Evaluation of Pre-analytical Biopsy Specimen Errors in the Pathology Laboratory of Hamadan School of Dentistry (2009-2010)

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ABSTRACT

Statement of Problem: Oral biopsy is important in the definite diagnosis of oral and maxillofacial lesions. This procedure as well as other laboratory services is prone to errors affecting the patients' safety.

Purpose: The purpose of this study was to evaluate pre-analytical biopsy specimen errors in the Oral Pathology Laboratory of Hamedan School of Dentistry, west of Iran.

Materials and Method: Ninety-one oral biopsy samples, obtained from departments of oral and maxillofacial surgery (34 samples, 37.3%), oral medicine (22 samples, 24.3%) and periodontics (10 samples, 10.9%), as well as private offices (16 samples, 17.6%) and hospitals (9 samples, 9.9%) were received and evaluated in the Oral Pathology Laboratory of Hamedan School of Dentistry considering pre-analytical errors.

Results: The errors in the request forms included unmentioned names of patients (7.7%), age (3.3%), clinical history (4.4%), site of biopsy (10.9%), differential diagnosis (18.7%) and the name of the requesting clinician (8.8%), as well as lack of radiographs (4.4%) and previous biopsy results (2.2%). Use of inappropriate fixative (5%), and specimen-containers with non-proportional volume (3%), and their small size inlets (3%) was also reported. Non-standard containers were seen in 19% of the cases, and mislabeling errors (31 missed, 2incomplete defects, and 1 incorrect) in 34% of the cases. Of 105 specimens, 6.67% were small in size, 1.90% superficially removed, and 0.95% had been traumatized. Out of the 5 containers with more than one specimen, 4 containers did not have any markers.

Conclusion: Considering the biopsy errors in the study specimens, training and surveillance to reduce the frequency of such errors seems necessary.

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Introduction

Any abnormal oral condition is recommended to be subjected to correct and timely evaluation and diagnosis [1]. Different ways have been suggested for their evaluation including taking biopsy samples and performing histological evaluation of the lesion [2].

Biopsy is clinically defined as cutting a piece of a living organism and studying it under the microscope for diagnostic and therapeutic purposes [1, 3]. Obtaining the appropriate piece of tissue in a biopsy is one of the major concerns in pathology labs which could affect the ultimate treatment outcome for patients [4-5]. Identifying the nature of the pathogenesis is only one of the determinants of a successful management of the disease [6].

A laboratory cycle resulting in histopathological

diagnosis comprises of 9 stages; 1.Sample inquiry, 2.Taking the sample, 3. Recording the information, 4.Transfer, 5.Preparation, 6.Analysis, 7. Report, 8. Interpretation, and 9.Therapeutic approaches [7-8]. Thus, the total testing process (TTP) is usually subdivided into three analytical phases and could be accompanied by pre- analytical (before admission and preparation of the sample), analytical (during the evaluation and analysis of the sample) and post-analytical (upon completion of the analyses) errors throughout the procedures [5]. The majority of errors originate in the pre-analytical phase followed by the post-analytical phase and finally the analytical phase [9-10]. Some errors in the pre-analytical phase include:

- smashing, excessive elongation, turned and shrinkage of the sample which results in histopathological artifacts in the microscopic view [1, 11-12].

- Autolysis of the biopsy sample may also occur as a result of delayed fixation or improper use of neutral buffer formalin solution, inappropriate concentration or inadequate volumes of the fixative solution [1, 13-18].

- Damage to the specimen may also occur during withdrawal of the sample from a small size inlet container [17-18].

- Failure to record the correct information on the containers for the samples may also result in irreversible errors [19-20] and laboratories may refuse to accept such samples from the clinicians [18].

Moreover, the samples should be accompanied by complete patient history including a thorough description of the lesion and the clinician's personal information [15]. These data should be recorded on the laboratory request form which is considered as the tool for communication between the pathologist and the clinician [15-16, 18].

