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Contrast-enhanced T1-weighted Dixon water- and fat-only images to assess osteitis and erosions according to RAMRIS in hands of patients with early rheumatoid arthritis

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ABSTRACT

Purpose: To assess the agreement between readers using contrast-enhanced T1-weighted Dixon water- and fat-only images and OMERACT-recommended sequences for the scoring of osteitis and erosions according to the rheumatoid arthritis (RA) MRI scoring system (RAMRIS) in hands of patients with early RA.

Materials and methods: Both hands of 24 patients (16 women, 8 men; mean age, 45.7 ± 14.5 [SD] years; age range: 25–70 years) with early RA were prospectively imaged with fat-saturated T2-weighted sequences, non-Dixon T1-weighted imaging prior to contrast material injection and T1-weighted Dixon imaging after contrast material injection at 1.5 T. There were Two radiologists separately quantified osteitis and erosions according to RAMRIS using contrast-enhanced T1-weighted Dixon water-only and fat-saturated T2-weighted images for osteitis and contrast-enhanced T1-weighted Dixon fat-only and T1-weighted images prior to contrast material injection for erosions. Intraclass correlation coefficients (ICC) were calculated to assess inter-technique, intra-observer and inter-observer agreement.

Results: Mean ICC for the agreement between Dixon and non-Dixon images ranged from 0.68 (95%CI: 0.20–0.90) to 0.99 (95%CI: 0.95–1.00) for the scoring of osteitis and from 0.77 (95%CI: 0.38–0.93) to 0.99 (95%CI: 0.95–1.00) for the scoring of erosions. Mean ICC for the agreement between first and second readings ranged from 0.94 (95%CI: 0.81–0.98) to 0.97 (95%CI: 0.91–0.99) for the scoring of osteitis using Dixon and 0.91 (95%CI: 0.72–0.97) to 0.98 (95%CI: 0.92–0.99) using non-Dixon images and from 0.80 (95%CI: 0.45–0.94) to 0.97 (95%CI: 0.91–0.99) for the scoring of erosions using Dixon and 0.72 (95%CI: 0.29–0.91) to 0.98 (95%CI: 0.92–0.99) using non-Dixon images.

Conclusion: Contrast-enhanced T1-weighted Dixon water- and fat-only images can serve as an alternative to fat-saturated T2-weighted and T1-weighted MRI sequences for the assessment of osteitis and erosions according to the RAMRIS scoring system in hands of patients with early RA.

1. Introduction

Since the progressive use of methotrexate and other disease modifying anti-rheumatic drugs, magnetic resonance imaging (MRI) has advantageously replaced radiographs to evaluate the outcome of patients with rheumatoid arthritis (RA) in clinical trials and assess therapeutic efficacy of new drugs [1,2]. The RA MRI scoring system (RAMRIS), developed by the Outcome Measures in Rheumatology (OMERACT) group, has become the method of reference to monitor RA disease activity at MRI of the hands in clinical

Abbreviations: 2D, two-dimensional; 3D, three-dimensional; GRE, gradient recalled echo; ICC, intra-class correlation coefficient; MRI, magnetic resonance imaging; OMERACT, outcome measures in rheumatology; RA, rheumatoid arthritis; RAMRIS, rheumatoid arthritis magnetic resonance imaging scoring system; SE, spin echo; SD, standard deviation; STIR, short tau inversion recovery.

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Table 1
Comparison between OMERACT-recommended protocol and similar protocols based on Dixon imaging to assess hands of patients with rheumatoid arthritis at MRI.

