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Research Protocol

Dentistry Section

AI-driven Convolutional Neural Network for Early Detection of Oral Premalignant Disorders and Oral Squamous Cell Carcinoma using Smartphone-captured Images: A Research Protocol

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ABSTRACT

Introduction: The overall prevalence in the world of 4.47% is seen in Oral Potentially Malignant Disorders (OPMD), with the maximum prevalence of 10.54% found in Asian populations with approximately 1% ability to transform into malignancy, considering the malignant transformation is comparatively less, the progression of the lesion leads to increase morbidity and mortality and will lead to obtrusive treatment for the patient. The psycho-stimulating qualities keep betel quid popular even though there is a risk of developing oral cancer. Hence, prompt detection of these OPMD is very crucial, so that the survival rate and treatment cost decrease. The need of the hour is low-cost, easy-to-use imaging devices so that an early diagnosis of OPMD and Oral Squamous Cell Carcinoma (OSCC) can be made.

Need of the study: In remote areas, populations are at higher risk due to limited resources and access to healthcare infrastructure. Low-cost, user-friendly screening devices, like a smartphone-simple touchscreen that can provide sufficient collection of images with transmission of data connected to the internet. An easily accessible high-performance Convolutional Neural Network (CNN) model for clinicians can be used to detect and classify clinically potentially malignant oral lesions and precancerous neoplasms so that an early diagnosis can be made. They can be used to detect and classify clinically oral potentially malignant lesions and precancerous neoplasms in the healthcare field, with promising results.

Aim: To evaluate the diagnostic reliability of Artificial Intelligence (AI)'s deep learning algorithm-based CNN algorithm for the detection of types of OPMD and OSCC lesions in smartphone-based photographic images for early diagnosis

Materials and Methods: The present cross-sectional study will be conducted in the Department of Oral Medicine and Radiology, Datta Meghe Institute of Higher Education and Research (DMIHER), Sawangi, Wardha, Maharashtra, India, from January 2024 to January 2026. The minimum subjects included in the study will be 217. The analysis will evaluate diagnostic accuracy metrics, including Sensitivity (S), Specificity (E), Positive Predictive Value (PPV), Negative Predictive Value (NPV) Area Under Curve (AUC) the Receiver Operating Characteristic (ROC) Curve for CNN performance. Image segmentation outcomes will be assessed using the Dice coefficient (F1) and IoU. Comparison with human experts will involve paired t-tests or Wilcoxon tests, supported by Cohen's Kappa for reliability. Subgroup analysis will stratify performance by OPMD subtypes and demographic variables. A $p<0.05$ will be considered statistically significant.

Keywords: Artificial intelligence, Mobile applications, Oral cancer, Precancerous lesions

INTRODUCTION

An overall prevalence of 4.47% is observed in OPMD, with the highest prevalence of 10.54% found in Asian populations [1]. Although the malignant transformation rate is relatively low at around 1%, any progression to malignancy significantly increases morbidity and mortality, resulting in more complex and burdensome treatment for the patient [2,3].

Betel quid (paan) chewing, whether containing tobacco or not, has long been recognised as a significant factor in the rise of oral cancer, with its impact noted as early as 1902 [4]. This practice has contributed to increasing mortality rates in Low- and Middle-Income Countries (LMICs), especially across Asia [5]. Despite the well-documented cancer risks, the psycho-stimulating properties of betel quid continue to sustain its popularity. Therefore, early identification of OPMD is essential to enhance survival rates and reduce treatment costs. Traditional visual inspection methods yield a sensitivity of 60% and a specificity of 98.5% [6-8].

While histopathological examination remains the gold standard for confirming OPMD diagnosis, several adjunctive diagnostic technologies have been introduced to assist clinicians and General Practitioners (GP) in the preliminary evaluation of such lesions before performing a biopsy [9].

There is a pressing need for affordable, user-friendly imaging tools that facilitate early detection with improved sensitivity strongly associated with better survival outcomes [10]. In underserved or remote communities, limited healthcare access places populations at higher risk. CNNs, a branch of artificial intelligence, can be trained to analyse data and make diagnostic predictions [11]. Modern smartphones, with their intuitive touchscreen interfaces, provide a convenient platform for image capture and data transmission, making them suitable for cancer screening applications. Rapid advancements in camera technology- such as high resolution, low noise, and white light imaging- support the acquisition of high-quality oral photographs for clinical use [12].

To overcome the inconsistency in diagnostic performance due to smartphone limitations, a dependable white light imaging approach combined with resampling techniques and a robust CNN model can greatly enhance disease recognition capabilities. This helps minimise diagnostic variability, which often compromises

accuracy. CNNs can be leveraged for automated image analysis and classification [13], showing strong potential in identifying and categorising oral potentially malignant lesions and precancerous conditions in clinical settings.

