International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

Study of Fine Needle Aspiration Cytology of Salivary Gland Lesions According to the Milan System with Histopathological Correlation – A Prospective Study

Dr. Meeraba Jadeja[1], Dr. Jagdish Dalsania[2], Dr. Milan Purohit[3], Dr. Bhumika Dadhania[4], Dr. Gauravi Dhruva[5]

[1]3rd year Resident, Department of Pathology, PDU Medical College and Hospital, Rajkot, India
[2]Associate Professor, Department of Pathology, PDU Medical College and Hospital, Rajkot, India
[3]Associate Professor, Department of Pathology, PDU Medical College and Hospital, Rajkot, India
[4]Assistant Professor, Department of Pathology, PDU Medical College and Hospital, Rajkot, India
[5]Professor and Head, Department of Pathology, PDU Medical College and Hospital, Rajkot, India

Corresponding Author:

Dr. Meeraba Jadeja
3rd year Resident, Department of Pathology, PDU Medical College and Hospital, Rajkot, India

Received: 08-01-2026
Accepted: 04-02-2026
Available online: 08-02-2026

ABSTRACT

Introduction: Salivary gland lesions are commonly encountered in clinical practice. Fine Needle Aspiration Cytology (FNAC) is a reliable, minimally invasive, and cost-effective diagnostic tool with high specificity and sensitivity. The Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) provides a standardized, evidence-based framework for accurate diagnosis and management of these lesions. We have undertaken this study for evaluation of salivary gland lesions by this newly introduced grading system for predicting the malignant potential of these lesions.

Materials and Methods: The present study was carried out in cytopathology and histopathology laboratory of department of pathology, PDU Medical College and Hospital, Rajkot during the 1st August 2024 to 31st July 2025. All the cases referred to the department of Pathology from the Department of Surgery, ENT, and Dental Surgery for evaluation of salivary gland lesions were included in the study. FNAC is a diagnostic tool in which cells are extracted from a palpable swelling using 23-24G needle with disposable syringes and smears are prepared and stained with H&E, MGG and Papanicolauou stain whenever it was required. All the cases were categories according to MSRSGC. and available histopathology reports were used for correlation.

Result: We have received 94 salivary gland lesions for aspiration over a period of 1 year. The most affected age group was from 21 to 35 years. Most of the study subjects were presented with parotid swellings (75%) followed by submandibular gland (23%). As per the MSRSGC classification system, 26 cases were categorized as non-neoplastic while 68 as neoplastic lesions. Of the non-neoplastic cases, 02(3%) were grouped in category I, 24 (24%) in category II. Out of the 68 salivary gland neoplasms, 49(52%) cases were in category IVa and 7(8%) cases in category IVb 3(4%) cases in category V, and 9(9%) cases in category VI. Out of total 94 cases, 36 patients were correlated with histopathological findings. The sensitivity of FNAC was 75% and specificity was 100%.

Conclusion: FNAC, when interpreted using the MSRSGC, provides a reliable and standardized method for diagnosing salivary gland lesions. The Milan System improves diagnostic accuracy, facilitates appropriate clinical management, and helps predict malignancy risk. Correlation with histopathology confirms FNAC as an excellent initial diagnostic tool, particularly for distinguishing benign from malignant salivary gland lesions.

Keywords: *Cytology, Salivary gland, Milan system, Histopathological correlation.*

INTRODUCTION

Salivary gland lesions encompass a wide range of non-neoplastic and neoplastic entities with diverse histomorphological features. Accurate preoperative diagnosis is crucial for planning the appropriate surgical approach and management. Fine Needle Aspiration Cytology (FNAC) has become the preferred initial diagnostic procedure for evaluating salivary gland swellings due to its simplicity, minimal invasiveness, and rapid turnaround time[1].

However, diagnostic terminology and reporting criteria have historically varied across institutions, resulting in inconsistent interpretations and reporting[2]. To address this, the **Milan System for Reporting Salivary Gland Cytopathology (MSRSGC)** was introduced, providing a standardized reporting structure with defined diagnostic categories and associated risk of malignancy (ROM).

