

# Role of fine-needle aspiration cytology in the evaluation of salivary gland lesion with utilization of Milan system for reporting



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Submission: 04-08-2023

Revision: 29-11-2023

Publication: 01-01-2024

## ABSTRACT

**Background:** Fine-needle aspiration cytology (FNAC) plays a role in the pre-operative diagnosis of salivary gland mass lesion. Salivary gland neoplasm accounts for 6% of all head and neck tumors. It is widely used safe and relatively non-traumatic procedure that can quickly provide important information. "The Milan system for reporting salivary gland cytopathology" (MSRSGC) was introduced, providing a guide for diagnosis and management according to the risk of malignancy (ROM) in different categories. **Aims and Objectives:** The objectives of the study are as follows: (1) To evaluate different types of salivary gland lesion in tertiary care center. (2) To see application of Milan system in the present scenario. **Materials and Methods:** A hospital-based and prospective study was conducted between March 2021 and September 2022 on all cases of salivary gland lesions who were referred for FNAC to the Department of Pathology at Netaji Subhash Chandra Bose Medical College Hospital in Jabalpur, Madhya Pradesh. In the present study, we categorize salivary gland cytopathology result as per Milan system (MSRSGC) and calculated diagnostic accuracy and ROM in each category of Milan system (MSRSGC). **Results:** Seventy seven cases distributed according to Milan category as follows: Non-diagnostic (ND) (2.59), non-neoplastic (NN) (29.33%), atypia of undetermined significance (AUS) (1.29%), 4a. Benign (29.87%), 4b. Salivary gland neoplasm of uncertain malignant potential (SUMP) (1.29%), suspicious of malignancy (SOM) (1.29%), and malignancy (10.38%). Out of 77 cases, histological follow-up was available in 27 cases and the ROM was calculated. The ROM for each category of the Milan system is as follows: ND (0%), NN (6.66%), AUS (100%), 4a. Benign (9.09%), 4b. SUMP (0%), SOM (100%), and Malignancy (100%). The sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy were 77.7%, 100%, 100%, 92.59%, and 94.11%. **Conclusion:** FNAC of the salivary gland lesions is a safe, minimum invasive, and reliable diagnostic procedure. The Milan system of reporting is a risk stratification system which can improve the overall effectiveness of reporting.

**Key words:** Fine-needle aspiration cytology; Milan system for reporting salivary gland cytopathology; Salivary gland lesion

## INTRODUCTION

Salivary glands are exocrine organ responsible for the production and secretion of saliva and consists of parotid,

submandibular, sublingual, and minor salivary gland that are numerous and widely distributed throughout the mouth. Salivary gland neoplasm accounts for 6% of all head-and-neck tumors.<sup>1</sup>

### Access this article online

#### Website:

<http://nepjol.info/index.php/AJMS>

DOI: 10.3126/ajms.v15i1.57363

E-ISSN: 2091-0576

P-ISSN: 2467-9100

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The most common location of salivary gland tumor is the parotid gland up to 80% followed by the submandibular gland 10–15% and the sublingual gland with minor gland. Fortunately, 80% of salivary gland lesions are benign.<sup>2,3</sup>

Fine-needle aspiration cytology (FNAC) is a well-established technique for the evaluation of salivary gland lesions, reporting of salivary glands is challenging due to heterogeneity and morphological overlap between the spectrum of lesions.<sup>4,5</sup>

To meet the challenge “The Milan system for reporting salivary gland cytopathology” (MSRSGC) was introduced, providing a guide for diagnosis and management according to the risk of malignancy (ROM) in different categories.<sup>6</sup>

The cytological features were evaluated, and cases were classified according to MSRSGC as follows:

- Category 1: Non-diagnostic (ND)
- Category 2: Non-neoplastic (NN)
- Category 3: Atypia of undetermined significance (AUS)
- Category 4a: Neoplasm: Benign (NB)
- Category 4b: Salivary gland neoplasm of uncertain malignant potential (SUMP)
- Category 5: Suspicious of malignancy (SOM)
- Category 6: Malignant (M).

