ORIGINAL RESEARCH

Agreement Between Clinical and Histopathological Diagnoses of Oral and Maxillofacial Lesions and Influencing Factors: A Five-Year Retrospective Study

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Purpose: Diagnosing oral and maxillofacial lesions is a multi-step, multidisciplinary process. If a clinical diagnosis is achievable, then a histopathological diagnosis is indicated to support and confirm the diagnosis. Histopathological examination of tissue biopsies is therefore an essential part of the diagnosis and/or treatment plan. The purpose of this study was to investigate the agreement between the clinical and histopathological diagnoses of oral and maxillofacial lesions and the patient, lesion, and healthcare provider factors that may affect this agreement.

Patients and Methods: This was an observational, cross-sectional study of all patients who had been referred to the Oral Pathology Central Laboratory at the Faculty of Dentistry and University Dental Hospital at King Abdulaziz University in Jeddah, Saudi Arabia, between 2018 and 2022 for diagnosis of oral and maxillofacial lesions. Data extracted included information about the referring dental provider such as their clinical experience (number of years), specialty, certification, and education. Agreement between the clinical and histopathological diagnoses was evaluated, and logistic regression was used to assess provider characteristics associated with the accuracy of diagnosis.

Results: The clinical and pathological diagnoses were concordant in 44.1% (n=378) of cases, and concordance was highest for odontogenic tumors (72.7%, n=24), significantly higher than for inflammatory lesions (37.3%, n=111). The anatomical locations with the highest diagnostic accuracy were the ventral surface of the tongue (71.4%, n=5), followed by the lips (52.6%, n=20). Patient age and sex and the dentist's years of experience were not associated with diagnostic agreement (p=0.2, p=0.9, and p=0.08, respectively). However, concordant diagnoses were significantly associated with the dentist's rank (p=0.02) and specialty (p=0.01). Clinical diagnoses made by oral surgeons at the time of biopsy were 1.6-times more likely (p=0.01) to agree with the pathological diagnosis compared with those made by other specialties when controlling for education, certification, and years of experience.

Conclusion: These data are a reminder that a clinical diagnosis alone is not sufficient to secure the final diagnosis and to plan treatment. Histopathological examination remains essential for most oral and maxillofacial lesions.

Keywords: dentist, oral diseases, clinical diagnosis, biopsy, histopathological diagnosis

Introduction

Oral diseases include a wide range of conditions such as cysts and benign and malignant salivary gland, odontogenic, and non-odontogenic neoplasms, amongst others. Dentists play an important role in the diagnosis and treatment of these lesions. Many oral diseases have similar clinical features, and when treatment is based only on a clinical diagnosis without histopathological confirmation, misdiagnosis can have adverse consequences, particularly when the lesion is precancerous or cancerous.[1] Thus, a confirmatory histopathological examination is required when clinical features are uncertain or shared by different lesions to secure the final diagnosis and to guide holistic management.[2,3] To avoid misdiagnosis and inappropriate management, the American Academy of Oral and Maxillofacial Pathology (AAOMP) has recommended that all "abnormal tissue be submitted promptly for microscopic evaluation and analysis", underscoring the

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importance of histopathological studies as the gold standard for achieving a definitive diagnosis. Thus, tissue biopsy of oral lesions is within the purview of the general dental practitioner (GDP).[3]

GDPs are often the first providers to hear about clinical symptoms and observe any oral abnormality. GDPs represent most (73.9%) of the dental workforce in the Saudi health system (5182 and 13,743 in the government and private sectors, respectively, not including practitioners described as "advanced general dentists" and "family dentists").[4] For initial clinical diagnosis and proper referral handling, GDPs must be aware of the sites and probabilities of occurrence of oral and maxillofacial lesions, however, to ensure a reliable diagnosis, cooperation between clinicians and pathologists is necessary.

