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A Single Center's Experience with the Novel Acquire Endoscopic Ultrasound Fine Needle Biopsy Device

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Abstract

Background: Solid pancreatic masses require sampling before a diagnosis can be made. Historically, diagnostic accuracy rates vary between 78% and 95% with fine needle aspiration (FNA). The Acquire needle (Boston Scientific) is a newly manufactured endoscopic ultrasound (EUS) fine needle biopsy (FNB) device created to increase diagnostic yield. The aim of this study was to compare diagnostic yield of the Acquire needle to our institution's standard EUS sampling needles.

Methods: This is a retrospective study of patients who underwent EUS tissue acquisition (EUS-TA) for solid pancreatic masses using our 22G standard needles (n=58) and the 22G novel needle (n=23). The primary outcome was overall diagnostic yield. The secondary outcome was diagnostic rate based on location of the pancreatic lesion.

Results: Nineteen of the 23 (83%) pancreatic masses biopsied using the novel needle device were diagnostic, compared with 32 of 58 (55%) biopsied using the control needles (p=0.0237). Diagnostic rates specific to the lesions in the pancreatic head were 75% (n=12) in the Acquire group and 53% (n=20) in the control group (p=0.1452). Diagnostic rates specific to the lesions in the pancreatic body were 100% (n=7) in the Acquire group and 60% (n=12) in the control group (p=0.0681).

Conclusions: The Acquire is a novel EUS fine needle biopsy device that provides excellent diagnostic accuracy, demonstrating a statistically significant increase in overall diagnostic rate when directly compared to our institution's standard tissue acquisition needles (ProCore and Expect). To our knowledge, this is the first ever study to directly compare the diagnostic yield of the Acquire needle with biopsy needles used in current standard practice.

Keywords: Endoscopic ultrasound; Fine needle biopsy device; Pancreatic

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Introduction

Patients with pancreatic cancer have the one of the lowest survival rates of all cancers. For all stages combined, the 5-year relative survival rate is 8%. Over 50% of patients are not diagnosed until they have late stage disease; reducing 5-year survival rate to only 3% [1]. These devastating facts necessitate attempts to improve diagnostic methodology. Thus, over the last couple of decades, many studies have focused on the development of more accurate, more efficient, less invasive methods, with fewer complications [2]. Traditionally, pancreatic masses have been diagnosed through biopsy guided by endoscopic retrograde cholangiography, computed tomography, or surgery [2]. Now, with the advent of endoscopic ultrasound (EUS), samples of pancreatic lesions can be acquired through one of two ways: fine needle aspiration (FNA) or fine needle biopsy (FNB) [3-7]. FNA entails sampling of the pancreatic mass for cytologic analysis, whereas FNB involves sampling of the pancreatic mass for histopathologic analysis. Histopathology can provide a more conclusive diagnosis than cytology alone [3].

In this study report, we describe our initial experience with the novel Acquire FNB device (Boston Scientific); we hypothesized that the Acquire would provide better diagnostic accuracy than the other FNA and FNB needles used at our institution, which include the EchoTip ProCore (FNB; Cook Endoscopy) and the Expect (FNA; Boston Scientific). To our knowledge, there is no current literature addressing the diagnostic yield of the novel Acquire needle device.

Background

EUS-FNA, which has a 78% to 95% diagnostic accuracy, was first developed in 1992 [2]. In 2002, EUS-FNB became available, initially employing a Tru-cut biopsy needle (Quick-core; Cook Endoscopy) [5]. The Tru-cut needle, however, had its limitations and ultimately did not yield any greater diagnostic accuracy than standard FNA techniques [6]. In 2011, the ProCore needle (Cook Endoscopy) was developed in response to the inadequacies of the Tru-cut needle and provided increased user-maneuverability and more expansive coverage of the pancreas [4]. Since then, numerous other FNB needles have been produced but none have increased diagnostic accuracy compared to standard FNA needles. Despite numerous studies examining needle stiffness, needle gauge, and needle cutting mechanisms, the exact characteristics of a FNB needle that could lead to greater diagnostic yield have not yet been clearly delineated. Most recently, the Acquire and the SharkCore (Medtronic Corporation) EUS-FNB devices have been developed but definitive study reports comparing these needles with their predecessors are pending [3].