REVIEW OF LITERATURE

Artificial intelligence's deep learning model-based CNN is increasing the scope in Oral Medicine and Radiology but is still under development in the field of dentistry, especially in oral medicine and radiology field [14]. The CNN network which has been used in various studies for detection of OPMD and OSCC but are expensive and not easily assessable. Hybridisation- use of other CNN like YOLO and fast res-CNN. Multiple simple algorithms work together to complement and augment each other [15]. YOLO- It is also widely used for real-time object detection. 2-3 algorithms will create a fusion layer. Additional patient parameters for improved predictions that will enhance risk assessment by taking patient history, such as smoking or tobacco chewing, can provide critical insights into the risk factors associated with oral lesions. A more comprehensive dataset that includes both clinical imaging data and patient history can enhance its learning capabilities. Incorporating patient history into the prediction model aligns with clinical practices, where understanding a patient's background is crucial for diagnosis of OPMD and OSCC and treatment planning. The proposed model can help in improving the detection of OPMD and OSCC, which will be an inexpensive and non-invasive tool.

Warin K et al., (2022) evaluated oral photographs so as to classify and detect OPMD by using CNN algorithms [15]. In this retrospective study, a total of 600 oral photograph images were taken and categorised into 300 images of OPMD and 300 images of normal oral mucosa. DenseNet-121 and ResNet-50 which are CNN-based classification models were used. Faster R-CNN and YOLOv4 were used for creating detection models. The images were selected for training, validating, and testing data. The performance of the CNN models was evaluated by oral and maxillofacial surgeons. Higher efficiency was seen in DenseNet-121 and ResNet-50 in diagnosing, with an Area Under (AUC) the Receiver Operating Characteristic (ROC) Curve of 95%. The highest detection performance was seen with Faster R- CNN of 74.34%. The sensitivity and specificity were 100% and 90%, respectively was for CNN- based classification model. The values were 91.73% and 92.27%, respectively were for oral andmaxillofacial surgeons. In conclusion, for the classification and detection of OPMD in oral photographs, DenseNet-121, ResNet-50 and Faster R-CNN models had potential.

The study conducted by Warin K et al., (2022) studied data of 980 oral photographic images for classification and detection of OPMD and OSCC to evaluate the performance of deep CNN algorithms, divided into 365 images of OSCC, 315 images of OPMD and 300 images of non-pathological sites [16]. DenseNet-169, ResNet-101, SqueezeNet and Swin-S CNN were used for image classification and faster R-CNN, YOLOv5, RetinaNet and CenterNet2 for multiclass object detection models. The AUC for DenseNet-196 were 1.00 and 0.98 on OSCC and OPMD, respectively. DenseNet-196 has the best multiclass image classification performance. These values were in order with the performance of experts and seniors to GPs. CNN-based models have ability for the identification of OSCC and OPMD in oral photographic images was the conclusion made by the authors. GP can use this as a diagnostic tool for the early detection of oral cancer to obtain satisfactory performance.

Birur NP et al., (2022) studied CNN which would help Frontline Healthcare Workers (FHW) for early detection of suspicious oral lesions (malignant/ potentially-malignant disorders) [17]. They had used a Tertiary-Care Hospital with limited resources in India. FHWs or along with specialists or oral cancer specialists screened the patients independently. A total of 5025 patients participated in the study, 4728 had telediagnosis. About 752 patients had online specialists whereas 102 had to undergo biopsy. The mobile phone and cloud used simple and complex CNN, respectively. A high sensitivity of 94% was shown by onsite specialist when compared to histology. A sensitivity of 95% and specificity of 84% was seen in telediagnosis. Phone integrated, CNN (Mobile-net) had sensitivity of 82%) and Cloud- based CNN (VGG19) had sensitivity of 87%. Thus, they concluded that mobile enabled images is useful for oral cancer screening.

The photographic images for an automated system for detecting OPMD were studied by Tanriver G et al., (2021) [18]. They used computer vision techniques. The model used by them was able to detect oral lesions and classify the detected region into three categories (benign, OPMD, carcinoma). The feasibility of deep learning-based model usage can be made for the automated detection and classification of oral lesions.

