



DEPARTMENT OF DERMATOVENEROLOGY

**CONSISTENCY BETWEEN CLINICAL AND PATHOLOGICAL DIAGNOSIS
OF SKIN DISEASES FROM SKIN BIOPSY DONE IN SPHMMC
DERMATOVENEROLOGY OPD**

**A THESIS SUBMITTED TO DEPARTMENT OF DERMATOVENEROLOGY
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SPECIALITY CERTIFICATE IN DERMATOVENEROLOGY**

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Declaration

I, the undersigned declare that this thesis is my original work in partial fulfillment of the requirement for specialty certificate in Dermatovenerology. I also declare that it has never been presented in this or any other university and that all resources and materials used in the thesis have been duly acknowledged.

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ABBREVIATION AND ACRONYMS

1. AOR Adjusted odds ratio
2. COR Crude odds ratio
3. IRB Institutional Review Board
4. OPD Out Patient Department
5. OR Operation Room
6. SPHMMC Saint Paul Hospital Millennium Medical Collage
7. SPSS Statistical Package of Social Science
8. UV Ultraviolet

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Abstract

BACKGROUND: Histopathology is the gold standard diagnostic tool for diagnosing skin disorders in addition to history and physical examination. The interpretation of a skin biopsy requires Clinicopathological correlation and the most accurate diagnosis is the one that most closely correlates with the clinical features and helps in planning the most appropriate clinical intervention.

OBJECTIVE: To determine the consistency between clinical and histopathological diagnosis of skin disease from skin biopsies done in SPHMMC Dermatovenerology OPD and to identify the factors affecting the correlation.

METHOD: Retrospective cross-sectional study of histopathology request form and final pathology result from skin biopsy done in Dermatovenerology OPD in SPHMMC from September 2019 to August 2022 was done. The total skin biopsy done over this period is 260. The collected data was edited, coded and entered in to SPSS version 21.0 software for analysis. The level of statistical significance was at $P < 0.05$. Results are summarized and presented by tables, texts and graphs.

RESULT: A total of 220 histopathologic request form and their results were analyzed to assess the correlation between clinical and histopathological diagnosis. 49.1% were definitive consistent, 27.7% descriptive consistent, 12.3% definitive inconsistent and 10.9% were descriptive inconsistent. There was high rate of clinicopathological correlation in sufficiently filled request forms (AOR: 3.779, 95 % CI: 1.709 – 8.356) and in some disease conditions like vesiculobullous (AOR: 12.553, 95 % CI: 1.185 – 132.843) and malignancy (AOR: 8.48, 95 % CI: 1.793 – 40.094). No correlation was observed with clinicopathologic consistency and biopsy type, number of differential diagnosis, disease duration and site of biopsy.

CONCLUSION: The consistency between clinical and histopathological diagnosis in this study was found to be 76.8%. The adequacy of the clinical information provided to the pathologist and the type of the disease was found to affect the correlation

KEY WORDS: Dermatopathology, Skin biopsy, Clinicopathological consistency

1 INTRODUCTION

1.1 BACKGROUND

Skin is the largest organ in the body providing many different functions including; acting as a mechanical barrier against the external environment, UV protection, Thermoregulation, Wound healing and repairing, Sensation, secretion of vitamins and in energy metabolism.

The diagnosis and treatment of cutaneous diseases requires detailed medical history and physical examination including recognizing the primary lesion and reaction pattern.

Many skin diseases can be diagnosed by a simple clinical examination, but sometimes relatively simple diagnostic procedures are required for additional valuable information towards reaching final diagnosis. A few such procedures are Skin biopsy, Potassium hydroxide preparation for fungal infections, Tzanck smear (cytological technique), examination under Wood's light(1).

Skin biopsy is one of the most common and widely used dermatologic procedure for diagnosing a wide range of skin disorders in conditions when there is diagnostic dilemma or clinical diagnosis alone is difficult.

The science and art of Dermatopathology was started in early 19th century Europe with the writings of pioneers like SIMON, VON BAERENSPRUNG, UNNA AND GANS. JULIUS ROSENBAUM (1807-1874) picked up GILBERT BRESCHET'S suggestion of microscopic studies of skin lesion and first spoke of Dermatopathologists. Tradition of dermatologists writing about histopathological aspect of skin disease was carried on by researchers like F. PINKUS, A. CIVATTE, J. DARIER, H. MONTGOMERY, H. PINKUS, W. LEVER and more recently R.K. WINKELMANN, E. WILSON JONES AND A.B. ACKERMANN(1).

Although there are many types of skin biopsy (Incisional, Excisional, Curettage, Shave) Punch biopsy is the preferred method by dermatologists. Diagnostic accuracy of punch biopsy depends upon a number of factors such as choice of lesion, choice of site, technique of biopsy, proper mention of history and clinical diagnosis in biopsy requisition form, proper tissue fixation and staining and adequate cooperation between dermatologist and pathologist(2).

In most cases, it is better to take sample from well-developed lesions since the histopathologic features become more specific as the disease advance with some exceptions, as in the case of vesiculobullous and pustular eruptions, during such cases it is preferable to take biopsy early to avoid any secondary changes, such as regeneration, scarring, or secondary infection. If no primary lesions are available at the time of biopsy, the lesion edge must be included for a better yield(3).

The site of the biopsy has also a significant effect in the final histopathology result. For example, in the case of inflammatory conditions since the maximal induration and elevation is over the center of the lesion it is better to take the sample there and for autoimmune blistering conditions including perilesional skin increases the yield(3).

In order to reach an accurate diagnosis, multiple biopsies from different sites may be needed in certain diseases, such as in the early stages of mycosis fungoides. In the event of a skin disease that involves multiple types of lesion or lesions that are in different stages of evolution, it is advisable to take several biopsies to cover all contributing pathologies. Other diseases require two separate biopsies for precise evaluation. Disorders of hypo- or hyperpigmentation cannot be properly evaluated unless a sample of normal skin is submitted along with the abnormal skin for comparison(3).

