

255P - CHALLENGES TO ASSESS BONE METASTASES IN BLINDED INDEPENDENT CENTRAL REVIEW (BICR) OF BREAST CANCER TRIALS USING RECIST 1.1

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INTRODUCTION

Bone metastases are very common in breast cancer (BC) patients and may be difficult to assess for independent central readers.

The commonly used RECIST 1.1 criteria recognize the challenges of **assessing bone metastases on baseline** and **in measuring treatment response**.

- According to the criteria, bone lesions on baseline are mainly considered unmeasurable, except in the presence of osteolytic lesions with measurable soft tissue component (Fig. 1).
- The response assessment of bone lesions is often difficult due to increased sclerosis or previously inconspicuous lesions may appear more evident and sclerotic on follow-up CT images (Fig. 2).
- It may also be difficult to distinguish osteoblastic activity on bone scan of a successful treatment (flare) from progressive disease for several months (Fig. 3).

OBJECTIVES

- TO DOCUMENT THE PROPORTION OF READER DISCREPANCIES OF BONE LESIONS ON BASELINE
- TO EVALUATE CONTRIBUTION OF BONE LESION ASSESSMENT TO THE OVERALL ASSESSMENT

METHODS

We analyzed:

- Two breast cancer trials that included 355 patients involving 7 radiologists
- The discordance rate of bone metastases selection on baseline among the paired readers
- The impact of bone lesions on the overall response

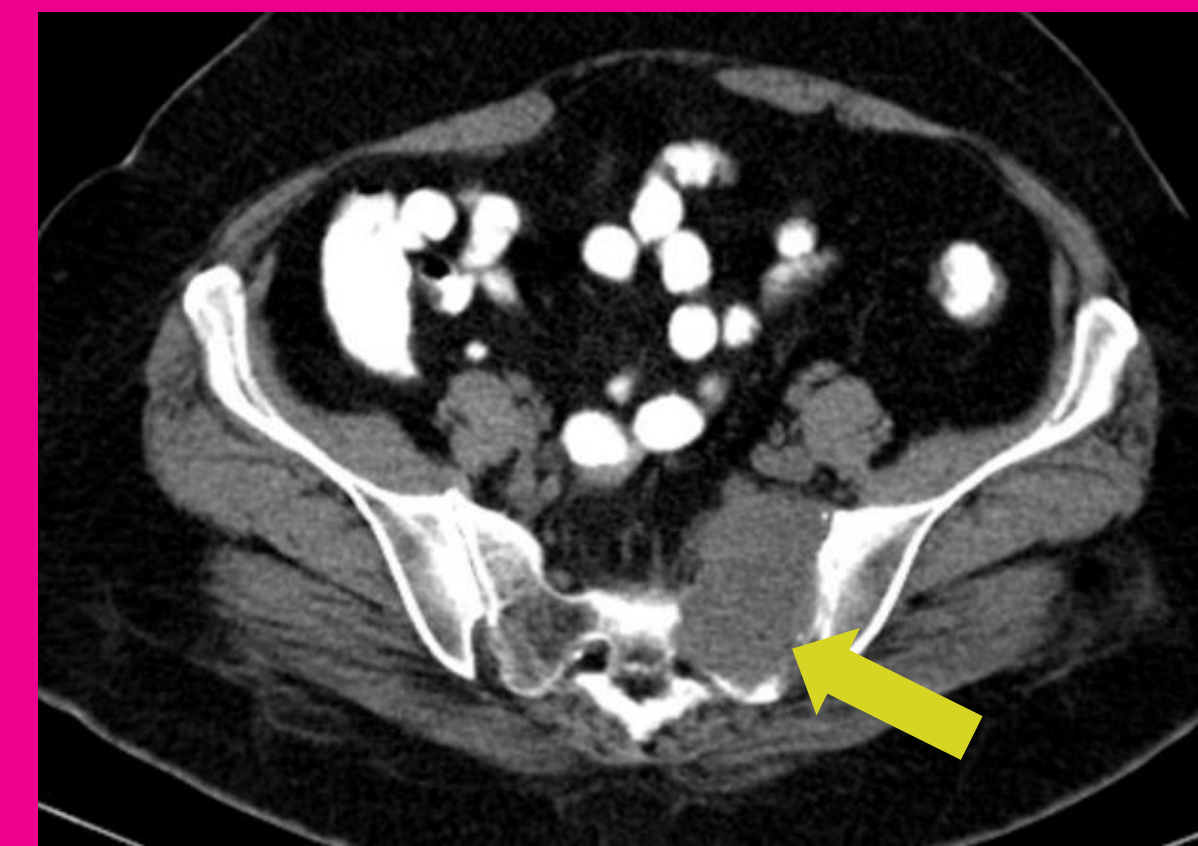


Fig. 1 Axial CT of the pelvis of a BC patient demonstrates a bone metastasis with soft tissue component of >10 mm (arrow) and is considered measurable by RECIST 1.1.

