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# Diagnostic Utility of Milan System of Reporting in Fnac of Various Salivary Gland Lesions with Histopathological Correlation in a Tertiary Care Centre.

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**ABSTRACT:**
Salivary glands are unique amongst the secretory glands with the most heterogeneous group of tumors exhibiting the greatest histological diversity. According to literature, salivary gland tumors are probably the most complex among human neoplasms, due to their broad spectrum resulting from a multiple tumor cell differentiation, its cell arrangements and extracellular matrix synthesis produced by certain tumor cells. Therefore, this study describes the prevalence of salivary gland lesions, in a hospital based example of tertiary care center and characterizes them according to Milan reporting system. The Milan system for reporting salivary gland cytopathology (MSRSGC) is a new reporting system for salivary gland developed by an international consortium of experienced healthcare professionals(1).It is an evidence based system which correlates diagnostic categories with ROM (risk of malignancy) and clinical managementstrategies.(2,3)

**Background &Aims**:
1. To access the efficiency of Milan system for reporting salivary gland cytopathology in accurate prediction of salivary gland lesions.
2. To assess the usefulness of cytological study as an initial diagnosis procedure before other invasive investigations in the diagnosis of salivary glandlesions.
3. To correlate histomorphological spectrum of salivary gland lesions and to know their pattern of distribution according to Milan reportingsystem.
4. To assess the accuracy and reliability of FNAC in interpretation of salivary gland lesions by Milan reportingsystem.
5. To investigate the discordant cases in detail to establish the source oferrors.

## I. INTRODUCTION

Salivary glands lesions can be resulted from tumors, infections and inflammatory process or cysts. Sometimes it can be difficult to establish whether pathology arise from gland itself or from the surrounding structures. Non neoplastic salivary glands lesions include calculus disease, acute or chronic inflammatory lesions and vascular lesions. Numerous pathologies involve the salivary glands and may clinically present as facial or neck lump, diffuse swelling and pain. The inflammation of salivaryglands (sialadenitis) may be due to trauma, viral and bacterial infections or autoimmuneorigin.

The cytological evaluation of salivary gland tumor however is limited by wide range of heterogeneous nature of benign and malignant tumors arising in these areas, many of which share similar or overlapping cytological features, making the diagnosis of tumors difficult. The salivary glands lesion, although not so common, both major and minor salivary gland can be affected by variety of inflammatory and neoplastic diseases.(4)

The exact etiology of salivary gland neoplasm remain unknown, however several factors are implicated in their genesis.(5) Correlation of patient age and karyotype group with development benign mixed tumors have also beenreported.The parotid gland is the most common site for all types of tumors as reported. About 65-80% lesions arise within the parotid; 10% in the submandibular gland and remainder in minor salivary glands.(6)The incidence of malignancy is the highest for the tumor of sublingual glands amongst the minor salivary glands.(7)The most

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common malignant in tumor minor salivary gland is adenoid cystic carcinoma.Salivary gland tumors of various types have been described arising from lymph nodes located in or around major salivary glands, presumably on basis of ectopic salivary tissue.[8] In India, benign tumors were encountered mainly between ages of 7 to 76 years and the greatest incidence is in the 3rd and 4th decade.[7]In malignant tumors also age spectrum is wide; but in general they appear in late age, with mean age varying between 42 to 55 years.[8]Most series of cases show preponderance for females especially if only parotid glands are considered.The commonest symptom is a painless slow growing lump with no functional disability. The duration varies from few months to many years. Other symptoms as pain, facial palsy, and sudden increase in size are infrequent and indicate that tumor has assumed an invasivecharacter.[9]If the tumor is immobile, located deep in the parotid, or its relation to adjacent structures is in question, then certain diagnostic studies may be of value, such as:Plain X-rayfilm, Sialography, Ultrasonography, CT scan and M.R.I.

