Authors' objectives
To systematically review the literature in order to examine the diagnostic value of digital rectal examination (DRE) for the diagnosis of prostate cancer in a primary care setting.

Searching
MEDLINE was searched from 1993 to 1995. FAMLI, a specialist family practice database, was also searched but no search dates were given. Some general practice journals were handsearched. The reference lists of the included studies were checked for additional citations. No language restrictions were reported.

Study selection

Study designs of evaluations included in the review
Diagnostic accuracy studies were eligible for the review.

Specific interventions included in the review
Studies investigating DRE were eligible for inclusion. The included studies defined DRE as positive using a variety of criteria, e.g. prostatic enlargement, nodularity, asymmetry, suspiciousness, induration and irregularity.

Reference standard test against which the new test was compared
Studies where the biopsy and/or surgical pathology results were the reference standard for the diagnosis of prostate cancer were eligible for inclusion.

Participants included in the review
Studies that assessed unselected series of men with prostate-related signs or symptoms were eligible for inclusion.

Outcomes assessed in the review
The primary outcomes of interest were diagnostic indices including sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). Studies were only included in the review if they reported sufficient details to construct a 2x2 table of test performance.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
Methodological aspects of all studies were assessed using a list of criteria proposed by the Cochrane Methods Working Group on Systematic Review of Diagnostic and Screening Tests (see Other Publications of Related Interest). This included aspects of study validity, applicability of the results, details of the test procedure, and indirect measures of quality and applicability. The factors that were considered to be characteristic of high-quality studies included the following: DRE was performed on a complete population with no pre-testing; all patients also underwent prostate specific antigen (PSA) testing and/or transrectal ultrasonography (TRUS); all patients with a positive DRE test were eligible for the reference test; all patients with a negative DRE but a positive PSA test or TRUS were eligible for the reference test; and more than 90% of the entire population underwent the reference test.

The authors do not state how the papers were assessed for quality, or how many of the reviewers performed the quality assessment.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.
Data were extracted on the following: study characteristics: authorship; year of publication; setting; referral filter; sample size; prevalence; percentage not tested using the reference standard; age range; reference standard used and cut points used in administering the DRE.

**Methods of synthesis**

How were the studies combined?

Statistical pooling was conducted using a random-effects model. A meta-analysis of subgroups was conducted where appropriate. Studies of higher quality were assessed in a sensitivity analysis. The influence on the diagnostic indices of individual factors was assessed by multiple linear regression.

How were differences between studies investigated?

The chi-squared test for homogeneity was used to assess between-study differences. Differences in the studies were discussed in the narrative. The influence of the setting of the study and methodological considerations on the accuracy of DRE was assessed by multiple linear regression.

**Results of the review**

The review included 14 diagnostic accuracy studies with data from 21,839 patients.

The prevalence of rates of detected cancers ranged from 1.2 to 7.3% between the studies. No significant association between sensitivity and (1 minus specificity) was seen on the Spearman's rank test (p=0.12).

When the results of all 14 studies were pooled, the sensitivity was 59% (95% confidence interval, CI: 51, 67) and ranged from 38% (specificity 95%) to 79% (specificity 97%). The specificity was 94% (95% CI: 91, 96) and ranged from 69% (sensitivity 67%) to 99% (sensitivity 57 to 65%). The PPV was 28% (95% CI: 20, 36) and ranged from 8% (NPV 98%) to 68% (NPV 99%). The NPV was 99% (95% CI: 98, 99) and ranged from 96% (PPV 21%) to 100% (NPV 22%).

When only the 5 'good quality' studies were included in the analysis, the values were somewhat higher: the sensitivity was 64% (95% CI: 47, 80) and ranged from 38% (specificity 95%) to 79% (specificity 97%). The specificity was 97% (95% CI: 95, 99) and ranged from 90% (sensitivity 74%) to 99% (sensitivity 57 to 65%). The PPV was 47% (95% CI: 29, 64) and ranged from 21% (NPV 98%) to 68% (NPV 99%). The NPV was 99% (95% CI: 98, 99) and ranged from 98% (PPV 21 to 38%) to 99% (PPV 55 to 68%).

Study heterogeneity was highly significant for almost all indicators in both groups.

Linear regression indicated that none of the independent variables showed any significant relation with any of the diagnostic indicators that were studied.

**Authors’ conclusions**

In the general practice setting, DRE has a high specificity and NPV but a low sensitivity and PPV.

**CRD commentary**

The study was a well-conducted systematic review of the literature, which was based on searches of appropriate databases. However, no search terms were given and there was no attempt to search for unpublished literature. The quality of the studies was assessed appropriately using a Cochrane Collaboration scheme, and the results of the assessment were reported both in the text of the review and in supporting tables.

The authors conducted a pooled analysis of sensitivity and specificity and assessed heterogeneity in the linear regression analysis. However, in light of the heterogeneity between the studies, a narrative synthesis may have been more appropriate than statistical pooling. Nevertheless, the results appear to have been well pooled and the conclusions appear to be appropriate given the evidence.

**Implications of the review for practice and research**
Practice: The authors state that the DRE may have a place as an initial test when screening for prostate cancer. A negative result of DRE has a high predictive value. However, the moderate sensitivity should prevent the general practitioner from drawing conclusions on the sole basis of this result. Owing to its very low PPV, a positive test cannot be advocated as the basis for any important diagnosis without further confirmation.

Research: The authors did not state any implications for further research.

Bibliographic details

PubMedID
10625141

Original Paper URL
http://fampra.oupjournals.org/cgi/content/full/16/6/621

Other publications of related interest

This additional published commentary may also be of interest. DRE screening for prostate cancer. Bandolier 2000;74:5-6.

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Aged; Clinical Trials as Topic; Humans; Incidence; Male; Middle Aged; Netherlands /epidemiology; Palpation /methods; Predictive Value of Tests; Primary Health Care /methods; Prostatic Neoplasms /diagnosis /epidemiology; Rectum; Sensitivity and Specificity

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.