Several scientists including Start and colleagues [17], Zarbo and Nakhleh [21], Seoane and coworkers [11], Sharif and colleagues [18], and Makary and coworkers have reported different types of pre-analytical errors in laboratory procedures, however, the number of studies in this regard is limited [7]. Furthermore, the frequency of the reported errors vary significantly among different studies which may be due to differences in the definition of error and the methods implied to identify the errors [7]. Considering the inconsistency between different reports on the pre-analytical errors in different settings, we aimed to report the pre-analytical errors associated with the samples sent to the Oral and Maxillofacial Pathology lab in Hamedan School of Dentistry, Hamedan Iran during 2009-2010.

Materials and Method

This cross sectional study was carried out on biopsy samples sent to the Laboratory of Oral Pathology in Hamedan School of Dentistry, Hamedan Iran during 2009-2010.

Power calculation was performed according to a pilot study using the following formula: $N = \frac{p(1-p)Z^2_{1-\frac{\alpha}{2}}}{d2}$.

Considering prevalence of biopsy specimen errors p =0.38, normal standard value at 95% confidence level $Z_{1-\frac{\alpha}{2}}$ =1.96 and absolute error d =0.1, the required sample size (N) was calculated as 91. These 91 specimens were received from different departments of dental school (department of oral and maxillofacial surgery, department of oral medicine, department of periodontics), private clinics and hospitals. 91 samples were evaluated in terms of:

A) Histopathology request forms: Patient's name and age, clinical history, differential diagnosis, site of biopsy, previous biopsy report, radiography, differential diagnosis and name of referring clinician

B) Sample preservation: type and volume of the fixative solution, inlet container and container size

C) Sample container: Container Material (disposable cups, glass or plastic container), lid of the containers (lid less, compressive lid or screw lid), the labels on the containers (correct label, incomplete label, wrong label or without label)

D) Sample quality: Adequacy of sample size, being intact samples (Traumatize or healthy)

Data from all the samples were retrieved and reported as descriptive data.

Results

Of the total of 91 samples, 34 samples (37.3%) were sent from the oral and maxillofacial surgery department, 22 samples (24.3%) from the department of oral medicine, 10 samples (10.9%) from the periodontics

Table 1 Distribution of errors associated with 91 request forms

Error in	Number (%)	Explanation
Patient's name	7 (7.7)	A) 4 samples missing name on the request form but name present on the label (3 cases from hospitals, 1 case from dept of oral & maxillofacial surgery B) 1 sample missing name on the request form and the label (from dept of oral & maxillofacial surgery) C) 1 sample with inconsistency between the name on the request form and the name on the label (from dept of oral & maxillofacial surgery) D) 1 sample with incomplete name (from private clinic)
Patient's age	3 (3.3)	Patient's age missing(all from private clinics)
Clinical history	4 (4.4)	Clinical history missing (3 cases from private clinics , 1 case from dept of oral medicine)
Site of biopsy	10 (9)	A) 6 samples lacked information about the anatomic specifications of the biopsy but the side of the biopsy was defined (from dept of oral medicine , private clinics and oral & maxillofacial surgery 3, 2 and 1 cases Respectively) B) 2 samples lacked information about the anatomic specifications and the side of the biopsy (both of private clinics C) 2 samples lacked information about the side of the biopsy but the anatomic specifications was defined (1 case from hospital, 1 cases from dept of oral & maxillofacial surgery
Previous biopsy report	2 (2.2)	5 cases have previously been subjected to biopsy. 2 cases did not have the previous report available (both of dept of oral & maxillofacial surgery)
Radiography	4 (4.4)	Of the 27 cases that required radiographic evaluation, 4 cases lacked a radiograph. (2 cases from hospitals, 2 cases from dept of oral & maxillofacial surgery)
Differential diagnosis	17 (18.7)	17 cases missed a differential diagnosis (7 cases from dept of oral & maxillofacial surgery, 6 cases from hospitals, 2 from dept of oral medicine 1 case from dept of periodontics and 1 case from private clinic)
Name of referring clinician	8 (8.8)	A) 7 cases missed the clinician's name (3cases from dept of oral & maxillofacial surgery , 2 from dept of oral medicine , 2 cases from dept of periodontics) B) In 1 case, the clinician's name was not legible (from private clinic)