Lin H et al., (2021) conducted a retrospective study wherein they studied the deep learning algorithm [19]. They used an effective smartphone-based imaging diagnosis method, for automatic detection of oral diseases. Five categories of diseases in an oral dataset were formed, and to prevent the variability obtained, resampling method was performed using hand-held smartphone cameras. HR-Net was used for oral cancer detection. An 83.0% of sensitivity, 96.6% of specificity, 84.3% precision, and 83.6% F1 on 455 test images were obtained. VGG16,ResNet50, and DenseNet1 in terms of sensitivity, specificity, precision, and F1 proved to be less efficient than HR-Net. They achieved the Centre positioning method had better F1 score than that of a simulated random positioning method, around 8%. The resampling method had additional 6% of better performance.

Warin K et al., (2021) developed an automated classification and detection model for oral cancer screening by using the CNN deep learning algorithms [14]. In an oral and maxillofacial centre, they had collected 700 clinical oral photographs retrospectively comprising of 350 images of OSCC and 350 images of normal oral mucosa. DenseNet121 and faster R-CNN models were used. They randomly selected 490, 70 and 140 oral images were for training data, validating and testing data, respectively. DenseNet121 model obtained a precision, F1 score, sensitivity, specificity of and an AUROC better than Faster R-CNN model.

The above review of literature helps us to conclude that CNN can be used for the early detection of OPMD and OSCC lesions in smartphone based photographic images for early diagnosis but requires a more comprehensive dataset that includes both clinical imaging data and patient history that can enhance its learning capabilities.

The present study aims to evaluate the diagnostic reliability of Artificial Intelligence's deep learning algorithm-based CNN algorithm for the detection of types of OPMD and OSCC lesions in smartphone-based photographic images for early diagnosis.

Objectives of the study:

1. To evaluate Artificial Intelligence's deep learning algorithm based CNN for types and detection of OPMD.
2. To evaluate the image segmentation of OPMD and oral cancer lesions detected in smartphone-based photographic images using Artificial Intelligence's deep learning algorithm.

Null hypothesis: The use of Artificial Intelligence's CNN applied to smartphone-based photographic images does not improve the automatic detection and classification of OPMD and OSCC for early diagnosis.

Alternate hypothesis: Artificial Intelligence's deep learning algorithm-based CNN for automatic types and detection of OPMD and OSCC by using smartphone-based photographic images can be used for early diagnosis.

MATERIALS AND METHODS

The present cross-sectional study will be performed in the department of Oral Medicine and Radiology, Datta Meghe Institute of Higher Education and Research (DMIHER), Sawangi, Wardha, Maharashtra, India, from January 2025 to January 2026. The informed consent will be taken from the patients with the Institutional Ethical Clearance number is DMIHER(DU)/IEC/2024/276. The registration number for this study trial is CTRI/2024/12/078020. The final date of registration was 12th December 2024.

Inclusion criteria:

- Patients who are above 18 years of age, healthy people and subjects who are diagnosed clinically with OPMD or OSCC.
- The OPMD cases will be divided into homogeneous, which will be low-risk cases, and non homogeneous, which will be high-risk cases, based on clinical manifestations.

Exclusion criteria:

- Subjects who are undergoing treatment for OPMD or OSCC.
- Subjects who are suffering from systemic diseases, severe internal accompanying diseases like Systemic Lupus Erythematosus (SLE), Discoid Lupus Erythematosus (DLE), HIV/AIDS, diagnosis of other tumours (for e.g.,: laryngeal cancer or nasal cavity tumours)

Sample size calculation: The analysis will evaluate diagnostic accuracy metrics including sensitivity, specificity, PPV, NPV, ROC and AUC for CNN performance. Image segmentation outcomes will be assessed using Dice coefficient (F1) and IOU. Comparison with human experts will involve paired t-tests or Wilcoxon tests, supported by Cohen's Kappa for reliability. Subgroup analysis will stratify performance by OPMD subtypes and demographic variables. Statistical software such as SPSS for significance testing at $p<0.05$ will be utilised.

Minimum sample size required

$$N=\frac{Z^2_{1-\alpha/2)2}*p*(1-p)}{D^2}.$$

Z_(1-α/2)=1.96, at 5% level of significance

Sensitivity of smartphone-based imaging diagnosis method, = 83% [19].

D= estimated error (5 %) =0.05

$= ((1.96)^2* (0.83)*(1- 0.83) / (0.05)^2 = 217.$

Minimum sample size required for the study 217

Study Procedure

Image-capturing method: The camera grid of the handheld iPhone 14 pro smartphone will be used to locate the center of the lesion of the oral images. The faint grid keeps the area of lesion to be used as the fixed Region Of Interest (ROI). The camera grid helps the lesion to be placed at the center to obtain an accurate and appropriate image without any blurring or errors. This will aid in removing any irrelevant background. The images will be taken of only those patients who have given informed and approved consent. All methods will be carried out in accordance with relevant guidelines and regulations. The image will be uploaded with diagnostic software via Wi-Fi.

