RESEARCH ARTICLE

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Analysis of Discrepancy Index between Clinical and Histopathological Diagnosis of Oral Lesions

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Abstract

Objective: To analyze the discrepancy index between the clinical and histological diagnosis of oral lesions. **Materials and method:** A sample of 910 cases from year 2013-2021 were analyzed using non probability convenience sampling technique. This included patient records and histopathological reports of patients treated at IIDC & H and FUCD & H. Clinical presentations were classified under five categories; growth/swelling, vesico-ulcerative, white, red/pigmented, and cystic lesions. To evaluate the details of diagnostic discrepancies, the data was categorized into 4 major groups: 1) Neoplastic-Neoplastic,2) Non-Neoplastic-Non-Neoplastic ,3) Neoplastic-Non-Neoplastic and 4) Non-Neoplastic-Neoplastic. The association between clinical diagnosis and histopathological diagnosis was calculated by using pearson chi square test and statistical significance was considered with the p value less than (0.05). **Results:** Most common clinical presentation was swelling/growth; 601 (66%), followed by ulceration; 223 (24.5%). There were 528 (58%) incisional and 382 (42%) excisional biopsies. The definitive diagnosis based on histopathological findings showed malignant neoplasms as the commonest category; 287 (31.5%) followed by inflammatory/reactive lesions 271 (29.8%). A consensus was noted between the clinical and histologic diagnosis in 74.8% cases, while a discrepancy index of 25.1 % was calculated. Regarding diagnostic discrepancy among four major categories of our research, maximum discrepancy was noted in neoplastic-nonneoplastic category (29.6%) and minimum discrepancy was noted in malignant – benign category (2.7%). Statistically significant difference between the clinical and histopathological diagnosis was observed with a p value of 0.000. **Conclusion:** Considerable amount of diagnostic discordance was observed in all types of pathologies analyzed in the study.

Keywords: Diagnostic discrepancy- discrepancy index- oral lesions

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Introduction

Diagnostic accuracy may be defined as a combination of physician's expertise, skill, and knowledge in analyzing and interpreting information from a patient regarding the ailment and devising a suitable treatment plan in concordance with any other members who may be involved. Recently, a new but important trend is emerging which focuses on the need for recording any errors, or as we call incidents of inaccurate diagnosis, which can later be used to help improve and institutionalize diagnostics. This has a tremendous potential in helping patients care (Vhriterhire et al., 2018). It is, however, to be stressed that diagnostics are dependent on laboratory reports and importantly pathology reports which if inaccurate may lead to inaccurate diagnosis. Such an outcome may not be detected at an early stage in such a scenario and is likely to result in poor decision making (Vhriterhire et al., 2018). This is where discrepancy studies come in which are helpful in analyzing the differential diagnosis of two or more physicians with the help of data, if resourced properly in pathology departments and even in surgical pathology. This means that past cases must be available which can be constantly peer-reviewed as part of a qualitative assessment process and enhance skills and expertise (Thway and Fisher, 2009).

The maxillofacial region generally and the oral cavity in particular presents with a myriad of pathologies which at an early stage are difficult to detect due to varying degree of its presentation and confusing nature. However, if these can be identified at an early stage with an introspective eye of the treating dentist, and diagnosed properly; there could be drastic improvements in the treatment outcomes. The importance that an early diagnosis in such cases

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holds for qualitative healthcare provision can be surmised by the fact that head and neck tumors have a median potential doubling time of six to seven days (Kulkarni et al., 2013). The key to early diagnosis, thus remains in detailed cellular analysis which can only happen through referrals in case there is an even a hint of a doubt through presentation of an ambiguous lesion (Bagul et al., 2012).

This study is therefore an effort to document and discuss the discrepancies in clinical and histopathological diagnosis of oral and maxillofacial pathologies, which were encountered over a period of ten years in two tertiary care hospitals of Islamabad. The objective is that by highlighting an existing deficiency, we can ultimately emphasize on why histopathological examination is vital in such cases for early diagnosis which in turn leads to minimizing the risks associated with defects in diagnosis (Feng et al., 2014).

