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Original article

Tomosynthesis performance compared to radiography and computed tomography for sacroiliac joint structural damage detection in patients with suspected axial spondyloarthritis

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ABSTRACT

Purpose: To compare tomosynthesis performance to radiography for the differentiation of sacroiliitis versus normal or degenerative changes in sacroiliac joints in patients with suspected axial spondyloarthritis (SpA).
Materials and methods: Radiography, tomosynthesis and CT of sacroiliac joints (29 patients) were performed on the same day in consecutive patients with suspected SpA. The examinations were retrospectively read independently, blinded by two radiologists (one junior and one senior, and twice by one junior). Interobserver and intraobserver agreement was evaluated using the kappa coefficient. Effective doses for each imaging sensitivity, specificity and accuracy were assessed and compared with CT as gold standard.
Results: CT detected 15/58 joints with sacroiliitis. The imaging sensitivity, specificity and accuracy were 60%, 84% and 44%, respectively, for radiography and 87%, 91% and 77% for tomosynthesis. The mean effective dose for tomosynthesis was significantly lower than that of CT (5-fold less) and significantly higher than that of radiography (8-fold more).
Conclusion: Tomosynthesis is superior to radiography for sacroiliitis detection in patients with suspected SpA, with 5-fold less radiation exposure than CT.

1. Introduction

Axial spondyloarthritis (SpA) is a common chronic inflammatory rheumatic disease (prevalence range: 0.32−1.4 [1]) that has benefitted from major advances in therapeutic management in recent years. However, SpA diagnosis remains complicated, because of the high heterogeneity in clinical manifestations at onset and the frequent absence of any clinically detectable disease signs. Diagnosis is generally based on an in-depth medical investigation and examination, combined with radiologic assessment and/or HLA B27 gene testing. No single test alone is currently sufficient for SpA diagnosis, while radiologic investigation of sacroiliac joints to detect signs of sacroiliitis is the most useful strategy since it is an early and consistent manifestation of this disease.

Sacroiliitis is indeed a major diagnostic criterion according to the modified New York classification [2] based onradiography and the more recent Assessment of Spondyloarthritis International Society (ASAS) classification [3] using conventional radiography or magnetic resonance imaging (MRI). Historically, sacroiliitis diagnosis has primarily been based on conventional radiography findings but the utility of this technique in the early phases of the disease is limited since structural changes are only detectable several years after onset of the disease. Moreover, the clinical efficacy of radiography is limited due to its low accuracy and poor intraobserver and interobserver agreement [4]. Yet early clearcut SpA diagnosis is essential since treatment with biologic DMARDs could be useful in the early stages of the disease.

Sacroiliac joint osteoarthritis is the main entity considered in the differential diagnosis of sacroiliitis since it is 20-fold more frequent [5] and could potentially lead to SpA misdiagnosis. ASAS criteria for MRI of sacroiliitis, based mainly on bone marrow edema detection, also known as inflammatory damage, have known limits, particularly because of the false positive results often obtained when screening obese, older or highly physically active patients. However, combining these criteria with assessments of structural changes (e.g. erosion, joint space alteration, sclerosis and ankyloses) may enhance the specificity [6]. Structural damage interpretation is limited when using

Abbreviations: SpA, spondyloarthritis; ASAS, assessment of Spondyloarthritis International Society; RA, rheumatoid arthritis

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MRI, so CT could be performed in difficult cases [7] since it is currently considered to be the best examination for structural damage and abnormality detection [8]. Radiation exposure is, however, higher with CT compared to radiography, which may be an issue when managing young patients who might require multiple examinations for diagnosis or follow-up. Moreover, unlike MRI, in current clinical practice CT scan is unable to detect bone edema [9].

Tomosynthesis is a conventional tomography imaging technique based on the reconstruction of several planar X-rays and has long been used in breast imaging [10]. This technique avoids anatomical overlap, which can be useful in the evaluation of tilted sacroiliac joints. It has also previously been used in musculoskeletal imaging, for instance to detect erosions in rheumatoid arthritis or to diagnose peripheral fractures [11−13]. Moreover, this technology is now commonly available and inexpensive, thereby warranting its use in SpA screening instead of CT scan. Lastly, various studies have revealed intermediary radiation exposure levels with this technique as compared to radiography and CT.