This study aims to evaluate the cytomorphological features of salivary gland lesions according to the MSRSGC, and to correlate cytological diagnoses with histopathological findings wherever available.

MATERIALS AND METHODS

Study Design and Duration

A prospective observational study was conducted in the Cytopathology and Histopathology Laboratory, Department of Pathology, P.D.U Medical College and Hospital, Rajkot, Gujarat over a period of **one year**, involving **94 patients** presenting with salivary gland swellings. All the cases referred to the department of Pathology from the Department of Surgery, ENT, and Dental Surgery for evaluation of salivary gland lesions were included in the study.

Procedure

FNAC was performed using a **22–24 gauge needle**, with 10 mL syringe. Both **air-dried** and **alcohol-fixed** smears were prepared and stained using:

- **Hematoxylin and Eosin (H&E)**
- **May-Grünwald Giemsa (MGG)**
- **Papanicolaou (PAP)**

Categorization

Each case was classified according to the **Milan System for Reporting Salivary Gland Cytopathology (MSRSGC)** into one of the following categories:

1. **Category I:** Non-diagnostic / Unsatisfactory
2. **Category II:** Non-neoplastic
3. **Category III:** Atypia of undetermined significance (AUS)
4. **Category IVa:** Benign neoplasm
5. **Category IVb:** Salivary gland neoplasm of uncertain malignant potential (SUMP)
6. **Category V:** Suspicious for malignancy
7. **Category VI:** Malignant

Histopathological Correlation

Surgical excision or biopsy specimens were available for 36 cases, which were compared with their corresponding cytological diagnosis to determine diagnostic accuracy.

Statistical Analysis

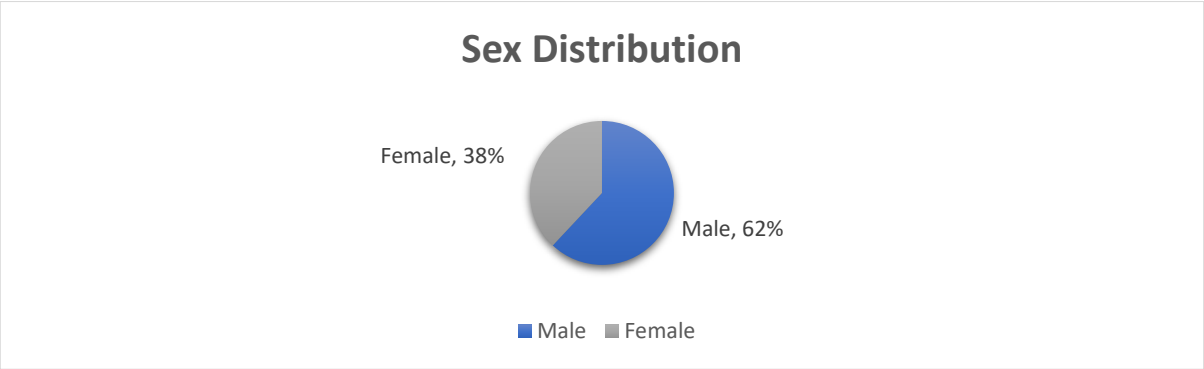
Sensitivity, specificity, and diagnostic accuracy were calculated using standard formulas

RESULTS

Distribution of cases according to sex, age, and site of involvement of the lesion.