The subjects will be screened independently by the oral medicine specialist. The medical history and image collection will be carried out in the daily Outpatient Clinic of the Oral Medicine and Radiology Department and on patients of the hospital. Histopathologic reports may be required if a subsequent biopsy is performed. Histopathologic reports will be considered as the gold standard. A patient with oral cancer would undergo histopathologic examination. As proposed by the American Joint Committee on Cancer (AJCC), according to the TNM clinical staging system, stage I-IV will be OSCC cancer [20]. The OSCC images of the lip, buccal mucosa, tongue, and hard palate, upper and lower alveolar ridge will be characterised as exophytic, or endophytic or ulcerative in various areas of the oral cavity. Homogenous or low-risk OPMD may not have a histopathologic report. Thus, based on clinical features, the oral images will be under four categories, i.e., normal, homogenous OPMD, non-homogenous OPMD, and OSCC. A white patch or a lesion, uniformly flat and thin in nature, and have a smooth or fissured surface with no atrophic or erosive lesions will be considered as homogenous OPMD. Non-homogenous OPMD will be mixed red and white lesions which are atrophied or with irregular surface texture. A nodular lesion from the mucosal surface or a deep ulcer with a rough surface, everted both with unclear borders will be considered as OSCC.

The normal healthy mucosa presents with homogenous, neither white nor red patches. Each lesion will have one picture. If there are multiple lesions in a patient, many images will be taken. In a healthy individual, numerous oral images can be taken which belong to different anatomic sites of oral cavity like buccal mucosa, labial mucosa, tongue, palate and floor of the mouth. One oral medicine specialist will take part in this research project to ensure appropriate annotation and it will be quality reviewed by an expert. These images/datasets obtained will be used to train CNN. Finally, CNN will be able to predict the OSCC and OPMD via an input image.

Preprocessing: The central area is obtained by cropping the irrelevant structures from the image to obtain the useful part of the image. All photographic images will be uploaded to the web application for image annotation. Due to manual segmentation, the image used for CNN training, validation, and testing will be the largest area of intersection annotations. CNN models will be used in order to classify and detect lesions in the oral photographicimages. The CNN-based system takes one oral image at a time as an input. YOLO and Fast Res-CNN will be trained. Some of the oral images will be randomly assigned as training data for OPMD and OSCC. Some of the images will be used as validation and will be used as testing data to confirm the accuracy. This oral dataset will be used to analyse the images. In the training stage, 2-3 algorithm will create a fusion layer which increases the accuracy. To alleviate the effect of variability in images by using the proposed image-capturing method, hybrid data will be created.

Primary outcome: Diagnostic accuracy (sensitivity, specificity, PPV, NPV) of AI-based CNN for detecting OPMD and OSCC. It will be assessed by using below formulae. Sensitivity is the ability of a test or instrument to yield a positive result for a subject that has that disease. Specificity is the ability of the test or instrument to obtain normal range or negative results for a person who does not have a disease. PPV is determine, out of all of the positive findings, how many are true positives; NPV is determine, out of all of the negative findings, how many are true negatives.

Sensitivity=(True Positives (A))/ (True Positives (A)+ False Negatives (C))

Specificity=(True Negatives (D))/ (True Negatives (D)+False Positives (B))

PPV=(True Positives (A))/ (True Positives (A)+False Positives (B))

NPV=(True Negatives (D))/ (True Negatives (D)+False Negatives(C))

Secondary outcomes: AI performance in classifying OPMD subtypes and OSCC. Image segmentation accuracy for lesions in smartphone images. Image segmentation outcomes will be assessed using Dice coefficient (F1) and IOU. The F1 score is the Dice coefficient of the set of retrieved data and the set of relevant data. It is calculated as

Dice= 2True Positive (A))/ (2True Positives (A)+False Positives (B) + False Negatives (C))

Jaccard index, also known as Intersection over Union (IoU), is the area of the intersection over union of the predicted segmentation and the ground truth

IoU= True Positive (A))/ (True Positives (A)+False Positives (B) + False Negatives (C)).

STATISTICAL ANALYSIS

The results will be collected, data obtained will be entered into an Excel sheet and Statistical Package for Social Sciences (SPSS) Software version 29 will be utilised for Statistical Analysis. The analysis will be performed in terms of Sensitivity (S), Specificity (E), PPV, NPV Area under (AUC) the Receiver Operating Characteristic (ROC) Curve.

Declaration

Availability of data and materials: Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

Authors' contribution: MGC: Drafted the protocol of the research project; SD: Guided and proof read the research project; UP: Explained the technical aspects. All authors read and approved the final research protocol.

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