■ WRIST & HAND

Clinical and cost implications of using immediate MRI in the management of patients with a suspected scaphoid fracture and negative radiographs

RESULTS FROM THE SMART TRIAL

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Aims

The aim of the Scaphoid Magnetic Resonance Imaging in Trauma (SMaRT) trial was to evaluate the clinical and cost implications of using immediate MRI in the acute management of patients with a suspected fracture of the scaphoid with negative radiographs.

Patients and Methods

Patients who presented to the emergency department (ED) with a suspected fracture of the scaphoid and negative radiographs were randomized to a control group, who did not undergo further imaging in the ED, or an intervention group, who had an MRI of the wrist as an additional test during the initial ED attendance. Most participants were male (52% control, 61% intervention), with a mean age of 36.2 years (18 to 73) in the control group and 38.2 years (20 to 71) in the intervention group. The primary outcome was total cost impact at three months post-recruitment. Secondary outcomes included total costs at six months, the assessment of clinical findings, diagnostic accuracy, and the participants' self-reported level of satisfaction. Differences in cost were estimated using generalized linear models with gamma errors.

Results

The mean cost up to three months post-recruitment per participant was £542.40 (SD £855.20, n = 65) for the control group and £368.40 (SD £338.60, n = 67) for the intervention group, leading to an estimated cost difference of £174 (95% confidence interval (CI) -£30 to £378; p = 0.094). The cost difference per participant increased to £266 (95% CI £3.30 to £528; p = 0.047) at six months. Overall, 6.2% of participants (4/65, control group) and 10.4% of participants (7/67, intervention group) had sustained a fracture of the scaphoid (p = 0.37). In addition, 7.7% of participants (5/65, control group) and 22.4% of participants (15/67, intervention group) had other fractures diagnosed (p = 0.019). The use of MRI was associated with higher diagnostic accuracy both in the diagnosis of a fracture of the scaphoid (100.0% *vs* 93.8%) and of any other fracture (98.5% *vs* 84.6%).

Conclusion

The use of immediate MRI in the management of participants with a suspected fracture of the scaphoid and negative radiographs led to cost savings while improving the pathway's diagnostic accuracy and patient satisfaction.

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The management of a suspected scaphoid fracture remains challenging, due to the low incidence of a true fracture in a patient who presents with a suspected scaphoid fracture, the limited accuracy of radiographs as an initial imaging modality, and the potential for complications resulting from misdiagnosis. Despite the limited ability of radiographs to rule out a scaphoid fracture decisively on presentation,[1] the use of advanced imaging, such as CT or MRI, has traditionally been reserved for the later stages of clinical management in the United Kingdom.

Table I. Inclusion and exclusion criteria used in the Scaphoid Magnetic Resonance Imaging in Trauma (SMaRT) trial

Criteria
Inclusion
Only patients screened during normal MRI working hours (weekdays: 7.30am to 6pm; weekends and Bank Holidays: 9am to 4pm).
Patients aged 16 years or over presenting to the emergency department with clinical history and examination consistent with a suspected scaphoid fracture (listed below) but negative findings on the initial four-view radiograph.
Isolated pain/tenderness over the anatomical snuff box or scaphoid tubercle or pain in the scaphoid region during axial loading of the first metacarpal.
History of recent fall (less than 14 days) on an outstretched hand, wrist injury, or poor history associated with examination findings suggestive of scaphoid fracture.
Exclusion
Confirmed scaphoid fracture following the initial four-view radiograph.
Confirmed ipsilateral upper limb injury/injuries (e.g. wrist/forearm/arm injury) following initial radiograph, regardless of the findings around the suspected scaphoid fracture.
Patients from outside the hospital's catchment area who are not willing to be followed up in the hospital.
Patients not admitted through the emergency department.

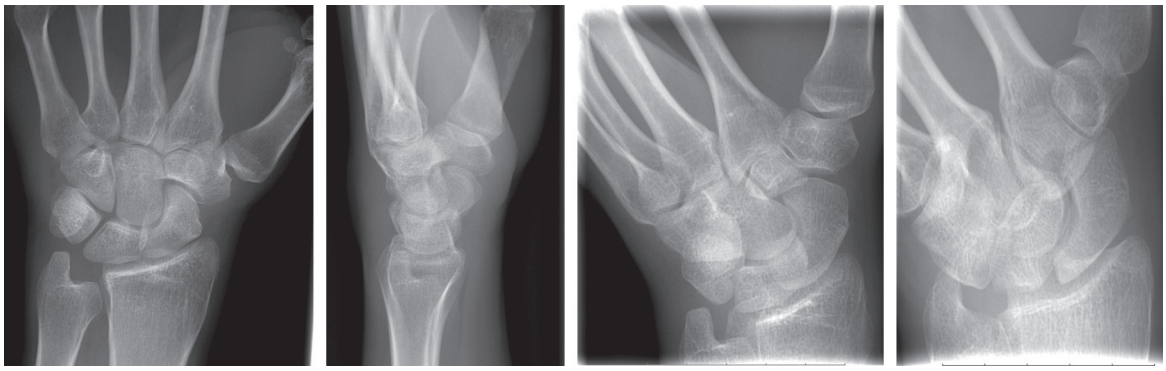

Fig. 1

A scaphoid series of a patient with negative radiographs who was randomized to the intervention (MRI) arm of the trial.

At present, there is a lack of economic evidence about the use of advanced imaging in the acute management of a suspected scaphoid fracture.[1] Given clinical evidence that shows that advanced imaging is a more accurate method of diagnosing a scaphoid fracture,[2] we designed this pragmatic trial to analyze the potential impact of using immediate MRI to make the diagnosis.

The aims of this trial were to test the diagnostic accuracy of using immediate MRI to assess patients with a suspected scaphoid fracture who presented to the emergency department with negative radiographs, and to determine the three- and six-month cost implications. We compared this with the current pathway, which relies on the acute use of radiographs only, wrist immobilization, and fracture clinic follow-up with radiographs.

