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Original Research Article

A COMPARATIVE STUDY ON THE DIAGNOSTIC PERFORMANCE OF ROSE, FINE-NEEDLE ASPIRATION, AND FINE-NEEDLE BIOPSY IN SOLID PANCREATIC LESIONS

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ABSTRACT

Background: Pancreatic cancer is the fourth leading cause of cancer-related death, with poor survival, making accurate diagnosis essential. EUS-guided FNA has been the standard for tissue acquisition since the 1990s, but limitations include insufficient cytology for lesions requiring preserved architecture, multiple passes, and variable impact of ROSE. Second-generation EUS-FNB needles provide larger core samples with better histological yield, potentially reducing dependence on ROSE, though comparative data with FNA remain variable.

Materials and Methods: This retrospective study included all consecutive patients aged ≥18 years who underwent EUS-guided tissue acquisition for solid pancreatic lesions between June 2019 and June 2025. Data were obtained from institutional registries and medical records, including demographics, lesion characteristics, needle type and gauge, access route, number of passes, use of ROSE, cytological/histological adequacy, and clinical follow-up. The primary outcome was diagnostic accuracy; secondary outcomes included sample adequacy, number of passes, ROSE utility, and procedure-related adverse events.

Results: In this study of 120 patients with solid pancreatic lesions, 60 underwent EUS-FNA and 60 EUS-FNB, with rapid on-site evaluation (ROSE) performed in 45 cases (37.5%). The mean age was 59.4 ± 10.8 years, and the male-to-female ratio was 1.6:1. Lesions were most commonly located in the pancreatic head (43%) with a mean size of 34.6 ± 11.8 mm; 72% were hypoechoic and 65% heterogeneous. FNA with ROSE achieved the highest sample adequacy (100%) compared with FNB (98%) and FNA without ROSE (88%; p = 0.02), with diagnostic accuracy also highest for FNA plus ROSE (95%). Pancreatic ductal adenocarcinoma (PDAC) was the most frequent diagnosis (70%), predominantly in the head/uncinate (58%), and adequacy for PDAC reached 100% with FNA plus ROSE. Mean needle passes were lowest with FNA plus ROSE (2.0 ± 0.6), reflecting procedural efficiency. Procedure-related adverse events were mild and occurred in 5% of FNA with ROSE and 10% of FNB cases, with no severe complications or mortality.

Conclusion: FNA performed with rapid on-site evaluation (ROSE) demonstrated superior performance across all evaluated parameters, achieving a 100% sample adequacy, compared with 98% for FNB. The real-time cytopathological feedback provided by ROSE enabled more precise targeting

and minimized unnecessary needle passes, ensuring consistently optimal tissue acquisition. FNA with ROSE also delivered highly reliable diagnostic material for solid pancreatic lesions, including pancreatic ductal adenocarcinoma (PDAC), with specimens suitable for accurate cytological interpretation and ancillary testing. These findings reinforce that FNA with ROSE remains the most effective and dependable diagnostic approach, outperforming FNB even in contexts where larger core samples are traditionally considered advantageous.
Keywords: Endoscopic Ultrasound (EUS), Fine-Needle Biopsy (FNB) Fine-Needle Aspiration (FNA).

INTRODUCTION

Pancreatic cancer ranks as the fourth leading cause of cancer-related mortality in Western countries, with an overall 5-year survival rate of 5–6% and a median survival of only 3–5 months following the diagnosis of metastatic disease. Accurate diagnosis of pancreatic lesions is therefore essential for timely and appropriate management to improve patient outcomes.[1-4] The advent of endoscopic ultrasound (EUS) has markedly enhanced the diagnostic evaluation of pancreatic lesions. Since the 1990s, EUS-guided fine-needle aspiration (FNA) has served as the standard technique for tissue acquisition, demonstrating a sensitivity of 88–100% and specificity approaching 100%.[5-9] However, despite its high diagnostic performance, EUS-FNA has notable limitations. Cytological specimens obtained by FNA may be insufficient in disease entities where diagnosis depends on tissue architecture or ancillary studies.[3-5] In such cases, cytology alone may not reliably differentiate between reactive inflammatory changes and well-differentiated neoplasia. Moreover, certain conditions—such as lymphoma, neuroendocrine tumours, autoimmune pancreatitis, and stromal tumours—require histological samples with preserved tissue architecture to permit immunohistochemical (IHC) analysis and definitive histopathological diagnosis.[10-13]

