Accuracy of diagnostic performance of confocal laser endomicroscopy in characterising pancreatic cysts: A systematic review

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ABSTRACT

Introduction: Pancreatic cystic lesions (PCLs) are becoming more frequently diagnosed due to the improved cross-sectional imaging. Although some of them are harmless, others are malignant in nature, and proper diagnosis is very crucial. This systematised review evaluates the diagnostic effectiveness of nCLE in characterising pancreatic cysts in terms of sensitivity, specificity, diagnostic yield, as well as its strengths versus conventional diagnostic techniques.

Materials and Methods: The systematic literature search was performed in PubMed, Scopus, and Google Scholar, including papers published between 2011 and March 2025. The inclusion criteria were randomised, prospective, and retrospective research in which nCLE diagnostic accuracy was reported in PCLs. Meta-analysis was conducted using PRISMA guidelines for data extraction, risk of bias assessment, and sensitivity analyses.

Results: The inclusion criteria were met in seventeen studies. As shown, nCLE was usually superior to cytology, cyst fluid carcinoembryonic antigen (CEA), and traditional EUS-FNA. Sensitivity was reported to be between 59-98% and specificity is between 82-100%. Of seven studies (n=216 cases) analysed by meta-analysis, the pooled sensitivity was 0.89 (fixed-effects) and 0.88 (random-effects), the heterogeneity was high (I2=74%). The Funnel plot analysis identified the possibility of publication bias and small-study effects. Robustness was ensured through sensitivity analysis, which was always pooled between 0.86-0.92.

Conclusion: It has been noted that nCLE improves diagnostic confidence, reduces indeterminate results, and has the potential to positively influence the economy and clinical management. The current evidence is strongly in favour of the clinical utility of nCLE, more large-scale, multi-centred, and methodologically sound trials are necessary to determine the diagnostic performance of the technique, develop standardised protocols, and evaluate long-term effects on patient outcomes and healthcare systems.

KEYWORDS:
Confocal; Diagnosis; Pancreatic Cyst; Endoscopic ultrasound-guided fine-needle aspiration

INTRODUCTION

Pancreatic cystic lesions (PCL) are progressively identified, with an occurrence of 2.1% to 2.6%. PCL is diagnosed frequently because of the growing use of magnetic resonance imaging (MRI) and computed tomography scans (CT scans).[1,2] Pancreatic cystic lesions (PCL) are progressively identified, with an occurrence of 2.1% to 2.6%. PCLs need careful assessment due to their potential for malignancy.[3] By determining the presence of high-risk features and utilising cutting-edge technologies like needle-based confocal laser endomicroscopy (nCLE) and molecular markers, endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) and laboratory techniques, optimal surveillance can be achieved by balancing the risk of pancreatic cancer mortality against cost and surveillance burden. Surgical removal is recommended for lesions with malignant potential, including cystic neuroendocrine neoplasms, mucinous cystadenomas and branch duct intraductal papillary mucinous neoplasms (BD-IPMNs).[4]

Current imaging techniques are not optimal for determining their malignant potential. Inaccurate diagnoses could lead to missed lesions or unnecessary surgery.[5] Presently, endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) with cystic fluid examination remains the most effective nonsurgical approach for detecting the characteristics of PCLs.[6,7] However, Thornton et al.,7 demonstrated cytology has low sensitivity but has good specificity whereas Napoleón et al.,8 argued cytology can achieve up to 60% of sensitivity for malignancy while maintaining high specificity. Cyst fluid carcinoembryonic antigen (CEA) with a threshold of 192ng/ml, is recognised as a more accurate diagnostic indicator as compared to cytology and EUS for distinguishing non-mucinous and mucinous PCLs.[6] In contrast, van der Waaij et al.,[9] identified low levels of CEA as a specific biomarker for distinguishing between benign and premalignant cysts. Nonetheless, the diagnostic limitations of these techniques resulted in suboptimal management of patients, possibly leading to excessive repetitive surgical interventions and follow-ups.[10,11] Implications are crucial, impacting patients by leading to higher mortality and morbidity rates and also imposing a financial burden on the healthcare system because of ineffective interventions.[12,13]