Certain diseases show better biopsy outcomes if biopsies are sampled from specific sites. The arms, upper legs and trunks are optimal for disseminating dermatoses. If possible, biopsies taken from the inferior aspects of the lower extremities should be avoided as these regions often exhibit changes of stasis. The lower extremities have also been reported to show the lowest incidence of positive Immunofluorescent findings in several diseases, including bullous pemphigoid. In addition, biopsies should not generally be taken from bony prominences because these sites commonly show nonspecific lymphocytic infiltrates and display epidermal hyperplasia(3).

The information recorded on the histopathology request form is a crucial data set provided by the treating dermatologist to the reporting pathologist. Pathologists rely upon clinical information provided to interpret the histopathology findings. Similarly, a good biopsy report is vital for the clinician to arrive at a diagnosis(4).

The interpretation of a skin biopsy requires clinicopathological correlation. The most accurate diagnosis is the one that most closely correlates with the clinical features and helps in planning the most appropriate clinical intervention(5).

1.2 STATEMENT OF THE PROBLEM

The management of skin diseases requires a pertinent diagnosis, which in many occasions constitutes a complex process of incorporating the clinical features with the histopathologic findings. Most skin disorders have overlapping clinical presentation and in order to solve these diagnostic dilemma and reach at a diagnosis skin biopsy is undertaken in majority of the cases. Diagnostic accuracy of biopsy depends upon a number of factors such as choice of lesion, choice of site, technique of biopsy, proper-mention of history and clinical diagnosis in biopsy requisition form, proper tissue fixation and staining and adequate cooperation between dermatologist and pathologist(2). On histopathology also most dermatologic disorders have similar findings, and to reach at a final diagnosis incorporating the clinical description with the histopathologic findings is important.

The information recorded on the histopathology request form is a crucial data set provided by the treating dermatologist to the reporting pathologist. Pathologists rely upon clinical information provided to interpret the histopathology findings. Similarly, a good biopsy report is vital for the clinician to arrive at a diagnosis (6).

Skin lesions go through different stages and histopathological features of disease change when diseases progress. Because of this nature of the dermatological diseases, cooperation of Dermatologists and pathologists are crucial in diagnosis of inflammatory and other neoplastic diseases (13).

From my experience there were times in our OPD in which patients come with histopathology result which was totally different from what we were initially considering by clinical examination and more than one biopsy was needed to reach at a final diagnosis which is inconvenient to both the patient and treating physician regarding the time, cost and availability of materials. Other than just a hypothesis like inappropriate biopsy site and technique, inadequate sample and request form no specific reasons were found for this inconsistency.

To my knowledge no such study was done both in this study area and in Ethiopia. So the aim of this study is to determine the level of clinicopathologic consistency in the diagnosis of the different skin diseases from skin biopsies done in dermatology OPD and to identify the factors affecting the consistency.

1.3. SIGNIFICANCE OF THE STUDY

Since we are living in a resource limited country and most of our people have low income, diagnosing of skin lesion at the first biopsy is beneficial to both the community as well as the government with regard to avoidance of resource wastage, patient inconvenience and mismanagement. SPHMMC is a referral hospital and most patients attending the OPD are from rural side, and as the level of inconsistency in clinical and pathological diagnosis increased patients will be obliged to have repeat biopsy, stay in town and prone to unnecessary expense and inconvenience and by the time they need treatment most of them will not afford and will be in trouble. Since skin biopsy is the gold standard diagnosis modality in dermatology having inconsistent pathology result will make patients prone to mismanagement and years of suffering due to lack of appropriate treatment, so assessing the level of clinicopathological correlation and identifying some of the factors affecting the consistency will try to solve the above-mentioned problems.

In-addition findings of this study will help the health professional to practice appropriate skin biopsy technique in order to reach accurate diagnosis and provide quality care to the community. The study also will have a great input to program managers and policy makers for future designing, proper implementation and evaluation of programs for prevention of inconsistent clinicopathologic correlation. Furthermore, it will be used as baseline data for further studies in the study area.

2 LITERATURE REVIEW

2.1 OVERVIEW OF SKIN BIOPSY

Skin biopsy is one of the most important diagnostic procedures performed in Dermatology practice(4). Inflammatory and neoplastic diseases of the skin comprise the overwhelming majority of cases in routine Dermatopathological and Dermatologic practice(6). Biopsy of an inflammatory dermatosis is more complicated because often several dermatoses appear histologically similar. Subtle changes in the infiltrate or architectural pattern lead to variability in the morphological appearance of a given inflammatory disease, making histopathological diagnosis intrinsically difficult(7).

The histopathology of infectious diseases, i.e., direct microscopic visualization of tissue samples for identification of the infectious agent, is particularly useful when cultures cannot be made or the infectious agent is slow growing or fastidious. Since culture alone cannot distinguish between colonization and true tissue invasion microscopy adds a lot of information, If invasion is seen, true pathogenicity is actually represented (8). In certain situations, changes in the host tissue histology with or without the actual presence of pathogen would hint at the type of infection. For example, presence of caseous granulomas hints to the infection by *Mycobacterium tuberculosis*. Similarly, tissue infiltration with a particular type of cell, e.g., eosinophil, would go for parasitic infection(8).

Blistering diseases are alarming skin conditions where blister formation occurs in various ways and cannot be differentiated clinically. Many of these blistering diseases mimic each other clinically and on histopathology, therefore immunofluorescence methods are used as adjunct to routine histological examination for diagnosing vesicobullous lesions of skin(9).

