Diagnostic accuracy of Fine-Needle Aspiration (FNA) in comparison to Core Needle Biposy (CNB) in salivary gland lesion: A systemic review and meta-analysis

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ABSTRACT

Background: Salivary gland tumors comprise 6% of total head and neck tumors. Parotid, being the major gland involved forms 80% of the cases while submandibular gland tumors make up 10-15% of the cases. However, the histopathology and cytology of these tumors are complex due to diverse patterns of growth and morphology exhibited by tumor cells, making the diagnosis a challenge. Despite being widely used as a preoperative diagnostic tool, fine needle aspiration yields results that are less than satisfactory, are time-consuming, and require local anesthesia. Most inaccurate results are due to insufficient samples. To overcome this, core needle biopsy using (Ultrasound) US guidance is used. It helps in obtaining a larger specimen, has higher sensitivity, and most importantly, can help assess the status of capsular invasion along with tumor grading. While choosing the right method of diagnosis is extremely crucial to the management of tumors, this study aims to ascertain the superior method to accelerate preoperative diagnosis and management.

Method: Detailed search through the medical literature was done using PubMed, Google Scholar, and Cochrane Library databases for the collection of relevant data. It was extracted keeping into consideration the inclusion and exclusion criteria. A total of 16 RCTs with a total of 2068 patients were selected. Meta-analysis was done using the two writers who independently assessed the caliber of each included study. The Cochrane tool was also used for bias risk apprehension. The statistical software packages RevMan (Review Manager, version 5.3), SPSS (Statistical Package for the Social Sciences, version 20), and Excel in Stata 14 were used to perform the statistical analyses.

Results: FNAC as a tool for preoperative diagnosis has a sensitivity of 93%, a specificity of 98.5%, and a positive predictive value of 0.972 in comparison to Core Needle Biposy (CNB) in the diagnosis and intervention regarding Salivary gland tumors.

Conclusion: The results suggest Core Needle Biposy (CNB) as a superior modality in the preoperative diagnosis of salivary gland tumors as compared to FNAC. However, FNAC can be used as a preliminary step in the process of diagnosis. Nevertheless, CNB overcomes the shortcomings of FNAC, making it a better method.

Keywords: FNA; CNB; Salivary gland tumors; Meta-analysis

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INTRODUCTION

The salivary glands comprise three paired major glands (parotid, submandibular, and sublingual glands) and 600–1000 minor glands distributed widely beneath the mucosa of the oral cavity, palate, paranasal sinuses, and upper respiratory tract. Approximately 6% of all head and neck tumors occur within the salivary glands. 80% of these occur within the parotid gland, 10–15% within the submandibular gland, and the remaining 5–10% within the sublingual and minor salivary glands. Approximately 50% of submandibular gland neoplasms are benign, with pleo-morphic adenoma accounting for over a third; 50% are malignant, with adenoid cystic carcinoma being the most common, accounting for 25% of cases [1]. The histopathology and cytology of salivary gland tumors are extremely sophisticated, even for experienced pathologists, demonstrating a highly diverse mix of cell types and growth patterns and overlapping morphologic features [2-4].

Hence, the presence of a circumscribed mass or diffuse swelling of a salivary gland can represent a major diagnostic and therapeutic challenge [5]. The preoperative diagnosis of salivary gland masses is extremely important in order to avoid unnecessary surgery for nonmalignant lesions, as well as for therapeutic planning for the management of malignant tumors. Two techniques are being applied for the same.

Fine-Needle Aspiration (FNA) is a well-accepted and widely used technique for the preoperative diagnosis of salivary gland masses, with consistent specificity values of 98.5% and a sensitivity of 93% [6]. However, the results are less than satisfactory in providing a specific histopathological diagnosis and tumor grading in the case of malignancy. Although expertise in interpreting the samples is important, most inaccurate diagnoses can be attributed to suboptimal or insufficient sampling [7-9]. It also requires local anesthesia and the procedure time is somewhat longer than other modalities [10-15].

