

Neck lump clinics: is on-site assessment of fine needle aspirate diagnostic adequacy cost-effective?

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Abstract

Objectives: To establish the diagnostic adequacy of ultrasound-guided fine needle aspiration cytology samples at the East Berkshire neck lump clinic, and to perform a cost-benefit analysis related to the hypothetical addition of an on-site cytology technician (required to review fine needle aspiration specimen adequacy).

Method: The adequacy of all ultrasound-guided fine needle aspiration procedures was reviewed from 1 January to 30 June 2011. These results were used in the cost-benefit analysis related to on-site cytology assessment.

Results: Of the 307 ultrasound-guided fine needle aspiration cytology procedures performed over 6 months, 67 (22 per cent) were reported to be non-diagnostic. Operator experience was found to correlate significantly with diagnostic adequacy ($p < 0.001$). Only 5 per cent of all fine needle aspirations were initially non-diagnostic but diagnostic on repeat sampling. This suggests that the financial and time costs of on-site fine needle aspirate adequacy assessment would outweigh any benefit.

Conclusion: In this series, the experience of individuals performing fine needle aspirations was the most important factor related to adequacy.

Key words: Neck; Biopsy, Fine-Needle; Ultrasonography; Cost-Benefit Analysis

Introduction

A rapid-access clinic, dedicated to the assessment and management of patients with neck lumps, was established for the East Berkshire catchment area in 1996, as described by Vowles *et al.*¹ At its inception, the clinic was staffed by one consultant otolaryngologist and one consultant radiologist. All new patients who presented with neck masses underwent an ultrasound scan of their neck, as well as an ultrasound-guided fine needle aspiration (FNA) biopsy of the lump if clinically appropriate; these investigations were performed by the attending radiologist. In order to cope with an expanding local patient population and consequent increased demand, the staffing level was subsequently increased to two consultant ENT surgeons, and one consultant oral and maxillofacial surgeon. In addition, two consultant radiologists now perform ultrasound scans and FNA biopsies. The clinic takes place on a weekly basis as before.

At present, the East Berkshire neck lump clinic is not truly a 'one-stop' service as cytological analysis of FNA specimens takes place at a different site to the clinic. The lack of an on-site cytologist increases the

risk that the FNA specimens obtained under ultrasound guidance may not give diagnostic information, on account of insufficient cellular material or contamination with excessive blood. This in turn may result in diagnostic delay and repeated clinic attendances for the purposes of further FNA attempts. Indeed, guidance published by the National Institute for Health and Clinical Excellence (NICE) in 2004 recommended that a neck lump clinic setup should also include 'an experienced on-site cytologist who can provide FNA [cytology] in the clinic to determine the nature of the lump'.² These guidelines do acknowledge, however, the 'significant cost implications' associated with this recommendation, with an estimated annual cost of providing this service of £20 000 per clinic.

At the East Berkshire neck lump clinic, the recruitment of an on-site cytologist (to perform diagnostic cytological analysis of FNA samples as per the NICE guidelines) is not currently deemed feasible, primarily on account of an absence of suitable laboratory infrastructure at the clinic site. A more realistic alternative is the employment of an on-site cytology technician to assess the adequacy of FNA samples obtained by the radiologists.

This study aimed to assess the potential benefits of an on-site cytology technician. This involved an initial review of the diagnostic adequacy of radiologist-performed ultrasound-guided FNA biopsies over a six-month period at the East Berkshire neck lump clinic. The results from this analysis were in turn used with other published data to estimate the costs of employing an on-site cytology technician, thereby allowing a cost-benefit calculation to be conducted.

Materials and methods

Details of all ultrasound examinations and FNA procedures performed at the East Berkshire neck lump clinic from 1 January to 30 June 2011 were obtained from the Heatherwood and Wexham Park Picture Archiving and Communication Systems and electronic pathology results database respectively. The electronic patient records were also examined to identify all those patients with initially non-diagnostic FNAs, in order to determine their ultimate outcome. To facilitate data analysis, neck lump types were divided into those originating from lymph nodes, salivary glands, thyroid or other tissue.

