

HippoAI Validation Plan

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Device Name:

HippoAI: Algorithm for calculating Hippocampus volume from curated Hippocampus MR volumes.

General Information

Intended Use

This algorithm is intended to be used for calculating Hippocampus volume from Hippocampus MR volumes created from the HippoCrop tool, to give clinicians a means to quantify the progression of Alzheimer's disease.

Training Data collection

The original MR brain scans were obtained from the Medical Segmentation Decathlon "Hippocampus" dataset (see: <http://medicaldecathlon.com/>) and were stored as NIFTI files. These MR scans were then processed using a tool called HippoCrop. HippoCrop creates a rectangular image of the Hippocampus and the area surrounding it from T2 MRI Brain scans. The images from the HippoCrop tool were then analyzed and the volume of the Hippocampus was calculated for each image. Images that did not fall within the range of Hippocampus volumes as depicted in the established Hippocampus volume ground truth (see ground through section for further details), were discarded. The resulting images (around 260) were then split into training, validation and test datasets. The training dataset comprised of about 208 out of 260 of the images.

Data labeling

Data labels that correspond to a given volume attempt to capture the dimensionality within the image volumes, 0 represents the background, 1 represents an anterior dimension, and 2 represents a posterior dimension. The unit of measurement for the dimensions is referenced from the NIFTI file header and is millimeters.

Ground Truth

To establish a ground truth for the data used with this algorithm, the following paper "Hippocampal volume across age" was referenced (see: <https://www.sciencedirect.com/science/article/pii/S2213158219302542>), along with this paper the HippoFit calculator was used to better understand the correlation between Hippocampal volume and age (see: <http://www.smanohar.com/biobank/calculator.html>). From the paper the below figure depicting the right Hippocampus volume for Women between the ages of 52 and 71, indicates that the volume of the Hippocampus ranges between 3100 cubic millimeters and 4600 cubic millimeters.

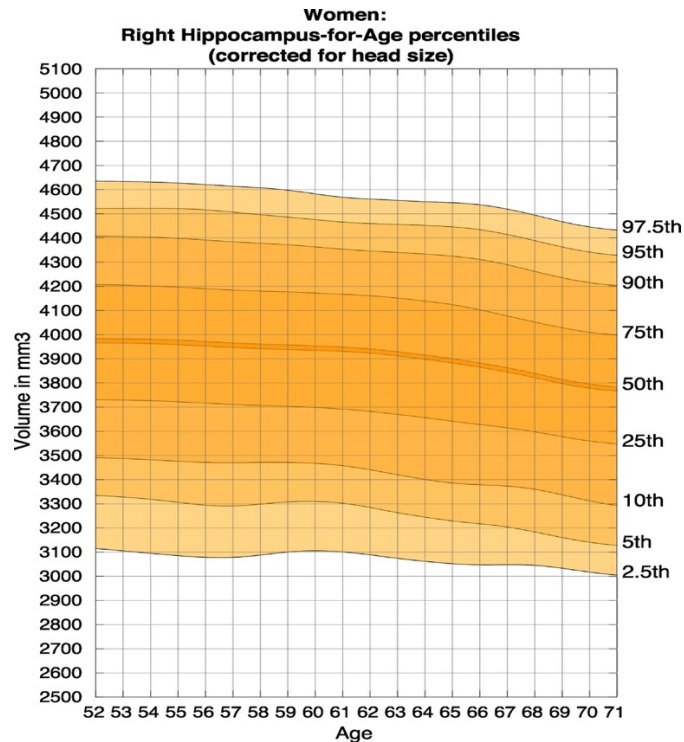


Figure 1: Nomogram - Female, Right Hippocampus Volume, Corrected for Head Size

Source: Nobis, L., Manohar, S.G., Smith, S.M., Alfaro-Almagro, F., Jenkinson, M., Mackay, C.E., Husain, M. Hippocampal volume across age: Nomograms derived from over 19,700 people in UK Biobank. *Neuroimage: Clinical*, 23(2019), pp. 2213-1582.

Performance Metrics

The performance of the algorithm was measured by computing the Dice and Jaccard similarity coefficients between the inferred labels created from the algorithm and labels from a test dataset of around 26 volumes. The Dice and Jaccard similarity coefficients were then averaged to provide an overall performance for the algorithm. In the real world physically measuring the volume of the Hippocampus in the imaging volume and loading imaging volumes generated from the algorithm and measuring the Hippocampus in these images would present a more robust and reassuring albeit more tedious way to assess performance. Another intermediary approach maybe to use computed Hausdorff distances between the algorithm generated Hippocampus imaging volumes and target volumes.

Clinical Considerations

This algorithm has been developed and trained around images that isolate the Hippocampus from the HippoCrop tool, utilizing full MR brain scans, therefore would not work with this algorithm. The algorithm is designed to interface with a health care facility's PACs system and can retrieve DICOM images that have been filtered through the Hippocrop tool for use. The algorithm also writes a final DICOM report that can be viewed in a clinical viewing system.