Methods

This was a retrospective study, approved by the local institutional review board (ID 2016-1186, approved 12/20/16), that was performed at a tertiary care center for all patients who underwent EUS tissue acquisition (EUS-TA) for solid pancreatic masses using our standard needles (ProCore and/or Expect), between January 2015 and May 2016 (n=94), and the Acquire needle, between July 2016 and January 2017 (n=23). Case data was retrieved from our institution's EUS database.

The primary objective of this study was to determine any differences in diagnostic yield between the novel Acquire FNB needle (experimental arm) and our standard needles (ProCore and Expect; control arm). Secondary objectives included diagnostic accuracy based on location of the pancreatic mass (e.g., pancreatic body versus pancreatic head).

In our retrospective study, the Acquire arm included patients who had undergone pancreatic mass biopsy with an Acquire needle device only 22G needles were used (n=23). The control arm included patients who had undergone pancreatic mass biopsy with the ProCore and/or Expect needles (n=94) using a range of gauges. This cohort was then narrowed to those biopsied using only 22G needles (n=58).

All EUS-TAs were performed by expert endoscopists at our institution. All histologic and cytologic analyses were performed by expert pathologists at our institution who were blinded to needle type and gauge. All histologic samples were treated with formalin and sectioned for hematoxylin and eosin staining per standard protocol. All cytologic specimens were also prepared via standard protocol.

A Fisher's exact test was used to analyze the data and help determine whether there were significant differences between the two groups of needles (ProCore/Expect versus Acquire) with respect to the primary endpoint of diagnostic yield (percentage of cases that had adequate tissue and were able to give a final diagnosis of malignant or benign tumor) as well as the secondary endpoint of diagnostic yield based on location of the pancreatic mass. Results were considered statistically significant if the 2-sided p-value was less than 0.05 (P<0.05). Patient demographics were described using means and ranges. The size of pancreatic mass measured using EUS was expressed as median (range).

Table 1: Demographics and clinical characteristics of the experimental and the control arms.

Characteristics	Acquire (EUS-FNB)	Control (EUS-TA)[1]
Age, y		
Mean (std. deviation)	68 ± 11.8	65 ± 10.3
Sex, no. (%)		
Male	12 (52%)	30 (52%)
Female	11 (48%)	28 (48%)
Size of mass on EUS, mm		
Median (range)	23 (1.9-50)	24 (9-60)
Lesion location, no. (%)		
Pancreatic head	16 (70%)	38 (66%)
Pancreatic body	7 (30%)	20 (34%)

[1]Standard EUS-TA refers to the control arm (ProCore FNB and Expect FNA). The needles were either used alone or in combination, the choice being at the endoscopist's discretion.

Results

Initially, 117 EUS-TAs for solid pancreatic lesions were found to have occurred between January 2015 and January 2017. Of the original 117 cases, 23EUS-TAs was carried out using the Acquire and 94 using the control needles (ProCore, Expect, or both). Of the 94 control cases, only 58 were carried out using a 22-gauge needle to sample masses in the pancreatic head or body.

Of the 23 cases using the Acquire, 30% (n=7) were in the pancreatic body and 70% (n=16) were in the pancreatic head. Of the 58 control cases, 34% (n=20) were in the pancreatic body and 66% (n=38) were in the pancreatic head (Table 1). There were no significant differences between the Acquire and control patient arms with respect to age and gender.

The difference in overall diagnostic yield (following sampling of both pancreatic head and body masses) was statistically significant when comparing the Acquire arm (83%) to the control arm (55%; p=0.0237; Table 2). Subgroup analysis demonstrated that among pancreatic head tissue acquisition alone, 75% (n=12) of samples were diagnostic in the Acquire arm, whereas 53% (n=20) were diagnostic in the control arm, a difference that was statistically insignificant (p=0.1452). Furthermore, among tissue acquisitions from the pancreatic body, 100% (n=7) were diagnostic in the Acquire arm, compared to 60% (n=12) in the control arm (p=0.0681), a difference that was also statistically insignificant.

It is also important to note that 6 of the 23 cases in the Acquire arm had previously non-diagnostic results using standard FNA tissue sampling. Four of these cases provided diagnostic results after repeat EUS-TA with the Acquire needle, 3 of which were consistent with malignancy. One of the 6 cases provided a paucicellular sample,

Table 2: Diagnostic yield comparing the Acquire and the control arms.