	OMERACT-recommended protocol based on 3 different sequences	Full Dixon-based protocol based on 3 different Dixon sequences	Short Dixon-based protocol based on 1 Dixon sequence
Erosions	T1-weighted sequence	T1-weighted Dixon in-phase images	Contrast-enhanced T1-weighted Dixon fat-only images
Osteitis	Fat-saturated T2-weighted sequence or STIR sequence	T2-weighted Dixon water-only images	Contrast-enhanced T1-weighted Dixon water-only images
Synovitis Tenosynovitis	Contrast-enhanced (fat-saturated) T1-weighted sequence	Contrast-enhanced T1-weighted Dixon water-only images	Contrast-enhanced T1-weighted Dixon water-only images

MRI = magnetic resonance imaging; OMERACT = outcome measures in rheumatology; STIR = short tau inversion recovery.

trials [3,4]. OMERACT group recommends several MRI sequences to perform RAMRIS [4]. They included:

- contrast-enhanced T1-weighted imaging to assess synovitis and tenosynovitis, usually obtained after saturation of the fat signal [5,6];
- non-contrast-enhanced T1-weighted imaging to assess erosions;
- fat-saturated T2-weighted or short tau inversion recovery (STIR) imaging to assess osteitis.

The Dixon method is based on the simultaneous acquisition of in-phase and out-of-phase images with subsequent calculation of "water-only" (*i.e.*, fat-suppressed) and "fat-only" (*i.e.*, water-suppressed) images [7]. Previous studies demonstrated the effectiveness of the fat suppression obtained by the Dixon method at MRI of the hands [8–10]. MRI protocols based on various Dixon sequences have been demonstrated more reproducible than protocols based on fat saturation to assess disease activity according to RAMRIS in hands with early arthritis using: (*i*), contrast-enhanced T1-weighted Dixon water-only images to assess synovitis and tenosynovitis; (*ii*), T2-weighted Dixon water-only images to assess osteitis; and, (*iii*), non-contrast-enhanced T1-weighted Dixon in-phase images to assess erosions [11]. However, the robustness of such MRI protocols based on various Dixon sequences comes at the cost of an increased imaging acquisition time.

Previous studies demonstrated the value of contrast-enhanced fat-suppressed T1-weighted images for the RAMRIS scoring of osteitis [12] and T2-weigted Dixon fat-only images for the detection of bone changes [13–18]. We hypothesized that water- and fat-only images obtained from contrast-enhanced T1-weigthed Dixon sequences in hands of patients with early RA could be an alternative to the sequences recommended by the OMERACT for the assessment of osteitis and erosions, therefore obviating the need for pre-contrast sequences (Table 1).

The purpose of this study was to assess the agreement of readers using contrast-enhanced T1-weighed Dixon water- and fat-only images and the OMERACT-recommended sequences for the assessment of osteitis and erosions at MRI of the hands of patients with early RA.

2. Materials and methods

2.1. Patients

Study participants were recruited by two senior rheumatologists (M.S., with 20 years of experience and P.D., with 30 years of experience in rheumatology) among new outpatients of our Department of Rheumatology between January 2016 and December 2017. Inclusion criteria were:

- age > 18 years;
- recent diagnosis of rheumatoid arthritis by a senior rheumatologist based on clinical and biological data meeting the ACR/EULAR 2010 RA classification criteria [19];
- no history of treatment by disease-modifying anti-rheumatic drugs;
- no contraindication to MRI.

Exclusion criteria were incomplete examinations and archiving errors.

This prospective study was performed with institutional review board approval and after the obtention of written informed consent from each study participant.

2.2. MR imaging

MRI examinations were performed on a 1.5 T MR scanner (Optima® MR450w; General Electric Healthcare) with a flexible 16-channel medium-sized extremity coil (Flex coil; General Electric Healthcare). Study participants were positioned in prone procubitus with arms extended above head and hands joined palm-to-palm [5]. Hands were separated by a 4-mm-thick plastic plate and maintained with straps. The flexible coil was placed around the hands and maintained with straps.

