



Transrectal endoscopic ultrasound-guided fine-needle aspiration biopsy for qualitative diagnosis of pelvic space-occupying lesions: a diagnostic test

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Background: Endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) is an effective technique for qualitative diagnosis of space occupying lesions in and around the wall of the digestive tract. At present, there are many studies on EUS-FNA via the upper gastrointestinal route, while there are few studies on EUS-FNA via the lower gastrointestinal route, especially for Chinese patients with pelvic mass. Therefore, this study sought to evaluate the value of transrectal EUS-FNA in the qualitative diagnosis of pelvic masses in Chinese patients.

Methods: The clinical data of 35 patients with pelvic masses who underwent EUS-FNA at our hospital were collected from September 2014 to December 2021. Among these patients, 10 underwent surgical treatment after EUS-FNA, and a diagnosis was made based on a pathologic evaluation. The EUS-FNA biopsy results were compared to the final diagnostic results to calculate the sensitivity, specificity, positive predictive value, negative predictive value and accuracy of EUS-FNA in the diagnosis of malignant pelvic mass. For the 10 patients who underwent surgery, the final diagnoses were based on the pathologic findings of surgical specimens, and for the 25 patients who did not undergo surgery, the final diagnoses were based on the malignant pathological results of EUS-FNA or clinical follow-up results.

Results: Among the 35 patients, 12 had benign lesions, including pelvic abscesses, cysts, and inflammatory masses, and 23 had malignant lesions, including mesenchymal tumors, leiomyosarcomas, teratomas, and malignant tumors with pelvic metastases. There were no complications resulting from the biopsy punctures. The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of EUS-FNAs for the diagnosis of malignant pelvic masses were 91.3% (21/23), 100.0% (12/12), 100.0% (21/21), 85.7% (12/14), and 94.3% (33/35), respectively.

Conclusions: EUS-FNA is a safe and effective method for the qualitative diagnosis of pelvic masses, and has good clinical application value.

Keywords: Endoscopic ultrasound (EUS); fine needle biopsy; pelvic mass; diagnosis

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Introduction

As a common medical condition, pelvic space-occupying lesions include a wide variety of benign and malignant diseases. Patients with a pelvic space-occupying lesion usually have abdominal pain and distension. Masses are palpable on abdominal examination, and the diagnosis is usually made by ultrasound, computed tomography (CT), or magnetic resonance imaging (MRI). Most benign pelvic space-occupying lesions can be treated in a conservative manner. A qualitative diagnosis through non-surgical means is preferable for such conditions, and if possible, can be used to guide the subsequent treatments. CT or MRI provide important clues for diagnosing malignant pelvic space-occupying lesions, but do not offer a qualitative diagnosis, which is usually achieved by a pathologic evaluation. Percutaneous biopsy may be very difficult to perform in this anatomic region due to the presence of tissue structures blocking the puncture path and the high risk of complications of puncture. Transrectal endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) is a potentially valuable tool for diagnosing pelvic space-occupying lesions near the rectum and sigmoid colon. This diagnostic technique can obtain diseased tissues for cytologic and histologic examinations, which further lays the foundation for distinguishing between benign and malignant lesions.

EUS-FNA biopsy is a diagnostic technique that involves the use of dedicated biopsy needles for aspiration biopsies in real time. Compared to conventional abdominal ultrasound or CT-guided percutaneous FNA, EUS-FNA has the benefits of a shorter puncture distance and higher safety. EUS-FNA has matured into a minimally invasive diagnostic endoscopic technique that is used to differentiate between benign and malignant lesions (1).

In recent years, EUS-FNA has been widely applied to diagnose lesions in the digestive tract and nearby areas. This diagnostic technique is suitable for diagnosing submucosal tumors in the digestive tract (2), and space-occupying lesions in the lymph nodes (3), mediastinum (4,5), pancreas (6,7), liver (8), and adrenal glands (9,10). The clinical value of EUS-FNA for diagnosing space-occupying lesions in these organs has been widely acknowledged. EUS-FNA is usually performed for the qualitative diagnosis of lesions via the upper digestive tract. However, several studies have examined the qualitative diagnosis of lesions occupying the digestive tract, pelvis, and nearby areas using EUS-FNA via the lower digestive tract (11-14); although a meta-

analysis was included in these studies, some of them had small sample sizes, and some of them excluded occupying lesions in the digestive wall. Moreover, there was a lack of comprehensive pathological diagnosis types of EUS-FNA, and the subjects were mainly European or American patients.

