



European Association of Urology – Press Release

[Major study shows prostate MRI reveals more cancers which need treatment, and reduces overdiagnosis compared to standard biopsy](#)

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Copenhagen: A large international study has shown that an MRI scan can reduce the number of invasive prostate biopsies by up to 28%. The PRECISION¹ trial shows that using MRI to target prostate biopsies leads to more of the harmful prostate cancers, and fewer harmless cancers being diagnosed. Given that more than a million men in Europe undergo a prostate biopsy every year, the authors believe that this work could change clinical practice. The results are presented at the European Association of Urology Congress in Copenhagen, with simultaneous publication in the *New England Journal of Medicine*².

Why is this important?

Dr Veeru Kasivisvanathan of University College London and first author of the study, said:

“PRECISION is the first international multi-centre randomised trial to show the benefits of using MRI at the start of the prostate cancer diagnosis process.

In men who need to have investigation for prostate cancer for the first time, PRECISION shows that using an MRI to identify suspected cancer in the prostate and performing a prostate biopsy targeted to the MRI information, leads to more cancers being diagnosed than the standard way that we have been performing prostate biopsy for the last 25 years.”

Dr Caroline Moore, Reader in Urology at University College London and senior author of the study commented:

“We compared standard prostate biopsy to the use of MRI, offering targeted biopsies to only those men who had a suspicious MRI. The MRI pathway detected more harmful cancers that needed treatment, and it reduced overdiagnosis of harmless cancers, even though fewer men had a biopsy in the MRI arm.”

Professor Mark Emberton of University College London commented:

“This study was the first to allow men to avoid a biopsy. If high quality MRI can be achieved across Europe, then over a quarter of the 1 million men who currently undergo a biopsy could safely avoid it.”

Background

Prostate cancer is currently diagnosed by examining biopsy samples taken from the prostate via a procedure called TRUS (TRansrectal UUltraSound guided prostate biopsy). This means taking around 10-12 samples from the prostate using a probe with a special needle. The ultrasound-guided procedure means inserting a probe into the anus under local anaesthetic. It is uncomfortable, costly, and carries a slight risk of infection, but because it involves estimating the position of a possible tumour, it also means that tumours are often missed³. The PRECISION study investigates whether an MRI scan can avoid the need for biopsy in some patients, or give better diagnostic information where a biopsy is necessary.

What did they do?

Researchers from 23 centres randomly allocated 500 men to be examined either with a standard 10-12 core TRUS biopsy, or with an initial MRI scan followed by a targeted biopsy if the MRI showed an abnormality. The main aim was to assess what proportion of men were diagnosed with clinically significant prostate cancer (defined as a Gleason Grade of $\geq 3+4$) which is harmful cancer that is desirable to find. It also aimed to assess the proportion of men who were diagnosed with clinically insignificant cancer (Gleason Grade 3+3) which is desirable to avoid as it doesn't benefit from treatment.

What were the results?

The researchers found that 71 (28%) of the 252 men in the MRI arm of the study avoided the need for a subsequent biopsy. Of those who needed a biopsy, the researchers detected clinically significant cancer in 95 (38%) of the 252 men, compared with 64 (26%) of the 248 men who received only the TRUS biopsy.

"This shows that a diagnostic pathway with initial MRI assessment followed by biopsy when required, can not only reduce the overall number of biopsies performed, but can give more accurate results than TRUS-biopsy alone. We also found that patients who had MRI had fewer side effects than those who just had the standard TRUS biopsy. This is because the MRI allows some men to avoid biopsy and in those who need one, is able to better indicate which area of the prostate needs to be investigated, so you don't need to randomly sample the whole prostate and can use fewer biopsy cores", said Dr Kasivisvanathan.

What does this mean practically?

Several elements need to be considered for MRI to be generally adopted in the diagnostic process. As Dr Kasivisvanathan, who was awarded a National Institute for Health and Research Doctoral Fellowship to carry out the study, said:

"The ability to perform good quality MRI and the ability to interpret the MRI information are specialist skills. We will therefore need appropriate training for clinicians to use the technology and changes in health services to increase availability and capacity to perform

prostate MRI. In the long-term, this new diagnostic pathway can be cost-effective. Costs can be saved by the reduction in the number of men undergoing biopsy in the first place, by the earlier diagnosis of harmful cancers and in the avoidance of the diagnosis of harmless cancers.”

Prostate cancer statistics

Prostate cancer is the most common male cancer, with around 400,000 new cases every year in Europe. In the UK, there are over 46,000 new cases of prostate cancer every year, leading to more than 11,000 deaths⁴. 2015 figures show that for the first time there were more prostate cancer deaths than breast cancer deaths in the UK.

Commenting, Professor Hein Van Poppel, (EAU Adjunct Secretary General, University Hospitals of the Leuven), said:

“This is a significant study. Prostate cancer can only really be confirmed by a biopsy, which is invasive and, like almost all medical procedures, carries some risk of side-effects. Of course, in the majority of men who have a biopsy no cancer is found. This work shows that using MRI to decide whether or not to perform a biopsy has the potential to save around a quarter of a million European men each year from going through the biopsy procedure, and so may be cost-effective in the long run. MRI use also shows up small aggressive cancers at a curable stage, and allows us to delay or simply not perform biopsies for some cancers which will not turn out to be dangerous. We need time to digest the study, but at first reading it looks like it has the potential to change clinical practice.”