To our knowledge, no previous studies have been carried out to assess the accuracy of tomosynthesis in sacroiliitis joint disease diagnosis. The aim of this prospective study was thus to compare the performance of tomosynthesis and radiography for the differentiation of sacroiliitis versus normal or degenerative sacroiliac joints based on the detection of structural damage in patients with suspected SpA, while using CT as gold standard.

2. Materials and methods

2.1. Ethical considerations

The study was approved by the local ethics committee named « Comité de Protection des Personnes Sud-Méditerranée II » (ID-RCB: 2018-A00964−51; ClinicalTrials.gov ID NCT03689881) and all patients signed an informed consent form.

2.2. Patients

A prospective diagnostic accuracy study was performed at the University Hospital of Montpellier (France) from October 2018 to June 2019.

Patients eligible for inclusion were consecutive patients (≥ 18 years old) with clinically suspected SpA who had been referred by a rheumatologist to our radiology department for radiography or CT to screen for sacroiliac joint structural changes. Complementary imaging modalities (tomosynthesis and radiography or CT) were conducted after the patients had signed the informed consent form. Patients were excluded if they were pregnant or breastfeeding, under tutorship or guardianship, had a history of trauma or infection, or were being treated for SpA.

2.3. Imaging examinations

Radiography, tomosynthesis and CT were performed on the same day. Digital radiographic examinations (Platinium dRF DMS Imaging/APELEM, Maugio, France or Axiome Luminos dRF SIEMENS, Munich, Germany) were performed according to standard protocols for sacroiliac joint exploration with 90−96 kV tube voltage and 320−400 mA tube current.

Tomosynthesis examinations were conducted using a digital radiographic system with a tomosynthesis option (Platinium dRF DMS Imaging/APELEM, Maugio, France). The detector was fixed while continuous horizontal movements of the X-ray tube were performed around the standard orthogonal posteroanterior position within 8 s, with a total angle of 64° Coronal plane images were obtained.

CT examinations of the whole sacroiliac joint were performed on a 64-slice CT scanner (Revolution GSI or Discovery, GE Healthcare, Milwaukee, WI, USA) with a tube voltage of 120 kV, 64 × 0.625 mm detector collimation, 0.51 pitch and active automatic current modulation, with a noise index of 35. The image slice thickness was 0.625 mm, and images were reconstructed with both standard and bonereconstruction kernels.

2.4. Image assessment

Images were assessed using Universal Viewer 6.0 software (GE Healthcare, Milwaukee, WI, USA) which is designed to display medical images. Tomosynthesis and CT were assessed in cine mode. CT images were viewed with axial and coronal reformatting. Tomosynthesis images were viewed only in the coronal plane. Observers were allowed to change the window width and level and to use zooming.

Each examination was retrospectively reviewed by two radiologists − a junior radiologist (5 years of general radiology) and a senior musculoskeletal (MSK) radiologist (7 years of general radiology and 2 years of MSK radiology) − independently and blinded (anonymized), a altering the order of reading between the different modalities. Each of the three modalities was read with a 1-month delay.

In case of discrepancy between observers regarding abnormality detection, a final interpretation was obtained by consensus during a second session.

A second reading was also performed by the junior radiologist for intraobserver agreement assessment after a 3 month delay.

2.5. Primary outcome

The primary outcome was the differentiation of sacroiliitis versus normal or degenerative sacroiliac joints based on the presence or absence of structural damage. The senior review was considered for the main objective. Structural findings were defined and assessed as follows (ASAS handbook [3]): blurring of joint margins; erosions defined as bony defects at the joint margin; subchondral sclerosis; joint width; ankylosis defined as facing bone buds that have fused together to form bone bridges across the joint; and osteophytes defined as juxta-articular bony outgrowths.

The reported diagnoses were “normal sacroiliac”, “sacroiliitis” (grade 1 to 4) or “degenerative changes”.

Sacroiliitis was scored using the New-York grading criteria (1984) [2] as follows: grade 1: suspicious changes (blurring of joint margins); grade 2: minimum abnormality (small localized areas with erosion or sclerosis, without alteration in the joint width); grade 3: unequivocal abnormality (moderate or advanced sacroiliitis with erosions, evidence of sclerosis, widening, narrowing or partial ankylosis); and grade 4: severe abnormality (total ankylosis).

