Clinical audit of ultrasound guided fine needle aspiration in a general cytopathology service

**ABSTRACT**

**Background:** Studies on ultrasonography (USG) guided fine needle aspiration cytology (FNAC) have been conducted in specialized settings such as thyroid, breast, and intra-abdominal aspirates. There is a paucity of literature on the practices of guided FNAC in a general cytopathology service.

**Aim:** The aim was to determine prevailing practices of USG guided FNAC in a general cytopathology service of a teaching hospital.

**Settings and Design:** Metropolitan hospital, clinical audit.

**Materials and Methods:** Audit of 112 USG guided percutaneous FNAC done over 12 months.

**Statistical Analysis:** Data were coded, entered in an excel spreadsheet and analyzed by translating into percentages and proportions.

**Results:** The 112 guided FNACs included constituted 36 thyroid (32.14%), 45 intra-abdominal (40.17%), 11 breast (9.82%), 10 superficial lymph node (8.92%) and 10 soft tissue and miscellaneous (8.92%) lesions. Previous freehand FNAC was documented on the requisition forms in 14 cases. The reports were: Inadequate 33 (29.46%), nondiagnostic descriptive 35 (31.25%) or diagnostic 44 (39.28%). Inadequacy rates of aspirates from thyroid were 11 (30.56%) breast were 2 (18.18%), and intra-abdominal lesions were 13 (28.88%). Majority of the reports were nonstructured: 108 (96.42%) and nonrecommendatory: 101 (90.17%).

**Conclusions:** Reporting practices varied and did not conform to a uniform structure. The inadequacy rates of breast and thyroid aspirates were comparable to the rates in the literature. Comparable studies were not available for intra-abdominal aspirates.

**Key words:** Clinical audit; cytopathology; fine needle aspiration biopsy; fine needle aspiration cytology

**Introduction**

Audit means a systematic and critical evaluation of the services and is essentially a cyclical process, a re-audit being performed after incorporating the recommendations provided.[1] Clinical audits in the laboratory are useful for assessing and modifying the prevailing laboratory and clinical practices, and providing feedback to its users.[2]

US-guided fine needle aspiration (FNA) service can improve inadequacy and patient satisfaction remarkably if used judiciously with proper indications and supervision;[3,4] however, freehand FNA cytology (FNAC) is a more cost effective technique.[5]

Ours is a general cytopathology service in a teaching hospital where patients are referred from all the hospital departments to a clinic located in the out-patients department. In our setup ultrasonography (USG) guided FNAC is conducted twice a week in the Radiology Department with a portable ultrasound machine. The service is run jointly by Pathology and Radiology Departments. Inadequate aspirates and the need to repeat the procedure are inherent to our system because ours is a teaching institution, involving the training of postgraduate students and residents. Various studies have...
been conducted in specialized settings such as thyroid, and breast aspirates.\textsuperscript{6-10} We could not find any studies on the practices of USG guided FNAC in a general cytopathology service, without specialized clinics. This audit was carried out in order to identify problem areas and to take remedial measures.

Materials and Methods

The study setting was a tertiary care, teaching hospital in a metropolitan city. All the USG guided FNAC over a period of One-year were included in a retrospective, analytical, clinical audit of laboratory services. Clearance from the ethical committee of the institution was obtained; patient anonymity was maintained by coding the data. As previous data for comparison of the prevailing practices was not available; this was a primary data collection. Data were collected from the cytopathology records. Details included patients’ age and sex; site of guided FNAC; size of the lesion; the outcome of the aspirate; outcome of the previous freehand FNAC, if conducted; relevant radiological investigations, if documented; and whether the report was structured or recommendatory.

The outcome of the reports issued was recorded as diagnostic, nondiagnostic descriptive, or inadequate. During the period of the audit, the Bethesda system of thyroid cytopathology reporting was in use in our laboratory.\textsuperscript{11} We documented whether complete or incomplete radiological details were recorded on the cytopathology requisition forms. Radiological findings with diagnostic interpretation were taken to constitute complete radiological details. Only description or listing of the radiological findings without interpretation was taken to constitute incomplete radiological details. Data were entered in a spreadsheet and analyzed by translating it into percentages and proportions.

