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A prospective randomized study comparing 25-G and 22-G needles of a new platform for endoscopic ultrasound-guided fine needle aspiration of solid masses

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ABSTRACT

Background: A new needle platform for endoscopic ultrasound-guided fine-needle aspiration biopsy has been developed that allows interchangeability of all needle sizes.
Aims: To prospectively compare the efficacy of the new 25-G needles and 22-G needles for obtaining an adequate aspirate of solid masses.
Methods: Randomized controlled trial of 144 patients referred for endoscopic ultrasound-guided fine-needle aspiration of solid pancreatic masses, intraparietal tumours, or lymph-nodes, randomized to the 25-G or 22-G needle arms.
Results: An adequate specimen was obtained from 74.3% of cases. The sample tended to be more adequate in the 25-G compared to the 22-G group (81% vs. 68%; $p = 0.09$). Crossover was required in 14 (19%) and 12 (17%) cases in the 22-G and in the 25-G groups, respectively ($p = 0.7$). The overall rate of adequacy improved from 74% before crossover to 90% after crossover ($p < 0.01$). When comparing the two groups after crossover, the rate of obtaining adequate samples was significantly higher in the 25-G arm than in the 22-G arm (95.8% vs. 86.1%; $p = 0.03$).
Conclusions: The 25-G needle was superior to the 22-G needle for endoscopic ultrasound-guided fine-needle aspiration biopsy. The adequacy and diagnostic accuracy improved after crossover, reaching 90%.

1. Introduction

Endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) biopsy is a reliable, safe, and effective technique for obtaining samples from gastrointestinal (GI) wall lesions and from organs adjacent to the GI tract (pancreas, lymph nodes, extraluminal masses). Needles available for EUS-FNA include 19-G, 22-G, and 25-G needles. The majority of published studies reported excellent EUS-FNA results when using the 22-G needle and performing EUS-FNA with rapid on-site evaluation (ROSE) [1,2]. The 19-G needle could be useful for obtaining a histological sample for immunohistochemistry, but it is sometimes difficult to pass it through the echoendoscope into hard, fibrotic masses that are located deep within an area. In the setting of percutaneous biopsy, larger-diameter needles do not always provide better diagnostic accuracy [3,4]. The 25-G needle has been thought to be the best choice because of its easy manoeuvrability in every endoscope position and its penetrating thin tip that is easy to advance, even into deep lesions. Moreover, the aspirate obtained by a 25-G needle may be less contaminated by blood cells, making the evaluation easier for cytopathologists [5]. In the past few years, many series have suggested that the 25-G needle performs as well, if not better, than the 22-G needle [6–12]. Data from a randomized clinical trial confirm that the 25-G needle may work equally well as the 22-G need when used for EUS-FNA of solid pancreatic masses [13]. A new needle device has been developed that allows interchangeability of needle size while using the same needle shelter. The clinical impact of this new needle still needs to be demonstrated. The aim of the present

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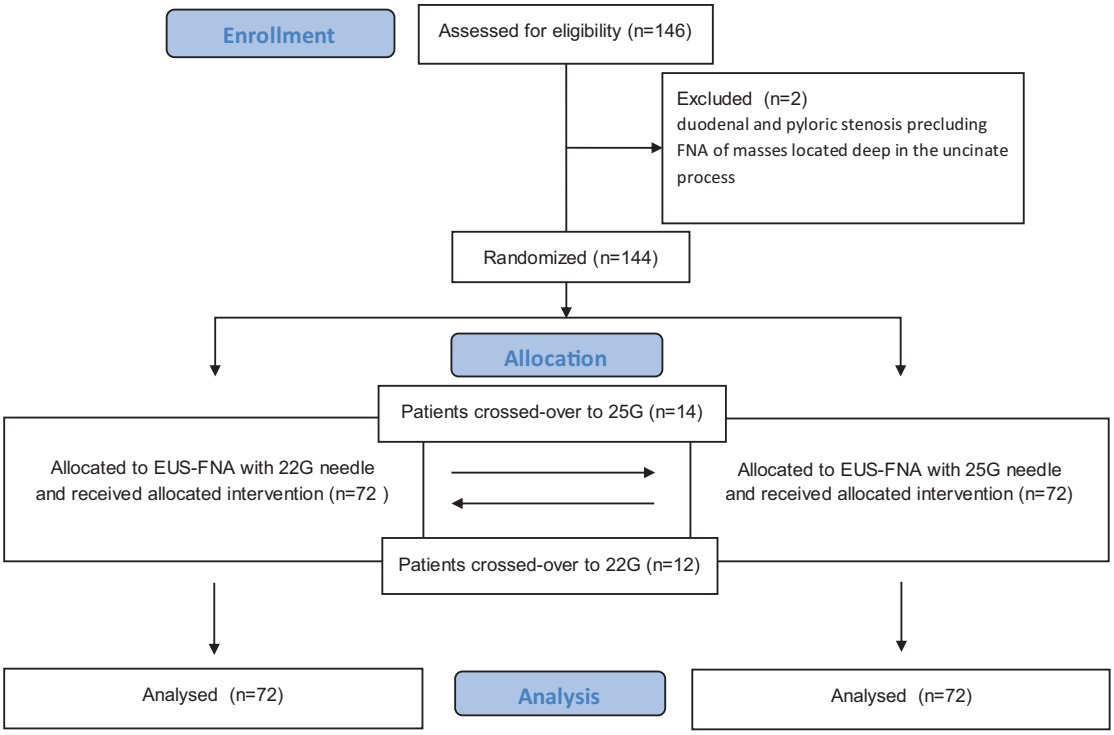