Degenerative findings were defined as joint space narrowing, subchondral sclerosis, subchondral cysts or osteophytes [14].

The sacroiliac joint was considered normal if there were no abnormal structural findings.

2.6. Secondary outcomes

Secondary outcomes were inter- and intraobserver agreement with tomosynthesis, image quality and diagnostic confidence rate.

Tomosynthesis and plain radiography radiation exposure was assessed based on the effective dose, derived from the dose area product of each examination using a conversion factor of 0.13 mSv. $Gy^{-1}.cm^{-2}$ [15].

Similarly, the CT effective dose was calculated from the dose length product of each acquisition using a conversion factor of 0.013 mSv. $Gy^{-1}.cm^{-1}$ [16]

The image quality was subjectively assessed according to 3 categories: “no artifact”, “minor artifact” and “major artifact”.

We also used a 5-point scale (Likert scale) to assess the diagnostic confidence rate [17] as "strongly disagree", "disagree", "neither agree or disagree", "agree" and "strongly agree".

2.7. Statistical analysis

The data were analyzed by the clinical research and epidemiology unit using SAS 9.4 software (SAS Institute Inc, Cary, USA). A p value < 0.05 was considered statistically significant. The sample size was calculated using a desired accuracy precision of 20% for tomosynthesis versus CT. The planned required number of subjects was 30 patients. Continuous parametric data were presented as means ± standard deviation (SD), while categorical variables were presented as numbers and percentages. Tomosynthesis and radiography imaging sensitivity, specificity and accuracy were assessed using CT consensus as gold standard.

Normal sacroiliac and degenerative changes were grouped into "non-sacroiliitis" versus "sacroiliitis" for imaging sensitivity, specificity and accuracy assessment.

Intraobserver and interobserver agreement was assessed using the kappa coefficient (K) with a 95% confidence interval [18]. Interobserver evaluation was performed based on data from the senior radiologist and the junior radiologist's second reading. Intraobserver agreement was assessed using data from the junior radiologist's two readings. The strength of agreement was rated fair for kappa values ≤ 0.40, moderate for kappa values ≤ 0.60, substantial for kappa values ≤ 0.8 and almost perfect for kappa values ≥ 0.81.

3. Results

3.1. Study population

A total of 29 patients were included (11 men, 18 women), with a mean age of 43 (± 9.99) years, and a total of 58 sacroiliac joints were available for analysis. The mean body mass index was 25.8 (± 6.38) kg/m^2. The average symptom duration was 20.3 months (± 22.0).

3.2. Intraobserver and interobserver agreement variation

Comparisons of intraobserver and interobserver agreement variation for tomosynthesis accuracy are summarized in Table 1. Intraobserver agreement (between junior 1st and 2nd reads was strong (kappa = 0.94 [0.83 - 1]) for tomosynthesis, and low (kappa = 0.37 [0.1 - 0.65]) for radiography. Agreement between readers was moderate for tomosynthesis (kappa = 0.72 [0.52 - 0.92]) and moderate for radiography (kappa = 0.40 [0.14 – 0.67]). The difference in intraobserver agreement was statistically significant between tomosynthesis and radiography, but there was no significant difference in interobserver agreement.

Table 1
Inter- and intraobserver agreement.

	Intraobserver agreement	Interobserver agreement
Tomosynthesis	0.94 [0.83 - 1]	0.72 [0.52 - 0.92]
Radiography	0.37 [0.1 - 0.65]	0.4 [0.14 – 0.67]

3.3. Radiography, tomosynthesis and CT findings

The sacroiliitis detection rates are shown in Table 2. CT detected 15/58 sacroiliac joints (SIJ) with sacroiliitisand 43/58 as non-sacroiliitis. Radiography detected 16/58 SIJ with sacroiliitis and 42/58 non-sacroiliitis. Tomosynthesis detected 17/58 SIJ with sacroiliitis and 41/58 non-sacroiliitis. Fig. 1 presents sacroiliitis with erosions not detected by radiography but visible via tomosynthesis and confirmed by the CT scan.

Fig. 2 shows degenerative sacroiliac changes with typical findings obtained by radiography, tomosynthesis and CT.