In the present study, we retrospectively reviewed the transrectal EUS-FNA results of 35 Chinese patients with pelvic space-occupying lesions inside and outside the wall of the digestive canal. And cytopathology, histopathology, liquid-based pathology, and immunopathology were detected in almost every EUS-FNA biopsy patient.

On this basis, we examined the effectiveness, safety, and feasibility of using EUS-FNA for differential diagnosis of benign and malignant pelvic space-occupying lesions. We present the following article in accordance with the STARD reporting checklist (available at <https://tcr.amegroups.com/article/view/10.21037/tcr-22-2057/rc>).

Methods

Case data

We conducted a retrospective analysis at a single center (The Second Affiliated Hospital of Soochow University). The patients were consecutive cases in whom pelvic space-occupying lesions were detected by CT and/or MRI scans and who later underwent transrectal EUS-FNA after admission to our hospital between September 2014 and December 2021. No exclusion criteria were established in the present study. All the patients signed the written informed consent form for EUS-FNA. In total, 35 patients were recruited, comprising 22 females and 13 males (average age: 59.4 years; age range: 29–91 years). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics committee of the Second Affiliated Hospital of Soochow University (No. JD-HG-2022-46) and informed consent was taken from all the patients.

Study methods

A Fuji SU-7000 or SU-8000 EUS system (Tokyo, Japan) was used, along with a 19- or 22-G Cook EchoTip Ultra Needle (Winston-Salem, NC, USA). After a preoperative examination and cleansing enema, the patient laid on the left side and received intravenous sedation or anesthesia. Electrocardiogram monitoring and nasal catheter oxygen

inhalation were maintained throughout the operation. A linear-array echoendoscope was inserted at a distance of 20 cm from the anus to inspect the rectal wall and pelvis. If any lesions were noted, the lesion size, morphology, position, and anatomic relationship with the surrounding organs and tissues were recorded.

The FNA was performed using color Doppler ultrasound at the optimal site along the shortest possible route while avoiding the large blood vessels. The FNA of the lesions was performed under real-time ultrasound guidance. The core needle was removed and connected to a negative-pressure syringe to repeatedly withdraw the diseased tissues for cytologic, histologic, and immunopathologic examinations. If the lesions were cystic in nature, cytologic smears were prepared, a tumor-marker test, and bacterial culture were carried out using the cystic fluid withdrawn by the FNA.

Postoperative treatment

After surgery, the patients were returned to the ward for bedrest. If the patients had no discomfort after fasting from food and water for 2 h postoperatively, a low-residue diet was started. Adverse reactions were recorded, including abdominal pain, hematochezia, and fever. An oral antibiotic (3rd-generation cephalosporin or fluoroquinolone) was administered for 2 days after surgery to prevent infection. The patients also received carbazochrome sodium sulfonate via intravenous drip for hemostasis and fluid replacement therapy, including nutritional support. The patients were observed for complications daily for 3 days after surgery.

Diagnoses with EUS-FNA

The finding of cancer cells, heterocysts, or malignant findings by any of the 3 (cytologic, histologic, and immunopathologic) examinations satisfied the diagnosis of a malignant lesion; otherwise, the lesions were considered benign.

Final diagnosis

The final diagnosis served as the reference against which the EUS-FNA-based diagnosis was compared. For the patients who underwent surgery after EUS-FNA, the final qualitative diagnosis was based on the benign or malignant pathological results. For patients who did not undergo or could not undergo surgery, if EUS-FNA

pathological diagnosis was malignant, the final diagnosis was malignant. If EUS-FNA pathological diagnosis was benign, the final diagnosis was based on at least 6 months of clinical follow-up data after EUS-FNA including past medical history, clinical symptoms and signs, imaging findings such as CT, MRI.

Statistical method

This was a retrospective diagnostic test study of EUS-FNA. The final diagnosis was considered the gold standard. The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of EUS-FNA in providing a diagnosis of malignant pelvic space-occupying lesions were calculated.

