Diagnostic accuracy of the PROMIS study – Authors' reply

Hashim U Ahmed [a,e,f], Louise C Brown [d], Richard Kaplan [d], Chris Parker [c], Mark Emberton [a,b]

a Division of Surgery and Interventional Science, Faculty of Medical Sciences, University College London, London, UK

b Department of Urology, University College London Hospitals NHS Foundation Trust, London, UK

c Department of Academic Urology, Royal Marsden Hospital, Sutton, UK

d Medical Research Council Clinical Trials Unit at University College London, London, UK

e Division of Surgery, Department of Surgery and Cancer, Imperial College London, London W6 8RF, UK

f Imperial Urology, Imperial College Healthcare NHS Trust, London, UK

Correspondence to hashim.ahmed@imperial.ac.uk

We thank Simpa S Salami and colleagues for raising three important issues.

First, the primary role of a triage test is to rule out clinically significant prostate cancer and by doing so help the patient avoid an unnecessary biopsy. If the MRI does reveal an abnormality with a high probability of prostate cancer it should be targeted. The PROMIS[1] study did not address the issue of targeting because it was a blinded study. Other studies have investigated this and several others are currently recruiting.[2]

Second, we disagree that the performance of multi parametric MRI parallels that of prostate-specific antigen. In PROMIS, prostate-specific antigen did not contribute to the prediction of clinically significant prostate cancer. By contrast, the MRI-derived Likert score was closely correlated with clinically significant prostate cancer.

Third, we agree that our prevailing assumptions about clinically significant prostate cancer should be questioned. Nonetheless, increasing evidence suggests that lesions with a Gleason score of 6 do not have hallmarks of malignancy[3] and that many tumours with a Gleason score of 3 + 4 = 7 do well without immediate treatment,[4] whether diagnosed initially or even if missed by a transrectal ultrasound-guided prostate biopsy.[5] One of the most striking attributes of MRI within PROMIS was the complete absence of any misclassification of cancers with Gleason grade group III, IV, or V.

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References

1 HU Ahmed, A El-Shater Bosaily, LC Brown, et al.

Diagnostic accuracy of multi-parametric MRI and TRUS biopsy in prostate cancer (PROMIS): a paired validating confirmatory study

Lancet, 389 (2017), pp. 815-822

2 F Porpiglia, M Manfredi, F Mele, et al.

Diagnostic pathway with multiparametric magnetic resonance imaging versus standard pathway: results from a randomized prospective study in biopsy-naïve patients with suspected prostate cancer

Eur Urol (2016)

3 HU Ahmed, M Arya, A Freeman, M Emberton

Do low-grade and low-volume prostate cancers bear the hallmarks of malignancy?

Lancet Oncol, 13 (2012), pp. e509-e517

4 HU Ahmed

Prostate cancer: time for active surveillance of intermediate-risk disease?

Nat Rev Urol, 10 (2013), pp. 6-8

5 N Klemann, MA Røder, JT Helgstrand, et al.

Risk of prostate cancer diagnosis and mortality in men with a benign initial transrectal ultrasound-guided biopsy set: a population-based study

Lancet Oncol, 18 (2017), pp. 221-229