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"Evaluation of the Endoscopic Ultrasound Aspiration Needle (EUS-AN) for Tissue Sampling in a Simplified Laboratory Setting: Performance, Durability, and Potential Applications"

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Abstract

Endoscopic ultrasound (EUS)-guided needle aspiration has become a cornerstone technique for obtaining tissue samples in the diagnosis of gastrointestinal tumors. The Endoscopic Ultrasound Aspiration Needle (EUS-AN) is widely utilized in clinical settings with ultrasound guidance. However, its performance and practicality in non-clinical environments—such as training laboratories and research settings where imaging modalities may not be available—have not been thoroughly investigated. This study aimed to evaluate the usability, efficiency, and structural integrity of the EUS-AN in a simplified laboratory setting using real tissue models, without ultrasound guidance. The performance of the EUS-AN was assessed using fresh chicken tissue to simulate submucosal structures. The procedure included controlled needle insertion, vacuum-assisted aspiration, and evaluation of sample quality. Key components analyzed were the sharp bevel tip, adjustable sheath, and vacuum-assisted syringe system. Parameters such as penetration efficiency, tissue aspiration, sample integrity, and needle durability were systematically measured over multiple use cycles. The EUS-AN demonstrated smooth and consistent tissue penetration with minimal resistance. Vacuum-assisted aspiration yielded intact samples without fragmentation, indicating preserved tissue architecture. Post-procedural inspection revealed no structural damage, bending, or clogging of the needle after repeated use. The entire sampling procedure was completed efficiently, confirming its ease of use and practicality in a non-clinical setting. The EUS-AN proved to be a reliable and efficient tool for tissue sampling outside traditional clinical environments. Its robust design and high-performance features support its potential application in research, educational training, and resource-limited settings, thereby broadening its utility beyond conventional EUS-guided procedures.

Keywords: Endoscopic Ultrasound Aspiration Needle (EUS-AN), Tissue Sampling, Non-clinical Settings, Vacuum-assisted Aspiration, Submucosal Tissue Model, Needle Durability and Performance

Introduction

Endoscopic ultrasound (EUS)-guided needle aspiration has emerged as a critical technique for obtaining tissue samples in patients with gastrointestinal tumors [1]. Over the past few decades, significant advancements in gastroenterology have been driven by the transition from conventional endoscopy to EUS,

a transformative technology that allows for the visualization and access of deep-seated organs and structures within the body [2,3]. The Endoscopic Ultrasound Aspiration Needle (EUS-AN) is a core instrument in EUS-guided procedures, designed to facilitate minimally invasive tissue and fluid sampling [4]. It plays a crucial role in diagnosing and managing gastrointestinal and pancreatic lesions by enabling high-precision biopsy collection and the targeted delivery of therapeutic agents [5,6].

Despite its well-established clinical applications, further exploration of its performance in controlled laboratory settings remains necessary to expand its utility beyond conventional imaging-assisted procedures [7]. Traditional applications of EUS-AN rely on real-time ultrasound guidance to target lesions accurately [8]. However, resource-limited settings, training environments, and experimental research scenarios often lack access to sophisticated imaging modalities [9]. This limitation presents a gap in understanding how the device performs under simplified conditions without ultrasound support. Evaluating the usability and efficiency of the EUS-AN in a non-clinical setting, where real-time imaging is not available, is essential for expanding its applicability beyond conventional clinical use [10].

This study aims to assess the performance of the Endoscopic Ultrasound Aspiration Needle (EUS-AN) in a simplified laboratory setting using real tissue models. Specifically, the research seeks to demonstrate the functionality of the EUS-AN without ultrasound guidance and evaluate its ability to perforate, aspirate, and preserve tissue specimens. Additionally, the study aims to analyze the effectiveness of the device's core components, including the sharp bevel tip, adjustable sheath, and vacuum-assisted syringe system, in ensuring precise and efficient tissue sampling. Furthermore, the feasibility of using the EUS-AN for research, training, and resource-limited applications will be examined to explore its broader applicability beyond conventional clinical settings.