2.2 FACTORS AFFECTING CLINICOPATHOLOGICAL CORRELATION

There are various factors that can influence the outcome of a biopsy, including choice of lesion and site, type and technique of biopsy, adequacy of clinical description on the requisition form, proper tissue fixation and staining and adequate cooperation between dermatologist and pathologist (5).

Quite a number of researches were done across the world at different time period to investigate the consistency of clinical diagnosis with their subsequent pathological diagnosis in various categories of skin disease and the factors affecting this consistency.

Many of the researches on clinicopathological consistency have supported the importance of providing adequate clinical information to the pathologist(4).

In a retrospective study done in a tertiary care hospital in India over a period of 1year A total of 403 skin biopsy requisition forms and their reports were analyzed. 46.5% were given a definite pathological diagnosis consistent with the clinical diagnosis, 21% were given a descriptive pathological diagnosis consistent with the clinical diagnosis, 6% had a definite pathological diagnosis inconsistent with clinical diagnosis and 26.5% had a descriptive pathological diagnosis inconsistent with the clinical diagnosis. There was a high level of clinicopathological consistency in the genetic diseases (100%), followed by bullous diseases (79.1%), environmental diseases (73.3%), and inflammatory dermatoses (72%). Clinicopathological consistency was low for malignant tumors, metabolic diseases, diseases of adnexal structures, regional and special dermatoses, and pigmentary disorders(4). It was concluded that providing adequate clinical information and performing additional tests influence clinicopathological consistency. Disease duration, type of biopsy or specifying the site of biopsy, or location of skin disease had no significant effect on clinicopathological consistency(4).

In a descriptive study conducted at the Dermatology center\ Medical City Teaching Hospital Iraq during the period from the 1st of April 2017 to the 1st of April 2018 a total of 440 patients underwent skin biopsy and from these, 142 patients were presented at the clinicopathological meeting and 32 patients were excluded from the study because their histopathological reports have no specific diagnosis, so 110 patients were included in this study. Regarding the consistency between the provisional clinical diagnosis and histopathological diagnosis, 19 cases (17%) were consistent, 75cases (68%) were corroborative, and 16 cases (15%) were inconsistent(10). The study outlines the importance of supplying

the pathologist with important clinical data, also the importance of joined discussion between the dermatologist and the pathologist.

Another study entitled "Spectrum of non-neoplastic skin diseases in Bhopal and its vicinity by and their clinico-histopathological correlation" was conducted at Tertiary Health Care Centre, Bhopal over a period of 5 years. 795 skin biopsies were received for different neoplastic and non-neoplastic skin lesions, of these 270 were clinically diagnosed as non-neoplastic skin lesions, which were analyzed and confirmed histologically. Definitive histopathological diagnosis was possible in 209 cases. In rest of the 61 cases, no histopathological diagnosis could be made as in 22 cases biopsy was inadequate to comment upon while in 39 cases no specific pattern of disease was observed. Clinicopathological agreement was observed in 63% cases. While in 21.4% cases final diagnosis was different from probable clinical diagnosis. And in rest of the 15.6% cases no definitive diagnosis could be made(1). Maximum clinicopathological agreement was seen in pigmentary disorders, followed by infectious inflammatory dermatoses. While the maximum number of non-conclusive and inadequate biopsies was from non- infectious inflammatory dermatoses, it emphasizes the importance of performing the skin biopsy at appropriate phase of the disease, from proper site, of proper thickness especially in cases of non-infectious inflammatory dermatoses(1).

In another cross-sectional descriptive study conducted over a period of one year in a tertiary care center in Pakistan 371 of 28466cases undergoing skin biopsy were reviewed and their histopathological reports evaluated for consistency with clinical diagnosis. Of these, 67.4% cases were consistent, 19.1% were corroborative and 13.5% were inconsistent with clinical diagnosis. Histopathological diagnosis was consistent with the provisional diagnosis maximally in skin tumors and minimally in miscellaneous group. And concluded that Providing a good history, provisional and differential diagnosis to the pathologist while sending skin biopsy yields a high accuracy in pathological report(2).

In a different study conducted to assess the influence of evaluation of clinical picture on the histopathologic diagnosis of inflammatory skin disorders One-hundred biopsy specimens were digitalized and stored on 3 DVDs along with the clinical images. All cases were evaluated by 9 independent full-time dermatopathologists, initially without looking at the clinical pictures and subsequently after checking them. All diagnoses were finally compared with the “reference” diagnosis established in Graz, Austria, and the results were statistically analyzed. After evaluation of the clinical images, the number of dermatopathologists making a correct diagnosis was increased in 70 cases,

unchanged in 25 cases, and decreased in 5 cases. The total number of correct diagnoses increased from 332 (diagnoses before evaluation of clinical pictures) to 481 (diagnoses after evaluation of clinical pictures), with a 16.6% increase in the total. The study finally concluded that clinical pictures should be added to biopsy request slips of inflammatory skin disorders whenever possible, as they allow a better interpretation of histopathologic finding(11).

Another retrospective study at the Department of Pathology, in a tertiary care hospital in Egypt, was done between August 2013 and June 2014 to correlate the clinical diagnosis with histopathologic diagnosis and to determine the correlation rank order of differentials with histopathologic diagnosis. 455 skin biopsies signed out as inflammatory lesions were identified using the laboratory information system. In 339/412 (82.3%) cases, the final diagnosis was the first differential. In 70/412 (16.9%) cases, the final diagnosis was listed as the second or third differential and in 3/412 (0.007%) cases as the fourth and fifth. Among the 37 discordant cases where the clinical details were available, the clinical description correlated with the final diagnosis in 15 cases; clinical and histopathologic diagnoses fell under the same broad disease category in 19 cases. Only 3/37 cases were truly discordant, and concluded that a longer list of differential diagnosis is not helpful. In addition to the clinical diagnosis, providing a detailed history in terms of description, distribution and duration of lesions enhances the chances of obtaining a correct histopathological diagnosis(12).

