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Original Article

Diagnostic accuracy of lower endoscopic ultrasound-guided fine-needle aspiration for pelvic lesions: a systematic review and meta-analysis

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Abstract: Objective: This study aimed to undertake a systematic review and meta-analysis to estimate the accuracy of endoscopic ultrasound-guided fine-needle aspiration for pelvic lesions. Methods: The major databases, MEDLINE, EMBASE, Cochrane Library and CBM were searched systematically for studies in English and Chinese languages that assessed the diagnostic value of endoscopic ultrasound-guided fine-needle aspiration for pelvic lesions between January 1990 and May 2015. In this study, the pelvic lesion was defined as any mass seen with imaging modality in the pelvic area including perirectal and intraluminal lesions. Related studies were selected according to predefined inclusion and exclusion criteria. Two reviewers extracted and verified the data independently. The software of Meta-Disc 1.4 was applied for statistical analysis. Results: A total of 15 studies with 580 patients were included for analysis. Cytology, histology or clinical and imaging follow-up was used as the reference standard for all eligible lesions. The pooled sensitivity, specificity, PLR, NLR and DOR of EUS-FNA in the diagnosis of pelvic lesions were 0.87 (95% CI: 0.83-0.90), 0.98 (95% CI: 0.95-0.99), 17.17 (95% CI: 9.68-30.46), 0.15 (95% CI: 0.09-0.24) and 96.11 (95% CI: 48.88-189.00), respectively. The area under the curve (AUC) was 0.9531. Conclusions: This meta-analysis shows that endoscopic ultrasound-guided fine-needle aspiration has high diagnostic value for identifying lower digestive tract intraluminal and perirectal lesions.

Keywords: Pelvic lesions, ultrasound-guide, accuracy, meta-analysis

Introduction

Endoscopic ultrasonography (EUS) is a combination of endoscopy and intraluminal sonography, enabling both an endoscopic view and ultrasound imaging. Correspondingly, EUS improved noticeably visualization of the gastrointestinal tract and adjacent structures. Although EUS has been widely used to measure the invasion depth of a tumor, to identify the origin of the wall layer of a sub epithelial lesion and to accurately stage gastrointestinal malignancies, it cannot reliably differentiate benign from malignant lesions or neoplastic from inflammatory processes alone [1, 2].

With the development of technology, advances have permitted the performance of fine needle aspiration (FNA) biopsy under EUS guidance [3]. This method allows clinicians to acquire appropriate tissue samples from target lesions for cytological and/or histological examination. Thus, in order to obtain an accurate diagnosis, many benign pelvic lesions can be managed conservatively, but surgical removal is recommended when the lesion is diagnosed as malignant.

Many authors have reported the usefulness of EUS-FNA in the diagnosis of the pancreas, lymph node, supper gastrointestinal tract wall, retroperitoneum, liver, biliary tree, and adrenal glands [4, 5]. Some recent meta-analyses have evaluated the diagnostic of pancreatic cancer, which found the pooled sensitivities and specificities were 88-89%, 96-99%, respectively [6, 7]. However, there were scant data on the utility of EUS-FNA in pelvic lesions. Although some previous studies have evaluated the diagnostic yield of pelvic lesions, to our knowledge, most