To address these objectives, the research is guided by several key questions. The study investigates whether the EUS-AN can effectively obtain high-quality tissue samples in a non-clinical environment and whether its sharp bevel tip and adjustable sheath contribute to precise functionality in a simplified setting. Additionally, the study seeks to compare the device's performance in a non-imaging setup to its conventional use with ultrasound guidance. Another critical question explores whether the EUS-AN can serve as a practical tool for training and research, particularly in scenarios where advanced imaging technologies may not be available.

The hypothesis of this study posits that the EUS-AN will successfully acquire high-quality tissue samples with minimal resistance, even in the absence of ultrasound guidance. It is further hypothesized that the device's design features, including the sharp bevel tip and adjustable sheath, will allow for controlled and efficient sampling, thereby supporting its potential use in non-clinical environments for training and research purposes.

The significance of this study lies in its potential to expand the utility of the EUS-AN beyond its conventional clinical applications. By validating the device's effectiveness in a simplified laboratory setting, this research provides insights into its usability for training, experimentation, and resource-limited conditions. The findings may contribute to the development of alternative methodologies for medical education and procedural training, offering a cost-effective approach to tissue sampling [11]. Additionally, the study's outcomes may encourage further innovations in endoscopic needle technology, ultimately enhancing its accessibility and applicability in diverse medical and research settings [12].

Literature Review

EUS-guided biopsies are recognized as reliable, safe, and effective techniques for obtaining tissue samples for cytological or histological examination, whether as a primary diagnostic method or when conventional biopsy techniques have failed [1,2]. Techniques such as EUS-guided fine-needle aspiration (FNA) and EUS-guided trucut biopsy have proven especially valuable in the diagnostic assessment of both benign and malignant gastrointestinal conditions, as well as for accurate staging of malignancies affecting the gastrointestinal tract and adjacent organs [3,4].

The diagnostic yield of EUS-guided biopsies is influenced by several factors, including the location, size, and echogenic characteristics of the target tissue, as well as technical aspects such as needle type, operator experience, and number of passes performed [5].

Endoscopic ultrasound-guided needle aspiration (EUS-AN) enables cytological assessment of aspirated samples from lesions adjacent to the gastrointestinal tract, including lymph nodes, pancreas, adrenal glands, and liver [6]. This technique has become indispensable in managing pancreatic, hepatic, and mediastinal lesions, especially when other diagnostic tools are inconclusive or not feasible [7].

EUS-FNA has proven especially useful for sampling mucosal and submucosal lesions that previously yielded non-diagnostic results through conventional endoscopic biopsies. It also allows targeted sampling of peri-intestinal structures such as lymph nodes and retroperitoneal masses [8]. With the rise of neoadjuvant treatment strategies—particularly in pancreatic cancer—tissue confirmation has become essential prior to initiating therapy, thus increasing the demand for precise and minimally invasive diagnostic modalities such as EUS-guided needle aspiration [9,10].

Materials and Methods

1. Device Design

The Endoscopic Ultrasound Aspiration Needle (EUS-AN) is engineered to enhance the accuracy and efficiency of tissue sampling in a minimally invasive manner. The following are the core design features and their respective functionalities:

1.1 Adjustable Sheath and Needle Length

- The EUS-AN offers an adjustable working length ranging from 137.5 cm to 141.5 cm, with a needle extension capacity of 0 cm to 8 cm.
- This feature ensures compatibility with various procedural requirements and echoendoscope configurations.

1.2 Sharp Bevel Tip

- The needle tip is precisely beveled to minimize tissue resistance during insertion.
- This design allows for smooth penetration with minimal trauma, enhancing sample integrity during retrieval.

1.3 Vacuum-Assisted Aspiration System

- The device includes a syringe with a one-way stopcock system, enabling controlled suction during tissue aspiration.
- This mechanism ensures efficient and high-quality specimen collection.

1.4 Multiple Gauge Sizes

- The EUS-AN is available in 19G, 22G, and 25G, providing flexibility for diverse diagnostic and clinical needs.

1.5 Echogenic Features

- Although echogenic tips were not utilized in this study, the needle can be manufactured with echogenic coatings to aid in sonographic visualization during imaging-guided procedures.

2. Applications and Significance

2.1 Applications

- **Diagnostic:** Biopsy of lesions for diagnosis of malignancies, pancreatic cysts, and inflammatory conditions.
- **Therapeutic:** Delivery of injectable agents or placement of fiducial markers for radiotherapy.
- **Educational and Research Use:** Utilized in preclinical research and for training medical professionals in endoscopic techniques.