Materials and Methods

After taking ethical approval (letter # FF/FUCD/632/ERC/32) from the Institutional Review Board at Fauji Foundation Dental College and Hospital, a cross-sectional, retrospective study design was used to analyze 09 years data (2013-2021) from record files at Fauji Foundation Dental Hospital and Islamic International Dental Hospital.

World Health Organization (WHO) calculator was used to calculate the sample size. This generated a minimum sample size of 347 (confidence level=95%, confidence interval=5%, prevalence=65%), nonetheless, we were able to retrieve and analyze a total of 910 cases.

The data was collected during the months of February-June 2022, using nonprobability convenience sampling. The information submitted along with the biopsy and histopathological reports of patients were retrieved from the records of the Oral Pathology and Oral Surgery Departments at Islamic International Dental Hospital and Fauji Foundation Dental Hospital. The patients reporting to this department sign consent that their records may be employed for research purposes. Information about age, gender, site, biopsy type (incisional/excisional), clinical presentation, differential and definitive diagnosis were recorded. A note was made about the discrepancy between clinical and histopathological diagnosis. Entries with incomplete information were discarded.

Clinical presentations were classified under five categories; growth/swelling, vesico-ulcerative, white, red/pigmented, and cystic lesions.

The discrepancy index was calculated using the

$$\text{Discrepancy index (Di)} = \frac{\text{Number of incompatible cases}}{\text{Total number of cases in the study}} \times \frac{100}{1}$$

To further evaluate the details of diagnostic discrepancies, the data was categorized into 4 major groups along with subcategories in the 1st group as follows:

1. Neoplastic-----Neoplastic

a) Benign-Malignant & Malignant – Benign

b) Benign-Benign & Malignant-Malignant

2. Non-Neoplastic----Non-Neoplastic

(Includes Inflammatory, reactive, cystic, premalignant, and other lesions)

3. Neoplastic-----Non-Neoplastic

4. Non-Neoplastic------Neoplastic

The data was entered in the Statistical Package for Social Science (SPSS) (IBM Corp, Armonk, NY, USA) version 20. The information about age, gender, site, and type of biopsy was recorded as categorical data , thus results were presented in the form of frequencies and percentages only. The clinical presentation was presented as percentages classified under the 5 predefined categories. The discrepancy between clinical and histopathological/definitive diagnosis was recorded as present, absent or can not be assessed. The association between clinical diagnosis and histopathological diagnosis was calculated by using pearson chi square test and statistical significance was considered with the p value less than (0.05). Moreover, association between diagnostic discrepancy and biopsy site, type, clinical presentation, lesion and tissue type was also calculated using pearson chi square test and statistically significant relationship was taken at a p value of less than (0.05).

Results

A total record of 910 cases submitted to the Oral Pathology service was collected. There were 449 (49.5%) males and 458 (50.5%) females. The patient's ages were recorded as decades and were distributed between the 1st and 9th decade with the highest number of cases (188) were reported in their 5th decade of life. The most common presentation described in the clinical history was swelling/growth; 601 (66%), followed by ulceration; 223 (24.5%). There were 528 (58%) incisional and 382 (42%) excisional biopsies amongst which 695 (76.3%) were soft and 215 (23.6%) were hard tissue biopsies. The most common site of biopsy was alveolar mucosa; 217 (23.8%), followed by buccal mucosa; 172 (18.9%). The definitive diagnosis based on histopathological findings showed malignant neoplasms as the commonest category; 287 (31.5%) followed by inflammatory/reactive lesions 271 (29.8%). Details of the different categories based on histological diagnosis are shown in Figure 1.

A consensus was noted between the clinical and histologic diagnosis in 651 (74.8%) cases, while a discrepancy index of 25.1 % was calculated as a total of 219 cases showed disparity between the clinical and histologic diagnosis. DI could not be assessed in 40 cases as clinical/provisional diagnosis was not available in these cases. Moreover, 163 out of 695 (23.4%) soft tissue and 56 out of 215 (26%) hard tissue biopsies showed disparity between clinical and histopathological diagnosis. Regarding diagnostic discrepancy among four major categories of our research, maximum discrepancy was noted in neoplastic-nonneoplastic category (29.6%) and minimum discrepancy was noted in malignant – benign category (2.7%).

