpal fractures; 1 had trapezoid and metacarpal

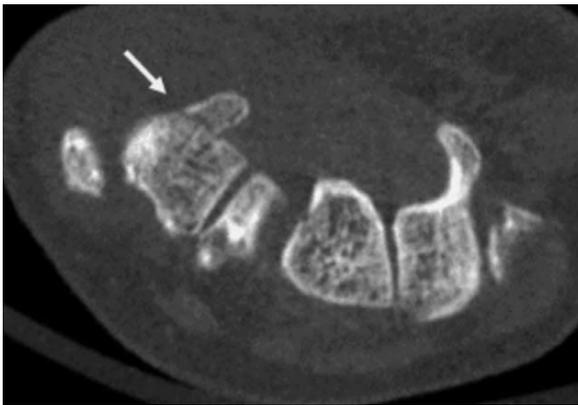


Fig. 2. 48 year old male who fell from a scooter. CBCT demonstrated a radiographically occult trapezium tubercle fracture (arrow).

The initial X-ray demonstrated a fracture in 19.1% (n=13/68) of cases. All patients with a negative or equivocal initial X-ray had CBCT (n=55). Of these, 16 were performed at the same attendance, (mean 1.2 hrs from ED arrival; range 0.4-2.45). For the remaining 39 patients this meant a second hospital attendance, most commonly due to the initial presentation being to a peripheral hospital site (n=33). The definitive diagnosis was available within 2 days in 94.1% of cases.

The CBCT scan confirmed 2 X-ray suspected fractures and demonstrated an additional 9 injuries. Independent retrospective review of the X-ray and CBCT images confirmed that the additional fractures (n=9) seen on CBCT were not evident on the initial radiographs. The fracture location varied, with only one additional scaphoid fracture identified and CBCT diagnosed fractures being predominately trapezium (Table 1) (Figs. 2 and 3) with radial styloid fractures also being identified (Fig. 4). Overall, there was no difference in age profile between the radial fracture and other fractures groups (46.5 ± 18.6 years vs 46.1 ± 16.3 years; $t=0.058$; $p=0.477$) although there were a greater proportion of females with a radial fracture (75% vs 50%; $X^2=1.371$; $p=0.242$).

Based on the 2-week and 6-week follow-up data, eight patients had a further telephone review (n=2) or physical evaluation by an ED consultant (n=3) or in fracture clinic (n=3). Of these, three patients (4.4%) were subsequently referred for



Fig. 3. 58 year old female presenting following a fall and tender scaphoid area. The X-ray was normal. CBCT demonstrated a lucent acute fracture line at the trapezium (arrow).

MRI to investigate their persistent symptoms, with no bony injuries identified.

Discussion

ED attendances during the study period were down across the NHS [22-25]. Indeed the study centre saw a 61% reduction in ED referred scaphoid X-rays compared to previous years. We believe this is related to the study opening 19 days prior to the first lockdown as a result of the coronavirus pandemic, and consequent reduction in outdoor activities, particularly sport. This is also likely to have resulted in the participant demographics which did not reflect the usual younger, male profile expected in suspected scaphoid fractures [23]. As a result of this change in attendance the planned recruitment strategy did not achieve the expected sample but the results are still valuable in confirming the opportunities afforded by the new pathway.

Over-treatment of suspected scaphoid injuries is an ongoing challenge [1]. Cohen et al. [26] stated that less than 10%



Fig. 4. 22 years old male with FOOSH. Radiographically occult (4a) intra-articular distal radius fracture was identified on CBCT (4b arrow).

of patients placed on follow up pathways are ever diagnosed with a fracture. In our study, 20% of those referred for CBCT were confirmed positive for bony injury, although the number of scaphoid fractures were small. Interestingly, the high incidence of trapezium fractures corresponds to the findings of Gibney et al. in their CBCT study of radiocarpal injuries [27]. This also again raises questions as to whether modern imaging techniques may refute the accuracy of the well cited 3-5% scaphoid fracture incidence [28]. The data does suggest that the number of fractures to the carpus may be underestimated using the conventional imaging strategies, although some of the injuries may be self-limiting and therefore not followed up with cross-sectional techniques.

Our findings confirm the effectiveness of the early CBCT pathway in terms of reducing hospital attendances and health-care resource use, as well as encouraging early mobilisation. This correlates with Vitez et al. who suggest that CBCT should be considered as a first line imaging modality for wrist injuries [29]. Our research also confirms the proposed strategy of discharge with safety net advice for re-presentation if symptoms persist, with potential for follow-up MRI as appropriate. X-rays remain the primary imaging tool, and with their low cost and easy access are unlikely to be replaced in the medium term, despite their poor sensitivity. The number of radial fractures

diagnosed on X-ray likely relates to the poor specificity of clinical assessment and/or the inappropriate referral for scaphoid imaging rather than dedicated wrist X-rays and may reflect the demographic profile of the sample. The use of CT (including CBCT) as a diagnostic imaging tool in the investigation of suspected scaphoid, or radiocarpal, injuries does result in an increased radiation dose burden to the patient. However, the availability of 3D imaging may also facilitate early treatment planning and negate the need for additional investigations for those with a confirmed fracture [30].

Limitations

Planned prior to the COVID-19 pandemic, the study had estimated a recruitment figure of 130 participants and therefore the lower recruitment rate reduces its strength and further research on the utility of CBCT or CT, particularly compared to MRI, in the diagnosis of scaphoid and other wrist injuries is required.

The pragmatic study design and relatively low numbers mean that all patients did not receive an MRI scan and therefore the sensitivity and specificity of CBCT cannot be confirmed. Patients were followed up by the research team at 2 and 6-weeks, with electronic records were interrogated for the

three months following initial attendance to identify hospital re-presentation or further imaging. As a result longer term re-presentation with ongoing symptoms were not investigated.

Conclusion

Based upon the prospective study findings we believe that patients with a negative CBCT (or CT) scan can be discharged with a splint and guidance, provided there is a safety net for escalating persistent symptoms. Early definitive diagnosis using cross-sectional imaging can enable early treatment for the injury, reducing the risks of complications associated with late identification of a scaphoid fracture.

CBCT is an emerging technology which may provide additional imaging capacity to enable access to more cross-sectional imaging of peripheral injuries. Further research is required to investigate the clinical and economic benefits afforded by new pathways.

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