




# OPEN Creating a retinal image database to develop an automated screening tool for diabetic retinopathy in India

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Diabetic retinopathy (DR), a prevalent microvascular complication of diabetes, is the fifth leading cause of blindness worldwide. Given the critical nature of the disease, it is paramount that individuals with diabetes undergo annual screening for early and timely detection of DR, facilitating prompt ophthalmic assessment and intervention. However, screening for DR, which involves assessing visual acuity and retinal examination through ophthalmoscopy or retinal photography, presents a significant global challenge due to the massive volume of individuals requiring annual reviews. To counter this challenge, there has been an increasing interest in the potential of artificial intelligence (AI) tools for automated diagnosis of DR. The AI tools primarily utilize deep learning (DL) techniques and are tailored to analyse extensive medical image data and provide diagnostic outputs, essentially streamline the DR screening process. However, the development of such AI tools requires access to a comprehensive retinal image database with a plethora of high-resolution fundus images from various cameras, covering all DR lesions. Additionally, the accurate training of these AI algorithms necessitates skilled professionals, such as optometrists or ophthalmologists, to provide reliable ground truths that ensure the precision of the diagnostic outputs. To address these prerequisites, we have initiated a study involving multiple institutions to establish a large-scale online 'Retinal Image Database' in India, aiming to contribute significantly to DR research. This paper delineates the methodology employed for this significant undertaking, detailing the steps taken to create the large retinal image database, as well as the framework for developing a cost-effective, robust AI-based DR diagnostic tool. Our work is expected to mark a significant stride in DR detection and management, promising a more efficient and scalable solution for tackling this global health challenge.

**Keywords** Diabetic retinopathy, Artificial intelligence, Deep learning, Retinal images, Grading platform, Retinal image database, Fundus photographs

Advancements in artificial intelligence (AI) have paved the way for new solutions in healthcare, particularly in the early detection and diagnosis of complex conditions like diabetic retinopathy (DR). This holds significant

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importance in countries like India, which is home to over 100 million individuals with diabetes, around 3 million of whom have sight-threatening DR<sup>1,2</sup>.

Traditional DR screening methods, such as direct examination by ophthalmologists, are limited due to the sheer number of patients and the relative scarcity of available specialists. India, for instance, has roughly 20,000 ophthalmologists to cater to the vast population requiring annual screening<sup>3,4</sup>. However, with the emergence of innovative solutions like retinal colour photography, the landscape of DR screening is changing. Coupled with advances in retinal imaging and telemedicine, DR screening has become more efficient and cost-effective, especially in resource-limited settings<sup>5</sup>.

Fundus imaging, a non-invasive method capturing images of the optic disc, macula, and retinal microvasculature, has been pivotal in detecting not only DR, but also other eye disorders like glaucoma, age-related macular degeneration (ARMD), and hypertensive retinopathy<sup>6</sup>. It plays a key role in facilitating early DR detection, thus potentially preventing vision loss<sup>7</sup>.

AI, particularly deep learning (DL), has shown remarkable success in analysing complex image-based data. The integration of AI algorithms with high-resolution retinal imaging has proven effective for DR screening and other image-reliant conditions like ARMD, Retinopathy of Prematurity (ROP), and glaucoma<sup>8–10</sup>.

However, the effectiveness of these AI algorithms is dependent on the availability of 'ground truth,' or accurately labelled data. This labelled data, comprised of retinal images each associated with a specific diagnosis, allows AI models to learn and perform tasks like DR detection and classification of its severity.

The need for such labelled data underscores the importance of comprehensive, well-annotated databases of retinal images<sup>10,11</sup>. Existing databases, such as the India Diabetic Retinopathy Image Dataset (IDRiD), have contributed significantly to training and testing automated DR screening algorithms, but have their limitations. For instance, the IDRiD, while being a pioneering initiative in India, is relatively small in size and only covers a limited spectrum of DR lesions<sup>12</sup>.

Globally, other databases such as the Messidor database from France and the EyePACS database from the United States have also been used extensively for AI training<sup>8</sup>. However, these datasets are restricted by their geographical and demographic representations, thereby limiting the diversity of clinical manifestations covered. Additionally, variation in imaging protocols across these databases poses challenges in generalising AI models.

With these gaps in mind, the goal of this multi-centric study is to develop a large, thoroughly annotated DR database that can provide a robust training foundation for an automated DR diagnostic algorithm. This protocol paper describes the methodology employed for creating this extensive online 'Retinal Image Database'. The overarching aim is to leverage the capabilities of AI to create a cost-effective, efficient, and scalable DR diagnostic tool suited to India's unique demographic and clinical landscape.