Six SIJ were misdiagnosed by tomosynthesis: four were considered as sacroiliitis while being classified as normal by CT and two joints were diagnosed as non-sacroiliitis while being classified as sacroiliitis by CT. Thirteen SIJ were misdiagnosed by radiography: seven were considered as sacroiliitis while being classified as non-sacroiliitis by CT and six joints were diagnosed as non-sacroiliitis while being classified as sacroiliitis by CT.

When CT was used as gold standard, the sensitivity (Se), specificity (Spe), accuracy (Youden index), positive predictive value (PPV) and negative predictive value (NPV) for radiography were: Se = 0.60 ± 0.13, Spe = 0.84 ± 0.06, Youden index = 0.44, PPV = 0.86 ± 0.05 and NPV = 0.57 ± 0.12 (p = 0.0023) and Se = 0.86 ± 0.09, Spe= 0.90 ± 0.04, Youden index = 0.77, PPV=0.77 ± 0.10 and NPV=0.95 ± 0.03 ($p < 0.0001$), respectively, for tomosynthesis.

3.4. Tomosynthesis versus radiography

The radiography and tomosynthesis imaging sensitivity, specificity and accuracy findings are shown in Table 3. Compared to radiography, tomosynthesis increased the sensitivity (60% versus 87%, respectively - $p < 0.05$), specificity (84% versus 91% - $p < 0.05$), PPV (50% versus 76% - $p < 0.05$), NPV (82% versus 95% - $p < 0.05$) and accuracy (44% versus 77%) for structural lesion detection.

3.5. Dosimetry

The average effective dose was 0.17±0.13 mSv for radiography, 1.51±0.48 mSv for tomosynthesis and 6.46±4.24 mSv for CT. Tomosynthesis radiation exposure was significantly lower than that of CT ($p < 0.05$), with a 77% decrease in exposure.

3.6. Diagnostic confidence rate

For radiography, the diagnostic confidence rate was estimated at 50–70% for five patients, 70–85% for ten patients, 85–95% for nine patients and 95–100% for five patients (Fig. 3). For tomosynthesis,

Table 2
"Sacroiliitis" and "non-sacroiliitis" detection rate.

	Sacroiliitis					Non-Sacroiliitis		
	Grade 1	Grade 2	Grade 3	Grade 4	Total	Degenerative	Normal	Total
CT	0	10	5	0	**15**	28	15	**43**
	0.0%	17.2%	8.6%	0%	**25.9%**	48.3%	25.9%	**74.1%**
Radiography	1	9	6	0	**16**	13	15	**42**
	1.7%	15.5%	10.3%	0%	**27.6%**	22.4%	25.9%	**72.4%**
Tomosynthesis	0	9	6	0	**17**	22	29	**41**
	0.0%	15.5%	10.3%	0%	**29.3%**	37.9%	50.0%	**70.7%**

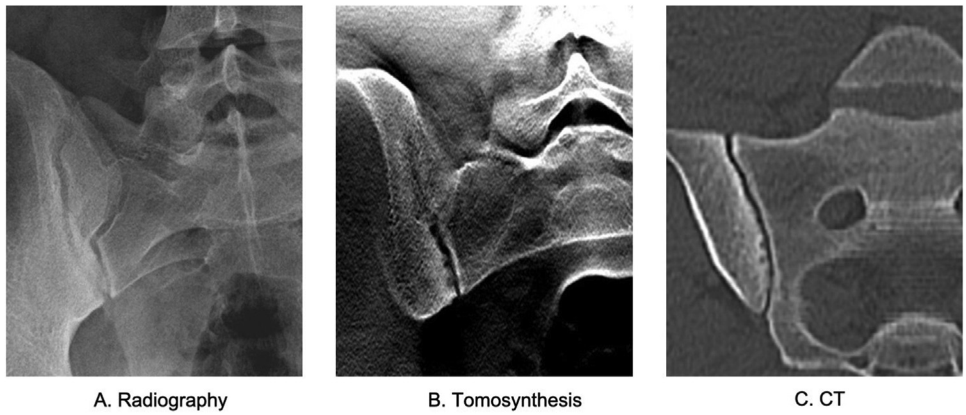

Fig. 1. Sacroiliitis viewed by radiography, tomosynthesis and CT
Right sacroiliitis with erosions, not visible via radiography (Fig. 1a), visible via tomosynthesis (Fig. 1b) and confirmed by the CT scan (Fig. 1c).