It develops as an outgrowth of buccal epithelium, which latter on canalize and branches repeatedly to form ductal- acinar system. The epithelial buds that form parotid and submandibular gland appear during 6th week of embryonic life and those for the Sublingual glands appear during 7th to 8thweek.[10,11]

ANATOMY AND HISTOLOGY

There are two groups:[5,12]

I. Major salivary glands whichinclude
a) Parotid gland
b) Submaxillary gland/ submandibulargland
c) Sublingualgland

II. Minor salivary tissue in lips, gingival, palates, tongue and tonsillarareas.

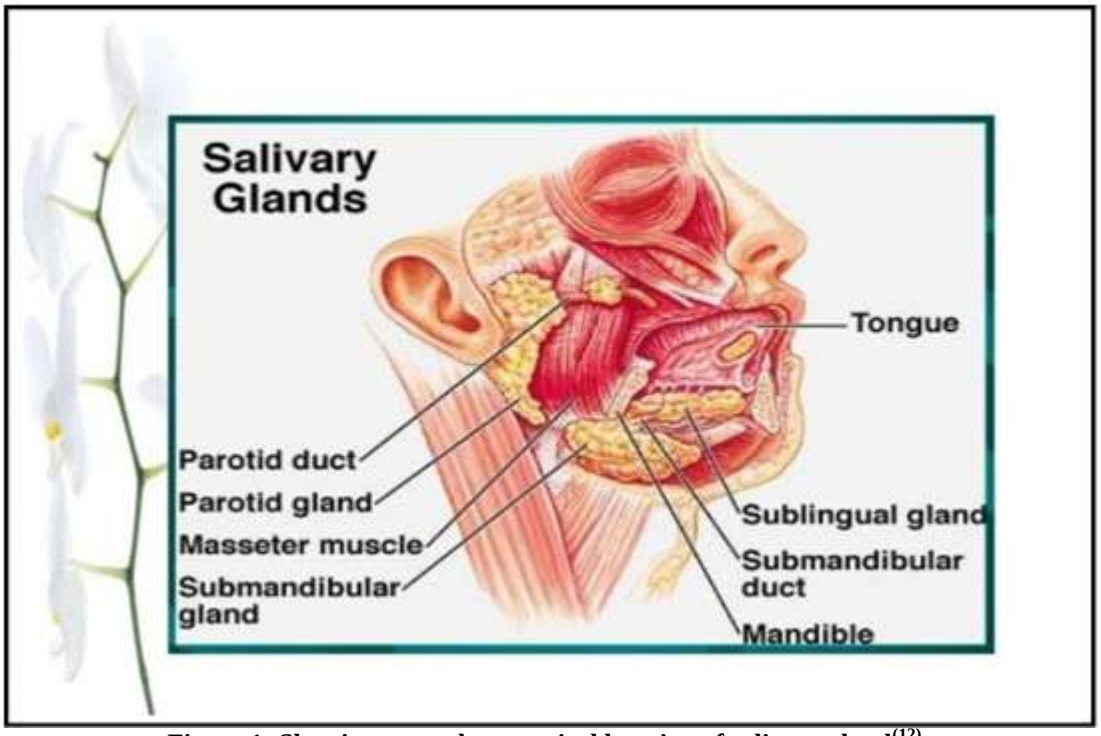


**Figure 1: Showing normal anatomical location of salivary gland[12]**

CYTOMORPHOLOGY OF SALIVARY GLAND TUMORS:[13,14,15]

Normal Salivary Gland:

Smears from normal and near normal glands are usually scanty, heavy admixture with blood is frequent. The acinar cells form cohesive tissue fragments.Serous acinar cells have abundant, finely vacuolated cytoplasm, a small round dark nucleus towards the base of the cell and a small nucleolus. Acini contains mucous secreting cellsalso.Ductal cells are less plentiful, they form small cohesive flat sheets or tubules. The cells are smaller, the cytoplasm is dense, sometimes squamoid with round to oval nucleus.Oncocytic cells with granular, markedly eosinophilic cytoplasm and round nuclei are found in ducts and acini.Myoepithelial cells with elongated nuclei are also seen. They appearto be involved with

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histogenesis of pleomorphic adenoma.

**Material and Method**

This study comprises patients of salivary glands lesions. The FNAC was carried out at our tertiary care hospital during the period from 2017- 2021. Cases were correlated histopathologically.The aspiration was carried out on patients admitted in ENT ward and Surgical Wards, Guru Gobind Hospital, Jamnagar without local anesthesia.

**EQUIPMENTS OF FNAC:[16,17]**

- Syringe : 5ml disposable plasticsyringe
- Needles: 22 to 23 gauge disposable needle with outer diameter of 0.6 to 0.8mm and length varying from 2.54 to 3.8cm
- Cleaned microscopic glass slides, 76*26mm for preparing the smear
- Coverslips
- Fixation consisting of ether and alcohol mixture in equal proportion
- Cotton gauzepieces
- Spiritswabs
- Test tubes for collection of fluids if on aspiration, fluid was obtained.

