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# Application of Probabilistic Approach in Reporting Breast Lesions on Fine Needle Aspiration Cytology: Institutional Study

Ankit Singh<sup>1</sup>, Amit Kumar Nirmal<sup>2</sup>, Vidushi Mishra<sup>3</sup>, Jay Kant Jha<sup>4</sup>

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## ABSTRACT

**Introduction:** Cancer of breast is among the most common cancer throughout the world. In Indian women rising incidence of breast cancer remains to concern. Due to lack of health awareness and limited breast cancer screening program the majority of these patients are diagnosed at relatively advanced stages. The FNAC becomes first choice of clinicians for the diagnosis of breast lump.

**Aim:** Present study is aimed to apply probabilistic approach in reporting breast lesions on Fine Needle Aspiration Cytology, its correlation and accuracy study.

**Materials and Method:** This was prospective crosssectional study of 188 consecutive patients having palpable breast lump at our institute from period July 2016 to March 2017. FNAC of breast lesions were categorized and histologic correlation was done wherever possible.

**Results:** The total of 188 patients FNAC was evaluated and correlation with histopathology was done in 109 cases. The cases were categorized depending on the cytomorphological features into 1-6 categories scheme proposed by Wang and Ducatman as positive, suspicious, proliferative with atypia, proliferative without atypia, unremarkable and unsatisfactory. The probability of finding carcinoma on histopathology for: Positive for carcinoma, suspicious for carcinoma, epithelial proliferative lesion with atypia, epithelial proliferative lesion without atypia, unremarkable and unsatisfactory were, 100%, 100%, 63.6%, 2.6%, 0% and 0% respectively.

**Conclusion:** FNAC is widely adopted method for diagnosing breast malignancies. Clinical, imaging and cytopathology examination gives accurate diagnosis of breast carcinoma. The probabilistic approach is easy to apply, uniform method and gives accurate diagnosis in reporting of breast FNAC.

**Keywords:** *Cytomorphological breast, Cytological features, Diagnosis of breast lump*

## INTRODUCTION

For rapid diagnosing of breast lump FNAC act as ideal initial diagnostic modality. It is simple safe cost effective and gives rapid reports, so in preoperative as-

essment of breast masses, the FNAC has become most popular and immensely popular diagnostic procedure. It shows high accuracy, sensitivity and specificity.<sup>1,2</sup> The sensitivity of FNAC in diagnosis of breast lesion is 90-95%.<sup>3</sup> In various conditions such as hypocellular aspirate, overlapping between benign and malignant lesions like low grade tubular carcinoma, atypical hyperplasia, low grade carcinoma, carcinoma-in-situ, papillary lesions etc., the interpretation is difficult. So many authorities recognized this limitation in finding breast pathology and advised to use probabilistic approach to categorize breast lesions to minimize false negative

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and false positive results in reporting of breast FNAC.<sup>4,6</sup> This categorization will help both the cytopathologists and clinicians.

## MATERIAL AND METHOD

This study was a prospective cross-sectional study carried out in the Department of Pathology, Saraswathi Institute of Medical Sciences and associated Hospital, Hapur, over a period of 9 months from July 2016 to March 2017. Total 188 patients with palpable breast lump were examined. FNAC was done after taking a written consent from patient. FNAC was performed by pathologist under aseptic condition, using disposable 10ml plastic syringe with 22-23 gauge needles. Smears were stained using Giemsa, Papanicolaou and Haematoxylin and Eosin stain. The histopathological examination of surgically excised breast specimens was done using Haematoxylin and Eosin stain. Immunohistochemistry study for ER, PR and HER-2 neu was done on malignant specimens. Cases according to sex, age, site, multicentricity, bilaterality were tabulated. Out of total 188 FNAC cases 109 were correlated with histopathological reports. Of the remaining 79 cases, which were from inflammatory etiology like mastitis, abscess were medically treated and responded and hence, surgical excision was not done. Also some cases from category of epithelial proliferative lesion without atypia were lost to follow-up. The standard protocol was prepared for each patient for breast pathology reporting.

The FNAC smears were categorized into following criteria.<sup>4,5,6</sup>

1) Positive for carcinoma - all four of the following criteria must be met.

a) Cellular dyshesion refers to presence of abundant single epithelial cells or loosely cohesive groups of epithelial cells (this excludes singly bare bipolar cells and stromal cells).

b) Cytologic atypia may be variable but should at least include high nuclear: cytoplasmic ratio and markedly eccentrically located nuclei. Other useful feature which may or may not be present depending on the level of pleomorphism, include nuclear membrane irregularity, coarse and clumped chromatin, multiple and irregular nucleoli.

c) One cell population refers to one population of atypical epithelial cells, as opposed to mix population of

atypical and benign appearing epithelial cells or atypical epithelial cells and stromal cells.

d) Hyper cellularity refers to atypical cell population only, rather than increased cellularity due to another component such as inflammatory or stromal cells.

2) Suspicious for carcinoma-When any three of the above features for malignancy are present, a suspicious diagnosis is given.

3) Epithelial proliferative lesion (EPL) with atypia- This diagnosis is made when specimen is cellular with many epithelial cells and when epithelial cells present in groups show significant crowding and overlapping and/or specimen show one other feature of malignancy (cellular dyshesion, one cell population, cellular atypia).

4) Epithelial proliferative lesion (EPL) without atypia- This category is used when a specimen is cellular with many epithelial cells and epithelial cells in group show no or mild crowding and overlapping with, obvious myoepithelial cells present. Most fibroadenoma tends to fall in this category.

5) Unremarkable- When none of the four features of carcinoma was present, such lesions were described as unremarkable.

6) Non diagnostic/unsatisfactory- If specimen is acellular or extremely hypo cellular and when it does not yield an explanation of lesion based on information provided by clinician, it was reported as unsatisfactory.

Cyto-histological correlation was done in each category. The cytological pictures are given in

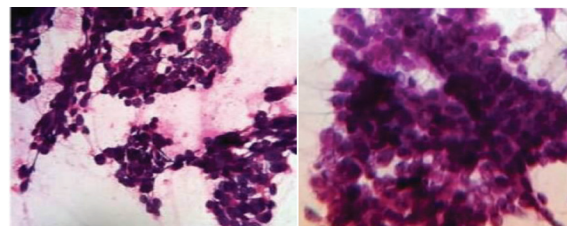


Fig 1

Fig 2

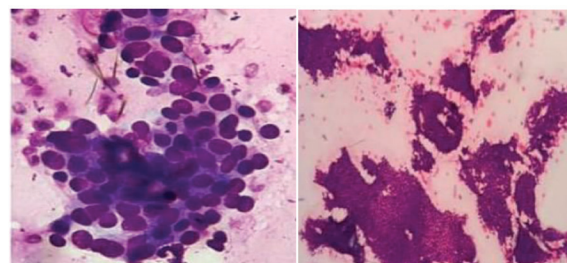


Fig 3

Fig 4

Fig-1: Photomicrograph showing loosely cohesive group of malignant epithelial cells. There is marked nuclear pleomorphism with hyperchromatic nuclei. Positive for carcinoma (H&E stain 400X)

Fig-2: Photomicrograph showing hypercellular smears with atypia, high N/C ratio and pleomorphic nuclei with occasional nucleoli. (H&E stain, 400X)

Fig-3: Photomicrograph showing ductal epithelial cells in cluster. There is mild overcrowding and overlapping of nuclei and some amount of nuclear atypia-EPL with atypia (H&E stain, X400)

Fig-4: Photomicrograph showing bimodal population of ductal epithelial and myoepithelial cells in large clusters without atypia, suggestive of fibroadenoma. (H&E stain, 100x)

### RESULTS

Out of total 188 patients, 186 (99%) were females and only 2 (1%) were male. 96 (51%) cases complained lump on left side, 90 (48%) felt lump on right side and 2 (1%) patients had lump bilaterally. Youngest patient was of 16 years of age and oldest was 82 years of age. Maximum number of patients were 52 (27.8%) from age group of 41-50 years, followed by 42 (22.3%) from age group of 31-40 years. Least number of patient were 4 (2.1%) from category of >70 years group. According to the diagnosis on FNAC, maximum number of patients 84 (44.6%) were put under category of EPL without atypia, followed by 47 (25%) in category of Positive for carcinoma. Eight patients (4.5%) were diagnosed under category of suspicious for carcinoma whereas, 11 patients (5.8%) were diagnosed to have EPL with atypia. Rest were either unremarkable or unsatisfactory. Out of 188 cases we received 109 specimens were available for histopathology evaluation as modified radical mastectomy, toilet mastectomy or lumpectomy. Out of these 109 cases, maximum number of specimen 42 were from category of positive for carcinoma followed by 39 specimen from category of EPL without atypia. When applied probabilistic approach to find carcinoma in each category we found 100% probability of finding carcinoma

in; Positive for carcinoma and suspicious for carcinoma category. While 63.6% and 2.6% probability was found in EPL with atypia and EPL without atypia respectively. And no case was found positive in unremarkable and unsatisfactory category. There was no false positive case.

**Table 1: Showing distribution of cases according to sex**

Sex	Frequency	Percentage (%)
Male	02	01
Female	186	99
<b>Total</b>	<b>188</b>	<b>100</b>

**Table 2: Showing distribution of cases according to site**

Location	Frequency	Percentage (%)
Left	96	51
Right	90	48
Bilateral	02	1
<b>Total</b>	<b>188</b>	<b>100</b>

**Table 3: Showing distribution of cases according to age**

Age Group (years)	Frequency	Percentage (%)
11-20	12	6.4
21-30	39	20.7
31-40	42	22.3
41-50	52	27.8
51-60	29	15.4
61-70	10	5.3
>70	04	2.1
<b>Total</b>	<b>188</b>	<b>100</b>

**Table 4: Showing Probability of finding carcinoma in 1-6 categories of cytology**

Apply probabilistic approach between FNAC diagnosis and finding carcinoma on histology in each of six cytology categories					
Cytology diagnosis	Histology Diagnosis			Total	Probability of finding carcinoma (%)
	Positive	DCIS	Benign		
Positive for carcinoma	42	00	00	42	100
Suspicious for carcinoma	08	00	00	08	100
EPL with atypia	07	00	04	11	63.6
EPL without atypia	00	01	38	39	2.6
Unremarkable	00	00	07	07	0
Unsatisfactory	00	00	02	02	0

EPL=epithelial proliferative lesion, DCIS=ductal carcinoma in situ

## DISCUSSION

The breast carcinoma incidence is continuously on the rise. So in breast lump patient it is essential to establish correct diagnostic procedures, staging of the disease and to detect it in early period. Now a day's clinical examination of breast lump, mammography with FNAC is considered as widely accepted approach for diagnosis of breast lesions. Various studies in literature showed the sensitivity of FNAC in diagnosis of breast lesion is 90-95%.<sup>7,8</sup> If there is no disagreement on triple diagnosis, the clinician can give definite treatment based on cytological diagnosis without histopathological confirmation.<sup>9</sup> Therefore a uniform terminology and reporting system with high reproducibility should be used in breast FNAC reporting. Various criteria are recommended for classification of breast FNAC. National cancer Institute Conference 1996 recommends 5 categories as benign, atypical, suspicious, malignant and unsatisfactory.<sup>10</sup> Wang and Ducatman<sup>4</sup>, Ayata G et al.<sup>5</sup>, criteria was used in our study to categorize breast cytomorphological features as these are reproducible, reduces subjectivity and useful for quality control procedures.<sup>11</sup>

In our study all lesions from cytologically diagnosed as positive for carcinoma category were malignant on histopathological report, thus showing 100% sensitivity and 100% accuracy. Similar findings were noted by Rupam T U et al.<sup>12</sup> The probability of finding carcinoma on histopathology for suspicious for carcinoma category was 100%. For epithelial proliferative lesion with atyp-

ia probability was 63.6%. In this category there were 7 cases out of 11 which came out to be positive for carcinoma. Two cases out of 7 were lobular carcinoma, three were papillary carcinoma, one was DCIS with micro invasive foci, one was adenoid cystic carcinoma. It shows that cytological atypical features are clinically significant which rises possibility of breast cancer.<sup>4,13</sup> FNAC of lobular hyperplasia and invasive lobular carcinoma is associated with high rate of false negative and equivocal diagnosis.<sup>14</sup> The percentage of lesion of suspicious for carcinoma on cytology with malignant on histopathology were 84% in study of Ayata G et al.,<sup>5</sup> 93% by Wang H et al.,<sup>4</sup> represent a brief comparison between the histological finding compared to other similar studies. This study showed 97.4% accuracy in lesion of epithelial proliferative lesion without atypia. One case out of 39 cases in his category was found to be DCIS. In unremarkable/ unsatisfactory categories correlation was 100%. No positive case for carcinoma was detected in these two categories on histopathology. Out of 10 cases of unsatisfactory smears, 2 specimens were available for histopathological correlation, 1 showed fibroadenoma and 1 showed benign phyllodes tumor. Whereas out of 28 cases of unremarkable, 7 were available for histopathological correlation, 2 were gynaecomastia, 3 were mastitis and 2 came out to be fibroadenoma. The study by Panjvani S et al.,<sup>15</sup> Pandya A et al.,<sup>16</sup> were correlated with our study. In the category of epithelial proliferative lesion with atypia remains the gray zone due to overlapping features on benign epithelial proliferative lesions

mainly fibroadenoma and low grade well differentiated carcinoma.<sup>3,17</sup> Also cases of sclerosis adenosis, tubular adenoma/carcinoma, proliferative fibrocystic diseases of breast etc should be properly looked for any evidence of malignant change. When uncertainty about diagnosis in such cases is noted, it has to be evaluated further by core biopsy, frozen section and histopathological study.