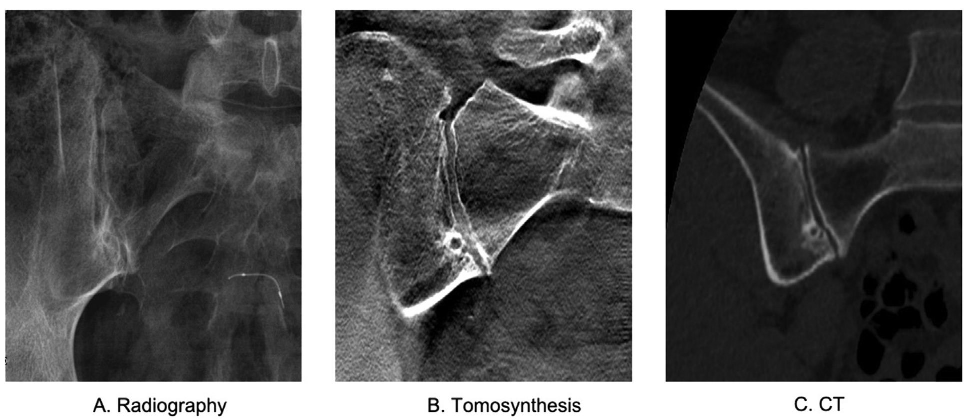

Fig. 2. Degenerative sacroiliac changes detected by radiography, tomosynthesis and CT
Radiography (Fig. 2a), Tomosynthesis (Fig. 2b) and CT (Fig. 2c) showing degenerative sacroiliac changes with typical findings, such as subchondral sclerosis, subchondral cysts and osteophytes.

the diagnostic confidence rate was estimated at 50–70% for one patient, 70–85% for ten patients, 85–95% for 14 patients and 95–100% for four patients. For CT, the diagnostic confidence rate was estimated at 70–85% for four patients, 85–95% for six patients and 95–100% for 19 patients.

S1: senior radiologist; J1: junior radiologist – first read; J2: junior radiologist- second read.

3.7. Image quality

Eight (28%) radiographs showed minor but interpretable artifacts and 21 (72%) were artifact-free.

Two (7%) tomosynthesis examinations showed major artifacts, 16 (55%) minor but interpretable artifacts, and 11 (38%) were artifact-free.

All CT examinations were artifact-free.

Table 3
Radiography and tomosynthesis imaging sSensitivity, specificity and accuracy of radiography and tomosynthesis.

	Radiography			Tomosynthesis		
	Senior 1	Junior 1	Junior 2	Senior 1	Junior 1	Junior 2
Sensitivity	60.0%	46.7%	33.3%	86.7%	66.7%	73.3%
Specificity	83.7%	83.7%	81.4%	90.7%	100%	100%
PPV	50.0%	50.0%	38.45%	76.5%	100%	100%
NPV	81.8%	81.8%	77.8%	95.1%	89.6%	91.4%
Accuracy	43.7%	30.4%	14.7%	77.4%	66.7%	73.3%

PPV: positive predictive value; NPV: negative predictive value.

4. Discussion

The aim of this prospective study was to compare the performance of tomosynthesis and radiography imaging for sacroiliitis detection in patients with suspected SpA. We also assessed inter- and intraobserver agreement, radiation exposure, image quality and the diagnostic confidence rate.

The study findings revealed that tomosynthesis was better than radiography in detecting sacroiliitis, with 5-fold lower radiation exposure than that of CT and high imaging sensitivity, specificity and accuracy (87%, 91% and 77%, respectively). The use of tomosynthesis instead of radiography increased the sacroiliitis detection rate by 50% and halved the number of false positives. Tomosynthesis enhanced lesion detection, as also shown in previous studies on rheumatic inflammatory diseases such as rheumatoid arthritis (RA) [13]. For the hand and wrist, the use of tomosynthesis increased the sensitivity by 20%, with specificity being identical to that obtained in RA. Moreover, identical results were obtained for sacroiliac structural lesion detection, with a 27% increase in sensitivity and 7% increase in specificity using tomosynthesis. In our opinion, these differences might be explained by the fact that the tomographic image acquisitions overcame the problem of anatomical sacroiliac joint overlap.

