



Original Research Article

Audit of repeat fine needle aspiration cytology – reasons demystified – a retrospective analytical study in a tertiary care hospital

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ABSTRACT

Introduction: Fine needle aspiration cytology (FNAC) is a valuable diagnostic tool in evaluation of mass lesions. One of the major limitations of FNAC is the need for repeat aspiration which imposes workload on the laboratory and stress on the patient as well as on the aspirator. There are only few studies which have focused on the issue of repeat aspiration especially the factors associated with repeat FNAC.

Aim: Present study was conducted with the aim to determine the factors associated with repeat FNAC.

Materials and Methods: This was a retrospective, analytical laboratory audit of 350 repeat FNAC over a duration of two years. Age, sex, site of FNAC, reasons for repeat and outcome of repeats were recorded. Reason for repeat and final outcome of repeat FNAC were considered as outcome measures.

Results: Repeat FNAC accounted to 20.94% (350/1671) of all FNAC performed. Maximum number of repeat FNAC were from thyroid 96/351 (27.4%) followed by soft tissue 86 (24.6%) and breast 81 (23.1%). The outcome of repeat FNAC were diagnostic in 279 (79.7%), non-diagnostic 47 (13.4%) and loss of patient follow-up in 24 (6.9%) cases. Reasons for repeat were inadequate aspirates in 223 (63.7%), non-representative material in 118 (33.7%) and suspicious cells to be repeated in 9 (2.6%). Logistic regression analysis revealed that organ of FNAC, month of FNAC and reason for repeat FNAC were independent variables linked with outcome of FNAC.

Conclusion: FNAC as an investigative modality has immense diagnostic utility and this potential is fettered by inadequate aspirates and descriptive reporting in certain cases. The tricky cases were often encountered in thyroid, soft tissue and breast lesions. Regular audit of repeat FNACs gives us an insight into conditions where a diligent and meticulous approach is required.

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1. Introduction

A clinical audit is a methodical process meant at improving the quality of health care. It encompasses procedures used for treatment and diagnosis along with resources and outcome involved in patient care.¹

Laboratory audit is conducted to measure the performance of laboratory tests against a set measure of standards. Apart from this, an audit can be performed on the “process” and “outcome” aspect of laboratory tests. An improved process always results in a good outcome.^{2,3}

Fine needle aspiration cytology (FNAC) is a valuable diagnostic tool in evaluation of mass lesions. One of the major limitations of FNAC is the need for repeat aspiration which imposes workload on the laboratory and stress on the patient as well as on the aspirator.⁴

Laboratory audits addressing issues concerned with FNAC of individual organs like thyroid, breast, and ultrasound guided FNAC have been reported.^{5–7} Albeit, there are only few studies which have focused on the issue of repeat aspiration especially the factors associated with repeat FNAC.

Hence this laboratory audit study was planned with the aim to determine the factors associated with repeat FNAC

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on cases presenting to FNAC clinic at a tertiary care hospital over a duration of two years. An attempt was made to determine the association between repeat FNAC and other variables like age, gender, site of FNAC, reason for repeat, number of repeats and outcome of repeat FNAC.

2. Material and Methods

This was a retrospective, analytical laboratory audit of 350 repeat FNAC cases over a duration of two years. The sampling method adopted was universal sampling. Demographic details were noted from the case records.

2.1. Definition of variables

Repeat FNAC was defined as cases in whom repeat FNAC was either advised by the cytopathologist in view of insufficient material or in the presence of sufficient material, the details were obscured by blood or presence of drying artefact or repeat FNAC was advised by clinician in view of inconsistent clinical and cytological correlates.

All aspects of the cytopathology report were collected like age, gender, hospital number, FNAC number, site of FNAC, type of aspirate, reason for repeat FNAC and outcome of repeat FNAC. Final outcome of repeat FNAC like diagnostic report, non-diagnostic report or lot for follow up were considered as outcome measure. Institutional ethics committee clearance was obtained.

2.2. Statistical analysis

Data was analyzed using SPSS software. Data was expressed as mean, percentages and proportions. Chi square and Fischer's test was used to establish association between categorical variables. Univariate and subsequently multivariate binary logistic regression analysis were used to determine the factors that predict repeat FNAC. p value <0.05 was considered as statistically significant.

