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Establishing the optimal number of passes during EUS-guided fine needle biopsy for the diagnosis of pancreatic solid lesions: a prospective multicentre

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Affiliations below.

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Trial registration: NCT05436704, ClinicalTrials.gov (http://www.clinicaltrials.gov/), Prospective, longitudinal

Abstract:
Background and study aims: The optimal number of needle passes during endoscopic ultrasound-guided fine-needle biopsy (EUS-FNB) is not yet established. We aimed to perform a per-pass analysis of the diagnostic accuracy of EUS-FNB of solid pancreatic lesions using a 22G Franseen needle.

Patients and methods: Consecutive patients with solid pancreatic lesions referred to 11 Italian centers were prospectively enrolled. Three needle passes were performed; specimens were collected after each pass and processed individually as standard histology following macroscopic on-site evaluation (MOSE) by the endoscopist. The primary endpoint was diagnostic accuracy of each sequential pass. Final diagnosis was established on surgical pathology or based on clinical course of at least six months. Secondary endpoints were specimen adequacy, MOSE reliability, factors impacting diagnostic accuracy, and procedure-related adverse events.

Results: 504 samples from 168 patients were evaluated. Diagnostic accuracy was 90.5% (85.0%-94.1%) after one pass and 97.6% (94.1%-99.3%) after two passes (p<0.01). Similarly, diagnostic sensitivity and sample adequacy were significantly higher adding the second needle pass (90.2%, 84.6%-94.3% vs 97.5%, 93.8%-99.3%, p=0.009 and 91.1%, 85.7%-94.9% vs 98.2%, 95.8%-99.3%, p=0.009, one pass vs two passes, respectively). Accuracy, sensitivity, and adequacy remained the same after the third pass. The concordance between MOSE and histological evaluation was 89.9%. The number of passes was the only factor associated with accuracy. One case of mild acute pancreatitis (0.6%) was managed conservatively.

Conclusions: At least two passes should be performed for the diagnosis of solid pancreatic lesions. MOSE is a reliable tool to predict the histological adequacy of specimens.

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INTRODUCTION

Endoscopic ultrasound-guided tissue acquisition (EUS-TA) is the recommended technique for the sampling of solid pancreatic lesions [1]. During the last decades, EUS-TA has evolved owing to improvements in diagnostic sensitivity, such as needle size [1], sampling technique [2], use of different types of suctions [3], and the employment of rapid on-site evaluation (ROSE) [4]. However, one of the major breakthroughs has been reached with the availability of third generation needles which carry the design of end-cutting tips (e.g., Franseen or fork-tip needles). The excellent diagnostic and histological yields over standard fine-needle aspiration (FNA) [5, 6] has shifted clinical practice from FNA to fine-needle biopsy (FNB).

Furthermore, the role of ROSE has been weighed [4] in favor of macroscopic on-site evaluation (MOSE). The MOSE of acquired tissue by the endoscopist was first proposed by Iwashita et al, using an FNA 19G needle [7]. More recently, MOSE using end-cutting needles has been associated with high sample adequacy, suggesting the possibility of replacing ROSE [8, 9]. Finally, in the absence of ROSE, guidelines have recommended 3 to 4 needle passes using an FNA needle and 2 to 3 passes using a reverse-bevel FNB needle.

However, the optimal number of needle passes performed using end-cutting needles for the sampling of pancreatic solid lesions has not yet been established. Additionally, specifically designed studies aimed at determining the optimal number of needle passes are lacking. A recent randomized study demonstrated that the adequacy (based on MOSE) of samples collected with a Franseen needle was associated with a lower number of needle passes compared with the conventional 3 passes [8]. Moreover, in a recent randomized study where fork-tip needles were used, a minimal incremental value of accuracy was observed with the second pass [6]. However, the study reported no further gain after adding a third pass. Differently, no data about the number of passes to be performed using a Franseen needle has been published.

To fill this gap, we performed a prospective multicenter study with the primary aim of evaluating the diagnostic accuracy of FNB performed using a 22G Franseen needle with 1, 2, and 3 needle passes. Secondary aims were specimen adequacy with 1, 2, and 3 needle passes, reliability of MOSE to establish sample adequacy at histology, factors impacting diagnostic accuracy, and procedure-related adverse events (AEs) rate.

