Fine needle aspiration at endoscopic ultrasound with a novel side-port needle: a pilot experience

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Abstract:
Background: Diagnostic yield of endoscopic ultrasound-guided fine-needle aspiration (EUS FNA) varies relating to the equipment used and the site targeted. Multiple needle passes are usually required to obtain a diagnosis. A new needle incorporating a side port carries a theoretical advantage regarding acquisition of cytological material.
Methods: To demonstrate the safety and efficacy of the Olympus side-port needle across a spectrum of indications for EUS FNA, a prospective collection of 16 consecutive cases was undertaken at a tertiary gastroenterology referral centre in metropolitan Sydney, Australia. EUS FNA was performed with the novel Olympus side-port needle. EUS FNA was otherwise performed in the conventional fashion. The number of needle passes required for diagnosis, number of passes total, diagnosis on cytology and conclusive diagnosis were recorded.
Results: Diagnostic material was obtained at the first pass in 56.2% of patients. Mean number of passes required to reach a diagnosis was 2.1. Diagnosis was made on first pass in 62.5% of solid non-lymph-node lesions. The diagnosis was reached in 94%.
Conclusions: The novel side-port needle is safe and effective; further evaluation with a prospective randomized trial is warranted.

Keywords: endoscopic ultrasound, fine needle aspiration biopsy, needle, procore

Introduction

Detailed images of the upper gastrointestinal tract and adjacent structures can be obtained with endoscopic ultrasound (EUS). Fine-needle aspiration (FNA) of lesions visualized with EUS plays a crucial role in the diagnosis and staging of benign and malignant mass lesions of these structures [Giovannini *et al*. 1995; Shin *et al*. 2002; Vilmann *et al*. 1993; Wiersema *et al*. 1994], and complication rates are low [Adler *et al*. 2005; Affi *et al*. 2001; Eloubeidi *et al*. 2006; Giovannini *et al*. 1995; Varadarajulu and Eloubeidi, 2004] occurring in between 1% and 2.5% of cases.

The role of EUS guided FNA (EUS FNA) in the investigation of suspected pancreatic malignancy, abnormal lymph nodes and pancreatic cystic lesions is well established [De Witt, 2006; Giovannini *et al*. 1995; Gress *et al*. 2001; Rocca *et al*. 2007; Vazquez-Sequeiros, 2007; Vilmann *et al*. 1995]. Multiple passes at EUS FNA are often required to obtain sufficient material for diagnosis; five or six passes for solid pancreatic lesions and four passes for lymph nodes [Conway *et al*. 2009; Erickson *et al*. 2000; Yamao *et al*. 2009]. This prolongs the procedure and exposes the patient to an increased risk of biopsy related complications [Sakamoto *et al*. 2009; Wiersema *et al*. 1997].

The diagnostic yield of EUS FNA varies relating to the equipment used [Erickson *et al*. 2000; Yusuf *et al*. 2009] and site targeted [LeBlanc *et al*. 2004; O'Toole *et al*. 2001]. Recent advances may increase yield [Bruno *et al*. 2009; Erickson *et al*. 2000; Larghi *et al*. 2005; Nguyen *et al*. 2008; O'Toole *et al*. 2001; Palazzo *et al*. 1999; Puri *et al*. 2009; Siddiqui *et al*. 2009], however this rarely exceeds 90%.

The Olympus Prototype Side-Port Needle (Olympus Corp, Japan) (Figure 1) was developed by the authors in conjunction with Olympus Tokyo, to increase tissue acquisition and reduce the required number of passes at EUS FNA. This