Search strategy

PubMed search using (clinical audit) AND (biopsy, fine needle); and (USG, interventional) AND (biopsy, fine needle) yielded 24 and 228 results, respectively. The audits in this search pertained to specialized breast and thyroid clinics. A search of the Cochrane database using keywords “clinical audit OR medical audit” yielded 19 results. None of these audits reviewed data on USG guided FNAC; however, one large review of 118 studies\textsuperscript{12} focusing on audits and feedback was found. With this strategy, combined with a manual search, we were unable to find an audit of USG guided FNA in a general cytopathology service.

Results

During the 12 month period of the audit, out of 7795 FNAs, 112 USG guided FNACs were performed. The patients were seen by appointment, twice a week.

A total of 55 (49.10%) out of the 112 patients undergoing USG guided FNAC were between 30 and 50 years of age; 30 (26.79%) were more than 50 years of age; 16 (14.29%) were <20 years of age; 80 (71.42%) were females.

The number of USG guided FNACs conducted by organ were recorded. Of the 112 guided aspirates conducted, 45 (40.17%) were from intra-abdominal lesions, 36 (32.14%) from thyroid, 11 (9.82%) from breast, 10 (8.92%) from superficial lymph nodes and 10 (8.92%) from soft tissues and other miscellaneous sites. The 45 intra-abdominal aspirates included 10 lesions of intra-abdominal lymph nodes, 9 gastrointestinal tract, 9 gall bladder, 7 liver, 4 ovary, 4 spleen, and 1 each from kidney and pancreas.

The size by ultrasound of the lesions taken-up for guided FNAC is given in Table 1. The size of the lesions was not recorded on the cytopathology requisition forms in 67 (59.82%) out of the 112 aspirates performed, 37 (33.03%) lesions were recorded as more than 1 cm in size, and 8 (7.14%) as <1 cm in size.

Record of previous freehand FNAC conducted was available in 14 (12.50%) out of the 112 aspirates performed under ultrasound guidance. The 14 previous freehand FNAC included 6 thyroid aspirates, 4 superficial lymph nodes, 3 breasts, and 1 intra-abdominal aspirate. These 14 aspirates included 7 inadequate, 4 nondiagnostic descriptive, and 1 diagnostic

| Organ                      | Size (mm) | <5 | 5-10 | 10-20 | >20 | Not recorded | Total |
|---------------------------|-----------|----|------|-------|-----|--------------|-------|
| Thyroid                   |           | 1  | 2    | 8     | 1   | 24           | 36    |
| Breast                    |           | 0  | 2    | 2     | 3   | 4            | 11    |
| Superficial lymph nodes   |           | 0  | 2    | 2     | 2   | 4            | 10    |
| Intra-abdominal lesions   |           | 0  | 0    | 15    |     | 30           | 45    |
| Soft tissues and miscellaneous |       | 1  | 0    | 2     | 2   | 5            | 10    |
| Total                     |           | 2  | 6    | 14    | 23  | 67           | 112   |


aspirate. The outcomes of 2 previous freehand FNACs were not documented on the cytopathology requisition forms.

Complete details of radiological investigations were not recorded on any of the forms. Radiological investigations were incompletely documented in 82 (73.21%) cases and not documented in 30 (26.78%).

The outcomes of the aspirates conducted are given in Table 2. Of the 112 aspirates conducted, 44 (39.28%) were diagnostic, 35 (31.25%) reports were nondiagnostic descriptive, and 33 (29.46%) were inadequate.

The 36 aspirates from thyroid included 16 (44.44%) diagnostic reports, 11 (30.55%) inadequate reports, and 9 (25.0%) nondiagnostic descriptive reports. The 11 aspirates from breast included 5 diagnostic reports, 4 descriptive reports, and 2 inadequate reports. The superficial lymph nodes included 5 inadequate reports, 3 diagnostic reports, and 2 descriptive reports. The 45 intra-abdominal aspirates included 20 (44.44%) diagnostic reports, 13 (28.88%) inadequate reports, and 12 (26.66%) nondiagnostic descriptive reports.

Of the 112 aspirates conducted 108 (96.42%) reports issued were not structured, and 101 (90.17%) reports issued were not recommendatory.

Discussion

We were surprised by the small numbers of guided FNAC. Prior to this audit, the general perception in our department was otherwise. We now think that, USG guided FNA appear to generate a disruption in the general work-flow disproportionate to their numbers; and, therefore, need to be addressed and reformed.