Table 1: - SEX DISTRIBUTION OF PATIENTS

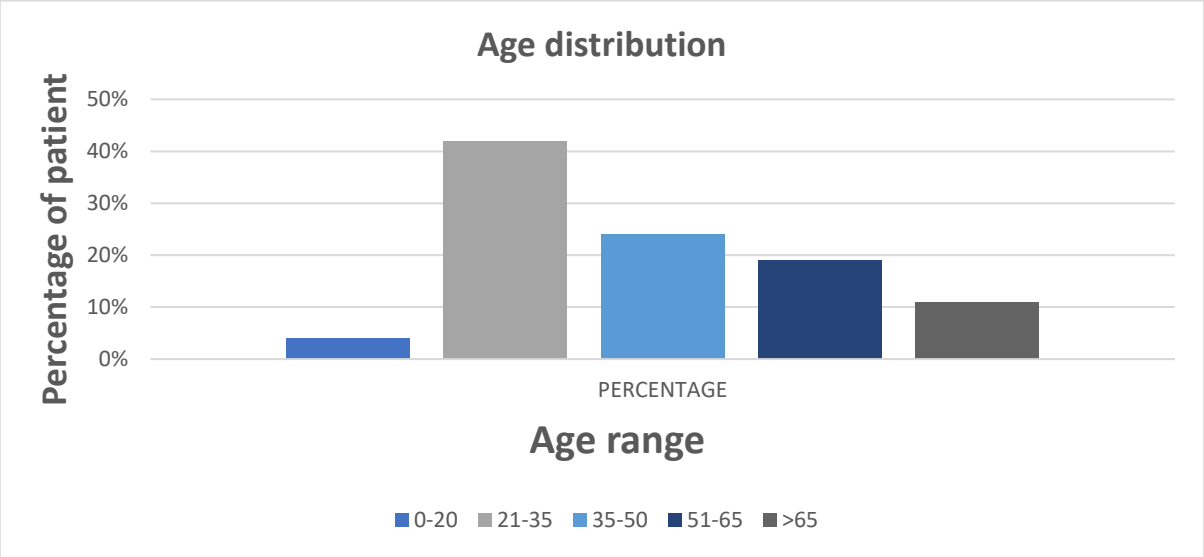
SEX	CASES	PERCENTAGE
MALE	58	62%
FEMALE	36	38%
TOTAL	94	100%



A male predominance was observed (male-to-female ratio **1.8:1**), consistent with previous studies[4–6].

Table 2: - AGE WISE DISTRIBUTION OF SALIVARY GLAND LESION

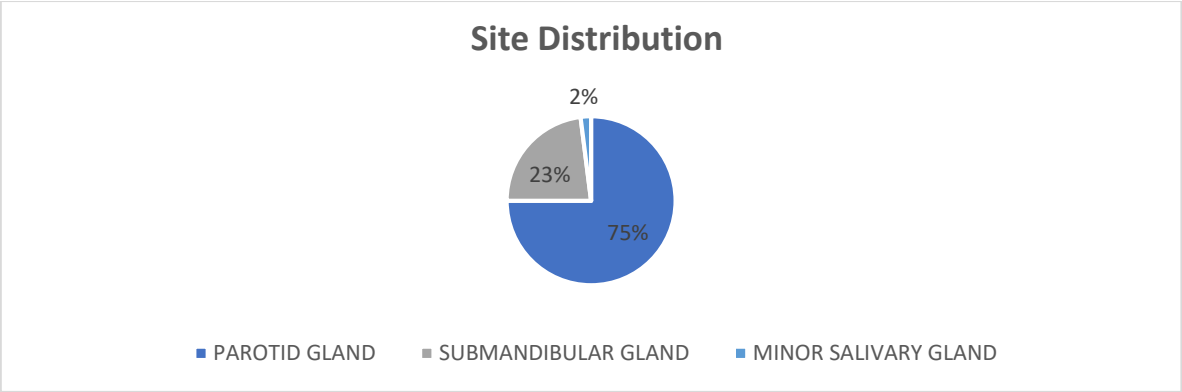
AGE RANGE	CASES	PERCENTAGE
0-20	04	4%
21-35	39	42%
35-50	23	24%
51-65	18	19%
>65	10	11%
TOTAL	94	100%



In our study we had male predominance and most of the cases were seen in the age group of 21-35 years.