### CONCLUSION

Application of probabilistic approach is easy to apply, accurate and uniform to categorize the breast lesions for FNAC reporting. This scheme of definite criteria for reporting FNA results according to the probability of diagnosing breast carcinoma provides a rational basis to guide in management of cases.

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**Conflict of Interest**- None

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# Study of Exfoliative Cytology of Ascetic Fluid in the Diagnosis of Abdominal Tuberculosis in Chhattisgarh Population of Both Sexes

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## ABSTRACT

45 male and female aged between 20 to 60 having the symptoms of TB were selected for the study and their cytological study of AF was done to rule out abdomen TB. Appearance of AF in male patients was reddish 2 (44%), transparent 5(11.1%), (cobweb formation 8(17.7%), straw and cloudy 30(66.6%), in female Reddish 3(6.6%), transparent 6(13.3%) (cobweb formation 10(22.2%), straw and cloudy 26(57.7%). In the cytomorphological study of AF Histolytes were 2(4.4%), mesothelial (occasional ) 8(17.7%), mixed inflammatory cell 6(13.3%), predominantly lymphocytes 11(24.4%) good cellularity 18(40%)

In females histocytes were 3(6.6%) mesothelial (occasional ) 6(13.3%) mixed inflammatory cells 5(11.1%) predominantly lymphocytes 10(22.2%) good clarity 21(45.6%) culture and staining of AF in males positive AFB was 5(11.1%) 2-in staining of AF positive result was 9(20%) and in females 7(15%) presence of good cellularity and absence of mesothelial cells and predominant lymphocyte is constant findings in TB of abdomen this study will certainly help the clinician and pathologist also to rule out the TB with various rare clinical presentations

**Keywords** – AF = Ascetic fluid, TB = tuberculosis Bacilli z-n = Ziehl – Nelson, cytology.

## INTRODUCTION

Abdomen tuberculosis peritonitis and abdomen remains a diagnostic challenge for clinicians. AS tuberculosis (TB) remains a public challenge worldwide <sup>(1)(2)</sup> tuberculous peritonitis and abdomen is one of the most frequent extra pulmonary location of TB the delayed diagnosis of abdomen and TB has been proven as the most important factor for its high mortality <sup>(3)(4)</sup> this high mortality rate in untreated patients warrants for early treatment because in India TB is often co-infected with HIV. <sup>(5)</sup> Emergence of multidrug resistant bacilli and rapid spread of HIV have created total loss of immunity are great challenge to clinician to the control TB Hence attempt is made to study the ascetic fluid with

microscopic identification of AFB and cytological study in the diagnosis TB of abdomen

## MATERIAL AND METHOD

45 males and 45 females aged between 20 to 60 years admitted in the Raipur institute of Raipur 492001 Chhattisgarh The patients belongs to middle socio-economic status. The HIV patients were excluded from the study. The selected patients were taken for study chest x-ray, Routine blood examination was also done. AFB study was also done the ascetic fluid smears were stained with Z-N staining PAP Giemsa. The duration of this study was about two years

## OBSERVATION AND RESULTS

Tables 1 – Appearance of ascetic fluid in both sexes of abdominal both sexed TB in males- reddish AF was 2 (4.4%) and transparent was 5(11.1%) cob web formation was 8 (17.7%) straw and cloudy was 30 (66.6%). In females Reddish AF was 3(6.6%) transparent 6(13.3%), cobweb formation was 10(22.2%), straw and cloudy

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26(57.7%)

Tables-2 cytomorphological study of AF in both sexes.

In males histocytes 2(4.4%) mesothelial (occasional) 8 (17.7%) mixed inflammatory cell 6(13.3%), predominantly lymphocyte 11(24.4%), good cellularity 18(40%). In females histocytes 3(6.6%) Mesothelial cells (occasional) 6(13.3%), mixed inflammatory cells

5(11.1%), predominantly lymphocytes 10(22.2%) good cellularity 21.(46.6%)

Table 3- study of culture and staining of AF in Both sexes. In males culture of AFB – positive 5(11.11) and negative 40(88.8%) Z-N staining of AF – Positive 9(20%) and –ve 36(80%)

In females – culture of AFB of AF positive 4(8.8%) negative 41(91.11%) Z-N staining of AF positive 7(15%) and negative 3.8(84.4%)

**Tables-1: Appearance of ascetic fluid in both sexes**

Colour of the blood	No of male (45)	Percentage (%)	No of females (45)	Percentage (%)
Reddish	2	4.4	3	6.6
Transparent	5	11.1	6	13.3
Cob web formation	8	17.7	10	22.2
Straw and cloudy	30	66.6	26	57.7

**Table – 2: Cytomorphological study of AF in both sexes**

Cytological type	No of males 45	Percentage (%)	No of females 45	Percentage (%)
Histocytes	2	4.4	3	6.6
Mesothelial (occasional) cells	8	17.7	6	13.3
Mixed in flammatory cells	11	24.4	10	22.2
Predominantly lymphocyte	18	40	21	46.6

(Good clarity = 200 – 1000 cells / mm<sup>3</sup>)

Occasional = less than 5% of total cellulites

**Table -3: Study of Ascietic fluid of culture and stains of in both sexes**

Particulars	No of males 45		Percentage (%)		No of females 45		Percentage (%)	
	+ ve	-ve	+ve	-ve	+ve	-ve	+ve	-ve
Culture of AFB of Ascietic fluid	5	40	11.1	88.8	4	41	8.8	91.11
Z-N staining of Ascietic fluid	9	36	20	80	7	38	15	84.4

## DISCUSSION

In the present study of cytology of AF in the diagnosis of abdominal TB in Chhattisgarh population of both sexes

The appearance of AF in males – reddish 2(4.4%) transparent 5(11.1%) cob web formation 8(17.7%) straw and cloudy 30 (66.6%) in females reddish 3(6.6%) transparent 6(13.3%) cob web formation 10(22.2%) straw and cloudy 26(57.7%) (table – 1)

In this cyto morphological study of AF in both sexes in males Histocytes 2(4.4%) mesothelial (occasional) 8 (17.7%) mixed inflammatory cells 6(13.3%), predominantly lymphocytes 11(24.4%) good cellularity 18(40%). In females histocytes 3(6.6%) mesothelial cells (occasionally) 6(13.3%) mixed inflammatory cells 5(11.1%) predominantly lymphocytes 10(22.2%) good cellularity 21.(46.6%) in the study of culture and staining of AF in both sexes in males culture AFB positive 5(11.1) negative 40(88.8%)

Z – N staining of AF was positive 9(20%) negative 36(80%) in females – culture of AFB of AF positive 4(8.8%) negative 41(91.%) Z-N staining of AF positive 7(15%) and negative 38(84.4%)

The peritoneal cavity of abdomen drained by the lymphatic vessels the stomas on the peritoneal surface of the diaphragm have been by due to absorption fibrin plugs and fibrous adhesions may obstruct the these lymphatic vessels especially in the cirrhosis, facilitating ascites. It is due to increased hepatic lymph production, faulty disposal of hormone, salt and water retention and disturbed excretion of these substance appear to be the main cause of ascites. in the peritoneal or abdominal infection ascites develop as a result of irritation. The patient presenting with ascites may be the indicative of non specific inflammation by TB, cirrhosis of liver or renal pathologies or neoplasm. Mountex test has little diagnostic value. In the abdominal tuberculosis, pulmonary TB evidence of chest x-ray in 50% of cases. ELISA, SAFA (soluble antigen fluorescent antibody) provide information about TB but their positivity restricted to 85 – 95% in the abdominal TB but ELISA remain positive even after therapy and reproducibility of Elisa is poor. This Elisa is not in the reach of middle class or poor people due to costly price Hence study of AF is quite useful for diagnosis of TB in this abdominal TB.<sup>(6)</sup> Presence of good cellularity, absence

of mesothelial cells and predominate of lymphocytes is constant and positive findings. Esino philia are not found in a singles case abdominal TB is the commonest cause of ascites.<sup>(7)</sup> TB of abdomen can involve any part of the abdomen (GIT) and is the sixth most frequent site of extra pulmonary involvement. <sup>(8)</sup> It can have varied presentation, frequently mimicking other common and rare diseases. Rare clinical presentation include dysphagia, odynophagia and mid oesophageal ulcer due to oesophageal TB, dyspepsia and gastric outlet obstruction due to gastro duodenal TB, lower abdominal pain and haematochezia due to colonic TB and annular rectal stricture and multiple perianal fistulae due to rectal and anal TB <sup>(9)</sup> hence efficiency of cytological study of AF was quite helpful <sup>(10)</sup>

## SUMMARY AND CONCLUSION

The present study of explorative cytology of AF in the diagnosis abdominal TB in Chhattisgarh population of both sexes is quite useful to clinician to diagnose the TB of abdomen because it present rare clinical symptoms, moreover it is associated HIV infections but this demands further histo- pathological and bio-mechanical study at micro cellular level because exact formation and mechanism of formation of AF is still unclear.

This research paper is approved by ethical committee of R I M S Raipur 492001 Chhattisgarh

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# Effect of Clobazam as Add-On Antiepileptic Drug in Patients with Epilepsy

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## ABSTRACT

**Background & Objectives:** The use of clobazam in epilepsy has increased since its introduction in 1975. However, it has not been audited for its overall usefulness in Indian set up. The present study was aimed to evaluate usage pattern, retention rate, effectiveness and tolerability of clobazam during routine practice in an outpatient epilepsy clinic of a tertiary care hospital in Hapur region, Uttar Pradesh, India.

**Method:** This study was performed on the patients prescribed antiepileptic medication who had clobazam as last added drug in their treatment regimen during January 2014 - December 2016. These patients were followed up for two OPD visits. The primary points evaluated were retention rate, percentage of seizure-free patients and reasons for discontinuing clobazam.

**Results:** Of the 417 consecutive patients, 132 (31.7%) were on clobazam treatment for more than four years (median 6 yr, range 4-15 yr). No seizure for previous 12 months was considered as seizure free and was observed in 151 (36.2%) patients. There was no improvement in seizure control in 32 (7.7%) patients. A decrease in seizure severity without any change in seizure frequency was observed in 76 (18.2%) patients. Clobazam was discontinued by 15 (3.6%) patients due to complaints like drowsiness (13), fatigue/tiredness (8), headache (6), poor memory (6), irritable behaviour (5), abdominal pain (3) and dizziness (3).

**Conclusion:** Our results provide valuable information about the clinical use of clobazam as add-on antiepileptic drug therapy in the management of patients with epilepsy.

**Keywords:** Antiepileptic drugs, clobazam, epilepsy, retention rate

## INTRODUCTION

Clobazam (CLB) is in use for almost four decades since its introduction in 1975<sup>1</sup>. Its use has expanded from anxiety to epilepsy including Lennox-Gastaut syndrome (LGS)<sup>2,3</sup>. This broad spectrum antiepileptic prevents recurrence of febrile seizures also<sup>4</sup>. According to a Canadian study, more than 10 per cent treatment refractory patients achieved seizure freedom with

clobazam over a period of seven years. Despite being a benzodiazepine, clobazam has lower sedative effects<sup>5,6</sup>.

Efficacy and safety of a drug are established through rigorous randomized controlled trials. However, audits in clinical practice compliment the information derived from these trials<sup>7</sup>. Audits also take into consideration the ethnic variations which especially play an important role in the pharmacotherapy of epilepsy<sup>8,9</sup>. Though studies in Indian population have demonstrated the efficacy of CLB as mono therapy in adult patients<sup>10</sup> and in refractory childhood epilepsy<sup>11</sup>, data regarding the usage pattern, efficacy and safety of clobazam in different treatment regimens are limited. Hence, in the present study, patients with epilepsy (PWE) prescribed CLB were assessed for usage pattern, retention rate, drug

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load, outcome in terms of seizure freedom, improvement in seizure severity and discontinuation due to adverse effects in a tertiary healthcare set up in north India.

## MATERIAL & METHOD

The present study was an observational study in which patients were recruited from a consecutive sample of consenting PWE attending the epilepsy clinic in outpatient department (OPD) of Neurology, Saraswathi Institute of Medical Sciences Hapur (U.P) India, between January 2014 - December 2016. Patients of all age and either gender taking CLB were included in the evaluation. CLB was the last antiepileptic drug (AED) added to the regimen for these patients. Patients, for whom another AED was added to the regimen after CLB addition, were excluded from the evaluation.

Exclusion criteria also included patients with symptomatic chronic illness or other co-morbid condition like hypertension, metabolic syndrome, renal disorder, *etc.* which predated epilepsy. Patients who had, during the clinical audit period, a surgical resection were also excluded from the evaluation.

Data collected at enrolment and used for the patient analysis included gender, age, age at onset of

seizures, type(s) and frequency of seizures, epilepsy characteristics according to the International League Against Epilepsy<sup>12</sup>, details of current AED regimens (including dosages and duration) and concomitant medications. Data were recorded on paper based case report forms and subsequently entered in a computerized coded, allowing cross data sheet checking at any time. Epilepsy characteristics including number of seizures were ascertained from seizure diaries maintained by all patients as these patients were on a regular follow up with the epilepsy clinic.