**PROCEDURE:[16,17]**

**Aspiration technique:**

- Explanation of procedure to the patient, with onset of it. All asepticprecaution weretaken.
- Check the potency of syringe andneedle.
- With one hand fix the lesion and with other hand pierce the lesionwith needletip.
- Apply negative pressure by pulling plunger and move needle backandforward.
- Once material is inside the hub, release negativepressure.
- Prepare slides from aspiratedmaterial.

**Needle biopsy without aspiration:**In this technique, needle is inserted and is moved back and forward in various direction without applying negative pressure.

**Advantage:** Admixture of blood is less.Whenever fluid was aspirated, it was centrifuged and sediment used for preparing smears and subsequently fixed andstained.

**Fixation and staining:**Smear is fixed in absolute alcohol which is followed by staining with haematoxylin and eosin or MGG and PAP stain.

**For histological specimens:**Paraffin embedded tissue sections obtained from salivary gland tissue were stained with haematoxylin and eosin and few special stains were performed whenever required.

## II. OBSERVATION AND RESULTS

Total 100 patients in whom aspirations from salivary gland lesions were performed. In 96 cases satisfactory material was obtained. 4 cases were with inadequate material. 52 Cases were followed up as biopsy was available for correlation. 21 Cases of acute or chronic inflammatory lesions resolved after proper antibiotic therapy. So surgical removal was not required.

So, total 52 cases were histologically correlated.

**TABLE – 1**
**INCIDENCE AND DISTRIBUTION OF CASES**
**(According to Milan Reporting system)**

| Category no. | Diagnostic Category | No.of Cases |
|---|---|---|
| 1. | NON- DIAGNOSIC | 04 |
| 2. | NON NEOPLASTIC | 31 |
| 3. | ATYPIA OF UNDETERMINED SIGNIFICANCE | 07 |
| 4. | NEOPLASM | 50 |
| 5. | SUSPICIOUS FOR MALIGNANCY | 01 |

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| | | |
|---|---|---|
| 6. | MALIGNANT | 07 |
| | TOTAL | 100 |

**TABLE – 2:SITE AND INCIDENCE OF SALIVARY GLANDLESIONS**

| Category no. | Diagnostic Category | Parotid | Submandi-bular | Minor glands | Total |
|---|---|---|---|---|---|
| **1.** | **Non Diagnostic** | 02 | 02 | 00 | 04 |
| **2.** | **Non -Neoplastic** | | | | |
| | Acute Sialadenitis | 01 | 05 | 00 | 06 |
| | Chronic Sialadenitis | 06 | 09 | 00 | 15 |
| | Granulomatous Sialadenitis | 07 | 03 | 00 | 10 |
| **3.** | **Atypia of Undetermined Significance** | | | | |
| | Mucous Retention Cyst | 02 | 00 | 01 | 03 |
| | Chronic Sialadenitis with oncocytic metaplasia | 01 | 00 | 00 | 01 |
| | ?Chronic Sialadenitis ?Warthin'stumour | 03 | 00 | 00 | 00 |
| **4.** | **Neoplasm** | | | | |
| | **1).Benign** | | | | |
| | Pleomorphic Adenoma | 34 | 03 | 01 | 38 |
| | Warthin's tumour | 08 | 02 | 00 | 10 |
| | Oncocytoma | 01 | 00 | 00 | 01 |
| | **2).Salivary Gland Neoplasm of Uncertain Malignant Potential ( SUMP)** | | | | |

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| | | | | | |
|---|---|---|---|---|---|
| | Cellular Pleomorphic Adenoma | 01 | 00 | 00 | 01 |
| **5.** | **Suspicious for Malignancy** | 01 | 00 | 00 | 01 |
| **6.** | **Malignanant** | | | | |
| | Myoepithelial Carcinoma | 01 | 00 | 00 | 01 |
| | Mucoepidermoid Carcinoma | 01 | 01 | 00 | 02 |
| | Adenoid Cystic Carcinoma | 01 | 00 | 01 | 02 |
| | Metastatic tumours | 01 | 01 | 00 | 02 |
| | **Total** | **71** | **26** | **03** | **100** |

From the above table, it is evident that parotid gland was the commonest gland involved (71%) followed by Submandibular (26%) and minor salivaryglands(03%).