The other technique being employed, Core Needle Biopsy (CNB) under US guidance, is used frequently for masses in the head and neck area. It advocates a unique set of advantages over either palpation-guided or US-guided FNA, including the ability to obtain a larger specimen with preserved tissue architecture for possible immunohistochemical staining. This potentially contributes to the low nondiagnostic rate and high average sensitivity (92%) and specificity (100%) of this procedure, with little variation in its ability to detect malignant tumors in salivary glands [16-18]. The limitation arises cepending upon the body part that is being biopsied, as it may require general anesthesia for the entire duration of procesure or atleast anesthertic sedative and also may require monitored anesthesia care during as well as after the procedure.

While both techniques are being employed in the health care management of salivary masses, it is important to establish the superior technique in order to ensure an appropriate, efficient, effective, and accurate diagnosis of salivary lesions that could potentially perpetuate dire consequences. This study aims to compare FNA biopsy with core needle biopsy as a diagnostic modality of salivary gland masses (Figure 1).
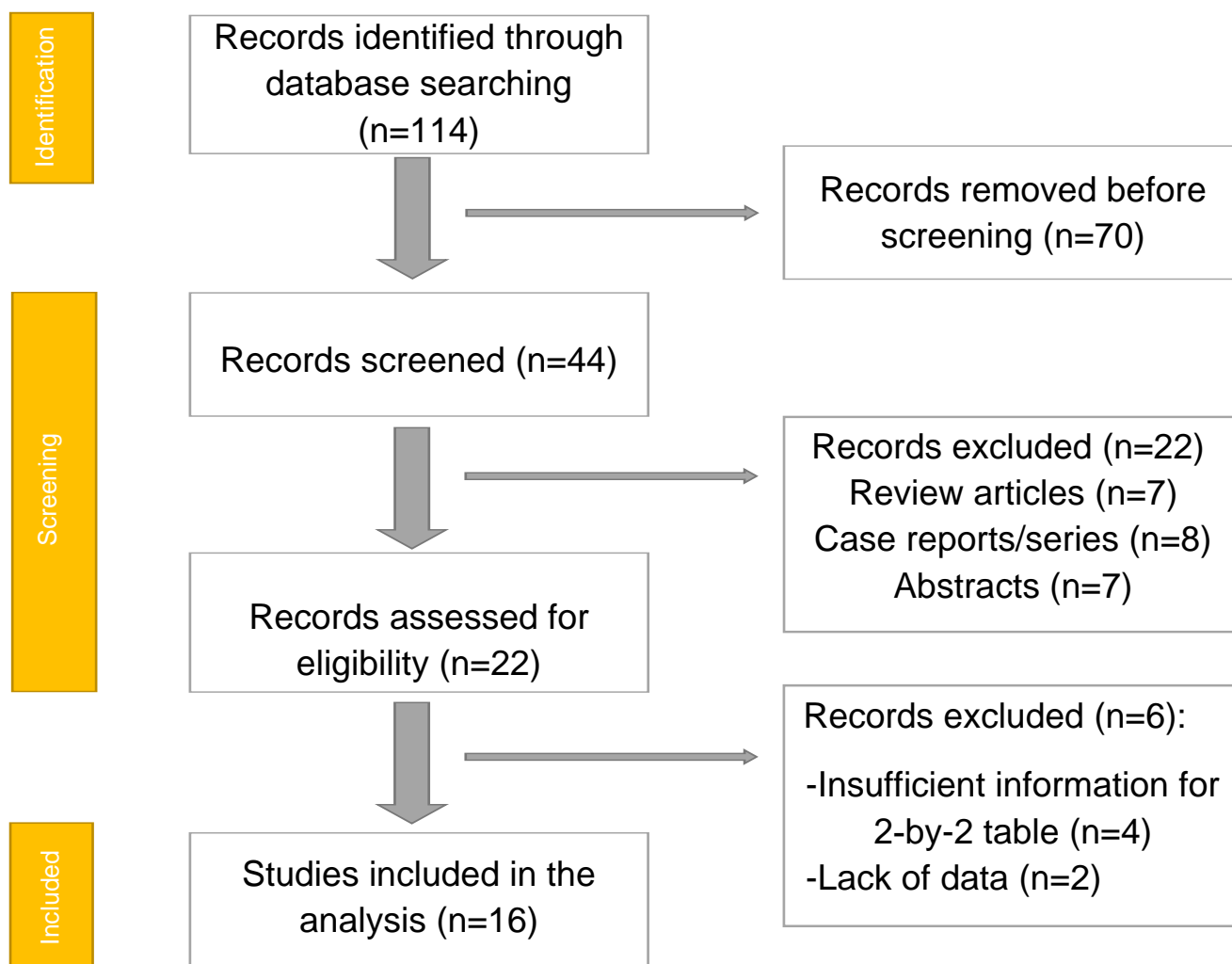
Identification

