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ABSTRACT

Performance of the Finnish prostate cancer screening trial based on process indicators

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The aim of cancer screening is to reduce mortality and improve quality of life. Evaluation of this effectiveness ultimately requires extensive follow-up. Therefore, intermediate or process indicators are used as necessary, but not sufficient, early evidence with the potential to predict the mortality effect. For prostate cancer, the effectiveness of screening is unknown and two large-scale trials are being carried out.

The Finnish prostate cancer screening trial is the largest component of the European Randomized Study of Screening for Prostate Cancer. The purpose of this thesis is to assess the Finnish prostate cancer screening trial with PSA, using intermediate endpoints, i.e., participation, PSA distribution, detection rate, sensitivity, specificity, predictive values and prognostic factors of screen-detected cancers.

Altogether 30 197 men were invited for the first screen and 20 793 (69%) attended. Among attendees 1 826 (9%) were screen-positives with PSA $\geq$ 4.0 ng/ml and additional 1 075 men were referred for diagnostic examination based on DRE or free to total PSA ratio among men with moderately increased level of PSA (3.0–3.9 ng/ml).

At the first screen 542 cancers were detected with detection rate of 2.6%. The positive predictive value of the PSA test at cut-off level of 4.0 ng/ml was 28%.

The sensitivity by age of the PSA test at PSA 4.0 ng/ml and with ancillary tests of TRUS and free to total PSA ratio determination was 85% based on interval cancers during the first screening interval. Specificity at the cut-off limits of the PSA test at PSA 3.0 ng/ml and with ancillary tests of DRE, TRUS and free to total PSA ratio was 94%, when adjusted for the cancers detected during the first interval.

The clinical stage distribution of the cancers detected at the first screen was favourable (T1-T2 M0) in 86% and only 3% of the cancers had distant metastases (M1). Of the screen-detected cancers, 6% were aggressive (Gleason 8–10).

It was concluded that the Finnish prostate cancer screening trial is acceptable to the target population; the test is capable of identifying a small proportion of men with a high risk of prostate cancer. Detection of aggressive, potentially lethal cancer implies that PSA testing does not detect only indolent cancers. The results on the process indicators justify the continuation of the Finnish prostate cancer screening trial for estimation of the ultimate effectiveness in terms of mortality reduction.

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