Our underlying hypothesis was that the early use of a more expensive but more sensitive diagnostic tool (i.e. MRI) could improve diagnostic accuracy and streamline follow-up. This would avoid later costs associated with the provision of unnecessary fracture clinic appointments and repeated diagnostic tests, ultimately leading to cost savings.

Patients and Methods

The Scaphoid Magnetic Resonance Imaging in Trauma (SMaRT) trial was a prospective, parallel, nonblinded, randomized trial. Participants were recruited from the ED at Guy's and St Thomas' NHS Foundation Trust in London. The SMaRT trial was designed as a pragmatic trial to assess the real-world effectiveness of immediate MRI as part of routine clinical practice in a heterogeneous population. The rationale, design, and ethical approval of the trial have previously been described and published.[3] The inclusion and exclusion criteria are given in Table I. Exclusion criteria included participants presenting outside normal MRI working hours (weekdays: 7.30am to 6pm; weekends and Bank Holidays: 9am to 4pm).

Participants were randomized using a web-based automatic 1:1 block randomization sequence generated by an external organisation (King's Clinical Trials Unit). Participants with negative radiographs (Fig. 1) were randomized either to a control group, with radiographs only in the ED, or an intervention group, which had an additional immediate short-sequence MRI while in the ED (Fig. 2). Three sequences were used with a slice thickness of 3 mm and a pixel size of T1 0.3 × 0.3, proton density fat supressed (PDFS) 0.5 × 0.5, and short T1 inversion recovery (STIR) 0.4 × 0.4. Figures 3a to 3c exhibit three sequences carried out with a slice thickness of 3 mm in a patient with a fracture of the waist of the scaphoid. All MRI scans were reported by musculoskeletal radiologists. A total of 136 participants were recruited, 68 in each group. In the intervention arm, five participants (7.3%) did not undergo MRI.

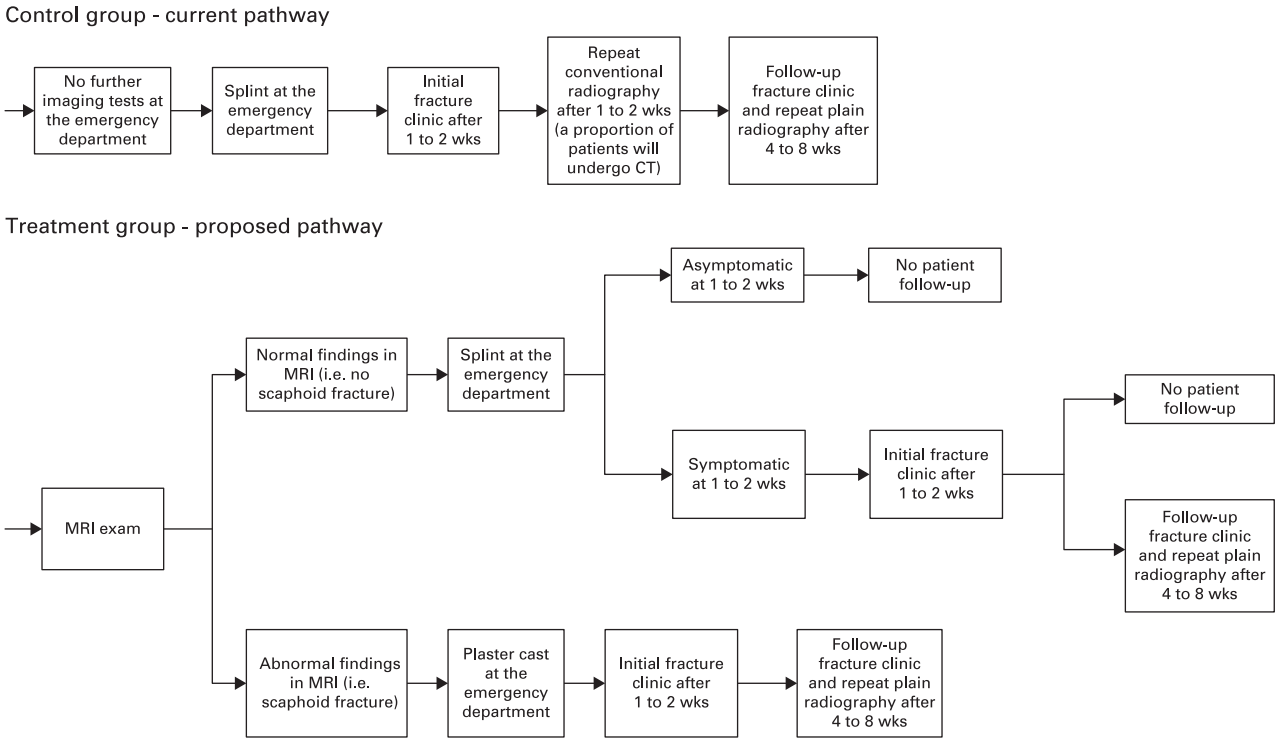

Fig. 2

Diagnostic and intervention pathways for participants randomized to the control and intervention groups.

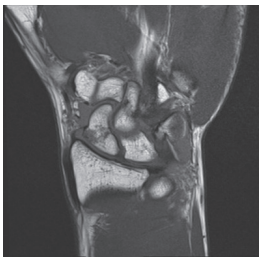

Fig. 3a

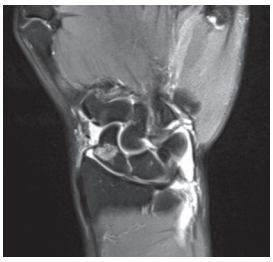

Fig. 3b

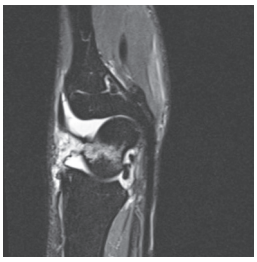

Fig. 3c

Imaging of a patient with fracture of the waist of the scaphoid showing the abbreviated MRI for: a) coronal T1; b) coronal proton density fat supressed (PDFS); and c) sagittal short T1 inversion recovery (STIR).