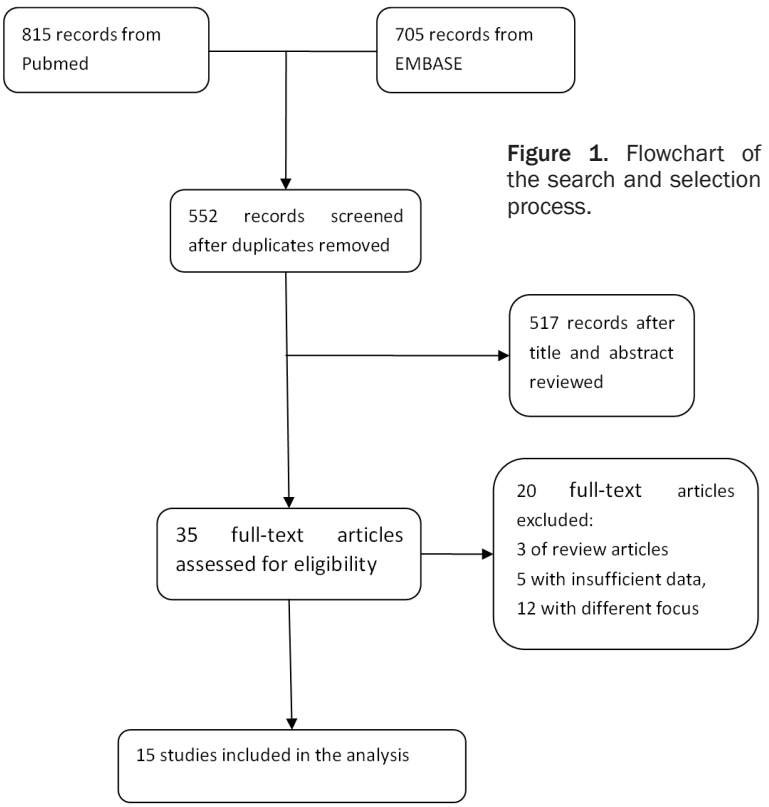

Figure 1. Flowchart of the search and selection process.

of the available studies were small series or case reports [8, 9]. Therefore, the current meta-analysis is undertaken to systematically assess the accuracy of EUS-FNA for differential diagnosis between benign and malignant pelvic lesions.

Methods

Search strategy

This article was performed according to the Preferred Reporting Items for Systemic reviews and Meta-Analysis (PRISMA) guidelines and the Assessment of Multiple Systematic Reviews (AMSTAR) tool [10, 11]. A systemic literature search of MEDLINE, EMBASE, CBM and the Cochrane Library databases was conducted for relevant studies, which were published from January 1990 to May 2015. The medical subject heading (MeSH) and text words were as following: ('EUS' OR 'endoscopic ultrasound' OR endoscopies OR 'ultrasonic endoscopy (ies)') AND (rectal OR rectum OR carcinoma OR 'colorectal carcinoma' OR 'rectal neoplasms' OR 'peirectalcarcinoma' OR 'pelvic lesions' OR 'pelvic tumor(s)') AND ('Sensitivity and specificity' OR diagnosis OR accuracy). The literature search was restricted with published in English and Chinese languages. In order to improve the coverage of literature search, a hand-search of the reference lists from selected articles was also performed to identify potential relevant articles.

Selection criteria

Two reviewers (F.Y.J. and H. Q.S.) independently selected the relevant articles according to predefined inclusion and exclusion criteria from the title and abstracts retrieved by the literature search. The inclusion criteria in this analysis including: (1) patients with ambiguous pelvic masses. In this study, the pelvic lesion was defined as any mass seen with imaging modality in the pelvic area including those perirectal and intraluminal lesions; (2) EUS-FNA was used for diagnostic purposes; (3) both retrospective and prospective clinical trial were contained; (4) sufficient data were provided to calculate the true-positive (TP), false-positive (FP), false-negative (FN) and true-negative (TN) values; (5) study population were minimum 10 patients. Exclusion criteria included (1) case reports, comments, review articles, guidelines, animal studies and cadaveric models. (2) The studies which EUS-FNA was examined not only in the lower digestive tract and perirectal lesions, but also other organs such as mediastinal, gastrohepatic, pancreatic were excluded as well.