Bacci et al found that nearly one-third (31.5%, n = 1566) of clinical diagnoses made by GDPs between 2006 and 2012 were inaccurate. Accurately describing the lesion and using accepted terminology improve the accuracy of the histopathological assessment.[5] After examining incorrect clinical diagnoses, Sarabadani et al recommended attention to detail in the clinical examination and history taking to improve the accuracy of the clinical diagnosis. Overall, careful evaluation of all clinical, radiographic, and histopathological findings is critical for securing a final correct diagnosis.[6] Previous studies have reported concordance rates of 50–81.2% between the clinical and histopathological diagnoses of oral and maxillofacial lesions.[7–15] Thus, it is vital that the referring clinician and pathologist communicate well, especially regarding the clinical findings of the lesion and use of precise, appropriate terminology in the pathology report.[16]

The aim of the present study was to quantify concordance between the clinical and histopathological diagnoses of oral and maxillofacial lesions in patients referred to the Oral Pathology Central Laboratory at the Faculty of Dentistry at King Abdulaziz University (KAUFD) and the University Dental Hospital (UDH). In doing so, we aimed to establish which provider characteristics are associated with the accuracy of diagnosis. Our null hypothesis was that the final (histopathological) diagnosis was not concordant with the primary (clinical) diagnosis.

Materials and Methods

This study is reported according to STROBE guidelines (see Supplementary Table 1). This was a descriptive, retrospective study of 858 patients referred to the Oral Pathology Central Laboratory at the KAUFD and UDH in Jeddah, Saudi Arabia, between 2018 and 2022. These patients were seeking treatment for and requiring biopsy of oral and maxillofacial lesions and subsequently received a histopathological report (n = 858). There were no age restrictions.

Inclusion criteria were a complete clinical file; definitive diagnosis based on the histopathological examination of the tissue biopsy; single or multiple biopsies taken; and an oral and maxillofacial lesion(s) confined to the area that involved one or more of the following tissues: bone, connective tissue, glandular, or mucosal tissues. Exclusion criteria were histopathology reports originating from another laboratory or institution and lesions located outside the oral and maxillofacial area.

The research ethics committee at the King Abdulaziz University Faculty of Dentistry (#079-08-22) approved the study protocol, which was conducted according to the Declaration of Helsinki. Participants were seeking Oral Pathology Central Laboratory services, and informed consent was obtained from all participants. For patients under 18 years of age, the parent or legal guardian provided the informed consent or assent.

Diagnostic classifications were adapted from Barnes[17] and Bezroukov.[18] Cases with inconclusive pathologic diagnoses were classified as miscellaneous, inconclusive, or nonspecific diagnoses. All records were retrieved from the KAUFD electronic health record system and the Oral Pathology Central Laboratory, as this laboratory was established in 2018 under the UDH and all records are documented in an electronic system. Biopsies were examined in the oral pathology central laboratory, which also accepts referrals from specialists and consultants who work in clinics outside KAUFD and UDH.

The retrieved information included patient characteristics (age and sex); location of the lesion; the nature of the lesion (benign or malignant); surface characteristics of peripheral lesions; the intraosseous or soft tissue origin of the lesion; and the clinical and histopathological diagnoses. For each patient, care provider information, ie, the number of years of clinical experience and professional rank, were recorded. Professional ranks were categorized into undergraduate students, postgraduate students (MSc or PhD students), Saudi Board residents, GDPs, and specialists or consultants.

The two authors, who are consultants in oral medicine and oral pathology, reviewed all oral pathology reports and evaluated the agreement between the clinical and histopathological diagnoses for each case.

Statistical Analysis

The primary outcome was the degree of concordance between the differential diagnoses made by referring dentists and the histopathological diagnosis made in the pathology lab. The secondary outcomes were factors affecting the agreement between the clinical and histopathological diagnoses of oral and maxillofacial lesions including patient characteristics (age and sex), characteristics of the lesion (location, nature (benign or malignant), surface characteristics of peripheral lesions, intraosseous or soft tissue origin of the lesion), and care provider information (clinical experience and professional rank).

Data were analyzed using SPSS v20 (IBM SPSS Statistics, Armonk, NY). Descriptive statistics were used to describe the characteristics of the study variables in the form of frequencies and percentages for categorical variables and means and standard deviations (SD) for continuous variables. Agreement between the differential diagnoses made by the referring dentists and the final histopathological diagnoses were assessed using Cohen's kappa coefficient. Chi-squared tests were used to assess relationships between categorical variables. Logistic regression was used to assess which provider characteristics were associated with correct diagnoses. Statistical significance was set at the 5% level.