Needle-based confocal laser endomicroscopy (nCLE) is a cutting-edge imaging technique that allows in vivo, real-time

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microscopic examination of the inner wall of a pancreatic cyst during an EUS-FNA process.[14] Konda et al.,[15] demonstrated the safety and feasibility of nCLE for the evaluation of PCLs and its accuracy was proven in an international multicentre study.[16] Subsequent studies investigated a nexus between histological characteristics and nCLE imaging, leading to the development of standardised nCLE criteria for distinguishing the most common types of PCLs.[17,18] Napoléon et al.,[19] conducted a CONTACT2 clinical trial that prospectively demonstrated the high sensitivity and specificity of nCLE for diagnosing PCLs in a large multicentre cohort of 78 cases with confirmed surgical or cytohistological diagnoses. Therefore, this review aims to comprehensively summarise and critically analyse the existing literature on the diagnostic performance of confocal laser endomicroscopy (CLE), specifically evaluating its sensitivity and specificity in detecting pancreatic cyst lesions. Moreover, this review investigates the efficacy of nCLE in the characterisation of pancreatic cyst lesions and its possible role as a promising diagnostic approach for PCL.

MATERIALS AND METHODS

This review was conducted following the methodological framework of a systematic literature review, adhering to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Figure 1).

Search strategy

PubMed/MEDLINE, Scopus and Google Scholar (electronic databases) were searched systematically from January 1, 2011, to March 31, 2025. The search used a strategy combining Medical Subject Headings (MeSH) and free-text terms, with the help of Boolean operators (AND, OR), to retrieve as many relevant studies as possible. diagnostic. Filters were used to reduce the results to human studies, English language and 2011 or later publications, which are approximately the time of introduction of nCLE in pancreatic imaging. In addition to database searches, the reference lists of the included studies were searched to identify further eligible records.

Inclusion criteria

This review included studies during the period 2011-2024, particularly focusing on the diagnosis of pancreatic cysts with confocal laser endomicroscopy, which were considered eligible. The studies that incorporated needle-based confocal laser endomicroscopy as a diagnostic process for treating illnesses other than pancreatic cysts, as well as those that did not discuss cysts in pancreatic diagnosis, and the sensitivity of the diagnosis were also excluded.

Data collection and preparation

After screening the eligible studies that met the specified criteria, studies were documented in Google Sheets. Each article was then reviewed individually and its relevance was approved for inclusion.

RESULTS

Study selection

A total of 351 studies were extracted from databases from between the years 2011 and 2024, of which 183 studies were found relevant to the review's aim after the removal of duplication. The following studies were conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Figure 1). After appropriate screening of the data based on title, abstract, and keywords, 43 studies were removed. Further exclusion of studies was based on the following reasons: needle-based confocal laser endomicroscopy used for diagnosing conditions beyond pancreatic cysts (n=45), didn’t discuss cyst in pancreatic diagnosis (n=22), non-English language (n=19), and non-human subject (n=18). Thus, 21 studies were considered for inclusion.[14-35]

Risk of bias assessment

All eligible studies were evaluated using a standardised risk-of-bias tool to conduct a quality appraisal. In this review, the studies were critically reviewed on methodological rigour such as patient selection and outcomes and transparency of reporting. Reports that were considered to have a serious risk of bias, including incomplete outcome reporting, unclear diagnostic reference standards, or serious methodological limitations, were excluded from the final synthesis to preserve the integrity of the review. Consequently, only studies with low to moderate risk of bias were retained, and thus the findings presented can be considered evidence of better methodological quality. This process of exclusion enhances the consistency of our combined findings and removes the risks of inaccurate or biased information, and gives more confidence to the estimates made on diagnostic accuracy in needle-based confocal laser endomicroscopy characterisation of pancreatic cysts.