Table 3: - SITE DISTRIBUTION OF SALIVARY GLAND LESION

SITE	CASES	PERCENTAGE
PAROTID GLAND	71	75%
SUBMANDIBULAR GLAND	22	23%
MINOR SALIVARY GLAND	01	2%
TOTAL	94	100%

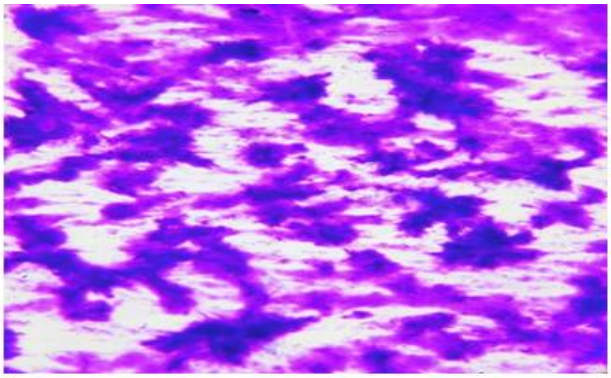


Patients had presented with lesions in all the major and minor salivary glands-parotid, submandibular and sublingual. The parotid gland was the most commonly affected site, aligning with findings in prior studies[7–9].

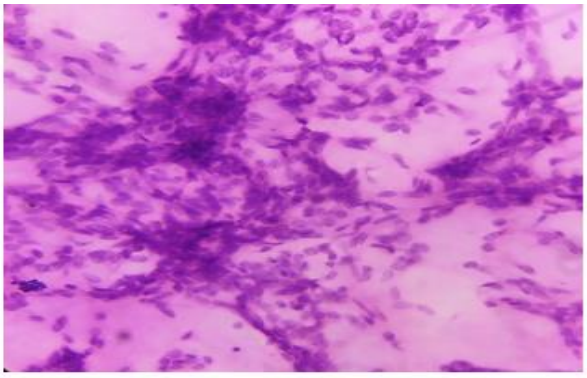
Table 4: - CYTOLOGICAL EVALUTION WAS DONE ACCORDING TO THE MILAN SYSTEM.

CATEGORY	CYTOLOGICAL DIAGNOSIS AND NO. OF CASES	PERCENTAGE
Category I: Non-diagnostic (ND)	Only hemorrhagic material aspirate (02)	3%
Category II: Non-neoplastic (NN)	Chronic sialadenitis (17), Acute on chronic sialadenitis (04), Acute on chronic parotitis (02), Autoimmune sialadenitis (01)	24%
Category III: Atypia of undetermined significance (AUS)	00	0%
Category IVa: Neoplasm: Benign (NB)	Pleomorphic adenoma (35), Warthin's tumor (14)	52%
Category IVb: Neoplasm: Salivary gland neoplasm of uncertain malignant potential (SUMP)	Basal cell adenoma (07)	8%
Category V: Suspicious of malignancy (SM)	Mixed tumor with necrosis (02) Suspicious of adenoid cystic carcinoma (01)	4%
Category VI: Malignant (M).	Mucoepidermoid carcinoma (06) Adenoid cystic carcinoma (03)	9%
TOTAL	94	100%

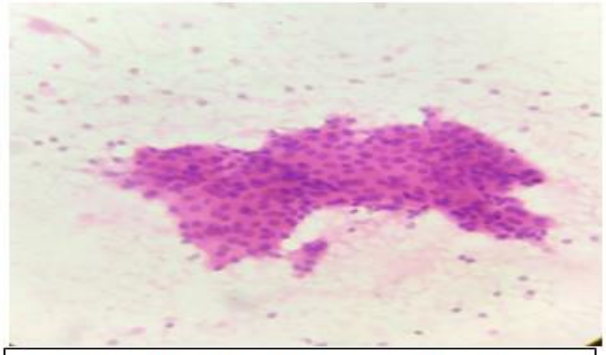
Overall, **26 (27%)** cases were non-neoplastic, and **68 (73%)** were neoplastic. **Pleomorphic adenoma** was the most common lesion, followed by **Warthin's tumor**.



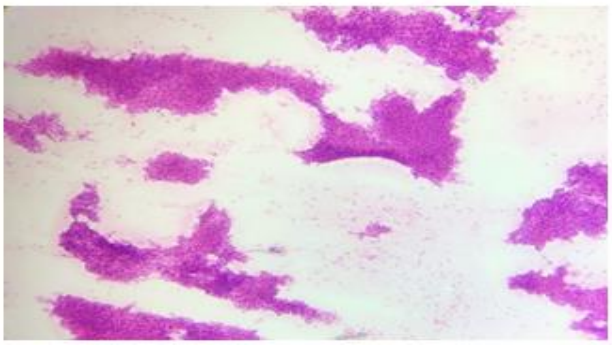
MGG STAIN: PLEOMORPHIC ADENOMA 10X, CHONDROMYXOID STROMA.