The MSRSGC: Implied ROM and recommended clinical management.

### Aims and objectives

The objectives of the study are as follows:

- (1) To evaluate different types of salivary gland lesions in tertiary care center
- (2) To see the application of Milan system in the present scenario.

## MATERIALS AND METHODS

In the present study, all cases of salivary gland lesions, referred to the cytopathology section of Netaji Subhash Chandra Bose Medical College, Hospital Jabalpur (M.P) from March 2021 to September 2022 were included in

the study. After informed consent and collection of available important previous examination reports, FNAC was performed using 22 or 23 gauze needles attached to a 10 mL disposable syringe. FNA was performed multiple times randomly in different areas of swelling. The aspirated material was expressed onto the slides and smears were prepared, dried, and stained with May-Grunwald-Giemsa stain and occasionally with PAP stain also. Confirmed salivary gland lesions were followed up and histopathological reports were obtained whenever possible. The aim of the present study is to evaluate various salivary gland lesions by FNAC and to categorize them as per the MSRSGC and see its utility in the present scenario.

### Statistical analysis

The data of the present study will be recorded/fed into the computers and after its proper validation, checked for error; coding and decoding will be compiled and analyzed with the help of SPSS 20 software for windows. Appropriate univariate and bivariate analysis and descriptive statistics will be carried out other statistical tests such as Student's *t*-test for continuous data and Fisher's exact test or  $\chi^2$  test for categorical data will also be applied if the necessity felt to support the hypothesis.

All means are expressed as mean  $\pm$  standard deviation and proportion as in percentage (%). The critical value for the significance of the results will be considered  $\leq 0.05$  level.

## RESULTS

The present study includes a total of 77 cases of salivary gland lesions with maximum number of cases in the parotid gland (59) followed by the submandibular gland (11) and minor salivary gland (7).

Maximum number of cases was in the age group of 40–60 years. (39%) followed by age group 20–40 years (33.8%) (Table 1).

In the present study, a maximum number of males (44.9%) showed Category IV (neoplastic) lesions and most females (64.3%) showed Category II (NN) lesions.

| Diagnostic category | Risk of malignancy (%) | Management                                     |
|---------------------|------------------------|--|
| Non-diagnostic      | 25                     | Clinical and radiologic correlation/repeat FNA |
| Non-neoplastic      | 10                     | Clinical follow-up and radiologic correlation  |
| AUS                 | 20                     | Repeat FNA or surgery                          |
| Neoplasm            |                        |  |
| Neoplasm: Benign    | <5                     | Surgery or clinical follow-up                  |
| Neoplasm: SUMP      | 35                     | Surgery  |
| SOM                 | 60                     | Surgery  |
| Malignant           | 90                     | Surgery  |

SUMP: Salivary gland neoplasm of uncertain malignant potential, SM: Suspicious of malignancy, AUS: Atypia of undetermined significance, FNA: Fine-needle aspiration, SOM: Suspicious of malignancy

A total number of male were 49 and female were 28 with M: F ratio 1.7:1 (Table 2).

In the parotid gland, most lesion was Category IV (neoplastic), that is, 44.1%. While submandibular gland lesions were mostly of Category II (NN) (81.8%). The minor salivary gland also showed a maximum lesion in Category IV (neoplastic) 42.9% (Table 3).

In all categories, salivary gland lesions were mostly mobile (Table 4).

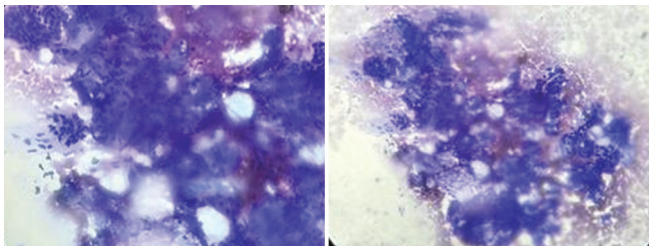
Maximum number of salivary lesions on cytology were of pleomorphic adenoma (28.5%). In malignancy of salivary gland, the most common malignancy in our study was mucoepidermoid carcinoma (MEC) (3.8%). Category III, V, and Category VI having 100% of ROM (Table 5).