Study characteristics

Seventeen studies were included in the systematic review after risk of bias assessment, the clinical and safety of needle-based confocal laser endomicroscopy (nCLE) in pancreatic cystic lesions (PCLs) have been addressed in a variety of study designs, including initial pilot studies, large prospective multicentre trials and meta-analyses. Pilot studies by Konda et al.,[15,16] have indicated that nCLE imaging was technically feasible in 17/18 EUS-FNA cases, with their former pilot study indicating that it was highly specific, almost 100% to detect pancreatic cystic neoplasia, although sensitivity was low (59%).[15] Expanding on this, Napoléon et al.,[19] stated that nCLE was accurate in diagnosing serous cystadenoma (87%), with a sensitivity value of 69% and a specificity value of 100% and can be used to differentiate between benign and malignant lesions. These findings have since been confirmed in other large-scale studies done by several single-centre and multicentre prospective and retrospective studies. As an illustration, Chin et al.[20] found 83.3% sensitivity, 75% specificity, and Krishna et al.[21] reported high diagnostic quality (sensitivity 94%, specificity 82%, accuracy 89%), with nCLE having demonstrated a great potential in the recognition of characteristic imaging patterns. Moreover, Cheeseman et al.,[22] emphasised that nCLE, as well as microforceps biopsy, had a high diagnostic yield (84.1% and 34.1% with cyst fluid cytology, respectively). Feng et al.,[23] added to these results by reporting accuracy of 94%, specificity of 100 %, and sensitivity of 75% in the detection of malignant mucinous cysts, but reported adverse events, including pancreatitis, bleeding, perforation, and infection. Similarly, Hao et al.,[24] noted high diagnostic values of pancreatic ductal adenocarcinoma at an accuracy of 90% and sensitivity of 90.3%. Multicentre and large-scale analysis is another source of evidence of the clinical usefulness of nCLE. In a multicentre prospective cohort of 206 patients, Napoléon et al.,[19] showed outstanding diagnoses of different types of pancreatic cysts with sensitivity and specificity of over 95% versus EUS and cyst-fluid CEA. Similarly, Krishna et al.,[25] demonstrated that EUS-nCLE had a better diagnostic accuracy 97% in differentiating between mucinous and non-mucinous PCLs as compared to the conventional cytology and CEA. This was also confirmed by Machicado et al.,[26] who reported that nCLE had a high diagnostic accuracy in non-mucinous cysts and a moderate accuracy in mucinous lesions, and their follow-up systematic training study Machicado et al.,[27] showed that endosonographers with low experience could be reliably trained to reach a diagnostic accuracy 82-96%. There have also been economic and management implications. According to Le Pen et al.,[28] the combination of EUS-FNA and nCLE yielded a high level of diagnostic (sensitivity 69%, specificity 100%) performance, which was not only better than EUS-FNA alone (sensitivity 20%, specificity 90%), but was also more cost-effective. In the same vein, Palazzo et al.,[14] showed that the combination of EUS-nCLE-FNA resulted in an increase of BD-IPMNs diagnosis by 48 to 65 cases and the decrease of indeterminate mucinous cysts by 35 to 16 cases, indicating its clinical practice-refining ability.

Adverse events (AEs) were typically rare and controllable in studies. During this time, individual reports reported pancreatitis[15,21,23] and bleeding, infection, and perforation[23,19] whereas large systematic reviews found AE rates of 2.6-6.6% on overall.[29] The two meta-analyses that are included in the review showed high pooled diagnostic performance with sensitivities of 83-98% and specificities of 82-100%. The sensitivity and specificity of nCLE shown by Wang et al.30 were presented with pooled sensitivity of 90% and a specificity of 96%, with an AUC of 0.94, which confirms high reliability of nCLE.