Results

Diagnoses with EUS-FNA

Among the 35 patients, 12 had a past history of a malignancy. The pelvic space-occupying lesions were primarily detected by CT or MRI due to the presenting symptoms, such as lower abdominal pain, abdominal distension, and a change in bowel habits, or a history of a malignancy. These patients were then admitted to the hospital for EUS-FNA. Among the included patients, 2 had lesions in the rectal wall, and 33 had lesions outside the rectal wall. The lesion diameters were 0.7–7.6 cm and primarily presented as anechoic signals or mixed echoes. The EUS-FNA procedures were performed transrectally, with each lesion punctured 2–5 times. Satisfactory cytologic and/or histologic samples were obtained from all patients (see *Figures 1,2*). No adverse reactions occurred after surgery, including abdominal pain, hematochezia, fevers, and perforations. The incidence of complications was 0.0%.

Final diagnoses

A total of 10 patients underwent surgery after EUS-FNA during which the results of the surgical pathologic evaluation were obtained. Among the 35 patients, the final findings were as follows: 9 cystic masses, including 4 pelvic abscesses, 3 pelvic cysts, 1 pelvic encapsulated hydrops, and 1 ovarian cystadenoma; 26 solid masses, including 2 inflammatory masses, 2 stromal tumors, 2 sarcomas, 1 schwannoma, and 1 teratoma; and 18 malignancies (ovarian cancer or after surgery for ovarian cancer,

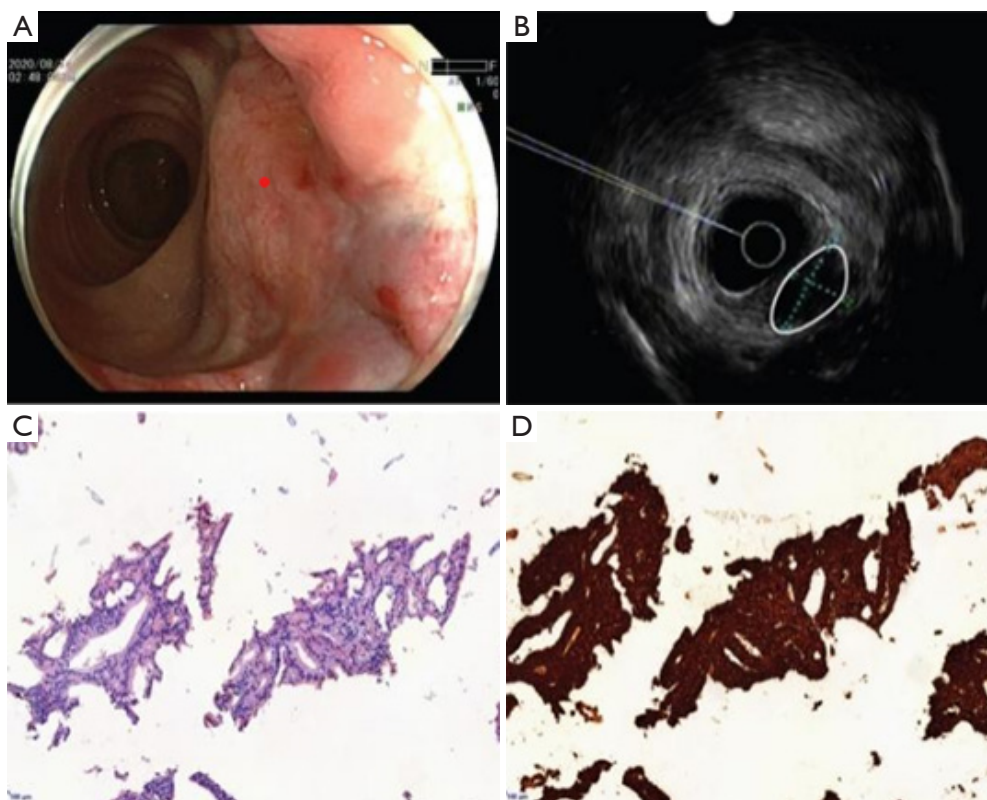


Figure 1 Prostate cancer with perirectal metastases. (A) A submucosal protuberance was observed in the dentate line by colonoscopy with a smooth surface (displayed in the red point). (B) EUS (with a small probe) revealed a hypoechoic lesion (displayed in the white circle) between the outside of the rectum and prostate, and the boundary between the lesion and the prostate was indistinct on some slices. (C) Hematoxylin and eosin staining revealed atypical glandular epithelial cell clusters with an inclination towards adenocarcinoma ($\times 40$). (D) Immunohistochemical staining PSA+ ($\times 100$). EUS, endoscopic ultrasound; PSA, prostate-specific antigen.