Most common salivary gland lesions were in Milan Category II NN (45.5%). Milan Category IV (neoplastic-benign) comprises (40.2%) of salivary gland lesion and is the second most common lesion. While ND, AUS, SUMP, SOM, and malignant comprise 2.59%, 1.29%, 1.29%, 1.29%, and 10.5%, respectively. In the present study, out of a total 77 cases, histological follow-up was possible only in 27 cases. Out of 27 cases, five cases were discordant (Table 6).

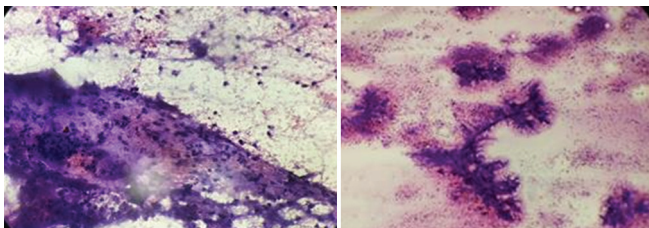
The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy are 77.7%, 100%, 100%, 92.59%, and 94.11%.

## IMAGES

### Category II

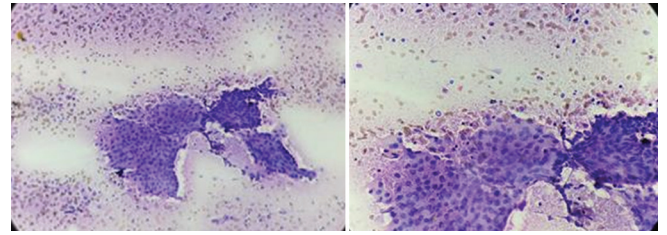


Sialadenitis: Cluster of salivary acinar cells.

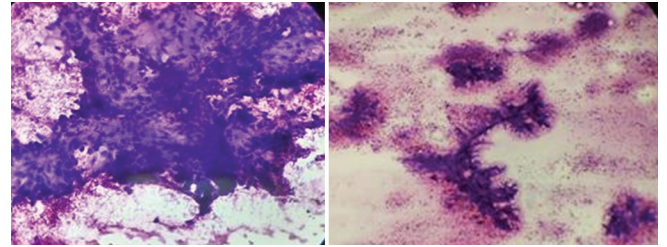


Acute sialadenitis: Plenty of neutrophils against a dirty necrotic background.

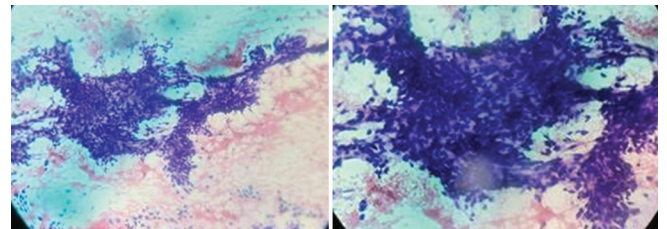
### Category IV (a)



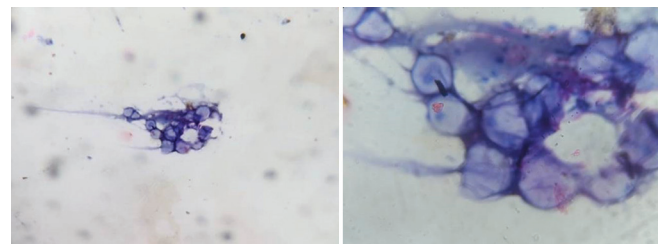
Warthin's tumor: Sheets of oncocytic cells admixed with lymphocytes in a fluid background.



Pleomorphic adenoma: Clusters of spindles-shaped myoepithelial cells in a chondromyxoid background along with a small sheet of benign epithelial cells.