Note: Professor van Poppel was not involved in this research, this is an independent comment

1 PRECISION (PRostate Evaluation for Clinically Important disease: Sampling using Image-guidance Or Not?), NCT02380027, was a randomized multicentre non-inferiority trial conducted in 25 centres in 11 countries. The study was funded by the National Institute for Health Research and the European Association of Urology Research Foundation, with study governance from University College London. The funders had no role in protocol development, data analysis or interpretation, or manuscript preparation. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, the Department of Health or the European Association of Urology Research Foundation.

2 The conference abstract, and a link to the full NEJM paper (*“MRI-Targeted versus Transrectal Ultrasound Biopsy for Prostate Cancer Diagnosis.”* Kasivisvanathan et al, DOI 10.1056/NEJMoa1801993, NEJM published 19 March 2018) are available in *Notes for Editors*.

3 For background, see <http://www.cancerresearchuk.org/about-cancer/prostate-cancer/getting-diagnosed/tests-diagnose/transrectal-ultrasound-guided-trus-biopsy>

4 European figures from <http://eco.iarc.fr/eucan/CancerOne.aspx?Cancer=29&Gender=1#block-table-f>. Actual UK figures are 46,690 new cases and 11,287 deaths in 2014, <http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/prostate-cancer>

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Notes for editors

**PLEASE MENTION THE EUROPEAN ASSOCIATION OF UROLOGY CONGRESS IN ANY STORY
RESULTING FROM THIS PRESS RELEASE**

The 33rd European Association of Urology conference takes place in Copenhagen from 16th to 20th March. This is the largest and most important urology congress in Europe, with up to 14,000 expected to attend. Conference website <http://eau18.uroweb.org/>

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The full NEJM paper is available to journalists on request from Tom Parkhill.

“MRI-Targeted versus Transrectal Ultrasound Biopsy for Prostate Cancer Diagnosis.”

Kasivisvanathan et al, *New England Journal of Medicine*, published 19 March 2018.

The DOI is 10.1056/NEJMoa1801993, available to journalists after the embargo at: www.nejm.org/doi/full/10.1056/NEJMoa1801993)

The EAU thanks *the New England Journal of Medicine* for their cooperation in making material available.

Conference Abstract: Prostate evaluation for clinically important disease: Sampling using image-guidance or not? (The PRECISION study, NCT02380027)

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Introduction & Objectives

Standard of care for prostate cancer diagnosis in biopsy naïve men is transrectal ultrasound guided prostate (TRUS) biopsy. Evidence is accumulating that MRI is useful in detecting clinically significant prostate cancer, and it is widely recommended after a negative biopsy. Controversy exists regarding its effectiveness before biopsy in all men. PRECISION aimed to evaluate whether multiparametric MRI and a targeted biopsy only (MRI±TB) was non-inferior to TRUS biopsy in the detection of clinically significant prostate cancer in biopsy naïve men.

Materials & Methods

PRECISION was a prospective, randomised, non-inferiority trial, carried out in 25 centres in 11 countries. 500 men were randomly allocated to 10-12 core TRUS-biopsy or MRI±TB. Men randomised to MRI±TB underwent MRI followed by targeted biopsy alone (without standard cores) if the PIRADSv2 score was ≥3. MRI was either 1.5 or 3.0 T with at least a pelvic phased array coil, interpreted by a local radiologist, and image- registration technique was left to local expertise. Men with a PIRADSv2 score of 1-2 were not offered biopsy. Men in the 10-12 core TRUS-biopsy arm did not undergo pre-biopsy MRI. The primary outcome was the proportion of men diagnosed with clinically significant cancer (Gleason grade (GG) ≥ 3+4), with the non-inferiority margin for the difference in proportions set at -5%. Planned secondary outcomes included the proportion of men with clinically insignificant cancer (GG 3+3). Ethical approval was obtained for the study.

Results

Baseline characteristics were similar in both MRI±TB and TRUS biopsy arms for mean age (64 vs 65), median PSA (6.8 vs 6.5), proportion of men with family history of prostate cancer (19% vs 16%) and proportion of men with abnormal digital rectal examination (14% vs 15%). Of 252 men randomised to MRI±TB, 71 (28%) avoided a biopsy. Clinically significant cancer was detected in 95 (38%) of 252 men in the MRI±TB arm compared to 64 (26%) of 248 men randomised to TRUS-biopsy (intention-to-treat analysis). Adjusting for centre effects, the absolute difference (MRI±TB versus TRUS-biopsy) in the proportion of men diagnosed with clinically significant prostate cancer was 11.7% (2-sided 95% CI 3.6 to 19.8; $p = 0.005$). The lower bound of the 95% CI for the difference is greater than -5% therefore MRI±TB was non-inferior to TRUS biopsy. Furthermore, the range of 95% CI was consistent with a claim of superiority of MRI±TB over TRUS-biopsy. MRI±TB also diagnosed fewer men with insignificant cancer than TRUS biopsy [23/252 (9%) vs 55/248 (22%), $p < 0.001$].

Conclusions

Several benefits may be conferred by changing the standard of care from TRUS biopsy with standard cores alone, to MRI and targeted biopsy alone in men with suspicious MRI. These include fewer men biopsied, fewer cores taken, greater number of significant cancers diagnosed, and lower chance of diagnosing low risk cancer.

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