3. Results

Out of total 1671 FNAC done over a duration of one year, repeat FNAC was asked for in 350 (20.94%) cases. Most common organ where repeat FNAC was performed was thyroid 96/351 (27.4%) followed by soft tissue 86 (24.6%), breast 81(23.1%), lymph node 73/351 (20.9%) and salivary gland 14/351 (4%). (Graph 1) When month wise data of repeat FNAC was analysed it was observed that repeat FNAC was seen most noticeably seen in the month of August i.e., 54 (15.4%) followed by July i.e., 38 (10.9%). (Graph 2) The FNAC were repeated to a maximum of three times and outcome was determined. The outcome of repeat FNAC were diagnostic in 279 (79.7%), non-diagnostic 47 (13.4%) and loss of patient follow-up in 24 (6.9%) cases. (Graph 3) Reasons for repeat were inadequate aspirates in 223 (63.7%), non-representative material in 118 (33.7%)

and suspicious cells to be repeated in 9 (2.6%) cases. (Graph 4) Based on univariate analysis, it was observed that the organ of FNAC and reason for repeat FNAC were independent variables linked with outcome of repeat FNAC. (Tables 1 and 2) In order to determine the factors that predict outcome of repeat FNAC logistic regression analysis using univariate and multivariate analysis was done and the results are depicted in table no 3.

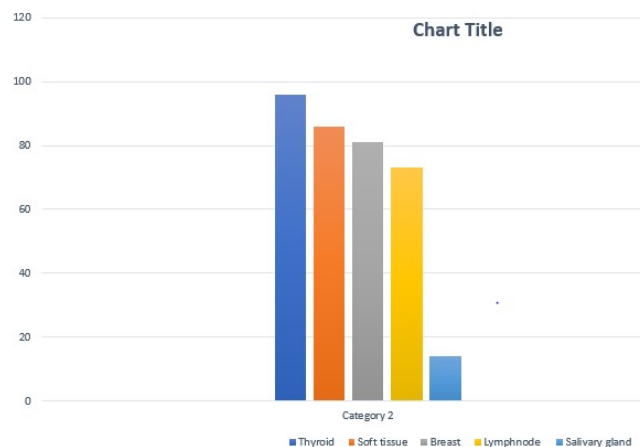
Repeat FNAC being done for thyroid as reference, the odds of having a diagnostic test result over the non-diagnostic result for breast and soft tissue was found to be 4.017 & 2.857 (a OR) which was statistically significant with a p value of 0.003 & 0.031 respectively.

Similarly, the odds of having a diagnostic test result over the non-diagnostic result for salivary gland was 2.182 but this was not statistically significant.

However, there was no difference between male and female gender and number of repeat FNAC of having diagnostic test result when repeated.

With age group of less than 10 years as reference, it was observed that the odds of getting a diagnostic result for repeat FNAC among age group of 11 to 20 years was 2.667, but this was not statistically significant.

In thyroid the most common diagnosis after repeat FNAC was colloid goitre with cystic change. In breast the most common diagnosis was infiltrating ductal carcinoma with lipoma being the most common diagnosis in soft tissue. In lymph node reactive lymphadenitis was the commonest diagnosis with chronic sialadenitis being the most common lesion diagnosed in salivary gland.



Graph 1: Depicts percentage of repeat FNAC – Organ wise

4. Discussion

A laboratory audit is usually performed to determine the quality of the service provided by the laboratory. Any test performed in the laboratory comes under the purview of laboratory audit, which may even involve the audit of a

Table 1: Depicts outcome of repeat FNAC – Organ wise

		Site of FNAC					Thyroid	Total
		Breast	Lymph node	Salivary Gland	Soft Tissue			
Outcome of repeat FNAC	Diagnostic	56	65	11	63	84	279	
	Non-Diagnostic	19	4	2	15	7	47	
	Patient lost for follow up	6	4	1	8	5	24	
	Total	81	73	14	86	96	350	

Table 2: Shows difference between outcome of repeat and various variables (Chi square test)