Fig. 1. Study flow-chart. EUS, endoscopic ultrasound; FNA, fine needle aspiration.

study was to compare the efficacy of the new 25-G needles and 22-G needles for obtaining an adequate aspirate of solid masses, and to explore the additional efficacy due to this new delivery platform.

2. Materials and methods

2.1. Patients

This was a prospective, randomized clinical trial in a single tertiary referral centre.

From August 2013 to October 2014, all consecutive patients referred to the Endoscopy Unit of the Humanitas Research Hospital for EUS examination and FNA of solid masses (inpatients and outpatients) were considered for enrolment; eligible patients were randomized to the 25-G arm or 22-G needle arm (Fig. 1). Inclusion criteria were as follows: age 18 years or older; solid pancreatic masses: primary carcinoma, neuroendocrine tumours (NET), or metastatic lesions; intraparietal GI tract tumours: gastrointestinal stromal tumours (GIST) or NET, and peri-GI tract masses (including lymph nodes) diagnosed by radiological techniques and confirmed by EUS; and ability to give informed consent according to national and local regulations. Exclusion criteria were anticoagulant therapy, no evidence of mass at EUS, international normalized ratio (INR) >1.5, platelet count $< 50 \times 10^3/\mu L$.

This clinical trial was approved by the Humanitas Research Hospital Institutional Review Board. The study was recorded at clinicaltrial.gov (NCT02246322). Written informed consent was obtained from all participants.

2.2. Device information

The Beacon bnx® needle (Medtronic, Newton, MA) is a new device (Fig. 2) whose main characteristics include: interchangeability of all needle sizes through a universal delivery system; ergonomic release button designed for multiple needle exchanges throughout the procedure; automated safety shield designed to be compliant with needle stick prevention standards; and four cutting edges designed to optimize tissue yield and coring potential.

3. EUS-FNA technique

Patients were randomized to undergo FNA with either a 25-G or a 22-G needle. EUS was performed by using linear array Olympus GF-UCT-180 series echoendoscopes (Olympus Europa SE & CO. KG, Hamburg, Germany) in combination with the new echoprocessor EU-ME2 (Olympus SE & CO. KG, Hamburg, Germany). Patients were under deep sedation with propofol and received anaesthesiology assistance during the procedure. The two operators (SC and AA) were both experienced endosonographers who had performed more than 2000 EUS each before the study began. FNA was performed under EUS guidance and by combining the fanning technique and the slow pull technique. The specimen was always first smeared and stained on a glass slide for ROSE. A cytotechnician

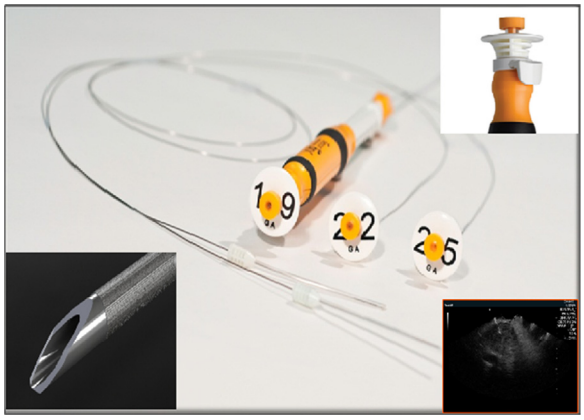

Fig. 2. The new needle platform. The quad bevel tip is designed with four cutting surfaces. The platform is designed for interchangeability of all needle sizes inside a universal delivery system.