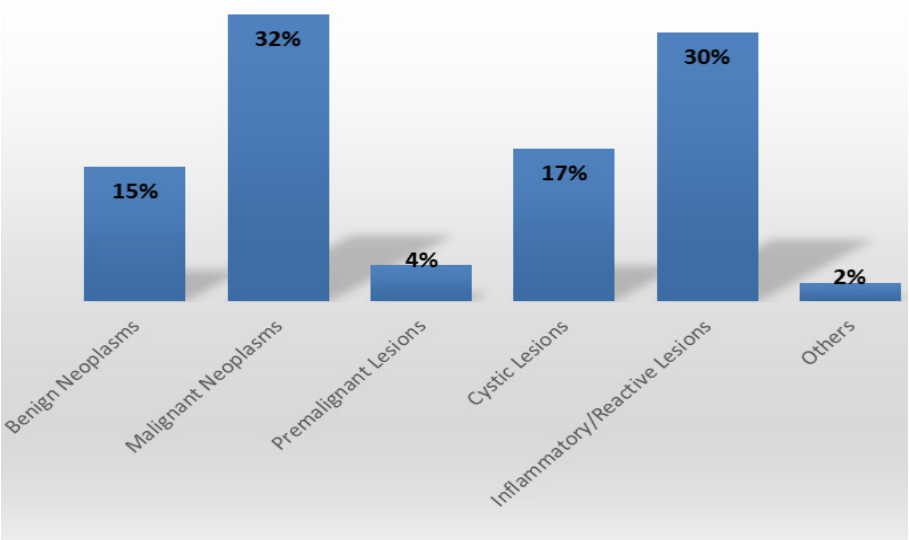

Figure 1. Frequency of Different Lesion Categories Based on Histopathological Diagnosis

Pearson chi square test was applied to assess statistically significant difference between the clinical and histopathological diagnosis and it showed a p value of 0.000. Same test was also applied to assess the association between the diagnostic discrepancy and other important variable of the study like type of biopsy, site, clinical presentation, lesion type etc; all of which showed statistically significant results with a p value of less than 0.05 except for type of biopsy and tissue type, details of the p values are shown in Table 1.

Neoplastic to Neoplastic

Twelve discrepancies were observed in benign to malignant category. Out of 5 fibromas, 2 turned out to be OSCC and 2 turned out to be basal cell carcinoma on definitive diagnosis. However, only six discrepancies were noticed in malignant to benign group (Table 2a).

Around 28 Neoplastic disorders clinically were on final diagnosis also neoplastic, however of a different category. 15 OSCC cases diagnosed provisionally were verrucous, BCC, Adenoid cystic on histology. (Table 2b). Similarly, 3 Pleomorphic adenomas were warthin tumors on definitive diagnosis.

Non-Neoplastic to Non-Neoplastic

In non-neoplastic to non-neoplastic category, around 27% discrepancies were observed in nonneoplastic disorders suspected clinically that turned out to non-neoplastic but a different class histologically (Table 3). The most common being pyogenic granuloma on clinical diagnosis that histologically in 9 cases came out to be inflammatory fibrous hyperplasia. Five OKCs turned out to be dentigerous and radicular cyst on biopsy, however 5 dentigerous cysts clinically also came out to be OKC.