Meta-Analysis

Forest Plot

Forest plot shows the sensitivity of a diagnostic test in seven studies that were done between 2013 and 2018 and as a group assessed 216 cases of disease, with each study in the estimation of sensitivity ranging between 0.59 and 0.94 (Figure 2). Konda et al.,[16] reported a sensitivity of 0.59 (95% CI: 0.36, 0.79) based on 22 cases, and Napoléon et al.,[17] reported a sensitivity of 0.69 (95% CI: 0.39, 0.91) based on 13 cases; both indicate moderate performance with wide CIs. Conversely, Krishna et al.,[18] found 0.94 (95% CI: 0.71, 1.00) in 17 cases, Chin et al.,[20] 0.83 (95% CI: 0.36, 1.00) in six cases, Krishna et al.,[21] 0.88 (95% CI: 0.73, 0.96) in 40 cases and Hao et al.[24] The sensitivity pooled under a fixed-effects model is 0.89 (95% CI: 0.84, 0.92) and random-effects model, which controls the heterogeneity (I2 =74.0, t2 =0.837, p=0.0008) is 0.88 (95% CI: 0.72, 0.96), meaning that it can detect the presence with high sensitivity with certain variability. The high heterogeneity implies perhaps a difference in study design or population, which means that clinical generalisability should be based on the random effects estimate. This defines its pooled sensitivity as a useful tool for reliably ruling out testing, but clinicians need to pay attention to specificity measures and circumstances-specific results, and subsequent studies to respond to heterogeneity by utilising standardised procedures and larger studies.

Funnel Plot

The meta-analysis of seven studies sensitivity funnel plot shows the evaluation of the publication bias and the heterogeneity of studies with sensitivity estimates versus the standard errors of these estimates (Figure 3). Studies by Konda et al.,[16] Napoléon et al.,[17] Krishna et al.,[18] Chin et al.,[20] Krishna et al.,[21] Napoléon et al.,[19] and Hao et al.,[24] are included in the plot with the different coloured markers on a 95% confidence interval funnel. Preferably, the data points must symmetrically be distributed throughout the funnel, with the smaller studies (greater standard errors) being more scattered and the larger studies (lesser standard errors) being around the pooled estimate. In this instance, there was an asymmetry in the plot, where Chin et al.[20] and Napoléon et al.,[15] with sensitivities of 0.83 and 0.69, respectively and greater standard errors (about 0.15) are above the lower boundary of the funnel, which may be underestimated or smaller sample bias. On the contrary, the larger studies, such as those of Hao et al.[24] and Krishna et al.[21], which have sensitivities of 0.94 and 0.88 and smaller standard errors (approximately 0.05-0.075), are more centred and are therefore stable. This asymmetry, especially the skewing of the smaller studies towards the left, can be due to publication bias, where the lower the sensitivity of a study, the higher its probability of publication/inclusion, which can bias the pooled estimate of 0.88 (random-effects model) downward. This implies that the test was sensitive in general, but the findings must be treated with caution, and an attempt to get access to unpublished data or study quality needs to be investigated so that you can establish the strength of these results in regard to your study.

Sensitivity Analysis

The sensitivity analysis of the meta-analysis of diagnostic test sensitivity (Figure 4), included seven studies published from 2013 to 2020 and 216 total diseased cases (leave-one-out, LOO), uses sensitivity analysis by dropping each study and re-estimating the effect size, quantifiers of heterogeneity (t2; I2), and additional p-values of the Cochran Q test. This method determines potential studies that overvalue your overall synthesis and gives an insight on the stability of the findings. Inclusion of Konda et al.[16] also provided a lower sensitivity of 0.59 based on 22 cases, so inclusion in the meta-analysis results in increasing the pooled estimate to 0.92 (95% CI: 0.82, 0.97) and the degree of heterogeneity decreases (t2=0.041, I2=34, p=0.1610) indicating this early study with moderate performance and increased uncertainty as a pull-down on the overall sensitivity and inclusion Likewise, without Napoléon et al.,[17] which has a sensitivity of 0.69 on 13 cases, gives a pooled value of 0.90 (95% CI: 0.73-0.97; t2=0.049, I2=43%), p=0.1670), has moderate effects on the overall value, but the heterogeneity was still significant but not quite as high as with the overall model (I2=74%). Inclusion of Krishna et al.,[18] which is a high-performer with17 cases, leads the result to 0.87 (95%, CI 0.66-0.96; t2=0.094, I2=77%, p=0.0896), although a higher I2 indicates greater