Quality assessment and data extraction

The following variables of the individual articles were extracted independently by two authors (F.Y.J. and H.Q.S.) onto a data sheet: the first author, country, date of publication, design, reference standard and the number of TP, TN, FP and FN diagnoses. Meanwhile, The methodological quality of each selected study was assessed by 2 reviewers (F.Y.J. and H.Q.S.) using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) tool which highlights the strengths and weaknesses of diag-

Table 1. Characteristics of included studies in the analysis

First author	Year	Country	Study design	Number of lesions	Reference standard	TP	FP	FN	TN	Sensitivity (%)	Specificity (%)
Harewood	2002	USA	Prospective	80	Histology	19	2	17	42	53	95
Sailer	2002	Germany	Prospective	48	Combined	21	0	3	24	88	100
Hara	2003	Japan	Retrospective	10	Combined	5	0	1	4	83	100
Shami	2004	USA	Prospective	21	Histology	17	0	2	2	89	100
Mohamadnejad	2010	India	Retrospective	32	Combined	18	0	2	12	90	100
Boo	1011	Korea	Prospective	11	Combined	7	0	1	3	88	100
Gleeson	2012	USA	Prospective	19	Combined	17	0	1	1	94	100
Mohamadnejad	2012	India	Retrospective	29	Combined	15	0	2	12	88	100
Maleki	2013	USA	Retrospective	48	Histology	29	0	4	15	88	100
Amin	2013	USA	Retrospective	41	Combined	20	0	2	19	91	100
Knight	2013	USA	Retrospective	27	Histology	16	2	2	7	89	78
Watanabe	2014	Japan	Retrospective	22	Histology	10	1	2	9	83	90
Albadine	2014	Canada	Retrospective	114	Histology	63	0	6	45	91	100
Rzouq	2014	USA	Retrospective	20	Histology	10	0	1	9	91	100
Esparrach	2015	Spain	Retrospective	58	Combined	39	0	1	18	98	100

Note: abbreviation: TP: true-positive, FP: false-positive, FN: false-negative, TN: true-negative.

nostic accuracy studies [12]. Each of 14 items requires a "yes", "no" or "unclear" answer. The results of the authors were compared and disagreements were resolved by discussion or by crosschecking with the other reviewers.

Statistical analysis

Based on the 2 × 2 table for each study, the statistical software Meta-Disc version 1.4 (Universidad Complutense, Madrid, Spain) was used to calculate the pooled sensitivity (Sen), specificity (Spe), positive and negative likelihood ratio (LR+/LR-), and diagnostic odds ratio (DOR) with their respective 95% confidence intervals (CIs) [13]. These parameters were used to picture Summary receiver operating characteristic (SROC) curve and the corresponding area under the curve (AUC) were obtained. Pooling was conducted using either Mantel-Haenszel method (fixed-effects model) or the Der Simonian Laird method (random-effects model), which was taken into account the heterogeneity between studies [14]. We used the chi-square (χ^2) and inconsistency index (I^2) for all measurements to assess the significance and magnitude of study heterogeneity [15]. χ^2 test shows a $P < 0.05$ or I^2 test exhibits > 50%, which indicated high heterogeneity and the random-effect model was selected. On the contrary, the fixed-effects model was used.

Results

Search results and study characteristics

The flow chart of inclusion and exclusion is shown in **Figure 1**. The search terms were used for initial search to identify 1620 reference articles. Among these, 376 relevant articles were selected and reviewed by two authors independently after the title and abstracts were screened. A total of 35 articles showed potential eligibility for full-text review. Finally, 15 studies (n=580) fulfilled the inclusion criteria and were included in this analysis [16-30].

The characteristics of the included studies were exhibited in **Table 1**. A total of 580 ambiguous pelvic lesions were involved in the 15 studies. Ten studies were retrospective and 5 were prospective. Majority of articles were published in recent 5 years and were confined to developed country. Moreover, two studies contained only 10 and 11 patients [18, 23]. Seven studies [16, 17, 24, 25, 27, 28, 30] used histology alone as the reference standard, and the others were combined with cytology, histology or clinical and imaging follow-up. Harewood et al. [24] reported the lowest sensitivity, which was significantly different from the others.