All study participants were imaged with non-Dixon T1-weighted imaging prior to contrast material injection, spin echo (SE) T2-weighted fat-saturated sequence and contrast-enhanced T1-weighted Dixon imaging. One half of the study participants was imaged with two-dimensional (2D) SE T1-weighted sequences in the axial and coronal planes ("2D SE T1" group) and the other half was imaged with axial three-dimensional (3D) fast spoiled gradient recalled echo (GRE) T1-weighted sequences ("3D GRE T1" group) according to the OMERACT recommendations [4]. All study participants were injected with 2 ml/kg of gadoterate meglumine (Dotarem®, Guerbet). All SE T2-weighted fat-saturated sequences were obtained in the coronal plane as recommended by the OMERACT [4]. MRI sequences parameters are summarized in Table 2. Investigated area extended from distal radio-ulnar joints to metacarpophalangeal joints of both hands.

In May 2019, a data manager (P.T., with 5 years of experience in research logistic) created separated sets of images with Dixon and non-Dixon images for each of the study participants. The Dixon-based sets contained contrast-enhanced T1-weighted Dixon water- and fat-only images. The non-Dixon sets contained T1-weighted images prior to contrast material injection and T2-weighted fat-saturated images. After deletion of study participant and fat suppression information, all the sets were randomized, numerically labelled and archived in our research picture archiving communication system (Carestream Vue 12.1.6.1005; Carestream Health, Inc., Canada).

Table 2
Parameters of the sequences used in the study.

	Contrast-enhanced 2D SE T1 Dixon	Contrast-enhanced 3D GRE T1 Dixon	Non-Dixon 2D SE T1	Non-Dixon 3D GRE T1	Fat-saturated 2D SE T2
Field of view (cm)	16.8–24	16–20	16.8–24	16–20	16.8–24
Slice thickness (mm)	2.5	1.6	2.5	1.6	2.5
Spacing (mm)	0.3	/	0.3	/	0.3
Repetition time (ms)	442–741(axial) 618–623 (coronal)	10.9–11.2	427–661 (axial) 535–550 (coronal)	6.8–6.9	5834–5909
Effectiveecho time (ms)	11.6	5.96	10.1	4.2	66.2
Flip angle (°)	160	12	160	12	160
Echo train length	3	/	3	/	11
Acquisition matrix	288 × 224	256 × 256	512 × 288	256 × 256	288 × 224
Reconstruction matrix	512 × 512	512 × 512	512 × 512	512 × 512	512 × 512
NEX	1	1	1	1	2
Bandwidth (kHz)	62.5	50	41.7	50	27.8
Number of slices	42–48	192	42–48	192	42
Duration	3 min 08 s (axial) 2 min 59 s (coronal)	6 min 09 s	1 min 11 s (axial) 1 min 09 s (coronal)	1 min 19 s	2 min 27 s

GRE = gradient recalled echo; SE = spin echo; 2D = two-dimensional; 3D = three-dimensional.

2.3. MR imaging analysis

Between June and August 2019, two radiologists (T.K. further referred to as R1, with four years and B.V., further referred to as R2, with 30 years of experience in musculoskeletal imaging and previous experience in RAMRIS scoring) separately analyzed the different sets of images to assess disease activity. In October 2019, R1 repeated the RAMRIS scoring of all the sets of images to evaluate intra-observer agreement. Osteitis was scored from 0 (no osteitis) to 3 (severe osteitis) and erosions from 0 (no erosion) to 10 (complete destruction) in 23 bones per hand (distal radius, distal ulna, carpal bones, metacarpal bases, metacarpal heads and proximal phalangeal bases) [4]. Readers were instructed to use fat-suppressed images to score osteitis (*i.e.*, contrast-enhanced T1-weighted Dixon water-only images and fat-saturated T2-weighted images) and fat-sensitive images to score erosions (*i.e.*, contrast-enhanced T1-weighted Dixon fat-only images and non-Dixon T1-weighted images prior to contrast material injection) [20].

