Comparison of palpation-guided fine-needle aspiration biopsy to ultrasound-guided fine-needle aspiration biopsy in the evaluation of thyroid nodules

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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 study examined two methods of fine-needle aspiration biopsy (FNAB) in the evaluation of thyroid nodules. The methods were palpation-guided FNAB and ultrasound-guided FNAB.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The patient population studied comprised nodular goiter patients who were admitted to the authors' outpatient thyroid clinic with four or fewer nodules.

Setting
The setting was secondary care. The economic study was carried out in Ankara, Turkey.

Dates to which data relate
The dates of the effectiveness and cost evidence were 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 economic analysis.

Study sample
A total of 215 consecutive patients (179 females) were enrolled in the study. Their mean age was 48.7 (+/- 13.5) years (range: 14 to 84). Eighty-five (39.5%) had a single nodule, 69 (32.1%) had two nodules, 33 (15.4%) had three nodules and 28 (13%) had four nodules. Further description of nodule types and sizes was given in the paper. Both forms of guided aspiration biopsy were used to evaluate 285 of the total 434 nodules in the same sample of 215 cases. Fifteen patients (7%) representing 26 nodules (9.1%) underwent surgery.

Study design
This was a diagnostic accuracy study. Both aspiration biopsy techniques were conducted on each nodule in the same order, namely palpation first and ultrasound second. The same operator performed all aspirations and the cytologist was kept blinded to which smears were performed in the guidance of either palpation or ultrasound.

**Analysis of effectiveness**
The data for all biopsies for both aspiration biopsy techniques were reported. The protocol permitted only one attempt per nodule using each of palpation-guided FNAB and ultrasound-guided FNAB. The primary outcomes used in the analysis were the rate of inadequate material, specificity, sensitivity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and the rates of false-negative and false-positive results.

**Effectiveness results**
The rates of inadequate material for palpation-guided FNAB (32.3%) and ultrasound-guided FNAB (21.4%) were significantly different, (p=0.004).

The nodules were divided arbitrarily into two groups. There were 157 (55.1%) small-sized nodules (10 - 15 mm) and 128 (44.9%) large-sized nodules (16 - 25 mm).

With palpation-guided FNAB, the rate of inadequate material was 59 (37.6%) for the small-sized group and 33 (25.8%) for the large-sized group, (p=0.03).

With ultrasound-guided FNAB, the rate of inadequate material was 38 (24.2%) for the small-sized group and 23 (18%) for the large-sized group, (p=0.02).

Comparing small- and large-sized groups with palpation-guided FNAB and ultrasound-guided FNAB revealed a statistically significant difference in small nodules only (37.6% versus 24.2%, p=0.009).

There was no statistically significant difference in large nodules (25.8% versus 18.0%, p=0.154).

In the sub-group of 26 nodules that underwent histology, the results for palpation-guided FNAB versus ultrasound-guided FNAB were as follows:

- sensitivity, 57.1% versus 85.7%;
- specificity, 84.2% versus 89.5%;
- PPV, 57.1% versus 75%;
- NPV, 84.2% versus 94.4%;
- accuracy, 76.9% versus FNAB 88.5%;
- false positives, 33.3% versus 25%; and
- false negatives, 15.8% versus 5.6%.

No statistical analysis of these findings was performed.

**Clinical conclusions**
The authors considered ultrasound-guided FNAB to be superior to palpation-guided FNAB with respect to obtaining adequate material, as well as providing a more accurate cytological evaluation.

**Measure of benefits used in the economic analysis**
There was no summary measure of benefits since a cost-consequences analysis was conducted.

**Direct costs**
Discounting was not required. To estimate the cost of procedures, the prices of thyroid ultrasonography, palpation-guided FNAB, ultrasound-guided FNAB and cytologic examination were obtained from 10 hospitals in the authors’ setting. The costs were then estimated using the mean price across the sample. Cost components, unit costs, resource quantities, dates and price years were not reported.

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

**Indirect Costs**
The indirect costs were not reported.

**Currency**
US dollars ($).

**Sensitivity analysis**
A second analysis considered the costs of performing second aspiration biopsies, using ultrasound-guided FNAB, in the event of inadequate material.

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

**Cost results**
The mean unit prices across 10 hospitals were $81.2 (+/- 65.3) for palpation-guided FNAB and $101.4 (+/- 86.8) for ultrasound-guided FNAB. Thus, the average difference was $20.2.

The total costs for the 285 nodules were estimated to be $17,458 for palpation-guided FNAB and $21,801 for ultrasound-guided FNAB.

In the sensitivity analysis, taking account of second aspiration biopsies in the event of inadequate material, the total costs increased to $26,787 (cost per case $124.6) for palpation-guided FNAB and $27,986 (cost per case $130.2) for ultrasound-guided FNAB. The unit cost-difference was $5.6.

**Synthesis of costs and benefits**
The costs and benefits were not combined.

**Authors' conclusions**
Ultrasound-guided fine-needle aspiration biopsy (FNAB) is a superior procedure to palpation-guided FNAB. The costs of the two methods do not differ significantly in Turkey or in other European countries where ultrasound-guided FNAB is less costly.

**CRD COMMENTARY - Selection of comparators**
The implicit justification for the comparators was that they were widely accepted as excellent diagnostic tools in the...
evaluation of thyroid nodules. It was unclear whether other diagnostic tools were excluded from the study. You should decide whether palpation-guided FNAB and ultrasound-guided FNAB represent current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a diagnostic accuracy study where both aspiration biopsy techniques were performed on each nodule in each patient. This was appropriate for the study question. The sample was one of convenience and is likely to represent the population of patients arriving at an outpatient clinic in Turkey. It was unclear how representative this group is of the wider population of patients with nodules requiring diagnosis. The analysis of effectiveness was handled credibly.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was, in effect, a cost-consequences study.

Validity of estimate of costs
Very little detail of the cost estimates was provided. It is not possible to judge whether all the relevant categories of costs were included because the costs and the quantities were not reported separately (a single price for each procedure being obtained from 10 local hospitals). No sensitivity analysis of the costs was conducted. Charges rather than unit costs might have been used. The price year was not reported.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was discussed, with the authors noting that the costs of the two treatments were similar or lower in other countries, but higher in the USA. The lack of clarity in the cost calculations means that the results reported could not currently be directly transposed to any other setting, even within Turkey. The authors did not present their results selectively. The authors’ conclusions do not adequately take the cost-difference between the techniques and the uncertainty into consideration. When the authors stated that the cost-difference was not significant, this was not in a strict statistical sense but was merely a point of view. The authors noted that the relatively small number of cancers in the surgical cases made it difficult to assess, for example, the true sensitivity and specificity. They did not note any further limitations to their study.

Implications of the study
The authors suggested that ultrasound-guided FNAB should always be used for nodules smaller than 15 mm in diameter and should be preferred for nodules larger than 15 mm in diameter.

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