	Acquire (n=23)	Control (n=58)	P-value
Overall diagnostic yield	19/23 (83%)	32/58 (55%)	0.0237
Diagnostic yield based on location			
Head	12/16 (75%)	20/38 (53%)	0.1452
Body	7/7 (100%)	12/20 (60%)	0.0681

Fisher's exact test was used to determine whether there were significant differences between the two needle groups (ProCore/Expect versus Acquire) with respect to diagnostic yield. Results were considered statistically significant if the 2-sided p-value was less than 0.05 (P<0.05).

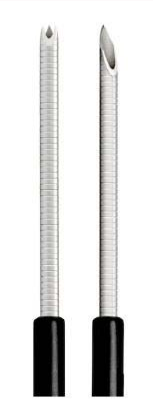

Figure 1: Design of the Acquire needle.
Figure used with permission from Boston Scientific. The Acquire is a novel needle device that has a 3-pronged design meant to provide increased stability, allowing for increased tissue yield with minimal tissue fragmentation.

similar to the prior result with a standard FNA needle and 1 of the 6 cases displayed mild atypia insufficient to make a diagnosis of malignancy.

Discussion

This retrospective study demonstrated that the Acquire needle provides excellent diagnostic yield in comparison to our institution's traditionally used EUS-TA needles, the EchoTip ProCore and the Expect. Our subgroup analysis further demonstrated increased diagnostic yield specific to tumor location.

The Acquire needle device has a 3-pronged design meant to provide increased stability, allowing for increased tissue yield with decreased tissue fragmentation (Figure 1) [8]. It is available in 22G and 25G sizes, although only the 22G needle was used in our study. The ProCore and Expect needles differ from the Acquire in terms of design. The EchoTip ProCore has a reverse bevel, which is meant to oppose movement of the target tissue caused by the force of the needle and thus promote a larger core biopsy with less fragmentation [7]. The Expect has a single prong made of cobalt chromium, intended for increased needle strength and the ability to perform strong single passes without catheter kinking [8].

It is important to consider the six cases from the experimental arm that had previously non-diagnostic biopsy results using standard FNA/FNB needles. The apparent superiority of the novel Acquire device was probably due to the comparatively larger quantity of tissue obtained from the core biopsy (providing the pathologist with a greater number of cells to examine), likely with a higher percentage of preserved morphological architecture (Figure 2). This would mean that the 3-pronged design indeed served its purpose. Preserved morphological architecture can reveal very slight cellular differences a factor that many diagnoses rely on, particularly that of the well-differentiated adenocarcinoma [9]. These results further confirm research demonstrating that same-gauge needles from different manufacturers can provide very different amounts and preservation of core tissue sample (Figure 2) [10].

Over the last couple of decades, there has been a significant amount of research focused on defining which characteristics of FNA and FNB needles can be altered to optimize diagnostic yield, including needle gauge, needle echogenicity, and needle design. The benefit of having an on-site pathologist should also be considered [2-6,9-19].

Figure 2: Tissue sample size comparison from two cases in the study. Tissue sample size following FNA with a standard FNA needle (left) compared with tissue sample size following FNB with the Acquire needle system (right). A penny is present as a reference for size. The same gauge needle (22G) was used for both sample acquisitions.

FNB was first developed in an attempt to acquire a larger amount of tissue than was possible with FNA for the purposes of histologic analysis. Since the debut of FNB, numerous studies have compared its diagnostic yield to FNA; however, very few statistically significant differences have been found [4]. Tru-cut, was the first FNB needle to become available. This needle was designed to be stiff and, thus, provide a core biopsy with sharp borders and enhanced tissue preservation [4]. A major limitation of this needle design was its inability to adequately sample a mass in multiple planes, whereas FNA needles at this time were much more flexible allowing for this multi-planar sampling (the ability to sample from multiple planes increases the chances that actual tumor tissue is obtained). As a result of these Tru-cut limitations, the ProCore needle was created, which had a reverse bevel design that resulted in a combination of the advantages of both the FNA needle and the Tru-cut FNB needle [11].