Records identified through database searching (n=114)

Records removed before screening (n=70)

Screening

Records screened (n=44)

Records excluded (n=22)
Review articles (n=7)
Case reports/series (n=8)
Abstracts (n=7)

Records assessed for eligibility (n=22)

Records excluded (n=6):

-Insufficient information for 2-by-2 table (n=4)
-Lack of data (n=2)

Included

Studies included in the analysis (n=16)

Fig. 1. PRISMA flow chart.

MATERIALS AND METHODS

Data collection

For all relevant literature, a search was done using PubMed, Google Scholar, and Cochrane Library databases. Full-text articles written only in English were considered.

The Medical Subject Headings (MeSH) and keywords 'Core Needle Biopsy(CNB)', 'Fine Needle Aspiration(FNA)', 'salivary gland tumors'. References, reviews, and meta-analyses were scanned for additional articles.

Inclusion and exclusion criteria

Titles and abstracts were screened, and duplicates and citations were removed. References of relevant papers were reviewed for possible additional articles. Papers with detailed patient information and statically supported results were selected.

The primary objective was to determine the diagnostic accuracy of fine needle aspiration for detecting salivary gland lesions in all patients.

We included studies that compared the outcome and accuracy of Core Needle Biopsy (CNB) with Fine Needle Aspiration (FNA) for suspected salivary gland lesions in the overall population including children, Pregnant patients, and Adults.

Therefore, the purpose of this study was to perform a systematic review and meta-analysis of the use of Fine Needle Aspiration (FNA) to diagnose Salivary gland lesions in the general population, *i.e.*, not limited to one subpopulation such as pregnant patients or children. The primary outcomes of interest are the sensitivity and specificity of FNA for this indication.

The inclusion criteria were as follows:

- Studies that included patients undergoing diagnosis on salivary glands or those having histologically verified cases.

- Prospective or retrospective studies.

- Studies that included core needle biopsy content or those comparing the diagnostic performance between FNA and CNB for salivary gland lesions.

- Studies in which data on the results of True Positives (TP), True Negatives (TN), False Positives (FP), and False Negatives (FN) were available. The exclusion criteria were: 1) Case

reports, case series, abstracts, review articles. 2) Non-english language articles.

Data extraction

Each qualifying paper was independently evaluated by two reviewers. Each article was analyzed for the number of patients, age, procedure modality, and incidence of the predecided complications. Further discussion or consultation with the author and a third party were used to resolve conflicts. The study's quality was assessed using the modified Jadad score. In the end, According to PRISMA, a total of 16 RCTs with a total of 2068 patients were selected.

Assessment of study quality

Two writers independently assessed the caliber of each included study. This test consists of 10 questions, each with a score between 0 and 2, with 20 being the maximum possible overall score. Two authors rated each article independently based on the above criteria. The inter observer agreement for study selection was determined using the weighted Cohen's kappa (K) coefficient. For deciding the bias risk for RCTs, we also employed the Cochrane tool. No assumptions were made about any missing or unclear information. There was no funding involved in collecting or reviewing data.

Statistical analysis

The statistical software packages RevMan (Review Manager, version 5.3), SPSS (Statistical Package for the Social Sciences, version 20), and Excel in Stata 14 were used to perform the statistical analyses.

The data was obtained and entered into analytic software [19]. Fixed or random-effects models were used to estimate sensitivity, specificity, Positive Predictive Value (PPV), Diagnostic Odds Ratios (DOR), and Relative Risk (RR) with 95 percent confidence intervals to examine critical clinical outcomes (CIs). Diagnosis accuracy and younden index were calculated for each result. Individual study sensitivity and specificity were plotted on forest plots and in the Receiver Operating Characteristic (ROC) curve. The prior odds ratio and positive and negative likelihood ratio and positive and negative post-test ratio are described in Fegan's analysis.