Subsequent clinical and radiological follow-up varied for each group depending on the initial imaging findings (Fig. 2). Participants in the control group were referred to a fracture clinic where further imaging (radiograph, CT, and/or MRI) was in some cases carried out as part of their standard care. The subsequent pathway for participants in the intervention group was dependent on the initial MRI findings. If a fracture was present, participants were placed in a below-elbow backslab, discharged from the ED, and then followed up in the next available fracture clinic. If the MRI showed no evidence of significant injury (either fracture or ligamentous disruption), the participant was given a wrist splint and discharged from the ED with a contact number to call if they had any questions about their condition. The contact card also asked the participant to contact the hospital if still symptomatic after 14 days, at which point follow-up in a specialist wrist clinic was arranged within a week. If their symptoms had resolved, no further clinic follow-up was organized.

Baseline and patient sociodemographic data included the participant's age, sex, employment status, mechanism of injury and history of previous scaphoid fracture (Table II). Most participants were male, 52% (control) and 61% (intervention), with a mean age of 36.2 years (18 to 73) in the control group and 38.2 years (20 to 71) in the intervention group. Over three-quarters of participants in both groups were employed full-time.

Clinical findings were classified into four categories: scaphoid fracture, other fracture, soft-tissue injury, and normal findings.

As part of the study, all participants were followed up for six months after recruitment (at months 1, 3, and 6) in

Table II. Sociodemographic and baseline characteristics of participants

Characteristic	Control group (n = 65)	Intervention group (n = 67)
Mean age, yrs (range)	36.2 (18 to 73)	38.2 (20 to 71)
Sex, male:female, n (%)	34:31 (*52.3:47.7*)	41:26 (*61.1:38.9*)
Employment status, n (%)		
Employee in full-time job (≥ 30 hrs/wk)	51 (*79*)	53 (*79.0*)
Employee in part-time job (< 30 hrs/wk)	6 (*9.2*)	2 (*3.0*)
Self-employed, full-time, or part-time	2 (*3.1*)	4 (*6.0*)
Full-time education at school, college, or university	0 (*0.0*)	3 (*4.5*)
Looking after the home	0 (*0.0*)	1 (*1.5*)
Wholly retired from work	1 (*1.5*)	1 (*1.5*)
Unemployed and available for work	3 (*4.6*)	1 (*1.5*)
Permanently sick/disabled	2 (*3.1*)	1 (*1.5*)
Doing something else	0 (*0.0*)	1 (*1.5*)
Previous scaphoid injury, yes:no, n (%)	10:55 (*15.0:85.0*)	11:56 (*16.4:83.6*)
Mechanism of injury, n (%)		
Fall on an outstretched hand	36 (*55*)	37 (*55*)
Other injury	29 (*45*)	30 (*45*)
Dominant hand, n (%)		
Left	7 (*11*)	5 (*7.5*)
Right	58 (*89*)	62 (*93*)
Arm injured, n (%)		
Left	33 (*51*)	27 (*40*)
Right	31 (*48*)	38 (*57*)
Both	1 (*1.5*)	2 (*3.0*)
Scaphoid fracture, n (%)	4 (*6.2*)	7 (*10.4*)
Other bone fractures, n (%)	5 (*7.7*)	15 (*22.4*)

addition to any of the clinical contacts that occurred as part of the participant's routine clinical care. Research-related contacts were made by a trained team member (TR, BM) either by telephone or by email (based on the participant's preference). These included the use of both non-standard questionnaires (resource use diary, patient satisfaction questionnaire) and standard questionnaires (five-level five-dimension EuroQol questionnaire (EQ-5D-5L)). These questionnaires assessed the participant's self-perceived pain score, quality of life, and satisfaction. All participants were invited to a face-to-face three-month research review appointment at which scaphoid radiographs were taken.

The primary outcome was to compare the three-month costs associated with both groups from a National Health Service (NHS) and Personal Social Services analytical perspective, consistent with National Institute for Health and Care Excellence (NICE) guidelines.[4] The estimate of the total costs was based on the summation of costs of any scaphoid-related healthcare event for each patient. The NHS resource use measurement was derived from the merging of different sources of information; primary and secondary care (ED, radiology, and electronic health records) databases and self-reported data from participants. This allowed resource use data to be validated by cross-referencing data from multiple sources. The valuation of unit costs was based on NHS reference costs 2016 to 2017,[5] the only exception being the immediate short-sequence wrist MRI, for which no tariff was available. This unit cost for the short-sequence MRI was estimated on the basis of time taken, using the known cost and duration of a full wrist MRI from NHS reference costs 2016 to 2017 (i.e. the short-sequence MRI and report was recorded to take a mean of 60% of the time of a full wrist MRI scan and report that costs £120.70). For primary care contacts, a mean cost per appointment (e.g. GP face-to-face/phone appointment) was derived from the Unit Costs of Health and Social Care 2016,[6] then inflated to 2016 to 2017 using the Hospital and Community Health Services (HCHS) index. Participants were not excluded from the analysis due to missing data. Only data from participants who withdrew informed consent were excluded from the analyses. If data were not available, mean values from the total sample were used.

The following secondary study outcomes were considered: cost analysis up to six months from recruitment; clinical findings; diagnostic accuracy (using the three-month radiograph as reference); participants' self-perceived pain and patient experience; time immobilized in cast; and time off work and informal care.

All analyses were based on the principle of intention-to-treat. This reflects the pragmatic design of the SMaRT trial, which aimed to simulate real-life clinical practice with non-compliance and deviations from protocol. Additionally, by not excluding non-compliers, no statistical power was lost.