## Construction and content

The primary outcome of this multicentric study, involving a collaboration of multiple institutions, is the creation of an AI-based tool designed for automated detection of DR. To achieve this, a comprehensive Indian retinal image database is being constructed through the accumulation and curation of anonymized, high-resolution retinal colour photos, also known as fundus images. These images are sourced retrospectively from the Madras Diabetes Research Foundation (MDRF), the Vision Research Foundation (VRF)/ Sankara Nethralaya (SN), all based in Chennai, India. This large database of labelled fundus images, integrated within a big data framework along with relevant systemic details, offers ground truth DR grades and diagnoses. These will be crucial in training and developing an AI-based algorithm for DR detection by the Indian Statistical Institute (ISI) in Kolkata and the National Institute of Technology (NIT) in Durgapur, India.

## Phases of study

The study design comprises three main phases, as demonstrated in the provided flow chart (Fig. 1).

Phase I: In this phase, we are creating a large DR database to store labelled retinal images within a big data framework. Various DR lesions on the fundus images are annotated and labelled to provide DR severity grading and recommendation on the platform.

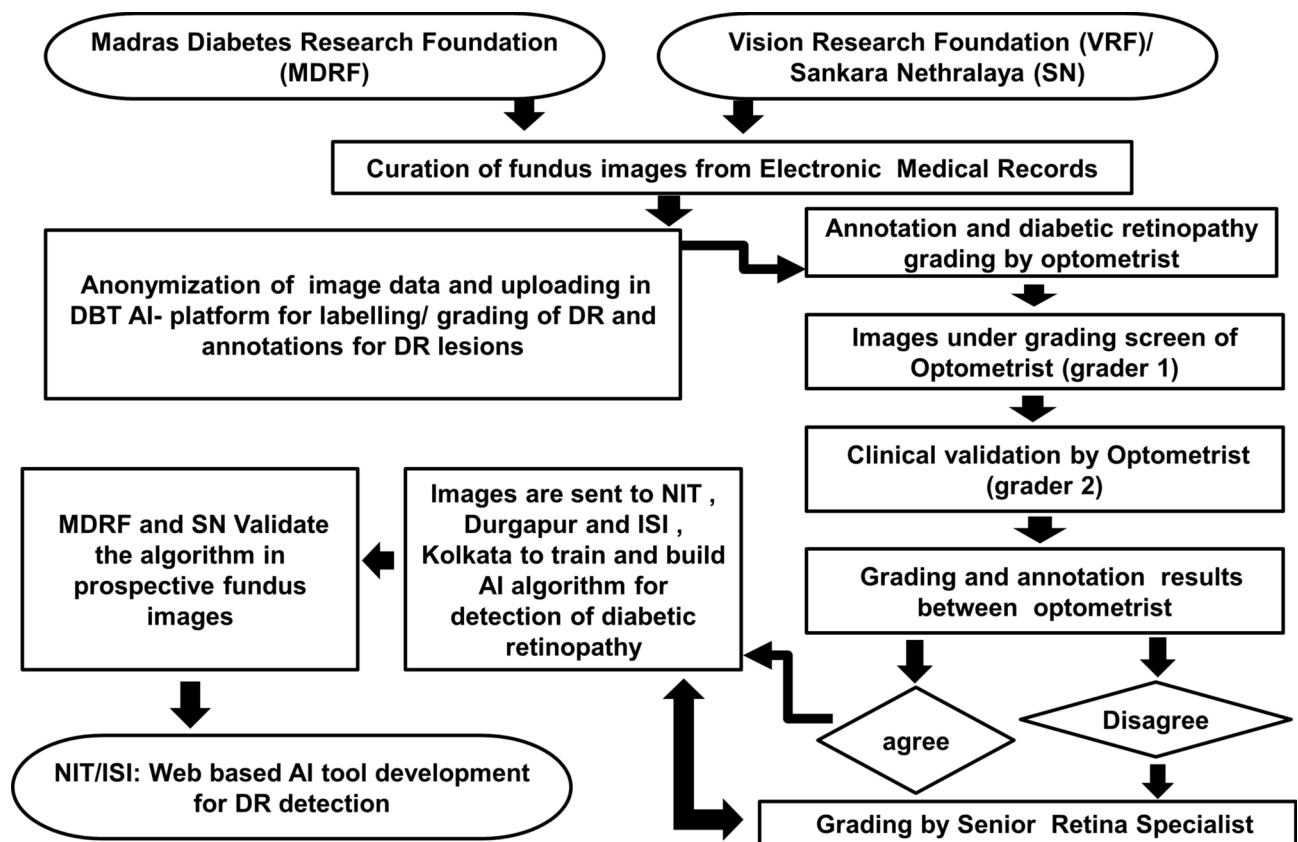
Phase II: The second phase revolves around training and development of a deep-learning algorithm tailored to diagnose DR based on fundus images.