Bias study

The risk of bias was evaluated by using QUADAS-2 analysis. This tool includes 4 domains as patient selection, index test, reference standard, flow of the patients, and timing of the index tests.

RESULTS

A total of 16 RCTs with 2068 patients were selected for the study (Table 1 and Figure 2).

Out of these tests, 8 tests showed a sensitivity of over 95%, and 14 tests provided a specificity of over 95%. And 7 tests showed both specificity and sensitivity over 95%. The value of true positive was 699, true negative was 1296, false negative was 53, and false positive was 20. With a confidence interval of 95%, sensitivity, specificity, and positive predictive values were calculated. A summary of this is available in Figure 2.

Tab. 1. Table of the description of papers.	Study	Location	Device	Needle size	Throw	Passes	Performed by	Site	Compression	Methodology	Complications	Follow up
	Olubaniyi et al.	U.K.	Spring loaded (Bard Magnum; C.R. Bard Inc., Covington, GA)	18-gauge (n=8)	Variable	Avg. 2 passes (1 to 4 passes)	Radiologist	All SMG	NA	Retrospective	0	NA
	Novoa et al.	Switzerland	NA	20 gauge		Avg. 2 passes	Otolaryngologist	Parotid: 96, SMG: 14, SLG: 1	15 minutes	Prospective non-randomized	0	7 years, no recurrences
	Eom et al.	South Korea	Spring activated needles (1.1 or 1.6 cm excursion; ACECUT; TSK, Tochigi, Japan)	18 gauge		1 pass (n=155), 2 passes (n=95), 3 passes (n=7)	Radiologist	Parotid: 192, SMG: 65	10-20 minutes	Retrospective	0	NA
	Song et al.	South Korea	Double action, spring activated needle (TSK ACE-CUT; Create Medic, Yokohama, Japan)	18 gauge		NA	Radiologist	Parotid: 171, SMG: 56, SLG: 1	NA	Retrospective	0	5 years (2008-2013), NA
	J R Buckland	U.K.	Spring-loaded (Biopty Bard)	18 gauge	20 mm	2 passes					0	
	Breeze et al.	U.K.	Spring-loaded (Biopty, Bard, Helsingborg, Sweden)	18 (n=16); 20 (n=38)	22 mm (n=16; variable 15 or 22 (n=38)	2-4, mean, 3	Radiologist	Parotid: 198		Prospective		

