IDS Study Proposal

Mucoscopy - an upcoming tool for oral mucosal disorders

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Proposed start date:10/1/2019
Proposed end date: 10/3/2019

Conflict of interest

Funding Sources

None

Financial or personal interest related to the proposed study

None

Interest in intellectual property rights subject of the study

None

Is a drug, device or other investigational product being used or evaluated?

No

Study design

Study type

Retrospective cohort study including a prospective data collection.

Study Outline

Rationale: The examination and evaluation of mucosal lesions located on the oral mucosa are considered problematic. Any invasive diagnostic procedure like biopsy is challenging to perform in the oral mucosa (vascular and pliant) as it is associated with heavy bleeding and also impairs the daily activities of the patient.[1]While dermatoscopy is useful for many skin lesions, pigmented and non-pigmented, only limited data exist regarding the dermatoscopy of mucosal lesion, with no precise description of dermatoscopic patterns for various underlying mucosal disorders. The diagnosis of such lesions is crucial, due to potential implications for management of patients.

Study design: We are aiming tocollect and analyze a large number of oral mucosal disorders including primary malignant tumors. The aim of this study specifically is to describe clinical and dermatoscopic features in a cohort of oral mucosal disorders and explore specificity of these features,with histopathological correlation in select disorders if available.
Dermoscopic characteristics of lesion of select disorders of the oral mucous membranes and lipsusing dermatoscope in polarized mode will be acquired and assessed. A chalazion clamp will be implementedfor difficult to see areas for dermoscopic image acquisition and assessment.The collected data of randomly selected mucosal disorders pigmented and non-pigmented, benign and malignant, macular, papularvascular lesions will be analyzed based on colors, dermatoscopic patterns, and vessels. Histopathological correlation will be done in select disorders.

Study population: All age groupswillbe included.

Inclusion criteria:

1. Oral mucosal lesion with at least onedermatoscopic image
2. All participanting centers should obtain at least five cases of randomly selected either benign or malignant, pigmented or non-pigmented, macular, papular or nodular lesions

3. Histopathological diagnosis in select disorders

Exclusion criteria:

1. Image of low quality
2. Lack of histopathological and clinical diagnosis

Duration of image information and collection:

The study is retrospective and the collection will be performed as long as necessary to collect enough cases for statistical evaluation.

Recorded data

Clinical macroscopic image (anonymous), dermatoscopic image(s), histopathologic diagnosis (if available), clinical information such as skin type and exact localization.

Methodology of data collection

Every participating center will provide a preformatted Spreadsheet document to fill out necessary information. All images and metadata transferred to the study center must be anonymous.

Statistical evaluation plan

Statistical analyses will be performed using the IBM SPSS 22.0 package (Statistical Package for Social Sciences, SPSS Inc., Chicago, Ill.). Absolute and relative frequencies for clinical characteristics, dermoscopic and histopathological criteria will be calculated. Uncorrected chi-square (or Fisher exact) test will be used for qualitative and Student T test for quantitative variables. P-values of comparisons will be corrected for multiple testing (e.g. Bonferroni).

Ethics

IRB approval will be obtained by the central academic institution.

Informed Consent Form

Informed and Written consent form if necessary by local law.

References:

1. Jha AK, Ganguly S. Chalazion clamp in dermatology revisited. Indian J DermatolVenereol. 2015;81:280-1.
2. Jha AK, Pathak J. Using a chalazion clamp to enhance dermoscopy of oral mucosal lesions. J Am AcadDermatol. 2017;76:e91-2.
3. Jha AK, Zeeshan MD, Jha Amar AK. Mucoscopy in lingual varicosities. Dermatol Pract Concept. 2018;8:54-5.

Authorship and compensation

Criteria for co-authorship

Providing at least 10 cases with clinic-dermoscopic-histopathological correlation

Criteria for named contribution

Completing one survey

Other compensations planned

None

Accessibility of results

Publish in a peer-reviewed journal

Requested resources from the IDS

Mailing list and linking from the IDS Website.