Real-time US versus CT determination of pubic arch interference for brachytherapy

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Real-time transrectal ultrasonography (US) in the dorsal lithotomy position using a model 128-XP scanner (Acuson) was compared with computed tomography (CT) in the supine position using a helic CT with 5-mm collimation (HiSpeed Advantage, GE Medical Systems).

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The population comprised patients with prostate gland carcinoma who were likely to require treatment with brachytherapy.

Setting
The setting was secondary care. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and cost data were collected between October 3rd 1997 and May 5th 1998. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
The authors did not report that power calculations were conducted to rule out the influence of chance on their results. To determine the accuracy of US, the sample comprised patients undergoing transrectal US for the determination of potential PAI during the dates of the study. The evaluation on new patients was stopped when the researchers were convinced that US had a high accuracy. The initial sample was appropriate for the study question since it included patients with potential PAI. No specific inclusion or exclusion criteria were reported. Fourteen patients were included in the assessment of US.
To compare the accuracy of CT with US, the sample included patients who underwent US and CT within 21 days of each other and who did not receive hormone therapy (to reduce the size of the prostate and so reduce the PAI) in the interim. There were 64 patients in the comparison of US and CT, 32 in each group. The mean age was 67.3 years (standard deviation, SD=7.2) in the CT group and 68.5 years (SD=6.4) in the US group.

**Study design**

There were two parts to the study of diagnostic accuracy. The first part determined the accuracy of transrectal US prediction of PAI. The reference standard was determined during follow-up, according to whether or not there was actual PAI at needle placement. The second part determined the accuracy of CT by using US as the reference test, as the first part of the study had shown US to be highly sensitive and specific (see 'Effectiveness Results' section). For the second part, both tests were performed on every patient included in the analysis. The authors stated that the tests were performed within 21 days of each other to minimise any possible changes to gland size. The authors did not report any blinding to the result of the first test.

**Analysis of effectiveness**

The sensitivity and specificity of US and CT were determined. The two groups were compared in terms of prostate volume at US, Gleason score, PSA level and TNM stage. They were reported to differ statistically in the size of the prostate. Prostate size may therefore have acted as a confounding factor.

**Effectiveness results**

US was 100% sensitive (95% confidence interval, CI: 40 - 100) and 100% specific (95% CI: 69 - 100).

CT was 100% sensitive (95% CI: 40 - 100) and 0% specific (95% CI: 0 - 52).

PAI overlap at US ranged from -5 to 7 mm (mean: 0.4 +/- 3.6). Note that the value of -5 mm indicated that there was a clearance.

PAI overlap at CT ranged from 8 to 20 mm (mean: 12.2 +/- 3.4).

**Clinical conclusions**

The authors concluded that their initial analysis confirmed that US was able to diagnose PAI accurately and that CT resulted in an overestimation of PAI.

**Measure of benefits used in the economic analysis**

The authors did not estimate a summary measure of health benefit. In effect, a cost-consequences analysis was conducted.

**Direct costs**

A perspective for the analysis was not reported, but it appears to have been that of the hospital or third-party payer. Discounting was not reported to have been carried out. However, the authors were interested in the immediate costs of screening and the study continued for less than one year (October 1997 to May 1998), thus making discounting unnecessary. The authors were concerned with the cost of the planning, staging and volume determination of US and CT examinations and that of hormone therapy. US and CT may be performed following the initial PAI assessment. The source of these cost estimates was not reported. The duration of hormone therapy used in the analysis was based on the mean duration of use from patients in the clinical study. The unit costs and the quantities were reported separately.

**Statistical analysis of costs**

No statistical analysis of the costs was reported.
**Indirect Costs**
The indirect costs were not reported to have been estimated, but would not have been relevant if the perspective were that of the hospital or third-party payer.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was reported.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The total cost (US, CT and hormone therapy) of all patients in the US group was $38,102. The cost per patient was $1,191.

The total cost (US, CT and hormone therapy) of all patients in the CT group was $84,996. The cost per patient was $2,656.

Examination with US saved $1,465 per patient.

**Synthesis of costs and benefits**
Not relevant.

**Authors' conclusions**
Computed tomography (CT) is unnecessary for the determination of pubic arch interference (PAI). It results in the overestimation of PAI and costs $1,465 more per patient.

**CRD COMMENTARY - Selection of comparators**
The authors compared US and CT in the determination of PAI. These alternatives were well explained with CT representing standard practice at the outset of the study. The hypothesis stated by the authors, that the difference in ability to detect PAI was due to patient position, could not necessarily be proven or refuted with the current study design.

**Validity of estimate of measure of effectiveness**
The analysis used a diagnostic design assessing the sensitivity and specificity of alternative methods of PAI determination. This design was appropriate for the authors' stated objectives (although not the specific hypothesis). The study sample was representative of the population since it included patients with prostate gland carcinoma who had suspected PAI. The two groups were compared at analysis, and differences in prostate gland size were highlighted and discussed. The authors acknowledged that this difference may well be a confounding factor in the results, but did not take any steps to reduce the impact of this potential bias.

**Validity of estimate of measure of benefit**
The authors did not estimate a summary measure of benefit. Therefore, in effect, a cost-consequences analysis was
Validity of estimate of costs
A perspective for the costing analysis was not reported, thus it is not possible to assess whether all the relevant costs were included. However, the costs estimated appear to represent the perspective of the hospital or third-party payer. Hospital overheads and staff time were not included in the estimates. Given the large actual and relative difference in cost between the two alternatives, small omissions in costs may well not have affected the authors' principal conclusions. The unit costs and the quantities were reported separately. This enables the reader to gain a good understanding of the key cost drivers and to apply the results to their own setting. However, the analysis would have been greatly improved had the source of the cost estimates and a price year been reported.

Other issues
The authors made appropriate comparisons of their findings with those of other authors, discussing work that found similar benefits of US. The issue of generalisability to other settings was not explicitly addressed. The results were not presented selectively. Although the conclusions were an accurate reflection of the scope of the study and of the results presented, the authors did not stress that US was shown to be a dominant strategy (giving greater sensitivity and specificity at a lower cost). A number of limitations were mentioned. Most notably, some patients with PAI at CT underwent hormonal therapy and did not undergo US until completion of this therapy. They were therefore not included in the study, thus creating selection bias.

Implications of the study
The authors recommended that CT "should be performed only if indicated for detecting possible distant metastases". There were no suggestions for further work.

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