Jose Cura	Spain	Spring-loaded (BioPince Argon Medical Devices, Plano, TX, USA)	18 gauge			Radiologist		3-5 minutes	Retrospective	1 hematoma, 1 superficial soft tissue infection that did not require admission	
K W Kesse	U.K.	Biopty Gun (Bard) (n=16), Magnum Gun (Bard) (n=38)	18 gauge (n=16), 20 gauge (n=38)	22 mm (n=16; variable 15 or 22 (n=38)	1-3, mean 2		Parotid: 54		Prospective	0	3.5 years
Naqvi et al.	Pakistan	NA	18 gauge		1 pass	NA	Parotid: 70, SMG: 38	NA	Retrospective	2 hematomas	3 years, NA
Park et al.	South Korea	NA			NA	Radiologist	Salivary glands (not specified)		Retrospective	0	2 years
Pfeiffer and Ridder	Germany	Spring-loaded (Magnum Gun; Bard, Covington, GA)	12 (n=78), 14 (n=41), 16 gauge (n=1), NA (n=1)	Variable (15 mm or 22 mm)	1.5 passes (mean 2.1)	NA	Parotid: 64, SMG: 12	NA	Observational	1 hematoma, 1 facial weakness due to local anesthesia	7 years, NA
Pratap et al.	U.K.	Spring loaded, disposable cutting needle (Temno; Bauer Medical, Clearwater, FL)	15 or 16 gauge (for suspected lymphoma or large lesion), 18 gauge		More than 1 pass (n=34)	NA	All parotid	NA	Retrospective	1 hematoma	No recurrences
Haldar et al.	U.K.	Spring-loaded (Magnum Gun; Bard, Covington, GA)	18 gauge (n=306), 20 gauge (n=7)	Variable (15 mm-22 mm)	1 pass (n=101), 2 passes (n=165), 3 passes (n=34)	Radiologist	All parotid		Retrospective	2 hematomas	16 years, 2 recurrences (malignant)
Taki et al.	Japan	Spring-loaded (ACECUT, TSK, Tochigi, Japan)	18 gauge	11 mm	2-4 passes (avg. 3 passes)	Radiologist	Parotid: 27, SMG: 10	NA	Retrospective	0	8 years, NA
Wan et al.	Taiwan	Spring-loaded (Magnum, Bard; Temno)	20 (n=1); 18 (n=20); 16 (n=26); 14 (n=6); mean, 16.6	15 mm	1 (n=1); 2 (n=32); 3 (n=17); 4 (n = 2); 5 (n = 1); mean, 2.4	Radiologist	Parotid: 53	30 minutes	Retrospective	1 hematoma	Mean 38 months, no recurrence
Huang et al.	Taiwan	Spring loaded (Bard Magnum, Covington, GA or Temno, Carefusion Co., San Diego, CA)	20 gauge (n=2), 18 gauge (n=34), 16 gauge (n=26), and 14 gauge (n=5)		1-5 passes	NA	All parotid	30 minutes	Retrospective	1 hematoma (surgical approach needed)	8 years, no recurrence

Note: SMG=Submandibular Gland; SLG=Sublingual Gland; Avg=Average

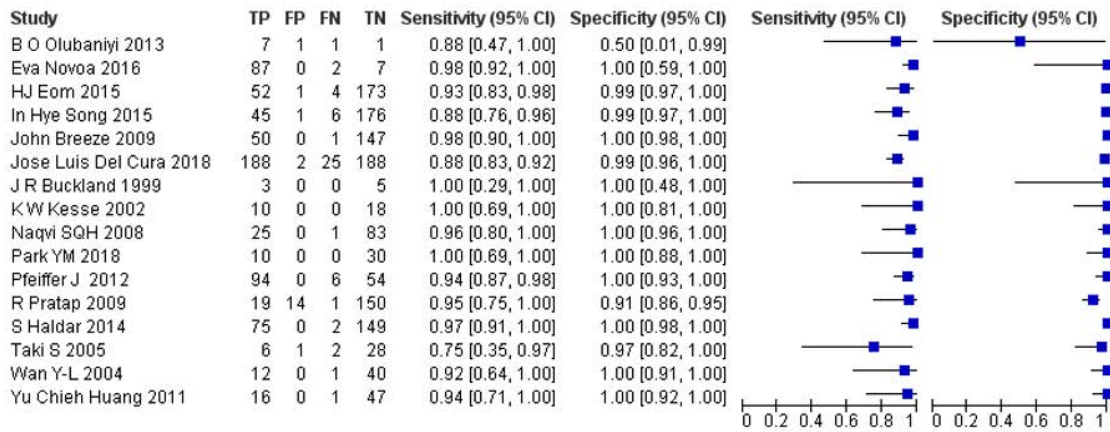| Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
B O Olubaniyi 2013	7	1	1	1	0.88 [0.47, 1.00]	0.50 [0.01, 0.99]		
Eva Novoa 2016	87	0	2	7	0.98 [0.92, 1.00]	1.00 [0.59, 1.00]		
HJ Eom 2015	52	1	4	173	0.93 [0.83, 0.98]	0.99 [0.97, 1.00]		
In Hye Song 2015	45	1	6	176	0.88 [0.76, 0.96]	0.99 [0.97, 1.00]		
John Breeze 2009	50	0	1	147	0.98 [0.90, 1.00]	1.00 [0.98, 1.00]		
Jose Luis Del Cura 2018	188	2	25	188	0.88 [0.83, 0.92]	0.99 [0.96, 1.00]		
J R Buckland 1999	3	0	0	5	1.00 [0.29, 1.00]	1.00 [0.48, 1.00]		
K W Kesse 2002	10	0	0	18	1.00 [0.69, 1.00]	1.00 [0.81, 1.00]		
Naqvi SQH 2008	25	0	1	83	0.96 [0.80, 1.00]	1.00 [0.96, 1.00]		
Park YM 2018	10	0	0	30	1.00 [0.69, 1.00]	1.00 [0.88, 1.00]		
Pfeiffer J 2012	94	0	6	54	0.94 [0.87, 0.98]	1.00 [0.93, 1.00]		
R Pratap 2009	19	14	1	150	0.95 [0.75, 1.00]	0.91 [0.86, 0.95]		
S Haldar 2014	75	0	2	149	0.97 [0.91, 1.00]	1.00 [0.98, 1.00]		
Taki S 2005	6	1	2	28	0.75 [0.35, 0.97]	0.97 [0.82, 1.00]		
Wan Y-L 2004	12	0	1	40	0.92 [0.64, 1.00]	1.00 [0.91, 1.00]		
Yu Chieh Huang 2011	16	0	1	47	0.94 [0.71, 1.00]	1.00 [0.92, 1.00]		