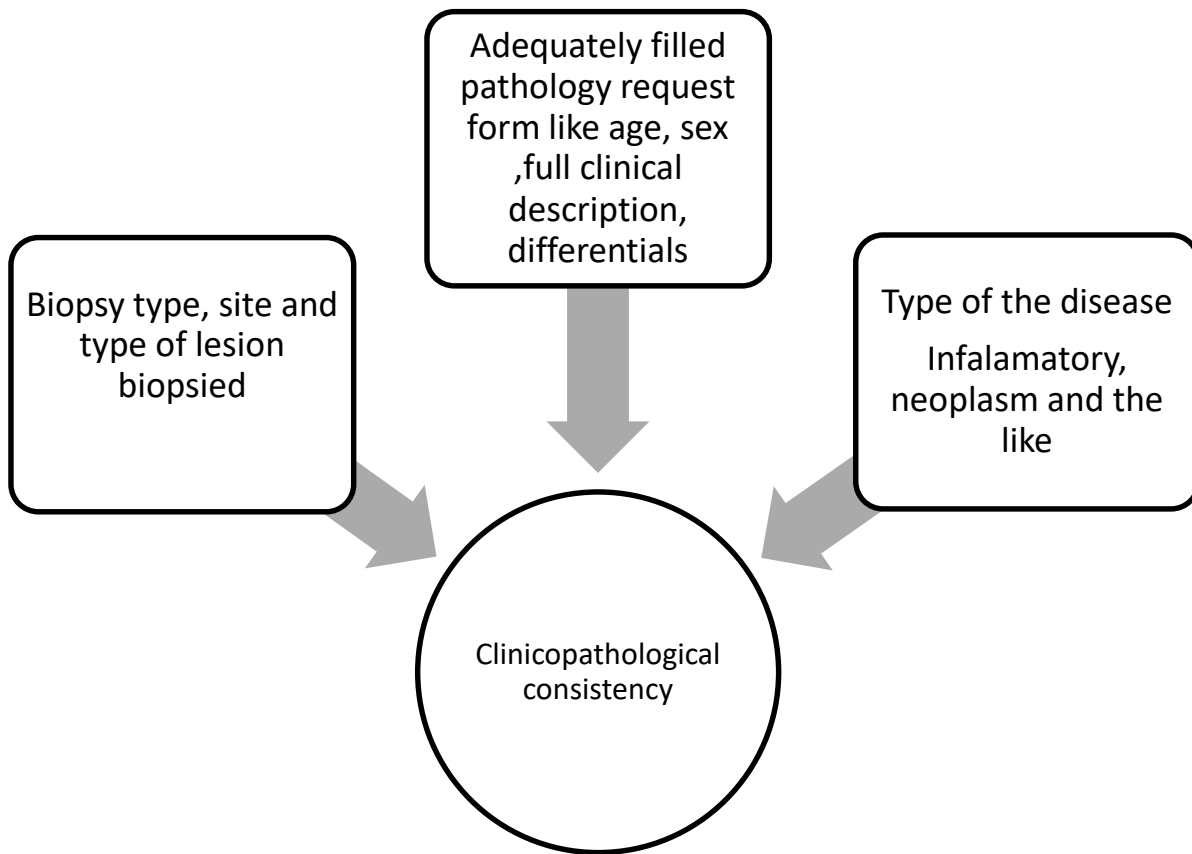


Figure1. Conceptual framework on factors affecting clinicopathologic consistency

3 OBJECTIVES

3.1 GENERAL OBJECTIVE

To assess the consistency of clinical and pathological diagnosis and factors affecting the consistency in the diagnosis of skin disease from skin biopsy done at SPHMMC Dermatovenerology OPD in AA Ethiopia 2023.

3.2 SPECIFIC OBJECTIVE

To measure the consistency of clinical and pathological diagnosis from skin biopsy done at Dermatovenerology OPD, SPHMMC.

To identify the factors affecting the consistency of clinical and pathological diagnosis from skin biopsy done at Dermatovenerology OPD, SPHMMC.

4 METHODS AND MATERIALS

4.1 STUDY DESIGN

An institution based retrospective cross-sectional study of histopathology request form and final biopsy report done over a period of 3 years at Dermatovenereology Department of SPHMMC was done.

4.2. STUDY AREA AND PERIOD

The study was conducted in Dermatovenereology Department of SPHMMC which is located in Addis Ababa Gulele subcity woreda 09. The hospital was established in 1968 with the objective of serving the poor and the medical school was established in 2007. The hospital currently provides a wide range of services in the various departments and Dermatovenereology is one of among the various departments, which provide a wide range of services in Dermatology out-patients clinic since 2007. The dermatovenereology department currently has 7 Dermatovenereologists, 1 Dermatologist and 1 Dermatopathologist and 6 Nurses and sees an average of 40-60 outpatient clients daily.

Dermatovenereology residency program was established in 2012 E.C and accepts on average 5 students per year and now preparing to accept the 6th batch. Currently the department has 15 residents.

Skin biopsy was started in SPHMMC since 2009 E.C and on average 150 biopsies will be done per year.

The study was conducted from January 2023 to march 2023.

4.3. POPULATION

4.3.1. SOURCE POPULATION

All skin biopsy done at Dermatovenereology OPD of SPHMMC.

4.3.2. STUDY POPULATION

All skin biopsy done at Dermatovenereology department minor OR and samples sent for histopathologic evaluation from September 2019 to August 2022 who meets the inclusion criteria.

