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Biliary plastic stent does not influence the accuracy of endoscopic ultrasound-guided sampling of pancreatic head masses performed with core biopsy needles

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ABSTRACT

Objective: While the presence of biliary stent significantly decreases the accuracy of endoscopic ultrasound (EUS) for pancreatic head cancer staging, its impact on the EUS-guided sampling accuracy is still debated. Furthermore, data on EUS-fine needle biopsy (EUS-FNB) using core biopsy needles in patients with pancreatic mass and biliary stent are lacking. The aim of this study was to evaluate the influence of biliary stent on the adequacy and accuracy of EUS-FNB in patients with pancreatic head mass.
Methods: All patients who underwent EUS-guided sampling with core needles of solid pancreatic head masses causing obstructive jaundice were retrospectively identified in a single tertiary referral center. Adequacy, defined as the rate of cases in which a tissue specimen for proper examination was achieved, with and without biliary stent, was the primary outcome measure. The diagnostic accuracy and complication rate were the secondary outcome measures.
Results: A total of 130 patients with pancreatic head mass causing biliary obstruction were included in the study: 74 cases of them were sampled without stent and 56 cases with plastic stent *in situ*. The adequacy was 96.4% in the stent group and 90.5% in the group without stent ($p = 0.190$). No significant differences were observed for sensitivity (88.9% *vs.* 85.9%), specificity (100% for both groups), and accuracy (89.3% *vs.* 86.5%) between those with and without stent, respectively. The accuracy was not influenced by the timing of stenting (<48 h or ≥48 h before EUS). No EUS-FNB related complications were recorded.
Conclusion: The presence of biliary stent does not influence the tissue sampling adequacy, the diagnostic accuracy and the complication rate of EUS-FNB of pancreatic head masses performed with core biopsy needles.

1. Introduction

Painless obstructive jaundice is the most characteristic sign of pancreatic head cancer. When a pancreatic tumor is suspected, the goal is to confirm the diagnosis and to determine the potential resectability of the lesion. Endoscopic ultrasound (EUS) has an established role both in the diagnosis and staging of pancreatic cancer [1]. EUS-guided fine-needle aspiration (FNA) is a well-established, safe, and effective technique for tissue sampling of solid pancreatic masses [2,3]. However, the diagnostic yield of EUS-FNA is influenced by several factors, such as the size and type of needles, the availability of rapid on-site evaluation (ROSE), a concomitant chronic pancreatitis or the presence of biliary stent [4]. Endoscopic retrograde cholangiopancreatography (ERCP) is the treatment of choice for patients with obstructive jaundice, as it enables biliary decompression by using plastic or self-expandable metal stents (SEMS). ERCP for biliary drainage should be performed after an accurate EUS examination. Indeed, the presence of biliary stent, of any type (*i.e.* plastic or metal stent), significantly decreases the accuracy of EUS staging owing to the stent-induced inflammation, acoustic reverberation and shadowing [5–7]. Furthermore, the presence of biliary stenting seems to negatively influence the diag-

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nostic yield of EUS-based tissue sampling [8]. Nevertheless, it is not uncommon to perform EUS in patients already carrying a biliary stent, due to the wider availability of ERCP in comparison to EUS.

Newly designed EUS-fine needle core biopsy (FNB) needles have been developed to improve diagnostic accuracy by obtaining cytological aspirates and histological core samples [9–12]. The main characteristic of this needle is represented by the presence of a side fenestration which presents a reverse bevel to hook and cut the tissue entrapping it into the needle [13].

Data on the performance of EUS-FNB with core biopsy needle in jaundiced patients with pancreatic mass and biliary stent is still lacking.

The aim of the current study was to evaluate the influence of biliary stent on the adequacy and accuracy of EUS-FNB in patients with pancreatic head masses.

2. Materials and methods

2.1. Patients and EUS-guided sampling procedures

All patients who underwent an EUS-FNB for the characterization of solid pancreatic head masses causing obstructive jaundice at "Augusto Murri" Hospital in Fermo (Italy) from January 2013 to July 2015 were retrospectively identified from a prospectively collected database. Only cases performed with core biopsy needles and who had at least 6 months' follow-up, were included. Pancreatic cystic lesions were excluded.

Early (within 48 h from the EUS procedure) and late (>48 h) complications were evaluated. EUS-guided tissue acquisition was performed by using convex array echoendoscopes (UCT-140, Olympus America, Inc. Melville NY). Tissue acquisition was done with the Echotip ProCore needles (Cook Endoscopy Inc., Limerick, Ireland). The needle size and the number of needle passes were chosen according to the operator preference. All EUS-FNBs procedures were performed by a single experienced endoscopist (FA) who has performed more than 1000 EUS procedures in his career and at least 100 EUS-FNA per year.