Table 2. Quality assessment by QUADAS criteria

Study (first author)	Representative spectrum	Eligibility criteria	Acceptable reference standard	Acceptable delay between tests	Partial verification avoided	Differential verification	Incorporation avoided	Details index test provided	Details reference standard provided	Index test results blinded	Reference standard results	Relevant clinical information	Uninterpretable results reported	Withdrawal explained
Harewood	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No
Sailer	Yes	Yes	Yes	Unclear	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear
Hara	Yes	Unclear	Yes	Unclear	Yes	No	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes
Shami	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	No	Yes	Unclear	Unclear	Yes	Yes
Mohamadnejad	Yes	Yes	Yes	Unclear	Yes	No	Yes	No	Unclear	Yes	Unclear	Yes	Yes	Yes
Boo	Yes	Yes	Yes	Unclear	Yes	No	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes
Gleeson	Yes	Yes	Yes	Unclear	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Unclear
Mohamadnejad	Yes	Yes	Yes	Unclear	Yes	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Unclear
Maleki	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Unclear
Amin	Yes	Yes	Yes	Unclear	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes
Knight	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	No	Yes	Unclear	Yes	Yes	Yes
Watanabe	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Unclear	Yes	Unclear	Yes	Unclear	Unclear
Albadine	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Unclear	Yes	Unclear	Yes	Unclear	Yes
Rzouq	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes
Esparrach	No	Yes	Yes	Unclear	Yes	No	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes

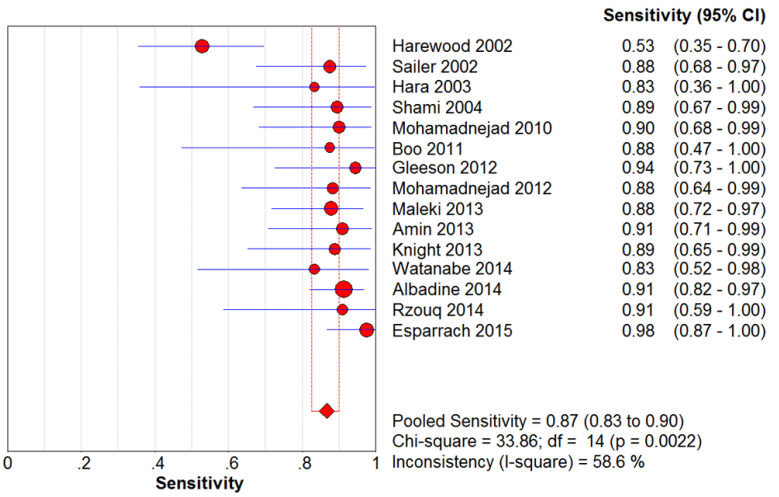

Figure 2. Pooled results of sensitivity.

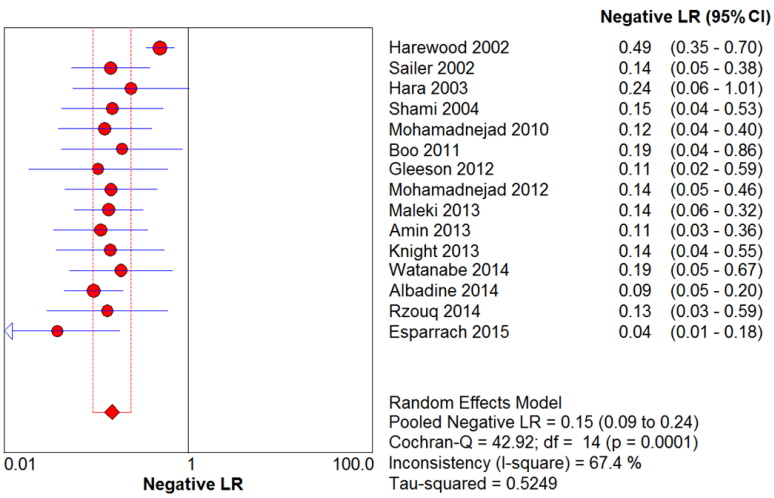

Figure 3. Pooled result of negative likelihood ratio.