## RESULTS

A total of 417 patients with epilepsy (male/female: 274/143; aged 3-66 yr, mean 22.1 yr, median 20 yr), on CLB treatment were enrolled. Age at the onset of seizures varied from infancy ( $\leq 1$ yr) to 56 yr (mean 13.1, median 11 yr). The duration of CLB use was 6.5–270 months (mean 13.3, median 18 months). The number of patients with age  $\leq 18$  yr and between 19-40 yr were 184 (44.1%) and 201 (48.2%), respectively. Only 7.7 per cent (32/417) patients were above the age of 40 yr. The detailed characteristics are mentioned in the Table.

**Table. Characteristics of patients in different outcome groups**

	Seizure free	$\geq 50\%$ seizure	$< 50\%$ seizure	No change in
	n (%)	reduction	reduction	seizure frequency
		n (%)	n (%)	n (%)
n (%)	151 (36.2)	158 (37.9)	76 (18.2)	32 (7.7)
Sex, male (%)	98 (23.5)	21 (5.0)	48 (11.5)	107 (25.7)
Age (yr)				
Median	22	19.5	20	13
Range	5-66	4-59	3-50	4.5-36
Age at onset of seizures (yr)				
Median	13	11.5	9	4.5
Range	0-56	0-43	0-45	0-22
Clobazam dose (mg/kg/day)				
Median	0.2	0.3	0.3	0.4
Range	0.04-1.25	0.06-1.03	0.06-1.03	0.11-1.75
Duration of clobazam use (months)				

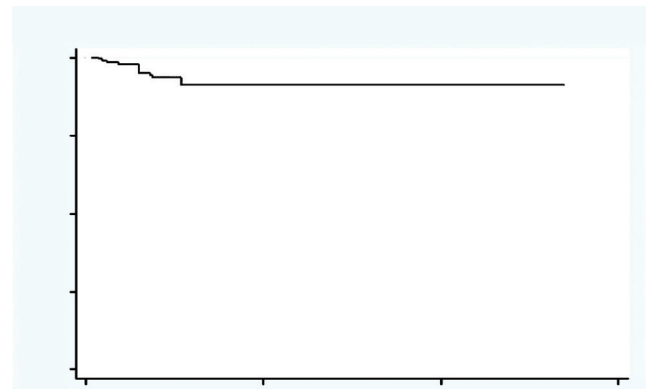
**Cont... Table. Characteristics of patients in different outcome groups**

Median	24	18	18	30
Range	7-270	6.5-186	7-186	7-126
Treatment regimens with clobazam n (%)				
First add-on (n=165)	68 (41.2)	70 (42.4)	27 (16.4)	0 (0)
Second add-on (n=186)	66 (35.5)	69 (37.1)	38 (20.4)	13 (7.0)
Third/fourth add-on (n=66)	17 (25.8)	19 (28.8)	11 (16.7)	19 (28.8)
Frequently used regimens with CLB n (%)				
Phenytoin (n=48)	16 (33.3)	25 (52.1)	7 (14.6)	0 (0)
Carbamazepine (n=47)	20 (42.6)	18 (38.3)	9 (19.1)	0 (0)
Sodium valproate (n=43)	19 (44.2)	16 (37.2)	8 (18.6)	0 (0)
Levetiracetam (n=10)	6 (60)	3 (30)	1 (10)	0 (0)
Phenytoin+Sodium valproate (n=36)	11(40.7)	12 (44.4)	3 (11.1)	1 (3.7)
Carbamazepine+Sodium valproate (n=27)	8 (29.6)	11 (40.7)	5 (18.5)	3 (11.1)
Carbamazepine+Levetiracetam (n=25)	11 (44)	8 (32)	6 (24)	0 (0)
Sodium valproate+Levetiracetam (n=22)	6 (27.3)	10 (45.5)	3 (13.6)	3 (13.6)

Type of seizures: According to the newer classification of seizures<sup>12</sup>, patients were divided into generalized seizures (46.3%, 193/417) and focal seizures (53.7%, 224/417). Among generalized seizures, 23 per cent patients presented with the symptoms of LGS such as clonic, tonic and atonic seizures. Among focal seizures, consciousness was impaired in two-third of the patients. Most patients (61%) had focal seizures with secondary generalization.

Concomitant antiepileptic drugs: CLB was in use in different treatment schedules *i.e.* as 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> add on AED. The mean number of AEDs used per person was  $2.8 \pm 0.8$  (range 1-5). The frequency of use of older AEDs *i.e.* valproate, carbamazepine and phenytoin in combination with clobazam was 45.8, 33.8 and 26.9 per cent, respectively. Among newer AEDs, use of levetiracetam (30.9%) was higher followed by lamotrigine (12%), oxcarbazepine (10.3%), zonisamide (4.8%), topiramate (6%) and lacosamide (1.9%). Maximum protection from seizures was observed in the patients who were on two or three add-on AEDs including CLB. The most frequently used concomitant antiepileptic drug treatment regimens in 151 patients who remained on CLB for at least 12 months is shown in the Table.

Retention rate: The retention rate analysis was performed with all 417 patients (range 6.5-270 months). The retention rates at 12, 24, 48 and 96 months were 66.9, 44.8, 19.7 and 6.5 per cent, respectively. Clobazam was discontinued in 15 patients (Fig. 1). Of these, CLB was first, second and third add-on therapy in 4, 8 and 3 patients, respectively.



**Fig. 1. Kaplan-Meier analysis for estimated retention rate of patients on clobazam (n = 417).**

Seizure freedom: In total, 151 patients (36.2%) were seizure free during the study evaluation period, *i.e.* 12 months of CLB treatment. Among seizure free patients, 62 (41.2%) patients were on CLB as first add-on drug.

There was no change in seizure control in 32 (7.7%) patients. The percentage of seizure-free patients in each treatment regimen is elucidated in the Table.

**Dosages of clobazam:** Clobazam was administered at 0.04-1.8 mg/kg/day, once daily or divided into two daily doses. The median dose of CLB was 0.3 mg/kg/day. The average CLB dose remained stable in 151 patients who were seizure free for 12 months. Throughout the study, patients in all four response categories took a wide range of CLB doses which varied from 0.1 mg/kg/day in seizure free patients to 1.8 mg/kg/day in patients who discontinued the drug (Fig. 2). The dose of CLB was found to be higher in patients with <50 per cent reduction in seizures and those with poor seizure control.

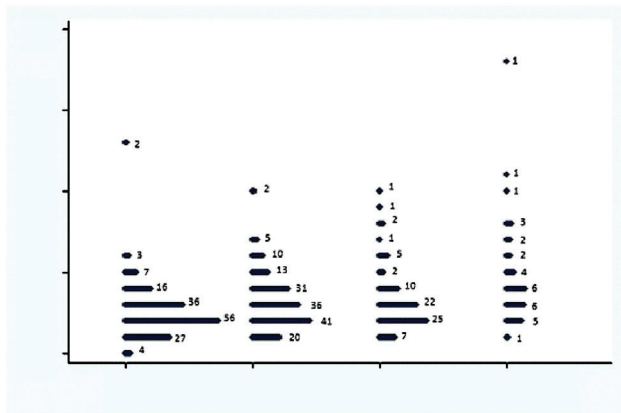


Fig. 2. Number of patients on clobazam dose (mg/kg/day) in various outcome groups. Group 1: seizure free (n=151), group 2:  $\geq 50$  per cent reduction in seizures (n=158), group 3: <50 per cent reduction in seizures (n=76), group 4: no change in seizure frequency (n=32). Each label represents as no. of patients.

## DISCUSSION

The present study showed clobazam as an effective and well tolerated add-on antiepileptic drug. The use of a single antiepileptic drug at the minimally effective dose, up to the maximum tolerated dose, is the standard therapy for epilepsy. However, many patients need more than one AED to improve seizure control. CLB is commonly used as add-on therapy, but it has demonstrated efficacy as monotherapy as well<sup>10,13,14</sup>.

Clobazam is used as a first-line antiepileptic drug in paediatric epilepsy in many countries and in spite of availability of other options, it continues to be used as an adjunctive therapy for patients with resistant epilepsy<sup>15</sup>. Two retrospective studies on the efficacy of clobazam as add-on therapy for paediatric patients reported significant

reductions in seizure frequency<sup>16,17</sup>. In the present study, CLB was found to be prescribed more frequently in children as compared to patients above 40 years.

The most frequent combinations of CLB were with carbamazepine, valproate, phenytoin, levetiracetam, lamotrigine and oxcarbazepine. In the present study, clobazam being broad spectrum was selected as add-on AED for patients with epilepsy who were not responding to other AEDs (focal seizures, focal evolving to bilateral convulsive and generalized seizures). Clobazam was used for varying reasons, firstly, during up titration and waiting period in patients who required build up of AEDs like lamotrigine (11.9%) and topiramate (5.9%); secondly, in drug resistant epilepsy with at least two add-on AEDs; thirdly, in case of drug rash with first line AEDs. The seizure control may or may not be directly attributable to CLB addition *per se* as patients were also receiving other first and second line AEDs.

Doses of 0.2–3.8 mg/kg/day have been used in trials evaluating the use of clobazam<sup>5,18</sup>. Observed dose range in the present study varied from 0.04-1.8 mg/kg/day on body weight basis. This dose range was in accordance with the previous studies<sup>11,19,20,21</sup>. Doses up to 0.2-0.3 mg/kg/day were most frequently prescribed and resulted in maximum percentage of patients gaining seizure control. Rarely, higher doses up to 1.8 mg/kg/day were prescribed in patients with poor seizure control. This is in contrast to the results of Ng *et al*<sup>22</sup>, where significant seizure reduction occurred at medium (0.5 mg/kg/day) and high (1 mg/kg/day) doses as compared to low (0.25 mg/kg/day) dose. It is likely that in Indian population, CLB is more effective at low dose (0.2-0.3 mg/kg/day). Evidence also supports lower likelihood of psychomotor impairment and sedation at lower doses of CLB<sup>23</sup>.

Clobazam is considered as a safe and effective AED. It has fewer side effects than phenytoin or carbamazepine<sup>13</sup>. In addition to decrease in seizure frequency, CLB improves global assessment consistent with improved cognitive and behavioural performance<sup>15,19</sup>. The percentage of patients who discontinue treatment due to adverse effects was 3.6 per cent in the present study as compared to the reported 12.5 and 16.6 per cent, respectively for low and high doses<sup>19</sup>. In the present study, CLB was preferred in patients with rash induced by other AEDs like phenytoin (n=2), carbamazepine (n=3) and valproate (n=2). This is in contrast to the findings of previous study in which combination of

CLB triggered the lamotrigine and valproate induced Steven Johnson Syndrome<sup>23</sup>. Somnolence followed by fatigue and tiredness were the common complaints in patients who discontinued CLB treatment. Studies have suggested that slow dose titration may help to avoid adverse effects and that when present, adverse effects may be reduced or eliminated with dose reduction<sup>20</sup>.

Kaplan-Meier analysis showed a little decrease in patients remaining on CLB reflecting a good retention rate. Efficacy was seen even in low doses of 10-20 mg daily. Seizure freedom is most likely to be seen in patients on first and second add on therapy with CLB. Although this finding was in concordance with the earlier observation that chances of seizure freedom declined with successive drug regimens<sup>24</sup>, the present study provided the evidence for the same.

Since the present study did not assess the role of concomitant AEDs in seizure freedom, head-on comparison with use of other AEDs as first add-on drug are needed to conclude with certainty if CLB reduces prescription load as first add-on therapy. In some patients, CLB could be substituted for other broad-spectrum AEDs, resulting in seizure freedom or a substantial reduction in seizure frequency.

The present results showed that clobazam was effective in both types of seizures *i.e.* generalized as well as focal. Seizure freedom was likely achieved in patients on first and second add-on therapy with clobazam.

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**Ethical Permission** –Taken from ethical committee of Institute

**Conflict of Interest**- None

## CONCLUSION

Our results provide valuable information about the clinical use of clobazam as add-on antiepileptic drug therapy in the management of patients with epilepsy.

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# Cytomorphological Study of Palpable Breast Lumps by FNAC

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## ABSTRACT

**Introduction:** Breast is an appendage of skin, breast lumps are very common complaint for women of all ages, but are particularly common during the reproductive years. Breast lumps may occur spontaneously or gradually, evaluating a breast mass can be a difficult task.

**Aim and Objective:** To assess the distribution of various cytomorphological patterns of clinically palpable breast lumps by Fine Needle Aspiration Cytology technique.

**Materials and Method:** A retrospective study over a period of 1 year 135 breast aspirates who attended the surgery outpatient department in Saraswathi institute of medical sciences and hospital from July 2015 to June 2016 was studied with clinical correlation and cytological analysis with FNAC. Smears were stained with H & E stain, and correlation with imaging studies, including mammography was done.

**Results:** Total of 135 cases were studied, out of these 96 (71.11%) were found benign and 25 (18.52%) were malignant. 10 (7.41%) cases given unsatisfactory results. Out of 135 cases of analysis, Fibroadenoma was the most common benign lesion found in 66 (48.89%) patients, followed by fibrocystic disease 14(10.37%) and mastitis/Breast abscess 4(2.96%) were common breast lesions on cytology. Malignant breast lesions constitute 25(18.51%) cases, among which Duct cell carcinoma 21(15.55%) cases were commonest type.

