Digestive and Liver Disease xxx (2018) xxx–xxx

Contents lists available at ScienceDirect

Digestive and Liver Disease

journal homepage: www.elsevier.com/locate/dld

Digestive Endoscopy

Performance of a new histology needle for EUS-guided fine needle biopsy: A retrospective multicenter study

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ARTICLE INFO

Article history:
Received 13 March 2017
Received in revised form 3 December 2017
Accepted 15 January 2018
Available online xxx

Keywords:
Endoscopic ultrasound
Fine needle aspiration
Fine needle biopsy
Tissue acquisition

ABSTRACT

Objective: Procurement of tissue core biopsy may overcome some of the limitations of EUS-FNA. We aimed at assessing the safety, core procurement yield and diagnostic accuracy of two novel available histology needles.
Methods: Data from consecutive patients with solid lesions who underwent EUS-FNB using the 25G-22G SharkCore™ needles were retrieved from 4 tertiary-care centers database.
Results: 146 patients (mean age 64 ± 12 years; M/F, 76/68) with 156 lesions (114 pancreatic) were identified. In 83 cases the 22G needle was used. 3.6 ± 1.2 passes per lesion were performed, without any major complications. A core biopsy was procured in 89.1% of cases. Considering malignant vs. non-malignant disease, the sensitivity, specificity, negative likelihood ratio, positive likelihood ratio, and diagnostic accuracy were 90.2% (95% CI, 83.7–94.3), 100% (95% CI, 87.2–100), 0.099 (95% CI, 0.058–0.170), 60.4 (95% CI, 3.86–947.4), and 92.3% (95% CI, 88.1–96.5). Procurement yield was significantly higher for the 22G (95.2% vs. 82.2%, p = 0.011), despite the fact that more needle passes were performed with the 25G needle (3.8 ± 1.3 vs. 3.4 ± 1.0, p = 0.028).
Conclusions: EUS-FNB using the 25G-22G SharkCore™ needles is able to reach a very good procurement yield and diagnostic accuracy. The 22G-size needle showed superior core procurement and diagnostic capabilities. Large prospective studies are warranted to further evaluate the use of these types of needles.

1. Introduction

In the last decade, various techniques and specifically designed needles to gather tissue core biopsy samples have been developed [1]. These efforts have been driven by the attempt to overcome some of the limitations of endoscopic ultrasound-guided fine needle aspiration (EUS-FNA), in particular the need for rapid on-site evaluation (ROSE) of the collected specimens required to reach a diagnostic accuracy greater than 90% [2–5]. The limited availability of ROSE throughout the world coupled with the lack of cytology expertise outside high volume tertiary care centers [6], has resulted in a limited perceived utility of EUS and has created a barrier to the dissemination of the procedure in the community and in many countries [7].

In centers where ROSE is not available, it has been recently recommended to perform EUS-guided fine needle biopsy (EUS-FNB) to acquire samples for histological evaluation [8]. This can result in a greater chance to be accurate, with the additional advantage of providing more available tissue for ancillary testing than a typical EUS-FNA sample. Moreover, there is increasing interest in evaluating core tissue samples for molecular markers that may serve

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https://doi.org/10.1016/j.dld.2018.01.128
1590-8658/

as prognostic predictors and targets for individualized chemotherapy in patients with cancer [9,10]. If this will occur, diagnostic EUS will be transformed into a more therapeutic procedure that will be performed not only to provide a diagnosis, but also to offer the possibility to establish the best therapy for each individual patient [11,12].

Among the available needles specifically designed to perform FNB, the 25G Procore™ (Cook Medical, Winston-Salem, North Carolina, USA) has been found to be able to gather tissue core samples in only about 40% of the cases [13,14]. In addition, no overall clear advantages of the 22G Procore™ (Cook Medical) over standard 22G FNA needles have been demonstrated [15]. Finally, very promising results have been firstly reported for the 19G Procore™, but they were not replicated in additional experiences [16,17]. Many studies, on the other hand, have described a high accuracy of standard 19G needles in acquiring tissue core biopsy samples for various indications [18–25]. The 19G needle, however, is not easy to be used from the duodenum and is in general avoided by non-expert endosonographers because of the fear of complications [26]. Based on these premises, a new needle for EUS-FNB, the SharkCore™ (Medtronic, Dublin, Ireland), has become available in three different sizes — 25G, 22G, and 19G. Preliminary data from prospective very small [27] or retrospective studies [28–31] on the smaller needles for both pancreatic and non-pancreatic lesions are encouraging, with no differences between 25G and 22G. However, no clear data of the clinical significance of these needles in a meaningful number of patients are available.

To answer this important question, we performed a retrospective evaluation of all the sampling procedures performed using the 25G or the 22G SharkCore™ needles in patients with solid lesions throughout the gastrointestinal (GI) tract and adjacent to it.