METHODS

Study design and patient population
This was a multicentric prospective study conducted at 11 Italian centers. After local ethic committee approval (protocol number HMD 487/22, 14/06/2022), the protocol was registered on ClinicalTrials.gov (NCT05436704). Consecutive adult patients referred for EUS-FNB for the diagnosis of solid pancreatic lesions were assessed for eligibility. Exclusion criteria were: 1) previous biopsy of the lesion with a diagnosis of malignancy; 2) cystic component larger than 25% of volume; 3) uncorrectable coagulopathy or use of anticoagulant that cannot be discontinued; 4) pregnancy or breast-feeding; 5) lack of informed consent.

Procedures and specimens processing

All the procedures were performed after obtaining informed consent under deep sedation or conscious sedation according to institutional policy. Only experienced endosonographers with > 400 EUS performed and not trained in cytopathology were involved. The needle used for the study was the 22G Franseen needle (Acquire Boston Scientific; Natick. Mass). The slow-pull technique was used in all cases: after the needle tip was inserted into the target lesion, the stylet was slowly withdrawn while several to-and-fro movements of the needle were performed [3]. The fanning technique was also used whenever possible [2]. As suggested by European Society of Gastrointestinal Endoscopy guidelines [1], up to three needle passes were performed for each lesion.

The specimen collected after each needle pass was handled and inspected by the endosonographer for MOSE evaluation. The worm-like whitish or yellowish material was aligned on a slide using a syringe needle and the length was assessed using a ruler [8]. After MOSE, the whole sample (including bloody material and clots) was placed in labeled formalin vial and processed independently as standard histology. A dedicated pathologist with at least 5 years of experience in gastrointestinal pathology at each participating site provided a diagnosis for each container and was not blinded from the results of the previous sample.

Technical failure was defined when biopsy was not performed at all. Incomplete procedure was defined when less than 3 passes were performed.

Definition and study endpoints

The primary endpoint was diagnostic accuracy of each sequential pass. Diagnostic accuracy was defined as the percentage of lesion corresponding to the final diagnosis [10] that was assessed on surgical specimen. In non-resected patients, final diagnosis was based on the evolution of the disease assessed for at least 6 months by a combination of clinical course, imaging studies, and/or
additional tissue sampling demonstrating progression in cancer-related lesions or disease stability in the benign lesions [10]. Histologic evaluations followed the Papanicolaou classification [11]. EUS samples reported as suspicious for malignancy were considered as malignant whereas those that contained inadequate material were included in the analysis and considered as negative for malignancy. In addition, other performance measures (i.e., sensitivity and specificity) were evaluated for each needle pass.

Specimen adequacy was defined as the percentage of lesions sampled in which the obtained material is representative of the target site and sufficient for diagnosis [10].

MOSE reliability was defined as the concordance rate between MOSE adequacy and presence of histologic core (i.e., presence of a tissue sample that allows for histologic and tissue architectural assessment) [10]. MOSE was defined as adequate if a macroscopic visible core (MVC) was obtained. MVC was defined as a worm-like whitish or yellowish material, not including fluid-like specimens, measuring at least 10-mm in the major axis [8].

Potential factors impacting diagnostic accuracy, such as age, sex, lesion location and size, biopsy route and number of needle passes were evaluated.

AEs were evaluated according to the American Society for Gastrointestinal Endoscopy workshop report [12].

Follow-up

After EUS-FNB, patients were observed in the recovery room for at least 2 hours and were contacted at 24 hours, 14 and 30 days after the procedure to record any AEs.

Follow-up was performed by the study investigator at each participating center by electronic chart review, outpatient visits, and telephone contacts. Follow-up was terminated in case of surgical resection or death.

Statistical analysis

Sample size was calculated based on evaluation of the primary outcome of diagnostic accuracy for evaluation of solid pancreatic lesions. The study hypothesis was that the first needle pass was equivalent to the conventional 3 passes. A sample size of 140 patients was required, based on the expected diagnostic accuracy of 96.7% after 3 passes and 93.4% after 1 needle pass with 22G FNB needle [6], an equivalence margin of ± 5%, power of 90%, and an alpha level of 5% (1-sided). Considering an expected drop-out rate of 20%, we decided to enroll 170 patients.
Equivalence was met for the primary endpoint if the limits of a two-sided 90% confidence interval (CI) excluded a difference between the two groups of more than 10%.