Results

This descriptive retrospective study included data from 858 patients with oral and maxillofacial lesions seen between 2018 and 2022.

Demographic Characteristics of the Referring Dentists

Over half of the referring dentists were consultants (59.2%, n = 508), and the rest were postgraduate students (26.1%, n = 224), board residents (11.3%, n = 97), and undergraduate students (3.4%, n = 29). Referrals were most often from oral surgeons (45.1%, n = 387), followed by endodontists (22.6%, n =194). Over half of referrals (58.9%, n = 505) were from dentists with >5 years of experience.

Clinical and Demographic Characteristics of the Patients

The mean (SD) age of the patients (n = 858) was 37.3 (7.3) years; 432 patients (50.3%) were male. The most common location of oral and maxillofacial lesions was the mandible (34.6%, n = 297), followed by the maxilla (26.2%, n = 225). The least common location was the floor of the mouth, present in only four of 858 cases (Table 1).

There was a wide variety of histopathological diagnoses of the oral and maxillofacial lesions. The most frequently reported diagnoses were cystic lesions (25.2%, n = 216), followed by inflammatory lesions (20.6%, n = 177) and reactive/adaptive lesions (15.0%, n = 129) (Table 2).

Agreement Between the Clinical and Pathological Diagnoses and Associated Factors

Table 3 shows the agreement between the clinical diagnosis (made by clinicians) and the histopathological diagnosis (made by the oral pathologist), stratified by location. In 378 cases (44.1%), the clinical diagnosis agreed with the histopathological diagnosis. The anatomical locations with greatest proportion of diagnostic accuracy were the ventral surface of the tongue (71.4%, n = 5), followed by the lips (52.6%, n = 20). The agreement between the differential diagnoses made by the referring dentists and the final histopathological diagnoses, as assessed using Cohen's kappa coefficient, was 0.388, indicating moderate agreement.

The relationship between patient and dentist demographics and accuracy of the clinical diagnosis is shown in Table 4. The patient's age and sex and dentist's years of experience were not associated with diagnostic agreement (p = 0.9, p = 0.3, and p = 0.08, respectively). However, concordant diagnoses were significantly associated with the dentist's rank (p = 0.02) and specialty (p = 0.01). The clinical diagnoses of consultants and oral surgeons were more likely to agree with the histopathological diagnosis compared with other ranks and specialties.

Table 1 Location of the Site of the Biopsies. 25 Patients Had Biopsies from More Than One Location

Location	n (%)
Mandible	297 (34.6)
Maxilla	225 (26.2)
Buccal mucosa	96 (11.2)
Lateral side of the tongue	63 (7.3)
Gingiva	40 (4.7)
Lip	38 (4.4)
Labial mucosa	36 (4.2)
Palate	31 (3.6)
Alveolar mucosa	24 (2.8)
Dorsal side of the tongue	22 (2.6)
Ventral side of the tongue	7 (0.8)
Floor of the mouth	4 (0.5)

Table 2 Histopathological Classification of the Oral Lesions

Classification (n = 858 lesions)	n (%)
Cystic	216 (25.2)
Inflammatory	177 (20.6)
Reactive/adaptive	129 (15.0)
Malignant tumors	88 (10.3)
Epithelial lesions	50 (5.8)
Immune-mediated diseases	45 (5.2)
Salivary gland diseases and tumors	40 (4.7)
Odontogenic tumors	33 (3.8)
Benign mesenchymal lesions	29 (3.4)
Bone	24 (2.8)
Miscellaneous	21 (2.4)
Pigmented	3 (0.3)
Tooth abnormalities	3 (0.3)

The agreement between the clinical and histopathological diagnoses stratified by type of lesion is shown in (Table 5). Inflammatory and miscellaneous lesions were less likely to have matching clinical and histopathological diagnoses compared with other types of lesions (p = 0.042 and p = 0.006, respectively). The clinical diagnosis of odontogenic tumors was significantly more likely to match the histopathological diagnosis (p = 0.001) compared with other types of lesions.

