

Impact of metal and plastic stents on endoscopic ultrasound-guided aspiration cytology and core histology of head of pancreas masses

Authors

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 Fig. 1s, Table 1s–4s

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ABSTRACT

Background Stents are frequently placed in patients with biliary obstruction due to a mass in the head of the pancreas. The impact of plastic or self-expandable metal stents (SEMSs) on endoscopic ultrasound (EUS)-guided tissue sampling is unclear. This study aimed to assess, using strict pathological criteria, whether stents impair fine-needle aspiration (FNA) or fine-needle biopsy (FNB).

Methods All patients with a solid mass in the head of the pancreas who underwent EUS-guided tissue sampling between 2010 and 2016 at our unit were included. Factors with possible impact on diagnostic performance were analyzed using logistic regression. Analysis was performed using both strict (malignant only) and less strict (suspicious for malignancy) cutoffs.

Results Of 631 individuals undergoing 698 procedures, 535 (84.8%) had a final diagnosis of malignancy, 141 had SEMS, 149 had plastic stents, and 341 had no stent. Using strict criteria, SEMS were associated with an increased occurrence of incorrect diagnosis of EUS tissue sampling, with an odds ratio (OR) of 1.96 (95% confidence interval [CI] 1.24–3.10). Increasing tumor size (OR 0.72, 95%CI 0.59–0.87), increasing number of passes (OR 0.84, 95%CI 0.72–0.99), and fork-tip biopsy needle (OR 0.52, 95%CI 0.31–0.86) were independently associated with a decrease in incorrect diagnosis. Repeat tissue sampling was more common with SEMSs (10.2%) than with plastic stents (2.9%) or no stents (4.5%) ($P < 0.02$).

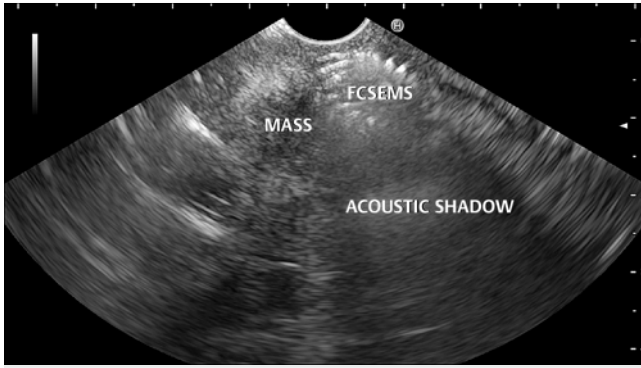
Conclusion SEMS use had a negative impact on tissue diagnosis in pancreatic head masses, whereas use of a fork-tip biopsy needle and increasing number of passes were independently associated with improved accuracy.

Introduction

Computed tomography is the recommended baseline test for diagnosis and staging of pancreatic cancer [1–2]. The majority of cases are inoperable at presentation and a tissue diagnosis is required prior to chemotherapy. Endoscopic ultrasound (EUS)-guided fine-needle aspiration (FNA) or fine-needle biopsy (FNB) are established as the first-line techniques when a tissue diagnosis is required [3].

A mass in the head of the pancreas commonly presents with biliary obstruction, which may require biliary stent placement, with metal stents being superior to plastic stents [4–6]. The presence of a biliary stent may adversely affect EUS assessment, including EUS-guided tissue sampling, owing to a reduction in image quality caused by acoustic reverberation and shadowing (► Fig. 1).

A number of previous studies have addressed the possible impact on tissue diagnosis (► Table 1). Three studies reported



► **Fig. 1** Linear endoscopic ultrasound image of a mass in the head of the pancreas, with a metal biliary stent that obscures the tumor. FCSEMS, fully covered self-expandable metal stent.

no effect on diagnostic performance [7–9], one reported a negative effect [10], and another showed a negative effect only in cases where a stent was placed immediately before EUS-FNA [11]. However, the majority of these previous studies were small and included few or no cases with self-expandable metal stents (SEMSs). Another limitation is that the majority of the studies classified biopsy results that were “suspicious for cancer” as diagnostic of malignancy, whereas a definitive diagnosis is required by many oncologists prior to offering chemotherapy. In addition, the effect of the new generation core needles compared with the FNA needles has not been assessed in this setting. The aim of the current study, therefore, was to assess whether the presence of plastic or metal stents impairs the diagnostic performance of EUS-guided tissue sampling in patients with a mass in the head of the pancreas.