2.4. Statistical analysis

Quantitative variables were expressed as means, standard deviations and ranges. Qualitative variables were expressed as raw numbers, proportions and percentages. Aggregated RAMRIS scores were calculated for osteitis ($RAMRIS^{osteitis}$) and erosions ($RAMRIS^{erosions}$) as the sum of the individual scores of both hands for osteitis and erosions respectively. When an individual score was declared not assessable on one MRI protocol, it was also considered non-assessable on the other MRI protocol of the same patient.

Clinical data, biological data and RAMRIS scores were compared between "2D SE T1" and "3D GRE T1" groups using independent sample *t*-test (normal distribution) or Mann-Whitney test (non-normal distribution) with a P-value < 0.05 considered as statistically significant. D'Agostino-Pearson test was used to test the normality of the distribution.

Inter-technique agreement, intra-observer agreement and inter-observer agreement were assessed using two-way mixed effects, consistency, single rater/measurement intra-class coefficients (ICC) with 95% confidence intervals (CI). The strength of agreement was interpreted as follows: ≤ 0, poor; 0.01–0.20, slight; 0.21–0.40, fair; 0.41–0.60, moderate; 0.61–0.80, substantial; and ≥ 0.81, excellent [21]. Statistical analysis was performed using Medcalc (MedCalc 19.1.3; MedCalc Software bv).

3. Results

3.1. Patients

Twenty-eight study participants were imaged with MRI, 4 (4/28; 14%) were excluded because of incomplete MRI protocol (Fig. 1). Complete MRI examinations were obtained in 24 study participants (16 [16/24; 67%] women, 8 [8/24; 33%] men) with a mean age of 45.7 ± 14.5 (SD) years (range: 28–70 years). There were no significant differences between the demographic and clinical data of the "2D SE T1" and "3D GRE T1" groups (Table 3). Osteitis and erosions were seen in 7 (7/12; 58%) and 4 participants (4/12; 33%) of the "2D SE T1" group and in 5 (5/12; 42%) and 4 participants (4/12; 33%) of the "3D GRE T1" group, respectively. $RAMRIS^{osteitis}$ and $RAMRIS^{erosions}$ of "2D SE T1" patients were not significantly different from those of "3D GRE T1" patients ($P = 0.422$ and $P = 0.757$, respectively) (Table 4).

3.2. Agreement for the RAMRIS scoring of osteitis

Agreement between $RAMRIS^{osteitis}$ obtained with contrast-enhanced T1-weighted Dixon water-only images and $RAMRIS^{osteitis}$ obtained with fat-saturated T2-weighted images was excellent in the "2D SE T1" group and substantial to excellent in the "3D GRE T1" group. Inter-technique, intra-observer and inter-observer agreement for osteitis are reported in Table 5 (Fig. 2).

3.3. Agreement for the RAMRIS scoring of erosions

Agreement between $RAMRIS^{erosions}$ obtained with contrast-enhanced T1-weighted Dixon fat-only images and $RAMRIS^{erosions}$ obtained with T1-weighted images was excellent in the "2D SE T1" group and substantial in the "3D GRE T1" group. Inter-technique, intra-observer and inter-observer agreement for erosions are reported in Table 6 (Fig. 3).

4. Discussion

OMERACT recommends several MRI sequences to perform RAMRIS including non-contrast-enhanced T1-weighted imaging to assess erosions, T2-weighted or STIR imaging to assess osteitis and contrast-enhanced T1-weighted imaging with or without fat saturation to assess synovitis and tenosynovitis [4]. Contrast material injection increases the conspicuity of synovitis and tenosynovitis [6,22,23]. Previous studies demonstrated that contrast-enhanced T1-weighted Dixon water-only images could replace contrast-enhanced fat-saturated T1-weighted images for