4.4. ELIGIBILITY CRITERIA

4.4.1. INCLUSION CRITERIA

All skin biopsy performed at SPHMMC Dermatovenereology minor OR with a request form and signed out histopathology report between September 2019 to August 2022

4.4.2. EXCLUSION CRITERIA

Those whose requests form not found, lost results and those without clinical diagnosis.

4.5. SAMPLE SIZE DETERMINATION AND SAMPLING TECHNIQUE

4.5.1. SAMPLE SIZE

All biopsy done at Dermatovenereology OPD that meets the inclusion criteria.

Total number of skin biopsy done from September 2019 to August 2022 is 260, so we took those who fulfill the inclusion criteria

4.6. STUDY VARIABLES

4.6.1. DEPENDENT VARIABLE

Consistency of clinical and pathological diagnosis

4.6.2. INDEPENDENT VARIABLE

Age

Sex

Disease duration

Biopsy site

Type of biopsy

Differential diagnosis

Clinical description

Previous biopsy

Additional test

Final pathology result

4.7. DATA COLLECTION PROCEDURE

4.7.1 DATA COLLECTION METHOD, INSTRUMENT AND PROCEDURE

The data was collected by reviewing histopathology request form and the final biopsy result using well-structured checklist prepared in SPHMMC. Two nurses from Pathology Department and one Dermatovenerology resident were recruited to collect data after given training on data collection tool and procedure.

4.8 DATA QUALITY MANAGEMENT

A well-structured checklist, which was developed after relevant literature review was utilized to ensure any relevant information, is not missing out. Pretesting on 5% of the sample was done and relevant amendments were done to it as necessary. Data collectors were given appropriate training prior to data collection and the overall data collection process was monitored for its completeness primarily by the principal investigator and the whole questionnaire was excluded if there was missing data.

4.9 DATA ANALYSIS

The collected data was edited, coded and entered in to Statistical Package for Social Science (SPSS) version 21.0 software for analysis. A descriptive analysis was presented using descriptive statistics such as frequency tables, bars, and percentages. Crude odds ratios (COR) and adjusted odds ratios (AOR) were analyzed with a 95% confidence level. Binary logistic regression was used first to see association between dependent and independent variables. Variables with bivariate logistic regression $P < 0.25$ were selected and transferred into multivariate logistic regression.

Model of goodness was assessed using Hosmer – Lemeshow model. The variables with p-value of <0.05 on multivariable logistic regression were reported to have significant association. Results were summarized and presented by tables, texts and graphs.

4.10 OPERATIONAL DEFINATION

Clinicopathologic consistency; when either of the following two are fulfilled

Definite, consistent- If the pathological diagnosis was definite and matched with one of the differential diagnoses

Descriptive, consistent- If the pathological diagnosis was descriptive and matched with one of the differential diagnoses

Clinicopathological inconsistency; when either of the following two are fulfilled

Definite, inconsistent- If the pathologist gave a definite diagnosis that did not match with any of the differential diagnoses

Descriptive, inconsistent- If the pathologist gave a descriptive diagnosis that did not match any of the differential diagnoses

Sufficient clinical description-

- When the primary lesion, secondary changes, location as well as distribution of the lesion and disease duration are well described.
- Pertinent medical history, if previous biopsy done, drug history and previous treatment applied to the site mentioned.

4.11 ETHICAL CONSIDERATION

Before the actual data collection Ethical approval was requested from SPHMMC Institutional Review Board. Waiver of informed consent was obtained after the objective of the study, the benefit and risk of

study was described. The information collected was kept confidential and to keep the confidentiality no personal identifiers was used on the data collection format.

4.12 DISSEMINATION OF RESULTS

The result of this study will be submitted to SPHMMC department of Dermatovenorology and public health. There will also be an attempt to publish the findings of the study and present the research in scientific conference.

5. RESULTS

5.1 General overview of request form

Of the 260 biopsies, Clinicopathologic consistency could not be assessed in 40 biopsies because of non-specific histopathologic diagnosis (n =28) and lack of clinical diagnosis (n =12), finally 220 biopsies were included in the final analysis.

Out of the 220, 113 (51.4%) were male patients and 107 (48.6%) were female patients. Most (62.3%) biopsies were obtained from adults between 19 and 49 years, followed by older adults (24.1%) and children (13.6%). The most frequent sites of skin biopsies were the lower extremity (25.5%) followed by trunk (23.6%), head and neck (20%) and upper extremity (16.8%). The most common type of skin biopsy was punch biopsy (63.6%) followed by excisional biopsy (19.1%) and incisional biopsy (17.3%). The most frequent histopathological diagnosis was benign neoplasm (21.4%) followed by malignant neoplasm (19.1%), eczematous (16.8%), papulosquamous (15.9%) and vesiculobullous disorders (7.7%). In around (81.4%) histopathologic request forms were sufficiently filled with adequate clinical description, whereas in (18.6%) the clinical description on the request form was insufficient.

Table 1. General characteristics of the request form

Variable	Variables category	Frequency	Percentage (%)
Age category	0-18	30	13.6
	19-49	137	62.3
	More than 50	53	24.1
Sex	Male	113	51.4

	Female	107	48.6
Type of biopsy	Punch biopsy	140	63.6
	Incisional biopsy	38	17.3
	Excisional biopsy	42	19.1
Biopsy site	Head and neck	44	20
	Trunk	52	23.6
	Upper extremity	37	16.8
	Lower extremity	56	25.5
	Genitalia	17	7.7
	Oral mucosa	6	2.7
Disease duration	1 day to 6 month	63	28.6
	More than 6 month	150	68.2
	Not mentioned	7	3.2
Clinical description	Insufficient	41	18.6
	Sufficient	179	81.4
Differential diagnosis	Not mentioned	15	6.8
	Mentioned	205	93.2
Final pathology result	Infectious	15	6.8
	Eczematous	37	16.8

	Papuloaquamous	35	15.9
	Benign neoplasm	47	21.4
	Malignant neoplasm	48	19.1
	Vesiculobullous	17	7.7
	Connective tissues	14	6.4
	others	13	5.9

5.2 Clinicopathologic consistency

After evaluating clinicopathological consistency in the diagnosis of skin disorders among all 220 biopsies, out of the 220 cases examined, 108 (49.1%) were given a definite pathological diagnosis consistent with the clinical diagnosis, 61 (27.1%) were given a descriptive pathological diagnosis consistent with the clinical diagnosis, 27 (12.3%) had a definite pathological diagnosis inconsistent with clinical diagnosis, and 24 (10.9%) had a descriptive pathological diagnosis inconsistent with the clinical diagnosis. Overall it was determined that 169 (76.8%) of the cases were clinicopathologically consistent and 51 (23.2%) of the cases were clinicopathologically inconsistent.