Methods

The cohort included consecutive adult patients with a solid mass in the head of the pancreas who underwent EUS-FNA/FNB between January 2010 and June 2016 at the Freeman Hospital, Newcastle-upon-Tyne, UK,

The study was a retrospective analysis of prospectively maintained endoscopy, radiology, and pathology databases. Mandatory fields in the databases included tumor size and location, number of passes, type of needle, gauge of needle, use of rapid on-site evaluation (ROSE) by a cytotechnologist, presence or otherwise of biliary stents, and pathological diagnosis. Dependent on cytotechnologist availability, ROSE was utilized in a proportion of endoscopy sessions between April 2009 and June 2013 without case selection.

Patients with a biliary stent constituted the intervention group and were compared with a control group of patients without stents. A minimum of 12 months’ follow-up was available. The procedures were performed by four experienced endosonographers who had each performed >300 pancreatic EUS sampling procedures before the start of the study.

All clinical information and the reports of any prior imaging were available at the time of the EUS procedure. All patients were managed by a dedicated pancreaticobiliary multidisciplinary team.

EUS-guided sampling

All procedures were performed with patients under conscious sedation. Pentax linear echo endoscopes (Pentax, Slough, UK) and Hitachi ultrasound workstations (Hitachi Medical Systems, Wellingborough, UK) were used.

► **Table 1** Previous studies investigating the impact of stent presence on tissue diagnosis.

Study	Cases	Stents	“Suspicious” categorized as malignant	ROSE	Stents impacting tissue diagnosis?
Fisher, 2011 [11]	268 FNA	170 without stents 98 with predominantly plastic stents ¹	Yes	>90% ²	Yes ⁴
Siddiqui, 2012 [7]	677 FNA	577 plastic 100 metal 0 without stents	Yes	100% ³	Excellent results with stents in situ
Ranney, 2012 [8]	214 FNA	105 plastic 45 metal; 64 without stent	Yes	100% ²	No
Kim, 2015 [10]	75 FNA 105 FNA/B	11 metal 64 plastic 105 without stent	Yes	45% ²	Yes No difference plastic vs. metal
Antonini, 2017 [9]	130 FNB	56 plastic 74 without stent	No	23% ²	No

FNA, fine-needle aspiration; FNB, fine-needle biopsy; ROSE, rapid on-site evaluation.

¹ Data on stent type were unavailable for 26 cases.

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⁴ Only if the stent was placed <1 day before EUS-FNA.

For EUS-guided FNA, 22- and 25-gauge needles (Cook Ireland, Limerick, Ireland) were used for the majority of procedures. A 19-gauge needle was used in two cases and these were excluded from the analysis. For FNB, reverse-bevel needles (22- and 25-gauge; Procore; Cook Ireland) and fork-tip needles (22- and 25-gauge; Sharkcore; Covidien/Medtronic, Whiteley, UK) were used. The FNA needle was the needle of choice in the earlier part of the study period. Subsequently, the reverse-bevel was favored and latterly the fork-tip.

Lesion assessment (measurement and site) was performed prior to puncture. For FNA, one spread slide was prepared per pass, and the remaining aspirate was placed into cytofix red solution (BD Surepath; Bioscience Healthcare, Nottingham, UK) and processed by liquid-based cytology. When a cytotechnologist was present, the prepared air-dried slide was stained with Diff-Quik stain (BD Surepath) and adequacy assessment was based on this material. Punctures were repeated until the biomedical scientist considered the sample to be adequate. In the absence of a cytotechnologist, the number of passes performed was at the discretion of the endosonographer.

For FNB, all passes were placed in one container of neutral buffered formalin, which was sent for standard histopathological processing; ROSE was not used.

Cytological and histological reporting

The final reporting was done by specialist pathologists. Samples for cytology and core biopsies were graded into one of five categories: inadequate, benign, atypical, suspicious for malignancy, and malignant [12].

Histologically, malignancy was diagnosed in the presence of atypical cells showing cytological and architectural features of malignancy. Malignant cells in intact stroma were regarded as a helpful feature but not a necessary requirement to make the diagnosis of malignancy.