Phase III: The final phase validates the developed AI-DR tool in real-time.

## Sample size

The AI algorithm is data hungry and requires a large dataset of retinal images for training for a robust algorithm to be developed for detection of DR. So retinal images with and without [DR] were provided from the DBT-AI-DR database to provide training. The sample size calculated in this study was determined on the basis of indicators of effectiveness like sensitivity and specificity for detection of any DR. The minimum sample size required for a targeted sensitivity and specificity of 96%, under the null hypothesis using a one-sided test, 0.025 alpha and 90% power was a minimum of 1825 images with DR and 1875 images without DR. Taking into consideration any ungradable images due to media opacities, the overall sample size of 2000 images with DR and 2000 images without DR has been calculated.

About 1974 anonymised fundus images without DR and 1798 retinal images with various grades of severity of DR have been uploaded with annotation and ground-truth labels in the DBT-AI-DR platform for the purpose of training the algorithm and then testing the AI-DR tool. Among the uploaded images, 134 were classified as ungradable. The reasons for ungradable images include media opacities like cataract, vitreous hemorrhage and poor mydriasis. Those with unclear and ungradable images were advised referral to meet the ophthalmologist for further management.



**Fig. 1.** Flow chart: artificial intelligence algorithm in diabetic retinopathy detection.

Subject	Analysis
Subject area	Diabetic retinopathy- screening and prediction
Types of data	retinal colour photograph/ fundus image
Data format	Anonymised Fundus image -JPEG, PNG format with annotations of the DR lesions and classification of severity of DR
Data Source	The data set of the fundus images will be acquired from Electronic Medical Record Database of Madras diabetes Research Foundation (MDRF) and Vision Research Foundation (VRF/SN), India
Data acquisition	Retinal Images 50° field of view macula centered posterior pole images from Zeiss FF 450 plus camera/ Topcon camera were retrieved from the database of MDRF/VRF
Parameters used to collect data	High resolution, good quality, macula-centred fundus images of individuals with diabetes and without and with diabetic retinopathy (DR)
Description of data collection	Fundus images are labelled with annotations and divided into five stages: No Diabetic retinopathy (DR), Mild Non-proliferative Diabetic Retinopathy (NPDR), Moderate NPDR, Severe NPDR and Proliferative (PDR)

**Table 1.** Specifications of images.

### Sampling design

The study protocol approval was obtained from the Institutional Ethics Committees of MDRF and VRF, prior to commencement of the study in 2019. The ground truth fundus images for training (with labelling and annotation of the 11 DR lesions) and validation are provided by MDRF and SN. The development of deep learning algorithms and analysis of retinal fundus pictures for the identification of DR were the main areas of interest for the ISI and NIT. Table 1 described the data flow diagram for this study's architecture.

### Development of DBT-AI-DR platform

The DBT-AI-DR grading platform that has been created runs in a web browser. It is custom developed specifically to handle the retinal image intake, DR grading procedure, and annotation features required to gather an unbiased and multi-grader validated training retinal image dataset for the development of the AI models.

The following are the platform's main characteristics.

### *Ingestion module*

A module that allows users to ingest images from a shared google drive folder into the DBT-AI grading platform (MDRF and SN) which was built in order to support a large volume of images in a user-friendly manner. This allows numerous ingestion users to utilise google drive as a user-friendly interface to source data from many users of MDRF and VRF sites and combine them into a large data lake.

### *Grading workflow*

Images to be graded are automatically assigned to the platform to the team of 8 optometrists. The ungradable images were removed from workflow at the first stage by the optometrist. For every image, a primary grader (optometrist) and a secondary grader (optometrist) was randomly assigned. The primary grader is responsible for classifying the image, annotating it, and recording all the clinical aspects of labelling the image. The secondary grader had access to the image after the primary grader had completed grading, and could approve or reject the grading/ annotation with comments. The primary grader would regrade the photograph if it is rejected. If there is still a disagreement after grading, the images are sent to the senior retina specialist/ ophthalmologist for the final assessment and DR grade.