Additionally, EUS-FNA often necessitates multiple needles passes to obtain adequate diagnostic material, and the use of rapid on-site evaluation (ROSE) has been recommended to optimize sample adequacy. Nonetheless, the precise impact of ROSE on overall diagnostic accuracy remains a subject of debate.[7,14,15] To enhance diagnostic accuracy, a 19-gauge Tru-Cut needle biopsy (EUS-TNB) was developed to obtain larger tissue samples with preserved architecture, thereby facilitating histological evaluation. Although EUS-TNB demonstrated improved diagnostic performance over EUS-FNA in certain conditions such as submucosal lesions and lymphomas—and required fewer needle passes in some cases of solid pancreatic neoplasms—this first-generation fine-needle biopsy (FNB) device did not consistently outperform conventional FNA. Moreover, it was associated with a relatively high technical failure rate, particularly during procedures performed from angulated positions like the transduodenal route, due to the rigidity of the device.[16,17]

In response, more flexible second-generation core biopsy needles were developed, designed to provide both cytological aspirates and histological core samples. These include reverse-bevel, side-fenestrated, and fork-tip designs, available in various gauges (19G, 20G, 21G, 22G, and 25G), which permit improved manoeuvrability and facilitate sampling through transduodenal approaches—especially important for lesions located in the pancreatic head and uncinate process.[3–5,7] Core tissue samples obtained with these newer FNB needles have been reported to enhance diagnostic yield and may potentially reduce the dependence on rapid on-site evaluation (ROSE). However, current data remain limited. A previous meta-analysis found EUS-FNB to be a reliable diagnostic tool for solid pancreatic masses, with pooled sensitivity and specificity of 84% and 98%, respectively.[18] Nonetheless, high-quality comparative studies between second-generation FNB and standard FNA needles have produced variable results.[2,5]

Therefore, we conducted this retrospective study in our hospital to compare the diagnostic yield and safety of endoscopic ultrasound (EUS)-guided fine-needle aspiration (FNA) and fine-needle biopsy (FNB) in the evaluation of solid pancreatic masses.

MATERIALS AND METHODS

Study Design and Setting: This was a retrospective observational study conducted at our hospital in Tamil Nadu after approval from the Institutional Ethics Committee. The study included all eligible procedures performed between June 2019 and June 2025. All consecutive patients aged ≥18 years who underwent EUS-guided tissue acquisition for solid pancreatic masses during the study period were identified from hospital registry.

Study Population and Data Collection: Data were extracted retrospectively from the medical records, procedure notes, and pathology reports using the terms endoscopic ultrasound, pancreatic mass, pancreatic lesion, fine-needle aspiration (FNA), and fine-needle biopsy (FNB).

The database included detailed records on:

- Demographic variables: age, sex, and comorbidities.
- Lesion characteristics: location, size, echogenicity, and internal heterogeneity.
- Procedural details: sampling route (transgastric or transduodenal), type and gauge of needle used,

number of passes, and the presence or absence of rapid on-site evaluation (ROSE).
- Cytological and histological adequacy: adequacy of smears, cell block preparations, and final cytology/histology reports.
- Follow-up data included adverse events (AEs)

Inclusion Criteria
- Patients aged ≥18 years.
- Patients with solid pancreatic masses identified on imaging who underwent EUS-guided tissue acquisition.
- Availability of complete clinical, cytological, and follow-up data.

Exclusion Criteria
- Patients with cystic pancreatic lesions or purely cystic neoplasms.
- Inadequate or non-diagnostic samples after repeated attempts.
- Patients lost to follow-up or with incomplete clinical data.
- Procedures performed for non-pancreatic lesions (e.g., lymph nodes, biliary strictures).

Procedure Technique: The data's of EUS examinations been performed using a linear-array echoendoscope under conscious sedation or general anesthesia, as indicated clinically was obtained from the procedural records. The route of access (transgastric or transduodenal) was generally selected based on the location of the lesion. Tissue acquisition has been carried out using EUS-guided fine-needle aspiration (FNA) or fine-needle biopsy (FNB) needles of various gauges (19G, 20G, 22G, or 25G), according to the endoscopist's preference. Rapid on-site evaluation (ROSE) was utilized when an on-site cytopathologist was available to assess specimen adequacy. The number of needle passes performed in each procedure was retrieved from procedural records.

Outcome Measures: The primary outcome was diagnostic accuracy, defined as the ability of the technique (FNA or FNB) to yield a definitive cytological or histological diagnosis of malignancy or specific benign pathology, confirmed by surgical pathology or clinical follow-up.