department, 16 samples (17.6%) came from private clinics, and 9 samples (9.9%) were collected from hospitals. 84 biopsies came in one container (A group), 6 biopsies came in two separate containers (a total of 12 containers, B group) and one biopsy came in 4 containers (C group)resulting in a total of 100 containers. 100 containers consisted of 105 pieces, 95 containers contained one piece of tissue and 5 containers (all belonged to A group) contained two pieces of tissue.

The errors associated with histopathological request forms ranged between 3.3% and 18.7% with the majority of cases lacking information on differential diagnosis (Table 1).

Sample preservation: All of errors were related to biopsies sent in one container (A group). In this group 5 container (5.95%) contained inappropriate fixative (normal saline: 4 cases received from department of oral and maxillofacial surgery and 1 case received from private clinic.)

3 containers (3.57%) were with inappropriate volume of the fixative solution received from the oral and maxillofacial surgery department, the periodontics department and private clinic.

The majority of Containers' errors were associated with the use of wrong container i.e. disposable cups or lidless containers and one third of them were without label (Tables 2a, 2b and 2c).

Concerning the quality of the biopsies, 6.67% of the errors were related to the size of the biopsy. Table 3 shows distribution of errors associated with the tissue characteristics included tissues without markers, tissue with too small size, folding of the tissue, inadequate

Table 2a Distribution of errors associated with 100 containers(number and percentage)

Group	n (%)	Disposable cups (Inappropriate) n (%)	Glass container (Inappropriate) n (%)	Plastic container (Appropriate) n (%)
A group	84 (92.31)	12* (14.29)	5** (5.95)	67 (79.76)
B group	6 (6.59)	0	2*** (16.7)	10 (83.3)
C group	1 (1.1)	0	0	4 (100)
Total	100 (100)	12 (12)	7 (7)	81 (81)

* 11 cases from dept of oral & maxillofacial surgery, 1 case from dept of oral medicine
** 4 cases from private clinics and 1 case from hospitals
*** Both cases from hospitals

Table 2b Distribution of errors associated with the lid of 100 containers (number and percentage)

Group	n (%)	Lid less (Inappropriate) n (%)	Compressive lid (Inappropriate) n (%)	Screwlid (Appropriate) n (%)
A group	84 (92.31)	13* (15.47)	35** (41.67)	36 (42.86)
B group	6 (6.59)	0	5*** (41.67)	7 (58.33)
C group	1 (1.1)	0	0	4 (100)
Total	100 (100)	13 (13)	40 (40)	47 (47)

* 11 disposable cups from dept of oral & maxillofacial surgery , 1 disposable cup from dept of oral medicine and 1 lidless plastic container from dept of periodontics)
** 16 cases from dept of oral & maxillofacial surgery,13 cases from private clinics , 4 cases from dept of oral medicine and 2 cases from dept of periodontics
*** 2 cases from dept of oral & maxillofacial surgery, 2 cases from private clinics and 1 case from dept of oral medicine

Table 2c Distribution of errors associated with label of 100 containers(number and percentage)

Group	n (%)	Without label n (%)	Wrong label n (%)	Incomplete label n (%)	Correct label n (%)
A group	84 (92.31)	29 * (34.52)	1** (1.19)	0	54 (64.29)
B group	6 (6.59)	2*** (16.7)	0	2**** (16.7)	8 (66.6)
C group	1 (1.1)	0	0	0	4 (100)
Total	100 (100)	31 (31)	1 (1)	2 (2)	66 (66)