Fig. 2. The forest plot of sensitivity and specificity.

The sensitivity of the test is 0.93 with a CI of 95% in a range of (0.898 to 0.61) the mean being (0.032). The specificity of the test is 0.985 with a CI of 95% in a range of (0.924 to 1.046) the mean being (0.061). The PPV is 0.972 with a CI of 95% in a range of (0.918 to 1.026) the mean being (0.054).

The summary of the ROC curve (Figure 3) shows that the Area Under the Curve ROC (AUC) was 0.9596. The overall Diagnostic Odds Ratio (DOR) was 854.626. Diagnostic accuracy is 0.965 and the Younden index is 0.914.

P value for Cochrane Q was 0.1817 and I2 was at 24.1%.

In Figure 4, a summary of Fagan's analysis can be observed, in conclusion, the prior probability of the test was 36. The positive likelihood ratio was 61 and the post-test ratio was 97. The negative likelihood ratio was 0.07 and the post-test ratio was 4.
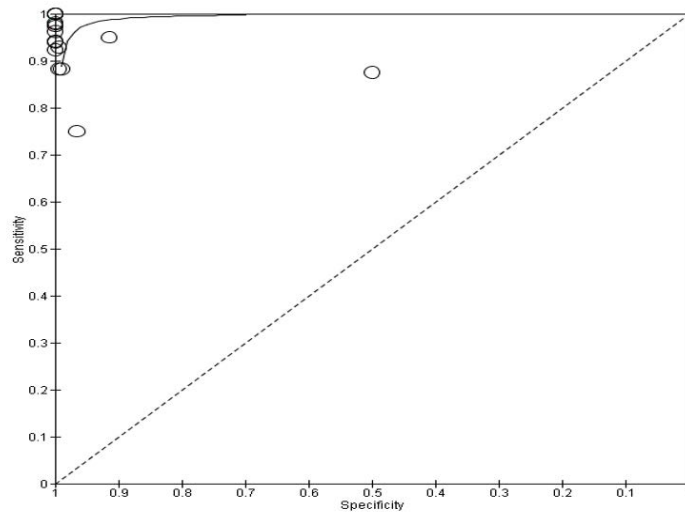

Fig. 3. The summary of receiver operating characteristic curve for CNB *vs.* FNA scan.
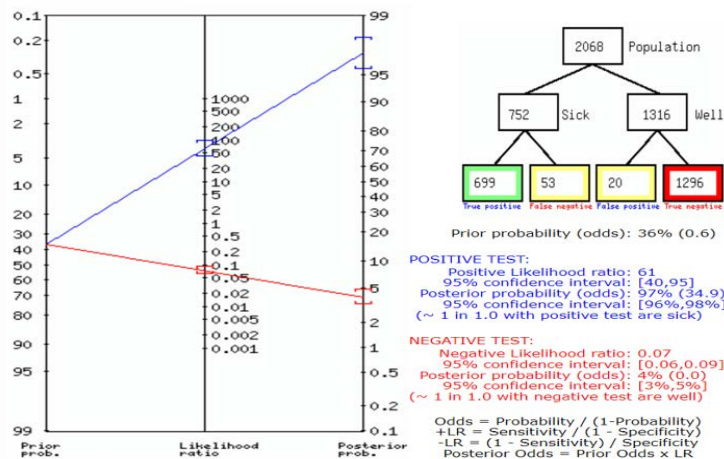

Fig. 4. Fagan's nomogram.