colorectal cancer or after surgery for colorectal cancer, prostate cancer, after surgery for gastric cancer, and pancreatic cancer) with pelvic metastases. There were 12 benign and 23 malignant lesions. A comparison of the pathologic diagnoses by EUS-FNA against the final diagnosis of each patient is presented in *Table 1* and *Figure 3*.

Diagnostic value of EUS-FNA

The diagnostic sensitivity of EUS-FNA for malignant pelvic space-occupying lesions was 91.3% (21/23), the specificity was 100.0% (12/12), the positive predictive value was 100.0% (21/21), the negative predictive value was 85.7% (12/14), and the accuracy was 94.3% (33/35) (see *Table 2*).

Discussion

EUS-FNA has become a standard technique for obtaining

samples of lesions occupying the wall of the digestive tract and nearby areas. EUS-FNA involves the use of a linear-array echoendoscope for surveillance to avoid the blood vessels around the lesions and the accurate insertion of a needle into the target lesions via the digestive tract. EUS-FNA is considered a useful technique to sample the target cells or tissues to determine the nature, source, and pathologic features of the lesions with high safety and low risk (15,16). To date, many studies involving EUS-FNA have focused on applications in diagnosing space-occupying lesions in the pancreas, liver, and mediastinum. However, few studies have reported on the use and diagnostic accuracy of EUS-FNA in pelvic space-occupying lesions (11-14). In the present study we retrospectively analyzed the medical records of 35 patients who underwent EUS-FNA for pelvic space-occupying lesions at our hospital over a 7-year period. The purpose of the study was to discuss the qualitative diagnostic effectiveness and safety of transrectal

