Pain after transrectal ultrasonography-guided prostate biopsy: the advantages of periprostatic local anaesthesia

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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
The health intervention examined in the study was periprostatic local anaesthesia (LA) during prostatic biopsy guided by transrectal ultrasonography (TRUS).

Type of intervention
Other: anaesthesia.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients requiring TRUS-guided biopsy and presenting an abnormal DRE and/or raised PSA level. Patients with a bleeding diathesis or on anticoagulation therapy, or with a history of radical prostatectomy or radiotherapy were excluded from the study.

Setting
The setting was hospital. The economic study was conducted at the Departments of Radiology and Urology at St George's Hospital in London, UK.

Dates to which data relate
Neither dates nor price year were reported.

Source of effectiveness data
A single study was used as the source of effectiveness evidence.

Link between effectiveness and cost data
The costing appears to have been performed prospectively on the same patient sample as that used in the effectiveness analysis, although very little detail was reported.

Study sample
Power calculations were not performed. A sample of 157 patients referred to the study hospital over a seven-month period was enrolled in the study. The patients were then randomised to receive either LA or no-LA: seventy-three subjects (mean age: 67.6 years; age range: 53 - 88 years) were included in the no-LA group and 85 patients (mean age: 68.2 years; age range: 45 - 88 years) in the LA group.
Study design

This was an open, randomised clinical trial, carried out in a single centre. Randomisation was performed sequentially. Patients were followed for one week and loss to follow-up was 19% in the no-LA group and 12% in the LA group.

Analysis of effectiveness

The clinical analysis was based on treatment completers only as only those patients who returned the questionnaire were evaluated. The health outcomes estimated in the analysis were pain severity; general practitioner (GP) visits after biopsy; episodes such as fever, pain, bleeding, or other adverse effects; use of analgesics; and number of days with haematuria, haematochezia, or haematospermia. Pain severity was assessed using a questionnaire based on a four-point scale (1 = no pain; 2 = mild pain; 3 = moderate pain; and 4 = severe pain), the questionnaire was given immediately after biopsy, and at varying intervals for one week afterward. The questionnaire was validated through a pilot study of 20 patients who underwent a biopsy with no-LA. The authors stated that study groups were generally comparable at baseline.

Effectiveness results

The effectiveness results were as follows:

The median pain severity at the time of biopsy was 1.95 (standard deviation, SD 0.65) in the no-LA group and 1.53 (SD 0.7) in the LA group and this difference was statistically significant, (p<0.001).

Pain scores were similar at 1 hour after biopsy (no-LA, 1.59 (SD 0.76) versus LA, 1.58(SD 0.76)), but median pain scores for the whole week were significantly lower in the LA group (1.2 (SD 0.28)) than in the no-LA group (1.3 (SD 0.33)), (p=0.0185).

GP visits after biopsy were 7 in the no-LA group and 9 in the LA group (the difference was not statistically significant).

The episodes of adverse effects were:

fever 0 (no-LA) and 1 (LA); pain 1 (no-LA) and 1 (LA); bleeding 5 (no-LA) and 5 (LA); other adverse effects 2 (no-LA) and 5 (LA).

The median number of days with haematuria was no-LA 2.3 (SD 2.4) and LA 2.6 (SD 2.4), with haematochezia no-LA 0.36 (SD 0.89) and LA 0.55 (SD 1.1) and with haematospermia no-LA 0.69 (SD 1.2) and LA 0.65 (SD 1.3).

The percentage of patients who would repeat biopsy was 95% in the no-LA group and 93% in the LA group.

As regards use of analgesics, 7 men in the LA group (9%) used analgesia for 1-3 days, while 8 patients in the no-LA group (14%) used analgesics for 1-6 days.

Clinical conclusions

The effectiveness analysis showed that LA was more effective than no-LA in reducing pain after biopsy and was associated with a trend towards less analgesic use.

Measure of benefits used in the economic analysis

Health outcomes were left disaggregated and no summary benefit measure was used in the analysis, thus a cost-consequences analysis was conducted.

Direct costs

Discounting was not conducted due to the short time horizon of the study. The economic analysis included the costs of TRUS-guided biopsy, additional needles for LA administration, and extra-time for the periprostatic LA injection.
Costs of treatment of adverse effects were not included as no patients experienced complications. Unit costs were reported. The cost/resource boundary adopted in the study was not stated, but it was likely to have been that of the hospital. Resource use was estimated during the trial, and the source of costs appears to have been the hospital where the study was conducted. The price year was not explicitly stated, but costs were estimated in the period 1999-2000.

**Statistical analysis of costs**
Costs were treated deterministically.

**Indirect Costs**
Indirect costs were not included in the study.

**Currency**
UK pounds sterling (€).

**Sensitivity analysis**
Sensitivity analyses were not conducted.

**Estimated benefits used in the economic analysis**
Please refer to the effectiveness results above.

**Cost results**
The annual cost of TRUS-guided procedures was 65,366, at a cost of 203.06 per procedure. The additional needles used for LA administration cost 2.80 per patient. The cost of LA injection was 3.00 per patient (966 per annum). Additional time for LA injection was 2-3 minutes. As a result, the extra cost of LA was negligible when total costs of the procedure were considered.

**Synthesis of costs and benefits**
Costs and benefits were not combined as a cost-consequences analysis was conducted.

**Authors' conclusions**
The authors concluded that periprostatic LA infiltration was a safe and simple procedure in patients undergoing TRUS-guided biopsy. It was well tolerated and significantly reduced pain. Its additional cost was minimal.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. No anaesthesia was selected, as the aim of the study was to assess the active value of LA. You, as a user of this database, should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness analysis was based on a randomised clinical trial, carried out in a single centre. Sequential randomisation was performed to reduce both confounding and bias. Although by analysing treatment completers only the author's risked introducing bias due to non-random drop out. The study sample appears to have been representative of the study population. Study groups were comparable at baseline in terms of age and previous interventions. However, power calculations were not performed to determine the sample size and the authors provided no evidence that the initial study sample was appropriate for the study question.
Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study (see validity of effectiveness comments above).

Validity of estimate of costs
The perspective of the study was not explicitly stated and only costs strictly associated with the biopsy were included in the analysis. Unit costs were reported and quantities of resources used were collected during the trial. The source of cost data was not explicitly stated, but appears to have been the study hospital. Costs were treated deterministically and no sensitivity analyses were conducted. The price year was not stated, thus making it difficult to reflate cost estimates in other settings. Costs were quite specific to the study setting and as a result should be treated with caution when generalising to another setting.

Other issues
The authors compared their findings with those from other studies, but did not address the issue of the generalisability of the study results to other settings as no sensitivity analyses were conducted. Thus the external validity of the analysis was quite low. The study enrolled patients requiring biopsy for the diagnosis of prostate cancer and this was reflected in the conclusions of the analysis.

Implications of the study
The authors highlight the fact that LA represents routine practice at the study institution and further research should assess the impact of LA on fibrosis and nerve-sparing radical prostatectomy.

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