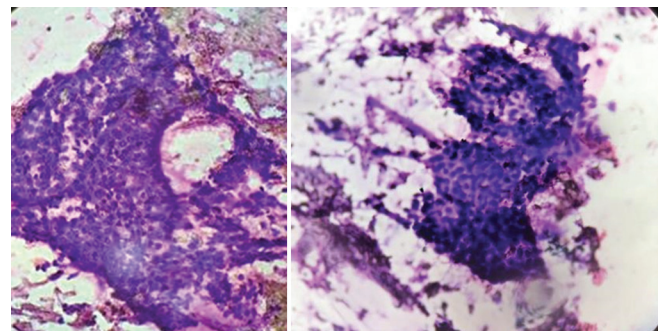


Schwannoma: Loose clusters of spindle cells in a fibrillary background.



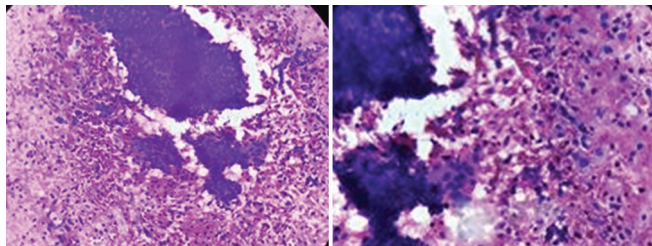
Lipoma: Few clusters of mature adipocyte and fibrofatty tissue against a hemorrhagic background.

### Category IV (b)

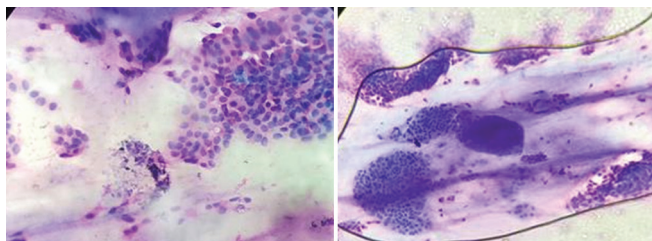


Basal cell adenoma: Cohesive cluster of small round cells with scanty cytoplasm and peripheral palisading.

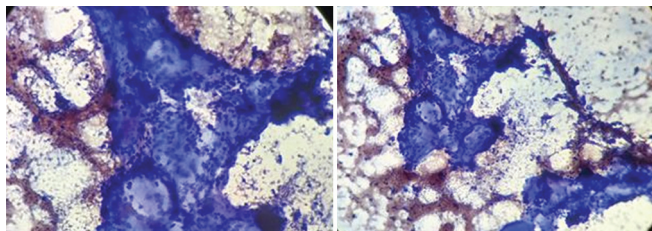
**Category VI**



Mucoepidermoid carcinoma: Sheets of squamoid-looking cells, along with numerous mucus-secreting cells having vacuolated cytoplasm.



Carcinoma X pleomorphic adenoma: Sheets of malignant cells and fibrillary matrix with embedded myoepithelial cells.



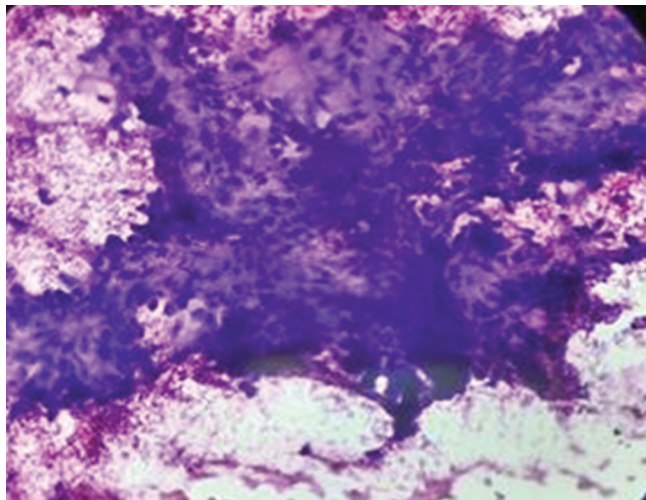
Adenoid cystic carcinoma: Small round cells arranged around a hyaline globule.