Cytologically, a malignant diagnosis required single cells and background necrosis, in a sufficiently cellular sample, in addition to the cytological and architectural abnormalities seen for a diagnosis of suspicious for malignancy.

For the purposes of this study, low grade malignant tumors (i.e. gastrointestinal stromal tumors, lymphoma, neuroendocrine tumors) were considered malignant.

The final diagnosis was based on malignant lesion histology obtained by biopsy or surgical resection. Nonsurgical patients with a nondiagnostic tissue sample but subsequent clinical and radiological disease progression consistent with malignancy were considered to have malignancy. A diagnosis of benign disease required negative histology and follow-up of at least 12 months without evidence of progression on interval imaging.

For analysis using strict criteria cutoffs, samples reported as malignant were categorized as positive for malignancy; all other samples were categorized as false negatives when the final diagnosis was malignant. Inadequate samples were classified as false negatives when the final diagnosis was malignant and as inaccurate when the final diagnosis was benign.

For analysis using less strict criteria, samples reported as malignant and those reported as suspicious were categorized

as positive for malignancy; all other samples were categorized as false negatives when the final diagnosis was malignant. Inadequate samples were classified as false negatives when the final diagnosis was malignant and as inaccurate when the final diagnosis was benign.

Outcome measures

The primary objective was to assess, using strict criteria, whether stents impair EUS-guided tissue sampling in patients with a solid mass in the head of the pancreas compared with patients without stents.

Secondary objectives were to assess, using less strict criteria, whether stents impair EUS-guided tissue sampling in patients with a solid mass in the head of the pancreas compared with patients without stents. In addition, the study also aimed to identify whether other variables (tumor size, needle type, needle gauge, number of passes, ROSE, increased experience as represented by passage of time) affected diagnostic performance.

Statistical analysis

Continuous variables are reported as mean (SD) if normally distributed and the median and interquartile range otherwise. Comparisons of continuous variables between the three stent groups were made using analysis of variance if the values followed the normal distribution, and the Kruskal-Wallis test otherwise. Categorical data were compared between stent groups using the chi-squared test.

The outcome variable was whether the patients had accurate tissue diagnosis, and this was considered as a binary measure (yes/no). All analysis was performed using logistic regression. The analysis was performed in two stages for two groups, one group using strict criteria and one group using less strict criteria, which considered suspicious results as diagnostic for malignancy. First, the separate association between each factor and the outcome was examined separately in a series of univariable analyses. Subsequently, a multivariable analysis (Stata version 13.1; StataCorp, College Station, Texas, USA) was also performed. The odds ratio (OR) and 95% confidence interval (CI) of each outcome were calculated. For the continuous variables, the ORs indicated the relative change in the odds of incorrect performance for a one-unit increase in each factor (unless otherwise indicated). A backward selection procedure was used to retain only the significant variables in the final analysis.

Ethics approval

As per the United Kingdom National Health Service research ethics guidance, ethical approval from an institutional review body was not required for this study. Institutional authorization to hold a prospective patient database for use for quality improvement was obtained. Written informed consent was obtained from all patients prior to the procedures.

Results

Baseline

Of the 1861 patients undergoing EUS and pancreatic tissue sampling during the study period, 631 (33.9%) underwent 698 procedures for a solid mass in the head of the pancreas (Fig. 1s, online-only in Supplementary Material). Baseline characteristics according to stent type used are shown in Table 1s.

Malignancy was proven in 535 individuals (84.8%) who underwent 581 procedures; 116 of these patients (21.7%) underwent surgery. ROSE was performed in 113 of all procedures (16.2%). An FNA needle was used in 41.5% of procedures and a core biopsy needle was used in 58.3% (reverse-bevel in 32.7% and fork-tip in 25.6%). In 39 procedures (5.6%), needle gauge was not reported and therefore these cases were excluded from regression analysis concerning needle gauge. Needle characteristics and use of ROSE according to type of stent are shown in Table 2s.