Non-Neoplastic to Neoplastic

Around 12.3% cases of non-neoplastic disorders were neoplastic on definitive diagnosis. Three OKC's and two dentigerous cysts turned out to be ameloblastoma on microscopy. There were 8 discrepancies in pyogenic

Table 1. Association between Diagnostic Discrepancy and Other Variables Using Pearson Chi Square test. (p - value Less than 0.05 Taken as Statistically Significant)

Variables	X^2	p value
Biopsy Type (Incisional or Excisional)	4.065	0.397
Tissue Type (Soft or Hard tissue)	0.61	0.737
Site	39.952	0.024
Clinical Presentation	33.878	0.000
Neoplastic/ Non Neoplastic	11.896	0.018
Benign Neoplasms	17.724	0.023
Malignant Neoplasms	110.106	0.000
Pre-malignant Disorders	21.55	0.001
Cysts	29.85	0.001
Inflammatory/ Reactive lesions	113.376	0.000
Others	79.19	0.000

Table 2a. Benign to Malignant & Malignant to Benign

Clinical Diagnosis (Benign)	Histopathological diagnosis (Malignant)	No. of cases
Fibroma	Adenoid cystic	1
	Basal Cell carcinoma	2
	OSCC*	4
Benign Neoplasm NOS*	Blue cell malignancy	1
Lipoma	Spindle cell neoplasm	1
Pleomorphic Adenoma	Mucoepidermoid carcinoma	2
	Adenocarcinoma(NOS)	1
Clinical Diagnosis (Malignant)	**Histopathological diagnosis (Benign)**	**No. of cases**
OSCC*	Pleomorphic Adenoma	2
	Ameloblastoma	1
	Fibroma	3
Total Cases		18

*NOS, Not otherwise specified; *OSCC, Oral Squamous cell Carcinoma

Table 2b. Benign to Benign & Malignant to Malignant

Clinical Diagnosis (Benign)	Histopathological diagnosis (Benign)	No. of cases
Ameloblastoma	Odontogenic myxoma	1
	AOT*	2
Fibroma	Lipoma	2
Neuroma	Pilomatrixoma	1
Osteoma	Pilomatrixoma	1
Pleomorphic adenoma	Warthin tumor	3
Clinical Diagnosis (malignant)	**Histopathological diagnosis (malignant)**	**No. of cases**
OSCC*	Verrucous carcinoma	4
	Adenocarcinoma(NOS)	1
	Adenoid cystic carcinoma	2
	Basal cell carcinoma	2
	MEC*	2
	Spindle cell neoplasm	2
	Blue cell malignancy	1
	PLGA*	1
Basal cell carcinoma	OSCC*	1
	Lymphoma	1
Mucoepidermoid Carcinoma	Lymphoma	1
	Rhabdomyosarcoma	1
Total Cases		29

AOT, Adenomatoid Odontogenic tumor; OSCC, Oral Squamous Cell Carcinoma; MEC, Mucoepidermoid Carcinoma; PLGA, Polymorphous low grade adenocarcinoma

granuloma suspected clinically, out of which 4 turned out to be malignant. Similarly, two cases of osteomyelitis also came out be malignant lesions histopathologically (Table 4).

Neoplastic to Non-Neoplastic

Maximum discrepancy was observed in Neoplastic/nonneoplastic category (29.6%) with OSCC being the most inconsistent one on clinical evaluation (49.2%) (Table 5).

Discussion

Our study showed that almost 75% (641/910 cases) of times there was a consensus between pathologist and clinician thoughts, somewhat close consensus of 89% has also been documented by another study by Vhriterhire et al., 2018 This means that the disparity index in our study was 25%. Another study from Portugal also observed a disagreement in 25.5% of oral cases (Ramos et al., 2021). However, an earlier retrospective study showed a disagreement in 12.1% of cases (Kalele et al., 2016) which is quite low as compared to our findings. Azita et al in their study they found consistency was three times more than inconsistency and largely accepted the clinician accuracy (Farzinnia et al., 2022).