Although the ProCore FNB needle was designed to increase tissue sample size and adequacy, as well as improve diagnostic accuracy by providing a core biopsy, a meta-analysis published this past year found that it did not necessarily fulfill these criteria [4]. The ProCore has gone head-to-head with standard FNA needles in a number of studies and the only relative difference found was that the ProCore device decreased the average number of needle passes necessary for diagnosis of a solid pancreatic mass [4,12-14]. Initially, the ProCore was available in a 19G size, which demonstrated a diagnostic accuracy that was greater than 90%. However, transduodenal passes were difficult [15], a problem that led to the manufacture of the 22G ProCore needle. The 22G ProCore needle was initially compared to the standard 22G FNA needle but no significant difference was found in diagnostic yield [16]. Subsequent studies showed that the 25G FNA needle was superior to the 22G FNA needle in terms of diagnostic yield; however when directly compared to the 22G FNB needle, no significant differences were found [12]. When the 25G ProCore needle was released, it was compared to the 22G FNA needle, but again no superiority was observed [9]. At one point, there was speculation that combined sampling of a single lesion with a 25G FNA and a 22G FNB needle could potentially lead to increased diagnostic yield. However, it was recently reported that, although use of the two-needle combination certainly increased cost, there was no improved diagnostic benefit [13].

Prior to the release of the Acquire needle biopsy device, the US Food and Drug Administration approved another novel needle for clinical use: the SharkCore. The SharkCore is a fork-tip FNB needle that has been shown to increase sample yield in comparison

to standard FNA needles. A recent study found that quality core biopsies were obtained from 95% of the SharkCore needle procedures as opposed to 59% from the FNA standard needles [17]. Moreover, the SharkCore needle was shown to decrease the number of passes necessary to acquire a tissue diagnosis [3,17]. While it does not appear that the SharkCore has been assessed in direct competition with the ProCore, the diagnostic yield of the SharkCore was recently shown to be approximately 88% [3]. This is similar to the mean yield of the ProCore, which was found in a separate study to be 81.1% [3-4]. Further studies demonstrated that diagnostic adequacy rates increased following SharkCore use when rapid onsite evaluation (ROSE) was available [18]. ROSE was added to a number of studies comparing various types of needle and typically resulted in an increase in diagnostic yield. Unfortunately, ROSE is expensive and requires ready availability of a cytopathologist, which is often not practical at many institutions. As yet, no studies have directly compared the SharkCore with the Acquire.

Although the effects of ROSE, needle gauge, and type of needle have been thoroughly investigated, data on the effect of a needle's echogenicity on diagnostic yield of solid pancreatic lesions are limited. Better echogenicity provides increased visibility using EUS, allowing for better tracking of needle placement during sampling and, theoretically, increased diagnostic yield. A recent study compared the different echogenicities of 6 commonly used FNA needles, in addition to 2 prototype needles that had polymeric coatings (Medi-Globe), with the aim of guiding further clinical research into EUS-TA. FNA needles with better echogenicity were ranked more highly than others by endosonographers taking part in the study. The top ranking needles were the two prototypes that had a polymeric coating over the tip and full shaft [19]. Further research is needed to define the effect of echogenicity on diagnostic yield of pancreatic mass lesions.

Our data are very compelling but it should be recognized that our study has some limitations. First, the Acquire device has only recently been available and thus our experimental sample size was small, particularly compared to that of the control group. Second, the study is retrospective in design and patients in the Acquire and control arms were not enrolled over the same time period; thus conditions may not have been exactly the same. Additionally, two different needles were used in the control arm (EchoTip ProCore and Expect) and, although past studies have shown no significant differences in diagnostic yield between these needles, this could have led to unnecessary variability in control arm results [4,9,16].

In conclusion, our preliminary data demonstrate that the Acquire needle device provides excellent diagnostic yield in comparison to our institution's traditional EUS-TA needles, warranting follow-up prospective studies. Not only were we able to show that the Acquire needle has superior diagnostic yield, but also that the Acquire is a reliable EUS-TA needle where standard FNA/FNB needles have failed. A direct comparison of the Acquire with other recently manufactured FNB needles, particularly the SharkCore, is worthy of future study.

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Author Contributions

MicheleS Barnhill wrote the manuscript and contributed to the conception and design of the project in addition to analysis and interpretation of the data.

Shannon J Morales contributed to the conception and design of the project, analysis and interpretation of the data, and critical revision of the manuscript.

Mohammed Albugeaey, Wadha AlJaser, and Walid Chalhoub were involved with conception and design of the project and analysis of the data.

Margaret Holmes and Jay Zeck contributed to analysis of the data.

Nadim Haddad contributed to conception and design of the project and final approval of the article.

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