### *Annotation tool*

Annotation tool provides a graphical tool to mark different types of clinical features of DR on top of the image.

Annotation tool created a provision for marking 11 kinds of lesions associated with DR namely 1. microaneurysms, 2. dot and blot haemorrhages, 3. hard exudates, 4. cotton wool spots 5. Intra-retinal microvascular abnormality (IRMA) 6. Venous changes (beading, looping) 7. Neo-vascularisation at the disc (NVD) 8. Neovascularization elsewhere in the retina (NVE) 9. Pre-retinal or vitreous haemorrhage 10. Fibrous proliferations and 11. Laser photocoagulation scars. The information is stored internally as an array of paths whereas a path is defined as array of points connected in an order.

### *Dashboard*

The dashboard provides a bird's eye view to the Principal Investigators (PI) of MDRF and VRF / Admins, on the total number of images at each stage of the workflow to track progress and resolve any open issues that is causing the bottleneck in the workflow process.

Download tool—allows the users involved in AI tool training and development to download the graded images and their associated data captured in the grading workflow. This is also the training dataset/ ground truth that is used to train the algorithm to develop the AI model that enables automatic detection and classification of newly given images.

The overall application is built as microservices based on technologies including Golang, NodeJS, JavaScript and MySQL server for storing relational data. The web application is deployed on a secure SSL endpoint for end-to-end encryption between the browser and the DBT-AI-DR platform.

## **Training of graders**

The retinal photographs were graded by certified optometrists/graders. Eight optometrists from MDRF and SN were trained in grading of fundus images by senior retina specialists and obtained certification in DR grading.

## **Curation of images**

High resolution retinal images from different fundus camera (Images for the study were retrieved from MDRF and SN Electronic Medical Records (EMR). The image id was masked for the Optometrist to upload and grade in the DBT-AI grading platform.

## **Image uploading process**

The retrieved anonymous fundus images were uploaded to the DBT-AI platform. Figure 2 provides a screenshot of the platform. The platform anonymized any patient identifiers if any on the image uploaded to the platform. All the certified optometrists were given individual user IDs and passwords for grading purposes.

The grading and annotation of DR for this study was based on the International Clinical Diabetic Retinopathy (ICDR) severity scale<sup>13</sup>. Figure 3 shows the various annotations of the DR lesions on the fundus images on the AI-DR platform. The ICDR severity scales provided a classification of 5 stages of DR as shown in Table 2: 1. Normal-No DR; 2. Mild non-proliferative DR (NPDR) 3. Moderate NPDR 4. Severe NPDR 5. Proliferative DR (PDR). The International Diabetic Macular Edema (DME) severity scale was used for grading of diabetic macular edema (DME) as mild, moderate and severe DME based on the distance from the centre of the fovea (Table 2). Referable DR (RDR) is defined as the presence of (i) moderate non-proliferative DR (NPDR) or higher and/or (ii) diabetic macular edema (DME) as shown in Fig. 4.

At the initiation of the study, training in DR grading was provided by senior retina specialists to eight optometrists. After training, they obtained international certification in DR grading. The grading of the retinal images by these trained certified graders was carried out at three levels. Two optometrists were involved in grading each image. Once the grading and annotation of the fundus image was completed by the first optometrist (primary), the image was sent to the second optometrist for the validation/ secondary check of annotation as well as grading. Any errors in annotation and grading were rectified at this step. The images were referred to a senior retina specialist (ophthalmologist) if there was a discrepancy between the two optometrists in grading and annotation for providing the final grade (Arbitration). Any disagreement in the retinopathy grading between the two graders was adjudicated by a third senior retina specialist whose DR grading was taken as final. The image dataset in the platform has been partitioned for use for 1. Training, 2. Validation, and 3. Testing of the AI tool.

**Fig. 2.** Retina image database platform.

### Automated detection of DR

After the uploading and labelling of anonymised fundus images has been carried out, the annotated images with the corresponding ground truth are being utilised for training the AI algorithm for the prediction of DR. The labelled dataset of images could be downloaded from the platform without editing options by the AI team at ISI and NIT for Phase II of the study.