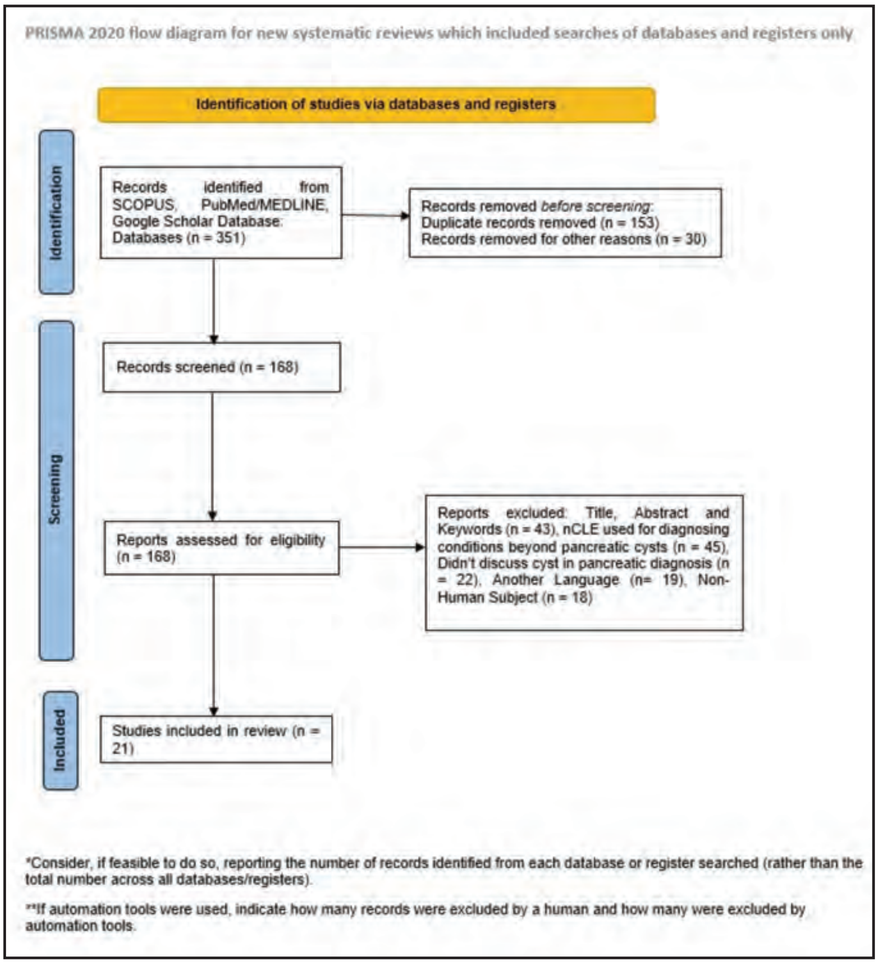

Fig. 1: PRISMA flow diagram

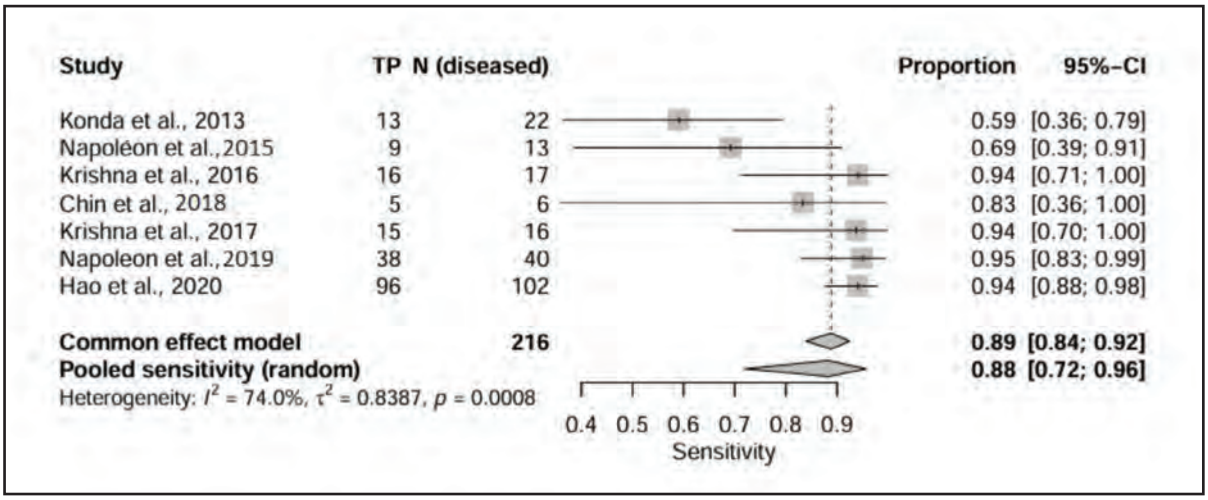

Fig. 2: Forest Plot

spread among the other studies, and thus the stabilising influence of this middle participant. The data are excluded on such a fine line (0.83 representing six cases) to include the Chin et al.,[20] study as the smallest (thus, the CI value represents the minimum possible values), but with a tremendously high heterogeneity I2=73%, indicating the contribution of such underpowered studies rather than a significant shift in the central tendency. The exclusion of Krishna et al.,[21] with a sensitivity of 0.88 on 40 cases reduces the pool to 0.87 (95% CI: 0.65, 0.96; t2=0.099, I2=67%, p=0.0918), indicating that it plays a moderating role in balancing the extremes of both low- and high-sensitivity