Tissue diagnosis

An inadequate sample was obtained in 69 procedures (9.9%). For all cases and using strict criteria, sensitivity was 72.6% (422/581). Using less strict criteria, sensitivity was 83.1% (483/581). If inadequate cases were also excluded, sensitivity was 89.4% (483/540). ► Table 2 shows the pathological classification of the 581 procedures (535 individuals), with a final diagnosis of malignancy, presented according to the presence and type of stent. Two neuroendocrine tumors with diagnostic samples and therefore classified as malignant had atypical cytology.

► **Table 2** Endoscopic ultrasound (EUS)-guided tissue sampling pathology outcomes in the 581 EUS procedures with cancer as a final diagnosis, shown according to stent usage.

Pathology results	SEMS, n (%) (n = 157)	Plastic, n (%) (n = 137)	Without stent, n (%) (n = 287)
Inadequate (n = 41)	11 (7.0)	9 (6.6)	21 (7.3)
Benign (n = 19)	10 (6.4)	4 (2.9)	5 (1.7)
Atypical (n = 40)	11 (7.0)	12 (8.8)	17 (5.9)
Suspicious (n = 61)	21 (13.4)	20 (14.6)	20 (7.0)
Malignant (n = 420)	104 (66.2)	92 (67.2)	224 (78.0)

SEMS, self-expandable metal stent.

Strict criteria group

Using strict criteria, sensitivity was 66.2% (104/157) in the SEMS cohort, 67.2% (92/137) in the plastic stent cohort, and 78.7% (226/287) in the cohort without a stent. EUS-guided tissue sampling had an overall accuracy of 73.2% (511/698); EUS-guided tissue sampling accuracy in patients with SEMS was

66.9% (109/163) compared with 68.9% (115/167) for patients with plastic stents and 78.0% (287/368) for those with no stents.

The univariable analysis of factors impacting tissue sampling (Table 3s) showed that the risk of inaccurate diagnosis was significantly lower with increasing year of measurement (representing increasing experience; OR 0.89), reverse-bevel needle (OR 0.64), and fork-tip needle (OR 0.51), increasing size of the tumor (OR 0.73), and increasing number of passes (OR 0.84). The risk of inaccurate diagnosis was increased by use of a stent (OR 1.68) and type of stent (OR 1.6 for plastic stent; OR 1.75 for SEMS). The use of ROSE, age and sex of patient, and needle gauge were not associated with an effect on tissue sampling.

When multivariable analysis was applied, only the number of needle passes (OR 0.84), fork-tip needle (OR 0.52), presence of SEMS (OR 1.96), and tumor size (OR 0.72) retained statistical significance (► Fig. 2).

In the 581 procedures with a final diagnosis of malignancy, repeat tissue sampling was more common when an SEMS was present (16/157 [10.2%]) than with no stent (13/287 [4.5%]; $P < 0.02$). In patients with plastic stents and malignancy, 4/137 (2.9%) were repeat procedures; there was no difference from those without stents but there was a significant difference compared with those with SEMS ($P = 0.02$).

Less strict criteria (suspicious for cancer included as malignant)

The results of the univariable analysis suggested that only number of passes (OR 0.74) and tumor size (OR 0.80) were statistically significant (Table 4s).

The results of the multivariable analysis (► Fig. 3) showed that ROSE (OR 0.43), number of passes (OR 0.76), tumor size (OR 0.81), and use of the fork-tip needle (OR 0.48) were associated with diagnosis. The use of ROSE was associated with a reduced occurrence of incorrect diagnosis, with the OR of such an outcome falling more than twofold. The odds of an incorrect diagnosis with a fork-tip needle were half those for patients in whom an FNA needle was used. As in the univariable analyses, a larger tumor size and a greater number of passes were associated with a reduced occurrence of incorrect diagnosis.

Discussion

To the best of our knowledge, this is the largest series to date where the effect of biliary stents on EUS-guided tissue sampling with FNA and two types of FNB needles has been investigated in patients with pancreatic head masses. In this study, which included 141 patients with SEMS, 149 with plastic stents, and 341 with no stent, we showed that using strict pathological criteria, SEMS had a negative impact on tissue diagnosis (OR 1.96) for pancreatic head masses. In addition, increasing tumor size, number of passes, and use of a fork-tip needle were independently associated with improved tissue sampling accuracy. The presence of a plastic stent did not have a significant impact. Our findings were robust to adjustment for potential confounders in multivariable analysis.