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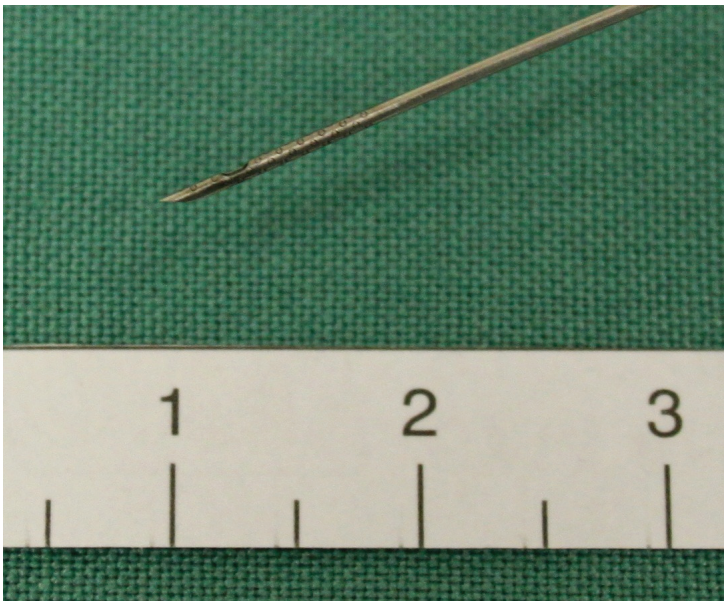

Figure 1. Olympus side-port needle. Laser etching on the tip for increased echogenicity, side port 4 mm from the end port.

device is a disposable 22-gage needle with a side port in addition to the standard end port. This report details the pilot experience with this needle. We evaluated the feasibility, safety and diagnostic yield of the side-port needle across a range of indications for EUS-FNA.

Patients and methods

Consecutive patients were recruited from a single tertiary referral centre between July and December 2009. Patients deemed suitable for EUS FNA were assessed by a physician prior to the procedure. Patients were given an information sheet and informed consent was obtained. Approval was gained from the ethics review board of the Sydney South West Area Health Service.

Exclusion criteria were standard contraindications to EUS FNA (profound thrombocytopenia or coagulopathy, severe comorbidities) and age less than 18. All lesions and indications for EUS FNA were included.

EUS FNA was performed in the left lateral position under conscious sedation with midazolam, fentanyl and propofol. Noninvasive blood pressure monitoring, pulse oximetry and cardiac monitoring were performed. Recovery was supervised for a minimum of 2 hours, and in follow up. An Olympus Linear Echoendoscope (UCT140-AL5) was used for each procedure. All procedures were performed by a single operator (AK), and were conducted on an outpatient basis.

A cytologist was present in the room for all cases except the fluid aspiration case ($n = 1$). FNA was performed according to standard protocol, with the Olympus side-port needle used at each pass. The Olympus side-port needle (Figure 1) is identical to the standard 22 gage EUS FNA needle, but has a second opening located 4 mm from the tip on the opposite side to the bevel. As with a standard EUS FNA needle, this needle moves freely within a protective sheath, permits passage of a stylet, and has an attachment for a suction device at the endoscopist end.

The results of each needle pass, and the number of passes taken to collect material sufficient for diagnosis were recorded. Prior to repeat aspiration, the cytologist examined the aspirated material. The decision to stop performing FNA was made when acquisition of adequate material was determined by the cytologist. When requested, further passes were taken for cell block and immunohistochemical analysis.

Results

Data were collected on our first 16 patients with a mean age of 57.6 years, 56% were female (Table 1). Seven cases were of masses in or around the pancreas (five head, two neck), six of

Table 1. Results.