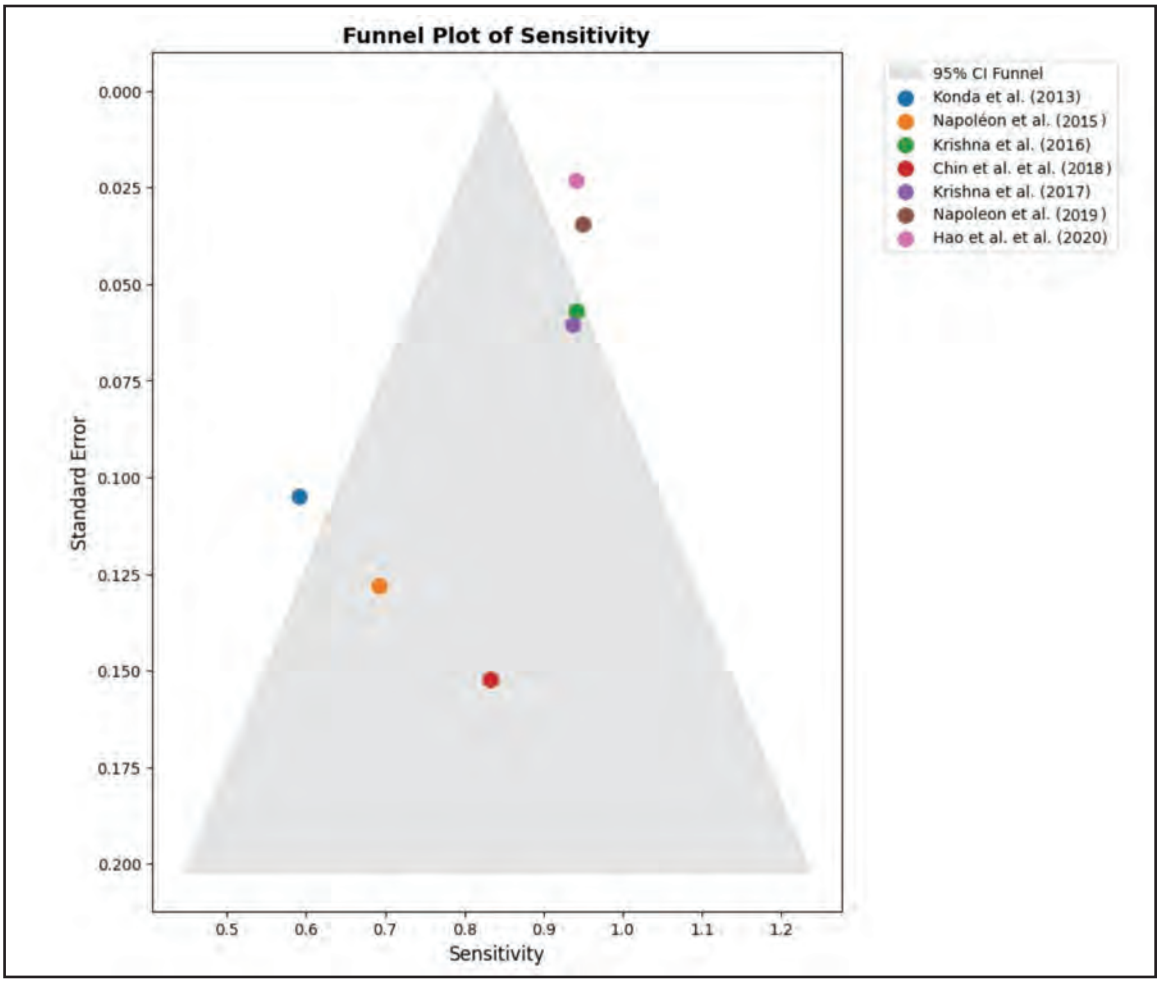

Fig. 3: Funnel Plot

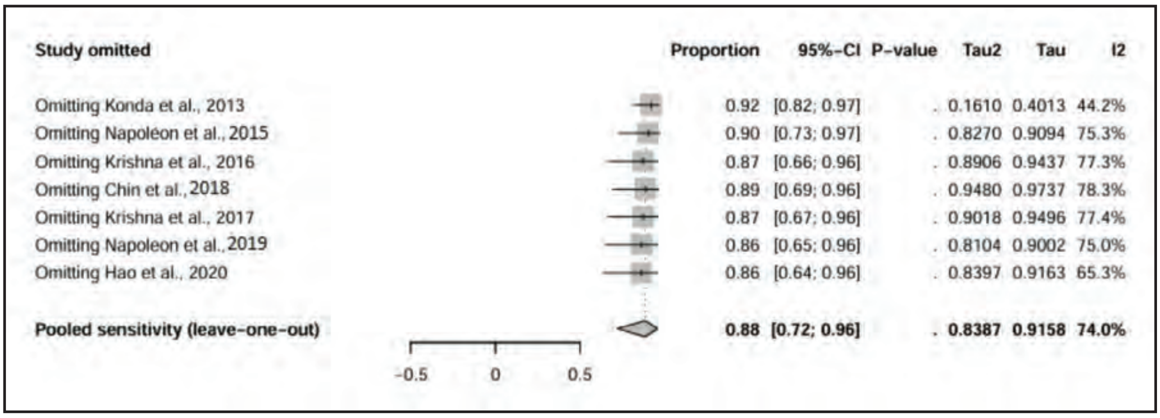

Fig. 4: Sensitivity Analysis

studies. Lastly, Omitting the largest study, Hao et al.[24] (0.94 of 102 cases) results in 0.86 (95% CI: 0.64-0.96; t2=0.116, I2=65%, p=0.0910), which is a slight decrease but still with a greater impact of this strong study, and the t2 value is slightly greater, which confirms the high-weight contribution of this strong dataset In all the LOO iterations, the pooled estimates appear clustering around 0.86-0.92, with CIs equalising the original (not very sensitive to the removal of a single study) and p-values above 0.05 (which means that the meta-analysis is very stable, and none of the results is influenced by a single study). The moderate-to-high persistence of I2 (34%-77) in the majority of situations validates the use of random-effects modelling and additional investigation of heterogeneity sources, but the range of changes is not as wide as it warrants the use of the 0.88 pooled sensitivity as a rule-out criterion in clinical use of your study setting, indicating the high performance of the diagnostic test is not an artifact of individual contributors.