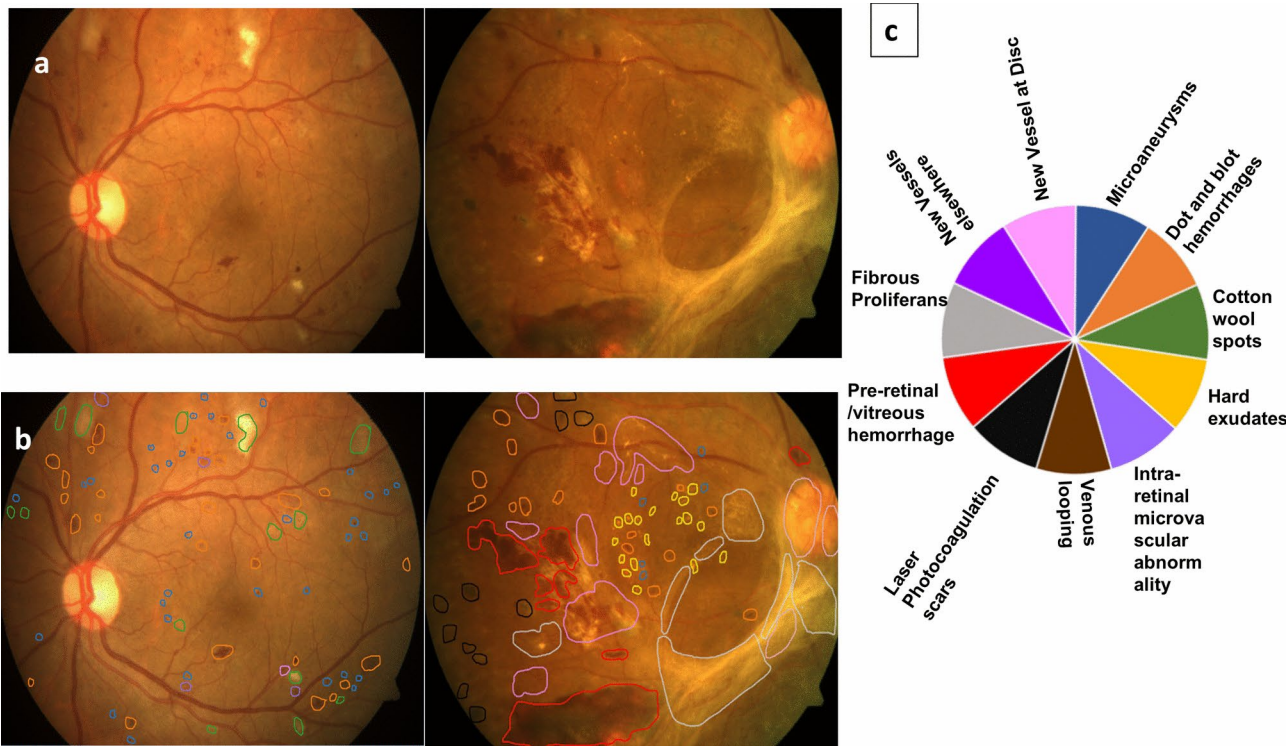
The labelled data set for training is being used to make the AI model learn how to perform a task. Ground truth annotations serve as reference labels that define the location and class of objects within an image which is essential for AI experts for design diagnostic tools. These annotations are required for training and evaluating object detection models. Therefore, it is essential to ensure accurate ground truths when the model is trained, with a reliable labelling protocol to ensure accurate performance of the automated algorithm.

The lesion-level annotations are available in the AI-DR database for eleven DR changes on the fundus images and these annotations are invaluable for the validation of several object detection methods such as single shot detector, Faster-RCNN, Retina-Net, and YOLO based frameworks. Our datasets provide annotations in specific formats such as JSON. The JSON file formats define the structure and organisation of the annotations, including bounding box coordinates, class labels, and colour code of different pathology.

For creating a binary mask of an image from a JSON file, two steps are followed, first, the json file is overlaid on the corresponding image and the binary mask of that image where the region of interest is located is created<sup>14</sup>. There are various phases involved in creating masks from JSON files for object detection. An outline of the procedure is given below:

1. First, we loaded the JSON file containing the object annotations to begin. The bounding box coordinates, class names, and other attributes related to the pathologies in the image are included in each annotation. The coordinates are overlaid on the original image to locate the lesion position. There is a one-to-one mapping for image and annotation of each patient, where each annotation of an image represents all pathologies present in the corresponding image.
2. We created a blank binary mask with the same dimensions as the source image. Loop through each object annotation in the JSON file as we go through the annotations. Extract the bounding box coordinates, which represent pathologies present. Draw a binary mask for each object using the bounding box coordinates on the blank mask image. Set the rest of the image to black (0 or lowest intensity) and the pixels inside the bounding box region to white (1 or highest intensity). This procedure basically creates a mask for the object





**Fig. 3.** Diabetic retinopathy lesions with annotations in the retinal image database (a): Retinal images with diabetic retinopathy (DR) lesions, (b) Retinal images with annotations of DR lesions (c) Color codes of the annotated DR lesions.