Cost differences between groups were assessed using generalized linear models (GLMs) with an identity-link and gamma distribution. This takes into account the lack of symmetry (i.e. the skewness) in the NHS cost data and provides estimated means to preserve the total cost.[7] Scaphoid fracture numbers and other binary outcomes and categorical data were analyzed

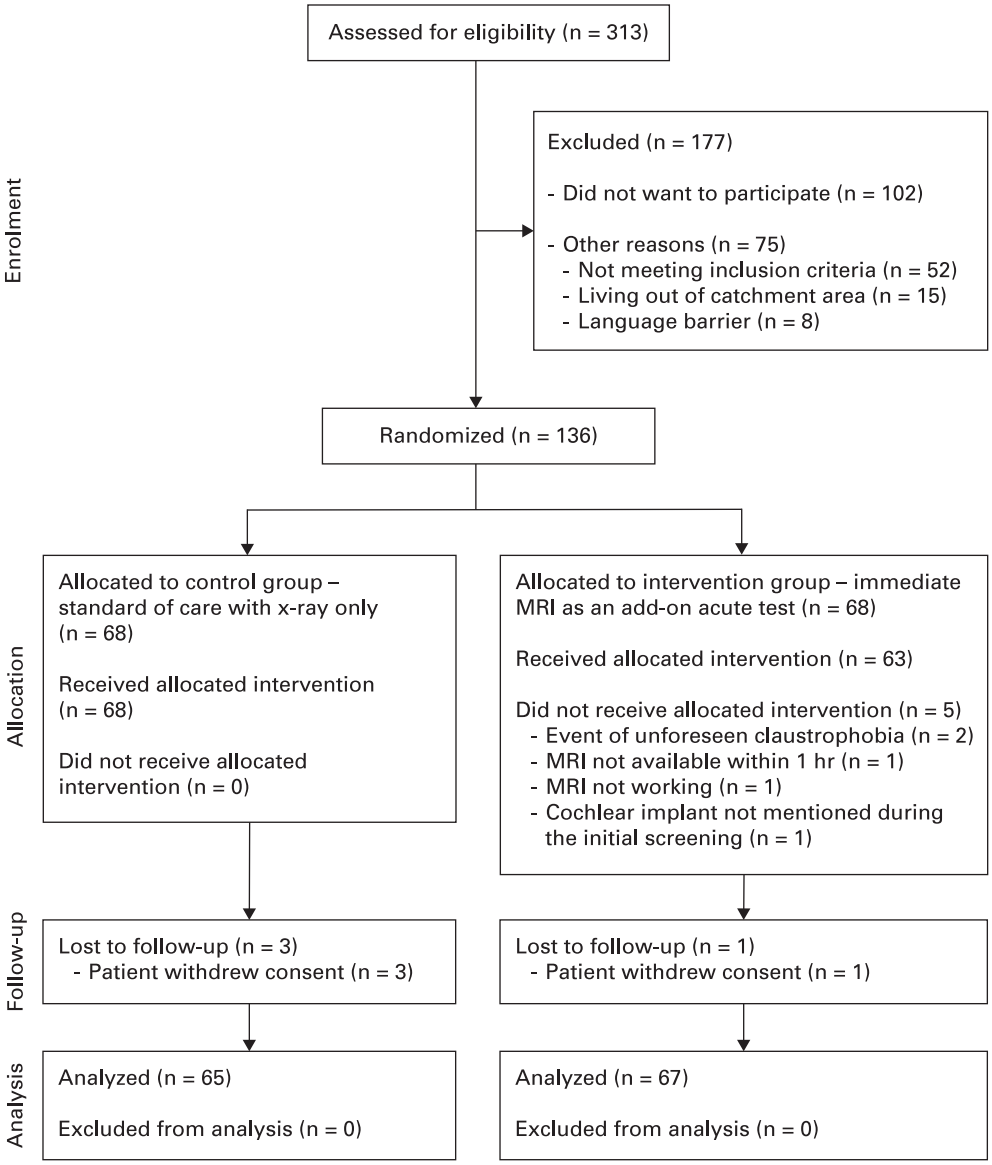

Fig. 4

Participant flow chart for the Scaphoid Magnetic Resonance Imaging in Trauma (SMaRT) trial.

using a chi-squared test. Differences in the mean pain score and time immobilized in plaster cast were assessed using the independent Student's *t*-test (tested for normality using the Shapiro–Wilk test). The Mann–Whitney U test was used to assess group differences for time off work or informal care and time to definitive diagnosis as they could not be transformed to a normal distribution. Group difference estimates and 95% confidence intervals (CIs) are reported with p-values ($p < 0.05$ denoted statistical significance). All analyses were performed using Stata 15.0. (StataCorp LLC, College Station, Texas).

The estimated sample size was estimated at 136 participants (68 in each group) based on the anticipated difference in the three-month cost per participant as per the published protocol.[3]

Results

Baseline data were complete for all participants (Table II). Four participants (three control, one intervention) withdrew informed consent and so were considered lost to follow-up (Fig. 4). The remaining 132 participants were included in the analysis.

A total of 11 scaphoid fractures (8.3%) were diagnosed up to three months: four (6.2%) in the control group and seven (10.4%) in the intervention group (Table III). This was not significantly different (chi-squared test; $p = 0.372$). A statistically significant difference in the detection of other (non-scaphoid) fractures was found (chi-squared test; $p = 0.019$), with a total of 20 fractures (15%) diagnosed: five (7.7%) in the control group and 15 (22%) in the intervention group (Table IV). A total of five soft-tissue/ligamentous injuries (3.8%) were diagnosed: one (1.5%)

Table III. Type of scaphoid fractures diagnosed in both groups

Number	Scaphoid fractures		
	Control group (n = 65)		**Intervention group (n = 67)**
1	Undisplaced fracture of scaphoid waist	Found on repeated radiograph eight days after ED visit	Undisplaced distal pole fracture
2	Undisplaced fracture of the proximal pole	Found on MRI 48 days after ED visit	Undisplaced fracture of scaphoid waist
3	Undisplaced fracture of the scaphoid waist	Found on MRI nine days after ED visit	Incomplete scaphoid waist fracture
4	Fracture of the scaphoid waist	Found on repeated radiograph 13 days after ED visit (diagnosed at a 2nd ED visit at a different hospital)	Scaphoid tubercle fracture
5			Impaction fracture of the radial cortex of the scaphoid, though no evidence of scaphoid waist displacement
6			Undisplaced impaction fracture of the scaphoid tubercle
7			Displaced fracture of the waist of the scaphoid