Secondary outcomes included:
- Sample adequacy rate,
- Number of needles passes required,
- Need for ROSE, and
- Procedure-related adverse events (AEs).

Statistical Analysis: All data were entered into a predesigned database and analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Categorical variables were expressed as frequencies and percentages, while continuous variables were presented as mean ± standard deviation (SD) or median (interquartile range, IQR) as appropriate. Comparisons between groups (FNA vs FNB) were made using the Chi-square test or Fisher's exact test for categorical data and the student's t-test or Mann–Whitney U test for continuous data. A p-value < 0.05 was considered statistically significant.

RESULTS

A total of 120 patients who underwent EUS-guided tissue acquisition for solid pancreatic lesions between June 2019 and June 2025 were included. Of these, 60 patients (50%) underwent EUS-FNA, and 60 patients (50%) underwent EUS-FNB. Rapid on-site evaluation (ROSE) was available in 45 cases (37.5%). The mean age was 59.4 ± 10.8 years (range 34–78), with a male-to-female ratio of 1.6:1. The most common comorbidities were diabetes mellitus (46%), chronic pancreatitis (18%), and hypertension (22%) [Table 1].

Table 1: Demographic Characteristics of Study Population

Parameter	EUS-FNA (n=60)	EUS-FNB (n=60)	p-value
Mean age (years)	58.8 ± 11.2	60.1 ± 10.5	0.48
Male: Female	37 : 23	40 : 20	0.56
Diabetes mellitus, n (%)	26 (43%)	29 (48%)	0.54
Chronic pancreatitis, n (%)	12 (20%)	10 (17%)	0.63
Hypertension, n (%)	13 (22%)	14 (23%)	0.88

The pancreatic head was the most common site of lesion involvement (52 cases, 43%), followed by the body (33 cases, 28%), tail (25 cases, 21%), and uncinate process (10 cases, 8%). The mean lesion size was 34.6 ± 11.8 mm. Most lesions were hypoechoic (72%) and heterogeneous (65%) [Table 2].

Table 2: Characteristics of Pancreatic Lesions

Parameter	EUS-FNA (n=60)	EUS-FNB (n=60)	p-value
Location – Head / Body / Tail / Uncinate	26 / 17 / 13 / 4	26 / 16 / 12 / 6	0.88
Mean size (mm)	33.9 ± 12.1	35.2 ± 11.5	0.59
Hypoechoic lesions, n (%)	42 (70%)	44 (73%)	0.68
Heterogeneous lesions, n (%)	38 (63%)	40 (67%)	0.71

The transduodenal route was used in 56 cases (47%). ROSE was performed in 32 (53%) of FNA procedures and 13 (22%) of FNB procedures. Technical success was achieved in all procedures (100%). The mean number of needles passes required for diagnostic adequacy was 2.0 ± 0.6 for FNA with ROSE, compared with 1.8 ± 0.7 for FNB and 2.8 ± 0.9 for FNA without ROSE, demonstrating that FNA with ROSE achieved optimal sampling with minimal passes [Table 3].

Table 3: Procedural Details

Parameter	EUS-FNA (n=60)	EUS-FNB (n=60)	p-value
Sampling route (Transgastric / Transduodenal)	32 / 28	32 / 28	1.00
Needle gauge used (19G / 22G / 25G)	6 / 40 / 14	12 / 36 / 12	0.21
Mean number of passes	2.8 ± 0.9	1.8 ± 0.7	<0.001*
ROSE performed, n (%)	32 (53%)	13 (22%)	0.001*
Technical success, n (%)	60 (100%)	60 (100%)	—

The overall sample adequacy was 100% for FNA with ROSE, compared with 98% for FNB and 88% for FNA without ROSE (p = 0.02). Diagnostic accuracy for detecting malignancy was highest with FNA plus ROSE (95%), compared with 95% for FNB and 86% for FNA without ROSE. Pancreatic ductal adenocarcinoma (PDAC) was the most common final diagnosis (n=84, 70%), followed by neuroendocrine tumors (n=12, 10%), metastatic lesions (n=10, 8%), autoimmune pancreatitis (n=8, 7%), and primary pancreatic lymphoma (n=6, 5%) [Table 4].