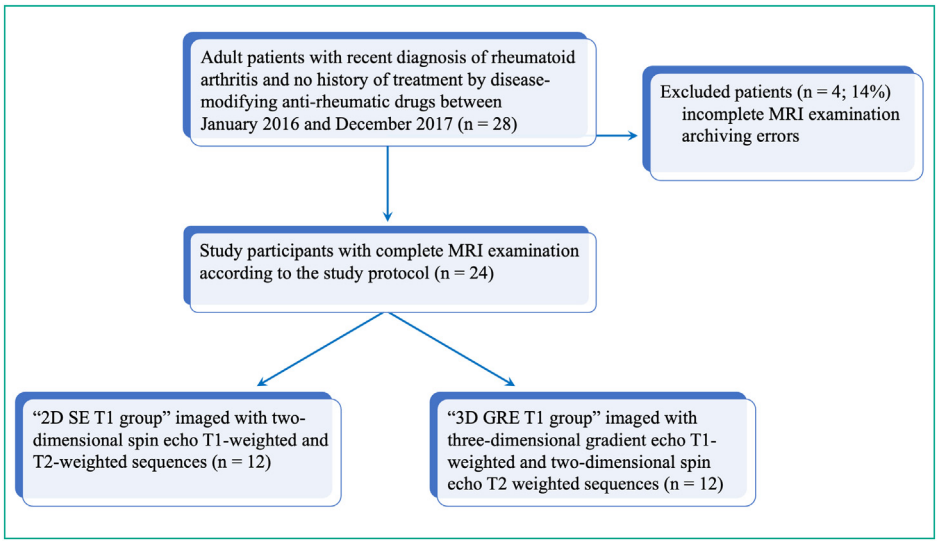

Fig. 1. Flow chart diagram of the study. MRI = magnetic resonance imaging; 2D = two dimension; 3D = three dimensional; GRE = gradient recalled echo; SE = spin echo.

Table 3
Comparison of demographic and clinical data between "2D SE T1" and "3D GRE T1" groups.

	2D SE T1 (n = 12)	3D GRE T1 (n = 12)	P value
Sex			> 0.999
Male	4 (4/12; 33%)	4 (4/12; 33%)	
Female	8 (8/12; 67%)	8 (8/12; 67%)	
Age (years)	46.8 ± 14.1 [25–69]	44.6 ± 15.4 [28–70]	0.664
Diagnosis			0.320
ACPA+ RA	8 (8/12; 67%)	12 (12/12; 100%)	
ACPA- RA	4 (4/12; 33%)	0 (0/12; 0%)	
Days between diagnosis and MRI	23.4 ± 22.9 [0–87]	26.4 ± 41.5 [7–156]	0.582
CRP blood level (mg/L) at diagnosis	30.1 ± 30.2 [2–99]	17.5 ± 21.5 [1–69]	0.214
DAS28-CRP at diagnosis	5.2 ± 1.1 [3.1–7.3]	4.7 ± 1.4 [2.4–7.0]	0.351

Quantitative data are expressed as means ± standard deviations; numbers in brackets are ranges. Qualitative data are expressed as raw numbers; numbers in parentheses are proportions followed by percentages. 2D = two-dimensional; 3D = three-dimensiona; ACPA = anti–citrullinated protein antibody; CRP = C-reactive protein; DAS = disease activity score; GRE = gradient recalled echo; RA = rheumatoid arthritis; SE = spin echo.

Table 4
Mean RAMRIS scores for osteitis and erosions for each group and each reader.