The presence of a cytopathologist in the EUS room to perform ROSE was based on the Pathology department's weekly internal schedule, which allowed for the availability of an expert and dedicated cytopathologist in the endoscopy room, up to two days per week.

A tissue core for histological analysis was defined as an architecturally intact piece of tissue measuring at least 550 μm along its greatest axis (corresponding approximately to the diameter of a high power microscopic field) [14].

The study was approved by the ethical committee of the hospital and written informed consent was obtained from all patients before the described procedures had began.

2.2. Outcome measures

The primary outcome measure was adequacy, defined as the rate of cases in which a tissue specimen for cytological examination was achieved.

Secondary outcome measures were accuracy, defined as the proportion of correct diagnoses made with and without stent, the proportion of cases in which the specimen fulfilled the definition of tissue core for histological evaluation and the complication rate. Standard references were the surgical specimen when available or other diagnostic investigations together with long-term follow-up (>6 months).

2.3. Statistical analysis

Overall accuracy, sensitivity, specificity, positive likelihood ratio, negative likelihood ratio and number needed to misdiagnose [15] were computed. For this study, definitive diagnoses were divided into neoplastic (including both benign and malignant neoplasms) and non-neoplastic cases. Samples inadequate for cytological evaluation were considered as false negatives. Continuous variables were reported as mean ± standard deviation (SD), whereas categorical variables were reported as proportions. Comparisons between the Stent group and no Stent group were performed with the unpaired *t* test and the Chi squared test as appropriate. A p value <0.05 was considered statistically significant. Statistical analyses were performed with SPSS version 22 for Mac (IBM Corporation, New York, NY, USA) and with R version 3.1.3 for Mac [16].

3. Results

A total of 130 patients with pancreatic head mass causing biliary obstruction were included in the study (60.8% male; mean age 69.7 ± SD 10.1 years); of them 74 cases of them were sampled without stent (no Stent group) and 56 cases with biliary stent *in situ* (Stent group). All patients in the "no Stent group" were naïve, *i.e.* not previously treated with stent placement; biliary stent was not removed before EUS examination in any case. The stents were all made of plastic. On-site cytopathologist was present for a total of 30 (23%) procedures, 16 cases with and 14 without stent *in situ*. The two groups did not differ on the basis of demographics and lesion site distribution. Overall, the needle size most frequently used was the 25G (55.3%), followed by the 22G (44.7%). A mean of 3.3 ± 0.8 needle passes per lesion was performed. The two groups (*i.e.*, Stent *vs.* No stent) did not differ as concerns the needle type used and the mean number of needle passes performed. The median follow-up time for these patients was 13 months (range 7–36 months). Of the biliary plastic stents placed in the 56 patients, 40 were 10Fr × 7 cm, 4 were 10Fr × 5 cm, and 12 were unknown. Details are provided in Table 1.

The adequacy was 96.4% in the Stent group and 90.5% in the group without stent (p = 0.190). No significant differences were observed for sensitivity (88.9% *vs.* 85.9%), specificity (100% for both groups), and accuracy (89.3% *vs.* 86.5%) between those with and without stent, respectively (Table 2). Excluding those patients performed with ROSE, in which the adequacy was 100%, in the remaining 100 patients the adequacy was 95.9% in patients with stent and 89.7% in patients without stent. Final diagnosis was: 122 (93.8%) cases of adenocarcinoma, 5 focal pancreatitis (3.8%), 2 neuroendocrine carcinomas (1.5%) and 1 metastasis (0.7%) (Table 3). False negative results were encountered in 4/56 (7.1%) cases with stent *vs.* 4/74 (5.4%) cases without stent. In 16 patients, EUS-FNB of pancreatic lesions resulted inconclusive. All these patients had high suspicion of a pancreatic malignancy and final diagnosis was confirmed by EUS-guided sampling of peri-pancreatic lymph nodes during the same session (n = 2), biopsy of liver metastases (n = 3), or by repeated EUS-FNB of the pancreatic lesion (n = 11). Of the 124 patients diagnosed with primary pancreatic malignancy (122 adenocarcinomas and 2 neuroendocrine tumors), 28 underwent surgery with confirmation of the diagnosis. The remaining 96 patients and the patient with pancreatic metastasis from colon carcinoma were referred for oncological palliative therapy. The 5 patients with focal pancreatitis were followed-up for a median of 21 months (range 13–36 months) and had an uneventful course.

The accuracy was not influenced by the timing of the stenting (*i.e.*, <48 h *vs.* ≥48 h before stenting) nor by the presence of an on-site pathologist (Table 4). A histological core was achieved in only