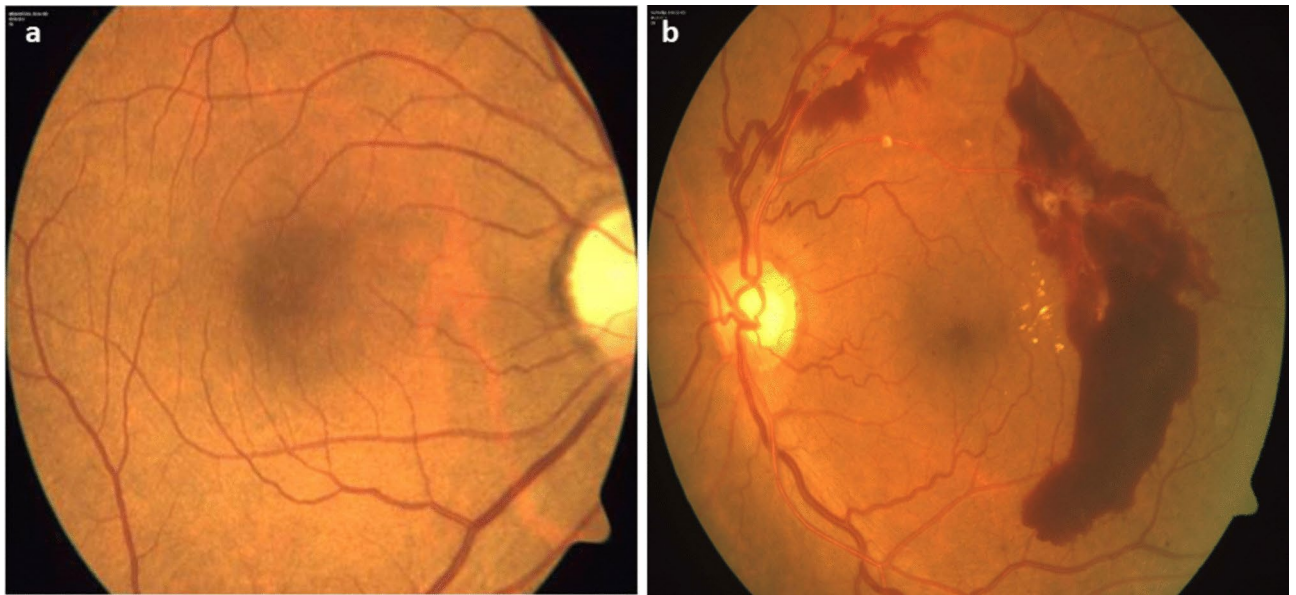
Proposed disease severity level	Findings observable on dilated ophthalmoscopy/fundus photograph
1. No apparent retinopathy (No DR)	No abnormalities
2. Mild nonproliferative diabetic retinopathy (NPDR)	Microaneurysms only
3. Moderate nonproliferative diabetic retinopathy (NPDR)	More than just microaneurysms, but less than severe NPDR (with additional lesions like hard exudates, cotton wool spots, intra-retinal haemorrhages)
4. Severe nonproliferative diabetic retinopathy (NPDR)	Any one of the following: (4:2:1 rule) 1. more than 20 intraretinal haemorrhages in each of 4 quadrants; 2. definite venous beading in 2 + quadrants; 3. Prominent intraretinal microvascular abnormalities (IRMA) in 1 + quadrant <i>and</i> no signs of PDR
5. Proliferative diabetic retinopathy (PDR)	One or more of the following: • Neovascularization Vitreous/preretinal haemorrhage
International diabetic macular edema (DME) disease severity scale	
DME absent	No retinal thickening or hard exudates in the macula
DME present 1. Mild DME 2. Moderate DME 3. Severe DME	Retinal thickening or hard exudates in the posterior pole but distant from the centre of the macula Retinal thickening and / or hard exudates approaching the centre of the macula but not involving the centre Retinal thickening and/ or hard exudates involving the centre of the macula

**Table 2.** International clinical classification of diabetic retinopathy and diabetic macular edema severity scale<sup>13</sup>.

by filling the region corresponding to it with white pixels. A binary mask for each pathology corresponding to an image is generated individually.