**TABLE – 3**
**CYTODIAGNOSIS AND ITS CORRELATION WITH HISTOPATHOLOGICAL DIAGNOSIS**

| **Category no.** | **CYTODIAGNOSIS** | **TOTALNO OFCASES** | **NO OFCASES** | **COMPATIBLE** | **PARTI-COMPA-TIBLE ALLY** | **INCOMPA- TIBLE** |
|---|---|---|---|---|---|---|
| 1 | Non Diagnostic | **04** | **00** | **00** | **00** | **00** |
| 2 | Non Neoplastic | **31** | **10 (21**)** | **10** | **00** | **00** |
| 3 | Atypia of undetermined signifance | **07** | **05 (02*)** | **03** | **01** | **01** |

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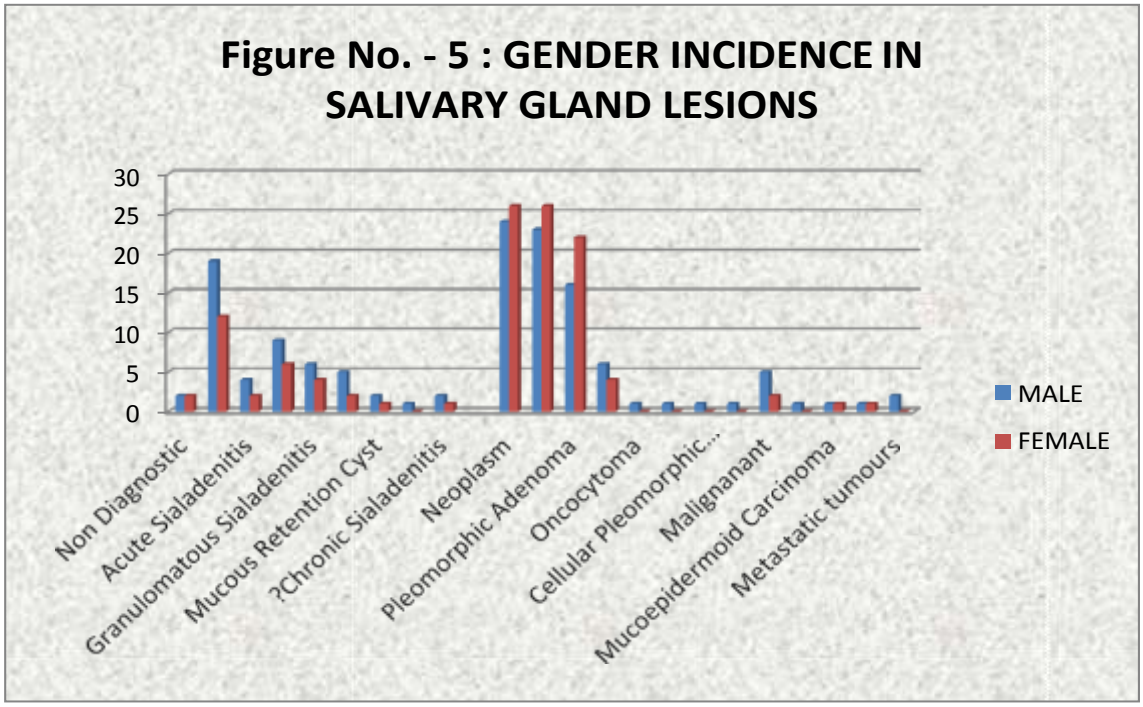
| | | | | | | |
|---|---|---|---|---|---|---|
| 4 | neoplasm | **50** | **30 (20*)** | **28** | **00** | **02** |
| 5 | Suspicious for malignancy | **01** | **01** | **01** | **00** | **00** |
| 6 | Malignant | **07** | **06 (01*)** | **04** | **01** | **01** |
| | **Total** | **100** | **52** | **46** | **02** | **04** |

23*Biopsy was not available
21**Cases of Non neoplastic category (Acute and chronic inflammatory conditions) resolved after proper antibiotic therapy without surgical interference.

**TABLE - 4**
**GENDERINCIDENCE IN SALIVARY GLAND LESION**




From above table, males have slight predominance than females in salivary gland lesions (1.2:1), but in cases of pleomorphic adenoma, female preponderance was observed.