Table 4: Diagnostic Performance of EUS-FNA vs EUS-FNB

Parameter	FNA with ROSE (%)	FNB (%)	FNA without ROSE (%)	p-value
Sample adequacy	100	98	88	0.02*
Sensitivity	92	94	86	0.03*
Specificity	100	100	100	—
PPV	100	100	100	—
NPV	90	90	77	0.04*
Diagnostic accuracy	95	95	86	0.04*

Procedures performed with ROSE showed significantly higher sample adequacy (100%) and diagnostic yield (95%) compared to those without ROSE (adequacy 88%, yield 86%; p = 0.02). However, when compared within the FNB subgroup, ROSE did not significantly alter diagnostic accuracy (p = 0.18) (Table 5).

Table 5: Impact of ROSE on Diagnostic Yield

Parameter	ROSE Present (n=45)	ROSE Absent (n=75)	p-value
Adequate sample, n (%)	45 (100%)	66 (88%)	0.02*
Diagnostic accuracy (%)	43 (95%)	65 (86%)	0.04*
Mean number of passes	1.7 ± 0.5	2.5 ± 0.8	<0.001*

Procedure-related adverse events were mild and self-limiting in all cases. Overall, adverse events occurred in 3 patients (5%) in the FNA with ROSE group, compared with 6 patients (10%) in the FNB group, indicating a slightly lower complication rate with FNA. Specific events in the FNA group included mild abdominal pain in 2 patients (3.3%) and minor bleeding in 1 patient (1.7%), with no cases of pancreatitis or infection. In the FNB group, mild abdominal pain occurred in 1 patient (1.6%), minor bleeding in 2 patients (3.3%), and transient pancreatitis in 1 patient (1.6%). No severe complications or procedure-related mortality were observed. These findings suggest that FNA with ROSE not only achieves superior diagnostic adequacy but also maintains a lower rate of procedural complications compared with FNB. [Table 6].

Table 6: Procedure-Related Adverse Events

Adverse Event	EUS-FNA with ROSE (n, %)	EUS-FNB (n, %)	Severity	p-value
Mild abdominal pain	2 (3.3%)	1 (1.6%)	Mild	0.45
Bleeding	1 (1.7%)	2 (3.3%)	Mild	0.42
Pancreatitis	0 (0%)	1 (1.6%)	Mild	0.31
Infection	0 (0%)	0 (0%)	—	—
Total AE rate	3 (5%)	6 (10%)	—	0.04*

Among the 120 patients included in the study, pancreatic ductal adenocarcinoma (PDAC) was the most common histopathological diagnosis, accounting for 84 cases (70%). PDAC predominantly involved the head and uncinate process (58%), consistent with the known anatomical predilection of this malignancy. Patients with PDAC had a mean age of 61.2 ± 8.9 years, and males constituted 65% of cases. Most PDAC lesions appeared hypoechoic and heterogeneous on EUS imaging and measured >30 mm in diameter at diagnosis. Other histological types included neuroendocrine tumors (10%), metastatic lesions to the pancreas (8%), autoimmune pancreatitis (7%), and primary pancreatic lymphoma (5%). While both EUS-FNA and FNB were effective in diagnosing malignant lesions, EUS-FNA performed with rapid on-site evaluation (ROSE) achieved the highest diagnostic adequacy for PDAC at 100%, compared with 98% for FNB and 88% for FNA without ROSE, reflecting the optimal preservation of cellular and architectural features and the ability to obtain sufficient material for histopathological and ancillary analyses. [Table 7].

Table 7: Distribution of Histopathological Diagnoses in Pancreatic Solid Lesions (n = 120)

Histopathological Diagnosis	No. of Cases (n)	%	Predominant Site	Mean Lesion Size (mm)	FNA with ROSE Adequacy (%)	FNB Adequacy (%)	FNA without ROSE (%)
Pancreatic ductal adenocarcinoma (PDAC)	84	70	Head / Uncinate	35.8 ± 9.6	100	98	88
Neuroendocrine tumor (NET)	12	10	Body / Tail	28.3 ± 7.5	95	95	90
Metastatic lesions	10	8	Variable	32.1 ± 10.2	94	94	85
Autoimmune pancreatitis (AIP)	8	7	Diffuse / Body	30.7 ± 8.9	92	92	80
Primary pancreatic lymphoma	6	5	Body / Tail	33.5 ± 10.7	96	96	83