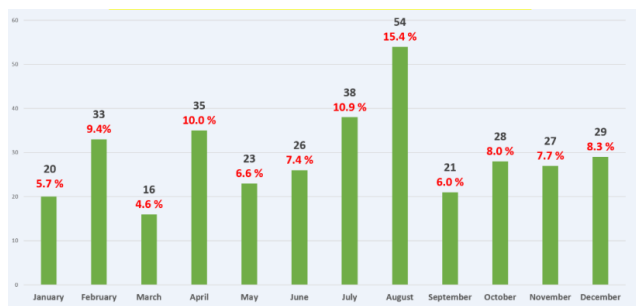
Variables	Outcome of repeat		p Value
	Diagnostic	Non-Diagnostic	
Age group	3 (<10 years)	2	0.3
	34 (11-20)	7	
	22 (21-30)	2	
	47 (31-40)	9	
	76 (41-50)	7	
	65 (>60)	12	
Gender	211 (M)	68	0.468
	33 (F)	14	
	56 (Thyroid)	19	
Site of FNAC	65 (LN)	4	0.003 (Sig)
	11 (Salivary gland)	2	
	63 (Breast)	15	
No of repeats	84 (Soft tissue)	7	0.838
	264 (First)	44	
	12 (second)	2	
	3 (Third)	1	
Reason for repeat FNAC	135 (Blood)	23	0.000 (Sig)
	21 (cyst fluid)	5	
	41 (Fat)	3	
	44 (Non representative)	00	
	29 (Scant)	16	
	9 (Suspicious)	00	

Table 3: Shows Logistic regression analysis results for various variables

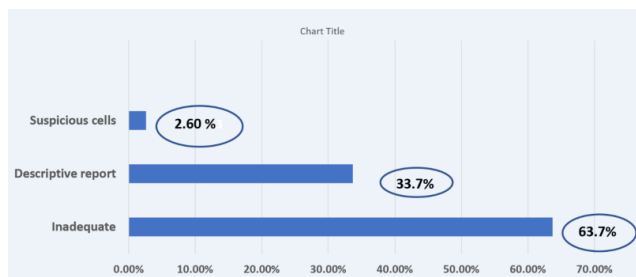
	Odds ratio	95% C.I. for EXP(B)		p value
Site of FNAC				
Thyroid	1			0.006
Breast	4.071	1.606	10.321	.003 (Sig)
LN	.738	.207	2.631	.640
Salivary	2.182	.402	11.854	.366
Soft Tissue	2.857	1.100	7.423	.031 (Sig)
No of repeats	1.236	.480	3.184	.660
Gender				
Male	.760	.384	1.503	.430
Age Group				
<10	1	.552	2.111	0.06
11-20	2.667	.380	18.738	.324
21-30	.824	.268	2.533	.735
31-40	.364	.070	1.878	.227
41-50	.766	.267	2.195	.620
51-60	.368	.123	1.102	.074
> 60	.738	.274	1.987	.548

Table 4: Problems encountered, the reasons and their solutions - Repeat FNAC

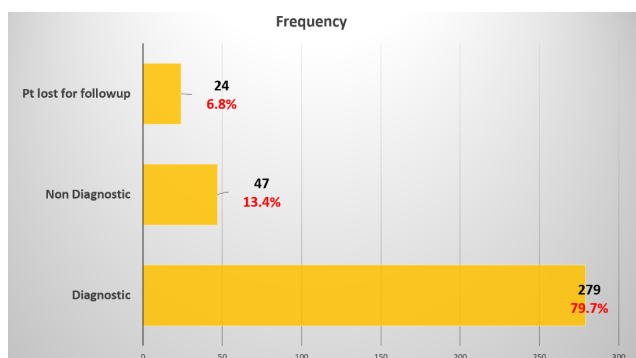
Problems	Reasons	Solutions
Month of July and August	New residents Short postings	-Careful mix and training of new personnel is important -Design and inculcate a training module for residents -Proficiency testing of the psychomotor skills for performing FNAC - entrustable professional activities
6.85% lost for follow up	Improvement in illness, biopsy, other test etc.	Meeting with clinicians, future audits Tracking system in place (Computerized)
Most common – Thyroid, Similar to Goyal et al	Inherent nature of lesion and inexperience aspirator	Triple approach Non aspiration technique Quick smearing
Lymph node Repeats	Suspicious for tuberculosis or non-diagnostic	Repeat FNAC on site or after 2 -3 weeks Increases diagnostic accuracy
Breast Repeats	Inherent nature of lesion and inexperience aspirator	Triple diagnosis in specialized breast clinics



Graph 2: Depicts Month frequency of repeat FNAC – Month wise



Graph 3: Depicts reasons for repeat FNAC



Graph 4: Depicts Outcome of repeat FNAC

“process”, provided the fact that when a corrective measure is implemented in that “process” of care subsequent to the audit, it results in the best outcome thereby improving quality.^{2,3,8}

Repeat FNAC is one of the major drawbacks of FNAC. Though the reasons of this are manifold, there is no single solution to tackle this issue which in turn depends on the reason for repeat. Furthermore, there are no explicit standards for the repeat FNAC till date.⁹ The literature reveals handful number of studies on cytology audit.⁵⁻⁹ Besides this, the published studies have focussed on diagnostic accuracy of various cytology procedures including the interpretative aspect. Moreover, the studies have concentrated on individual organ systems like breast, thyroid and lymph node. The studies on audit of repeat FNAC are few. Hence the present study was planned.