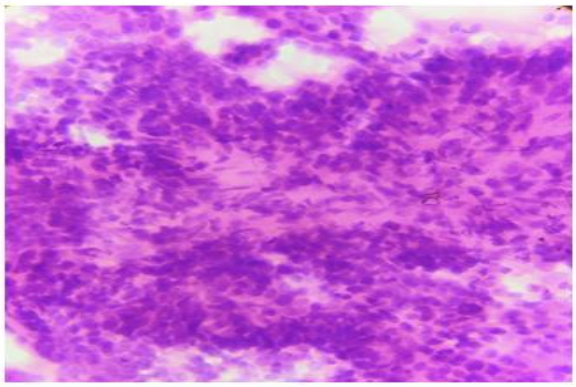
H AND E STAIN: PLEOMORPHIC ADENOMA 40X, EPITHELIAL AND MYOEPITHELIAL CELLS



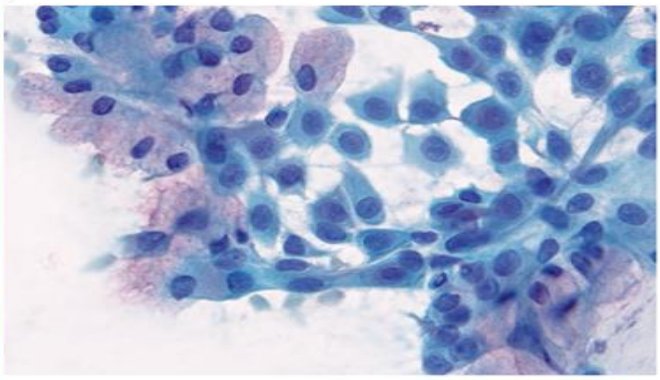
H AND E STAIN: WARTHIN'S TUMOR 40X , SHEETS OF ONCOCYTES, PROTEINACEOUS BACKGROUND AND LYMPHOCYTES



H and E Stain: Warthin's tumor 10X



H AND E STAIN: MIXED TUMOR 40X



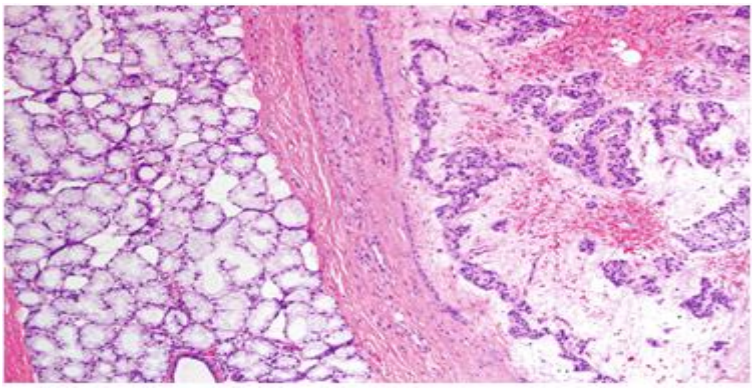
PAP STAIN: MUCOEPIDERMOID CARCINOMA, MUCINOUS CELLS, INTERMEDIATE CELLS

Histopathological Correlation (n = 36)

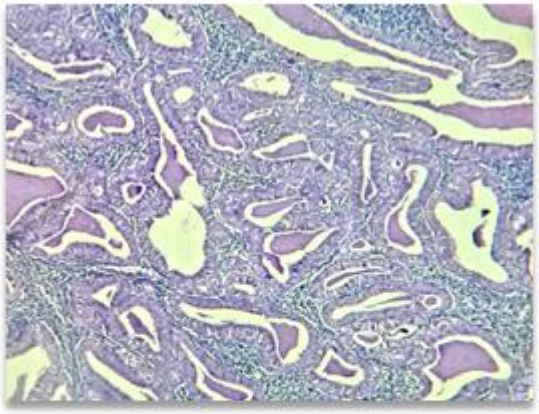
Out of the 36 cases available for histopathology:

Diagnosis cytology	Malignant on histology	Non neoplastic on histology	Benign on histology	Total
Malignant	09	00	00	09
Non neoplastic	00	22	02	24
Benign	03	03	55	61
Total	12	25	57	94

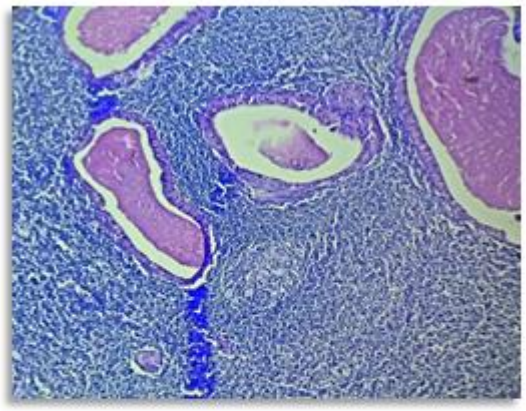
Parameter	Result
Sensitivity	75%
Specificity	100%
Diagnostic Accuracy	86%



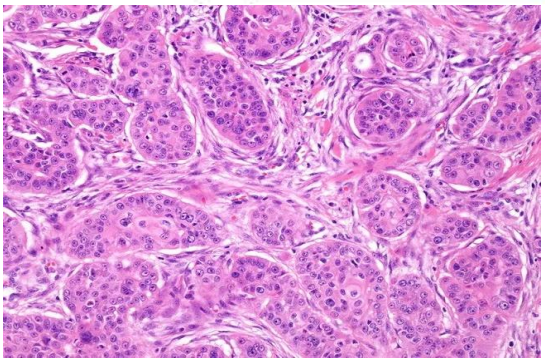
H and E Stain: Pleomorphic adenoma, chondromyxoid stroma and epithelial cells



H AND E STAIN: WARTHIN'S TUMOR 10X , DOUBLE LAYERED ONCOCYTIC CELLS WITH LYMPHOID STROMA



H AND E STAIN: WARTHIN'S TUMOR 40X , DOUBLE LAYERED ONCOCYTIC CELLS WITH GERMINAL CENTRE AND SURROUNDING LYMPHOID STROMA



Solid areas of the tumor are formed by different proportions of epidermoid (squamous) cells, mucus cells and intermediate cells.

DISCUSSION

The findings of this study reaffirm that **FNAC** is a highly specific, minimally invasive, and cost-effective diagnostic tool for evaluating salivary gland lesions[10–12]. The age and site distribution pattern observed aligns with previous studies, showing a predominance of parotid involvement and peak incidence in young to middle-aged adults.

The distribution of lesions in this study parallels prior research, with **parotid involvement** being the most common and **pleomorphic adenoma** the predominant benign tumor[4,6,8]. The observed **sensitivity (75%)** and **specificity (100%)** correspond with results reported by Manju et al., Sheetal et al., and Yogambal et al.[13–15]. Although certain low-grade or cystic malignancies may yield false-negative results, **false positives are rare**, confirming FNAC's reliability for surgical decision-making.

The **Milan System** standardizes salivary gland cytology reporting and bridges the diagnostic gap between cytopathologists and clinicians[3,16]. Its category-wise ROM assists in management planning, as summarized below:

- *Category II:* Conservative management
- *Category IVa:* Simple excision
- *Category VI:* Radical surgery or oncological therapy

Overall, the present findings closely align with previous Indian and international studies, demonstrating the effectiveness of MSRSGC in routine reporting and its clinical utility in guiding management.

Comparison of Risk of Malignancy (ROM) with Other Studies

MSRSGC Category	ROM (Present Study)	Faquin et al., 2018[3]	Rossi et al., 2017[9]	Baloch et al., 2018[10]	Manju et al., 2018[13]
I – Non-diagnostic	0%	25%	29%	25%	20%
II – Non-neoplastic	0%	10%	10%	10%	8%
III – AUS	—	20%	30%	29%	22%
IVa – Benign neoplasm	6%	5%	4%	4%	6%
IVb – SUMP	15%	35%	37%	38%	33%
V – Suspicious for malignancy	66%	60%	65%	69%	60%
VI – Malignant	100%	90%	96%	98%	92%

The ROM values in the present study are largely consistent with the established Milan System benchmarks. The slightly lower ROM in the **SUMP** and **Suspicious for malignancy** categories may be attributed to the smaller number of histologically correlated cases.