Figure 5 shows the original fundus image of mild NPDR without and with the masks. Once the masks have been generated it is stored in a suitable format, such as PNG for further use in object detection tasks or other pixel-level analyses. The masks can be paired with the original images or used separately, depending on the specific requirements of the application.

During training, the tool is fed with input images and it outputs a prediction. The output is compared to the ground truth label. The ground labels of 5 stages of DR as well as referable DR are available in the database platform. Therefore, the classification networks (viz. inception v3, ResNET and attention-based networks) would be used and validated on this database for evaluation of screening accuracy.



**Fig. 4.** (a) Normal retina and (b) diabetic retinopathy fundus image.

### Steps to overcome challenges in development of AI tool for DR detection

Steps are being taken in this study to avoid the challenges that are seen in previous AI studies<sup>15,16</sup>.

1. Ungradable images are a challenge in the grading of DR. Factors such as media opacities like cataract in older age, darker iris in Indians, affects the image quality and hence can decrease the sensitivity and specificity of DR screening, especially with non-mydriatic retinal imaging. As earlier studies have shown that mydriasis reduces the proportion of ungradable photographs from 26 to 5%, we have used only mydriatic retinal images in this study to train the AI algorithm.
2. To address the issue of lesser ungradable images we have used certified CE marked quality fundus cameras for retinal imaging, dilatation of the eyes (mydriasis) for better quality images, provided proper training and certification to optometrists/ photographer to follow standardised imaging protocols and obtain good quality high resolution images and provided robust training in DR grading to the graders who obtained certifications, prior to initiation of the study.
3. AI algorithms require clear good quality retina images to be fed as input. Robust curated image data is essential for accurate deep learning by the AI system. The database platform has retinal images from different fundus cameras of excellent quality.
4. AI algorithms require a reliable input ground truth DR grading to provide an accurate output. High inter-grader variability in DR severity grading can give rise to a paradox. In this study, it has been addressed by involvement of multiple certified graders and arbitration grading.
5. Training with a large amount of image data is required to develop robust AI algorithms. Training is being provided with a large sample size of retinal images based on the sample size calculated.