Table 3 Frequencies and Percentages of Clinical and Histopathological Diagnoses by Anatomical Site

Location	Clinical Diagnosis Matched Histopathological Diagnosis n=378 (44.1%)	Clinical Diagnosis Did Not Match Histopathological Diagnosis n=480 (55.9%)
Maxilla	92 (40.9)	133 (59.1)
Mandible	145 (48.8)	152 (51.2)
Palate	12 (38.7)	19 (61.3)
Alveolar mucosa	11 (45.8)	13 (54.2)
Buccal mucosa	35 (36.5)	61 (63.5)
Labial mucosa	13 (36.1)	23 (63.9)
Ventral side of the tongue	5 (71.4)	2 (28.6)
Dorsal side of the tongue	9 (40.9)	13 (59.1)
Lateral side of the tongue	26 (41.3)	37 (58.7)
Floor of the mouth	1 (25.0)	3 (75.0)
Gingiva	19 (47.5)	21 (52.5)
Lip	20 (52.6)	18 (47.4)

Table 4 Agreement Between the Clinical and Histopathological Diagnoses According to Patient and Dentist Variables

Characteristics	Categories	Clinical Diagnosis Matched Histopathological Diagnosis 378 (44.1%)	Clinical Diagnosis did not Match Histopathological Diagnosis 480 (55.9%)	p-value
Sex	Male	182 (42.1)	250 (57.9)	0.3
	Female	196 (46.0)	230 (54.0)	
Age of patient	0–9	12 (46.2)	14 (53.8)	0.9
	10–19	47 (46.1)	55 (53.9)	
	20–29	94 (47.0)	106 (53.0)	
	30–39	75 (43.1)	99 (56.9)	
	40–49	50 (40.7)	73 (59.3)	
	50–59	47 (42.3)	64 (57.7)	
	60–69	41 (44.6)	51 (55.4)	
	70–79	9 (37.5)	15 (62.5)	
	80–89	3 (50.0)	3 (50.0)	
Rank of dentist	Consultant/ Specialist	240 (47.2)	268 (52.8)	0.02*
	General Dentist/ Residents/ Students	138 (39.4)	212 (60.6)	

(*Continued*)

Table 4 (Continued).

Characteristics	Categories	Clinical Diagnosis Matched Histopathological Diagnosis 378 (44.1%)	Clinical Diagnosis did not Match Histopathological Diagnosis 480 (55.9%)	p-value
Specialty	Oral Surgery	197 (50.9)	190 (49.1)	0.01*
	Oral Medicine	56 (39.2)	87 (60.8)	
	Endodontics	74 (38.1)	120 (61.9)	
	Periodontics	8 (32.0)	17 (68.0)	
	Other specialties	3 (30.0)	7 (70.0)	
	Outside Consultations	40 (40.4)	59 (59.6)	
Years of experience	0–5 years	143 (40.5)	210 (59.5)	0.08
	> 5 years	235 (46.5)	270 (53.5)	

Note: *Indicates statistical significance.

Table 5 Correlations Between Diagnostic Concordance and Lesion Classification

Classification	Clinical Diagnosis Matched Histopathological Diagnosis	Clinical Diagnosis did not Match Histopathological Diagnosis	p-value
Cystic	102 (47.2)	114 (52.8)	0.279
Inflammatory	66 (37.3)	111 (62.7)	0.042*
Reactive/adaptive	55 (42.6)	74 (57.4)	0.724
Malignant tumors	37 (42.0)	51 (58.0)	0.688
Epithelial lesions	16 (32.0)	24 (68.0)	0.077
Immune-mediated diseases	22 (48.9)	23 (51.1)	0.502
Salivary gland diseases and tumors	22 (55.0)	18 (45.0)	0.153
Odontogenic tumors	24 (72.7)	9 (27.3)	0.001*
Benign mesenchymal lesions	17 (58.6)	12 (41.4)	0.108
Bone	12 (50.0)	12 (50.0)	0.552
Miscellaneous	3 (14.3)	18 (85.7)	0.006*
Pigmented	1 (33.3)	2 (66.7)	0.708
Tooth abnormalities	1 (33.3)	2 (66.7)	0.708

Note: *Indicates statistical significance.

Finally, logistic regression was used to assess which dental practitioner characteristics most influenced diagnostic agreement (Table 6). Clinical diagnoses made by oral surgeons were 1.6-times more likely to agree with the histopathological diagnosis compared with other specialties after controlling for education, certification, and years of experience (p = 0.03).