CONCLUSION

FNAC of salivary gland lesions, when interpreted using the **Milan System for Reporting Salivary Gland Cytopathology**, is an effective and reliable diagnostic modality with **high specificity** and **good sensitivity**. The system enhances diagnostic clarity, risk stratification, and clinical decision-making. Histopathological correlation further validates the diagnostic reliability of FNAC, especially in differentiating benign from malignant lesions.

REFERENCES

1. Orell SR, Sterrett GF, Whitaker D. *Fine Needle Aspiration Cytology*. 5th ed. Philadelphia: Churchill Livingstone Elsevier; 2012.
2. Seethala RR, LiVolsi VA, Baloch ZW. Relative accuracy of fine needle aspiration and frozen section in the diagnosis of salivary gland lesions. *Head Neck*. 2005;27(3):217–223.
3. Faquin WC, Rossi ED, Baloch Z, et al. *The Milan System for Reporting Salivary Gland Cytopathology*. Springer International Publishing; 2018.
4. Kala C, Kala S, Khan L. FNAC of salivary gland lesions: A study of 400 cases. *J Clin Diagn Res*. 2014;8(12):FC01–FC04.
5. Sonal B, Dhananjay P, Anjali P. Cytological study of salivary gland lesions: Experience from a tertiary care hospital. *Int J Res Med Sci*. 2016;4(12):5165–5169.
6. Sharma M, Chaturvedi AK, Agarwal D. Role of fine needle aspiration cytology in diagnosis of salivary gland lesions. *J Cytol*. 2018;35(2):79–84.
7. Das DK, Petkar MA, Al-Mane NM, Sheikh ZA, Al-Ayadhi A, Anim JT. Role of fine needle aspiration cytology in the diagnosis of swellings in the salivary gland regions: A study of 712 cases. *Med Princ Pract*. 2004;13(2):95–106.
8. Kocjan G, Nayak P, Lee A, et al. Salivary gland FNA cytology: Current concepts and review of the literature. *Diagn Cytopathol*. 2015;43(10):825–838.
9. Rossi ED, Wong LQ, Bizzarro T, et al. The Milan System for Reporting Salivary Gland Cytopathology: An international multi-institutional study. *Cancer Cytopathol*. 2017;125(10):757–766.
10. Baloch ZW, Faquin WC, Layfield LJ, et al. The Milan System for Reporting Salivary Gland Cytopathology: Analysis and suggestions of initial review. *Diagn Cytopathol*. 2018;46(9):751–759.
11. Layfield LJ, Glasgow BJ. Diagnosis of salivary gland tumors by fine needle aspiration cytology: A review of clinical utility and pitfalls. *Diagn Cytopathol*. 1991;7(3):267–272.
12. Kini SR. *Guides to Clinical Aspiration Biopsy: Salivary Glands*. New York: Igaku-Shoin; 1996.
13. Manju M, Kumar H, Bhatia A. Diagnostic accuracy of FNAC in salivary gland lesions with histopathological correlation. *Ann Pathol Lab Med*. 2018;5(7):A588–A592.
14. Sheetal S, Chandanwale SS, Annasaheb L, et al. Diagnostic utility of FNAC in salivary gland lesions using Milan system. *Int J Health Sci Res*. 2019;9(3):17–24.
15. Yogambal M, Rajaraman R, Arunalatha P, et al. Salivary gland lesions: Cytology and histopathology correlation study. *J Evid Based Med Healthc*. 2015;2(40):6648–6655.
16. Rossi ED, Faquin WC. The Milan System for Reporting Salivary Gland Cytopathology (MSRSGC): An evidence-based classification with management recommendations. *Cancer Cytopathol*. 2018;126(6):394–404.