Continuous data were presented as mean and standard deviation whereas categorical data were presented as numbers (percentages).

Normal distribution of variables was checked through Kolmogorov-Smirnov test.

Comparisons between paired groups were performed through McNemar’s test and p values were corrected through Bonferroni’s correction for multiple comparisons. Correlation between adequacy rates of samples evaluated on MOSE and adequacy evaluated by means of histology was performed by means of Cramer’s $\Phi$ test, where a $\Phi$ test between 0 and 0.3 represents weak correlation, between 0.3 and 0.6 moderate correlation, and between 0.6 and 1 strong correlation [13].

Correlation between baseline parameters and diagnostic accuracy was tested through univariate logistic regression analysis and the results were expressed in terms of odds ratio (OR) and 95% CIs.

All analyses were performed with *rms* package in R (R Foundation for Statistical Computing, Vienna, Austria).

**RESULTS**

**Patients**

From July 2022 to October 2022, 170 consecutive patients (75 males, mean age 67.1 years) were enrolled and 2 were lost to follow-up. All patients underwent EUS-FNB with 3 passes. Therefore, 168 patients were analyzed, and the per-protocol population completely reflected an intention-to-treat analysis. The flow-chart of the patients recruited in this study is reported in Figure 1. Table 1 summarizes baseline features of the patient population.

**Diagnostic accuracy**

Diagnostic accuracy was 90.5% (85.0%-94.1%) after 1 needle pass, 97.6% (94.1%-99.3%) after 2 passes, and 97.6% (94.1%-99.3%) after 3 needle passes, with 90.2% (84.6%-94.3%), 97.5% (93.8%-99.3%), and 97.5% (93.8%-99.3%) diagnostic sensitivity after 1, 2, and 3 needle passes, respectively. Specificity was 100% in all study groups. No statistically significant difference in terms of diagnostic accuracy was found between 2 and 3 passes ($p=1.0$), whereas both 2 and 3 passes significantly outperformed a single pass ($p=0.01$). Per-pass analysis of diagnostic measures is reported in Table 2.
The difference in the accuracy between 2 (or 3) passes and 1 pass was 7.1% (5% to 9.2%). The lower limit of the CI for the difference in diagnostic accuracy exceeded the equivalence margin of ± 5%, therefore, equivalence was not shown for the primary outcome.

Univariate regression analysis showed that only the number of passes was a significant predictor of diagnostic accuracy (OR 4.3, 1.4-13.2; p=0.01) (Table 3).

Secondary outcomes
Specimen adequacy rates were 91.1% (85.7%-94.9%) after 1 needle pass, 98.2% (95.8%-99.3%) after 2 passes, and 98.2% (95.8%-99.3%) after 3 needle passes. Again, a significant difference was observed in the comparison between 3 passes and 1 pass (p=0.009) and between 2 passes and 1 pass (p=0.009), whereas no difference was observed when comparing 2 vs 3 passes (p=1.0).

For MOSE reliability, 504 samples were evaluated and compared with histological assessment. MOSE was deemed adequate in 473/504 (93.8%) cases with a concordance rate with histology of 89.9% (453/504). Discordancy was observed in 25 out of 31 cases deemed not adequate and 26 out of 473 cases recorded as adequate at MOSE and eventually resulted adequate and inadequate at histology, respectively (Table 4). There was strong correlation between MOSE adequacy and adequacy assessed on histology (Cramer’s Φ= 0.63, p=0.007). The concordance between MOSE and histologic adequacy was 85.7%, 90.5%, and 93.5% after the first, second, and third pass, respectively.

One case of mild acute pancreatitis (0.6%) was registered and managed conservatively with 2 days of hospitalization. Moreover, 16 (9.5%) intraprocedural bleeding cases were registered and considered as “incidents” for not requiring any medical intervention nor prolongation of hospitalization. No cases of procedure-related death were observed.