2.2 Significance

- **Accuracy:** The adjustable sheath and sharp bevel tip facilitate precise lesion targeting.
- **Efficiency:** The vacuum-assisted system allows for rapid and reliable sample collection.
- **Safety:** The minimally invasive design minimizes patient discomfort and procedural risk.

3. Simulation Environment Setup

3.1 Experimental Model

- **Tissue Model:** Fresh chicken tissue was selected to simulate human submucosal structures due to its comparable density and texture.
- **Rationale:** This model enables realistic evaluation of device penetration, tissue aspiration, and specimen preservation without reliance on ultrasound imaging.

3.2 Device Configuration

- The EUS-AN was assembled with its accompanying vacuum-assisted syringe and one-way stopcock to replicate actual procedural conditions.
- The setup allowed assessment of the device's penetration efficiency, aspiration capability, sample integrity, and needle durability during repeated use.

Figure 1: Endoscopic Ultrasound Aspiration Needle

1. **Procedure**

Step 1: Device and Tissue Setup

Chicken tissue was put on a rigid, sterile base, which most nearly approximated the clinical situation. The needle was checked to be of adequate length for full retraction into the sheath before its insertion and the syringe was attached to the aspiration port.

Figure 2: Device Set-up

Step 2: Insertion of the Needle

The sheath length was set according to the target depth of penetration. A wide range of between 0 to 8 cm was available. The needle was manually inserted into the tissue at a controlled speed. The sharp bevel tip allowed easy and frictionless penetration.

Step 3: Tissue Aspiration

The vacuum syringe was activated by retracting the plunger to generate a suction force. Keeping the suction, the needle was rocked gently from side to side to maximize the tissue yield.

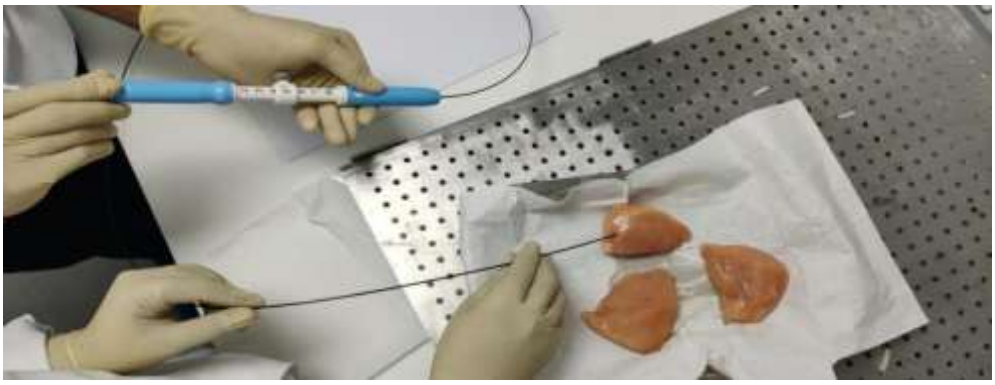

Figure 3: Insertion of Needle

Step 4: Sample Acquisition

Once aspirated, the sample was pushed out of the needle into a sterile collection device by flushing the needle with air using the syringe. Samples were evaluated for quality and quantity visually.

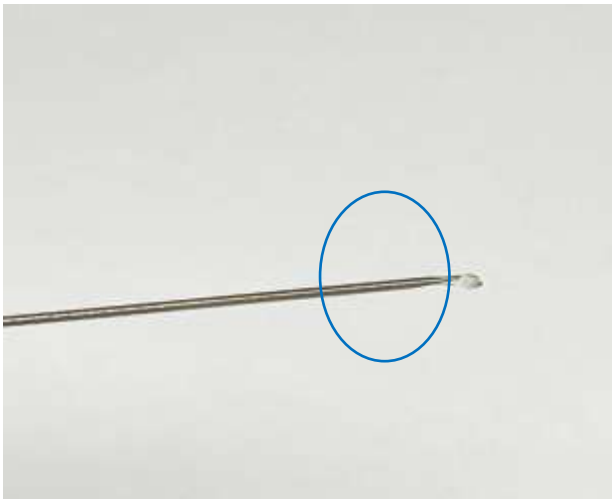

Figure 4: Acquired Sample in the Needle

Step 5: After Procedure Evaluation

The needle was carefully inspected for signs of bending, clogging, or other damage.