However, tomosynthesis did not perform as well as CT, notably due to the lower sensitivity. This may be explained by the inability of tomosynthesis to achieve multiplanar reformatting, which otherwise would have increased the detection rate and refined the diagnosis. The anatomical topography of radiographic findings could help guide the diagnosis. For instance, predominant abnormalities in mechanical stress areas would be highly suggestive of osteoarthritis. Yet using a

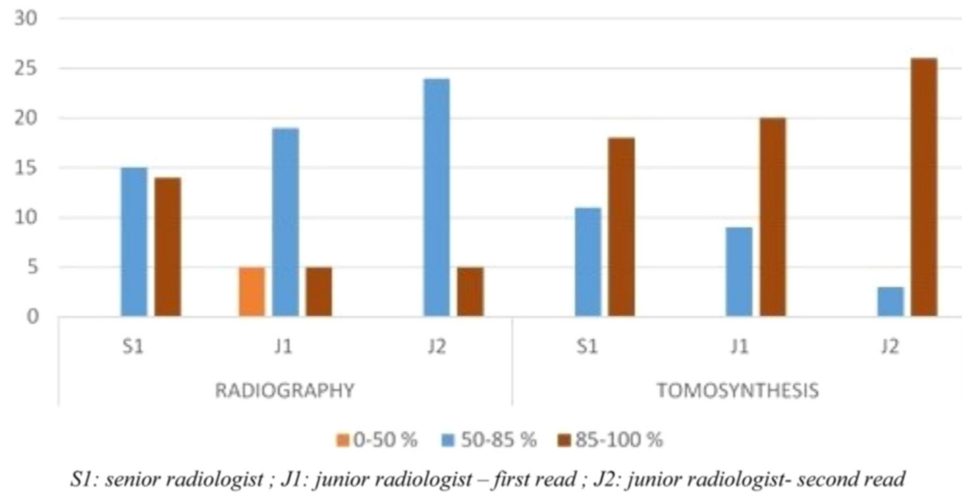

Fig. 3. Diagnostic confidence rate of radiography and tomosynthesis.

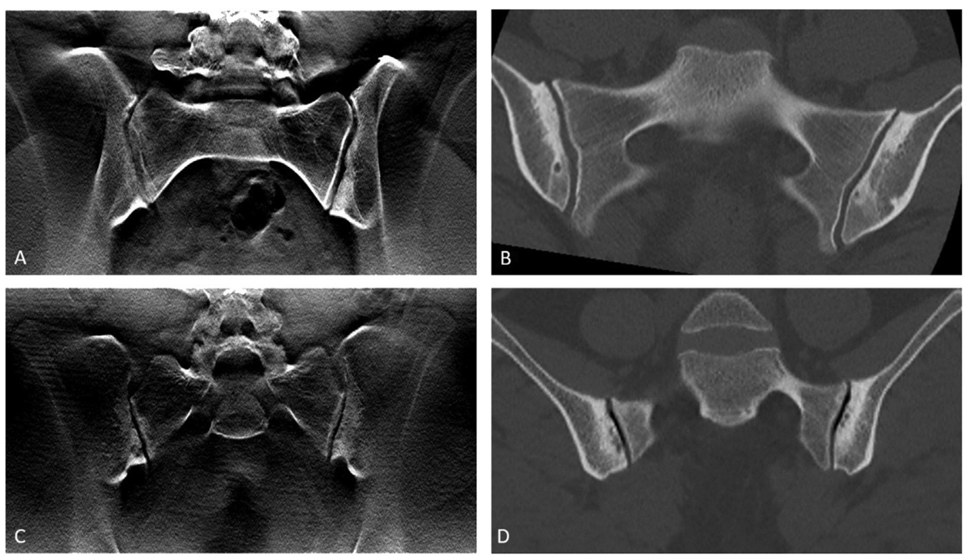

Fig. 4. Misdiagnosis with tomosynthesis imaging
Two patients with definite degenerative changes (as diagnosed by CT) that were mistaken for inflammatory structural changes with tomosynthesis imaging.
Blurring of the edges of the right joint may lead to a diagnosis of sacroilitis on tomosynthesis (Fig. 4a), whereas the joint is not blurred on the CT scan (Fig. 4b).
Erosive and sclerotic changes appear to be at the base of the sacroiliac joints during tomosynthesis (Fig. 4c), while they are actually located in the anteromedial area (Fig. 4d).

single coronal plane in tomosynthesis may complicate assessment of this topography. In addition, blurring generated by the technique could be confused withthe appearance due to early inflammatory process remodeling. Moreover, differentiation between structural changes due to inflammatory or degenerative processes may be more difficult with tomosynthesis than with CT, e.g. differentiating a small geode from an erosion may be too subtle and difficult. These elements could thus potentially lead to overdiagnosis of early sacroilitis (Fig. 4).