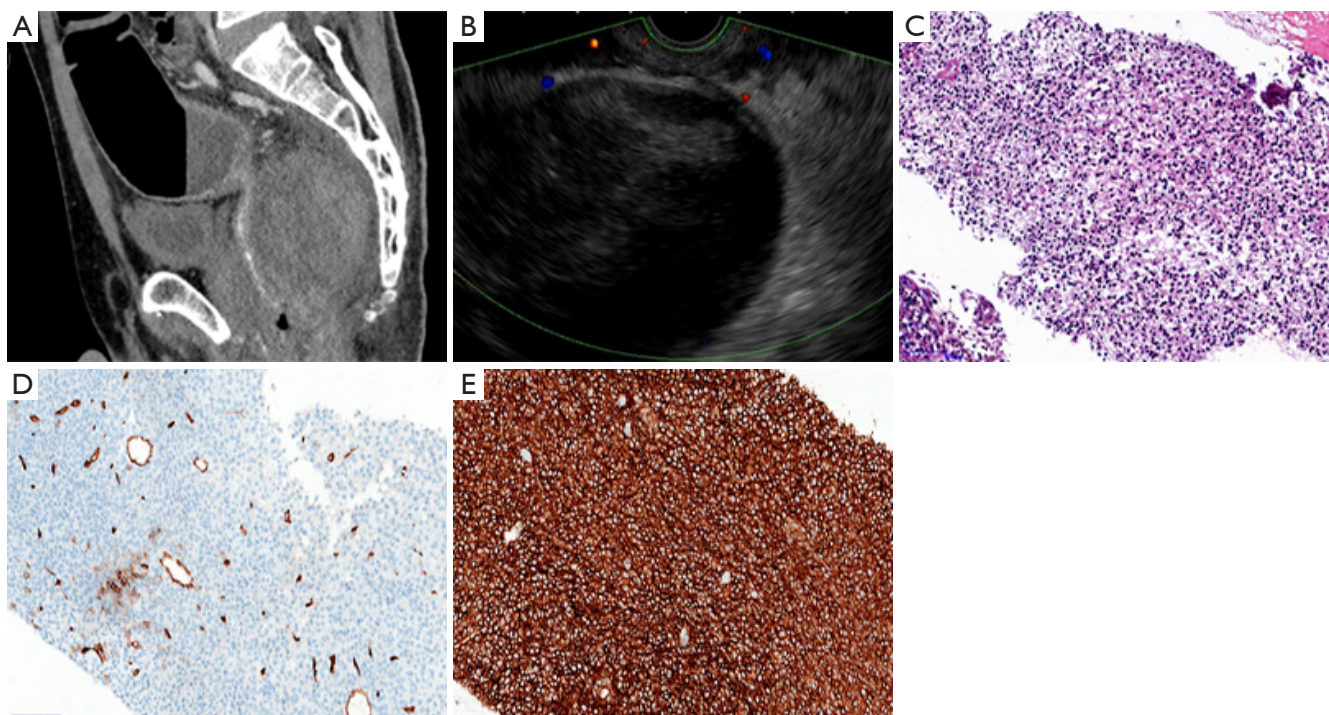


Figure 2 Pelvic sarcoma. (A) CT (sagittal view) revealed a quasi-circular mixed density lesion with distinct boundaries that was pushing the adjacent rectum towards the right. (B) EUS indicated a huge pelvic space-occupying lesion with intact an envelope, non-uniform echoes within the lesion, and local anechoic signals (the colored dots represented blood flow signal from the color doppler; the red dots represented the blood flow toward us; and the blue dots represented the blood flow away from us). (C) Hematoxylin and eosin staining revealed atypical cell clusters with deeply-stained nuclei ($\times 40$). (D) Immunohistochemical staining CD34⁺ ($\times 100$). (E) Immunohistochemical staining CD99⁺ ($\times 100$). CT, computed tomography; EUS, endoscopic ultrasound; CD34, cluster of differentiation 34; CD99, cluster of differentiation 99.

EUS-FNA in pelvic space-occupying lesions.

Pathologic results are considered the gold standard for diagnosing pelvic space-occupying lesions. The CT- or B-mode ultrasound-guided percutaneous FNA of pelvic space-occupying lesions carries a higher risk of complications, including bleeding, infections, and organ injuries. This diagnostic procedure is considered less safe, especially for space-occupying lesions that lie deep within the pelvis, are a greater distance from the skin and are smaller in size. A linear-array echoendoscope can clearly visualize the pelvic space-occupying lesions through the rectum, offering real-time dynamic surveillance of the puncture process. The use of color Doppler ultrasound facilitates the avoidance of great blood vessels and the choice of the shortest and safest puncture route, thus maximally reducing the risk of puncture-associated complications.

All of the patients included in this study underwent transrectal FNA. The patients took oral antibiotics for

2 days after surgery to prevent postoperative infections due to the presence of gut bacteria. None of the patients had any postoperative adverse reactions, including bleeding, infections, and abdominal pain. The incidence of postoperative complications was 0 and was thus lower than the overall incidence of complications associated with EUS-FNA reported in the previous literature (0.98%) (16). The above results indicated the high safety of transrectal EUS-FNA and the low risk of complications.

Among the published studies on the use of EUS-FNA for diagnosing pelvic space-occupying lesions, Rzouq *et al.* (11) performed EUS-FNA for space-occupying lesions within the pelvis or in the intestinal wall in 20 patients via the lower digestive tract. None of the patients developed post-puncture complications. All of the patients underwent surgical treatment after EUS-FNA to obtain the results of a surgical pathologic evaluation. The diagnostic sensitivity of EUS-FNA for differentiating between benign and malignant pelvic space-occupying lesions was 90.0%, the

Table 1 Comparison of the pathologic diagnoses by EUS-FNA versus the final diagnoses

