MRI can cut overdiagnoses in prostate-cancer screening by half

Most countries have not introduced nationwide prostate-cancer screening, as current methods result in overdiagnoses and excessive and unnecessary biopsies. A new study by researchers at Karolinska Institutet in Sweden, which is published in *The New England Journal of Medicine*, indicates that screening by magnetic resonance imaging (MRI) and targeted biopsies could potentially cut overdiagnoses by half. The results are presented today at the European Association of Urology Congress.

"Our results from a large, randomised study show that modern methods for prostate cancer screening maintain the benefits of screening, while decreasing the harms substantially. This addresses the greatest barrier to the introduction of nationwide screening," explains Tobias Nordström, associate professor of Urology at the Department of Clinical Sciences, Danderyd Hospital at Karolinska Institutet, who is in charge of the STHLM3MRI study.

Yearly, approximately 1,4 million men get a prostate cancer diagnosis and 375,000 men die from the disease. Previous studies have shown that organised screening can result in earlier detection and thereby reduce the risk of prostate-cancer deaths.

Current screening methods – PSA (prostate-specific antigen) tests combined with traditional biopsies – result in unnecessary biopsies, and the detection of numerous minor low-risk tumours. Consequently, no country except Lithuania has chosen to introduce a nationwide prostate-cancer screening programme, as the benefits do not exceed the disadvantages.

"Refined screening methods are required to reduce overdiagnosis and overtreatment of low-risk tumours, and prevent unnecessary biopsies and biopsy-related side-effects," explains Martin Eklund, associate professor at the Department of Medical Epidemiology and Biostatistics, Karolinska Institutet, with joint responsibility for the STHLM3MRI study.

The results of the STHLM3MRI study indicate that overdiagnoses can be halved by substituting traditional prostate biopsies with magnetic resonance imaging (MRI) and targeted biopsies. The number of unnecessary biopsies and the identification of minor low-risk tumours is reduced, while the new method can detect just as many clinically significant tumours.

STHLM3MRI is a randomised study conducted between 2018 and 2021 with participants from Stockholm County, which included 12,750 men. The participants first provided a blood sample for PSA analysis, as well as analysis by the new Stockholm3 test, developed by researchers at Karolinska Institutet. Men whose tests showed elevated levels were then randomly selected for traditional biopsies or MRI. In the MRI group, biopsies were conducted strictly on suspected tumours identified by MRI.

The study proceeded thereafter by investigating how the Stockholm3 test could be combined with MRI to further improve the method for prostate-cancer screening.

"We will soon present the second of the two main reports from the STHLM3MRI trial where we assess the role of a novel blood test as adjunct to MRI in prostate cancer screening. The future of prostate cancer diagnostics probably includes both improved blood-tests and MRI. Nationwide screening for breast and cervical cancer among women has been available in the Western world for some time. We are finally able to show that men can also reduce their risk of malignant cancer through nationwide prostate-cancer screening that utilises modern methods," Tobias Nordström concludes.

Professor Hendrik Van Poppel, Adjunct Secretary General of the European Association of Urology (EAU) said: "It is exciting to see breakthroughs such as this in the field of early detection of prostate cancer. An innovation such as STHLM3MRI makes an even more compelling case for the European Commission to ensure a risk stratified approach to early detection of prostate cancer is adopted across the whole of Europe. The EAU is working hard to ensure that early detection of prostate cancer is addressed in the implementation of Europe's Beating Cancer Plan in order to reduce mortality of Europe's most common male cancer while also dealing with the challenges of

overdiagnosis and overtreatment. We are really looking forward to seeing how STHLM3MRI can continue to contribute to this aim".

The research was financed by the Swedish Cancer Society, the Swedish Research Council, the Swedish Research Council for Health, Working Life and Welfare, Karolinska Institutet, Hagstrandska Minnesfonden, Region Stockholm, the Swedish Order of Druids, the Åke Wiberg Foundation, the Swedish e-Science Research Center (SeRC) and Prostatacancerförbundet (the Prostate Cancer Association). Henrik Grönberg, Martin Eklund and Tobias Nordström are partners of the company A3P Biomedical AB, which holds the development rights of the Stockholm3 test.

Publication: "MRI-targeted or standard biopsy in prostate cancer screening", M. Eklund, F. Jäderling, A. Discacciati, M. Bergman, M. Annerstedt, M. Aly, A. Glaessgen, S. Carlsson, H. Grönberg, T. Nordström, for the STHLM3 consortium. *The New England Journal of Medicine (NEJM)*, online 9 juli 2021, doi: 10.1056/NEJMoa2100852. https://doi.org/10.1056/NEJMoa2100852

For more information, please contact:

Tobias Nordström, associate professor, clinical urologist Department of Clinical Sciences, Danderyd Hospital, Karolinska Institutet General Surgery and Urology, Danderyds Hospital

Phone: +46 70 539 1791 Email: tobias.nordstrom@ki.se

Martin Eklund, associate professor Department of Medical Epidemiology and Biostatistics, Karolinska Institutet

Phone: +46 73 712 1611 Email: martin.eklund@ki.se

European Association of Urology Sarah Collen, EAU Policy Coordinator

Phone: +32 474 51 14 80 Email: s.collen@uroweb.org

<u>Karolinska Institutet</u> is one of the world's leading medical universities. Our vision is to advance knowledge about life and strive towards better health for all. Karolinska Institutet accounts for the single largest share of all academic medical research conducted in Sweden and offers the country's broadest range of education in medicine and health sciences. The Nobel Assembly at Karolinska Institutet selects the Nobel laureates in Physiology or Medicine.

About EAU21

Europe's biggest urology congress will take place from 8th-12th July 2021 in a virtual setting. With over 1,500 abstracts presented and moderated live, the Annual Congress of the European Association of Urology (EAU21) will be amongst Europe's biggest medical congresses in 2021.

Clinicians, scientists, and patients will meet to discuss topics such as:

- Prostate cancer: new developments to improve treatments of the most common male cancer
- Urinary incontinence: a growing concern for the elderly population
- Practice changing treatments for both bladder and kidney cancer
- Prevention and treatment of urinary stones; 1 in 10 people (55 million adults in Europe) will form a stone at some point
- Special track for representatives of patient advocacy group on Friday 9 July

...and many other conditions related to the male and female urinary tract system and male reproductive organs. Review the full scientific programme on https://eaucongress.uroweb.org/