**Conclusion:** Benign breast lesions are common than malignant lesions, fibroadenoma and fibrocystic disease are more common in benign disease. Fine-needle aspiration cytology is a rapid and effective method for the primary categorization of palpable breast lumps into benign, malignant, atypical, suspicious, and unsatisfactory categories.

**Keywords:** Palpable, Breast Lumps, Cytomorphology, FNAC

## INTRODUCTION

Breast is an appendage of skin, breast lumps are very common complaint for women of all ages, but are particularly common during the reproductive years. Breast lumps may occur spontaneously or gradually, evaluating a breast mass can be a difficult task. It may be difficult for the patient because of the anxiety associated with her underlying fear of a breast malignancy. Majority of breast symptoms or lesions will prove to be of a benign

etiology. Benign as well as malignant breast lesions are quite common in Indian population. It is the second most common cancer site after cancer cervix in Indian females. Breast carcinoma is the most common malignant neoplasm and the leading cause of death from cancer in women, with detected in India yearly.<sup>1</sup> Special tests such as more than 1million cases occurring worldwide annually.<sup>2</sup> Some benign diseases are associated with a slightly increased risk of cancer in future, depending on that patient's medical history, family history and risk factors. The use of various investigations depends on the history and examination findings. A mammography uses low energy x-rays to image the breast. For a woman over 30 years old presenting with a new breast lump a mammogram is an appropriate first investigation. It is

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also used in screening for breast cancer to detect breast lumps that cannot be felt. While a mammogram can identify suspicious features in breast lump, it cannot determine whether a lump is benign or not. Ultrasound is an appropriate first investigation for women who are under 30 years old or pregnant and have a breast lump. It is also useful in patients with a palpable breast lump and an abnormal mammogram result. Ultrasound can demonstrate if a mass is cystic or solid and can also be used to guide aspiration (e.g. for treatment of breast cyst) or biopsy. Fine needle aspiration is minor procedure; needle inserted into the breast lump and the syringe plunger is drawn out (aspirate) to obtain a sample of cells. The tissue or fluid sample taken can be examined for the presence of any cancerous cells. FNA can also be used to treat a breast cyst, by aspirating the fluid inside the cyst itself. FNAC is not only useful in diagnosis and further planning of treatment without need for biopsy, but also helpful in prognostication of the tumor factors such as nuclear grading, mitotic index, hormone receptor status and DNA contents.<sup>3</sup>

### AIM AND OBJECTIVES

To assess the distribution of various cytomorphological patterns of clinically palpable breast lumps by Fine Needle Aspiration Cytology technique.

### MATERIAL AND METHOD

A retrospective study were over a period of 1 year, 135 breast aspirates who attended the surgery outpatient department in Saraswathi institute of medical sciences and hospital from July 2015 to June 2016 on 135 female patients with clinically palpable breast lumps which were referred to the department of pathology for FNAC of breast. Physical examination with palpation followed by Fine Needle Aspiration Cytology was done by using 23 gauge needle attached to 10 cc disposable syringe. The sample was obtained with aspiration and non-aspiration techniques with minimum passes to minimize hemorrhage. Palpable axillary lymph nodes were aspirated to exclude metastasis. Wet fixed smears were stained with Haematoxylin and Eosin (H&E) stain, one for Papanicolaou stain whenever necessary, data was taken regarding the age of the patient, site of involvement, size of the lesion, cytological diagnosis and presence of metastasis in case of malignancies, correlation with available imaging studies including mammography was done.

## RESULTS

A total of 135 FNAC of palpable breast lumps were done in the cytopathology department of pathology in Saraswathi Institute of Medical Sciences, Hapur. The age of the patients in the present study varied from 17-75 years. Maximum number of lesions (31.11%) was seen in age group of 20 to 30 years, followed by 30 to 40 years (24.44%), and 50 to 60 years (20.74%). In >70 years age only 2 lesions (1.48%) were noticed (table-1).

The cytological spectrum of various breast lesions in the present study shows that out of the total 135 cases, benign lesions were 96(71.11%), atypical cases 3(2.22%), suspicious cases 1(0.74%), frankly malignant 25(18.52%), unsatisfactory 10(7.41%) were reported (table-2).

Total of 25 malignant breast lesions were analyzed. Out of 135 breast aspirates 10(7.4%) cases yielded inadequate aspiration material(or) diagnosis was equivocal. Out of 135 cases, benign breast lesions 96(71.11%) were most common lesions in young females, among which fibroadenoma constitute 66(48.89%) cases were the commonest presentation. Out of 135 breast aspirates, (table-3) fibrocystic disease were 14(10.37%), benign epithelial hyperplasia were 3(2.22%), breast abscess 4(2.96%), duct ectasia 2(1.48%), simple cyst 1(0.7%), granulomatous mastitis 2(1.48%), fat necrosis 1(0.7%), and galactocoele 1(0.7%) cases were reported. Out of total 135 aspirates 25(18.52%) cases were reported as malignant lesions. Among which Duct cell carcinoma constitute 21(15.55%) cases, lobular carcinoma 2(1.48%), mucinous carcinoma and recurrent phyllodes tumour each 1(0.74%) case was reported (table 3).

**Table 1: Distribution of lesions according to age groups**

Age group in years	Number of cases	Percentage (%)
<20	12	8.89
21-30	42	31.11
31-40	33	24.44
41-50	10	7.41
51-60	28	20.74
61-70	08	5.92
>70	02	1.48
<b>Total</b>	135	

**Table 2: Cytological spectrum of various palpable breast lesions**

Cytological type	Number of cases	Percentage (%)
Benign	96	71.11
Atypical	03	2.22
Suspicious	01	0.74
Malignant	25	18.52
Unsatisfactory	10	7.41
Total	135	

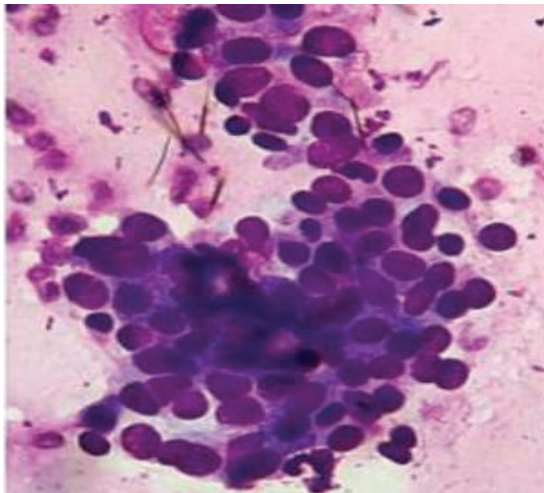
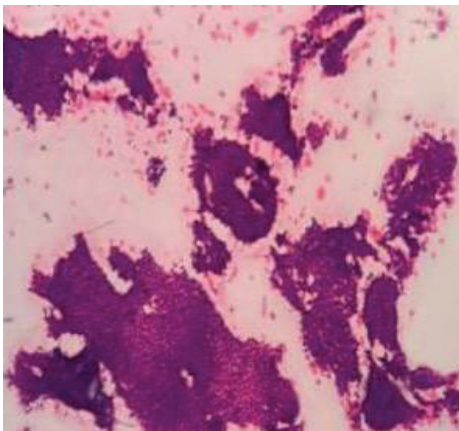
**Table3: Cytological diagnosis of breast lesions by FNAC (n=135)**

Category	Cytological diagnosis	Number of cases	Percentage (%)
<b>1. Inflammatory and Benign lesions</b>	Acute mastitis/ abscess	04	2.96
	Granulomatous mastitis	02	1.48
	Fat necrosis	01	0.74
	Duct ectasia	02	1.48
	Fibroadenoma	66	48.89
	Fibrocystic disease	14	10.37
	Simple cyst	01	0.74
	Epithelial hyperplasia	03	2.22
	Galactocele	01	0.74
	Benign phyllodes tumor	01	0.74
	Papillary lesion	01	0.74
<b>2. Atypical/ intermediate probably benign</b>	Epithelial hyperplasia with atypia	03	2.22
<b>3. Suspicious of malignancy</b>	Atypical cells suspicious of malignancy	01	0.74
<b>4. Malignancy</b>	Ductal carcinoma	21	15.55
	Lobular carcinoma	02	1.48
	Mucinous carcinoma	01	0.74
	Recurrent malignant phyllodes tumor	01	0.74
<b>5. Unsatisfactory</b>		10	7.41
<b>TOTAL</b>		<b>135</b>	

Regarding size of the breast lump, maximum size >10cm in 25(9.25%) cases, minimum size <5 cm in 95 (70.3%) cases were noticed. Regarding side wise distribution, left side was most commonly involved (59.25%), out of that left upper outer quadrant were most commonly involved. The clinical symptoms of patients presenting with suspected malignant lesion varies from painful lump (12%) to painless mass (32%), nipple retraction (20%), nipple discharge (4%) etc. (table 4).

**Table- 4: Presenting symptoms of malignant neoplastic lesions (n=25)**

S. No.	Presenting symptom	Number of cases	Percentage (%)
1	Painless lump in the breast	8	32
2	Nipple retraction	5	20
3	Palpable axillary lymph node 2 or more	5	20
4	Painfull lump	3	12
5	Ulceration fungation of mass	2	08
6	Nipple discharge	1	04
7	Sign & symptom of metastasis	1	04
<b>Total</b>		25	

**Fig-1: Photomicrograph showing Cytology of fibroadenoma (May Grunwald Giemsa, 400x)****Fig-2: Photomicrograph showing Cytology of ductal hyperplasia (May Grunwald Giemsa, 400x)**

## DISCUSSION

Breast is an easily accessible site for fine needle aspiration cytology. There is an increasing tendency to seek to confirm the diagnosis of the breast cancer at first consultation by some form of needle biopsy technique. The present series confirms the worth and clinical utility of fine needle aspiration cytology in the investigation of the patient with benign and malignant breast disease. The present study accounted for more numbers of benign cases and less number of malignant cases, correlation with Mohammed et al.,<sup>4</sup>Yeoh and Cha et al.,<sup>5</sup> Parkand Ham et al.,<sup>6</sup> and Rocha et al.<sup>7</sup> Incidence of suspicious, atypical lesions in the present study is almost same as that in other studies. In the present study fibroadenoma (48.89%) followed by fibrocystic disease (10.37%) and mastitis/breast abscess (2.96%) were the most common breast lesions on cytology, which is in agreement with Dominguez et al.,<sup>8</sup> (34.49%, 32.17%, and 1.55% respectively).

In the present study 25 malignant lesions were seen. While in study by Dominguez et al., 147 cases were seen. Duct cell carcinoma was most common in the present study with 47(17.40%)cases and 141(95.91%) in study by Domínguez et al.<sup>8</sup> Lobular carcinoma, Mucinous carcinomas were second most common tumors in this study with (1.48, 0.74%), while in study by Domínguez et al.<sup>8</sup> also seen in 1 (0.68%) case.

In the present study, maximum numbers of cytologically benign lesions were seen in the age group ranging from 17 to 45 years (table-1). This was similar to the findings by Khemka et al.,<sup>9</sup> who had maximum cytological benign cases in the age groups 15-44 years and 14-40 years respectively. Macintosh et al.,<sup>10</sup> had majority of benign cases in the age group 27-77 years. Maximum atypical category lesions were seen in the age group 31-68 years in the present study, while other studies do not mention this category in their study. In the present study, cytological suspicious lesions were most common in the age group 33-72 years almost similar findings have been reported by Macintosh et al.,<sup>10</sup> who reported maximum number of suspicious cases in the age groups 33-75 years and 31-75 years respectively. Malignant lesions were common in the age groups 35-77 years in the present study, 63-79 years in the study by Macintosh et al.,<sup>10</sup> and 41-75 years in the study by Rocha et al.<sup>7</sup> Unsatisfactory lesions were common in the age groups 19-55 years in the present

study and 14- 50 years in the study by Rocha et al.<sup>7</sup> So over all pattern of occurrence is as expected with benign lesions are seen in younger age group and suspicious and malignant in older age group. In the present study, both sides (right and left) were not equally involved by the different types of cytological lesions. This is in association with the findings of Reddy and Reddy<sup>11</sup> and Clegg-Lamprey and Hodasi<sup>12</sup> in which the left side was slightly more common. Upper and outer quadrant was the most commonly involved quadrant (31.48%) in the present study. This is in agreement with the findings of other studies like Reddy and Reddy <sup>11</sup> (54.20%), and Clegg- Lamprey and Hodasi<sup>12</sup> (42.40%). The exact cause of this finding is not known. This higher number of benign and lower number of malignant cases in other studies may be due to good follow up or more awareness amongst the patients. Cytomorphologically sometimes, lobular carcinoma can appear as poorly differentiated carcinoma, as no pattern is seen. Sometimes, mastitis cases can be confused with IDC. This may be because, in the background to heavy inflammation, few cells may appear more atypical. Hypocellularity and relatively mild nuclear atypia are the most common reasons for failure to diagnose a malignant breast lesion. In these cases careful attention to extreme nuclear pleomorphism and absence of naked bipolar cells along with radiologic suspicion should suggest a diagnosis of malignancy.<sup>13, 14</sup> In this study, we have realized that one cannot overlook the importance of clinical and radiological assessment for diagnosing breast lumps. This is especially so in cases that is labeled on cytology as atypical or suspicious. In such conditions, triple assessment (which assigns a score to a breast lesion by taking into consideration the clinical diagnosis, mammography diagnosis and the cytology diagnosis together and not any one diagnosis in isolation) is must. Triple test is particularly beneficial in a false negative scenario, in which the clinical decision to undertake a biopsy is usually based on index of suspicion and radiological imaging.