In the present study repeat FNAC was seen in 350 (20.94%) cases. This number was slightly higher than those reported by Goyal et al and Rathod et al, with a prevalence of repeat FNAC being 13.8% and 12.5% cases respectively.^{9,10} The repeats are an integral part of FNAC. However, there is no standard criteria set as to how many repeats are acceptable in a cytology laboratory. In our institution the rotation postings are such that one set of faculty and post graduates remain in cytology unit for a short duration of just two months. This may be the hindrance for the new faculty and postgraduates to acquire sufficient hands on skills in performing FNAC. This issue needs to be addressed at the administrative level and corrective actions initiated. Another reason would be that in 33% of cases the repeat FNAC was done in view of non-representative material. A good number among these were repeated just to prove or disprove a particular clinical diagnosis when there was discordance at the initial FNAC between the clinical and FNAC diagnosis. The authors favour this effort of the cytopathologist for whom patient care is of paramount interest.

Maximum number of repeats in the present study were from thyroid (27.4%) followed by soft tissue (24.6%). This was in accordance with the published data.^{9,10} The most

common cause of repeat FNAC is thyroid is an inadequate aspirate. Literature reveal varying rate of 33.6% to 2.8% inadequate aspirates in thyroid.^{11,12} In a study by Moslavac S et al the most common reason for repeat FNAC were inadequate/indeterminate smears and increasing size of nodule on ultrasound follow up.¹³ The outcome of repeat FNAC in their study was diagnostic in 82% cases. Likewise, studies have shown that repeat FNAC in thyroid is useful in inadequate smears and in growing nodules. Obtaining adequate material from thyroid FNAC has always been an uphill task, the reasons for it being multifactorial. High vascularity, cystic nature, complex lesions, calcific foci, small inaccessible lesion all account for the inadequate aspirates.¹⁴ This together compounded by the inexperience of the new faculties and residents, inability to select proper patient for FNAC, improper positioning etc poses challenges. Application of non-aspiration technique results in less blood and more cells. Much time should be spent on proper positioning of the patient, fixing the lesion and selecting the area for FNAC prior to the procedure. An ultrasound report in hand prior to performing the FNAC is recommended. Use of ultrasound guided FNAC in small, inaccessible, complex, cystic, fibrotic and calcified lesions is advocated. Onsite evaluation of adequacy leads to low inadequacy rate.¹⁵ Though the TBSRTC recommend an interval of at least 3 months between initial and repeat FNAC to prevent false positive diagnosis, studies have shown that there is no association between the time interval and the accuracy and diagnostic yield of repeat FNAC.¹⁶

A comparable similar proportion of soft tissue, breast, and lymph node lesions underwent repeat FNAC. In soft tissue lesions lipoma was the one most commonly repeated. The fat is usually washed out leading to inadequate smears. Use of wide bore needle and air drying the slides for Giemsa stain or use of spray fixatives would usually resolve this issue. In breast, similar to thyroid, the cystic nature of the lesion, fibrosis and small inaccessible lesions pose problems during aspiration. Studies have revealed an inadequacy rate of 8.5-46% in breast FNAC.¹⁷ We advocate use of ultrasound guided FNAC in selected cases to improve the diagnostic yield. Studies have revealed that inappropriate patient selection and inexperience of the aspirator as cause of repeat FNAC in breast. Similarly, artefact due to drying and obscuring of tumour cells by blood and inflammatory infiltrate often makes the interpretation challenging. Time and again the experts have highlighted the importance of use of non-aspiration technique, quick passes, and a quick smearing in avoiding these issues.

In lymph node most of the repeat aspirates were done in suspected cases of tuberculosis and lymphoma whenever there was a discordance between the initial FNAC diagnosis and the clinical diagnosis. In tuberculosis, it has been observed that the odds of finding a granuloma is increased in the repeat FNAC in the same sitting. Similarly, studies

have also noted that repeat FNAC done after a duration of 2 to 3 weeks in a suspected case of tuberculosis, when the initial FNAC was negative, improved the diagnostic accuracy.¹⁸ These findings substantiate the use of repeat FNAC in lymph nodes especially in suspected cases of tuberculosis. Similarly, in lymphomas with a predominant population of reactive mixed inflammatory infiltrate like Hodgkin's lymphoma, anaplastic large cell lymphoma and peripheral T cell lymphoma, the atypical cells may be scarce on initial FNA and the cytopathologist may not be confident to render a diagnosis of Lymphoma in these scenarios. In such cases a repeat FNAC comes to our rescue.