Number of cases	Diagnoses with EUS-FNA	Final diagnoses	Pathologic diagnoses after surgery	CT or MRI results
4	Pelvic abscess	Pelvic abscess	None	Pelvic abscess
3	Pelvic cyst	Pelvic cyst	Pelvic cysts in 2 cases/ 1 case did not undergo surgery	Cystic lesion in the posterior rectal space
1	Pelvic effusion	Pelvic effusion	None	Pelvic effusion
1	Glandular epithelial cells visible	Ovarian cystadenoma	None	Mucinous cystadenoma
2	Stromal tumor	Rectal/pelvic stromal tumor	Pelvic stromal tumor in 1 cases/1 case did not undergo surgery	Masses occupying the rectum/pouch of Douglas: stromal tumor suspected
2	Inflammatory mass	Pelvic inflammatory mass	None	Abnormal signals on the left side of the rectum/pouch of Douglas suspected to be inflammation
1	Schwannoma	Pelvic schwannoma	None	Abnormal signals in the right posterior part of the pelvis suspected to be a schwannoma
2	Sarcoma	Pelvic sarcoma	Sarcoma	Pelvic space-occupying lesion suspected to be a tumor (stromal or mesenchymal tumor?)
4	Metastatic adenocarcinoma	Ovarian cancer with pelvic and abdominal metastases	None	Ovarian cancer with multiple pelvic and abdominal metastases
1	Benign lesion	Ovarian cancer with pelvic metastases	None	Ovarian cancer with pelvic metastases
2	Metastatic adenocarcinoma	Ovarian cancer with postoperative pelvic metastasis	None	Soft tissue shadows in the right appendix/right side of the rectosigmoid junction after surgery for ovarian cancer
3	Metastatic adenocarcinoma	Rectal cancer with pelvic and abdominal metastasis	Adenocarcinoma	Abnormal signals outside of the rectal wall
1	Metastatic adenocarcinoma	Rectal cancer with postoperative pelvic metastases	None	Multiple pelvic nodules after surgery for rectal cancer
1	Metastatic adenocarcinoma	Colon cancer with postoperative pelvic metastases	Adenocarcinoma	Space-occupying lesion in the junction of the sigmoid and descending colon suspected to be colon cancer
1	Metastatic adenocarcinoma	Combined with postoperative pelvic metastases after surgery for colon cancer	Adenocarcinoma	Irregular abnormal signals in the pelvis after surgery for colon cancer suspected to be metastases
3	Metastatic adenocarcinoma	Combined with postoperative pelvic metastases after surgery for gastric cancer	None	Combined with postoperative pelvic metastases after surgery for gastric cancer
1	Metastatic adenocarcinoma	Prostate cancer with postoperative pelvic metastases	None	Prostatic calcification
1	Metastatic adenocarcinoma	Pancreatic cancer with pelvic metastases	None	Pancreatic body cancer with nodules in the anterior rectum suspected to be metastases
1	Inflammatory lesion	Malignant teratoma	None	Mass occupying the pouch of Douglas suspected to be a teratoma

EUS-FNA, endoscopic ultrasound-guided fine-needle aspiration; CT, computed tomography; MRI, magnetic resonance imaging.