ED, emergency department

Table IV. Type of other bone fractures (apart from scaphoid fractures) diagnosed in both groups

Number	Other bone fractures		
	Control group (n = 65)		**Intervention group (n = 67)**
1	Radial styloid fracture	Found on repeated radiograph nine days after ED visit	Undisplaced distal radial fracture
2	Undisplaced distal radius fracture	Found on CT 12 days after ED visit	Undisplaced triquetrum fracture (with partial lunotriquetral ligament tear)*
3	Undisplaced distal radius fracture	Found on repeated radiograph eight days after ED visit	Impaction fracture of the proximal articular surface of the second metacarpal
4	Undisplaced capitate fracture and bone contusions of pisiform and trapezium	Found on MRI eight days after ED visit	Undisplaced distal radius fracture
5	Undisplaced distal radius fracture	Found on MRI 11 days after ED visit	Cortical disruption of the articular surface of the distal radius
6			Undisplaced fracture of the distal radius with minor intraarticular extension
7			Undisplaced distal radius fracture
8			Fracture of the hook of the hamate (missed on MRI; found on CT 116 days after ED visit)
9			Base of fifth metacarpal intra-articular fracture with no displacement
10			Fracture of the distal radius
11			Undisplaced intra-articular distal radial fracture + nondisplaced transverse trabecular fracture of the base of the fifth metacarpal
12			Undisplaced fracture of the capitate
13			Pisiform fracture
14			Undisplaced trabecular fracture of the lunate (with TFCC injury)*
15			Undisplaced distal radius fracture

*Patients with concomitant soft-tissue injuries also included in Table V
ED, emergency department

in the control group and four (6.0%) in the intervention group (p = 0.102; Table V). Two of the patients in Table V with reported soft-tissue injuries also had bony injuries and were therefore included in Table IV, meaning that 17 patients in the intervention group had injuries other than scaphoid fractures detected (Fig. 5).

A total of 43 participants (64%) in the intervention group had a negative MRI (Fig. 5). In the control group, as part of the inclusion criteria, all participants had negative findings on the initial radiographs. Of these 65 participants, 55 (85%) were radiologically normal (including the three-month radiograph; Fig. 5). Two participants in the control group underwent surgery for a complete rupture of the scapholunate ligament and a minimally displaced fracture of the proximal pole of the scaphoid. One in the intervention group underwent surgery for a displaced fracture of the waist of the scaphoid (chi-squared test; p = 0.541). Figure 6 summarizes the follow-up pathway associated with all participants included in the control and intervention groups.

Data from primary and secondary care databases were 98.5% (n = 130) and 100% (n = 132) complete, respectively. The mean three-month cost per participant was £542 (£94 to £7116) in the control group and £368 (£166 to £2691) in the intervention

Table V. Type of soft-tissue/ligamentous injuries diagnosed in both groups

Number	Soft tissue injuries	
	Control group (n = 65)	**Intervention group (n = 67)**
1	Complete scapholunate ligament rupture	Partial lunotriquetral ligament tear (with undisplaced triquetrum fracture)*
2		Partial TFCC tear
3		TFCC tear involving foveal and ulnar styloid attachments
4		TFCC tear (with undisplaced trabecular fracture of the lunate)*

*Patients with concomitant fractures also included in Table IV
TFCC, triangular fibrocartilage complex

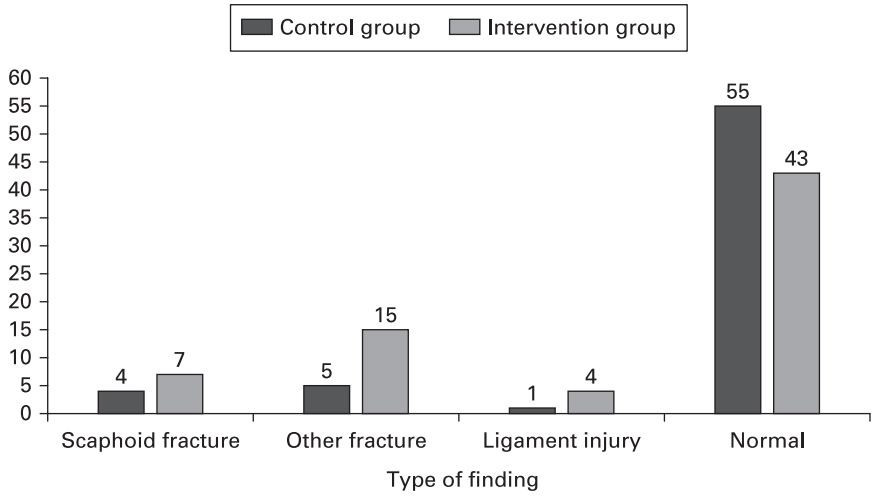

Fig. 5

Distribution of clinical findings by randomization group.

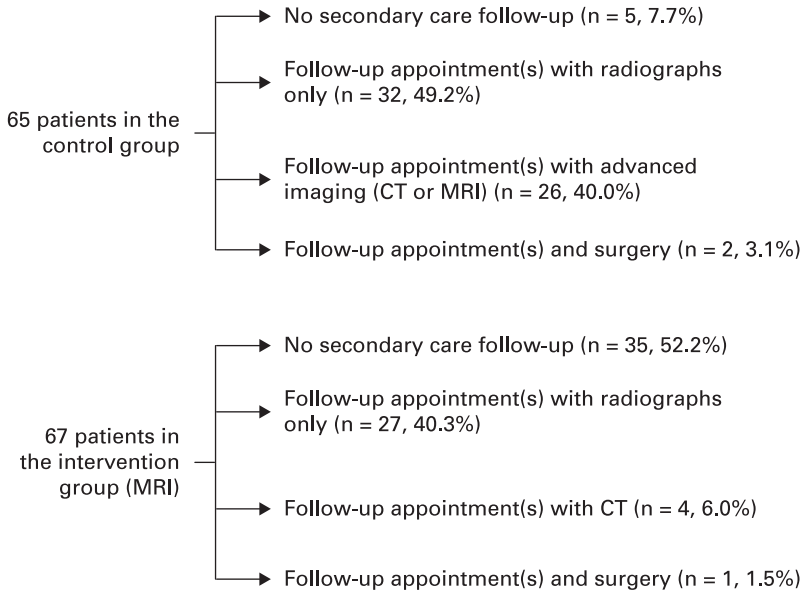

Fig. 6

Follow-up pathway for participants randomized to the control and intervention groups.