Age	Sex	Indication	Site biopsied	Passes for diagnosis	Total number of passes	Results	Final diagnosis
63	M	Pancreas mass	HOP	1	1	Adenocarcinoma	Adenocarcinoma
60	M	Pancreas mass	Ascites	1	1	Adenocarcinoma	Adenocarcinoma
45	F	Mediastinal LN, query sarcoid	LN	4	4	Consistent with sarcoidosis	Consistent with sarcoidosis
46	F	Subcarinal LN, query sarcoid	LN	4	4	Consistent with sarcoidosis	Consistent with sarcoidosis
68	F	Pancreatic tail cyst	Pancreas tail cyst	1	1	Pus drained	Klebsiella infection in pancreatic cyst
64	M	Pancreas mass	HOP	2	2	Dysplastic mucinous tumor	Adenocarcinoma at CT guided core biopsy
66	M	Subepithelial mass at COJ	s/m lesion	1	2	GIST	GIST
64	F	Mediastinal lymph node, query sarcoid	LN	3	3	Consistent with sarcoidosis	Consistent with sarcoidosis
65	F	Mass near pancreatic head	Mass	1	4	Adenocarcinoma	Adenocarcinoma
57	M	Subcarinal LN mass	LN mass	1	3	Abscess	Abscess
63	F	Pancreas mass	HOP	5	5	Suspicious for adenocarcinoma	Adenocarcinoma
53	F	Pancreas mass	Neck	1	1	Adenocarcinoma	Adenocarcinoma
63	F	Pancreas mass	Neck	5	5	Suspicious for adenocarcinoma	Adenocarcinoma
75	F	Lymphadenopathy	Mediastinal LN	2	2	Reactive lymph node	Reactive lymph node
28	M	LN mass	Mediastinal LN	1	1	Granuloma	Tuberculosis
41	M	Pancreas mass	HOP	1	1	Inflammatory cells	Pancreatitis

LN, lymph node; HOP, head of pancreas; s/m, submucosal; COJ, cardio-oesophageal junction; GIST, gastrointestinal stromal tumor; CT, computed tomography; M, male; F, female.

enlarged thoracic lymph nodes and one each of a pancreatic tail mass, a pancreatic tail cyst and a gastric subepithelial lesion.

The mean number of needle passes to obtain material sufficient for a diagnosis was 2.1. Material sufficient for diagnosis was obtained at the first needle pass in nine patients (56.2%). In solid non-lymph-node lesions the diagnosis was made on the first pass in five patients (62.5%). No more than five passes were required to make the diagnosis in any patient. The diagnosis was obtained in 15 of 16 patients (94%), or 13 of 16 patients (81%) if findings suspicious for adenocarcinoma are considered nondiagnostic.

There were no complications recorded at the time of procedure or in follow up. There were no patients in whom the device was unable to be used, and no incidence of device failure, buckling or blockage. The material obtained was felt to be more cellular and contain more stroma by the pathologist (Figures 2 and 3).

Discussion

EUS FNA is important in the diagnosis and staging of benign and malignant mass lesions of the upper gastrointestinal tract and adjacent structures. The technique is safe, reported complications rates varying from less than 1–2%. Complications such as bleeding, infection, perforation and pancreatitis vary with the tissue sampled, relevant anatomy and technical aspects of the procedure.

Reported sensitivities of EUS FNA vary widely according to site targeted and equipment used. Recent attention has been focused on increasing the diagnostic yield of EUS FNA with emphasis on needle caliber [Conway *et al.* 2009; Wiersema *et al.*