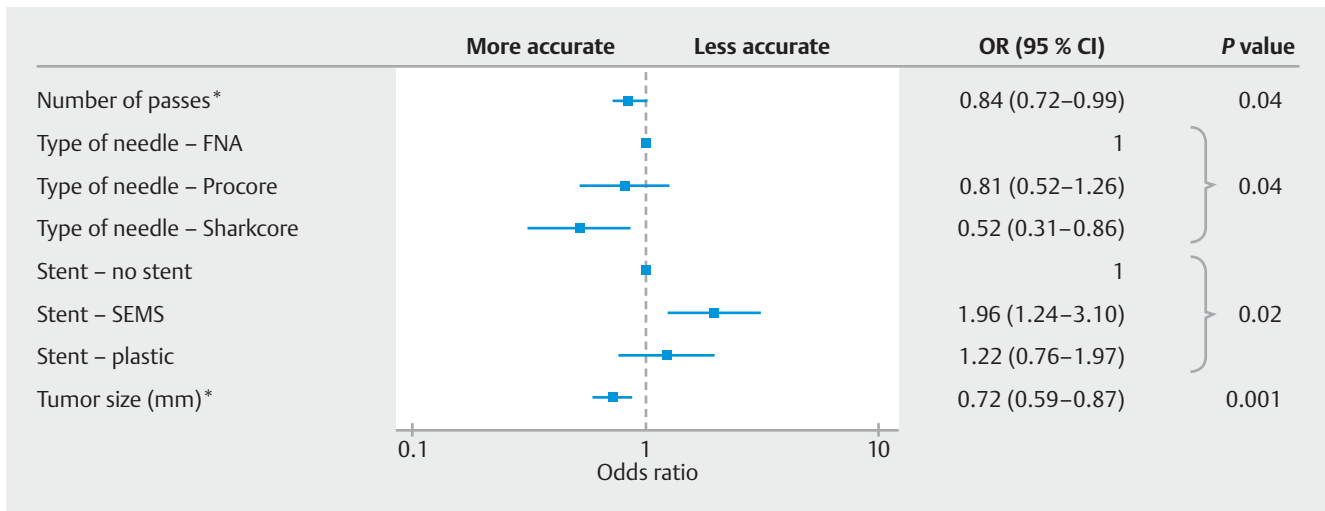


Fig. 2 Forest plot showing the results of multivariable analysis for factors with an impact on accuracy of endoscopic ultrasound-guided tissue sampling using strict criteria and only classifying samples reported as malignant as diagnostic of malignancy. CI, confidence interval; FNA, fine-needle aspiration; OR, odds ratio; ROSE, rapid on-site evaluation. *Increasing number of needle passes and increasing tumor size were associated with increased accuracy.