group (Table VI). As depicted in the three-month cost histogram (Fig. 7), 27 participants (40%) in the MRI group were in the £0 to £250 range, compared with only 11 (17%) in the control group. However, the minimum cost incurred by participants in the control group (£94, n = 4) was lower than that in the MRI group (£166, n = 22). In both cases, these participants needed no secondary care follow-up after the initial ED attendance (see Fig. 6). There was a reduction in mean cost in the intervention

Table VI. Cost analyses at months 3 and 6 post-recruitment

Mean total cost (SD; range)	Control group (n = 65)	Intervention group (n = 67)	Difference (control -intervention; 95% CI)	p-value*
3 mths	£542 (£855); £94 to £7116	£368 (£339); £166 to £2691	£174 (-£30 to £378)	0.094
6 mths	£661 (£1189); £94 to £7332	£395 (£345); £166 to £2691	£266 (£3.3 to £528)	0.047†

*Generalized linear models
†Statistically significant
CI, confidence interval

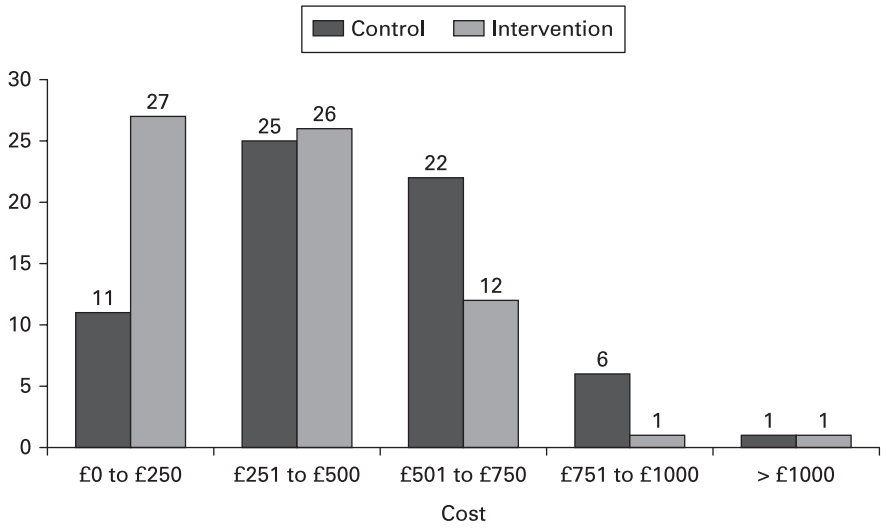

Fig. 7

Histogram for the three-month cost distribution for the control and intervention groups.

group of £174 per participant (95% CI -£30 to £378), but this was not statistically significant at three months (GLM; p = 0.094; Table VI).

The mean six-month cost per participant was £661 (£94 to £7332) in the control group and £395 (£166 to £2691) in the intervention group. The cost difference of £266 per participant (95% CI £3.30 to £528) was statistically significant (GLM; p = 0.047; Table VI).

The accuracy of the intervention group (immediate wrist MRI) and the control group (radiograph only) was compared against the three-month series of scaphoid radiographs, as the reference standard. The accuracy for detection of a scaphoid fracture was 93.8% in the control group and 100% in the intervention group. These data were calculated using a general accuracy equation and its respective estimate for both control and MRI groups in the detection of scaphoid fractures.

$$Accuracy = \frac{number\ of\ true\ negatives + number\ of\ true\ positives}{total\ of\ asessments}$$

$$Accuracy\ in\ the\ diagnosis\ of\ scaphoid\ fractures\ at$$

$$ED\left(control\ group\right) = \frac{61+0}{65} = 93.8\%$$

$$Accuracy\ in\ the\ diagnosis\ of\ scaphoid\ fractures\ at$$

$$ED\left(MRI\ group\right) = \frac{60+7}{67} = 100\%$$

If other fractures were also included, the accuracy decreased to 84.6% in the control group and 98.5% in the intervention group. These data were calculated using a general accuracy equation and its respective estimate for both control and MRI groups in the detection of any bone fracture. The MRI group had one false-negative result.

$$Accuracy\ in\ the\ diagnosis\ of\ any\ bone\ fracture\ at$$

$$ED\left(control\ group\right) = \frac{55+0}{65} = 84.6\%$$

$$Accuracy\ in\ the\ diagnosis\ of\ any\ bone\ fracture\ at$$

$$ED\left(MRI\ group\right) = \frac{47+19}{67} = 98.5\%$$

Mean self-reported pain scores based on a scale of 0 to 10 (with 0 being no pain at all and 10 the worst pain ever) were 3.61 in the control group (0.2 to 10.0) and 2.62 in the intervention group (0.1 to 6.4). The difference was not statistically significant (independent-samples Student's *t*-test; p = 0.074).