Results and analysis

Twenty-one clinics took place over the six-month period reviewed. In total, 465 ultrasound scans were performed over this period. Seventy-three per cent of these patients were female. The median age of the patients was 51 years (range 1–94 years). In total, 307 FNA procedures were performed in conjunction with an ultrasound scan. Approximately one-third of all the ultrasound scans performed (158 of 465, 34 per cent) provided diagnostic information that did not require an FNA. This situation arose most commonly for lymph nodes in the neck, where ultrasound can readily distinguish benign from malignant nodes on the basis of sonographic criteria.^{3,4} Patients with nodes deemed to be benign in appearance did not undergo FNA analysis. In addition, a number of patients referred with neck lumps did not have lumps that were suitable for FNA analysis, for instance patients who were found to have cervical ribs.

Of the 307 FNA procedures carried out, 184 (60 per cent) were performed for lumps arising from the thyroid gland, with the remaining lumps arising from enlarged lymph nodes, salivary glands and miscellaneous other sources (Figure 1). Sixty-seven of the FNA procedures (22 per cent) were reported to be non-diagnostic. Fine needle aspirate diagnostic adequacy was not related to tissue of origin as a whole (Table I), although 12 of the 21 FNAs obtained from isolated thyroid cysts (57 per cent) did not contain diagnostic cellular material. Fine needle aspirate adequacy was, however, found to be significantly related to the experience of the radiologist performing the FNA. With regards to the radiologist who had been working with the neck lump clinic since 1996, the non-diagnostic rate was 14 per cent (29 out of 211

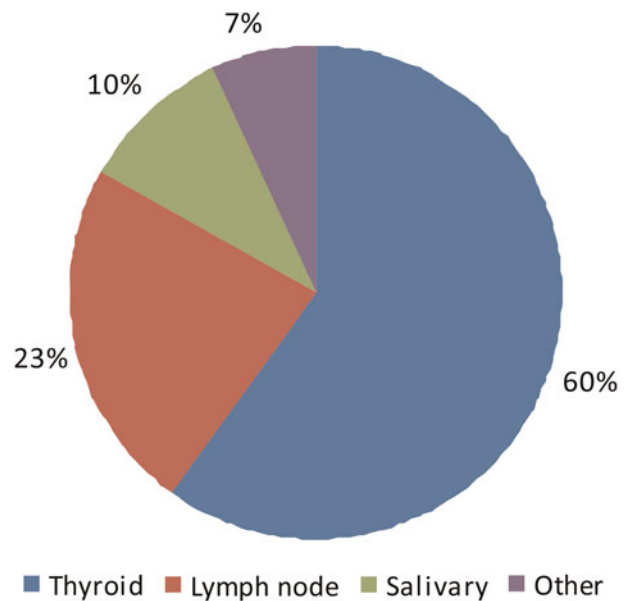


FIG. 1

Tissue of origin of fine needle aspiration samples obtained at the East Berkshire neck lump clinic from January to June 2011.

samples); by contrast, the non-diagnostic rate for the second radiologist appointed on a short-term basis in 2010 was 40 per cent (38 out of 96 samples). This difference was statistically significant ($p < 0.001$, analysed using the chi-square test).

Of the 67 non-diagnostic FNA specimens, 56 (84 per cent) were not associated with a subsequent diagnosis of malignancy. From the 11 non-diagnostic specimens that were subsequently found to be cancerous, 7 were associated with a diagnosis of lymphoma on subsequent excision biopsy (suspicion of this diagnosis having been raised by ultrasound criteria), 2 with a diagnosis of upper aerodigestive tract squamous cell carcinoma that had spread to the cervical lymph nodes (diagnosed on repeat FNA), 1 with anaplastic carcinoma of the thyroid (diagnosed on a follow-up core biopsy performed at the neck lump clinic) and 1 with a rare malignant peripheral nerve sheath tumour (diagnosed on open biopsy).