Quality assessment

All the included studies were of moderate to good quality based upon QUADAS 14 questions. Details about the methodological quality are presented in **Table 2**. Ten of 15 studies [17-19, 21-23, 26-28, 30] (66.7%) provided enough information in terms of the spectrum of participants included. The risk of differential verification bias was clearly presented in 8 studies [18-23, 26, 29], which underwent the combined reference standard (cytology, histology or clinical and imaging follow-up). In addition, none of the studies specifically described the interval time between the index test (EUS-FNA) and reference standard. Also, patient withdrawals were uncertain in 5 studies [17, 21, 22, 28, 29]. The execution of the reference standard was not reported in most studies [26-30].

Data analysis

To investigate the threshold effect and heterogeneity across studies is very important in the diagnostic text of meta-analysis. The threshold effect can be determined by calculating the sensitivity and specificity of the Spearman correlation coefficient. The result of this meta-analysis showed the Spearman correlation coefficient was -0.155 (P=0.581), which suggests it was feasible to pool the individual study.

With regard to the results of χ^2 test and I^2, it showed sensitivity (P=0.0022, I^2=58.6; **Figure 2**) and negative LR (P=0.0001, I^2=67.4; **Figure 3**), which indicated moderate heterogeneity existed between studies. By systematically removing one data set at a time to recalculate the pooled sensitivity and negative likelihood ratio, we found that significant values for study heterogeneity were mainly caused by one single study [14]. To account for heterogeneity, random effect model was applied to obtain the overall sensitivity and negative LR. In contrast, the other pooled estimates given (Spe: P=0.3298, I^2=11.0%; positive LR: P=0.6107, I^2=0.0%; DOR: P=0.6092, I^2=0.0%) displayed homogeneous across the studies were conducted by the fixed effect model.

Overall, the 15 eligible articles addressing the accuracy of EUS-FNA for pelvic lesions showed the pooled sensitivity, specificity, Positive LR, Negative LR, and DOR were 87% (95% CI, 0.83-0.90; **Figure 2**), 98% (95% CI, 0.95-0.99; **Figure 4**), 17.17 (95% CI, 9.68-30.46; **Figure 5**), 0.15 (95% CI, 0.09-0.24; **Figure 3**), 96.11 (95% CI, 48.88-189.00; **Figure 6**), respectively. The area under the receiver operating characteristic

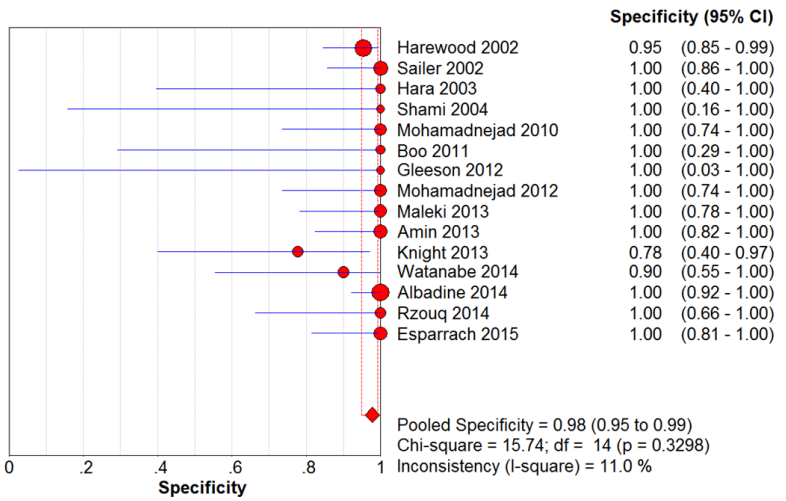

Figure 4. Pooled results of specificity.