Patient satisfaction was evaluated at three months post-recruitment, and included three elements: 1) acute ED management; 2) fracture clinic management of the suspected scaphoid fracture (Table VII); and 3) experience of participation in the research study (Table VIII). Although both groups reported similar levels of satisfaction with the overall ED visit (chi-squared test; p = 0.867), the intervention group showed a trend towards a higher level of satisfaction with how the injury was explained

Table VII. Patient experience questionnaire for the acute management of the pathway in the control (n = 22) and intervention (n = 41) groups

Questionnaire	Group	Very satisfied, n (%)	Satisfied, n (%)	Neutral, n (%)	Dissatisfied, n (%)	Very dissatisfied, n (%)
1. Presentation to the emergency department (ED)						
How well your injury was explained to you by staff	Control	9 (*43*)	10 (*48*)	1 (*4.8*)	1 (*4.8*)	0 (*0*)
	MRI	31 (*76*)	8 (*20*)	1 (*2.4*)	1 (*2.4*)	0 (*0*)
The information you received about any tests you needed	Control	7 (*33*)	12 (*57*)	1 (*4.8*)	1 (*4.8*)	0 (*0*)
	MRI	28 (*68*)	11 (*27*)	1 (*2.4*)	1 (*2.4*)	0 (*0*)
The information you received about the results of any tests	Control	9 (*47*)	7 (*37*)	2 (*11*)	1 (*5.3*)	0 (*0*)
	MRI	23 (*56*)	12 (*29*)	1 (*2.4*)	5 (*12*)	0 (*0*)
How you found the visit overall	Control	11 (*52*)	8 (*38*)	1 (*4.8*)	1 (*4.8*)	0 (*0*)
	MRI	22 (*54*)	14 (*34*)	4 (*9.8*)	1 (*2.4*)	0 (*0*)
2. Outpatient follow-up care						
Thinking about your visit(s) to the outpatient department in general, how did you find the following aspects of your care?						
The information you were given to manage your injury at home	Control	5 (*25*)	10 (*50*)	3 (*15*)	1 (*5.0*)	1 (*5.0*)
	MRI	18 (*50*)	14 (*39*)	3 (*8.3*)	1 (*2.8*)	0 (*0*)
The information you received about any extra tests you needed	Control	4 (*20*)	11 (*55*)	5 (*25*)	0 (*0.0*)	0 (*0*)
	MRI	13 (*39*)	14 (*42*)	5 (*15*)	1 (*3.0*)	0 (*0*)
The information you received about the results of any tests	Control	3 (*17*)	10 (*55*)	3 (*17*)	2 (*11*)	0 (*0*)
	MRI	17 (*52*)	11 (*33*)	3 (*9.1*)	2 (*6.1*)	0 (*0*)
How you found your visits to outpatients overall	Control	8 (*40*)	8 (*40*)	3 (*15*)	1 (*5.0*)	0 (*0*)
	MRI	17 (*49*)	15 (*43*)	3 (*8.6*)	0 (*0.0*)	0 (*0*)

Table VIII. Patient experience questionnaire for taking part in the trial for participants in the control (n = 22) and intervention (n = 41) groups

Questionnaire	Group	Strongly agree, n (%)	Agree, n (%)	Neutral, n (%)	Disagree, n (%)	Strongly disagree, n (%)
3. Participating in the study						
How far would you agree with the following statements on your experience of taking part in this study?						
I had a good overall experience of taking part in this study	Control	9 (*43*)	8 (*38*)	4 (*19*)	0 (0)	0 (*0*)
	MRI	27 (*68*)	12 (*30*)	1 (*2.5*)	0 (0)	0 (*0*)
		It improved my care, n (%)	**It made no difference, n (%)**	**It had a negative impact, n (%)**		
Do you think taking part in the study had any impact on your care?	Control	4 (*19*)	16 (*76*)	1 (*4.8*)		
	MRI	33 (*81*)	8 (*20*)	0 (*0*)		
		It improved my understanding, n (%)	**It made no difference, n (%)**	**It had a negative impact, n (%)**		
Do you feel that taking part in the study changed your understanding of your condition and treatment?	Control	14 (*67*)	6 (*29*)	1 (*4.8*)		
	MRI	31 (*76*)	10 (*24*)	0 (*0*)		

N/A, not applicable

(chi-squared test; p = 0.088), the information received about the tests (chi-squared test; p = 0.075), and the information received about the test results (chi-squared test; p = 0.154). Second, the difference in the proportion of participants in the two groups who were very satisfied with the outpatient management of their condition (48.6% *vs* 40.0%; Table VII) was not statistically significant (chi-squared test; p = 0.482). Third, participants in the MRI group showed a significantly higher level of satisfaction in terms of their overall experience of the trial (chi-squared test; p = 0.043), also reporting that taking part in the trial improved their clinical care (chi-squared test; p < 0.001; Table VIII).

The time taken to reach a definitive diagnosis in each group was estimated at 10.2 days (0 to 55) in the control group and 1.7 days (0 to 116) in the intervention group. Hence, intervention led to a quicker definitive diagnosis (Mann–Whitney U test; p < 0.001).

The time spent immobilized in a plaster cast was measured as a proxy to assess the potential societal impact of the intervention.[1] A total of 14 plaster casts were used in the control group and 20 in the intervention group. The mean time immobilized in a plaster cast was 25.9 days (7 to 38) in the control group and 36.1 days (3 to 54) in the intervention group. This difference was not statistically significant (independent-samples Student's *t*-test; p = 0.397).

The time off work and informal care due to a suspected scaphoid fracture was assessed. The mean time off work and informal care was 6.0 days (0.0 to 40.0) in the control group (n = 22) and 4.3 days (0 to 50) in the intervention group (n = 88). This difference was not statistically significant (Mann–Whitney U test; p = 0.408).

Discussion

To the best of our knowledge, this is the first randomized trial to evaluate the clinical and cost implications of using immediate MRI in the acute management of a suspected scaphoid fracture with negative radiographs. This is innovative, as previous real-world studies have only evaluated the use of advanced imaging two to five days after presentation to the ED.[1] Additionally, several measures of outcome were analyzed, providing a better understanding of the impact of the intervention.

The primary outcome was the total costs at three months post-recruitment. This timeline was deemed appropriate to capture most of the relevant NHS resource use given the short-term nature of the condition. The trial showed a trend towards the intervention being associated with lower costs per participant, although this was not significant (mean difference of £174 per participant; GLM; p = 0.094). The MRI group had a higher proportion of participants in the £0 to £250 range than the control group (40.3% *vs* 16.9%), although the minimum cost in the control group (£94, n = 4) was lower than that in the MRI group (£166, n = 22). These four control participants had no formal follow-up as they either cancelled the appointment (n = 2) or left the ED before having an appointment booked (n = 2). The 22 minimum-cost participants in the intervention group had major injuries excluded in the ED and needed no subsequent follow-up.