**Source of Funding**-None

**Ethical Permission** –Taken from ethical committee of Institute

**Conflict of Interest**- None

## CONCLUSION

Fine-needle aspiration cytology is a rapid and effective method for the primary categorization of

palpable breast lumps into benign, malignant, atypical, suspicious, and unsatisfactory categories. Benign breast lesions are common than malignant lesions, fibroadenoma and fibrocystic disease are more common in benign disease, whereas IDC accounts for the highest number of malignant lesions. Diagnostic accuracy of the procedure for malignant lesions is well established. More over FNAC can be repeated in cases of suspicious diagnosis or inadequate smear, further cases can be followed with biopsy for further confirmation. Due to rapid diagnosis we can reduce morbidity or mortality due to breast cancer and prevent further complications. Thus it is proved that early detection by FNAC and prompt management helps in reducing the morbidity and restricting the disease progression at the very initial stage. It also avoids unnecessary surgical intervention.

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# Cytohistopathological Correlation of Papanicolaou Smears: A Hospital based Study

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## ABSTRACT

**Background:** Carcinoma of cervix is the second most common cancer in women worldwide and the leading cause of death from cancer in several developing countries including India. The use of the cervical smear (Papanicolaou/Pap) as a screening tool has significantly reduced the incidence of cervical cancer. Cytohistopathological correlation of Pap smear is a widely accepted method of internal quality assurance and helps in the analysis of various factors leading to discrepant diagnosis. With the above view, the present study has been carried out to evaluate the cytohistopathological correlation of the various cervical lesions.

**Method:** The study was retrospective cross-sectional hospital based study carried out over a period of 1 year in which out of 500 pap smears screened, cytohistopathological correlation of 70 cases were obtained.

**Results:** Specificity in the present study was 84.2% and the sensitivity was 77.7%. The accuracy of Pap smears was 82.1%. The overall correlation between cytology and histopathology was found to be 57% with the highest correlation in the high grade squamous intraepithelial lesion (HSIL) category (87.5%).

**Conclusions:** The study provides good cytohistopathological correlation especially for high grade lesions. So we believe that the success of screening for cervical cancer is based on collection of adequate materials and correct interpretation of abnormal cells.

**Keywords:** Carcinoma cervix, Pap smears, Cytohistopathological, Correlation, HSIL, LSIL

## INTRODUCTION

Cancer of uterine cervix is the second most common cancer worldwide next to breast cancer and most common female cancer in many developing countries like India.<sup>1</sup> WHO global report 2014 states 266000 women died from cervical cancer in year 2012.<sup>2</sup> The age adjusted incidence rates (AARs) of cancer cervix has decreased in the urban Indian population. However, over 70 per cent of the Indian population resides in the rural areas; cancer cervix still constitutes the number one cancer in India.<sup>3</sup> Human papilloma virus

(HPV) is recognized as the primary causal factor in the development of cervical cancer.<sup>4</sup> The accessibility of the uterine cervix with propensity of its cells to exfoliate and a prolonged natural history of the premalignant lesions provides the best potential for the control of a cancer by population screening. Although Papanicolaou (Pap) cytology represents the most effective technique to prevent and detect the precancerous conditions of the uterine cervix before they become invasive cancer, its false negative yield due to the potential sampling and interpretation errors yield is still a reason of concern. Thus, the final diagnosis should be made on histologic examination to assess the accuracy of the cervical cytology. Cytohistopathological correlation of Pap smear is one of the recommendations of the European guidelines for quality assurance for the development of cytology laboratory performance and, in particular, to reduce falsenegative results.<sup>5</sup> With the above view, the present study has been carried out to evaluate the

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cytohistopathological correlation of the cervical lesions. It aimed at studying the incidence of various cervical abnormalities such as infections, dysplasia; conforming the diagnoses by histological examination and evaluating the accuracy of cervical cytology in the assessment of pre-invasive and invasive lesions of the uterine cervix.

### METHOD

This retrospective cross-sectional diagnostic test hospital based study was conducted in tertiary care hospital, over the period 1 year from July 2015 to June 2016. The study was approved by hospital based ethical committee. Out of 500 pap smears screened, 70 cases were selected whose corresponding histopathological sample was also received in the form of the cervical biopsy or hysterectomy performed for various medical indications. The study group included women from different age groups coming from a low socioeconomic background who was attending the gynecology outpatient department (OPD) for varying complaints. The Pap smears were taken with the Ayer's spatula on a clean glass slide and fixed immediately in 95% ethanol and ether equal parts. Staining of the slides was performed by means of the conventional Pap technique as reported in accordance with the Bethesda system 2001. Tissue material was fixed in 10% neutral buffered formalin solution and processed routinely with final embedding in paraffin blocks and stained with hematoxylin and eosin

(H and E). Both the cytology and histology slides were examined by two qualified pathologists in a double-blind fashion.

### RESULTS

The mean age of the patients was 38 years  $\pm$ 10.7 SD (range: 24 to 65 yrs.). Incidence of normal smears in the present day study was 11.4%. Majority of the patients who underwent Pap smears had evidence of infection (41.4%) including 5.7% of Trichomonas infections and 2.85 % due to Candida albicans. There were 9 cases of LSIL (Low grade squamous intraepithelial lesion) and 8 cases of HSIL (High grade squamous intraepithelial lesion) amounting to 12.8% and 11.4% respectively. One case of carcinoma was accurately diagnosed by the screening procedure. Majority of the patients of carcinoma cervix were in the 4th decade of life indicating a trend affecting younger population. 20% slides were considered to be inadequate when classified according to the Bethesda system in which one case of carcinoma was missing in the Pap smear due to inadequate cellularity. Observations are summarized in Table 1. Specificity in the present study was 84.2% and the sensitivity was 77.7%. The accuracy of Pap smears was 82.1%. The overall correlation between cytology and histopathology was found to be 57% with the highest correlation in the HSIL category (87.5%).

**Table 1: Summary of Pap smear cytology and histology findings.**

PAP	NAD	Cervicitis	CIN 1	CIN 2	CIN 3	Carcinoma in situ	Carcinoma	Total
Normal	2	5	-	-	-	-	-	7(3)
Inflammatory	6	19	4	-	-	-	-	29(3)
ASCUS	-	1	-	-	-	-	-	1
LSIL	1	3	3	1	-	-	1	9(2)
HSIL	-	1	-	3	-	1	3	8
Carcinoma	-	-	1	-	-	-	1	2
Inadequate	3	8	1	-	1	-	1	14(2)
<b>Total</b>	<b>12(2)</b>	<b>37(10)</b>	<b>9(5)</b>	<b>4(1)</b>	<b>1</b>	<b>1</b>	<b>6</b>	<b>70</b>

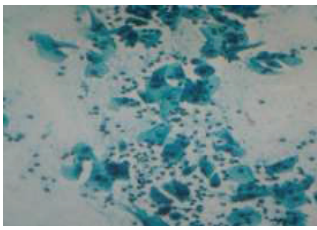


Figure 1: Pap smear showing mild inflammatory atypia (40X).

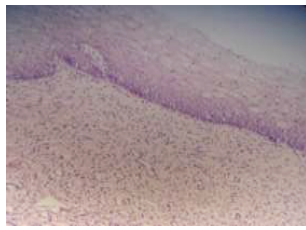


Figure 2: Cervix biopsy showing chronic cervicitis and koilocytic change (H and E, 40X).

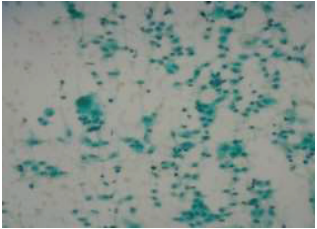


Figure 3: Pap smear showing high grade atypia (40X).

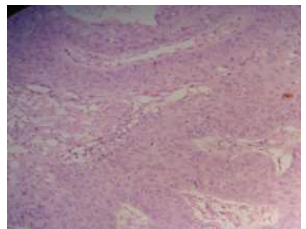


Figure 4: Cervix biopsy showing carcinoma in-situ (H and E, 40X).

## DISCUSSION

Most cervical cancers start from an area of dysplastic epithelium (transformation zone) which can be detected well by taking a good Pap smear, the best screening programme worldwide recommended for sexually active women.<sup>6-8</sup> This most widely used screening test as of today is simple and acceptable, but it has been found to have falsely high negative results ranging from 1.1-30%, Chhabra et al 2003 (18.7%), Ozkara et al 2002 (5.3%)<sup>9,10</sup> The false negatives of our study were 4 (22%). All these were LSIL cases. These variations have been attributed to difference to cytological expertise, variation in sampling techniques and preparation of the smear. Another important factor in the malignant lesions does not exfoliate at a constant rate. The other problems which led to under calling include air drying, inflammatory reaction and obscuring blood also noted. However, no case of HSIL or carcinoma was missed cytologically. These results are basically comparable to those reported in other major series using cytohistologic comparison and regarding sampling error and preparation artifact like drying artifacts, inadequate fixations, background materials and thick smears are the most common source of the false negative smears, screening and interpretation mistakes being relatives uncommon.<sup>11,12</sup> Because false negative rates are usually underestimated when using follow up controls, our value observation against

immediate histologic 'gold-standard' reflects an adequate and effective screening program for cervical cancer.<sup>13</sup> Collecting material for cytology with an endocervical brush and the new Pap smear screening techniques using liquid based Pap (thin-prep Pap, autocyte PREPTM System) appear to increase sensitivity as this techniques prevent air drying artifacts, have minimum background material and increase the cellularity.<sup>14</sup> It also offers the possibility of HPV, DNA testing with hybrid capture technology especially performed in cellular residues of the liquid based cytology collection kits which appears to be most cost effective (Ferenzy 1997).<sup>15</sup> Alwahaibi et al shows false positive in 32.2% while Abali R et al show 43.0% false positives.<sup>16,17</sup> In the present study, the 6 cases of false positive smears (15.7%) were also reexamined. 4 were diagnosed as LSIL, 1 as ASCUS and 1 as HSIL. In these cases biopsy examination failed to demonstrate any tissue abnormality and smear reviews confirmed the presence of abnormal cells. This might be explained by the occasional inaccuracy of cervical biopsy in detecting focal lesions, especially of mild degree and those lesions located in difficult to sample areas such as the inner cervical canal. A colposcopically guided cone biopsy may be a solution to this and must therefore be advocated whenever possible. After the introduction of the Bethesda system few new confusions and questions have been raised. One among them is regarding the significance of ASCUS. The incidence of ASCUS in present study was 1.4% while Naik et al 2015 showed 2.8% incidence as opposed to Mihaela et al 2011 who reported very large proportion of ASCUS cases 47.9%.<sup>18,19</sup> In terms of diagnostic group discrepancy, a two category discrepancy occurred in few cases suggesting that this is a true problem in cytopathology.<sup>13</sup> The proportional distribution of their cases into ASCUS, ASCUS-H or LSIL suggests that different factors ultimately influence the proper cytological interpretation of abnormal cells. In our experience, the clinical impact of discordance is limited, because of these cases; we routinely recommend a repeat Pap smear before any further therapy such as cone biopsy or hysterectomy.

Therefore, our study showed that the sensitivity rate of cervical cytology screening is high (77.7%) especially in detecting HSIL (87.5%) when specimens are adequate. This is in comparison to studies like of Jain et al with sensitivity of 78 % or 76% in the Saha et al study.<sup>20,21</sup> Likewise, in the study by Jain et al, specificity was only 26.9% while Saha et al showed 83.3% specificity which

was 84.1% in our study.<sup>21,22</sup> As shown in Table 2, Nawaz et al (2005) showed 74% correlation while Rasbridge et al (2005) showed 81.2% correlation between cytology and biopsy in their study which was 57% in the present study and which was increased to 92.8% within one degree of histopathological abnormality.<sup>23,24,25</sup> The overall accuracy of Pap smear reporting was 84.6% by Naik et al whereas the present study showed 82.1% accuracy.18 Nevertheless relatively low correlation of accepted, histologically specific cytologic classification with the biopsy diagnoses is disappointing and raising some question as to the reliability of the very specific cytologic diagnosis is borderline lesions.

**Table 2:** Comparison of Pap smear values in different studies (%).

Study	Sensitivity	Specificity	PPV	NPV	Diagnostic accuracy
Saha et al, 2005	76	83.3	86.4	71.4	79.4
Bruce et al, 1996	89.4	64.8	88.9	-	-
Naik et al, 2015	79.4	58.3	86.1	46.6	74.5
Di Bonito et al, 1993	76.3	93	80.2	91.3	-
Present study	77.7	84.1	70	88.8	82.1

**Source of Funding**-None

**Ethical Permission** –Taken from ethical committee of Institute

**Conflict of Interest**- None

### CONCLUSION

In conclusion we believe that the success of screening for cervical cancer is based on collection of adequate materials and correct interpretation of abnormal cells. Therefore better awareness, motivation programs along with the use of thin-Prep Pap liquid based cytology technique to reduce inadequate sampling errors and the HPV, DNA testing for early detection of cervical lesions is recommended for a virtual 100% prevention of cervical cancer in the years to come.