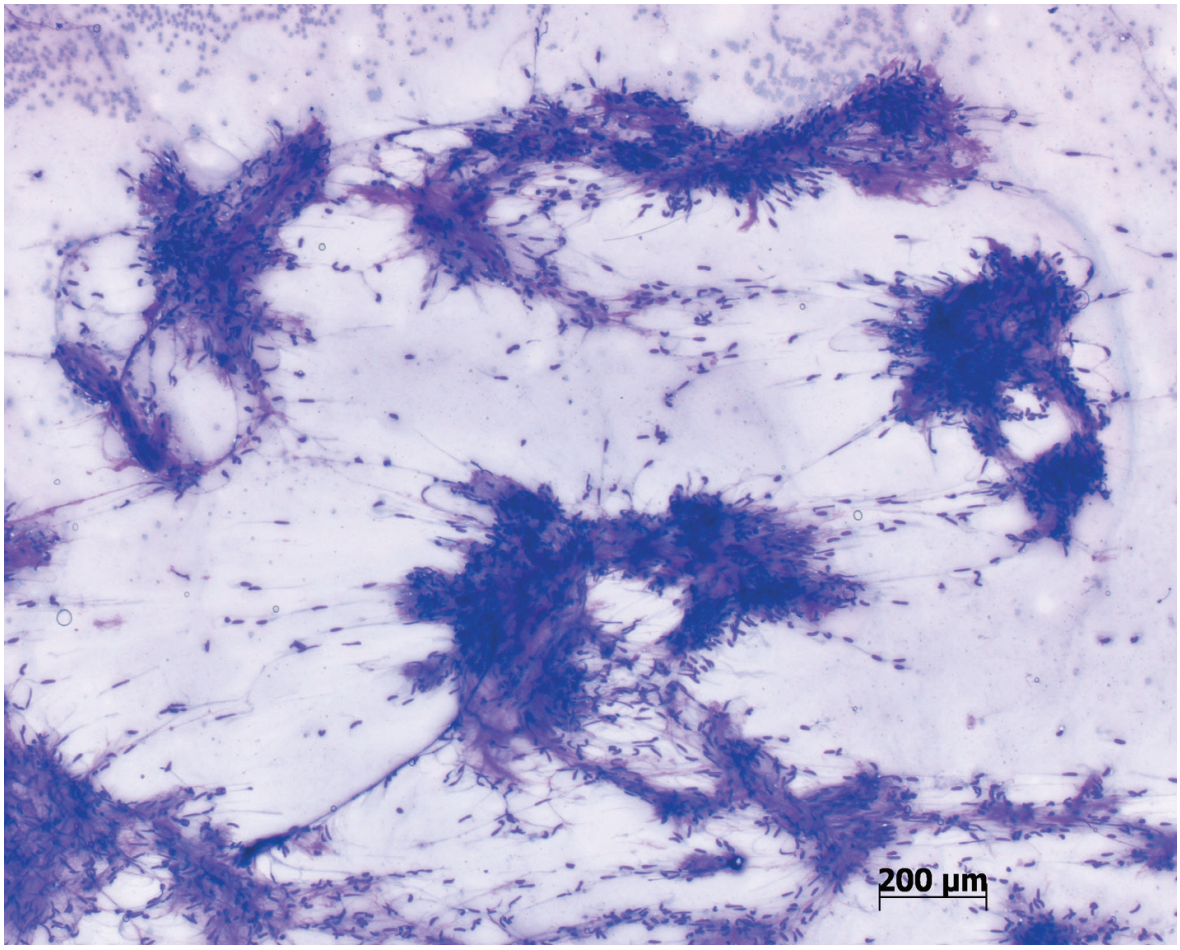

Figure 2. Cytology smear showing large volume cellular acquisition from a gastric gastrointestinal stromal tumor.

1997; Siddiqui *et al.* 2009; Nguyen *et al.* 2008] and new devices, such as brushes [Bruno *et al.* 2009] and low [Puri *et al.* 2009] or high [Larghi *et al.* 2005] suction devices for EUS FNA. The diagnostic yield in these studies rarely exceeds 90% of cases.

Whilst it is not clear that an increasing number of needle passes increases the risks associated with EUS FNA, the prolonged procedure time associated with multiple passes is unpleasant, and may result in increased complications. During multiple passes, the risk of needle buckling or kinking increases. Despite high diagnostic rates with standard 22 and 25 gage needles, devices requiring fewer passes are needed.

The side port appears to have a different method of tissue acquisition to traditional needles. The exact mechanism for this is unknown. Cellular acquisition from the side port may be from a grating effect when cells are sucked into the port and the in–out movement is then applied shearing tissue that has been sucked into the needle. We used syringe suction for all cases and have not evaluated this needle in the setting of no suction. An alternative explanation is that twice as much cellular material is engaged with suction as there are twice the number of holes in the needle tip.

There are clear limitations to this pilot study. The sample size is small, and whilst successful and safe use was demonstrated across a spectrum of indications, this meant case selection was heterogeneous, making analysis of the success of this needle in particular situations difficult. Also, not all cases were of pancreatic masses, a group typically requiring more needle passes for a diagnosis.

In addition we only evaluated suction FNA when many experts suggest FNA without suction to be adequate. Further studies comparing this needle to traditional needles and techniques are required. We believe this needle may provide a benefit in the drainage of fluids such as cysts and ascites.