**DISCUSSION**

In the present study, salivary gland lesions were most commonly found in 40–60 years. Age group with males is more commonly affected than females. The parotid gland was the most common salivary gland affected. Similar findings were found in various previous studies on salivary glands by Rohilla et al., Vishwanathan et al., Veer et al., Kala et al., Pujani et al., etc.

In the present study, we classify salivary gland cytology according to MSRSCG and ROM was calculated in each category.

**Category I (ND)**



It includes cases in which aspirates were insufficient for cytological diagnosis. Rare or absent cells, <60 lesional cells<sup>3</sup>, or poorly prepared slides with artifacts<sup>7</sup> were included in ND category.

In the non-diagnostic category, we have two cases. In both cases, cytology showed mainly blood and very few 2–3 epithelial cells which were not sufficient for definitive diagnosis so they were categorized into Category I. In such cases where aspirate is insufficient one should repeat from multiple sites and do guide FNAC if possible. However, repeated FNAC and histological follow-up was not possible in our case as the patient did not turn up for further checkup.

**Category II (NN)**

It includes benign entities such as sialadenitis, reactive lymph node, and granulomatous infection. In the present study, there were 35 cases categorized in the NN category. Acute suppurative lesion was the most common lesion on cytology in this category. Out of 35 cases, clinical follow-up was available in 11 cases. All of which showed resolution with clinical treatment. Out of 35 cases, only four cases were operated and on histology, three were diagnosed as cystic lesion which was in concordance with cytology report but one case was misinterpreted as benign cystic lesion on cytology turned out to be a MEC on histology. ROM was 6.6% in this category which is

| Age (year) | Frequency (%) |
|------------|---------------|
| 10–20      | 10 (13.0)     |
| 20–40      | 26 (33.8)     |
| 40–60      | 30 (39.0)     |
| 60–80      | 10 (13.0)     |
| 80–100     | 1 (1.2)       |

similar to Rossi et al., Rohilla et al., studies have shown a ROM ranging from 0% to 20%. MEC poses a diagnostic challenge as all their components squamous, intermediate and mucinous are not always present simultaneously in an aspirate. Moreover, due to cystic nature of MEC, often mucinous fluid is aspirated showing few foamy cells only in a mucinous background.

In our study, also one case of MEC was diagnosed as a cystic lesion on cytology as only fluid was aspirated and no other elements were seen. In cystic lesion of salivary gland, one should reaspirate the lesion after the complete evacuation of fluid. If possible, do ultrasonography guided FNAC from solid area to avoid FN diagnosis on cytology. ROM in this category for the present study is 6.66% which is in concordance to previous studies Rohilla et al.,<sup>8</sup> Veer et al.,<sup>9</sup> Pujani et al.<sup>10</sup> and Singh et al.<sup>11</sup>

### Category III (AUS)

Criteria:<sup>11</sup>

- Samples are indefinite for a neoplasm; a neoplastic process cannot be excluded after examination of all the cellular material
- A majority of these FNAs will represent reactive atypia or poorly sampled neoplasms.

In our study, there was one case which was categorized as AUS. Aspirate was paucicellular in this category and was showing few atypical epithelial cells, having a high N: C ratio and mildly pleomorphic nucleus. Background showed mucinous material and hemorrhage.

We advised for repeat FNAC under ultrasound guidance but the patient was operated and on histological examination, it came out to be a MEC.

This category was introduced to reduce the no of false negative cases in NN Category II.

According to the Milan system, this category should comprise <10% of salivary gland lesions on FNAC. ROM in this Category III (AUS) according to the Milan system is 20%. In our study, this category comprises 1.29% of salivary gland lesion and ROM is 100% which is similar to ROM in various studies Veer et al., Pujani et al., and Gaikwad et al.<sup>11</sup>

In the present study, such a high ROM in Category III may be probably because of the small sample size.