Table 6 Logistic Regression Analysis to Investigate Dentist-Related Factors Affecting Agreement of Diagnoses

Variable	Odds Ratio 95% CI	p-value
Consultants vs general dentists, Saudi Board residents, and undergraduate students	1.6 (0.7–3.6)	0.23
Oral surgery vs other specialties	1.6 (1.1–2.5)	0.03*
Oral medicine vs other specialties	1.0 (0.6–1.7)	0.91
Endodontists vs other specialties	1.0 (0.6–1.6)	0.97
More than 5 years' experience vs 5 years or less	0.6 (0.3–1.4)	0.27

Note: *Indicates statistical significance.

Discussion

This study examined the discrepancy between the clinical and the histopathological diagnoses of 858 oral and maxillofacial lesions. As some oral and maxillofacial lesions occur more frequently in one sex or at a certain age, these factors might influence the clinical diagnosis.[19] However, we found no significant relationship between diagnostic agreement and patient sex or age.

The clinical and histopathological diagnoses of oral and maxillofacial lesions agreed in 44.1% (n = 378) of cases, which shows that the results support our null hypothesis that the primary (clinical) diagnosis was not concordant with final (histopathological) diagnosis in most of the cases (55.9%).

This figure is similar to previous studies, where the agreement between clinical and histological diagnoses ranged from 44.6% to 84.5%, with higher percentages associated with biopsies performed by oral and maxillofacial surgeons.[1,11] The diagnostic accuracy for odontogenic tumors was 72.7% (n = 24), higher than suspected malignant tumors, inflammatory lesions, and miscellaneous lesions [42% (n = 37), 37.3% (n = 66), and 14.3% (n = 3), respectively]. Cysts or inflammatory lesions were most commonly biopsied, because these lesions have many clinical and radiographic mimics and often require biopsy to establish the final diagnosis. Our findings differ from Farzinnia et al[12] (n = 3001 over a 12-year period), who reported an agreement close to 75% between the clinical and histopathological diagnoses of oral and maxillofacial lesions and a largely acceptable clinical accuracy. In their study, Anadza et al[20] found that benign neoplasms were seldom diagnosed inaccurately. This might be because these lesions are mainly viral (eg, papillomas) or due to continuous irritation (eg, fibroepithelial polyps) and have characteristic features and sites that make them easier to identify. Tyndrof et al[21] reported an 89% agreement between clinical and histopathological diagnoses, while other studies have reported an overall range of disagreement of 20–50%,[5,6,10–16,22] similar to our value of 55.9% disagreement. Goutzanis et al reported high agreement between the clinical and histopathological diagnoses of pre-cancerous or malignant lesions (96.4%), while the overall agreement between clinical and histopathological diagnoses was 74.9%.[23]

Possible reasons for a lack of agreement between the clinical and histopathological diagnoses include insufficient clinical information on the histopathological form (to help with clinicopathological correlation) and limited provider experience; for example, only considering mucosal or skin surface abnormalities might lead to misdiagnosis. Insufficient training and experience might make it difficult to distinguish between types of lesions that share the same symptoms and/or clinical appearance. An accurate histopathological examination requires that dental care providers follow recommended biopsy procedures and send necessary clinical information using the proper forms. Accuracy also depends on the competency of the histopathologist.

An incorrect diagnosis can cause permanent harm to the patient. For example, if an inflammatory oral and maxillofacial lesion, such as a radicular cyst, is incorrectly diagnosed as an invasive odontogenic tumor or cyst, treatment will be unnecessarily invasive. Surgery always carries a risk of morbidity and in this case the loss of a large part of, or even the entire, jaw.

The most common biopsy location in the present study was the mandible (34.6%), similar to previously,[15] followed by the maxilla (26.2%) and buccal mucosa (11.2%). The lesion location associated with the highest diagnostic disagreement was the floor of the mouth (75%). We found that the most common pathology was cystic lesions (25.2%), followed by inflammatory and reactive/adaptive lesions (20.6% and 15%, respectively). These results are similar to Alhindi et al[24] who reported that the

majority of diagnoses were soft tissue lesions, although the most common pathological diagnoses were reactive/adaptive followed by cystic and inflammatory.