In effect, this was the rationale for the intervention, as the upfront costs of acquiring an immediate MRI avoided later costs associated with outpatient appointments and further diagnostic tests in a proportion of the participants. Therefore, the cost distribution in the control group was more positively skewed: 28 participants (43%) in the control group cost between £500 and £1000 compared with only 13 in the intervention group (19%). This was due to the higher number of appointments that were needed either to diagnose or to rule out a scaphoid fracture in the control group. Both groups had one participant each who incurred costs of over £1000. These two participants needed surgical repair of a complete rupture of the scapholunate ligament (control group) and a displaced fracture of the waist of the scaphoid (intervention group), resulting in a maximum per patient cost of £7116 in the control group and £2691 in the intervention group.

A six-month cost analysis was also undertaken. The mean cost difference per participant between the two groups was found to be higher at six months than at three months (£266 *vs* £174) and was statistically significant (GLM; p = 0.047).

While the number of scaphoid fractures detected in each group was not significantly different (seven in the intervention group, four in the control group), the diagnosis was certainly made more quickly in the intervention group (mean 9.5 days *vs* 1.7 days; p < 0.001). Three of the scaphoid fractures seen in the MRI group were minor (Table III). The use of immediate MRI was, however, associated with a statistically higher number of other fractures being identified (e.g. capitate fracture, distal radial fracture), and again the diagnoses were made early. Given the randomized design of the trial, a similar incidence of fractures would be anticipated. This raises three potential scenarios: some clinically important injuries not being diagnosed in the control group, some clinically unimportant injuries being diagnosed in the MRI group, or a mixture of both of these phenomena. In this study it does not appear that any clinically important injuries were missed in the control group, rather that some of the injuries diagnosed by early MRI were not clinically important (Table IV).

Other authors have previously highlighted the potential for the routine use of MRI in the acute situation to lead to overdiagnosis and overtreatment: in other words, MRI can be oversensitive to phenomena such as bone bruising or minor soft-tissue injuries that are clinically unimportant.[8,9] This is particularly concerning if MRI is used on all patients who present with radial-sided wrist pain after injury, whereas in this study it was only used in patients with negative radiographs, as recommended. In addition, in our study, a three-month radiograph was used to rule out missed diagnoses, and a 1.5 Tesla scanner (Siemens Healthineers, Munich, Germany) was used.

The more important message is that patients with negative radiographs but positive findings on MRI should be examined in the fracture clinic with these caveats in mind. Isolated bone bruising may well be of limited clinical importance: if the patient's symptoms are improving rapidly, they can be allowed to settle while using intermittent splintage for comfort.

What our study does show, however, is that despite the fact that a relatively high number of patients were diagnosed with lesions that required follow-up in the intervention group, a far greater number of patients (35/68) did not require follow-up at all, a reflection of the greater specificity of MRI scans in this context. By contrast, all patients in the control group needed follow-up. Thus, this pathway was at least cost-neutral at three months, and cost-saving at six months.

The accuracy of radiographs and immediate MRI in the diagnosis of scaphoid fractures in the ED was 93.8% and 100%, respectively. This means that MRI was able to correctly include or exclude a scaphoid fracture in all participants. Conversely, in 6.2% of the cases, initial radiographs gave false-negative findings. If we extend this analysis to all fractures, radiographs have reported accuracy of 84.6% and MRI of 98.5%. The MRI group had one false-negative finding, as one participant was subsequently found to have a fracture of the hook of the hamate. This injury was picked up using the original MRI dataset at the three-month research clinic, and review of the imaging does suggest that the radiological diagnosis was missed.

The results show a significant and expected difference in time to definitive diagnosis, which from the patient's perspective could be seen to be one of the most important advantages of early MRI. We did, therefore, find a trend towards higher patient satisfaction in the intervention group, although this was not statistically significant. There was a definite perceived advantage to the quality of care received in the intervention group when asking trial participants about their experience of the study.

Finally, it was hypothesized that the use of immediate MRI would lead to fewer participants being immobilized in a cast.

This would ultimately decrease the number of days off work and informal care. This hypothesis was refuted by the trial data as the intervention detected more injuries that required initial cast immobilization. Nonetheless, the intervention showed a nonsignificant trend towards a lower number of days off work, perhaps because participants immobilized in a splint still needed time off work because of their wrist pain and/or to attend NHS appointments.

There were limitations to this study. Our exclusion criteria reflected operational challenges associated with the availability of MRI and subsequent reporting. This affected the generalizability of the trial as its findings are not directly transferrable to patients who present in the evening or at weekends, or to other healthcare systems. Further research into the use of different staff models (e.g. reporting radiographers) to include or exclude significant injuries quickly on the basis of the immediate MRI are being considered. Another important trial limitation was the lack of blinding. This constitutes a trial limitation as it might have led to conscious or unconscious bias from the participant and/or the routine care team staff.

In conclusion, the SMaRT trial has addressed a gap in the clinical and economic evidence, with implications for clinical practice and research. The results showed that the immediate use of MRI in the management of a scaphoid fracture was associated with a trend towards reduced costs at three months (although not statistically significant), and a significant decrease in total costs at six months post-recruitment. Furthermore, the intervention led to a quicker diagnosis, improved diagnostic accuracy, and higher patient satisfaction. In summary, the use of immediate MRI in the ED should be considered as an additional test in the management of suspected scaphoid fractures in the NHS.

Take home message

- Compared with the current standard of care, the use of immediate MRI in the management of suspected scaphoid fractures was cost-neutral at three months, and demonstrated cost savings at six months post-injury.
- Immediate MRI allows a quicker and more accurate diagnosis of suspected scaphoid fractures with higher levels of patient satisfaction.

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