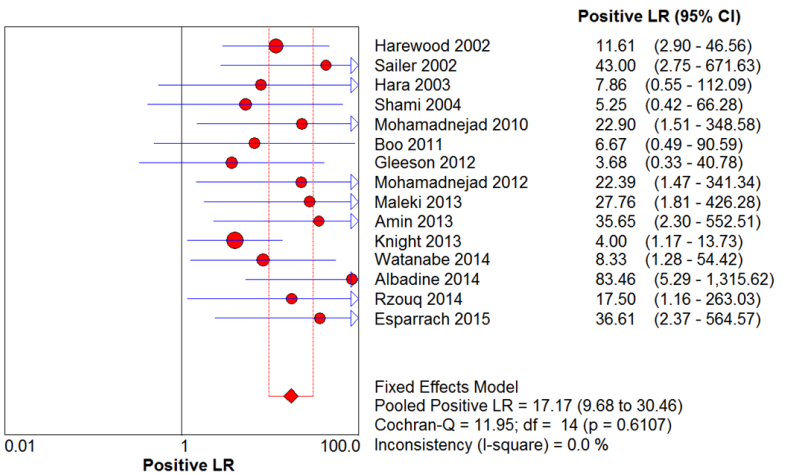

Figure 5. Pooled result of positive likelihood ratio.

curve was 0.9531 (**Figure 7**), suggesting an excellent performance of accuracy.

Discussion

Wide varieties of intramural and extramural pelvic masses are frequently encountered in clinical practice. The primary site of the tumors included colorectal, pelvic lymph node metastasis, pelvic urologic malignancy, ovary, and female lower genital tract [16]. Many imaging modalities such as CT, MRI, and abdominal ultrasound, have been reported with lower sensitivity and specificity in this field. Transrectal EUS-FNA as a new type of reliable diagnostic modality is superior to imaging alone in both benign and malignant lesions, because this method not only allows detailed visualization of the rectosigmoid wall and adjacent pelvic organs, but also can obtain tissue samples in a reliable and minimally invasive manner [17, 31]. It could provide sufficient information about the nature of masses. Thus, it is invaluable to the staging and management of colorectal cancer and extremely helpful for accurate establishing the presence of primary, local recurrence or extra pelvic metastases of other malignancy [19]. Moreover, EUS-FNA is a safe procedure with low complication rate. According to the previous studies, the overall complication rates were estimated to be between only 0.3% and 2.2% [32].

This meta-analysis summarizes the available evidence on the value of EUS with FNA in the diagnosis of pelvic lesions. Our findings revealed the value of EUS-FNA mainly lying in its high specificity. And false-negative diagnoses of EUS-guided biopsy still appear in the whole studies, which are resulting mainly from sampling error, or by technical problems in the process of collecting and handling of specimens [23]. The likelihood ratio is a measurement to describe the chance of illness. According to Altman [33], a condition which contained an LR+ > 10 and an LR- < 0.2 was regarded as a highly useful test. In our study, LR- and LR+ were 0.15 (95% CI, 0.09-0.24), 11.02 (95% CI, 6.27-19.36), respectively, which clearly indicated that EUS-FNA is a valuable tool. In addition, the condition that the AUC of any diagnostic test is very close to 1 indicates that the test is very excellent. So, the AUC of SROC curves for EUS-FNA also highlighted the significant role EUS-FNA plays in diagnosis of pelvic lesions.

In this analysis, however, there are still several limitations. First, the results of the QUADAS appraisal tool presented a few methodological