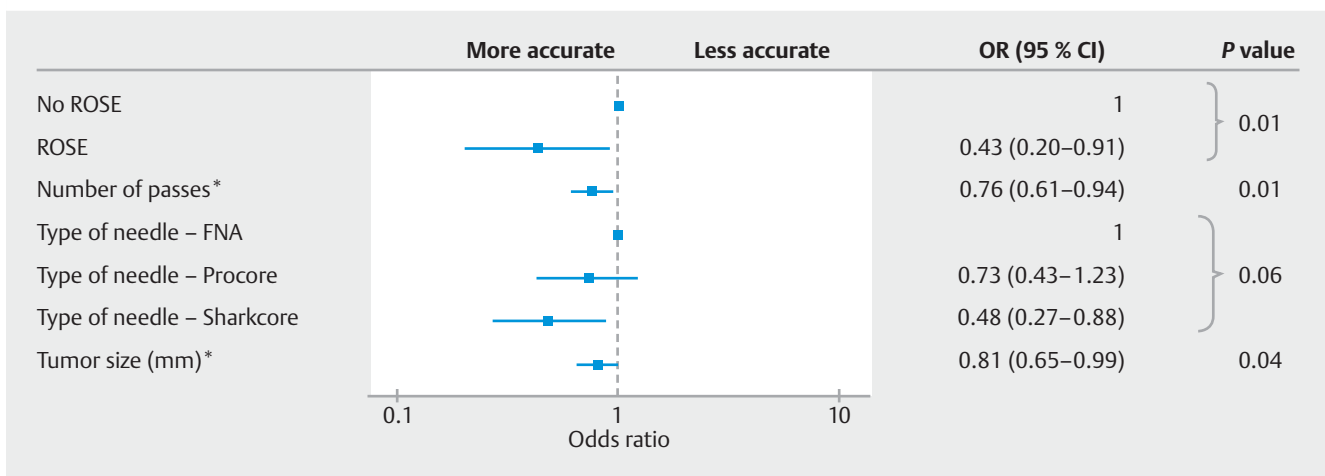


Fig. 3 Forest plot showing the results of multivariable analysis for factors with an impact on accuracy of endoscopic ultrasound-guided tissue sampling classifying samples reported as suspicious or malignant as diagnostic of malignancy (less strict criteria). CI, confidence interval; FNA, fine-needle aspiration; OR, odds ratio; ROSE, rapid on-site evaluation. *Increasing number of needle passes and increasing tumor size was associated with increased accuracy.

A final diagnosis of cancer was significantly more common in individuals with SEMs (97.2%) and plastic stents (86.6%) than in those with no stent (78.9%). In addition, there was a significant difference in size of mass between those with SEMs, plastic stents, and no stent. This difference is unlikely to have impacted on the findings of the study; indeed, despite the higher prevalence of malignancy and larger masses in the SEMs group, the diagnostic performance of EUS-guided tissue sampling was found to be reduced in multivariable analysis.

Several studies have documented that SEMs are superior to plastic stents for preoperative drainage and palliation of biliary obstruction secondary to a stricture in the head of the pancreas [4–6]. Consequently, SEMs are increasingly preferred to plastic stents for both preoperative and palliative biliary drainage.

Only a minority of patients presenting with pancreatic cancer are suitable for surgical resection, with a reported resection rate of 9.8% in England [13]. The main therapeutic option therefore is chemotherapy, prior to which a tissue diagnosis is required. In the current study, multivariable analysis showed that the presence of an SEM significantly reduced the diagnostic performance of EUS-guided tissue sampling. Several previous studies have investigated whether the presence of biliary stents influences the results of EUS-guided tissue sampling, with conflicting results. Siddiqui et al. [7] found no negative effect of SEMs on diagnostic accuracy in a study in which 577 patients with plastic stents (accuracy 99.8%) were compared with 100 patients with SEMs (accuracy 100%). However, the study did not include patients without stents, all sampling was per-

formed with a 22-gauge FNA needle, ROSE was used in 100%, and multivariable analysis was not performed. In addition, inadequate samples were excluded from the analysis and suspicious cytology was classified as true positive. Fisher et al. [11] studied 170 patients without stents and 98 with predominantly plastic stents, of which 87 were placed >1 day before EUS-FNA and 11 were placed <1 day prior to EUS-FNA; ROSE was used for the majority of cases. The tissue diagnosis rate was not significantly different between patients with no stents (92.4%) and those with a stent placed >1 day prior to EUS-FNA (88.5%); but in the small group of patients with a stent placed immediately before EUS-FNA, there were significantly more indeterminate results. Ranney et al. [8] found no difference in EUS-FNA accuracy between no stent and stent (93.7% vs. 95.3%) or between plastic stents and SEMs (95.2% vs. 95.5%) in a cohort of 214 patients, 150 of whom received stents (105 plastic, 45 SEMs); ROSE was available for all cases. As in the Fisher study [11], only FNA was used and suspicious cytology was classified as a true positive. Recently, Antonini et al. [9] reported on a study investigating the effect of the presence of plastic stents on sampling with reverse-bevel needles in a cohort of 130 patients (74 without and 56 with a stent); ROSE was available for 23% of the procedures. Adequacy of tissue was defined as a tissue specimen suitable for cytological examination. In this study, inadequate samples (insufficient material) were classified as false negatives. The authors found no significant difference in accuracy with a stent present (89.3%) or absent (86.5%). On multivariable analysis, increasing number of passes and use of a 22-gauge needle were associated with increased accuracy. Conversely Kim et al. found that the presence of a biliary stent was associated with a significant decrease in accuracy of EUS-guided tissue sampling, compared with no stent (77% vs. 89%, respectively) [10]. In 180 patients, 75 with stents (64 plastic and 11 SEMs), multivariable analysis showed that having a biliary stent (OR 0.37), ROSE (OR 9.24), and reverse-bevel biopsy (OR 2.60) affected EUS-FNA accuracy. However, suspicious cytology was classified as true positive and inadequate samples were excluded.