Of the 67 initially non-diagnostic FNA specimens, 28 (42 per cent) were associated with a subsequent diagnostic FNA. The results of these repeat FNAs were consistent with: benign thyroid pathology

TABLE I
FINE NEEDLE ASPIRATE ADEQUACY BASED ON TISSUE TYPE

Origin of FNA	Non-diagnostic rate (%)
Thyroid	20
Lymph node	25
Salivary	20
Other	30

FNA = fine needle aspirate

(graded as Thy 2) in 18 patients, reactive lymphadenopathy in 4 patients, indeterminate thyroid pathology or a follicular neoplasm (Thy 3) in 3 patients, metastatic squamous cell carcinoma in 2 patients and lymphoproliferative disorder in 1 patient.

Of the 39 patients with non-diagnostic FNAs who did not have a repeat diagnostic FNA, 18 were deemed to have benign pathology on clinical grounds, and had either been discharged or were under continued follow up at the time of writing. This cohort mostly presented with thyroid cysts. A further 18 patients underwent surgical removal of their neck lump for diagnostic or therapeutic purposes. A diagnosis of lymphoma was the most common outcome in this second cohort, followed by tuberculous and reactive lymphadenitis. Of the remaining three patients, one was diagnosed with cervical tuberculous lymphadenitis following growth of mycobacterium tuberculosis from their initial needle aspirate, one was lost to follow up and one died of unrelated causes prior to follow up.

Cost-benefit analysis

It has been suggested that on-site cytological assessment of neck lump FNA adequacy could help to reduce the diagnostic investigation time and lessen the number of follow-up appointments a patient must attend by permitting the immediate repetition of non-diagnostic FNAs at the first clinic visit. This potentially results in financial savings for a trust, and reduces the likelihood of non-compliance with cancer waiting time targets and the associated financial penalty. It is important to note, however (as exemplified by the results above), that not every non-diagnostic FNA will be diagnostic if repeated. This is especially true for cases of suspected lymphoma presenting with cervical lymphadenopathy: in order to diagnose and classify lymphoma, information regarding the architecture of a lymph node is required, which can only be obtained with a core biopsy or open surgical biopsy.^{5,6} It is primarily for this reason that only 42 per cent of initially non-diagnostic FNAs were repeated and found to be diagnostic.

Taking this figure into account, there were only 28 non-diagnostic FNAs associated with a subsequent diagnostic FNA (5 per cent of all FNAs performed over the 6-month period) that could in theory be detected by an on-site cytology technician. These 28 inadequate FNAs could be repeated immediately, potentially saving 28 follow-up appointments and associated ultrasound scans. In addition, the 28 non-diagnostic FNAs would not require a cytologist report, representing a saving of 420 minutes (7 hours) of cytologist time if one assumes that it takes 15 minutes to report an FNA specimen.

From a financial perspective, the cost of a follow-up appointment for ENT departments, according to the national Payment By Results tariff, is £63.⁷ No cost information is available for an ultrasound-guided

FNA, but the tariff for an ultrasound that takes longer than 20 minutes is £66.⁷ A cytologist is reported to cost £81 per hour.⁸ The potential financial savings associated with the detection and immediate repetition of non-diagnostic FNAs, over 6 months, would therefore be: $(28 \times £63) + (28 \times £66) + (7 \times £81) = £1764 + £1848 + £567 = £4179$. The cost of employing a cytology technician to assess FNA adequacy is reported to be £20 per hour.⁸ With 21 clinics over the 6 month period, each lasting 3 hours, the cost of on-site cytology assessment would be: $21 \times 3 \times £20 = £1260$. In theory, the net saving associated with on-site cytology assessment of neck lump FNAs by a cytology technician is $£4179 - £1260 = £2919$ over 6 months, or £5838 per annum. A flow chart illustrating these cost comparisons is presented in [Figure 2](#).

Unfortunately, not every non-diagnostic FNA will be detected through a process of on-site cytology assessment: only a reduction in the non-diagnostic rate can be expected, rather than elimination of non-diagnostic FNAs completely. The figures available for the reduction in non-diagnostic FNAs through on-site cytology assessment range from 70 per cent at best⁸ to no difference whatsoever.⁹ At best, therefore, the financial savings associated with on-site cytology assessment are in fact $(70 \text{ per cent} \times £4179) - £1260 = £1665$ per 6 months or £3330 per annum. A reduction in the non-diagnostic FNA rate of 30 per cent or less will result in the costs of an on-site cytology technician outweighing the potential savings.