Bias study

Publication bias: The summary of publication bias is shown in Table 2 and Figure 5. Out of 16 RCTs, For the publication bias, In patient selection, bias was low in 15 studies, and unclear in 1. In the index test, it was low in 16 studies. While the reference standard was low in 7, and unclear in 9. The flow and timing were low in 15, and unclear in 1. The applicability concerns in patient selection were low in 16 studies. The reference standard was low in 16. And the index test was low in 16 studies (Figure 6).

Tab. 2. Risk of bias and applicability concern.		Risk of bias				Concerns about applicability		
	Reference	Patient selection	Index test	Reference standard	Flow and timing	Patient selection	Index test	Reference standard
	Olubaniyi, et al.	Low	Low	Unclear	Low	Low	Low	Low
	Novoa, et al.	Low	Low	Low	Low	Low	Low	Low
	Eom, et al.	Low	Low	Low	Low	Low	Low	Low
	Song, et al.	Low	Low	Low	Low	Low	Low	Low
	JR Buckland	Low	Low	Low	Low	Low	Low	Low
	Breeze	Low	Low	Unclear	Low	Low	Low	Low
	Jose Cura	Low	Low	Low	Low	Low	Low	Low
	K W Kesse	Low	Low	Low	Low	Low	Low	Low
	Naqvi	Low	Low	Unclear	Unclear	Low	Low	Low
	Park, et al.	Low	Low	Unclear	Low	Low	Low	Low
	Pfeiffer and Ridder	Low	Low	Unclear	Low	Low	Low	Low
	Pratap, et al.	Unclear	Low	Unclear	Low	Low	Low	Low
	Haldar, et al.	Low	Low	Unclear	Low	Low	Low	Low
	Taki, et al.	Low	Low	Unclear	Low	Low	Low	Low
	Wan	Low	Low	Low	Low	Low	Low	Low
	Huang, et al.	Low	Low	Unclear	Low	Low	Low	Low

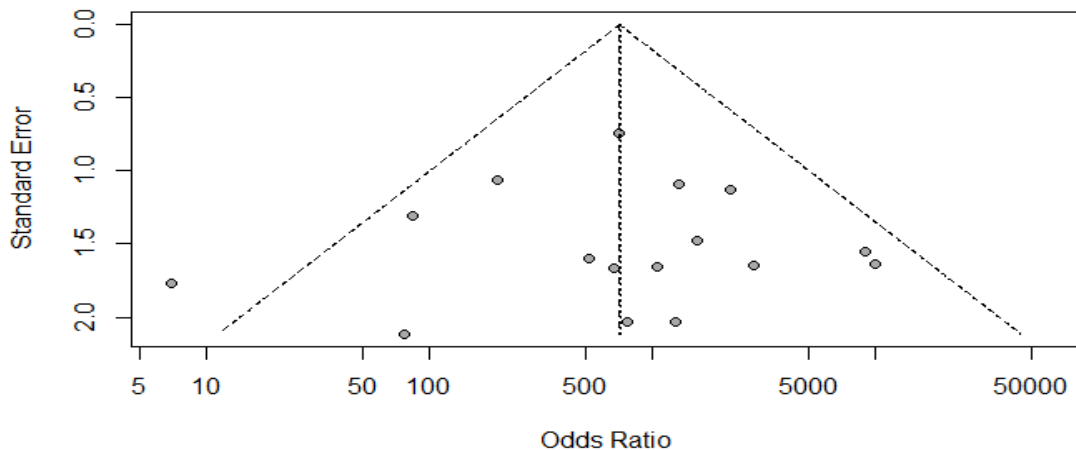**Fig. 5.** Summary of risk bias and applicability concern.