The diagnoses of oral surgeons were most likely to agree with the histopathological diagnosis, and the clinical diagnoses made by oral surgeons, dentists, and consultants with >5 years of experience were more likely to agree with the histopathological diagnoses compared with other ranks and specialties. Oral surgeons had more experience than other providers, which may also explain the accuracy of their clinical assessments and higher agreement. This is not surprising, given that oral surgeons are more exposed to these pathologies than other specialists.

It might be expected that consultants and specialists would exhibit greater diagnostic agreement with the histopathological diagnosis than their GDP colleagues. However, we found that the likelihood of diagnostic agreement was not related to years of professional experience. It may be necessary to review the educational curriculum to ensure that dentists are sufficiently trained in patient history taking and clinical examination, including lesion description, to better support the pathologist's diagnosis, especially when the diagnosis depends on clinical correlation.

The 55.9% (n = 480) lack of agreement between the clinical and pathological diagnoses at KAUFD over the study period indicates that pathological evaluation continues to be important for reducing errors in the diagnosis of oral and maxillofacial lesions. Clinicians should not solely rely on a clinical diagnosis. Given the high frequency of clinical misdiagnosis in the case of malignancies (58%), the seriousness of the consequences of incorrect treatment is clear. In a previous study, precancerous lesions were easily detected and correctly identified clinically by all clinicians, regardless of their rank, but even the most experienced clinicians were unable to identify all cases accurately and would have benefited from access to a histopathological diagnosis.[25]

An accurate histopathological examination depends on the clinical ability of the dental provider to biopsy the lesion correctly and take a sufficient patient history. Three factors are involved in the biopsy of a lesion: the selection of the biopsy location, use of a correct procedure, and fulfilment of the requirements of biopsy tissue. To avoid diagnostic errors and improve early disease detection and diagnosis, dental clinicians should also take a thorough history from the patient and then consult a pathologist, especially when aggressive treatment is planned, following proper and standard biopsy procedures.

This study has some limitations. It was conducted in single center, and this may affect the generalizability of the findings. In addition, the study was cross-sectional and observational, so subject to biases inherent in this study design. The study cohort was also heterogeneous, including a range of clinical lesions and non-standardized biopsy methods. About half of the biopsies were carried out by oral and maxillofacial surgeons, which may not reflect the more common oral and maxillofacial lesions managed by GDPs. Finally, in some cases, the histopathological studies did not produce a definitive diagnosis, precluding correlation with the clinical diagnosis.

There remain several gaps in knowledge about correlations between the clinical and histopathological diagnoses of oral and maxillofacial lesions and related influencing factors. Diagnostic disagreement may be reduced through the use of standardized biopsy forms and regular clinicopathological meetings in cases of diagnostic disagreement or difficult cases to reach a consensus to improve patient outcomes.

Future research endeavors could explore the effect of training attending clinicians and GDPs on oral and maxillofacial lesions. In addition, it would be useful to quantify the effect of any disagreement on clinical outcomes and patient-centered metrics like quality of life.

Conclusion

Here we report that diagnostic agreement between the clinical and histopathological diagnosis was greater in dentists practicing as oral surgeons. Odontogenic tumors were most likely to be clinically diagnosed correctly, followed by benign mesenchymal lesions, and the clinical diagnostic accuracy for inflammatory and miscellaneous lesions was relatively poor. Our data remind us that the clinical diagnosis alone is not sufficient to secure the final diagnosis. Histopathological examination is essential for the majority of oral and maxillofacial lesions. Besides minimizing misdiagnoses, this study could improve cost efficiency by increasing the accuracy of the first diagnostic step (clinical) and streamlining the diagnostic process, thus shortening the time to definitive treatment. Further multicenter studies are now recommended to further elaborate on the factors influencing clinical misdiagnosis of oral cavity lesions. We also recommend clinicopathological meetings and seminars with different specialties as

a means to decrease diagnostic disagreement between the various dental specialties and to provide an educational forum for continuing professional development.

Ethics Statement

Consent was obtained from all participants in this study. The research ethics committee at the King Abdulaziz University Faculty of Dentistry (#079-08-22) approved the study protocol.

Acknowledgments

The authors gratefully acknowledge assistance from Dr. Mohammed Al Hindi.

Disclosure

The authors report no conflicts of interest in this work.

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