In present study, 58% cases were of incisional biopsies

Table 3. Non-Neoplastic to Non-Neoplastic

Clinical Diagnosis	Histopathological diagnosis	No. of cases
Actinomycosis	Granulation tissue	1
Candiadiasis	Lichen planus	1
Cyst	COD*	1
	Normal mucosa	1
	Granulation tissue	3
OKC	Radicular cyst	3
	Chronic mucositis	2
	Dentigerous cyst	2
	Osteomyelitis	1
Osteomyelitis	Chronic mucositis	2
Dentigerous	OKC*	5
Eruption cyst	Granulation tissue	1
Giant cell lesion	IFH*	2
	Pyogenic granuloma	1
Lichen planus	Chronic mucositis	3
	Hyperkeratosis	2
	Dysplasia	2
Mucocele	Chronic mucositis	1
Pemphigus Vulgaris	Chronic Mucositis	1
Pyogenic granuloma	IFH*	10
	Peripheral Fibroma	4
	Peripheral giant cell granuloma	2
	Peripheral Ossifying Fibroma	3
	OKC*	1
Radicular cyst	Periapical granuloma	8
Ranula	Dermoid cyst	1
Reactive lymph node	Dermoid cyst	1
Sebaceous cyst	Epidermoid cyst	1`
Oral Submucous Fibrosis	Dysplasia	2
Total Cases		67

OKC, Odontogenic keratocyst; *IFH, Inflammatory Fibrous Hyperplasia; *COD, Cementosseous dysplasia

and 42% were excisional biopsy specimens, this is exactly similar to study done in Brazil with similar ratio of biopsy specimens (Cantanhede et al., 2016). Regarding diagnostic discrepancy 26% of incisional and 22% of excisional biopsy specimens showed diagnostic discrepancy.

In our study we did a detailed assessment of oral lesions submitted for histopathology. Amongst our 4 major groups, most cases that showed discrepancy belonged to neoplastic/non-neoplastic category. The category included lesions that were both benign/malignant on clinician suspicion and turned out to be non-neoplastic on histology. The most common lesion being OSCC (46/79 cases) that on histology were mostly chronic inflammation NOS, keratosis, dysplasia, mucormycosis etc. In present study in few cases, however OSCC suspected also came out to be benign tumor like pleomorphic adenoma, fibroma. Similarly, some inflammatory/reactive lesions were

Table 4. Non-Neoplastic to Neoplastic

Clinical Diagnosis	Histopathological diagnosis	No. of cases
Dentigerous cyst	AOT*	1
	Ameloblastoma	2
Fibrous dysplasia	Cementoblastoma	1
Giant cell lesion	Fibroma	1
	Spindle cell neoplasm	1
Granulation tissue	Fibroma	2
	OSCC*	2
Mucocele	Pleomorphic Adenoma	1
Nasolabial cyst	Spindle cell neoplasm	1
OKC*	Ameloblastoma	3
Osteomyelitis	Chondrosarcoma	1
	Osteosarcoma	1
	Epithelial neoplasm NOS*	1
Pyogenic Granuloma	Adenoid cystic carcinoma	1
	Mucoepidermoid Carcinoma	1
	OSCC*	2
Sebaceous cyst	Adenexal neoplasm	1
Leukoplakia	OSCC*	3
Total Cases		26

AOT, Adenomatoid Odontogenic Tumour; OKC, Odontogenic Keartocyst; OSCC, Oral Squamous cell carcinoma; NOS, Not otherwise specified

Table 5. Neoplastic to Non-Neoplastic

Clinical Diagnosis	Histopathological diagnosis	No. of cases
OSCC*	Keratosis	3
	Chronic Inflammation	19
	IFH*	4
	Mucormycosis	5
	Lymphadenopathy	1
	Dysplasia	14
Osteoma	Normal bone	1
Pleomorphic adenoma	Granulation tissue	2
	Sialadenitis	2
Ameloblastoma	CGCG*	8
	Normal mucosa	1
	OKC*	4
	Radicular cyst	1
	Inflammatory	1
Fibroma	Choristoma	1
	Mucositis	2
	Granulomatous Inflammation	1
	IFH*	2
	Mucocele	1
	OSF*	1
	Pyogenic granuloma	2
Melanoma	Nevi	1
Mucoepidermoid carcinoma	CGCG*	2
Total cases		79

CGCG, Central Giant cell granuloma; OKC, Odontogenic Keratocys; OSF, Oral submucous fibrosis

malignant on histology. Olujide et al., from Nigeria noted a 66% disparity in diagnosis of epithelial tumors of oral region (Soyele et al., 2019). The aggressive nature of OSCC infers a change of treatment plan, leading to the fact that histopathology remains the gold standard for definitive diagnosis. A clinician should be more cautious in suspecting malignancy without adequate clinical evidence.