Fig. 6. Funnel plot for publication bias.

DISCUSSION

The preoperative diagnosis of salivary gland masses carries significant inefficiencies in terms of accuracy as well as diagnostic lead time, primarily due to the difficulty of diagnosing low-grade carcinomas by cellular morphology alone. However, the diagnosis of salivary tumors is important to avoid unnecessary surgery on non-tumorous conditions, as well as for treatment planning of malignant tumors in a manner that prioritizes patient well-being, considering that the performance of revision surgery in a previously operated patient generates higher costs and is related with increased technical difficulties. As not all surgical decisions can be made intraoperatively without the informed consent of our patients, a correct preoperative diagnosis is of particular importance for patient counseling and planning of the operative procedure. Moreover, cytology and histology of salivary gland neoplasms show a highly diverse mixture of growth patterns and cell types, and overlapping morphologic features, which is a diagnostic challenge even for experienced pathologists. As stated before, the aim of this study pertains to exploring and establishing two diagnostic modalities, namely Fine Needle Aspiration (FNA) and Core Needle Biopsy (CNB) for the diagnosis of salivary masses.

FNAC underlines a sensitivity of 93%, a specificity of 98.5%, and a positive predictive value of 0.972, establishing promising value as a diagnostic tool from a pool of 16 studies. It is safe, quick to perform, minimally invasive, and has been the traditional biopsy method of choice in the major salivary glands. There is however significant variability in its performance and diagnostic accuracy across various institutions, dependent upon operator experience, use of ultrasound guidance, adequacy of sample, interpretative skills, on-site presence of a cytologist, and finally, the availability of ancillary methods such as flow cytometry for additional analysis [20]. Therefore, the high specificity and sensitivity reported in some centers is not generally reproducible where the circumstances for FNAC are not optimized. FNAC also cannot reliably differentiate low-grade lymphoma from reactive nodal hyperplasia and in most cases acts as an indicator of the need for an excision or other biopsy technique. The clinical characteristics and prognosis of these tumors are quite different according to the type, stage, and grade of the tumors, which determines the extent of surgery. FNA has the limitation of possibly providing insufficient information on uncommon histology, tumor grading, and staging of salivary masses, which have already been established to have a tricky diagnostic pattern in terms of histopathology. It is also accepted that well-differentiated adenocarcinomas can be histologically indistinguishable from benign adenomas unless there is capsular infiltration to indicate malignancy, indicating the need for a modality that circumvents this inability of FNA.

Core needle biopsy provides a larger sample with preservation of tissue architecture, which permits immunohistochemical staining. This enables tumor grading, differentiation of benign and malignant lesions, and more precise diagnosis. The status of capsular invasion can also be assessed, which enables a distinction to be made between adenoid cystic carcinoma and monomorphic adenoma, an important advantage over FNA. Core needle biopsy also does not depend on the experience of the practitioner while there are several reports showing that the success of FNA is dependent on the experience of the operator. According to these articles, the experience of the cytopathologists and operators could contribute to the variability of results, and this is not often reported [6]. It is more accurate, less heterogeneous in performance, and is associated with lower non-diagnostic rates compared to FNAC. The advantages being stated rightfully, CNB imparts a particular set of demerits in its application. It is more invasive than FNAC and uses a larger bore needle. Haematoma due to minor bleeding is documented in 1–2% of cases in the parotid gland. However, there are no reports of major complications or death in this or other studies evaluating the submandibular gland. Tumor seeding is an uncommon complication with only two reported cases in the parotid gland and appears to be related to tumor type, site of puncture, and increasing needle diameter.

CONCLUSION

In conclusion, core needle biopsy has significant advantages over fine needle aspiration and although more invasive, promises a more accurate diagnosis. There is perhaps room for the inclusion of FNA as a primary investigation, but the risk of a missed diagnosis is bothersome, the quantification of which is beyond the scope of this study.

LIMITATIONS

Our study is not without limitations. We could perhaps gain more clarity by taking into account more studies, more subgroups of patients as well as ethnicity-centered variations.

However, to the best of our analysis, we come to the conclusion that CNB supersedes FNA as a diagnostic modality for the assessment of salivary masses.

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