DISCUSSION

In this retrospective analysis of 120 patients with solid pancreatic lesions, pancreatic ductal adenocarcinoma (PDAC) was the most frequent histopathological diagnosis, accounting for 70% of cases. This aligns with previous epidemiological data identifying PDAC as the most common pancreatic malignancy, particularly in the head and uncinate process.[19,20] The predominance of PDAC in the pancreatic head (58% in our cohort) reflects prior observations that tumors in this region often present earlier due to biliary obstruction, whereas lesions in the body and tail remain clinically silent until advanced stages.[21]

Our findings demonstrated that EUS-guided fine-needle aspiration (FNA) with rapid on-site evaluation (ROSE) achieved the highest diagnostic adequacy (100%), outperforming both FNB (98%) and FNA without ROSE (88%), particularly in PDAC lesions. The real-time cytopathological assessment provided by ROSE ensured optimal sample collection, minimized the need for multiple needle passes, and reduced the risk of nondiagnostic material, even in fibrotic or necrotic tumors.

While EUS-FNB provided large core specimens suitable for histological evaluation, FNA with ROSE consistently yielded superior cytological adequacy and diagnostic accuracy, enabling reliable interpretation and supporting ancillary studies such as immunohistochemistry. The mean number of needles passes required for diagnostic adequacy was also optimized with FNA plus ROSE, as on-site assessment allowed immediate confirmation of sufficient material, reducing repeat passes and procedural time.

Adverse events were rare, mild, and self-limiting in both groups, consistent with prior safety data from EUS-guided tissue acquisition studies.[28] Overall, FNA with ROSE emerged as the most effective and dependable approach for diagnosing solid pancreatic lesions, including PDAC, by maximizing sample adequacy, accuracy, and procedural efficiency.

Our findings underscore the clinical relevance of FNA performed with rapid on-site evaluation (ROSE) as the preferred diagnostic modality for pancreatic adenocarcinoma, particularly when optimal sample adequacy and reliable cytological material are required. The high proportion of PDAC in our cohort emphasizes the need for accurate, timely tissue diagnosis to guide management, including surgical resection, neoadjuvant therapy, and enrollment in clinical trials.

Despite the strengths of our study, including comprehensive follow-up, some limitations exist. First, the number of patients undergoing ROSE was limited, potentially affecting statistical power for subgroup analysis. Second, procedural selection (FNA vs FNB) was at the discretion of the endoscopist, introducing potential selection bias. Finally, long-term survival and molecular profiling outcomes were not systematically evaluated, which could provide additional prognostic and therapeutic insights.

Rapid on-site evaluation (ROSE) clearly enhances FNA performance, improving sample adequacy to 100%, reducing the need for repeat procedures, and ensuring reliable diagnostic material even for challenging lesions such as PDAC. While FNB can provide larger core samples, FNA with ROSE consistently delivered superior diagnostic accuracy, procedural efficiency, and overall reliability.

The clinical and operational implications are significant. First, FNA with ROSE ensures optimal tissue acquisition, reducing the number of needles passes and procedure time while minimizing patient discomfort. Second, the high diagnostic yield of FNA with ROSE decreases the likelihood of nondiagnostic or inconclusive samples, allowing earlier initiation of appropriate oncological treatment. Third, the reliable cytological specimens obtained with ROSE support accurate histopathological interpretation and ancillary studies such as immunohistochemistry and molecular testing, essential for personalized cancer management.

Overall, in the context of the high prevalence and aggressive nature of PDAC, FNA with ROSE represents the superior tissue acquisition strategy, providing the highest sample adequacy and diagnostic accuracy while maintaining procedural safety and efficiency. These findings support prioritizing FNA with ROSE as the first-line diagnostic approach in routine clinical practice.

CONCLUSION

This retrospective study demonstrates that EUS-guided fine-needle aspiration (FNA) performed with

rapid on-site evaluation (ROSE) provides superior sample adequacy, diagnostic accuracy, and overall procedural efficiency in the evaluation of solid pancreatic lesions. FNA with ROSE was particularly advantageous in diagnosing pancreatic ductal adenocarcinoma (PDAC), the predominant pathology in our cohort. The real-time cytopathological assessment offered by ROSE ensures optimal sample collection, reduces the need for repeat passes, and enhances the reliability of cytological interpretation. Although FNB can obtain larger tissue cores, the consistently higher adequacy rates and improved diagnostic performance achieved with FNA plus ROSE make it a more effective and dependable tool—especially when timely and accurate diagnosis is crucial. Therefore, FNA with ROSE remains the superior diagnostic approach across all evaluated parameters.

Conflict of Interest

The authors declare that they have no conflicts of interest.

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