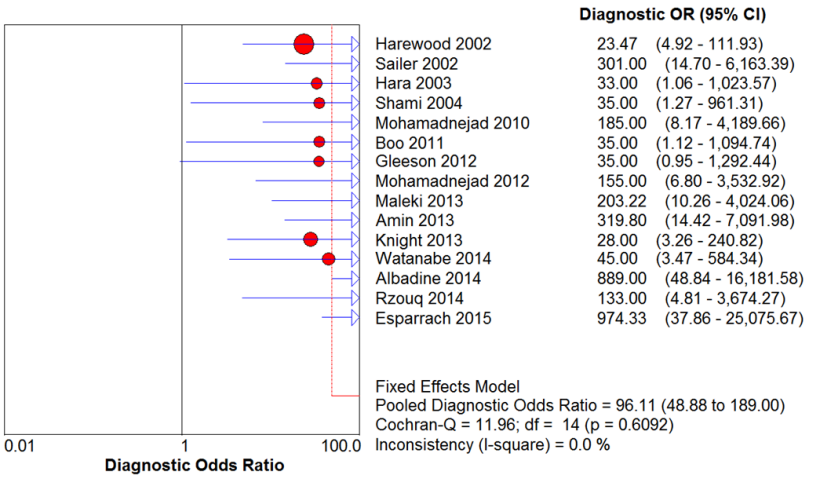

Figure 6. Diagnostic odds ratio.

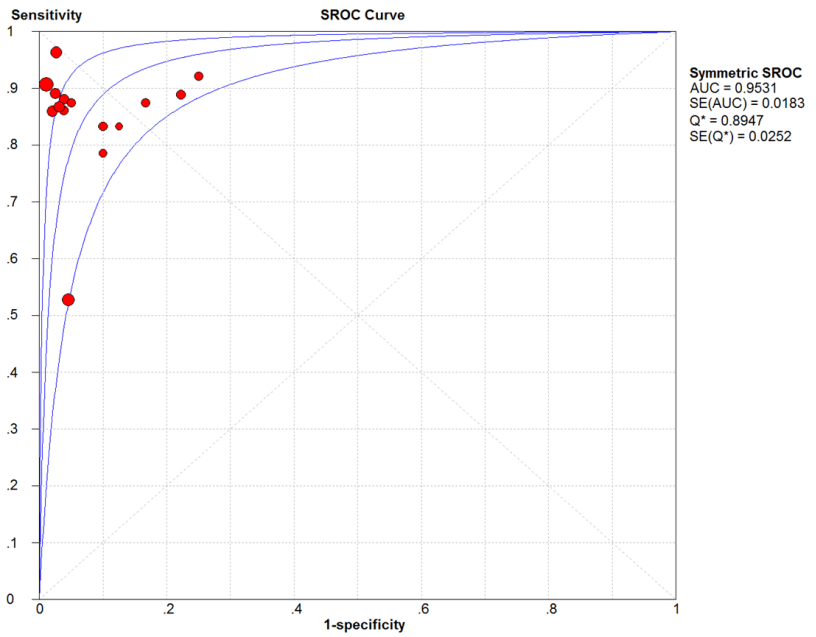

Figure 7. The area under the receiver operating characteristic curve.

limitations. None of the eligible studies precisely recorded the time duration between the index test and the reference test. Due to malignant tumor can be transferred within a period of time; this could lead to potential disease progression bias. In addition, we found that some studies used different reference standards based upon the EUS-FNA and clinical findings, which could inadvertently lead to partial reference bias within the studies. Second, moderate heterogeneity was found among individual studies. This may be mainly attributable to one study [24], which was noticeably aberrant with sensitivity, LR-and DOR. Harewood et al. demonstrated EUS-FAN did not significantly improve the tumor N staging accuracy. Another important factor is a result of differences in the skill and experience of the EUS examiner as well as patient characteristics, scanning techniques among studies, which may cause a reliability result in heterogeneity source. Finally, most of them were retrospective studies, which may weaken the evidence from the methodological quality assessment.

Conclusion

In summary, our findings illustrate that EUS-FNA is a safe, minimally invasive, reliable and effective modality that provides valuable and useful information in the diagnosis and management of patients with pelvic lesions. We strongly recommend the use of EUS-FNA in patients with suspected malignancy or when tissue diagnosis could change the patient treatment. Because of the limitation of its most retrospective approach in the present series, further prospective and high-quality trials in this evolving field are needed.

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Disclosure of conflict of interest

None.

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