Result:

The experiment conducted with the Endoscopic Ultrasound Aspiration Needle (EUS-AN) demonstrated its precision and efficiency in tissue sampling, providing consistent and reliable results. The sharp bevel tip of the needle proved to be highly effective in penetrating the chicken tissue. The insertion process was smooth and required minimal force, reflecting the device's well-designed ergonomics and ease of use. Across multiple replicates, no significant resistance was encountered that could have compromised either the sample quality or the operator's control during the procedure.

The aspirated tissue samples remained intact, showing no signs of fragmentation or damage as a result of the aspiration process. The consistency in texture and volume of the collected specimens confirmed that the needle effectively preserved the integrity of the tissue, ensuring their suitability for diagnostic purposes.

Following the completion of the experiment, the structural integrity of the needle was carefully assessed. No bending, clogging, or damage to the tip or casing was observed, even after multiple punctures and suction cycles. These findings confirmed the durability and robustness of the needle, demonstrating its ability to withstand repeated use without any structural compromise.

The entire aspiration procedure, from needle insertion to sample acquisition, was completed efficiently in a short duration. This rapid execution underscores the needle's effectiveness in environments where time efficiency is crucial, such as clinical and research settings.

Overall, the performance of the EUS-AN in terms of penetration, sample integrity, needle durability, and procedural efficiency was excellent, highlighting its potential for a wide range of diagnostic, research, and training applications.

Discussion:

The findings of this study reaffirm the practical utility of the Endoscopic Ultrasound Aspiration Needle (EUS-AN) as a reliable and efficient device for tissue sampling. The sharp bevel tip facilitated smooth and effortless penetration through tissue layers, reducing insertion resistance and minimizing tissue trauma. Additionally, the adjustable sheath allowed for variations in depth, ensuring the collection of high-quality samples with minimal artifacts, which is crucial in clinical settings where accurate histological evaluation is required.

The aspirated tissue samples remained intact and well-preserved, demonstrating the needle's ability to minimize mechanical stress during the aspiration process. This characteristic is particularly significant in pathological analysis, where maintaining tissue integrity is essential for accurate diagnosis. Furthermore, repeated testing revealed no structural damage, bending, or clogging of the needle, indicating its durability and reliability. These factors contribute to the device's consistent performance and its potential to reduce procedural complications.

Traditionally, EUS-AN devices are employed with ultrasound guidance to enhance lesion targeting accuracy. While ultrasound imaging is beneficial in clinical settings, it was not utilized in this study since the tissue target was directly accessible. Despite the absence of imaging support, the device exhibited effective functionality, suggesting that it may be applicable in alternative settings, including those with limited access to real-time imaging.

Conclusion:

The findings of this experimental study demonstrate that the Endoscopic Ultrasound Aspiration Needle (EUS-AN) is highly reliable and efficient for tissue sampling. Tissue penetration, aspiration of high-quality samples, and maintenance of structural integrity were effectively facilitated by the device, highlighting its robust design and practical usability.

The precision and control provided by the needle were attributed to its sharp bevel tip and adjustable length, which allowed for accurate targeting and ease of penetration. Furthermore, the vacuum-assisted syringe system ensured the rapid and efficient aspiration of tissue samples, minimizing procedural time.

The durability of the needle was confirmed, as it withstood extended use without any structural compromise. This suggests a reduced likelihood of failure during clinical procedures, reinforcing its suitability for repeated applications.

Given these attributes, the EUS-AN is considered a valuable tool for research, training, and use in resource-limited clinical environments where access to traditional imaging modalities may be unavailable. The successful demonstration of its functionality in a basic laboratory setting provides a foundation for further investigations into its potential applications in diagnostic and therapeutic practices.

However, some limitations were identified during the study. The use of chicken tissue as a model may not fully replicate the complexities of human tissue, which could affect the accuracy of extrapolating these findings to clinical scenarios. Additionally, the absence of real-time imaging support during the procedure may impact the precision of needle placement in more intricate clinical cases. Further studies incorporating

human tissue models and imaging guidance are recommended to validate the findings and expand the device's applicability in diverse medical settings.

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