	Reader 1 - 1st reading		Reader 1 - 2nd reading		Reader 2	
	Dixon	OMERACT	Dixon	OMERACT	Dixon	OMERACT
RAMRIS scores in "2D SE T1" patients (n = 12)						
Osteitis	7.0 ± 12.2 [0–38]	8.2 ± 14.3 [0–44]	7.7 ± 12.6 [0–34]	7.6 ± 12.8 [0–35]	11.9 ± 17.1 [0–48]	12.4 ± 18.5 [0–56]
Erosions	3.1 ± 6.7 [0–22]	3.8 ± 6.5 [0–19]	3.6 ± 7.0 [0–22]	3.9 ± 6.5 [0–20]	5.5 ± 7.2 [0–22]	2.8 ± 5.9 [0–20]
RAMRIS scores in "3D GRE T1" patients (n = 12)						
Osteitis	1.5 ± 2.2 [0–6]	2.5 ± 3.4 [0–10]	2.1 ± 2.5 [0–8]	2.4 ± 2.8 [0–8]	3.6 ± 4.0 [0–11]	4.1 ± 4.5 [0–12]
Erosions	0.6 ± 1.0 [0–3]	0.7 ± 1.0 [0–3]	1.0 ± 1.5 [0–4]	1.2 ± 1.6 [0–4]	1.9 ± 2.2 [0–6]	1.4 ± 1.8 [0–6]

Quantitative data are expressed as means ± standard deviations; numbers in brackets are ranges. 2D = two-dimensional; 3D = three-dimensional; GRE = gradient recalled echo; OMERACT = outcome measures in rheumatology; RAMRIS = rheumatoid arthritis magnetic resonance imaging scoring system; SE = spin echo.

the RAMRIS scoring of synovitis and tenosynovitis in hands of patients with RA [8,11]. Our results suggest that water- and fat-only images derived from contrast-enhanced T1-weigthed Dixon imaging can replace the non-contrast-enhanced sequences for the assessment of osteitis and erosions in early RA, therefore obviating the need for pre-contrast sequences.

The current study demonstrates that RAMRIS scoring of osteitis on contrast-enhanced T1-weighted Dixon water-only images is in agreement with that on fat-saturated T2-weighted images. Stomp et al. demonstrated that contrast-enhanced fat-saturated T1-weighted images could replace fat-saturated T2-weighted images for the RAMRIS scoring of osteitis [12]. We consequently hypothesize that contrast-enhanced T1-weighted Dixon water-only images could be used in replacement to T2-weighted fat-saturated images for the scoring of osteitis.

Our study also demonstrates that RAMRIS scoring of erosions on contrast-enhanced T1-weighted Dixon fat-only images is in agreement with that on T1-weighted images prior to contrast material

Table 5
Inter-technique, intra-observer and inter-observer agreement for the RAMRIS scoring of osteitis for the "2D SE T1" and "3D GRE T1" groups based on intra-class coefficients.

	"2D SE T1" ICC [95% CI]	"3D GRE T" Mean ICC [95% CI]
Inter-technique agreement for $RAMRIS^{osteitis}$		
Reader 1	0.99 [0.95; 1.00]	0.85 [0.57; 0.96]
Reader 2	0.98 [0.93; 0.99]	0.68 [0.20; 0.90]
Intra-observer agreement for $RAMRIS^{osteitis}$		
Contrast-enhanced T1-weighed Dixon water-only images	0.97 [0.91; 0.99]	0.94 [0.81; 0.98]
Fat-saturated T2-weighted images	0.98 [0.92; 0.99]	0.91 [0.72; 0.97]
Inter-observer agreement for $RAMRIS^{osteitis}$		
Contrast-enhanced T1-weighed Dixon water-only images	0.92 [0.74; 0.98]	0.80 [0.45; 0.94]
Fat-saturated T2-weighted images	0.96 [0.86; 0.99]	0.58 [0.04; 0.86]

2D = two-dimensional; 3D = three-dimensional; CI = confidence interval; GRE = gradient recalled echo; ICC = intra-class correlation coefficient; OMERACT = outcome measures in rheumatology; RAMRIS = rheumatoid arthritis magnetic resonance imaging scoring system; SE = spin echo.