DISCUSSION
In recent years, EUS-FNB with end-cutting needles have revolutionized the practice of EUS-TA of solid lesions. Major changes included the possibility of abandoning ROSE, the retrieval of histological specimens for the diagnosis of rare conditions [14-17], and the reduction of needle passes. To this end, most endoscopists hold that, in most cases, a sufficient sample for diagnosis is retrieved after the first pass using an end-cutting needle. Indeed, a recent study by Bang et al reported that a single pass of FNB with the Franseen needle could achieve a sensitivity of more than 90% to diagnose pancreatic cancer [18]. However, European Society of
Gastrointestinal Endoscopy guidelines suggests 2 to 3 passes with a reverse-bevel needle [1] and a recent prospective study comparing two different end-cutting needles demonstrated that at least 2 passes of FNB are required to achieve a diagnostic sensitivity of 90% in pancreatobiliary cancers [19]. Therefore, the number of passes is not yet standardized when an end-cutting needle is used for the sampling of solid pancreatic lesions.

For this reason, we performed a multicenter prospective study assessing the diagnostic accuracy of EUS-FNB after the first, second, and third needle pass using a Franseen 22G needle. We observed 90% accuracy after the first pass. This result can undoubtedly be considered (by itself) an amazing achievement compared to the reported performance of FNA. However, we found that the addition of a second pass significantly increased the diagnostic accuracy to 97%. In contrast, the accuracy remained the same after the third pass. The overall rate of accuracy reported in the present study agrees with recent literature [4-6, 20-22].

Our results reflect those of two randomized trials. In the first study, fork-tip needles were compared with reverse-bevel needles; the fork-tip needle was reported having 93%, 97%, and 97% accuracy after 1, 2, and 3 needle passes, respectively [6]. In the second RCT, the Franseen needle was compared with a different end-cutting needle with a 3-prong asymmetric tip [19]. The authors found that the second pass improved the diagnostic sensitivity from 85.1% to 91.5% and from 82.4% to 90.2%, for the Franseen needle and the end-cutting needle with a 3-prong asymmetric tip, respectively [19]. Moreover, we tested the equivalence of 1 pass versus 3 passes (that in this study reflect the comparison between 1 and 2 passes). Our hypothesis was not confirmed. Indeed, the difference in accuracy proportion between 2 (or 3) passes and 1 pass was 7.1%, thus exceeding the equivalence margin of 5%.

The robustness of our findings was confirmed using univariate analysis investigating factors associated with accuracy. We found that the number of passes was the only variable significantly associated with accuracy with an OR of 4.3. Similar results were observed when specimen adequacy was evaluated, with a significant improvement from 91% to 98% by adding a second needle pass. Based on our findings, at least 2 needle passes should be performed during EUS-FNB with end-cutting needles.

We also assessed the reliability of MOSE for establishing histologic adequacy. Overall, 504 passes were independently evaluated and MOSE results were compared with histological evaluation. The rate of concordance was close to 90% with a Cramer $\Phi$ of 0.63, representing a strong correlation. Overall, 51/504 (10%) specimens not concordant with histopathology were observed. Interestingly, among 31 cases deemed not adequate with MOSE, 25 (80.6%) were eventually
adequate on histology. On the other hand, only 26/473 (5.5%) cases evaluated as adequate with MOSE were deemed not adequate on histology. This finding possibly suggests that the adequacy cut-off of 10-mm white-yellowish core previously suggested [23] and used in the study should be reassessed in specifically designed clinical trials. Similar results were observed in a recent randomized trial comparing EUS-FNB driven by MOSE and EUS-FNB with 3 passes [8] where 7% of discordant specimens were observed. Moreover, in the same study, the addition of a second sample that was collected after MOSE adequacy to reach 3 passes as suggested by guidelines, improved the diagnostic adequacy and accuracy from 90% to 95% and from 93% to 98%, respectively. However, in the abovementioned study, both pancreatic and nonpancreatic lesions were included, and the number of passes was established on MOSE. In contrast, the present study assessed the crude association between MOSE and histology for each single pass. Importantly, in the present study, diagnostic accuracy was evaluated regardless of the MOSE results. MOSE was compared to histologic adequacy that doesn’t always reflect diagnostic accuracy. Therefore, even if the concordance of MOSE and histologic adequacy was close to 90% after the first pass, the present study demonstrated that a second pass should be performed to increase diagnostic accuracy regardless the result of MOSE after the first pass.

Besides accuracy, EUS-FNB represents a tool to provide tissue for molecular tests in the preoperative setting [24]. In a recent study, after the diagnosis was confirmed at ROSE, patients were randomized to undergo EUS-FNB with 2 or 3 dedicated passes for DNA and RNA extraction from paraffin blocks. Two passes performed similarly to 3, with no significant difference in the median concentration of DNA and RNA. Future studies should address if 2 passes only is sufficient for both diagnostic and molecular testing purposes.