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# Study of FNAC of Head and Neck Region in Chhattisgarh Population of Both Sexes

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## ABSTRACT

In the present 100 Patients of swelling or mass in head and neck 40 were male and 60 were female. Highest prevalence of lymph node lesion 20(50%) in males and 25 (41.6%) in females but thyroid lesion were more in females 18(30%) and in males 5(15.5%) salivary lesion 10(25%) in males 11(18.3%) in females soft tissue lesion 5(12.5%) in males 6(10%) females in the study of lymph node FNAC study tuberculosis lymphadenitis 8(40%) in males 9(36%) in males reactive lymphadenitis 4(20%) in males 5(20%) females supportive lymph were 3(15%) in males 4(16%) in females metastasis were 5(25%) in males and 7(28%) in females in the FNAC study of thyroid lesions benign nodular goiter 2(40%) in males 5(27.7%) in females follicular lesion was 1(20%) in males 2(11%) in females but Hashimoto thyroiditis was observed only in females 8(44.4%) only malignant thyroid were 2(40%) in males 5(45.4%) in females suppurative lymph were 3(15%) in males 4(16%) in females metastasis were 5(25%) in males and 7(28%) in muco-epidermis carcinoma 3(30%) in males 2(18.1%) in females chronic sialadenitis 3(30%) in males 4(36.3%) in females in the FNAC study of soft tissue lipane were 3(60%) in males 2(33.3%) in females haemangioma 2(40%) in males, 3(50%) in females basal cell carcinoma observed only in females 1(16.6%). This study will certainly help the pathologist to rule out first time of investigation rapidly pain less without Anesthesia without hospitalization of patient

**Keywords :** FNAC – fine needle aspiration cytology, Head and neck, Lymphadenitis, Thyroid.

## INTRODUCTION

A lump or mass is the most likely clinical problem to be encountered in the Head neck <sup>(1)</sup> evaluation of a neck mass is a common clinical dilemma and condition to which clinician routinely encounters<sup>(2)</sup> the common pathologies observed in head and neck are lump are lymphadenopathies (specific and non specific, acute or chronic) metastatic carcinoma, lymphoma, thyroid swellings (goiter nodules and cyst) and saliva gland swelling (sialadenitis cyst adenomas and carcinoma) the less common or occasional swellings in the neck are carotid body tumour branchial cyst, thyroglossal cyst, cystic hygroma and lumps of skin appendages

these are evaluated by FNAC is both diagnostic and therapeutic in cystic swelling<sup>(3)</sup> FNAC is rapid simple little expensive and minimally invasive provide use for different type head and neck swellings and presents. It can be done to OPD patients without anesthesia. More information to the clinician and surgeon to approach the patients efficiently Hence attempt was made to study the swellings of head and neck with FNAC method in both sexes.

## MATERIAL AND METHOD

The patients who were regularly visiting to Raipur institute of medical science Raipur Chhattisgarh were selected for the study 60 females and 40 males aged between 20 to 45 years adults were done FNAC study by using 22/23 gauze needle attached to 10 ml disposable syringe Air dried smears were stained with MGG (May Grunwald Giemsa) and 95% ethanol fixed smears were stained with PAP (papanicolaou) stain zhell- Nelson stain for AFB was done whenever required. The patient

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belonged to middle socio economical status most of them were labourers. The duration of study was about two years

**OBSERVATION AND RESULTS**

**Table 1-** study of different organs or parts by FNAC in both sexes with percentage in lymph nodes study 20(50%) were males and 25 (41.6%) were female in the study of thyroid 5(12.5%) were male and 18(30%) were females in the salivary gland study 10(25%) were male and 11(18.3%) were female in the study of soft tissue 5(12.5%) were male and 6(10%) were females

**Table -2** in the study of lesion of lymph nodes – tuberculosis lymphadenitis 8(40%) were male 9(36%) were female, reactive lymphadenitis 4(20%) were male 5(20%) were females supportive lymphadenitis 3(15%) were male 4(16%) were female metastatic study 5 (25%) were males 7(28%) were females

**Table 3** in the study of thyroid lesion benign goiter 2(40%) male 5(27.7%) were female in follicular lesion 1(20%) MALE AND 2(11.1%) FEMALE IN Hashimoto thyroiditis females in females only 8(44.4%) in malignant 2(40%) were male 3(16.6%) were female

**Table 4** in the study of lesion of saliva glands polymorph adenoma was 4(40%) in males 5(45.4%) in females in muco epidermoid carcinoma 3(30%) were male 2(18%) were female in chronic sialadenitis 3(30%) were male 4(36.3%) were females

**Table 5** study of soft tissue lesion lipoma were 3(60%) 2(33.3%) in females Haemangioma 2 (40%) in males 3(50%) in females basal cell carcinoma observed only in females

**Table -1: Study of different organ / parts by FNAC in both sexes with percentage**

Different organ	Male 40	%	Females 60	%
Lymph nodes	20	50	25	41.6
Thyroid	5	12.5	18	30
Salivary	10	25	11	18.3
Soft tissue	5	12.5	6	10

**Tables- 2: Study of lymph nodes in both sexes with percentage**

Lesion	Male 20	%	Female 25	%
Tuberculous lymphadenitis	8	40%	9	36
Reactive lymphadenitis	4	20%	5	20
Suppurative	3	15	4	16
Metastasis	5	25	7	28

**Table – 3: Study of thyroid lesions in both sexes with percentage**

Lesion	Male 5	%	Female 18	%
Benign nodular goitre	2	40	5	27.7
Follicular lesion	1	20	2	11.1
Hashimoto thyroiditis	-	-	8	44.4
Malignant	2	40	3	16.6

**Table – 4: Study of lesion in salivary gland in both sexes with percentage**

Lesion	Male 10	%	Female 11	%
Polymorph adenoma	4	40	5	45.4
Muco epidermoid carcinoma	3	30	2	18.1
Chronic sialadenitis	3	30	4	36.3

**Table – 5: Study of lesions in the soft tissue**

Lesion	Male 5	%	Female 6	%
Lipoma	3	60	2	33.3
Haemangioma	2	40	3	50
Basal cell carcinoma	-	-	1	16.6

**DISCUSSION**

In the present study of FNAC head and neck in

Chhattisgarh population of both sexes in this study females were more attached than males <sup>(4)(5)</sup> the prevalence of lymph node lesions were 20(50%) in males and 25(41.6%) in females thyroid enlargements 5(12.5%) were males 18(30%) in females in salivary lesion 10(25%) males and 11(18.3%) in females in soft tissue mass 5(12.5%) males 6(10%) in females (tables 1)

In the individual evaluation of lymph nodes tuberculosis lymph nodes were 8(40%) in males, 9(36%) in females in reactive lymphadenitis 4(20%) males 5(20%) females in suppurative lymphnodes 3(15%) in males 4(16%) in females in metastatic lesions 5(25%) in males 7(28%) in females (tables-2) in the individual assessment of thyroid lesions benign nodular goiter 2(40%) in males, 5(27.7%) in females follicular lesion 1(20%) in males 2(11.1%) but hashimoto thyroiditis observed only in females 8(44.4%). In malignancy of thyroid 2(40%) in males 3(16.6%) in females (tables 3)

In the study of lesion in salivary glands poly morph adenoma 4(40%) in males 5(45.4%). In females in mucoepidermoid carcinoma 3(30%) in males, 2(18.1%) in females. In chronic sialadenitis 3(30%) in males 4(36.3%) in females (tables 4). These finding were more or less in agreement with previous workers

In the study FNAC the highest prevalence of lymph node lesion were observed however thyroid lesion were commonest in females and males as well. But high incidence was in females the overall percentage lesions in salivary gland were more in males than females<sup>(9)</sup> same times false positive diagnosis by FNAC can be caused by regenerative epithelial hyperplasia and squamous metaplasia in in sialadentitis while false negative diagnose can be due to faulty technique central cystic haemorrhage or necrotic area devoid of diagnostic cells. Small malignant lesion adjacent to dominate mass but overall the procedure was simple and rapid obviating the need of surgical intervention. It is minimally invasive first line investigation with high sensitivity and specificity for the diagnosis of head and neck lesion

### SUMMARY AND CONCLUSION

The present study of FNAC of head and neck region in Chhattisgarh population in both sexes is quite useful to pathologist clinician surgeons moreover to radiologist to correlate the positive or negative findings and FNAC hence FNAC can be recommended as a first

line of investigation in the diagnosis of head and neck swellings moreover now days with increasing medical facilities any technique which speeds up the process of diagnosis limits the physical and psychological trauma to the patients and saves the time and expenditure of hospitalization It may also help the surgeon to select or avoid the surgeries

This research work is approved by ethical committee of R I M S Raipur of Chhattisgarh

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# Clinico-Cytopathological Evaluation of Skin Lesions with Special Reference to Bullous Lesions in Hapur Region

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## ABSTRACT

**Background:** Cytopathology of skin has been documented to be useful in the diagnosis of several skin lesions. The present study was conducted to correlate the clinical diagnosis with cytology and histopathology for the diagnosis of various nodular inflammatory lesions.

**Aims:** This study aims to evaluate cytopathology as a quick non-invasive method for early diagnosis of bullous lesions, neoplastic and preneoplastic skin lesions and to correlate the clinical, cytological and histopathological findings of various skin lesions.

**Materials and Method:** The study was retrospective hospital based study carried out over a period of 3 year in which 170 patients of skin lesions were included in the study. Skin scraping, Tzanck smears, slit smears and fine needle aspiration cytology (FNAC) were done to obtain material for cytological examination. Excisional biopsy, incisional biopsy and punch biopsy were done to obtain tissue for histopathological examination. The slides were stained with routine stains and special stains as and when required.

**Results:** Out of the 170 patients, 90 were males and 80 females. The most common non-neoplastic lesions observed were vesico-bullous lesions which comprised of 82 cases followed by neoplastic lesions which consisted of 48 cases, of which 12 were benign and 36 malignant. Concordant results between cytology and histopathology was seen in majority (91.7%) of lesions studied.

**Conclusion:** Cytology (scrape/imprint/slit smears and FNAC), performed skillfully and with perfection, leads to an early diagnosis in majority of the lesions, as the observed cytomorphological features of various skin lesions were fairly distinctive making cytology a fairly sensitive 'patient compliant' technique for rapid diagnosis of skin lesions.

**Keywords:** Bullous lesions, cytopathology, histopathology, skin lesions

## INTRODUCTION

Various lesions afflicting the skin range from non-specific dermatoses and inflammatory diseases to neoplastic changes of various components of the skin. Cytology and skin biopsy form the basis of differential diagnosis in clinically similar dermatosis, thereby

yielding important information to the pathologist and dermatologist. Though cytopathology was an excellent diagnostic tool in routine dermatologic practice,<sup>1</sup> studies relating to histopathological and cytological correlation are few.

## MATERIALS AND METHOD

These retrospective hospital based studies were conducted in tertiary care hospital, over the period 3 year from July 2013 to June 2016. In that time period, 170 patients with various skin lesions were included in the study. A detailed history of the patients was taken and physical examination findings recorded. Skin

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scraping was done for superficial lesions such as those with superficial ulcers and ulcerated tumors. Tzanck smears were made for bullous lesions.<sup>2</sup> A fresh vesicle or bulla with no signs of secondary infection was selected for making the smears. After clearing the peripheral portion, the bulla was incised with scalpel and the roof of bulla reflected. The base of blister was scraped gently and material spread on a clean glass slide. Slit smears were made in cases suspicious of leprosy.<sup>3</sup> Fine needle aspiration cytology (FNAC) was done in cases of suspected malignant tumors. Excisional, incisional and punch biopsy were done to obtain tissues for histopathological examination. Cytological smears were fixed in 95% ethanol and stained with Papanicolaou stain (PaP). Sections were routinely stained with hematoxylin and eosin (H and E) and special stains (VanGieson, reticulin and Ziehl Neelsen stain etc.) were employed wherever required. Concordance rate between cytological and histopathological diagnosis was analyzed.

## RESULT

Of the total 170 finally diagnosed cases, there were 82 cases of vesicobullous lesion, 48 neoplastic lesions and 40 granulomatous skin lesions. Histopathological confirmation was available in 120 cases.

### Vesicobullous Lesions

[Table 1] shows clinicopathological correlation of vesicobullous lesions. 82 cases of vesicobullous lesions comprised of three broad categories (A) viral infection (B) pemphigus (C) bullous impetigo.

#### (A) Viral infections

There were 18 cases of herpes simplex (HS), 22 cases of herpes zoster (HZ) and 10 cases of molluscum contagiosum. Mean age was 22.5 years for HS and 38 years for HZ/ varicella zoster (VZ). Patients from both HS, HZ/VZ infections presented with painful vesiculobullous eruptions with an erythematous base of short duration (two to five days). Smears from patients of herpes showed ballooning degeneration, multi nucleated giant cells and bland inclusion containing nuclei, molded against each other [Figure 1] and [Figure 2]. Distinction between HS and HZ was not significant in cytology. Biopsy from these cases showed intraepidermal bulla filled with serous fluid containing degenerating epithelial cells, ballooned cells and inclusion bodies.

#### (B) Pemphigus

In 18 of the 24 cases of pemphigus, Tzanck smears revealed acantholytic cells lying singly and in small clusters [Figure 4]. Distinction between Pemphigus vulgaris and Pemphigus foliaceus was not significant in cytology. Histopathology revealed suprabasal intraepidermal blister in P.vulgaris (20 cases) and subcorneal intraepidermal blister in and P. foliaceus (04 cases).