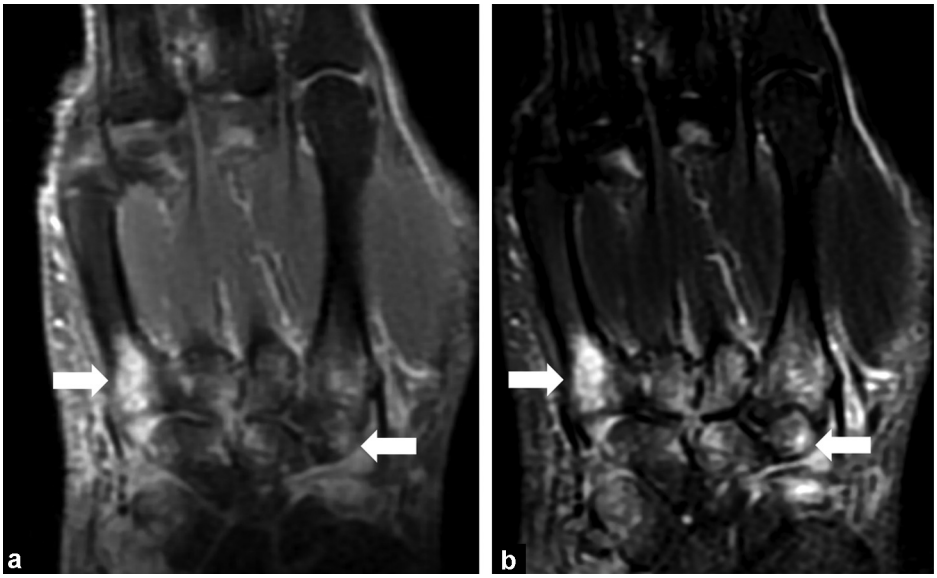

Fig. 2. Fifty-six-year-old man with rheumatoid arthritis. (a) Coronal contrast-enhanced two-dimensional spin-echo (SE) T1-weighted Dixon water-only image and (b) coronal two-dimensional SE T2-weighted fat-saturated image show similar appearance of carpal and metacarpal bones osteitis (arrows).

Table 6
Inter-technique, intra-observer and inter-observer agreement for the RAMRIS scoring of erosions for the "2D SE T1" and "3D GRE T1" groups based on intra-class coefficients.

	"2D SE T1" Mean ICC [95% CI]	"3D GRE T1" Mean ICC [95% CI]
Inter-technique agreement for $RAMRIS^{erosions}$		
Reader 1	0.99 [0.95; 1.00]	0.77 [0.38; 0.93]
Reader 2	0.98 [0.93; 0.99]	0.79 [0.42; 0.93]
Intra-observer agreement for $RAMRIS^{erosions}$		
Contrast-enhanced T1-weighed Dixon fat-only images	0.97 [0.91; 0.99]	0.80 [0.45; 0.94]
T1-weighted images	0.98 [0.92; 0.99]	0.72 [0.29; 0.91]
Inter-observer agreement for $RAMRIS^{erosions}$		
Contrast-enhanced T1-weighed Dixon fat-only images	0.92 [0.74; 0.98]	0.58 [0.04; 0.86]
T1-weighted images	0.96 [0.86; 0.99]	0.45 [-0.14; 0.80]

2D = two-dimensional; 3D = three-dimensional; CI = confidence interval; GRE = gradient recalled echo; ICC = intra-class coefficient; OMERACT = outcome measures in rheumatology; RAMRIS = rheumatoid arthritis magnetic resonance imaging scoring system; SE = spin echo.

injection. Previous studies demonstrated that T2-weighted Dixon fat-only images could replace standard T1-weighted images for the detection of bone metastases and chronic bone changes associated with degenerative disk disease or sacroiliitis [13–17]. As Dixon fat-only images obtained from T1-weighted sequences are insensitive to contrast material injection and identical to those obtained from T2-weighted sequences, we hypothesize that contrast-enhanced T1-weighted Dixon fat-only images could be an alternative to standard T1-weighted images for the RAMRIS scoring of bone erosions.