There is therefore considerable heterogeneity between the previous studies in terms of definition of malignancy, the inclusion or exclusion of inadequate samples, the use of multivariable analysis, and the number of SEMs included. Our study is the first to include FNA and two generations of core biopsy needles (reverse-bevel and fork-tip, respectively) in the multivariable analysis. Analysis was also performed using both strict criteria (classifying samples suspicious for malignancy as false negatives) and less strict criteria (classifying samples suspicious for malignancy as diagnostic), thereby allowing a full comparison with the previous literature. The diagnostic performance reported in the current study is in line with a previous large series that documented a sensitivity of 77% using strict criteria [14]. When suspicious samples were classified as true positives and inadequate samples were excluded, the overall sensitivity (89.4%) in our study is comparable to that reported in the literature by studies using similar criteria. If suspicious samples were classified as positive, stents (SEMs or plastic) no longer had an impact on accuracy, but accuracy was improved with

ROSE. This suggests that, at least in part, the difference between the present study and previous studies may be accounted for by the inclusion of suspicious samples as positive.

In the case of SEMs, this finding is consistent with the presence of a stent impairing the quality of the sample, and thereby increasing the difficulty of obtaining a definitive assessment of malignancy in a sample. The only two previous studies that included more than a handful of SEMs cases categorized suspicious samples as diagnostic and also reported no impact on diagnostic performance [7–8].

ROSE by a cytopathologist or cytotechnologist has been advocated as improving the diagnostic performance of EUS-FNA; however, data from observational studies are conflicting [15–16], though a previous meta-analysis reported an increase in diagnostic accuracy [17]. More recently, the one randomized controlled trial conducted to date found no benefit [18], and another meta-analysis [19] also found no improvement in diagnostic performance with ROSE. The results of the present study were consistent with this finding, with no benefit seen using strict pathological criteria. The use of strict criteria is important as not only does it reflect the true test performance, but suspicious pathology is not conventionally acceptable by oncologists before initiation of chemotherapy or recruitment into chemotherapy trials.

We also found that SEMs were associated with a significantly higher rate of repeat procedures. Although an economic analysis was not performed, repeat procedures are likely to increase costs and lead to delays in treatment. The most likely explanation for the negative impact of SEMs is the significant degree of acoustic shadowing, which hampers imaging of the tumor; this may make sampling challenging, particularly if the tumor is small or the bulk of it is posterior to the stent. Plastic stents, owing to their size and material, generate less acoustic shadowing. The Sharkcore needle is a novel device with a fork-tip and opposing bevel design. A number of recent studies in a mixed population, including pancreatic and nonpancreatic solid lesions, have documented improved histological yield compared with FNA [20], and similar diagnostic performance without ROSE vs. FNA with ROSE [21]. In a previous study of solid pancreatic lesions, the fork-tip needle had significantly higher sensitivity compared with the reverse-bevel needle [22]. In the current study, the fork-tip needle was independently associated with improved tissue diagnosis on multivariable analysis.

This study has several strengths, specifically the large number of cases, the use of strict pathological criteria, and the inclusion of all variables previously identified as potentially affecting diagnostic performance in multivariable analysis. This is also the first study to compare large numbers of patients with SEMs, plastic stents, and without stents. However, it does have some limitations, the most important being its retrospective design. The use of multivariable analyses reduces the possibility of residual confounding. Furthermore, the study design has precluded blinding, not only of endoscopists but also pathologists, to the procedural details including needle type. However, it is highly unlikely that the lack of blinding has materially contributed to the findings observed in this study.

In summary, the presence of SEMs had a negative impact on tissue sampling whereas the use of a fork-tip needle and increasing number of needle passes were associated with increased accuracy of tissue diagnosis. These findings have significant ramifications as SEMs are increasingly used.

In conclusion, this study supports the practice of ensuring that when EUS-guided tissue sampling and biliary drainage are required, EUS is performed before placement of an SEM.

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Competing interests

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