DISCUSSION

The analysis of the study was performed through a systematic review employing different databases to retrieve potential studies. It is crucial to evaluate and identify the risks of PCLs for shaping effective management techniques, considering the high morbidity rate of pancreatic surgery. Our findings suggest that nCLE demonstrates high diagnostic performance in characterising pancreatic cyst lesions and outperforms conventional diagnostic methods. These results were supported by Feng et al.,[23] who identified an accuracy of 94% and a specificity of 100%. In a similar vein, Krishna et al.,[25] observed 94% specificity, 98% sensitivity, and an overall accuracy of 97%, emphasising superior diagnostic performance of nCLE than conventional diagnostic techniques of PCLs. Machicado et al.,[26] indicated that nCLE is predominantly effective in diagnosing non-mucinous cysts and relatively less accurate for mucinous lesions. In addition, Hao et al.,[24] and Napolean et al.,[19] also advocated that nCLE can improve the diagnosis of indeterminate cysts and pancreatic serous cystadenoma, respectively.

Krishna et al.,[25] found EUS-nCLE was more accurately in diagnosing mucinous PCLs in comparison to CEA measurement and cytology analysis. Le Pan et al.,[28] revealed that EUS-FNA alone had a sensitivity of only 20%, while sensitivity reached 69% when nCLE was combined with EUS-FNA, highlighting the enhanced accuracy and drop-in misdiagnosis rate. Cheeseman et al.,[22] revealed that nCLE and MFB substantially improved the accurate detection of PCL as compared to composite standards. Recent high-quality studies through meta-analytical methods support these findings. Systematic reviews by Chin et al.,[29] revealed pancreatic cystic lesion assessments using nCLE showed opposing sensitivity outcomes (59-98%) and specificity (82-100%) and accuracy (71-99%) while confirming nCLE potential as an additional diagnostic method. Due to diverse study designs, studies were unable to determine aggregate diagnostic value statistics. Although improved accuracy with nCLE shows potential for lower unnecessary surgeries Chin et al.,[29] said the high cost of equipment and difficult learning curve for operators prevent widespread adoption. In their meta-analysis Wang et al.,[30] combined 10 studies with 547 patients to establish nCLE's diagnostic abilities through a pooled sensitivity of 90%, a specificity of 96% and an area under the curve (AUC) of 0.94, which demonstrated excellent diagnostic performance. The procedure produced a moderate adverse event rate of 6.6%, consisting of pancreatitis and intracystic bleeding, and mild pruritus cases. The analysis faced limitations from moderate-to-high heterogeneity combined with potential publication biases. The authors emphasised the importance of conducting multicentre trials at scale to achieve validation of these findings in standard clinical practice settings.[30] Bertani et al.[31] reported a diagnostic accuracy of 84%, a sensitivity of 80 %, and a specificity of 100 %, emphasising that EUS-nCLE has proven to be a better performer than standard EUS-FNA. Robles-Medranda et al.[32] demonstrated that the combined nCLE and EUS-guided MFB improves the identification of PCLs with potential malignancy. Konda et al.[16] also advocated the adoption of nCLE with EUS-FNA due to its high diagnostic accuracy. Furthermore, Konda et al.[15] evaluated the safety and feasibility of nCLE in clinical settings and concluded that nCLE is technically feasible in most of the pancreatic EUS-FNA cases. A multi-centre prospective study conducted by Machicado et al.,[27] reveals that a well-designed educational program plays an important role in enhancing the diagnostic accuracy of nCLE. This highlights the significance of standardised training for endo-sonographers to optimise the clinical benefits of nCLE.

The findings demonstrate nCLE provides superior diagnostics compared to conventional methods. Standard diagnostic algorithms can integrate nCLE techniques because of their low rate of adverse incident reports and potential to enhance EUS-FNA results while exposing minimal patient risk.

CONCLUSION

It has been noted that nCLE improves diagnostic confidence, decreases the indeterminate results and has the potential to positively influence the economy and clinical management. Negative occurrences, including pancreatitis, bleeding, and infection, have been mentioned, but these are relatively few and can be overcome, which can convict in the safety of this procedure. The effects of the learning curve and dependence on the operator were rarely considered but might be a dominant factor related to the diagnostic accuracy and reproducibility. With these limitations in consideration, the current evidence is strongly in favour of the clinical utility of nCLE, more large-scale, multi-centred, and methodologically sound trials are necessary to determine the diagnostic performance of the technique, develop standardised protocols, and evaluate long-term effects on patient outcomes and healthcare systems.

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