Table 2. Consistency of clinical and Histopathological diagnosis

Variable	Frequency	Percentage (%)
Clinicopathological consistent	169	76.8
Definite consistent	108	49.1
Descriptive consistent	61	27.7
Clinicopathological inconsistent	51	23.2
Definite inconsistent	27	12.3
Descriptive inconsistent	24	10.9

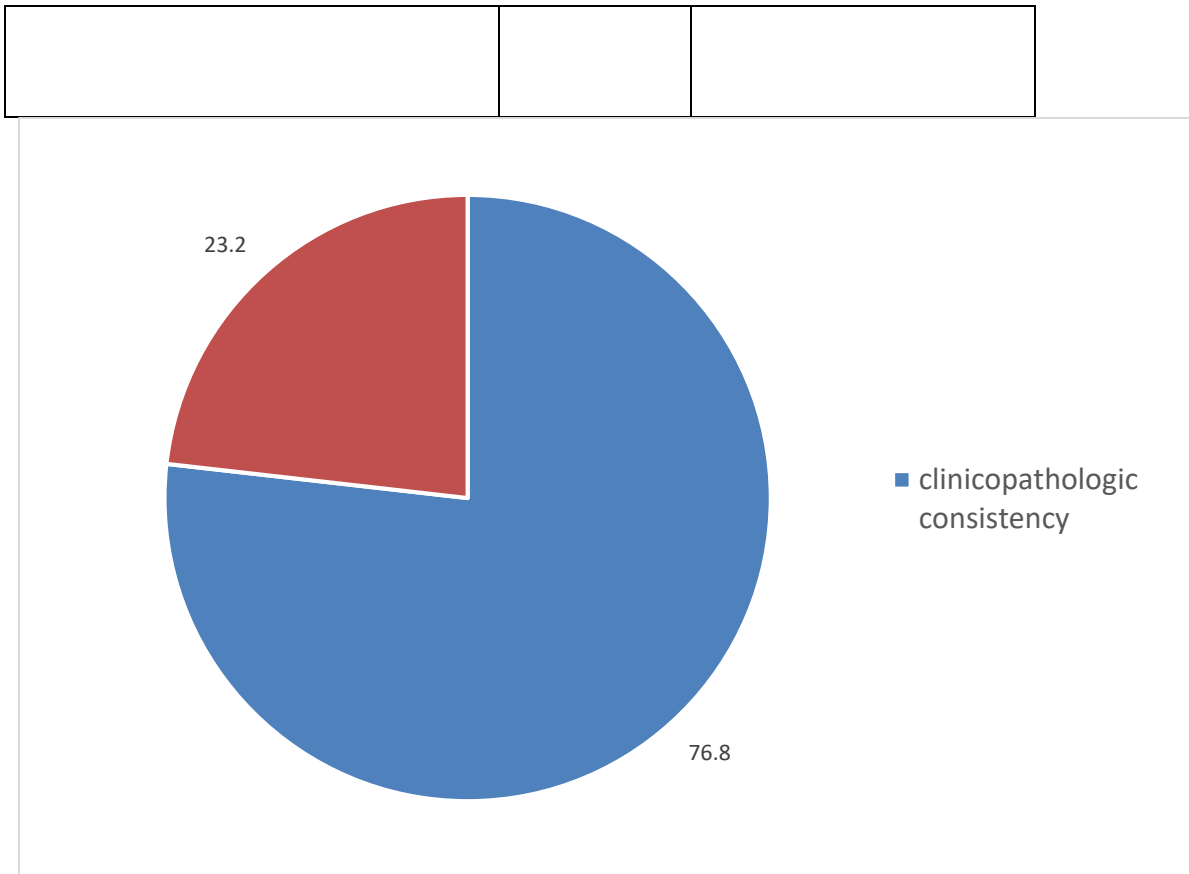


Figure 2. consistency of clinical and pathological diagnosis

5.3 Factors associated with clinicopathologic consistency

In these study variables which have p-value less than 0.25 in bivariate analysis were considered as candidate for multivariate analysis.

The variables that showed significant association in binary logistic regression model were age of the patient, type of biopsy, clinical description and final pathology result.

According to the multivariate logistic regression, the odds of clinicopathologic consistency were 3.8 times higher among those who have sufficient clinical description on the request form than those with insufficient clinical description (AOR: 3.779, 95 % CI: 1.709 – 8.356). Among the type of disease malignancies were 8.5 times more consistent (AOR: 8.48, 95 % CI: 1.793 – 40.094) and vesiculobullous conditions 12.6 times more consistent (AOR: 12.553, 95 % CI: 1.185 – 132.843) than infectious conditions. However, clinicopathologic consistency was not statistically associated with age, and type of biopsy in a multivariate logistic regression model.