Finally, our study confirms the excellent accuracy of EUS-FNB for the sampling of pancreatic solid lesions performed with an end-cutting needle even in the absence of ROSE. Our results support the data reported in a recent meta-analysis that highlighted the non-superiority of EUS-FNB + ROSE over EUS-FNB with newer end-cutting needles [19]. However, ROSE could have still a role when FNA needles are used.

Overall, the current data suggest sampling solid pancreatic lesions by performing 2 needle passes. After the collection of samples with 2 passes, MOSE can be performed where additional passes can be added in cases of MOSE inadequacy. This could shorten the procedure time with significant advantages, especially for patients with poor general conditions.

Our study has several limitations. First, the designated pathologist at each center evaluated all the three specimens from each patient. Therefore, the evaluation of the second sample could
potentially be biased by the evaluation of the first specimen. To overcome this, future studies should be specifically designed to compare samples containing one pass with those containing 2 passes together. Second, only the 22G Franseen needle with the slow-pull technique was used, thus our result could be different by using other devices or aspiration techniques. On the other hand, the performance of Franseen needles was comparable to fork-tip ones, and both ranked the highest performing FNB needles in a recent large meta-analysis including 16 randomized controlled trials [22]. Therefore, it is likely that these needles will become the most used in clinical practice. Similarly, the slow-pull technique showed equal histologic and accuracy rates compared with wet-suction for the evaluation of solid pancreatic lesions [3, 21]. Third, MOSE reliability in terms of agreement with histological adequacy was evaluated for each single pass, thus, it could be higher when 2 passes are placed together and assessed macroscopically. Finally, we limited our study to solid pancreatic lesions and no information were provided for extra pancreatic masses.

In conclusion, the rates of accuracy and specimen adequacy with only 1 pass using the 22G Franseen needle is remarkably high. Our study showed that the addition of a second pass significantly increases the performance of EUS-FNB whereas a third pass could be avoided. MOSE is a reliable tool to assess specimen adequacy and can be used to evaluate the need for additional passes.

FIGURE LEGENDS

Figure 1 Study flow-chart
Table 1  Baseline features of 168 patients analyzed.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, yr</strong></td>
<td>67.1</td>
</tr>
<tr>
<td></td>
<td>(11.5)</td>
</tr>
<tr>
<td><strong>Sex, N (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>75 (44.7%)</td>
</tr>
<tr>
<td>Female</td>
<td>93 (55.3%)</td>
</tr>
<tr>
<td><strong>Tumor site, N (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Uncinate process</td>
<td>16 (9.5%)</td>
</tr>
<tr>
<td>Head</td>
<td>75 (44.6%)</td>
</tr>
<tr>
<td>Neck</td>
<td>10 (6%)</td>
</tr>
<tr>
<td>Body</td>
<td>40 (23.8%)</td>
</tr>
<tr>
<td>Tail</td>
<td>27 (16.1%)</td>
</tr>
<tr>
<td><strong>Tumor size, mm</strong></td>
<td>31.9</td>
</tr>
<tr>
<td></td>
<td>(12.2)</td>
</tr>
<tr>
<td><strong>Biopsy route, N (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Transgastric</td>
<td>84 (50.0%)</td>
</tr>
<tr>
<td>Transduodenal</td>
<td>84 (50.0%)</td>
</tr>
<tr>
<td><strong>Final diagnosis, N (%)</strong></td>
<td></td>
</tr>
<tr>
<td>PDAC</td>
<td>127 (75.5%)</td>
</tr>
<tr>
<td>NET</td>
<td>18 (10.7%)</td>
</tr>
<tr>
<td>Metastasis</td>
<td>12 (7.1%)</td>
</tr>
<tr>
<td>Inflammatory</td>
<td>5 (3.2%)</td>
</tr>
<tr>
<td>Other*</td>
<td>6 (3.5%)</td>
</tr>
<tr>
<td><strong>Follow-up</strong></td>
<td></td>
</tr>
<tr>
<td>Median time, days (95% CI)</td>
<td>212 (168-254)</td>
</tr>
<tr>
<td>Surgical resection, N (%)</td>
<td>39 (23.2%)</td>
</tr>
</tbody>
</table>
*Other includes: Neuroendocrine carcinoma (2), autoimmune pancreatitis (1), intrapancreatic spleen (1), lymphoid tissue (1), schwannoma (1)

SD, standard deviation; PDAC, pancreatic ductal adenocarcinoma; NET, neuroendocrine tumor; CI, confidence interval

**Table 2**  
Diagnostic measures after one, two, and three needle passes observed in 168 patients who underwent endoscopic ultrasound-guided fine-needle biopsy of solid pancreatic lesions.