**The results were classified as follows:**

- **Correct diagnosis (compatible):** discussion of alternative diagnosisis notfollowed.
- **Discussion Diagnosis (Partially Compatible):** Suggested diagnosis may be partially correct regarding benign and malignant nature. But lesion is not otherwisespecified.
- **Incorrect Diagnosis (Incompatible):** Implies a false positive or false negative report regarding malignancy or totally misleading report about the true nature of aspiratedlesion.
- **Unsatisfactory Specimen:** No conclusive reading is possible or non- representative material.

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## III. PLAN OF DATA ANALYSIS:

True positivity was considered when the lesion was found to be malignant on both FNAC and evaluation of post-surgical specimen. False positive were those cases wherein cytology was reported as malignant but on evaluation histopathologically the lesion turned out to be of benign nature. True negative (TN) were benign on both cytology and histopathology. False negative (FN) were negative on cytology but positive for malignancy on histopathology. Sensitivity was the detection of disease when it was actually present and was a measure of detection of thyroid cancer by FNAC in our study. Similarly specificity was defined by the ability of FNAC to exclude malignancy, that is diagnose benign lesions. Diagnostic accuracy was calculated by using sensitivity and specificity.

## IV. DISCUSSION

The present study was a study of total 100 cases of salivary gland lesions between period from 2017 to 2021 were studied by FNAC and reported with Milan System of reporting in our institute. FNAC study was followed by histopathological examination for confirmation.

Manish Rohilla et al(2017), Veer Karuna et al(2019)MalathiMukundapai et al(2020), JF Val Bernal et al(2020) studied salivary gland lesions by fine needle aspiration cytology and categorised lesions according to Milan Reporting system. Histopathological correlation was done in all

**TABLE – 5**
**COMPARISON OF MAJOR STUDIES OF FNAC AND HISTOPATHOLOGY**

| Authors | Years | No. of cases | Sensitivity (%) | Specificity (%) | Diagnostic Accuracy (%) |
|---|---|---|---|---|---|
| M. Mukundapai et al[61] | 2020 | 253 | 86.76% | 93.75 | 89% |
| RohillaM et al[62] | 2017 | 631 | 79.4% | 98.3% | 91.4% |
| JF Val-Bernal et al[63] | 2020 | 185 | 88% | 91.8% | 91% |
| Karuna V et al[64] | 2019 | 105 | 85.0 | 98.14% | 94.59% |
| Present study | 2021 | 100 | 87.5% | 93.33% | 88.46% |

As shown in Table No.12 in the present study sensitivity, specificity and diagnostic accuracy was 87.5%, 93.33%, and 88.46 % respectively.
These results correlated with studies of MalathiMukundapai et al(18) and JF Val Bernal et al(19).

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**SITE:**

**TABLE – 6**
**COMPARISON OF FREQUENCY OF LOCATION**

| Study | Total Case | Parotid | Submandibular | Minor |
|---|---|---|---|---|
| K. Viswanathan et al[65] | 627 | 77.99% | 14.51% | 7.49% |
| JaslynJie Lin Lee et al66 | 1384 | 81.3% | 18.4% | 0.3% |
| RohillaM et al[62] | 631 | 61.3% | 35.7% | 3.0% |
| JM. Hollyfield et al[67] | 134 | 89% | 11% | 00% |
| Present study | 100 | 71% | 26% | 3.0% |

In present study parotid gland was the most common site followed by others submandibular, sublingual gland. Similar results were observed in literature[(20,21,22,23)].

**GENDER:**

**TABLE – 7**
**COMPARISON OF SEX DISTRIBUTION**

| Study | Male | Female | M:F ratio |
|---|---|---|---|
| K. Viswanathan et al[65] | 288 | 339 | 1:1.2 |
| JaslynJie Lin Lee et al[66] | 834 | 550 | 1.8:1 |
| RohillaM et al[62] | 420 | 211 | 1.7:1 |
| JM. Hollyfield et al[67] | 90 | 44 | 1.1:1 |
| Present study | 56 | 44 | 1.2:1 |

In present study, male preponderance was observed which correlates with the literature JM. Hollyfield et al[(23)].