Table 3. Factors associated with clinicopathological consistency among skin biopsies done in SPHMMC dermatology OPD, Addis Ababa, Ethiopia, 2023

Variables		Clinicopathologic correlation		COR (95%CI)	AOR (95%CI)	P value
		Consistent	Inconsistent			
Age	0 – 18 years	25	5	1	1	
	19 – 49 years	100	37	0.541(0.193- 1.517)	0.411(0.131-1.293)	0.128
	≥ 50 years	44	9	0.978(0.295 – 3.241)	0.690(0.181-2.632)	0.5587
Type of biopsy	Punch	104	36	1	1	
	Incision	30	8	1.298(0.545-3.089)	1.188(0.441-3.203)	0.733
	Excision	35	7	1.731(0.707 -4.239)	1.956 (0.706-5.417)	0.197
Clinical Description	Insufficient	22	19	1	1	
	Sufficient	147	32	3.967(1.925- 8.176)	3.779 (1.709 -8.356)	0.001*
Final pathology result	Infectious	9	6	1	1	
	Eczematous	20	17	0.784(0.232 – 2.653)	1.124(0.289-4.335)	0.865
	Papulosquamous	29	6	3.222(0.830- 12.509)	3.745(0.861- 16.293)	0.078
	Benign neoplasm	36	11	2.182(0.635 -7.495)	2,923 (0.760 -11,245)	0.119
	Malignant neoplasm	38	4	6.333(1.472 -27.242)	8.480(1.793 -40.094)	0.007*
	Vesiculobullous	16	1	10.667(1.103 -103.150)	12.553(1.185-132.94)	0.036*
	Connective tissue	11	3	2.444(0.473 -12.629)	5.266 (0.828 -33.501)	0.078
	Others	10	3	2.222(0.426 -11.603)	2.414 (0.415-13.716)	0.320

COR: Crude Odds Ratio; AOR: Adjusted odds ratio; CI: Confidence interval *variables of significant association (p value <0.05) in multivariable logistic regression

6 Discussion

The outcome of a skin biopsy is influenced by various factors such as quality of clinical data provided in the histopathological requisition forms, type of biopsy, type of the disease, selection of lesion biopsied, processing of tissue, and use of additional tests such as special stains immunohistochemistry, or direct immunofluorescence wherever indicated(4). Our study has revealed that Clinicopathological consistency in the diagnosis of skin disease is 76.8%. This finding was similar to a study done in Turkey where the Clinicopathological consistency was 76.8%(13). This study was also comparable to a study done in India and in Iraqi where the clinicopathological correlation was found to be 83.5%(2) and 74%(10) respectively. It was also comparable to a study done in Saudi Arabia where the clinicopathological consistency was 75.9%(14). However the consistency in our study was slightly higher than a study done in India where the clinicopathologic consistency was 67.5%(4). Another study in India also found the consistency to be 67.4%(15). On the other hand in a study done in India to assess the clinicopathological correlation in the diagnosis of inflammatory skin conditions found the consistency to be 90.5%(12).

The difference seen in various studies could be attributed to a difference in a number of cases studied, difference in the study group (some studies were performed on isolated conditions as inflammatory or malignancy whereas our study investigated all types dermatologic conditions), the difference on who examines the slides (Pathologist vs Dermatopathologist); in our study all the cases were examined by a Dermatopathologist as well as the difference in a study design(cross sectional vs retrospective).

Our study identified higher rate of clinicopathologic consistency on those request forms with sufficient clinical data described compared with the insufficiently filled forms with AOR of 3.778(1.708-8.356). this finding was similar to a study done in India(4),Iraqi(10) and Turkey(13). In support of this is a research done in Turkey in which accurate diagnoses were made at a rate of 55% without clinic knowledge of the patients, and accurate diagnoses were made at a rate of 78% after obtaining clinic knowledge(7). Several other studies also showed that providing high quality clinical information with the biopsy improves histopathological diagnostic accuracy, whereas blinding pathologists to the clinical data of biopsies referred by dermatologists or other physicians was associated with marked reduction in the rate of clinicopathological concordance(14). In another research done in USA to study the influence of clinical images on the histopathological reporting in which biopsies were evaluated by nine

independent full-time dermatopathologists before and after analyzing the clinical images. It was observed that there was a 16.6% increase in the diagnostic accuracy by dermatopathologists after evaluation of the clinical images.(11) With advancement in technology, adding clinical images could be sought as a valid tool to improve diagnosis.

Clinicopathological consistency also tends to vary among various groups of disorders. In our study we found high rate of clinicopathologic consistency among vesiculobullous and malignant conditions comparing with other inflammatory and infectious conditions with AOR of 12.553(1.185-132.943) and 8.480(1.793-40.094) respectively. This finding was similar to a research done in India(2)Saudi Arabia(14) and Turkey(13). But different to a study done in India(15). This finding can be explained by the fact that many inflammatory conditions (eczematous, papulosquamous and lichenoid) show similar histologic findings and thus it is difficult to diagnose on histopathology alone unless sufficient clinical description is provided. And also most malignant and vesiculobullous conditions have peculiar finding which aids in accurate diagnosis comparing with the inflammatory conditions.

This study found no associations with age and sex of the patient, type of biopsy and disease duration.

LIMITATION OF THE STUDY

- Since the study was done in one institution, it might not be generalized to the general population.
- The cross-sectional nature of the design
- Inadequate sample size

7. Conclusion

The clinicopathologic correlation in the diagnosis of skin disease from skin biopsies done in SPHMMC dermatologic OPD was 76.8%. Providing sufficient clinical description on the request form increase the diagnostic accuracy. Vesiculobullous and malignant conditions were also shown to have better clinicopathologic consistency.

Recommendation

For health professionals

Since adequacy of clinical description was an independent predictor of clinicopathologic consistency they should focus on providing sufficient information to the pathologist.

Training should be given to residents on biopsy technique

It would also be beneficial if pathologists and dermatologists work together and if possible they should prepare morning sessions together and discuss difficult cases and reach on diagnosis together.