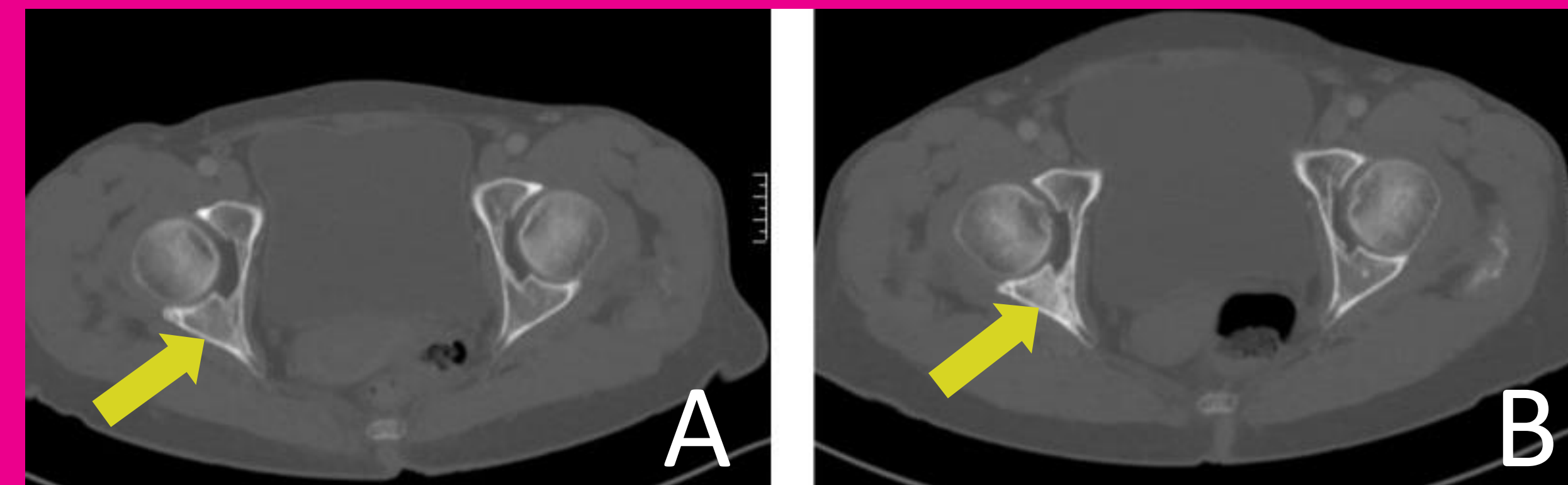


Fig. 2 Axial CT of a BC patient with skeletal metastasis on baseline (A) and at follow-up (B). The bone lesion (arrow) is more evident and sclerotic at follow-up.