Intra-abdominal lesions in this audit included lesions of the gastrointestinal tract, gall bladder, liver, intra-abdominal lymph nodes, ovary, spleen, kidney, and pancreas. We were unable to find in the literature studies describing the spectrum of patients with abdominal lumps taken-up for guided FNAC. Although, collectively this was the largest group, the variety of organs sampled were diverse. For definite conclusions to be drawn in this context, larger series of each organ may have to be audited.

The published audits and studies on guided FNAC were all conducted in western countries where specialized clinics are a norm.[13,14] In developing countries such as ours, most teaching institutions and government hospitals run a general cytopathology service. An understanding of the pitfalls of introducing such a service may be helpfull to them.

Varying recommendations have been provided in the literature regarding the use of guided FNAC in different organs.[3,8,9,15] For thyroid lesions, USG guided aspiration was initially recommended for lesions that were difficult to palpate, were predominantly cystic or had undergone a previously unsuccessful palpation guided biopsy.[3,16] A thyroid nodule detected by an imaging study having suspicious USG features (microcalcifications, local invasion, lymph node metastases, marked hypoehogenicity, irregular margins, solid composition, absence of a hypoechoic halo around the nodule, size > 1 cm, taller than wide shape, and intra nodular vascularity) should be considered for USG guided FNAC.[14,17] Thyroid cysts should be drained, and any residual solid component visible on ultrasound should be aspirated under guidance.[18] Few studies recommended universal application of ultrasound guidance for thyroid FNAC in view of increased accuracy and adequacy.[8] USG guided breast FNAC had been developed to sample the impalpable breast lesions detected during breast screening.[13] However, palpation guided FNAC is more cost effective as compared with USG guided FNAC as it can be performed without an ultrasound machine or assistance from other practitioners.[14] Our case mix is different, probably because the majority of our patients present with advanced disease and palpable lumps. We do not have a mammographic screening program for healthy, at risk women, which probably explains the small numbers of USG guided breast aspirates in this audit.

In our study, the size of the lesions, by ultrasound [Table 1], ranged from <5 mm to more than 2 cm, however; in the majority 67 (59.82%) of the cases the size of the lesion was not recorded on the cytopathology requisition forms. There was also no documentation whether the lesions were palpable or nonpalpable. Record of previous freehand FNAC was available in only 14 (12.50%) out of 112 aspirates, of which 11 were nondiagnostic. Radiological investigations were incompletely documented in 82 (73.21%) of the lesions and not documented at all in 30 (26.78%) of the lesions.
Patients are usually taken up for guided FNAC only when freehand FNAC performed is nondiagnostic, or when nonpalpable lesions are radiologically detected. A clear documentation of the indication though was not available on the forms, which limited our ability to comment on why US guided aspirates were requisitioned for these patients. We need to design a structured format for our requisition forms for USG guided FNA, so that this information is uniformly available for all patients.

The outcomes of the guided aspirates conducted were diagnostic only in 44 cases (39.28%) [Table 2]. From these poor outcomes, we conclude that the patient selection, localization of the lesion, and aspiration technique are areas that need to be addressed in our service.

The inadequacy rates of thyroid aspirates, 11 of 36 (30.55%), were comparable to the inadequacy rates in the literature, which vary from 33.6% to 2.8%.[3,19] In studies having a higher inadequacy rate, the aspirates were performed without onsite adequacy evaluation, and a single pass was done.[19] Lower inadequacy rates were achieved when FNA was performed by experienced physicians (>300 cases/year), with immediate onsite adequacy evaluation.[9,19-21] Other studies conducted showed that the number of passes required for obtaining adequate specimen varied with operator expertise and nodule size; however, 2-5 passes were generally sufficient, when immediate onsite adequacy assessment is not available.[9,22] In our setup, the aspirates were performed by operators with varying experience, using needles of varying caliber (22G-25G), without immediate onsite adequacy assessment. Although, the inadequacy rates in our study fall within the range reported in the literature, they were on the higher side and were an area of concern, which needs to be addressed.