Month wise analysis of repeat FNAC depicted an increase in the frequency during the month of August and July. This coincides with the newly joined residents being posted in cytology. Since ours is a teaching institute, the residents are required to acquire hands on experience in performing the FNAC and hence we allow them to perform the FNAC. However, in order to reduce the number of repeat FNAC, it was decided to perform the FNAC by both the resident as well as the experienced faculty posted together in the same setting henceforth. Similar findings were also reported by Goyal et al.⁹ Also, the temperament of the individual consultant may determine the number of requests for repeat. Some may feel a need to repeat while the others may opt for other diagnostic procedures such as biopsy. However, this may practically amount to only few of the repeat requests. Similarly, Goyal et al had addressed the issue of conflicts arising among the consultants over reporting of repeat cases, when patients present months or weeks after the initial FNAC.⁹ This issue is because the reporting consultant would be different for the initial and the repeat procedure. During such time the consultant who had initially performed the FNAC should take responsibility of final cytology report.

In the present study, the outcome of repeat FNAC was diagnostic in 79.7% of the cases. Similar finding was reported by other studies.^{9,10} This was higher than that reported in the study by Goyal et al, who obtained a diagnostic aspirate in 50 % of the repeats. This attests beyond doubt, the importance of repeat FNAC. In 13.4% of cases the result was non diagnostic. It is important to mention the reason for the non-diagnostic aspirate in the FNAC report and provide with a recommendation note for the other modes of investigations. In the present study 6.9% of patients were lost for follow up. Earlier researchers have suggested that for tracking the patients who had a non-diagnostic aspirate and who were lost for follow up, an adequate computerized tracking system should be made available in the laboratories and we support these recommendations.

We performed logistic regression analysis to determine the factors which can predict the outcome of repeat FNAC. Thyroid was considered as reference. We observed that the

odds of having a diagnostic test result was more in breast and soft tissue lesions. Similarly, there was no difference between male and female gender and number of repeat FNAC of having diagnostic test result when repeated. With age group of less than 10 as reference, it was observed that the odds of getting a diagnostic result for repeat FNAC among age group of 11 to 20 years was 2.667, but this was not statistically significant. We looked into the existing literature on audit of repeat FNAC and could not find any such detailed analysis with respect to the factors predicting outcome of repeat FNAC. We feel further studies are needed to analyse the different factors which play a role in improving the diagnostic yield in FNAC.

The most common reason for repeat FNAC in the present study was inadequate aspirates. This was similar to the other studies in literature. In % of cases a descriptive report was rendered. A descriptive report is in no way useful for the clinicians in decision making. Since a cytopathologist is trained personnel, he is expected to interpret the findings and mention the same in the report. Also, any recommendations like a request for repeat or other investigative modalities should be made.

Performing huge number of FNA alone does not result in acquiring expertise, however there is a need to design and inculcate a training module for residents before they can independently perform the procedure. Recording the number of repeats of each resident and providing constant feedback to them will help in improving the adequacy rate and thereby reducing the number of repeats. Proficiency testing of the psychomotor skills for performing FNAC independently should be done as per the guidelines provided by entrustable professional activities.¹⁸

A clear documentation of the reason for repeat FNAC, or a non-diagnostic report was not available in the majority of FNAC reports, we felt a need to develop a structured format for FNAC which will include these findings so that the same is available for all patients.

The major pitfall of the present study is the retrospective nature, small sample size and a single institution study. The auditing was not comprehensive, so the partial audit done in the study did not fulfil Oxford criteria IV and V. A complete re audit after implementation of remedial measures will determine the impact of corrective measures undertaken.

5. Conclusion

FNAC as an investigative modality has immense diagnostic utility and this potential is fettered by inadequate aspirates and descriptive reporting in certain cases. In majority of repeat FNAC, the outcome is diagnostic, which alone is well worth the effort. The tricky cases were often encountered in thyroid, soft tissue and breast lesions. Regular audit of repeat FNACs gives us an insight into conditions where a diligent and meticulous approach is required.

6. Acknowledgement

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7. Statement of Ethics

The research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. The study protocol was approved by institutional ethical committee, The reference number being 20/2019.

8. Conflict of Interest

None.

9. Sources of Funding

None.

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