A further limitation of on-site FNA cytology assessment is the extra time required for such an assessment to be performed. One study reported a significantly longer procedure time for ultrasound-guided FNAs with immediate cytological adequacy assessment (mean 44.4 minutes) compared with procedures without cytology assessment (mean 12.5 minutes).⁹ Furthermore, immediate cytology assessment was not found to improve diagnostic yield significantly in that study. A separate study found that immediate cytological adequacy assessment of thyroid FNAs resulted in a drop in the non-diagnostic rate from 14 to 9.5 per cent, but at a cost of 220 minutes of cytologists' time per additional diagnostic specimen.¹⁰ On-site cytology assessment of FNAs obtained at the East Berkshire neck lump clinic is therefore likely to impede patient throughput significantly; this is already limited, primarily by ultrasound scanning capacity.

Discussion

The overall non-diagnostic rate of 22 per cent for ultrasound-guided FNAs performed at the East Berkshire neck lump clinic compares quite favourably with other published data from the UK. A study by Howlett *et al.* published in 2007 reported a non-diagnostic rate of between 30 and 52 per cent for FNAs of neck lumps within the Sussex cancer network; the higher figure represents the non-diagnostic rate of palpation-guided FNAs of neck nodes, while the lower

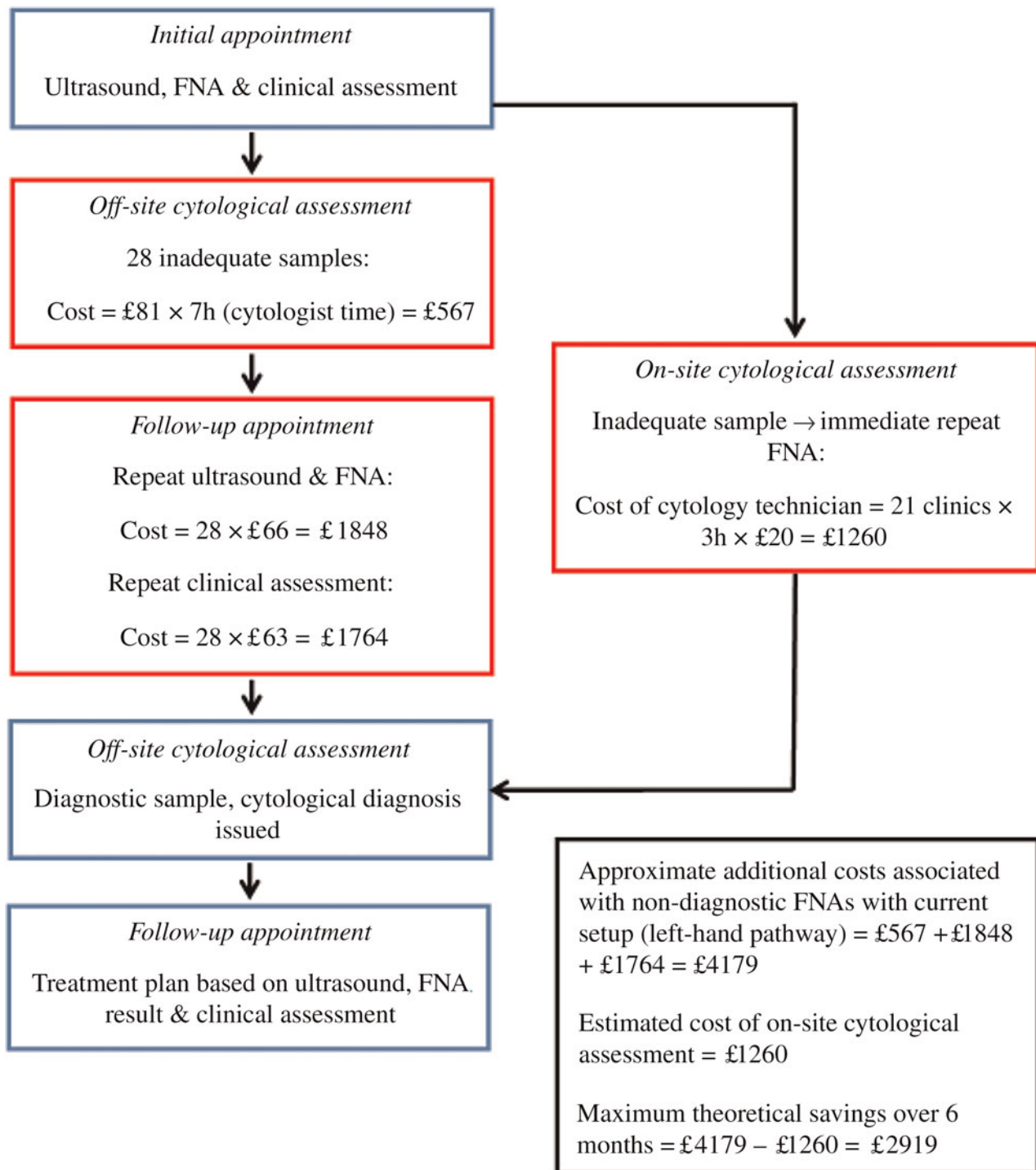


FIG. 2

Costs associated with inadequate fine needle aspirate (FNA) samples over six months ($n = 28$), showing comparison of current neck lump clinic setup (left-hand pathway) with hypothetical costs of on-site assessment of FNA adequacy by a cytology technician over six months (right-hand pathway). FNA = fine needle aspiration; h = hours

figure represents the non-diagnostic rate of ultrasound-guided FNAs of thyroid lumps.¹¹ Carr *et al.* demonstrated a 28 per cent non-diagnostic rate from an audit of neck lump FNAs conducted at Leeds General Infirmary.¹² Interestingly, this rate was the same both with and without ultrasound guidance, but this may relate to the reservation of ultrasound use for thyroid FNAs (acknowledged by the authors to be more

technically challenging), and presumably other smaller or less readily palpable neck lumps as well.

One study from Yale (by Ghofrani *et al.*) identified an overall non-diagnostic rate of 7.1 per cent for ultrasound-guided thyroid FNAs.¹³ It was also observed that the FNA diagnostic rate was proportional to radiologist experience, with a non-diagnostic rate of 5.4 per cent for experienced radiologists compared with 13.0