### Category IV-benign neoplasm (4a)

In this category, we had 29 cases. The most common cytological diagnosis was of pleomorphic adenoma

(22 cases) which is similar to various studies Rohilla et al.,<sup>8</sup> Veer et al.,<sup>9</sup> Kala et al.,<sup>6</sup> and Mishra et al.<sup>12</sup>

Cytological feature of pleomorphic adenoma usually reveals sheets and clusters of benign ductal epithelial cells, and myoepithelial cells against chondromyxoid background, which is similar to previous studies. Rohilla et al.,<sup>16</sup> Veer et al.,<sup>9</sup> Kala et al.,<sup>6</sup> and Mishra et al. Out of 29 cases in this category, 12 were operated. On histological examination, 11 cases showed concordance with cytological diagnosis and only one case showed discordance. One discordant case was of pleomorphic adenoma which on histology diagnosed as salivary duct carcinoma. Diagnostic accuracy of this cat in our study was 94.11%. Very high diagnostic accuracy 94.55% in the category was reported in various studies Hemavathy et al.<sup>13</sup>

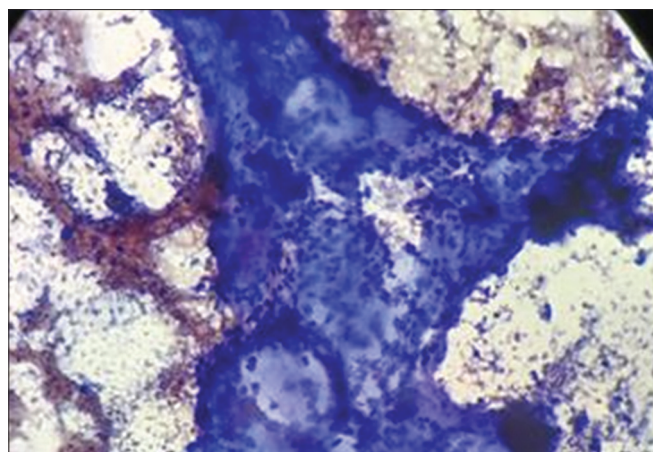
### Category 4b (SUMP)

The second category under neoplastic group is SUMP. This category includes aspirates where the features of diagnosis of a neoplasm are present, but a specific entity cannot be designated and malignancy cannot be ruled out. We had one (1.29%) case of basal cell neoplasm in this category, which showed few clusters of basaloid cells which was on histology confirmed as basal cell adenoma. Similar case was present in the case study of Singh et al.<sup>14</sup> ROM in this category in the present study is 0% which is in concordance with the previous studies of Manju kumari et al.

### Category 5 (SOM)

Majority of specimens are of high-grade carcinoma on histopathologic follow-up. In this category, salivary gland FNA are suggestive of a malignancy but not all criteria for a specific diagnosis are present. It is usually found that aspirates in this category are either deficient in quantity or in the quality of cytomorphological features of abnormal cells.<sup>15</sup> Similarly, in our study, there were high-grade features suggestive of malignancy, but exact differentiation and definite diagnosis could not be contemplated. A single case (1.29%) was placed in this category in which mucoid fluid was aspirated on FNAC. Smears revealed sheets of epithelial cells, having a high N/C ratio and hyperchromatic, pleomorphic nucleus, along with inflammatory cells mainly neutrophils and foamy macrophages against dirty proteinaceous background which was suggestive of salivary gland malignancy. On histological follow-up, it turned out to be a mucoepidermoid carcinoma. The ROM in this category for the present study is 100% which is similar to previous studies of Veer et al.,<sup>9</sup> Pujani et al.,<sup>10</sup> Mukundapai et al.,<sup>4</sup> Gaikwad et al.,<sup>11</sup> Singh et al.,<sup>14</sup> Val-Bernal et al.<sup>1</sup> and Kausik et al.,<sup>16</sup> Rossi et al., and Rohilla et al.