* 18 cases from dept of oral & maxillofacial surgery, 4 cases from dept of periodontics 4 cases from private clinics, 3 cases from dept of oral medicine
** From dept of oral & maxillofacial surgery, Inconsistency between the name on the label and the name in the request form
*** Both from hospitals
**** Both from hospitals , Only the location of the lesions mentioned on the labels

thickness and traumatized/healthy tissue. Of the 91 samples, 90 included the entire tissue, and in only one sample a part of the tissue was sent to our center and the other part of the tissue were referred to another center for histopathological evaluation.

Discussion

Laboratory errors have not been generally overseen and there is very little evidence concerning their frequency and type [22]. Thus, this study evaluated the errors associated with the pre-analytical phase of biopsies obtained from the oral region. The majority of errors originates from the pre-analytical phase and therefore has a more significant impact on the ultimate diagnosis and management of the disease [10, 23-24].

In this study, we defined four categories of errors; Errors associated with the laboratory request form, errors associated with preserving the biopsy, errors associated with the container of the biopsy and errors associated with the quality and quantity of the tissue.

The results revealed that from the first category of errors, failure to provide a differential diagnosis in the request form made up 18.7% of the errors. Other missing information on the request form included the anatomic location of the biopsy (10.9%), the clinician's name (8.8%), and the patient's name (7.7%). According to Nakhleh and Zarb's findings (1996), the frequency of errors in laboratory biopsies was six percent, 77% of

Table 3 Distribution of errors associated with the tissue characteristics of 105 biopsy pieces (number and percentage)

Group	Number of biopsy pieces (%)	Several tissues without markers in containers n (%)	Too small n (%)	Too superficial and twisted n (%)	Traumatized n (%)	Appropriate biopsy n (%)
A group	89 (84.76)	4* (4.49)	7** (7.86)	2*** (2.26)	1**** (1.12)	75 (84.27)
B group	12 (11.43)	0	0	0	0	12 (100)
C group	4 (3.81)	0	0	0	0	4 (100)
Total	105(100)	4 (3.81)	7 (6.67)	2 (1.90)	1 (0.95)	91 (86.67)

* 3 cases from dept of oral & maxillofacial surgery, 1 case from private clinic
** 3 cases from dept of oral medicine, 2 cases from private clinics , 1 case from dept of oral & maxillofacial surgery and 1 case from dept of periodontics
*** 1 case from dept of oral medicine and 1 case from dept of periodontics
**** from dept of periodontics

which were errors associated with the laboratory request form [21]. This value in our study was significantly greater than Novis's finding (2004) who reported a 0.73% frequency for incomplete request forms, while the sample size in Novis's study was even greater (n=771745) [25]. In Makary and colleagues' study (2007) only 91 out of 2135 samples were faulty [19]. Compared to these reports, the frequency of errors in our study was significantly higher than other centers. This signifies the importance of constant training of the health staff and their collaboration with the clinicians.

In the present report, failure to record a clinical diagnosis made up the majority of errors. Similarly, in 2007, Mamoon and coworkers reported that failure to provide a clinical diagnosis as well as a thorough clinical history is seen in 34% of the pre-analytical laboratory errors [18]. Novis also reported that missing information regarding the clinical diagnosis in the request form made up the majority of errors [25]. We revealed that 3.3% of the forms had missing information on patients' age whereas in Mamoon's, study this error had been reported to be 5.8% [18].

In the present study, 10 samples (10.9%) lacked information on the anatomic location of the biopsy. In Mamoon's study, 13% of the samples had the same error whereas in Makary's study, only 7 out of 2135 samples lacked information on the location of the biopsy [18-19].

Missing information regarding patient's age, the anatomic location of the biopsy, clinical history and differential diagnosis can affect the pathologist's diagnosis. Other errors including failure to record patient's name can lead to the loss of the sample or switching with other patients.