<table>
<thead>
<tr>
<th></th>
<th>One pass</th>
<th>Two passes</th>
<th>Three passes</th>
<th>Two passes vs one pass</th>
<th>Three passes vs one pass</th>
<th>Three passes vs two passes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity, %</strong></td>
<td>90.2</td>
<td>97.5</td>
<td>97.5</td>
<td><strong>p=0.009</strong></td>
<td><strong>p=0.009</strong></td>
<td>p=1</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(84.6-94.3)</td>
<td>(93.8-99.3)</td>
<td>(93.8-99.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Specificity, %</strong></td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(94.3-100)</td>
<td>(93.4-100)</td>
<td>(93.4-100)</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td><strong>Accuracy, %</strong></td>
<td>90.5</td>
<td>97.6</td>
<td>97.6</td>
<td><strong>p=0.01</strong></td>
<td><strong>p=0.01</strong></td>
<td>p=1</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(85.0-94.1)</td>
<td>(94.1-99.3)</td>
<td>(94.1-99.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Adequacy, %</strong></td>
<td>91.1</td>
<td>98.2</td>
<td>98.2</td>
<td><strong>p=0.009</strong></td>
<td><strong>p= 0.009</strong></td>
<td>p=1</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(85.7-94.9)</td>
<td>(95.8-99.3)</td>
<td>(95.8-99.3)</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

CI, Confidence interval
Table 3  Univariate analysis investigating factors associated with diagnostic accuracy.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odd ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (ref. ≤ 67 years)</td>
<td>2.7</td>
<td>0.3-26.7</td>
<td>0.39</td>
</tr>
<tr>
<td>Sex (ref. female)</td>
<td>1.8</td>
<td>0.7-5.4</td>
<td>0.76</td>
</tr>
<tr>
<td>Location (ref. head/uncinate)</td>
<td>0.4</td>
<td>0.03-3.8</td>
<td>0.41</td>
</tr>
<tr>
<td>Size (ref. ≤ 30 mm)</td>
<td>2.5</td>
<td>0.3-24.8</td>
<td>0.45</td>
</tr>
<tr>
<td>Biopsy route (ref. transgastric)</td>
<td>3.1</td>
<td>0.3-30.2</td>
<td>0.33</td>
</tr>
<tr>
<td>Number of passes (ref. one pass)</td>
<td>4.3</td>
<td>1.4-13.2</td>
<td><strong>0.01</strong></td>
</tr>
</tbody>
</table>

CI, Confidence interval
Table 4  Concordance between macroscopic on-site evaluation adequacy and presence of histologic core on 504 specimens collected during endoscopic ultrasound-guided fine-needle biopsy of solid pancreatic lesions.

<table>
<thead>
<tr>
<th>MOSE evaluation</th>
<th>Histological evaluation</th>
<th>Adequate</th>
<th>Not adequate</th>
<th>Total</th>
<th>Concordance</th>
<th>Cramer’s Φ</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate</td>
<td></td>
<td>447</td>
<td>26</td>
<td>473</td>
<td>89.9%</td>
<td>0.63</td>
<td>0.007</td>
</tr>
<tr>
<td>Not adequate</td>
<td></td>
<td>25</td>
<td>6</td>
<td>31</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>472</td>
<td>32</td>
<td></td>
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</tr>
</tbody>
</table>

MOSE, macroscopic on-site evaluation
REFERENCES


Figure 1  Study flow-chart

Patients with suspected solid pancreatic lesion assessed for eligibility = 192

Excluded = 22
- Lesion not seen at EUS (n=6)
- Bleeding disorder (n=4)
- Refused to be included (n=7)
- Cystic lesion on EUS (n=2)
- Biopsy performed using a 25G needle (n=3)

Patients enrolled = 170

Lost to follow-up (n=2)

Patients analyzed = 168

*EUS*, endoscopic ultrasound.