### Category 6 (Malignant)



This category consists of cases with diagnostic features of malignancy. The aim of introducing this category is to sub-classify tumors, especially into low grade and high grade because the approach to management of these cases is different. We had a total of 8 (10.38%) cases in this category. The most common entity was MEC (3.8%) on cytology. FNAC of MEC predominantly shows three types of cells including squamous, intermediate, and mucus-secreting cells with a dirty to mucoid background. The number of these cells and cystic components varies according to the differentiation of the tumor. Out of three cases of MEC, histopathology of two cases was available and findings were concordant. We had two cases of adenoid cystic carcinoma on cytology which was confirmed on histopathology. Followed by two cases of pleomorphic

**Table 2: Category-wise distribution of gender**

| Gender        | Cat I   | Cat II    | Cat III | Cat IV    | Cat V   | Cat VI   | Frequency (%) |
|---------------|---------|-----------|---------|-----------|---------|----------|---------------|
| Male, n (%)   | 1 (2.0) | 17 (34.7) | 1 (2.0) | 22 (44.9) | 1 (2.0) | 7 (14.3) | 49 (63.6)     |
| Female, n (%) | 1 (3.6) | 18 (64.3) | 0       | 8 (28.6)  | 0       | 1 (3.6)  | 28 (36.4)     |

**Table 3: Site distribution according to Milan category**

| Site                        | Site distribution |           |         |           |         |          |
|-----------------------------|-------------------|-----------|---------|-----------|---------|----------|
|                             | Cat I             | Cat II    | Cat III | Cat IV    | Cat V   | Cat VI   |
| Parotid gland, n (%)        | 1 (1.7)           | 24 (40.7) | 1 (1.7) | 26 (44.1) | 1 (1.7) | 6 (10.2) |
| Sub mandibular gland, n (%) | 1 (9.1)           | 9 (81.8)  | 0       | 1 (9.1)   | 0       | 0        |
| Minor salivary gland, n (%) | 0                 | 2 (28.6)  | 0       | 3 (42.9)  | 0       | 2 (28.6) |

**Table 4: Category-wise distribution of mobility**

| Mobility                   | Cytological category |           |         |           |         |          |
|----------------------------|----------------------|-----------|---------|-----------|---------|----------|
|                            | Cat I                | Cat II    | Cat III | Cat IV    | Cat V   | Cat VI   |
| Mobile, n (%)              | 2 (3.6)              | 29 (51.8) | 1 (1.8) | 20 (35.7) | 1 (1.8) | 3 (5.4)  |
| Non-mobile, n (%)          | 0                    | 4 (23.5)  | 0       | 8 (47.1)  | 0       | 5 (29.4) |
| Restricted mobility, n (%) | 0                    | 2 (50.0)  | 0       | 2 (50.0)  | 0       | 0        |

**Table 5: Distribution of salivary gland lesion**

| Milan category     | Cases                                 | Number of cases (%) | ROM (%) |
|--------------------|---------------------------------------|---------------------|---------|
| Non-diagnostic     | Hemorrhagic lesion                    | 2 (2.59)            | -       |
| Non-neoplastic     | Sialadenosis                          | 3 (3.8)             |         |
|                    | Acute sialadenitis                    | 4 (5.1)             |         |
|                    | Chronic sialadenitis                  | 5 (6.4)             |         |
|                    | Acute suppurative inflammatory lesion | 19 (24.6)           | 6.66    |
|                    | Benign cystic lesion                  | 4 (5.1)             |         |
| AUS                |                                       | 1 (1.29)            | 100     |
| Neoplasm<br>Benign | Pleomorphic adenoma                   | 22 (28.5)           | 9.09    |
|                    | Warthin tumor                         | 3 (3.8)             |         |
|                    | lipoma                                | 2 (2.5)             |         |
|                    | Schwannoma                            | 2 (2.5)             |         |
| SUMP               | Basal cell neoplasm                   | 1 (1.2)             |         |
| SM                 |                                       | 1 (1.29)            | 100     |
| Malignant          | Mucoepidermoid carcinoma              | 3 (3.8)             | 100     |
|                    | Adenoid cystic carcinoma              | 2 (2.5)             |         |
|                    | Carcinoma ex pleomorphism             | 2 (2.5)             |         |
|                    | Lymphoproliferative disorder          | 1 (1.2)             |         |