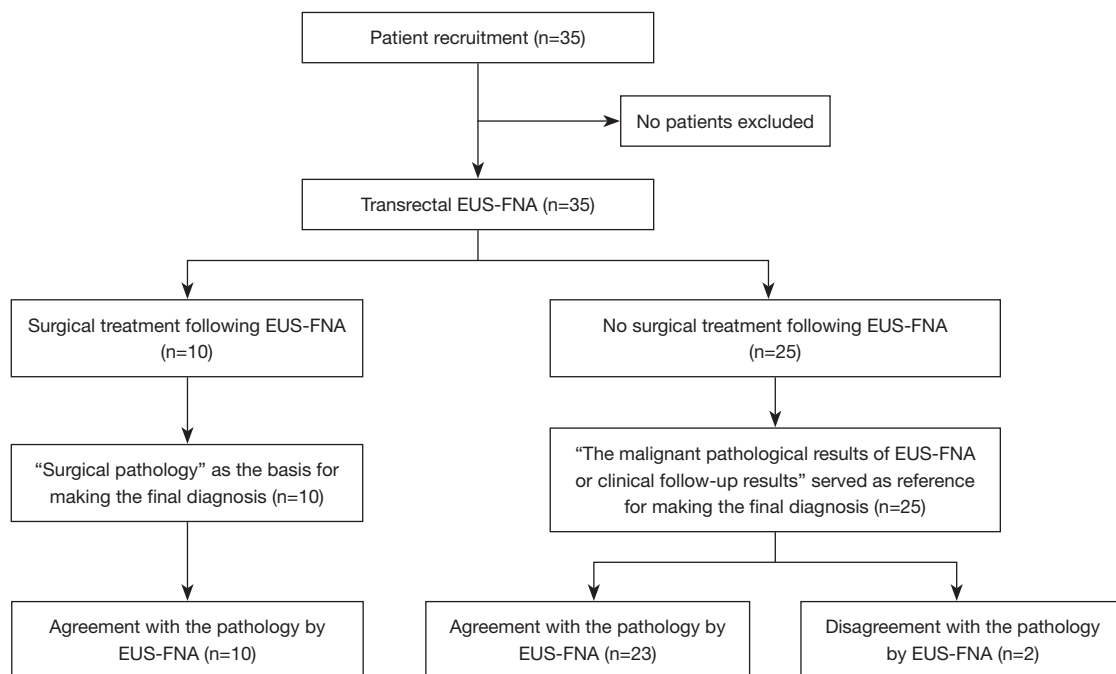


Figure 3 Flowchart comparing the pathologic diagnoses by EUS-FNA to the final diagnoses. EUS-FNA, endoscopic ultrasound-guided fine-needle aspiration.

Table 2 Diagnostic efficacy of EUS-FNA for pelvic space-occupying lesions

Result, n				Diagnostic efficacy, % (n/N) [95% CI]				
True positive	True negative	False positive	False negative	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Accuracy
21	12	0	2	91.3 (21/23) [79.8–102.8]	100.0 (12/12) [100.0–100.0]	100.0 (21/21) [100.0–100.0]	85.7 (12/14) [67.4–104.0]	94.3 (33/35) [80.8–99.3]

EUS-FNA, endoscopic ultrasound-guided fine-needle aspiration; CI, confidence interval.

specificity was 100.0%, the positive predictive value was 100.0%, and the negative predictive value was 90.0% (11). Another study of 21 patients with pelvic space-occupying lesions concluded that the diagnostic sensitivity of EUS-FNA via the lower digestive tract for malignant pelvic space-occupying lesions was 94.4%, the specificity was 100.0%, the positive predictive value was 100%, the negative predictive value was 66.7%, and the accuracy was 95.0% (12). A meta-analysis of 10 studies involving 246 patients with pelvic space-occupying lesions (13) showed that the diagnostic sensitivity of EUS-FNA for differentiating between benign and malignant lesions was 89.0%, the specificity was 93.0%, and the overall incidence of complications was 1.7% (there was 1 case of post-puncture bleeding and 2 cases of secondary abscesses after

puncture of the cystic lesions) (13).

Our reported diagnostic efficacy of EUS-FNA and the incidence of associated complications support the above-mentioned findings. Notably, the negative predictive value of EUS-FNA for malignant pelvic space-occupying lesions was low. Thus, we need to be especially aware of the risk of malignant pelvic space-occupying lesion missed diagnosis using EUS-FNA. In the current study, we had 1 missed diagnosis of ovarian cancer and 1 missed diagnosis of a malignant teratoma.

Among the 18 patients with pelvic metastases, the primary lesions were located in the ovaries, colorectum, stomach, prostate, and pancreas. EUS-FNA made correct diagnoses in 17 patients, but 1 diagnosis of ovarian cancer with pelvic metastases was missed. The diagnostic accuracy

of EUS-FNA for pelvic space-occupying lesions reached 94.4%. Comparable results have been reported in some international studies. Subtil *et al.* (17) reported a diagnostic accuracy of 90.3% among 46 patients with gynecologic tumors and suspected recurrent pelvic metastases using EUS-FNA; this result was similar to our results. Fernández-Esparrach *et al.* (18) concluded that EUS-FNA has a high diagnostic accuracy for perirectal recurrences of rectal cancer. There are also case reports in which EUS-FNA successfully diagnosed pelvic metastases from hepatocellular carcinoma (19), atypical pelvic recurrences of anal squamous cell carcinoma (20), and pelvic metastases from prostate cancer (21).