**AGE:**

**TABLE – 8**
**COMPARISON OF AGE DISTRIBUTION**

| Study | Age group (yrs) | Peak Incidence (mean age) |
|---|---|---|
| K. Viswanathan et al[65] | 13-100 | 57.9 |
| JaslynJie Lin Lee et al[66] | 05-96 | 53.39 |

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| | | |
|---|---|---|
| RohillaM et al[62] | 1-95 | 43.7 |
| JM. Hollyfield et al[67] | 6-89 | 58.3 |
| Present study | 5-80 | 40.3 |

In present study I included all age groups. Age of patients varied from 5 years to 80 years. Most of all lesions were common between 20-50 years of age with mean age of 40.3. This results correlated with study Rohilla M et al[(22)]

**TABLE – 9**
**CPMPARISON OF INCIDENCE AND DISTRIBUTION OF CACES ACCORDING TO MILAN REPORTIING CATEGORY**

| **Study** | **MILAN I** | **MILAN II** | **MILAN III** | **MILAN IV** | **MILAN V** | **MILAN VI** |
|---|---|---|---|---|---|---|
| K.Viswanathan et al[65] | 12% | 28.5% | 6.1% | 41.3% | 2.7% | 9.4% |
| Jaslyn Jie Lin Lee et al[66] | 28.9% | 18% | 9.8% | 43.5% | 1.6% | 3.2% |
| JM. Hollyfieldetal[67] | 15% | 23% | 15% | 38% | 02% | 11% |
| Dorinda Mullen et al[68] | 15.62% | 16.14% | 0.5% | 52.60% | 1.56% | 13.54% |
| Present study | 04% | 31% | 07% | 50% | 01% | 07% |

As shown in Table No.16 in the present study, there were 31% cases of Milan category II which correlates with study K. Viswanathan et al[(20)].There were 07% cases of Milan category III and 50% cases of Milan category IV which correlates with studies JaslynJie Lin Lee et al[(21)] and Dorinda Mullen et al[(24).] There were 01% cases of Milan category V and 07% cases of Milan category VI, which correlates with studies Dorinda Mullen et al[(24)] and K. Viswanathan et al[(20)].

**TABLE – 10**
**CPMPARISON OF MALIGNANCY RATE ACCORDING TO MILAN REPORTING CATEGORY**

| **Study** | **MILAN I** | **MILAN II** | **MILAN III** | **MILAN IV** | **MILAN V** | **MILAN VI** |
|---|---|---|---|---|---|---|

| | | | | | | |
|---|---|---|---|---|---|---|
| K.Viswanathan et al[65] | 6.7% | 7.1% | 38.9% | 39.2% | 92.9% | 92.3% |
| Jaslyn Jie Lin Lee et al[66] | 10% | 17.5% | 29.5% | 17.6% | 83.3% | 100% |
| JM. Hollyfield et al[67] | 38% | 17% | 33% | 37% | 67% | 100% |
| Rohilla M et al62 | - | 17.4% | 100% | 57.3% | 96% | 96% |
| Present study | - | 00% | 20% | 6.66% | 100% | 100% |

As shown in Table No. 17, malignancy rate for category III,V and VI were 20%, 100%, and 100% respectively, which correlates with studies JaslynJie Lin Lee et al(21), JM. Hollyfield et al(23) and Rohilla M etal(22)

## V. CONCLUSION:

FNACis reliable, cost effective, rapid and Histopathology is an accurate diagnostic procedure for salivary gland lesions. FNAC can be used as rapid preoperative diagnosis, as a good diagnostic hint and adjunct to histopathological diagnosis. The process of histopathological techniques has to pass through variousstеps, carrying errors with each step while in FNACerror is minimum as having few steps though diagnosis of histopathology is almost alwaysconfirmatory. The establishment of a "Milan System for Reporting salivary gland Cytopathology" represents an essential step towards improving the overall effectiveness of salivary gland FNAC through organizing diagnostic information in to a uniform& prognostic reporting terminology that leads to improvedpatient care. "Milan System for Reporting Salivary Gland cytopathology" correlates diagnostic categories with ROM(risk of malignancy) and clinical management strategies which helps in improvedpatient care. Application of Milan reporting system has immense value for standardization of reporting of salivary gland FNAC. It has provided acommon language of cytology reporting which is the foundation for a robust diagnostic services and facilitates rigorousauditandevaluationofdiagnosticperforma nces. The Milan reporting system has provided an international language and a basis for comparison and audit, which enable a greater collective understanding of the application of a rational risk stratification process that in turn informs evidence based management guidelines in salivary gland aspiration cytology.

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