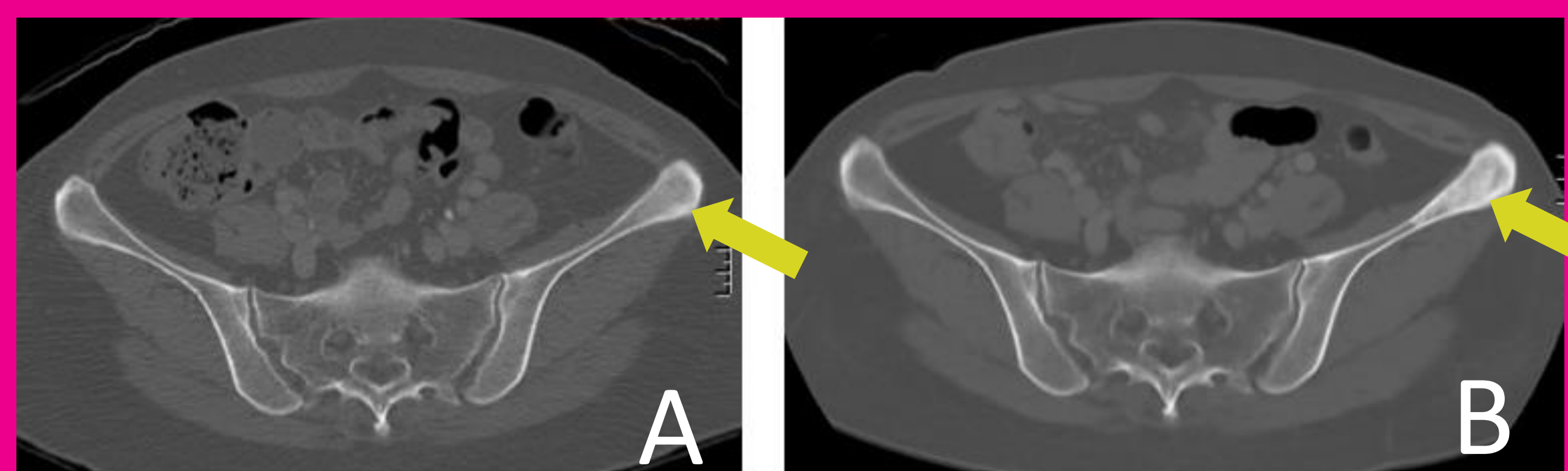


Fig. 3 Flare phenomenon or progression. Axial CT (A) and the corresponding bone scan (C) of a BC patient with skeletal metastasis (arrow) on baseline. The bone lesion in the follow-up is with increased sclerosis on CT images (B) and with increased activity on bone scan (D).

RESULTS

- Bone metastases were indicated on baseline in 218 from 355 patients (**61,4 %**).
- Bone lesions significantly contributed to the overall selected lesions (Fig. 4).
- The discrepancy rate of bone lesions on baseline was **41,3%**.
- 19 patients had a target lesion (TL) and 199 patients had a non-target lesion (NTL) in bone.
- 5 patients from 16 with a baseline bone NTL had progressive disease (PD) due to the specified bone lesion.

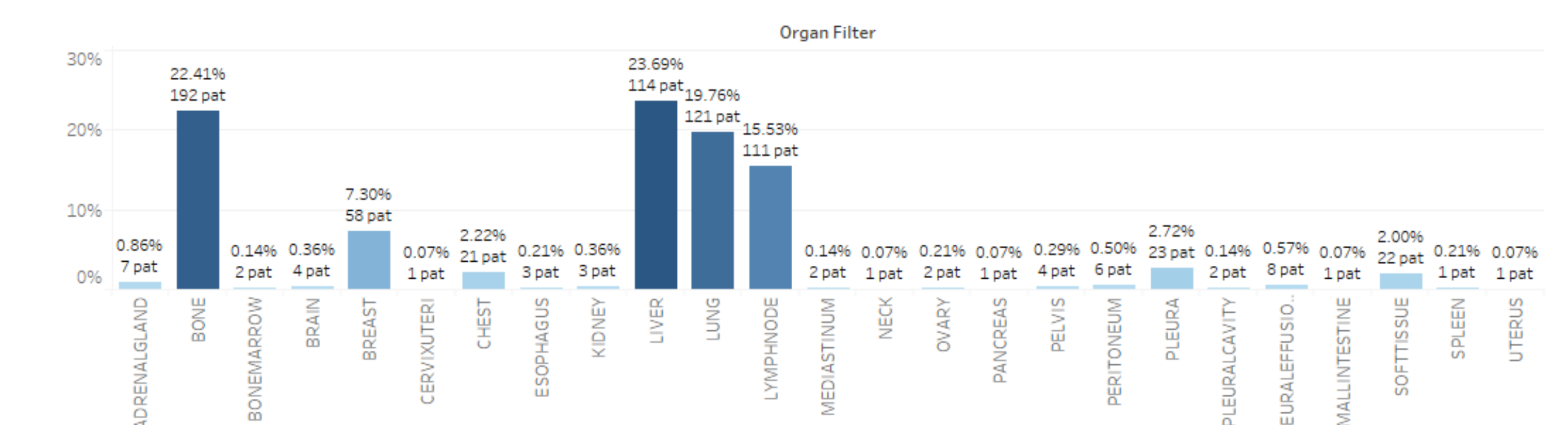


Fig. 4 The distribution of organ involvement (TL/NTL) in BC patients in one trial. The % of bone lesions from the overall recorded lesions was less than the % of recorded liver lesions. In absolute numbers more patients had skeletal involvement than liver involvement.

CONCLUSIONS

- Bone lesions are very common and were indicated predominantly by the readers as NTL.
- High discrepancy in the selection of bone metastases on baseline was found.
- Bone metastases did not contribute substantially to the overall PD assessment.