Our audit included 11 aspirates from breast. Our numbers are too small to compare the inadequacy rates to the rates reported in the literature (8.5-46%).[21] Other studies report that, on-site adequacy evaluation by a cytopathologist significantly improved the sample adequacy rates.[23,24]

Our audit included 45 intra-abdominal aspirates and 8 superficial lymph nodes. Comparable studies of inadequacy rates were not available in the published literature for intra-abdominal aspirates and guided aspirates of superficial lymph nodes; therefore it is difficult to judge this component of our service.

Our reports are issued by one of the ten consultants, who are on a monthly rotation. The majority of the reports 108 (96.42%), issued were nonstructured and nonrecommendaory 101 (90.17%). Literature recommends the use of a structured reporting system incorporating the Bethesda categorization of thyroid aspirates.[25] In consultation with core faculty members, we propose to design and incorporate a similar standard format of issuing the reports for other organ systems, which may help maintain uniformity, and improve the quality of reports issued.

**Limitations of our study**

The numbers of ultrasound-guided FNAC in our institution are small. While designing the audit, we did not anticipate such small numbers. The disproportionate burden that these aspirates appear to have on our system is worrisome. Perhaps establishing specialized clinics could contribute to developing greater expertise for aspirators; however, this has to be balanced with the indications for USG guided FNA. Attempting to increase numbers by including palpable lesions, only to train residents may be counter productive.

Comparing the adequacy rates of freehand FNAC of palpable lesions with USG guided FNACs could have yielded useful information; however, this parameter was not included when we designed the audit. We could not correlate the size and the adequacy of aspirates because the size of the lesions was not recorded on the majority of the requisition forms.

Ours being a general cytopathology service, the residents are required to perform guided aspirates of various organs. Our residents learn the skills of FNAC on real patients. The team consists of a pathologist (senior resident), a radiologist (postgraduate 2nd year, 3rd year or a senior resident), and a cytotechnologist. The needle is localized with the help of ultrasound guidance by the radiologist, and the pathologist is required to aspirate from the site. The radiologist and the pathologist both have varied degrees of experience and exposure of guided FNAC. No senior consultant is present during the procedure for supervision.

Barring thyroid and breast, the numbers of aspirates per organ in a year were very few. The residents, therefore, could not have had adequate hands on experience in performing guided aspirates of these organs. The number of cases needed to achieve proficiency may vary, depending on individual background, aptitude as well as the case mix.[14] Ljung et al.[26] have emphasized, that merely performing a large number of FNACs did not constitute adequate training. Training in procurement of samples, and consistent feedback significantly help in improving the specimen quality.[14] Hence, there is a need to evolve a training module, focused on the localization of the lesion using ultrasound guidance, as well as aspiration from the
lesions. The presence of a senior consultant during the procedure may also improve the training of the residents in guided FNAC. We propose to document the inadequacy rates of the FNAC’s performed by each resident, and provide consistent feedback to help improve the specimen quality. Proficiency testing of the individual care providers could also be incorporated. This would mean proficiency testing of the resident’s skills in FNAC, on the lines of the recently developed Entrustable Professional Activities [27] before allowing the resident to perform the procedure unsupervised. FNAC data in our institution is entered manually in registers and is not stored in an electronic database. This makes data extraction during audits a tedious and time taking process. Switching to an electronic database could make information easily available, and could help people to rapidly perform future audits and design appropriate interventions.

Conclusions

Reporting practices varied and did not conform to a uniform structure, majority of the reports being nonstructured and nonrecommendatory. The documentation of the relevant patient details on the cytopathology forms was inadequate. This lack of accountability, team coordination, and supervision by the faculty need to be addressed. The paper highlights the poor management of guided FNAC service by the pathologist and radiologist.

Recommendations

Subsequent audits should be done after incorporating the following changes. A training module focusing on improving the aspirator skills should be evolved. Proficiency testing of the residents should be performed, and consistent feedback regarding specimen quality should be provided. A synoptic reporting system should be evolved in order to maintain uniformity of reports. Computer programs for record keeping should be instituted. There should be an attempt to improve the documentation of relevant details (size, complete radiological details, indication of the procedure) on the cytopathology requisition forms. The requisition forms are being filled by the radiologists. We may consider designing structured or synoptic requisition forms may also help save time.

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How to cite this article: Mangla G, Arora VK, Singh N. Clinical audit of ultrasound guided fine needle aspiration in a general cytopathology service. J Cytol 2015;32:6-11.

Source of Support: Nil, Conflict of Interest: None declared.