#### (C) Bullous impetigo

08 cases of bullous impetigo were included in the study, all seen in children. Cytological examination revealed acantholytic cells with a large number of acute inflammatory infiltrate. Histopathological examination showed subcorneal pustules with superficial perivascular neutrophilic infiltrate.

Granulomatous Skin Lesions [Table 2] shows clinicopathological correlation of granulomatous lesions. 18 of the 40 cases were of lupus vulgaris. Clinically they presented with nodules and ulcerated plaques of long duration. Imprint smears in seven cases and histopathological examination showed epithelioid granulomas with or without caseation. 06 of the 14 cases showed positivity for acid fast bacilli (AFB). 22 cases of leprosy were studied and cases were categorized according to the Ridley Jopling classification.<sup>4</sup>

Of the 22 cases of leprosy, cytohistological correlation was available in 20; 16 were concordant and 04 discordant. 02 case which showed features of borderline tuberculoid leprosy on cytological examination, exhibited feature of tuberculoid leprosy on histopathology. 02 cases diagnosed as mid-borderline on cytology revealed feature of borderline leprosy on histological examination.

### Benign Neoplastic Lesions

[Table 3] shows the cytohistological correlation of neoplastic lesions. 12 of the 48 neoplastic lesions studied were epidermal inclusion cysts. Clinically, patients presented with subcutaneous round nodules, soft to firm measuring one to three cm. On cytology, smears showed keratinous material with anucleate and nucleated squamous with cell debris in the background. Histology showed cysts lined by stratified squamous epithelial with a distinct granular layer and lumen filled with keratinous material.

### Malignant Lesions

Of the 36 malignant lesions there were 16 cases of squamous cell carcinoma (SCC), 10 of basal cell carcinoma (BCC), 06 of malignant melanoma and 02 case each of Merckel cell carcinoma (MCC) and sebaceous gland carcinoma (SGC) [Table 3]. Clinically the lesions were ulcerated nodular growth with crusting and indurated margins.

10 cases of BCC presented clinically with single or multiple nodules and ulcerated swelling either on the cheek, or eyelid or forehead. Imprint smears revealed cohesive sheets of round to oval tumor cells having basophilic cytoplasm, uniform dark, oval nuclei with evenly distributed chromatin. Histology revealed closely packed oval cells of uniform size with scant cytoplasm, hyperchromatic nuclei with peripheral palisading.

06 cases of malignant melanoma were seen, all in males. Lesions showed mottled appearance due

to pigmentation with irregular borders. Abundant melanin pigment was seen along with poorly cohesive, variably sized round cells with eccentric round to oval hyperchromatic nuclei on cytology. Histology revealed atypical spindle shaped melanocytes at right angles to the epidermal surface. Abundant melanin pigment was found.

02 cases of MCC were seen in a 55-year-old male who presented with multiple nodules over the head and neck region. Cytology showed inadequate cellularity. Histological examination showed small round cells in the dermis in a diffuse pattern. The cells had scanty cytoplasm, round and vesicular nuclei with fine granular dusty chromatin and multiple nucleoli.

02 cases of sebaceous gland carcinoma were seen in a 40-year-old female who presented with a large mass on the back with multiple nodules having both solid and cystic areas.

**Table 1: Clinicopathological Correlation of Vesiculobullous Lesions**

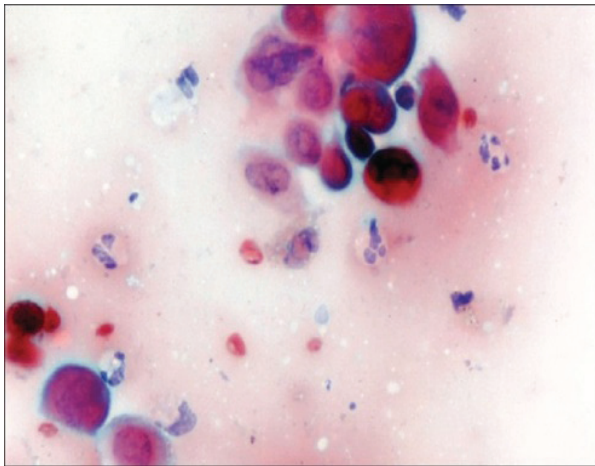
Clinical Diagnosis	Number of Cases	Cytology	Inadequate	Histopathology Correlation	Concordant
Herpes Simplex	18	18	--	06	06
Herpes Zoster	22	22	02	12	12
Pemphigus	24	24	06	18	18
Molluscum Contagiosum	10	10	02	08	08
Bullous Impetigo	08	08	--	06	04
<b>Total</b>	<b>82</b>	<b>82</b>	<b>10</b>	<b>50</b>	<b>28</b>

**Table 2: Clinicopathological Correlation of Granulomatous Lesions**

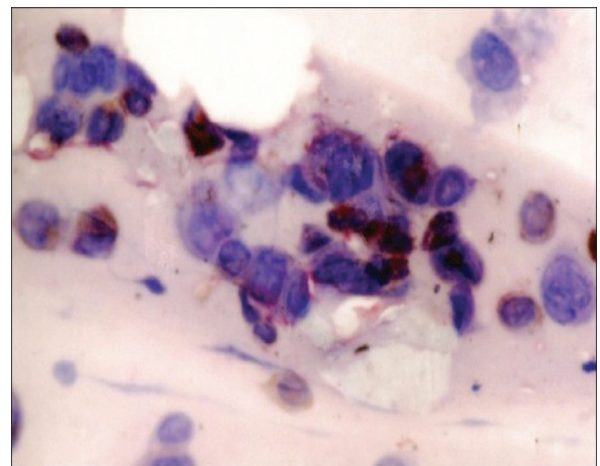
Clinical Diagnosis	Number of Cases	Cytology	Inadequate	Histopathology Correlation	Concordant
Lupus Vulgaris	18	18	04	14	14
Leprosy	22	22	02	20	16
<b>Total</b>	<b>40</b>	<b>40</b>	<b>06</b>	<b>34</b>	<b>30</b>

**Table 3: Clinicopathological Correlation of Neoplastic Lesions**

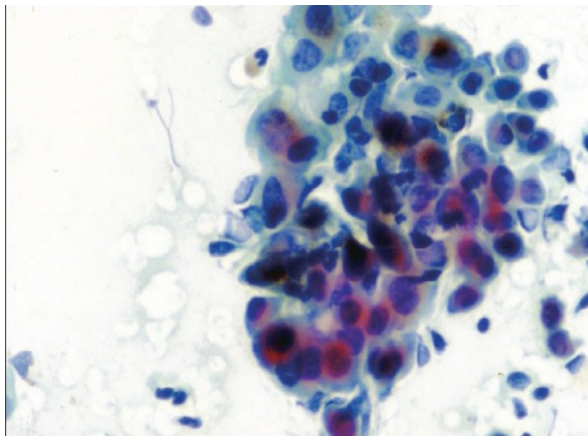
Clinical Diagnosis	Number of Cases	Cytology	Inadequate	Histopathology Correlation	Concordant
<b>BENIGN</b>					
Epidermal inclusion cyst	12	12	04	08	08
<b>MALIGNANT</b>					
Squamous cell carcinoma	16	16	--	16	14
Basal cell carcinoma	10	10	02	08	02
Malignant melanoma	06	06	04	02	02
Merkel cell carcinoma	02	02	02	--	--
Sebaceous gland carcinoma	02	02	--	02	02
<b>Total</b>	<b>48</b>	<b>48</b>	<b>12</b>	<b>36</b>	<b>28</b>



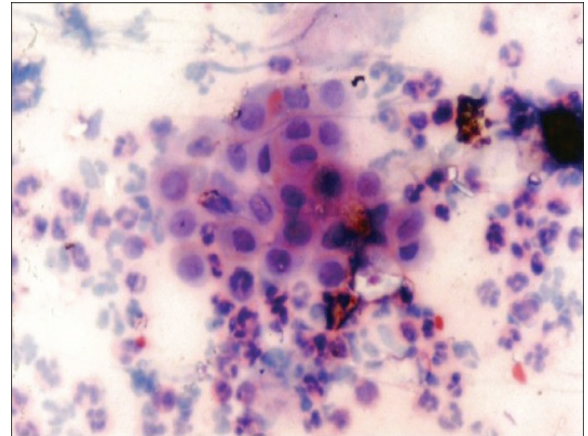
**Figure 1 :Herpes Simplex (Tzanck smear):** Mono and multi nucleate giant cells with bland inclusion containing nuclei. Molding is absent in the smear (Pap, X400)



**Figure 2 :Herpes Zoster (Tzanck smear):** Multi nucleated giant cells with bland inclusion containing nuclei against each other with variable amount of cytoplasm (Pap, X400)



**Figure 3 :Pemphigus (Tzanck smear):** Clusters of acantholytic cells with round hyperchromatic nucleus and darker staining peripheral cytoplasm (Pap, X400)



**Figure 4 :Bullous Impetigo (Tzanck smear):** Acantholytic cells with round hyperchromatic nucleus and plenty of neutrophils (Pap, X400)

## DISCUSSION

In this study we extensively studied the role of cytology in early and quick diagnosis of various skin lesions with particular emphasis on vesicobullous lesions.

### Vesicobullous Lesions

#### (a) Herpes Simplex / Zoster

Tzanck smears were prepared from fresh bullous lesions as described by Tzanck and his coworkers and Blank et al.<sup>5</sup> The average age incidence of herpes simplex in our study was 22.5 years whereas Crumpacker reported peak years of incidence one to five years.<sup>6</sup> Cytological features observed were in accordance with the findings of Graham et al.<sup>7</sup> No differentiation was seen between herpes simplex and herpes zoster on cytological grounds. Findings of histological examination were similar to those seen on cytology in all the 9 cases i.e., concordant result were obtained in nine cases (100%). Distinction between the two types of herpes infection was made purely on clinical grounds.

#### (b) Pemphigus

Findings in pemphigus were approximately similar to those observed by Sehgal.<sup>8</sup> In 06 cases cytological examination was inadequate for diagnosis. Distinction between Pemphigus vulgaris and Pemphigus foliaceus was not possible on cytology. On histology, 20 cases were diagnosed as Pemphigus vulgaris and 04 cases as Pemphigus foliaceus.

#### (c) Molluscum Contagiosum

In all the 10 cases of molluscum contagiosum, scrape smears were made. Cytology was inadequate in 02 case. Concordant result was seen in all the 08 cases (100%) similar to Patil et al.<sup>9</sup> who also showed cytology to be a rapid diagnostic method with high sensitivity and specificity.

#### (d) Bullous Impetigo

Tzanck smears were made in all 08 cases of bullous impetigo. Histological examination was done in 06 cases as 02 cases refused biopsy. 02 cases (33.3%) diagnosed as bullous impetigo showed features of herpes zoster on histological examination. The sensitivity of cytological examination (Tzanck smear) for the diagnosis of vesicobullous lesion was found to be as high as 96%.

## Granulomatous Lesions

#### (a) Lupus Vulgaris

In 18 cases of lupus vulgaris the mean age of presentation was 22 years, though Bhambhani et al. described maximum number of cases in the 0 - 10 years age group. 08 cases were seen on the face, similar to Bhambhani et al,<sup>10</sup> who also showed lesions on the face in 40% of cases.

#### (b) Leprosy

22 cases of leprosy were included in the study and categorized according to the Ridley Jopling classification.<sup>4</sup> The average age incidence in our study was 32.5 years. Farshcian and Kheirandish<sup>11</sup> showed the mean age of presentation to be 48.5 plus/minus 16.2 years. Out of 22 cases, cytological diagnosis of leprosy was made in 16 cases, while 02 cases was inconclusive. Histopathological examination confirmed the cytological diagnosis in eight of the 20 cases (80% concordance) whereas in 04 cases discordant results were seen. These 04 cases with cytological features of borderline tuberculoid (BT) and mid-borderline leprosy on histopathological examination showed features of tuberculoid leprosy and BT leprosy respectively. The sensitivity of cytology (slit smear, imprints, FNAC) for the diagnosis of various granulomatous lesions was found to be 88.2%. In the 10 cases, biopsy was not available.

## Neoplastic Lesions

Of the 12 benign lesions studied, accurate cytological diagnosis was made in 08, and 04 were hemorrhagic. Histopathological correlation was seen in all 08 cases (100% concordance). Observation was similar to those observed by Layfield and Glasgow.<sup>12</sup> SCC was the most common malignant skin lesion seen in our study comprising 16 cases of a total of 36 malignant lesions studied.

The average age incidence of malignant melanoma was 52.75 years. It correlated with the study by Hadju and Savino<sup>13</sup> who reported maximum number of cases in age group of 41-60 years. The presence of melanin pigment, intracellularly, in a large number of cells was the single most valuable morphological feature that favoured the diagnosis of malignant melanoma. Histopathological examination showed features of malignant melanoma though correlation between cytology and histopathology was available in only 02 cases.

Most cases of MCC reported in literature are in the head and neck region. We studied a 02 cases MCC case with nodules over the head and neck region. Cytological examination of the nodules in our case was hemorrhagic. Diagnosis of MCC was made on histopathology. Findings on histology were similar to those described by Anderson et al.<sup>14</sup> Immunohistochemistry was positive for neurofilament and chromogranin markers.