All of the above-mentioned studies show the high diagnostic value of EUS-FNA for pelvic metastases. Another study reported the diagnosis of a sodium polystyrene sulfonate crystal-induced pelvic inflammatory mass using EUS-FNA (22). In the present study, EUS-FNA diagnosed 2 females with pelvic inflammatory masses, both of whom were asymptomatic. Of these 2 patients, 1 was found to have a mass by pelvic CT re-examination after surgery for rectal cancer, and the other patient was diagnosed by CT scan during a routine physical examination. The inflammatory masses regressed upon follow-up re-examination in both cases.

To date, Chinese scholars have published very few studies on diagnosing pelvic space-occupying lesions using EUS-FNA. Gao *et al.* (23) reported on 52 patients who underwent transrectal EUS-FNA following the finding of pelvic space-occupying lesions by CT or MRI. Among these 52 patients, 10 had cystic masses, including cystadenomas and perirectal abscesses, and 42 had solid masses, including metastatic adenocarcinomas, stromal tumors, inflammatory masses, and lymphomas (23). The constituent ratios of different types of pelvic space-occupying lesions in Gao *et al.* study (23) were similar to the constituent ratios we reported. Sun *et al.* (24) reported EUS-FNA in 19 patients undergoing EUS-FNA for pelvic masses after radical resection of colon cancer. The diagnostic sensitivity was 86.7% (24), which was similar to the results we reported.

EUS-FNA cannot only diagnose pelvic space-occupying lesions but can also be used to treat pelvic abscesses. Gao *et al.* (23) reported on 6 patients with perirectal abscesses who underwent EUS-FNA to drain the pus, followed by lavage with a metronidazole injection. Among these 6 patients, 3 were followed for 2 months, and their abscess cavities healed (23). Another recent meta-analysis included 8 studies involving 135 patients with pelvic abscesses,

which revealed that the success rate of EUS-guided pelvic abscess puncture was 100.0%, the clinical success rate was 92.0%, and the incidence of adverse events was 9.4%, with stent dislocation being the primary complication (25).

We thus confirmed the feasibility of EUS-FNA as an alternative procedure for pelvic abscess drainage, which can minimize the necessity of surgical intervention and achieve long-term clinical success and an acceptable incidence of complications. Among the 4 patients with pelvic abscesses in our study, the causes were unknown in 1 patient. EUS-FNA for pus drainage plus the anti-infective treatment achieved poor efficacy in this patient, who later died of secondary systemic sepsis and septic shock. In this study, 2 patients had secondary infections after appendectomy or subtotal hysterectomy, and 1 patient had an infection secondary to a pelvic cyst. These 3 patients underwent EUS-FNA for pus drainage and anti-infective therapy, but without drug perfusion or stent placement for drainage. No adverse events occurred in any of these patients. The abscess cavities decreased considerably in size upon re-examination CT, and the symptoms, such as fever and abdominal pain receded. The above-described procedure had a pronounced efficacy.

Our study had several limitations. First, this retrospective study was only conducted at a single center, and the sample size was small. Second, the number of patients undergoing surgery after EUS-FNA was small. Thus, the results of surgical pathologic evaluations could not be used as the reference for making final diagnoses in all cases. This was likely because surgery was contraindicated in most patients who had metastases.

To conclude, EUS-FNA had high accuracy in making a qualitative diagnosis of pelvic space-occupying lesions, and the incidence of associated complications was extremely low. Thus, EUS-FNA is a qualitative diagnostic technique with proven safety, efficacy, and feasibility for pelvic space-occupying lesions. EUS-FNA has high clinical application value and delivers satisfactory therapeutic effects for pelvic abscesses; however, our conclusions need to be corroborated by studies with a larger sample size and conducted at multiple centers.

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Footnote

Reporting Checklist: The authors have completed the STARD

reporting checklist. Available at <https://tcr.amegroups.com/article/view/10.21037/tcr-22-2057/rc>

Data Sharing Statement: Available at <https://tcr.amegroups.com/article/view/10.21037/tcr-22-2057/dss>

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://tcr.amegroups.com/article/view/10.21037/tcr-22-2057/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics committee of the Second Affiliated Hospital of Soochow University (No. JD-HG-2022-46) and informed consent was taken from all the patients.

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