For the organization

They should create a link between dermatology and pathology department and make the request form electronic where incorporating of clinical images would be possible.

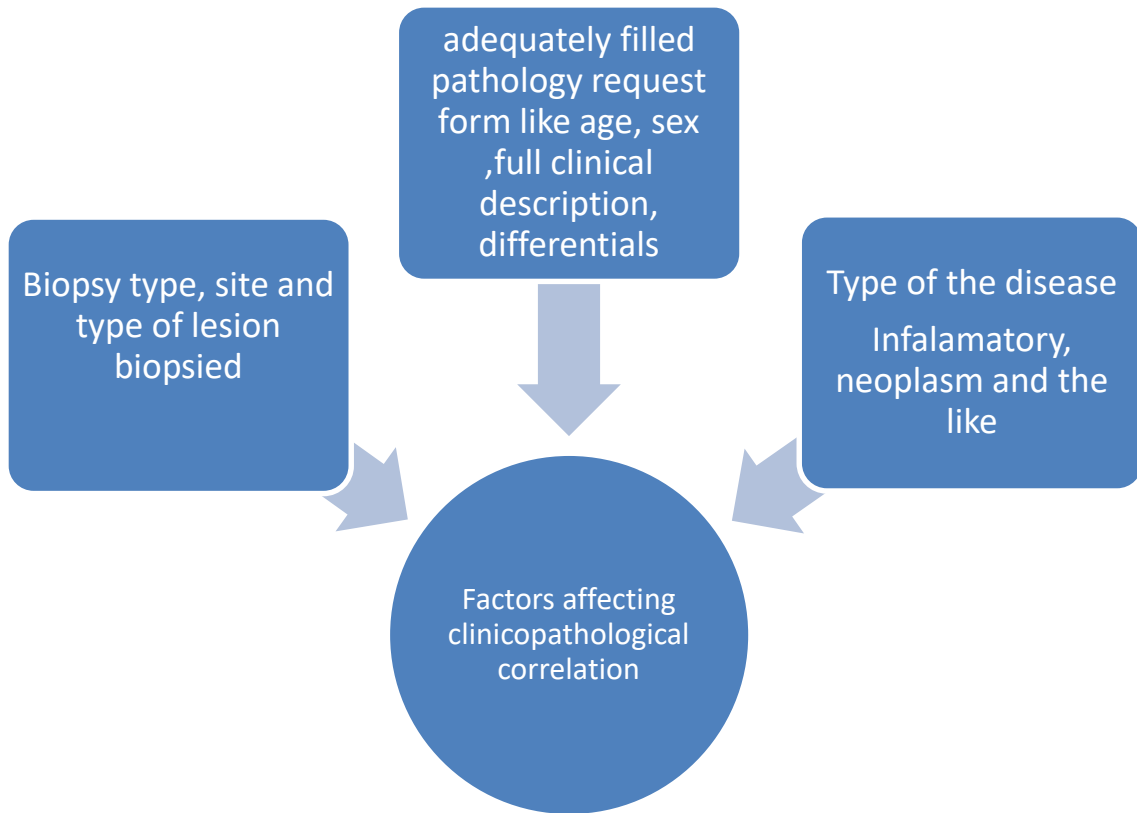
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9. ANNEX

ANNEX 1: CONCEPTUAL FRAMWORK



ANNEX 2: WAIVER OF INFORMED CONSENT

Title: clinicopathologic correlation in the diagnosis of skin disease from skin biopsy done at Dermatovenerology OPD of SPHMMC, Addis Ababa, Ethiopia.

My name is EYERUSALEM ABEBE and I am Dermatovenerology resident at SPHMMC. I am conducting a research on clinicopathologic correlation in the diagnosis of skin disease from skin biopsy done at SPHMMC Dermatology OPD. I prepared this information sheet to explain the purpose, risk and benefit of the study in order to get approval from SPHMMC IRB.

The research involves no more than minimal risk to the subject as the review of subjects medical record is for limited and non-sensitive information and will not collect identifiable private information. To minimize the risk of breach of confidentiality subject's medical record will be placed in a safe and locked room.

The research could not be practicably carried out without a waiver, since identifying and contacting all the potential subjects would not be feasible for a review of their medical record for information that would not change the care they would have already have received.

Subjects will not be provided with additional pertinent information after completion of the research as the result would have no effect on the subject. There is no anticipated benefit to subjects that would change what has already occurred.

For more information and question here is my contact address

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ANNEX 3: CHECKLIST

Checklist to assess the consistency of clinical and pathological diagnosis of skin diseases in Dermatovenerology OPD of SPHMMC 2022

Code-----

Date -----

Questions		
Age	Mentioned	Not mentioned
	If mentioned specify	
Sex	Mentioned	Not mentioned
	F	
	M	
Type of biopsy	Mentioned	Not mentioned
	Incisional	
	Excisional	
	Punch	
Biopsy site	Mentioned	Not mentioned
	Head\ Neck	
	Trunk	
	Upper extremity	
	Lower extremity	
	Genitalia	
	Oral mucosa	
Disease duration	Mentioned	Not mentioned
	If mentioned specify	
Clinical description	Sufficient	Insufficient
Differential diagnosis	Written	Not written

Final pathology result	Definite	Descriptive
	Infectious Eczematous Papulosquamous Benign neoplasm Malignant neoplasm Vesiculobullous Connective tissue Others	Infectious Eczematous Papulosquamous Benign neoplasm Malignant neoplasm Vesiculobullous Connective tissue Others
Additional test	Done	Not done
	If done mention	
Repeat skin biopsy	Done	Not done
	If done how many times	
Clinicopathologic correlation	Definite consistent	Definite inconsistent
	Descriptive consistent	Descriptive inconsistent