### Validation and benchmarking

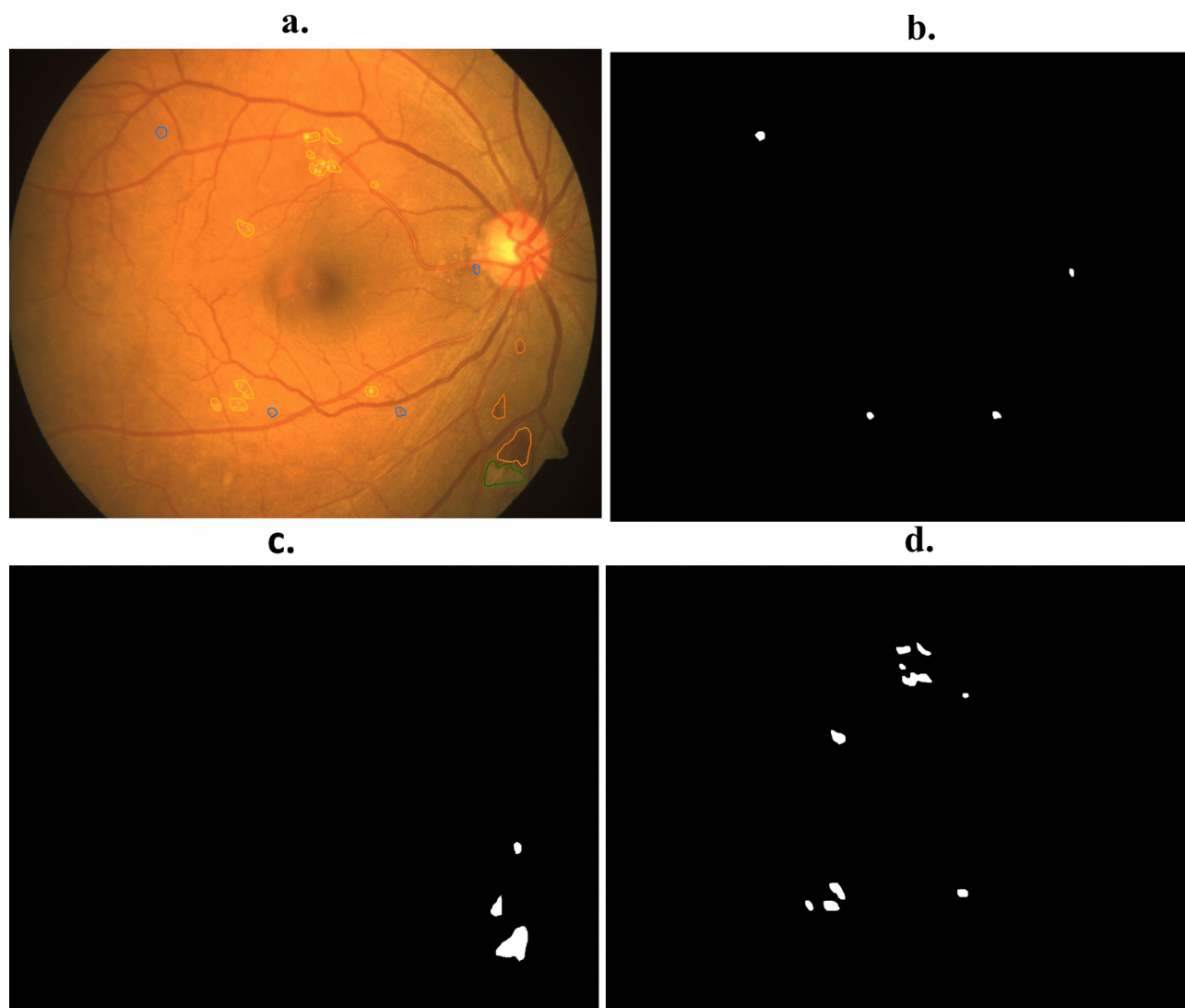
The reliability and performance of automated algorithms rely heavily on the quality of annotations in the image database. The availability of a benchmark dataset with ground truth annotations is crucial for evaluating and comparing different algorithms, but it can be challenging to establish a universally accepted benchmark due to the complexity and variability of diabetic retinopathy.

### Conclusions

This detailed protocol outlines a multicentric study aimed at creating an advanced AI-based tool for the automated detection of DR in India. This collaborative effort between multiple institutions is centred around the development and utilization of the first large, high-resolution annotated labelled retinal image database platform for DR in India.

Through rigorous training of certified optometrists for image grading, the implementation of standardized protocols for DR severity grading, and a robust AI model training and validation framework, we ensure the reliability and accuracy of our AI tool. The uniquely designed DBT-AI-DR platform presents a streamlined, user-friendly process for intake, grading, and annotation of retinal images.

By addressing the common challenges in AI-based DR detection, the study is tailored to maximize the accuracy of DR detection. This emphasis on high-quality, annotated image data, combined with expert grading, paves the way for the development of a robust, web-based AI tool.



**Fig. 5.** Diabetic retinopathy lesions with masks (a) Retinal image with microaneurysms, dot and blot hemorrhages and hard exudates (b) mask for microaneurysms (c) mask for dot and blot hemorrhages (d) mask for hard exudates.

In addition to enriching DR research through the availability of an annotated fundus image database, the implementation of this protocol is also expected to provide a basis for future research on AI-based detection and classification of other retinal diseases.

The innovative methodologies and insights gained from this study will continue to shape the landscape of AI in healthcare and ophthalmology, making significant strides towards improving patient care and health outcomes. The ultimate goal of this study is to provide a tool that can facilitate accurate DR diagnosis even in the absence of an ophthalmologist, which is expected to make a significant impact at the primary healthcare level. The development of this cost-effective, "Make in India" AI tool can further lead to its deployment in real-time, in telemedicine-based DR screening programs across the country.

### Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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## Author contributions

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## Declarations

## Competing interests

The authors declare no competing interests.

## Ethics approval

The study was conducted in accordance with the Ethical guidelines and principles set forth by Institutional Review Board Ethical Committee. Institutional Ethical Committees of Madras Diabetes Research Foundation, Chennai, India and Vision Research Foundation, Chennai, India approved the study in March 2021. There was no human study participant recruitment in the study. Institutional Ethical Committees of Madras Diabetes Research Foundation, Chennai, India and Vision Research Foundation, Chennai, India waived the informed consent and approved uploading of anonymised retinal images into the database. The study complied with the Declaration of Helsinki.

## Additional information

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