All tomosynthesis acquisitions could be analyzed without any major artifacts hampering interpretation. Nevertheless, we obtained more artifacts with tomosynthesis than with the radiography technique. These artifacts, such as blurring and ripples [19], are essentially inherent to the technique and do not alter the interpretation and must be mainstreamed into the image analysis. Indeed, the tomosynthesis reading errors were not related to any artifacts.

The tomosynthesis diagnostic confidence rate was higher than the radiography rate for both the junior and senior radiologists. We also observed that the diagnostic confidence of the senior radiologist was higher than that of the junior radiologist.

Moreover, this confidence rate tended to increase with the learning time (as shown by the junior radiologist's second read after a 3-month delay), while no such increase in confidence rate was obtained with radiography. This learning time pattern is crucial for this new technique, as demonstrated in this study by the increase in detection parameters at the second read for the junior radiologist. This intraobserver agreement was significantly better for tomosynthesis than for standard radiography. We found no significant differences in interobserver agreement between tomosynthesis and radiography, presumably due to a lack of statistical power. The agreement values for radiography were similar to those reported in the literature (kappa = 0.54) [4,20].

This study had certain limitations, including the fact that the study population included more women than men, and some of the subjects were over 45 years of age. This may not be representative of the population targeted for diagnostic assessment for suspected SpA. Meanwhile, the higher average age must be qualified, as the distinction between structural damage of sacroiliac joints and osteoarthritis is more complicated and relevant in this population. For this reason, CT is more often used for imaging older patients. We did not use and analyze the HLA B27 status of the patients because it is not relevant for radiological analysis to differentiate structural damage from degenerative remodeling. Otherwise, although the data should be qualified by the progressive implementation of low-dose or even ultralow-dose CT protocols (radiation exposure with tomosynthesis might be higher than that of a low-dose sacroiliac joint CT) [21], tomosynthesis imaging enabled us to decrease the effective doses by 5-fold as compared to CT acquisition. According to the linear no-threshold model, this would theoretically help reduce the risk of radiation-induced cancer to a similar extent [22]. A small number of patients was included in this study, although it was sufficient to demonstrate the superiority of tomosynthesis versus radiography but insufficient to analyze each structural change independently, especially erosions. Indeed, the presence of erosions has been shown to increase the SpA diagnosis specificity in the presence of bone edema on MRI [9]. It would therefore have been interesting to compare the ability of tomosynthesis to detect erosions relative to radiography and CT. As a supplement to this preliminary study, we are currently conducting a larger scale study with a different population that more closely resembles the population targetted for SpA screening.

5. Conclusion

This study highlighted that tomosynthesis was better than radiography for the detection of structural changes in the sacroiliac joints, with lower radiation exposure than CT, so it might therefore be considered as an alternative to standard radiography. In addition, X-ray tables are now often equipped with a tomosynthesis module, which allows tomosynthesis to be performed at the same time as the initial radiography. It could be an interesting tool to increase the specificity of MRI in difficult cases.

Ethical statements

The work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans.

The study was approved by the local ethics committee named “Comité de Protection des Personnes Sud-Méditerranée II » (ID-RCB: 2018-A00964-51) and saved on ClinicalTrials.gov (ID NCT03689881).

Informed consent was obtained for all subjects. The privacy rights of human subjects must always be observed.

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Declaration of Competing Interest

The authors declare that they have no conflict of interest.

CRediT authorship contribution statement

William Wantz: Conceptualization, Data curation, Investigation, Methodology, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Julien Le Roy:** Data curation, Formal analysis, Methodology, Validation, Visualization, Conceptualization, Writing – original draft, Writing – review & editing. **Cédric Lukas:** Data curation, Investigation, Validation, Visualization, Conceptualization, Writing – review & editing. **Catherine Cyteval:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Maxime Pastor:** Data curation, Formal analysis, Investigation, Methodology, Validation, Writing – review & editing.

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