Least discrepancy in our study was found in malignant/benign or benign to malignant category (18/219 cases 12%). A study conducted recently in AFIP, Rawalpindi found just 18% discrepancy in benign to malignant or vice versa. Furthermore, they also observed that most errors 75% being reported in the class in which neoplastic category remains same but there was change of specific histological diagnosis which can have an impact on management (Anwar et al., 2021). However, in present study around 12.7% cases were in disagreement that belonged to the same neoplastic category but with a change in specific histologic diagnostic entity. This huge disparity between the two studies is attributed to the fact that the aforementioned study measured the level of error and change in diagnosis for cases only referred for second opinion.

A diagnostic discrepancy was also observed in OKC to dentigerous/ameloblastoma or vice versa. This could be attributed to similar clinical and radiographic features of these odontogenic lesions. Similar observations were made by Alexandre et al., who recommended a thorough clinical evaluation and highlighted this diagnostic challenge. (Perez et al., 2022)This may be due to the fact that an uninflamed odontogenic cyst can be easily diagnosed on histology but inflammation in the cystic lining of any odontogenic cyst can be challenging to evaluate on microscopy (Chi et al., 2017). A recent article correlated histopathological and clinicoradiographic features of odontogenic keratocyst to avoid a diagnostic dilemma, it emphasized the need of clinopathological parameters to reach a definitive diagnosis in case of inflammation (J Parikh et al., 2022). Minor discrepancy was noted in few radicular cysts being diagnosed as periapical granuloma in present study. Ohoud et al, analyzed concordance between clinical and histopathological diagnoses in 137 periapical lesions of endodontic origin and concluded clinical/radiographic examinations are not able to preoperatively determine whether a periapical lesion is a cyst or a granuloma (Alotaibi et al., 2020).

In present study not much disparity in soft tissue lesions (23.4%) was seen,and it was comparable to hard tissue discrepancy (26%). Similarly, Safoura et al., in their study, found no significant difference in concordance index in soft tissue and intra-osseous lesions (Seifi et al., 2010). They observed correct clinical diagnosis in soft tissue and intra-osseous oral lesions was 66.2% and 66.6% respectively. However, in another study of Iran, the minimum rate of compatibility was related to malignant

osseous lesions (Emamverdizadeh et al., 2019).

While conducting this study some of the problem in communication were highlighted, the fore most being some clinicians were unable to provide enough clinical information to help in diagnosis as in our study, 40 cases were received without any provisional diagnosis, consequently the diagnostic discrepancy could not be asses in such cases. Generally, concordance rates can be improved by building a better collaboration between surgeons, pathologists, and other specialties. In this modern era since a pathologist is just one click away, a clinical picture of patient along with thorough clinical history; precise radiographic and imaging information; representative biopsy specimen, along with suitable means of carrying specimen to the lab, would also lead to better results.

In conclusion, this is the first study addressing the diagnostic discrepancy between the clinical and histopathological diagnosis of oral lesions in Pakistan and has observed a considerable amount of discordance in nearly all types of pathologies.

Recommendation

In modern era of scientific advancements, we still face the dilemma of diagnostic discrepancies but the synergistic approach between clinician and pathologist can help in bridging the gap.

Author Contribution Statement

Generated the ideas: Maqsood A, Zaib N; Contributed to the writing of the manuscript; Zaib N, Masood R, Kiyani A, Ansari FM; Acquisition of data & analysis; Ghayas S, Zaib N, Masood R, Kiyani A; Interpretation of data; Zaib N, Ansari FM, Maqsood A; Statistical analysis; Ansari FM, Ghayas S, Zaib N; Critical revision of the manuscript; Maqsood A, Zaib N, Kiyani A, Ansari FM; All authors approved the final revision.

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Conflict of interest

None declared.

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