Diagnostic accuracy of transrectal elastosonography (TRES) imaging for the diagnosis of prostate cancer: a systematic review and meta-analysis
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CRD summary
This review concluded that transrectal elastosonography appeared to improve the detection of prostate cancer compared with systematic biopsy and showed good accuracy compared with histopathology of the radical prostatectomy specimen. The reporting of review methods was contradictory in places and the results presented did not support the authors' conclusions, so the conclusions are unlikely to be reliable.

Authors' objectives
To assess the performance of transrectal elastosonography in the diagnosis of prostate cancer.

Searching
MEDLINE, EMBASE, CINAHL and Cochrane Central Register of Controlled Trials (CENTRAL) were searched from inception to March 2011; search terms were reported. Additional searches were made using ClinicalTrials.gov register, Google Scholar and unspecified urological journals. Bibliographies of retrieved articles and reviews were screened for additional studies. No language restrictions were applied, but only published studies were included.

Study selection
Diagnostic accuracy studies that compared transrectal elastosonography with one of two reference standards (transrectal ultrasound-guided prostate biopsy or histopathology of radical prostatectomy specimen) in men with suspected prostate cancer were eligible for inclusion.

Included studies were published from 2002 up to 2010. Half of the included studies were conducted in Europe, with the rest in Japan or the USA. Ten studies used transrectal ultrasound-guided biopsy as the reference standard; the other trials used histopathology of radical prostatectomy specimen. However, seven studies were not included in the meta-analysis because the reference standard did not conform to current practice (minimum ten transrectal ultrasound-guided biopsies).

Study participants were aged between 35 and 88 years. Prostate-specific antigen levels ranged from 0.2 to 200ng/dL with or without abnormal feeling prostates on digital rectal examination. Various ultrasound machines were used (details reported in the paper); half of the studies of the studies used an EUB 8500 Hitachi ultrasound with a 7.5MHz probe.

Two reviewers independently assessed studies for inclusion; any disagreement was resolved by discussion of consultation with a third reviewer.

Assessment of study quality
The methodological quality of the included studies was independently assessed by two reviewers using the STARD checklist.

Data extraction
Data were extracted to populate 2x2 contingency tables (numbers of true positive, false positive, false negative and true negative test results). These data were used to calculate sensitivity, specificity, and positive and negative predictive values for per patient and/or per biopsy. Per patient detection rates were also reported. Study authors were contacted for missing data as needed.

Two reviewers performed the data extraction.

Methods of synthesis
The pooled diagnostic odds ratio, with 95% confidence intervals, was calculated using a random-effects model. Ranges
of sensitivity and specificity estimates from individual studies were presented. A summary receiver operating characteristic curve was also presented.

Data were presented separately for studies which used histopathology of radical prostatectomy specimen as the reference standard and those which used transrectal ultrasound-guided prostate biopsy.

**Results of the review**

Sixteen studies, with 2,278 participants, were included in the review, with eight studies included in the meta-analyses. The authors reported that included studies lacked standardisation of technique and were poorly reported. No study clearly reported blinded interpretation of the index test and reference standard. All studies were considered to be vulnerable to spectrum bias.

**Studies using histopathology of radical prostatectomy specimen as the reference standard** (four studies): Sensitivity ranged from 71% to 82% and specificity ranged from 60 to 95%. The pooled diagnostic odds ratio was 19.64 (95% CI 7.71 to 50.03).

**Studies using transrectal ultrasound-guided prostate biopsy (minimum 10) as the reference standard**: Six studies reported per patient data with sensitivities that ranged from 26% to 87%, and specificities that ranged from 17% to 76%; the pooled diagnostic odds ratio was 2.10 (95% CI 0.53 to 8.70). Two studies reported per biopsy data with sensitivity estimates that were 36% and 69%, and the corresponding specificities were 89% and 93%; the pooled diagnostic odds ratio was 12.10 (95% CI 5.08 to 29.02).

**Authors’ conclusions**

Transrectal elastosonography appeared to improve the detection of prostate cancer compared with systematic biopsy and showed good accuracy when evaluated against histopathology of the radical prostatectomy specimen. However, the included studies lacked standardisation of technique, were poorly reported, and used a variety of outcome measures.

**CRD commentary**

The review reported a clear objective and inclusion criteria. A range of sources were searched for relevant studies and no language restrictions were applied, which maximised the likely retrieval of relevant studies. The review process included measures to minimise error and bias.

The abstract stated that quality was assessed with a validated quality assessment tool for diagnostic accuracy studies, but quality assessment actually used the STARD checklist, a reporting guideline for test accuracy studies and not a validated quality assessment tool. Similarly, the abstract and some figure labelling implied that meta-analyses used a hierarchical model, whereas the data reported, the numbers of studies included in some analyses, and the software used appear to contradict this. Since it was not clear what meta-analytic methods were actually used, it was difficult to fully assess the validity of pooled estimates. However, the values of pooled diagnostic odds ratios would appear limited where sensitivity and specificity estimates vary so widely. The authors’ conclusion that transrectal elastosonography appeared to improve the detection of prostate cancer compared with systematic biopsy was not supported by the data; no comparative data were presented. Similarly, reported accuracy (using histology of the radical prostatectomy sample as the reference standard) was variable and not adequate to support the authors’ conclusions.

The review has a number of limitations and the authors’ conclusions are unlikely to be reliable.

**Implications of the review for practice and research**

**Practice**: The authors stated that transrectal elastosonography-guided biopsy increased the detection of prostate cancer compared with the available standard, and may reduce the number of core biopsies required. They further noted that this was a new technique and practitioners should be trained in its application; the technique should be standardised and references standards should be agreed.

**Research**: The authors stated that further better-designed studies were needed to assess the role of transrectal elastosonography in the diagnosis of prostate cancer. They specified that studies should use standardised ultrasound parameters, agreed reference standards, and be adequately powered to assess relevant outcomes (outcome measures must include outcomes assessed by patients and ideally health economic outcome measures). They further stated that the impact of transrectal elastosonography detection on the Gleason pattern of prostate cancer, location of disease, size
of lesions, need for repeat biopsies, and correlation with multiparametric magnetic resonance imaging findings need to be examined.

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