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Fast-MRI Feasibility in Biopsy-naïve Patients: Clarifications on the Study Methods and Results

Filippo Russo a, Simone Mazzetti a,b,*, Daniele Regge a,b, Ilaria Ambrosini a,b, Valentina Giannini a,b, Matteo Manfredi a, Stefano De Luca c, Enrico Bollito d, Francesco Porpiglia c

a Department of Radiology, Candiolo Cancer Institute, FPO-IRCCS, Candiolo, Turin, Italy; b Department of Surgical Sciences, University of Turin, Turin, Italy; c Department of Urology, University of Turin, San Luigi Gonzaga Hospital, Orbassano, Turin, Italy; d Department of Pathology, University of Turin, San Luigi Gonzaga Hospital, Orbassano, Turin, Italy.

We thank Professor Padhani et al for their interest and critique of our study on the first randomised controlled trial comparing multiparametric magnetic resonance imaging (mpMRI) with fast MRI in the detection of clinically significant prostate cancer (csPCa) in biopsy-naïve men [1]. We are glad to respond to the issues pointed out in their Editorial [2].

First, we agree that a 5% noninferiority margin would have given more power to the study. However, the trial was designed before the 2020 European Association of Urology guidelines [3], when the routine use of mpMRI in biopsy-naïve men was not recommended. Therefore, the noninferiority margin was set considering standard biopsy as the comparator, which has a detection rate for csPCa of 46–48% [4,5]. Moreover, as already recognised by the authors, the sample size for a 5% noninferiority margin would have quadrupled the number of patients enrolled, hampering the implementation of this first exploratory single-centre comparison study.

Second, the authors of the Editorial were perplexed by the reasoning that led us to choose a 2:1 allocation ratio. The rationale to collect a more representative sample of the new imaging test (ie, fast MRI) was suggested by Dumville et al [6], who reported several situations in which unequal group sizes in a trial may be beneficial, including costs, the learning curve, and ethical considerations. Most importantly, in our study we hypothesized that unequal randomisation would have reduced the impact of the learning curve in reporting fast MRI.

The point with which we disagree is about men who did not undergo biopsy. Indeed, the final analysis included only men who underwent biopsy, which was the reference standard for this study, regardless of MRI findings. As clarified in our discussion section [1], an intention-to-treat analysis was not performed and long-term follow-up for the cases who withdrew study consent was not carried out.

Another critique we do not support is the comparison of Prostate Imaging-Reporting and Data System (PI-RADS) 3 cases between our paper and the 4M study [7]. Padhani et al [2] compared the results of fast MRI (11%) with biparametric MRI (7.8%) instead of mpMRI (6.4%). This led to an inconsistent comparison with our findings, since the actual increase in PI-RADS 3 cases from mpMRI to fast MRI in the 4M study was 72%, and not the 37% reported by Padhani et al [2].

Finally, we disagree that the comparison with the 4M study is invalid because of differences in technique, since it was previously demonstrated that a 3-T scanner with no endorectal receiver coil (ERC) provides comparable image quality to that obtained on 1.5-T MRI with an ERC [8].

In conclusion, we agree with Padhani et al [2] that our study is just a first promising step in exploring the role of fast MRI in the diagnosis of PCa. Further validation in a multi-vendor, multiobserver setting will be necessary to assess whether fast MRI can be implemented in clinical practice.

Conflicts of interest: The authors have nothing to disclose.

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* Corresponding author. Department of Radiology, Candiolo Cancer Institute, FPO-IRCCS, Strada Provinciale 142, km 3.95, 10060 Candiolo, Turin, Italy.
Tel. +39 011 9933237; Fax: +39 011 9933527.

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