per cent for radiologists with less experience (in the absence of on-site cytological assessment). That study was described as being the first to look specifically at operator experience. The results from our series would appear to corroborate the findings of that study. Although our data indicate that experience accounts for a more marked reduction in FNA non-diagnostic rates in absolute terms than that of Ghofrani *et al.* the difference is less notable in relative terms: greater experience was associated with a 65 per cent reduction in the observed FNA non-diagnostic rate in our data series, which is similar to the 58 per cent reduction noted by Ghofrani *et al.*

- **Diagnostic adequacy of fine needle aspirate (FNAs) from neck lumps depends on a number of factors may be better?**
- **On-site cytology assessment of FNAs may improve diagnostic rate may be better?**
- **In this study, the key factor relating to FNA adequacy was operator experience**
- **Benefits of on-site FNA adequacy assessment are unlikely to outweigh associated costs**

With regards to the cost-benefit analysis, the data from the current study suggest that the employment of a cytology technician to assess FNA adequacy is unlikely to be cost-effective. There is evidence to suggest that immediate cytological assessment of FNA samples from neck lumps may not be beneficial.⁹ In addition, the increased procedural time associated with on-site cytological assessment is likely to impede patient throughput to the extent that a significant increase in the number of clinics (or extra ultrasound-guided FNA slots at a minimum) would be required in order to maintain current patient throughput. The costs associated with this will almost certainly outweigh the theoretical £3330 savings per annum by a significant margin.

Investment in a dedicated, experienced head and neck radiologist to perform neck lump FNAs is likely to be the most helpful intervention to reduce the non-diagnostic rate of FNAs performed in our neck lump clinic, rather than on-site cytology assessment. Further work to compare non-diagnostic FNA rates and FNA procedure times at centres that employ immediate cytological assessment with those that do not have such a facility would perhaps help to resolve any remaining uncertainty regarding the cost-effectiveness of on-site

cytological adequacy assessment in the context of neck lump clinics.

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