Finally, we demonstrated that the reproducibility of the RAMRIS scoring on Dixon images was similar or superior to that of the OMERACT-recommended sequences. Intra- and inter-observer agreement were higher in the "2D SE T1" group than in the "3D GRE T1" group for both osteitis and erosions whatever the sequences. Gradient echo sequences have been reported poor for the evaluation of bone marrow, but useful for the detection of erosions [24,25]. However, previous studies investigating the use of Dixon fat-only images for bone evaluation did not use gradient echo sequences [13–15].

We previously demonstrated the robustness of an MRI protocol based on various Dixon sequences in hands of patients with suspicion of RA [11]. However, such protocols come at the

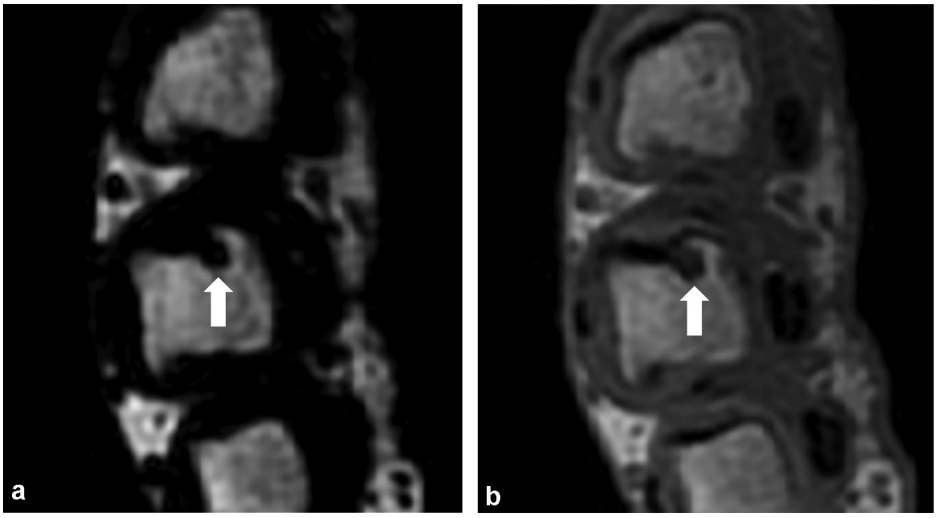

Fig. 3. Sixty-year-old man with rheumatoid arthritis. (a) Axial contrast-enhanced three-dimensional gradient recalled echo (GRE) T1-weighted Dixon fat-only image and (b) axial three-dimensional GRE non-Dixon T1-weighted image without contrast material injection show a similar appearance of metacarpal head erosion (arrows).

cost of an increased imaging acquisition time. Our current study demonstrates that an MRI protocol based on contrast-enhanced T1-weigthed Dixon imaging alone using water-only images for the assessment of osteitis and fat-only images for the assessment of erosions can be an alternative to the sequences recommended by the OMERACT to assess disease activity according to RAMRIS in hands with early RA.

The monocentric nature and the limited number of patients and readers are major limitations of this study. Scores of osteitis and erosions were mild in our study, especially in patients imaged with 3D GRE T1-weighted sequences, reflecting the earliness of the diagnosis of RA in the study participants [26,27]. Definitely, a multicentric study including different magnets and manufacturers along with early and late-stage RA should be performed.

In conclusion, contrast-enhanced T1-weighted Dixon water- and fat-only images can be an alternative to the OMERACT-recommended MRI sequences for the assessment of osteitis and erosions according to RAMRIS scoring system in hands of patients with early RA.

Human rights

The authors declare that the work described has been carried out in accordance with the Declaration of Helsinki of the World Medical Association revised in 2013 for experiments involving humans.

Informed consent and ethical approval

The local institutional review board approved this prospective study. Written informed consent was obtained from each participant.

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Authors' contributions

All authors attest that they meet the current International Committee of Medical Journal Editors (ICMJE) criteria for Authorship. All authors have contributed to, read and approved the final version of the manuscript.

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Disclosure of interest

The authors declare that they have no competing interest.

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