2. Material and methods

2.1. Patients

All consecutive patients with solid lesions of the GI tract or adjacent to it who, between February 2015 and November 2015, underwent EUS-FNB using the 22G or the 25G SharkCore™ needles in four Italian centers were retrospectively retrieved from each single institution database. Patients with neoplastic invasion of the gastrointestinal wall in whom biopsies could be taken endoscopically were not included in the present cohort.

The protocol to perform retrospective revision of the performed cases was approved by the Medical Ethics Committees. All patients gave their informed consent prior to the EUS-FNB.

2.2. Study device

The SharkCore™ 22G and 25G needles are both made of stainless steel, with a nitinol stylet. These devices feature a newly designed multifaceted opposing bevel incorporating two sharp points of different lengths (the 'fork-tip') and 6 cutting-edge surfaces, intended to promote tissue capture as it is sheared off with maintenance of its architecture (Fig. 1).

2.3. EUS sampling procedures

All EUS procedures were performed by advanced echoendoscopists, with the patients under conscious or deep sedation using a conventional linear EUS scope (GF-UC180T, Olympus Medical System Europe, or EG3870UTK, Pentax Europe GmbH, Hamburg, Germany). Once the lesion inside the GI wall or adjacent to it was identified by EUS, an eligible puncture site without intervening vessels was selected. Puncture of the lesion using the 22G or the 25G SharkCore™ needles was performed with the stylet in place prior to needle advancement out of the sheath in order to avoid its inadvertent puncture. Different sampling techniques were used based on each endosonographer preference. Multiple needle passes were performed in all patients and all the collected material was placed directly in formalin for subsequent analyses. The formalin-fixed specimens were processed into paraffin according to standard routine methods. Sections of 5 μm were cut and stained with hematoxylin and eosin for conventional histology and with the proper immunostaining when necessary to reach a definitive diagnosis.

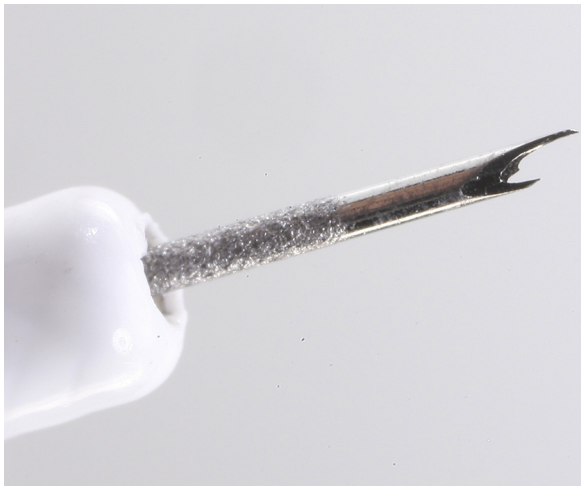

Fig. 1. The tip design of the newly developed SharkCore™ EUS-FNB needle, featuring a multifaceted opposing bevel incorporating two sharp points and 6 cutting-edge surfaces, intended to promote tissue capture with maintenance of its architecture; reproduced with the permission of Medtronic.

2.4. Histopatologic definitions

The procured sample was defined as being a tissue core biopsy sample when an architecturally intact piece of tissue sufficient for histological evaluation of the targeted lesion was present and could be evaluated. A fragment that did not meet the criteria for architecturally intact histology but could still yield a diagnosis based on cell morphology was classified as a cytological sample.

2.5. Outcome measurements

Procurement yield was defined as the percentage of cases in which a histologically interpretable specimen could be retrieved. Diagnostic accuracy was defined by the rate of correct diagnosis obtained through analysis of the tissue samples acquired with SharkCore™ needles. When examination of the acquired specimen was diagnostic for malignancy, this was considered the definitive diagnosis. For patients with a sample non-diagnostic for malignancy or for a specific benign disease, the presence or exclusion of malignancy was based on following criteria: the histopathological examination of the surgically resected specimen when available, the results of other diagnostic investigations such as CT-guided and/or laparoscopic biopsy indicating the presence of malignancy, and/or the long-term clinical follow-up, including follow-up imaging. For this purpose, these patients were evaluated for a minimum of 6 months.

2.6. Statistical analysis

Frequencies, percentages, and means ± standard deviation (SD) were used, as appropriate, for descriptive analysis. Sensitivity, specificity, positive likelihood ratio, and negative likelihood ratio were calculated. For the purpose of these analyses, defini-

Please cite this article in press as: Attili F, et al. Performance of a new histology needle for EUS-guided fine needle biopsy: A retrospective multicenter study. Dig Liver Dis (2018), https://doi.org/10.1016/j.dld.2018.01.128