Validation Plan for Hippocampal Volume Quantification

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Intended Use

The U-Net architecture Convolutional Neural Network model was used to measure hippocampus volume from MRI images with this algorithm. Specifically, it identifies the individual MRI images that belong to one Series, analyses every slice in the 3D volume and outputs a hippocampal volume report for radiologists in the clinical setting. With the use of this algorithm, radiologists will be able to compare series from one to the next with similar results, reducing the variances in measurements due to interobserver variability.

Neurodegenerative brain disorders such as Alzheimer's disease should be diagnosed and tracked with the aid of MRI images and the patient's medical history.

Indication for Use

For images of the brain taken from an axial position, this algorithm may be utilized.

Training Data

Data for this training dataset was collected from the Medical Decathlon competition, which consisted of 260 NIFTI files, one for each MRI image volume and one for each segmentation mask. The training dataset is formed by cropping the original T2 MRI scans of the brain, displaying only the area around the hippocampus.

Clinical Validation Data Requirements

A clinical validation dataset with a clinical facility and unlimited budget will be needed to demonstrate the effectiveness of the model.

The dataset should include all the following:

- Since there was no demographic information available about the medical decathlon, images should be collected from both genders and all ages.
- The training dataset for MRIs does not contain labels, so they need to be generated. To develop the algorithm, radiologist hire a team of radiologists to view and label each slice of the MRI scans using a tool such as 3DSlicer. The ground truth will be the results of this team's scrutiny of the same dataset of MRI scans. A minimum of 3 radiologists is required in order to account for interobserver variability. We will weigh their labels according to how long they have been in the business.

Model Training and Performance

U-Net architecture was used to train the algorithm. This algorithm outputs the probability of each pixel being in a specific class. Adam Optimiser was used, and it was set to minimize the cross entropy loss with a learning rate 0f 0.0002 and have run it for 10 epochs.

Algorithm Performance

Dice and Jaccard similarity coefficients are used to assess the model's performance, which indicates its similarity to the ground truth.

Device Limitations

T2MRI brain images cropped to the hippocampus region perform well with algorithm. MRI brain scans taken at uncropped angles won't perform as well.