In the present study, while only less than one third of the samples were retrieved from hospitals and private clinics, the greatest request form errors have been recorded from these centers. This was consistent with Makary's report who also revealed that samples coming from hospitals or private clinics (0.512%) display more errors in terms of the data on the laboratory request forms compared to samples coming from their own centers (0.346%) [19]. Although this finding may be due to bias and more attention to lack of error detection during the study, it may be also because of higher level of training and more supplies in university centers.

Therefore, continuous education of healthcare workers who send biopsies for pathology laboratories after graduation should be noted.

Correct fixation of the biopsy is another important consideration in preparing the sample for pathological evaluation. A correct fixative can preserve the details of the tissue which could potentially be a determining factor in the diagnosis of the disease. An inappropriate fixative solution can deteriorate the tissue and alter the results of the evaluation. The concentration and volume of the fixative solution as well as the container in which the biopsy is stored and transferred to the laboratory is also important in preserving the tissue consistency and characteristics. The container should have a proper opening to avoid tissue damage during bring out [14-18].

In our study, in the category of errors associated with tissue preservation, application of inappropriate fixative solution, use of a container with inadequate volume of fixation solution and containers with unaccepted opening s made up 5%, 3% and 3% of the errors, respectively. These errors however comprised a greater percentage in Mamoon's study where disparity between the container and the sample and inadequate amount of the fixative solution have been reported to be28.7% and 38.2% respectively [18]. In another study investigated by Start and colleagues, 8 biopsies underwent autolysis because of inadequate volume of fixative solution [17].

While plastic containers with sealable lids are recommended for tissue storage to avoid formalin evaporation [26], the present study demonstrated that 19% of the samples were sent in disposable cups (n=12) or glass containers (n=7), 13% failed to have a lid and 40% had an unsuited lid. In Garner's study, similarly, inappropriate storage of the biopsy through its transfer to the laboratory comprised the greatest part of errors [27]. Lidless containers may result in loss of biopsies or spread of infection specially for polluted samples. Glass containers should also be avoided due to the chance of breakage and harm to the staff or samples. We observed that 31% of the samples failed to have a label. Francis and colleagues also reported a high frequency of this type of error [28]. In Wagar's study, this error was reported in 4.6% of the cases [4]. In Mamoon's study, only 0.44% of the samples (n=22) came in without any

labels [18]. Only one of the samples in the present study came with the wrong label. Wagar also reported that one percent of the cases had the wrong label [4]. Label errors seem to vary among different centers and are associated with the experience and expertise of the staff and the level of supervision in each center.

In our study, a total of 15.73% of the samples were either too small (n=7), or failed to have markings in two-piece biopsies (n=4), too superficial and turned (n=2) and traumatized (n=1).

Tissue associated errors comprised a larger percentage of errors in Seoane's study. In his study, 10.2% of the biopsies provided by oral surgeons were smashed, 13% were torn and 2.3% came in many pieces. The amount of smashed, torn and multi-pieced biopsies sent by general dentists were 27.1%, 11.3% and 6.2%, respectively [11].

In the present study, one specimen came in half and upon follow-up; we realized that half of the tissue had been sent to another center for evaluation. Though we failed to find a similar error in other reports, one of the principles of sending biopsies for evaluation is to send all pieces of the biopsy completely to avoid confusion of diagnosis by different centers [14].

Complete elimination of errors in laboratory procedures just as any other procedure is hard to achieve. Yet, setting a series of instructions for the healthcare workers to follow in the pre-analytical phase as well as automation of the procedure, continuous education of the staff, and careful supervision of the health centers can reduce the potential errors [7].

Conclusion

The results of the present study reveal a considerable occurrence of errors in pre-analytical phase. This signifies the importance of constant training of the health staff and their collaboration with the clinicians and the introduction of a standard model for both the clinician and the oral pathologist to minimize the errors associated with pathology laboratories.

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