A rare cases of SGC over the back was diagnosed in a 40-year-old female. Most of the cases of SGC reported in the literature are of the eyelid.

The study was conducted to correlate the clinical diagnosis with cytology and histopathology for the diagnosis of various non-neoplastic and neoplastic lesions. A total of 170 cases of clinically diagnosed skin lesions were studied. Cytohistological correlation was available in 120 of 170 cases. In 110 cases (91.7%) an accurate diagnosis was made by cytology whereas in 10 cases (8.3%) discordant results were seen thus a considerably high degree of correlation was achieved among cytological and histological modalities of diagnosis, especially in vesicobullous lesions. The sensitivity of cytology in diagnosing vesicobullous lesions, granulomatous lesions and neoplastic lesions was 96, 88.2 and 88.9% respectively. It was seen that biopsy provided complete tissue details for accurate diagnosis of skin lesions; however, diagnosis takes a longer time as compared to the early diagnosis provided by cytology. Yet it may not be readily available, as is evident from this study, where 50 cases (29.4%) of skin lesion did not comply with a request for biopsy.

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## CONCLUSION

Cytology (scrape/imprint/slit smears and FNAC), performed skillfully and with perfection, leads to an early diagnosis in majority of the lesions, as the observed cytomorphological features of various skin lesions were fairly distinctive making cytology a fairly sensitive ‘patient compliant’ technique for rapid diagnosis of skin lesions.

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# Traditional Legal Categories of Repudiation as Divorce in Islamic Law

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## ABSTRACT

The term *talaq* is commonly translated as «repudiation» or simply «divorce». In classical Islamic law it refers to the husband's right to dissolve the marriage by simply announcing to his wife that he repudiates her. It requires neither justification nor court approval. Classical jurists imposed certain restrictions on valid repudiation. For example, the declaration must be made in clear terms; the husband must be of sound mind and not coerced. Changing social conditions have led to increasing dissatisfaction with traditional Islamic law of divorce since the early 20th century. Various reforms have been undertaken in an attempt to restrict the husband's right of unilateral repudiation and give women greater ability to initiate divorce.

**Keywords :** Divorce, Islam , Classical jurists

## INTRODUCTION

Historically, the rules of divorce were governed by sharia, as interpreted by traditional Islamic jurisprudence, and they differed depending on the legal school. Historical practice sometimes diverged from legal theory. Divorce in Islam can take a variety of forms, some initiated by the husband and some initiated by the wife. The main traditional legal categories are *talaq* (repudiation), *khul* (mutual divorce), judicial divorce and oaths. The theory and practice of divorce in the Islamic world have varied according to time and place.

In pre-Islamic times, men kept their wives in a state of “limbo” by continually repudiating them and taking them back at will. The Quran limited the number of repudiations to three, after which the man cannot take his wife back without an intervening marriage to another man. Actual legal practice sometimes deviated from the precepts of the legal school that was dominant in the area, at times to women's benefit and at times to their disadvantage. The husband's prerogative of repudiation

is commonly rationalized with reference to the fact that Islamic law of marriage imposes financial obligations only on the husband, including payment of the mahr and providing maintenance. Additionally, classical jurists were of the opinion that “the female nature is wanting in rationality and self-control”.

Talaq is considered in Islam to be a reprehensible means of divorce. The husband can end marriage through three types of oaths: the oath of continence (*īlā* and *izhar*), the denial of paternity (*lian*), and conditional talāq. The first two types were pre-Islamic practices confirmed by the Quran (2:226–227 for *ila*, and 58:2–4 for *izhar*), which also makes clear that *izhar* is reprehensible despite being legally valid. In the *li'an* oath, the husband denies paternity of his wife's child. The wife is given an opportunity to take an oath denying infidelity, and if she does so and the husband persists in his accusation, the marriage is dissolved by a judge and the couple can never remarry. In the oath of conditional talāq, the husband declares that he will divorce his wife if he or she performs a certain act. This oath can serve as a protection for the wife or as a threat by the husband, depending on the specified act. Studies of practices under Mamluk and Ottoman rule found no instances of the oaths of *li'an* or abstinence being used, while conditional talaq seems to have played a prominent

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role. It was used to issue various threats to the wife as well as to make promises. The wife obtains custody of the children until their majority (whose definition varies according to legal school), while the father retains guardianship.

A divorced woman could keep custody of the children unless she remarried and her husband claimed custody, in which case it generally passed to one of her female relatives. Under the Mamluks, women could waive the right to child support in order to obtain extended custody. Islamic law does not recognize the concept of communal property, and division of property is based on its attribution to either spouse. The wife obtains custody of the children until their majority (whose definition varies according to legal school), while the father retains guardianship. Child custody practices under Ottoman rule appear to have followed the rules of Hanafi jurisprudence, although in Ottoman Egypt children generally stayed with their divorced mother beyond the prescribed age. A divorced woman could keep custody of the children unless she remarried and her husband claimed custody, in which case it generally passed to one of her female relatives. Under the Mamluks, women could waive the right to child support in order to obtain extended custody. Different explanations have been proposed for this phenomenon. Several scholars have argued that because these laws are more extensively specified in the Quran and hadith than others, it has been difficult for believers to accept deviating from these rules. In particular, control over the norms of divorce shifted from traditional jurists to the state, though they generally remained “within the orbit of Islamic law”.<sup>[1]</sup>

In modern times, as personal status (family) laws were codified, they generally remained “within the orbit of Islamic law”, but control over the norms of divorce shifted from traditional jurists to the state.<sup>[2]</sup>

According to the Quran, marriage is intended to be unbounded in time, as indicated by its characterization as a “firm bond” and by the rules governing divorce. The relationship between the spouses should ideally be based on love (*mawadda wa rahma*, 30:21) and important decisions concerning both spouses should be made by mutual consent. When marital harmony cannot be attained, the Quran allows and even advises the spouses to bring the marriage to an end (2:231), although this decision is not to be taken lightly, and the community

is called upon to intervene by appointing arbiters from the two families to attempt a reconciliation (4:35). The Quran establishes two further means to avoid hasty divorces. It prescribes two waiting periods of three months before the divorce is final in order to give the husband time to reconsider his decision. Moreover, a man who takes an oath not to have sexual intercourse with his wife, which would lead to automatic divorce, is allowed a four-month period to break his oath (2:226). Before Islam, divorce among the Arabs was governed by unwritten customary law, which varied according to region and tribe, and its observance depended on the authority of the individuals and groups involved. In this system, women were particularly vulnerable. The Quranic rules of marriage and divorce provided a fixed set of norms for all Muslims, backed by divine authority and enforced by the community.<sup>[3]</sup>

The Quran substantially reformed the gender inequity of divorce practices that existed in pre-Islamic Arabia, although some patriarchal elements survived and others flourished during later centuries. The early Islamic reforms included giving the wife a possibility to initiate divorce, abrogation of the husband’s claim to his wife’s property, condemnation of divorce without compelling reason, criminalizing unfounded claims of infidelity made by the husband, and institution of financial responsibilities of the husband toward his divorced wife. The subject of divorce is addressed in four different surahs of the Quran, including the general principle articulated in 2:231: The initial declaration of talaq is a revocable repudiation which does not terminate the marriage. The husband can revoke the repudiation at any time during the waiting period (*iddah*) which lasts three full menstrual cycles. The waiting period is intended to give the couple an opportunity for reconciliation, and also a means to ensure that the wife is not pregnant. Resumption of sexual relations automatically retracts the repudiation. The wife retains all her rights during the waiting period. The divorce becomes final when the waiting period expires. This is called a “minor” divorce (*bayn baynuna sughra*) and the couple can remarry. If the husband repudiates his wife for the third time, it triggers a “major” divorce (*bayn baynuna kubra*), after which the couple cannot remarry without an intervening consummated marriage to another man. This is known as *nikah halala*.

Some legal schools held that a triple talaq performed in a single meeting constituted a “major” divorce, while

others classified it as a “minor” divorce. Upon talaq, the wife is entitled to the full payment of *mahr* if it had not already been paid. The husband is obligated to financially support her until the end of the waiting period or the delivery of her child, if she is pregnant. In addition, she has a right to child support and any past due maintenance, which Islamic law requires to be paid regularly in the course of marriage. Talaq was considered to be disastrous for the woman because it deprived her of long-term protection and financial support, preventing her from remarrying, since this would cause her to lose child custody. This led to repudiation without good reason being considered socially improper. Khul is a contractual type of divorce that is initiated by the wife. It is justified on the authority of verse 2:228: A marriage can also be dissolved by means of judicial divorce. Either spouse can petition a qadi court to obtain judicial divorce, but they must have compelling grounds for dissolving the marriage. The court starts the process by appointing an arbitrator from each of their families in order to seek a mediated reconciliation. If this effort fails, the court adjudicates the dispute by apportioning fault for the breakdown of the marriage with the associated financial consequences. Examples of fault are cruelty; husband’s failure to provide maintenance or pay the immediate instalment of *mahr*; infidelity; desertion; moral or social incompatibility; certain ailments; and imprisonment harmful to the marriage. Judicial divorce can also be sought over violations of terms stipulated in the marriage contract. Different legal schools recognized different subsets of these grounds for divorce. *Ila* is an oath whereby the husband vows to refrain from sexual relations with his wife for at least four months. If he fulfils his oath, the marriage is dissolved; if he breaks it, the marriage continues. In the *izhar* oath a man declares that his wife is as sexually prohibited to him as his mother. The husband is able to break the oath and resume the marriage. Breaking either oath requires expiation by means of feeding the poor or fasting.<sup>[4]</sup>

Additionally, the pre-Islamic bride wealth (*mahr*), which was paid by the groom to the bride’s family, was transformed into a dower, which became property of the wife, though some scholars believe that the practice of giving at least a part of the *mahr* to the bride began shortly before the advent of Islam.<sup>[5]</sup>

## CLASSICAL ISLAMIC LAW OR SHARIA

Classical Islamic law is derived from the scriptural sources of Islam (Quran and hadith) using various methodologies developed by different legal schools. Family disputes were handled in sharia courts presided over by a judge (*qadi*) who had enough legal education to decide some legal questions and queried a mufti if faced with a difficult legal issue. In the modern era, sharia-based laws were widely replaced by statutes based on European models, and its classical rules were largely retained only in personal status (family) laws. Important changes in family laws took place in the modern era. The laws underwent codification by legislative bodies and were also displaced from their original context into modern legal systems, which generally followed Western practices in court procedure and legal education.<sup>[6]</sup>

In court proceedings, they mediated between the letter of the law and exigences of the local social and moral concerns, with the overarching aim of ensuring social harmony<sup>[7]</sup>

In contrast, Wael Hallaq sees it as a legacy of colonialism: changing family laws would have provided no benefit in colonial administration, and colonial powers promoted the theory that these laws were sacred to the population, advertising their preservation as a mark of respect, which in turn led to them being taken up as a point of reference in modern Muslim identity politics. This severed them both from the classical interpretative tradition and from the institutional foundations of the pre-modern legal system into which they were embedded.<sup>[8]</sup>

This delegation can be made at the time of drawing up the marriage contract (*nikah*) or during the marriage, with or without conditions. Delegated repudiation is called *talāq al-tafawud* or *tafwid*.<sup>[9]</sup>

## DOWER (MAHR) IN DIVORCE

*Mahr* is a nuptial gift made by groom to the bride at the time of marriage. Upon receipt, it becomes her sole property with complete freedom of use and disposal. The marriage contract is not valid without the *mahr*. The amount of the *mahr* generally depended on the socio-economic status of the bride. The payment of a portion of the *mahr* was commonly deferred and served as a deterrent to the exercise of the right of unilateral divorce by the husband, although classical jurists disagreed about

the permissibility and manner of deferring payment of the mahr<sup>[10]</sup>

Islamic jurisprudence has clear guidance on handling of mahr in the case of divorce, depending on who asks for the divorce and whether or not the intercourse occurred. If the husband asks for a divorce and intercourse has occurred, he pays full *mahr*; if the husband asks for a divorce and the intercourse has not occurred, the husband pays half the dower; if the wife asks for a divorce and intercourse has occurred, the husband pays half the *mahr*; and if the wife asks for a divorce and is still an intercourse has not occurred, then no *mahr* is required to be paid by the husband.<sup>[11]</sup>

### PREVALENCE

According to Yossef Rapoport, in the 15th century, the rate of divorce was higher than it is today in the modern Middle East, which has generally low rates of divorce. In 15th century Egypt, Al-Sakhawi recorded the marital history of 500 women, the largest sample on marriage in the Middle Ages, and found that at least a third of all women in the Mamluk Sultanate of Egypt and Syria married more than once, with many marrying three or more times. According to Al-Sakhawi, as many as three out of ten marriages in 15th century Cairo ended in divorce. In the early 20th century, some villages in western Java and the Malay peninsula had divorce rates as high as 70%.<sup>[12]</sup>

### CONCLUSION

Changing social conditions have led to increasing dissatisfaction with traditional Islamic law of divorce since the early 20th century. Various reforms have been undertaken in an attempt to restrict the husband's right of unilateral repudiation and give women greater ability to initiate divorce. The Muslim Women (Protection of Rights on Divorce) Act was a controversially named landmark legislation passed by the parliament of India in 1986 to allegedly protect the rights of Muslim women who have been divorced by, or have obtained divorce from, their husbands and to provide for matters connected therewith or incidental thereto.

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