AUS: Atypia of undetermined significance, SUMP: Salivary gland neoplasm of uncertain malignant potential, SOM: Suspicious of malignancy

**Table 6: Cytohistological correlation**

| Milan category | Number of cases on cytology, n (%) | Follow-up | Concordant  | Discordant                |
|----------------|------------------------------------|-----------|---|---------------------------|
| Non-diagnostic | 2 (2.59)                           |           | -   |                           |
| Non-neoplastic | 35 (45.5)                          | 4         | 3   | Mucoepidermoid carcinoma_ |
| AUS            | 1 (1.29)                           | 1         | -   | Low-grade MEC             |
| Neoplasm       |                                    |           |   |                           |
| Benign         | 29 (39)                            | 11        | 9 PA<br>1 lipoma  | Salivary duct carcinoma_  |
| SUMP           | 1 (1.29)                           | 1         | -   | Basal cell adenoma        |
| SOM            | 1 (1.29)                           | 1         | -   | Mucoepidermoid carcinoma  |
| Malignant      | 8 (10.5)                           | 6         | 2 MEC<br>1 Ca X PA<br>2 ACC<br>Lymphoproliferative disorder | -                         |

MEC: Mucoepidermoid carcinoma, AUS: Atypia of undetermined significance, SUMP: Salivary gland neoplasm of uncertain malignant potential, SOM: Suspicious of malignancy

ex-adenoca which was turned out to be MEC on histology. One case was given lymphoproliferative disorder. No follow-up was available of those cases.

ROM in this category was 100% which is similar to the result of Pujani et al.,<sup>10</sup> Singh et al.,<sup>14</sup> Val-Bernal et al.<sup>1</sup> and Jha et al.<sup>17</sup>

Out of a total of 77 cases, histology was available in 24 cases (31.16%). Cytohistological concordance was noted in 19 cases (79.16%). TP, TN, FP, and FN are 25, 07, 0, and 02, respectively.

Overall Sensitivity, specificity, PPV, NPV, and diagnostic accuracy were 77.7%, 100%, 100%, 92.59%, and 94.11%, respectively, which is very close to the statistical parameters of previous studies of Pujani et al.,<sup>10</sup> Gaikwad et al.,<sup>11</sup> Chen et al., and Rohilla et al.<sup>8</sup>

Limitation of the present study is the small sample size and lesser number of histological follow-ups. However, a wide spectrum of salivary gland lesions was included in the study. Further study for a longer duration so that it includes a large sample size and with proper management protocol is required.

#### Limitations of the study

Limitation of the present study is the small sample size and lesser number of histological follow-ups.

## CONCLUSION

FNAC of the salivary gland lesions is a safe, minimum invasive, and reliable diagnostic procedure.

The Milan system of reporting is a risk stratification system which can improve the overall effectiveness of reporting and application to help in the stratification of salivary gland lesion reporting.

“MSRSGC”, providing guide for clinical management according to ROM in different categories.

The overall goal of the MSRSGC is to improve the effectiveness of salivary gland FNA by providing a uniform system with the ultimate result of better communication and improved patient care.

## ACKNOWLEDGEMENT

The author would like to express our gratitude to all those who contributed to the success of this research. Special thanks to the Department of Pathology and Technical staff for their valuable insights and support throughout this study.

## DATA AVAILABILITY

All data have been collected from Netaji Subhash Chandra Bose Medical College cytology section, of the department of pathology.

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#### Authors Contribution:

**AA-** Data collection, follow up of cases of salivary gland lesion, manuscript writing, **RN-** FNAC, reporting of all cases, analysis and interpretation of patient data regarding the salivary gland lesion, **MD-** Contribution in manuscript writing, **KS-** Referral of cases of salivary gland lesion from department of ENT to department of Pathology, Cytology section, **JSD-** Statistical Analysis.

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**Source of Support:** Nil, **Conflicts of Interest:** None declared.