European Association of Urology **Press release**

New results suggest combining MRI with conventional prostate surveillance may give a generally effective prostate screening system

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Madrid, 23 March. Initial results from the Göteborg randomised screening trial indicates that using MRI (Magnetic Resonance Imaging) alongside conventional prostate cancer screening seems to offer improved cancer detection and can help avoid unnecessary biopsies.

Prostate cancer is the third most common male cancer in Europe, accounting for over 92,000 deaths in 2012 (9% of male deaths).* Screening for prostate cancer is a controversial issue, with until recently, little clear evidence that existing screening procedures, using PSA (to be followed by biopsies), were effective. In general, either the screening has tended to miss many cancers, or to give false positives, meaning that many men are subject to invasive testing and perhaps treatment which was just not necessary.

The Göteborg Trial is the Swedish arm of the European Randomized Study of Screening for Prostate Cancer (ERSPC), which is the largest randomized prostate cancer screening trial in the world. In 2014 results from this trial showed a significant mortality reduction with prostate-specific antigen (PSA) screening for men aged 55-69 years of age. Now new work, presented at the European Association of Urology Conference in Madrid, shows that using MRI may further improve the accuracy of prostate cancer screening. This research has been awarded the EAU's First Prize for the Best Abstract by a Resident

A group of Swedish and US researchers, led by Prof Jonas Hugosson took 384 patients attending the Göteborg trial, and asked 124 of these to go for an MRI prior to having a biopsy. Those with a suspicious MRI, or with a PSA $\geq$ 3 ng/ml, were referred for biopsy. These biopsies were both standard samples, where 10 tissue samples are taken at random from the prostate, and targeted biopsies, where samples were taken from the suspicious areas seen on the MRI.

The results showed that the combining PSA and MRI, followed by MRI-targeted biopsy only in men with suspicious MRI gave better prostate cancer detection (as confirmed by biopsy) than PSA scores alone followed by standard random biopsy (7.0% versus 5.2%). The results also showed that more significant (potentially aggressive) cancers were detected with PSA + MRI combined compared with using PSA as a stand-alone test in screening.

Analysing the results, the Göteborg group suggests that this combination may point to a strategy to maximise success in prostate cancer screening.

According to researcher, Dr Anna Grenabo-Bergdahl:

"From these initial results it looks like we can combine PSA levels with MRI scans to give more accurate screening results. This strategy would allow us to take men with lower PSA scores, and give them MRI scans, to confirm whether or not a biopsy is absolutely necessary. Another benefit is that the MRI helps us locate the suspect area, meaning that if we have to do a confirmatory biopsy, we have a much better idea of where the problem might be. This avoids patient stress, and means we are less likely to miss cancers".

She continued:

"These results from the pilot study are very encouraging, but now they need to be confirmed. We are starting a trial of 40,000 patients in the Göteborg area. If we can replicate the results from our pilot study this may lead to a paradigm shift in future screening and fundamentally change the way we handle early detection of prostate cancer".

Commenting, European Association of Urology Treasurer, Professor Manfred Wirth (Dresden) said:

"These initial results, which confirm some of the work we have been doing here in Dresden, show that MRI-targeted biopsy has the potential to change how we diagnose prostate cancer. There are still real issues to address; for example MRI is currently not cost-effective to use in routine screening. As the authors say, we are still some way off considering using MRI for routine screening, and we need a bigger study to validate these results. But this is a positive proof of principle, and certainly merits more investigation".

ENDS

Notes for Editors

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

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The 15th European Association of Urology conference takes place in Madrid from 20-24th March. This is the largest and most important urology congress in Europe, with up to 13,000 expected to attend. Conference website http://eaumadrid2015.uroweb.org/

* Data from http://www.cancerresearchuk.org/cancer-info/cancerstats/types/prostate/mortality/uk-prostate-cancer-mortality-statistics#source24

ABSTRACT

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Introduction & Objectives
Screening for prostate cancer (PC) with prostate specific antigen (PSA) effectively reduces PC mortality but is associated with over-diagnosis due to frequent diagnosis of cancers with low malignant potential, but also under-diagnosis of cancers that are detected too late. Multi-parametric 3T magnetic resonance imaging (MRI) including T2, contrast enhancement and diffusion-weighted imaging and targeted biopsies (TB) has shown potential to more accurately detect significant PC. We plan to launch a large randomized trial to determine whether screening with PSA + MRI of the prostate can improve upon the benefits and harms of screening. These are the results of our pilot study conducted during 2013-2014.

Material & Methods
Of 384 attendees in the 10th and last screening round of the Goteborg randomised screening trial, 124 men with a median age of 69.5 and a PSA of ≥1.8 ng/ml underwent a pre-biopsy MRI. Men with suspicious lesions on MRI and/or a PSA ≥3 ng/ml were referred for biopsy. Ten-core systematic biopsy (SB) was performed blinded to MRI results, and 3 additional MRI-TB were performed in men with suspicious MRIs. Proportions of significant PC and number needed to biopsy (NNB) to detect one PC were compared between 3 screening strategies including PSA ≥3 + SB, PSA ≥3 + MRI + TB and PSA ≥1.8 + MRI + TB.

Results
In total, 28 PC were detected at biopsy in these men who had been previously screened to a large extent (47% previously biopsied). The accuracy of PCdetection for PSA ≥1.8 + MRI was significantly improved compared to PSA ≥3 alone, AUC 0.77 (CI 0.6707 – 0.8621) vs. 0.58 (0.48 – 0.69), p=0.035. MRI missed 7 PC of which 5 were Gleason 3+3 and 2 Gleason 3+4.

Conclusions
A screening strategy with a lowered PSA cut-off followed by TB in MRI-positive men only seems to have the potential to increase benefit (improved diagnosis) and reduce harm (lower over-diagnosis). Results from this pilot study encouraged us to initiate the full-sized trial aiming at randomising 40,000 men. If the results from our pilot study could be replicated it may lead to a paradigm shift in future screening and fundamentally change the way we handle early detection of PC.

Attendees in the 10th screening round (n=384)	PSA ≥3 (SB)	PSA ≥3+susp MRI (TB)	PSA ≥1.8+susp MRI (TB)
Proportion with an MRI indication	-	19.8%	44.8%
Proportion with a biopsy indication	20.0%	6.5%	14.8%
PC detection rate (all)	5.2%	3.8%	7.0 %
Sign cancer detection rate	4.0%	3.6%	5.9%
NNB to detect one PC	4	2	2
Number of MRIs per avoided biopsy	-	3	3

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