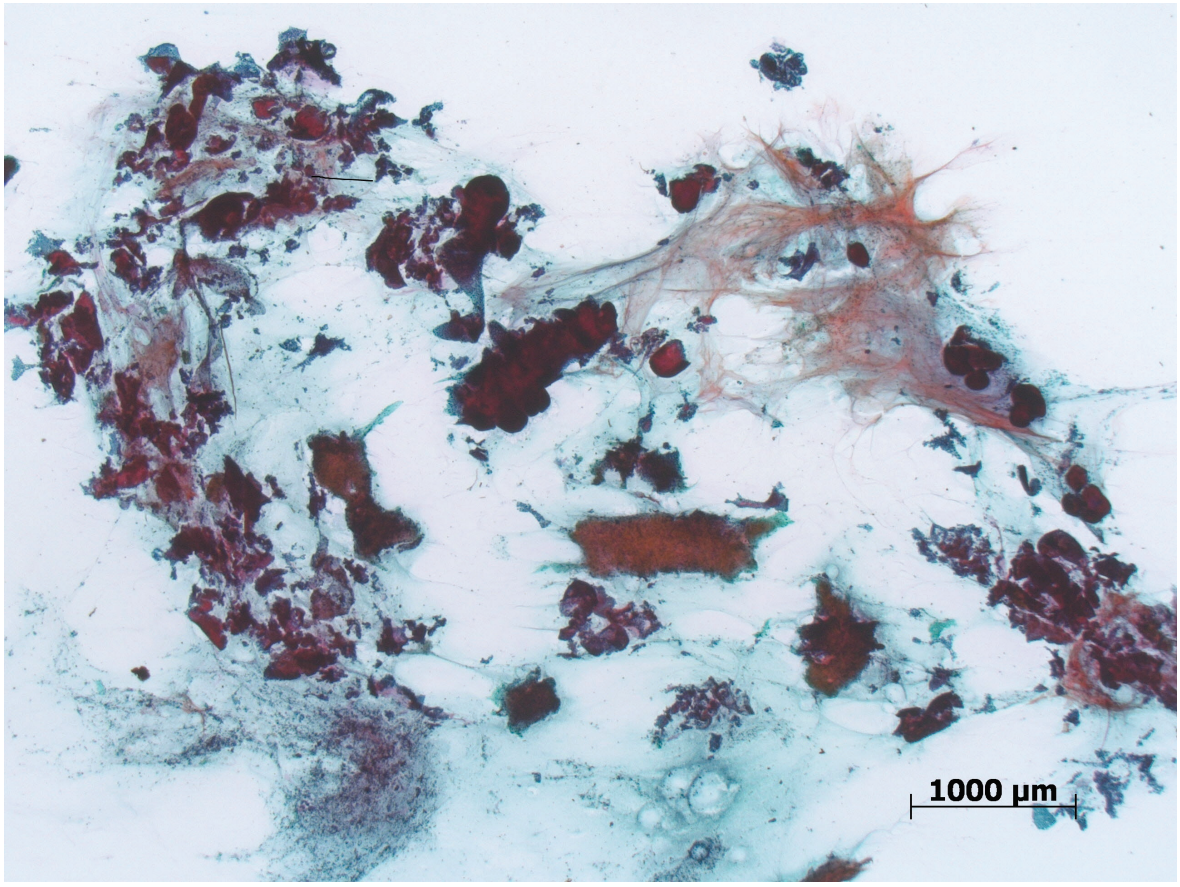

Figure 3. Cytology smear from a pancreatic adenocarcinoma showing large volumes of malignant sheets and stromal tissue, a feature rarely seen with standard final needle aspiration.

Subjectively, fluid drainage was easier and the additional side port may explain this. Side ports in many drainage devices and catheters exist as a standard feature.

This report details a pilot experience of EUS FNA with the Olympus side-port needle. The technique of FNA using this needle shows promise and has a high diagnostic yield, often at first pass. This technique appears safe and effective in standard indications for EUS FNA without any incidents of complication or device failure in this series. Further evaluation of this device is warranted, and prospective trials are underway.

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Conflict of interest statement

The authors declare no conflicts of interest in preparing this article.

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