Stroke Imaging Research Group
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Project Report Establishing a Testbed for Evaluation of Automated Imaging Analysis Tools for Stroke Imaging – VAI-S

Background

Imaging is the pivotal tool for diagnosis, prognostication and follow-up of stroke patients. Stroke is a medical emergency and every minute counts, since it has been shown that on average 2 million neurons are lost per minute during an ischemic stroke (Saver 2006). During recent decades effective therapies have been developed for ischemic stroke (Emberson 2014, Goyal 2016, Saver 2016), and novel treatments are also being introduced for intracranial hemorrhages (Parry-Jones 2020).

In recent decades, fully automated imaging analysis tools have been developed. Such imaging tools may function as screening tools to alert the human reader when a significant finding is indicated (Chilamkurthy 2018). It may also contribute automated analysis tasks that are difficult or time-consuming for a human reader, such as volume segmentation (Campbell 2012, Maragkos 2021).

These automated imaging tools are often developed by applying Machine Learning (ML) principles on large datasets. Drawbacks with this method is that it is unclear exactly how the algorithm makes its decisions and what its performance may be on datasets that are different to those used for training and evaluation of the algorithm. Such differences may for example be that the algorithm is trained on more homogenous imaging datasets than what it is exposed to in clinical practice (Celi 2022, Varoquaux 2022). Furthermore, it is difficult to compare the performance of two or more automated imaging tools. Lastly, there is not well established how safety and performance of automated imaging tools should be monitored (Liu 2022, Vasudevan 2022). These factors are important to monitor performance, and also for the acceptance of automated imaging tools among the healthcare professions (Tucci 2021).

Aims

The primary aim of the project was to design the requirements of a test-environment – validation platform – for automated imaging tools.

The secondary aim was to implement the initial phases of such a validation platform and perform testing of commercially available automated imaging tools targeting stroke imaging.

Stroke Imaging

Within stroke imaging, the following major imaging tasks are of interest for applications of automated imaging tools:

- Acute Ischemia Detection and Volume, either as semi-quantitative such as ASPECT score, or volumetric
- Automated Vessel Occlusion analysis
- Cerebral Perfusion Analysis
- Intracranial hemorrhage detection and volumetric measurement

- Volumetric analysis of intracranial structures including brain volume, ventricular volume, white matter hyperintensity volume.

Medicolegal Considerations

There is an increasing understanding of the importance of patient privacy that is also reflected in the legislation. Within the European Union, the GDPR provides a legislative framework for privacy and protection of individual healthcare data.

For stroke imaging this has fundamental implications. The imaging data can be argued to be identifiable individual data in itself, since a reconstruction of the face can be made by the images, thereby potentially identifying individuals by commonly used facial recognition software even if the images have been anonymized. Since this has not yet been tried against the GDPR, Healthcare providers in Europe are making their own interpretations on how stroke imaging datasets may be used (Läkemedelsverket 2021 and 2021), especially if anonymized imaging data can be shared to developers of automated imaging tools, or if stroke imaging datasets may be sent for analysis, for example in cloud-based solutions where the analysis is done outside of the protected healthcare provider's IT-environment.

During the initial phase of the project, we performed an in-depth analysis of the medicolegal aspects of stroke imaging, and the implication of the design of the validation platform. Our conclusion was that anonymized CT-images should be considered as individual data in itself, due to the possibility to reconstruct an identifiable facial image from the dataset. Therefore, the validation platform cannot be made publicly available, instead it needs to be handled as personal data. Our conclusion was that anonymized CT-images should be considered as individual data in itself, due to the possibility to reconstruct an identifiable facial image from the dataset. Therefore, the validation platform cannot be made publicly available, instead it needs to be handled as personal data

The most common way to develop or validate automated imaging tools is to collect large imaging data in a separate database where the image analysis is performed. With the abovementioned considerations concerning privacy, this is not desirable. From a data maintenance perspective, this is also not desirable, since the establishing and maintenance of such a large imaging database will be associated with extensive work, privacy risks and costs.

An alternative approach is that of Federated Learning, where the imaging dataset is not collected into a central database, but instead the analysis tools are distributed to the various databases where the source data is kept.

Our conclusion was that evaluation of automated imaging tools should be done within the IT-environment of the healthcare provider. If evaluation is to be done based on images stored at several locations, a federated analysis is to be employed where the image analysis is done at each separate location, and the aggregated results pooled for the analysis.

Research-PACS

Ethical application for stroke imaging validation platforms (Dnr 2023-00387-01) was granted 230222 by the Swedish Ethical Review Authority.

Based on the initial analysis of the medicolegal and technical aspects of the VAI-S project we initiated the process to set up and maintain a research PACS at Skåne University Hospital.

Sectra was selected to deliver the research PACS. All functionality was not available at installation and several parts of the solution necessary for the research work were developed and refined in collaboration with Sectra. It is connected to Sectra's Amplifier solution to facilitate access to AI-software. This research PACS is owned and maintained by the Department of Radiology at SUS to ensure its longevity also after the end of this project.

Validation platforms

Our first validation platform for stroke is based on a regional population for the evaluation of IntraCerebral Hemorrhage (ICH) and has been used to evaluate the Qure.ER software by Qure.ai, and the VIOLA software from Oslo University. It is currently used for validation of the next version of the Qure.ER software by Qure.ai.

Our second validation platform for stroke is based on a regional population for the evaluation of Large Vessel Occlusions (LVO) It hs been used to evaluate the Canon CINA LVO solution. It is currently used to validate the Qure.ER-LVO solution by Qure.ai.

Our third validation platform is focusing on Photon Counting CT Angiography CT.

Our fourth validation platform is based on a regional population operated for chronic subdural hematoma (CSDH). We believe this will be a future field for automated image analysis software, but there are no commercially available solutions yet.

Publications within the project

1. Hillal A, Sultani G, Ramgren B, Norrving B, Wassélius J, Ullberg T. Accuracy of automated intracerebral hemorrhage volume measurement on non-contrast computed tomography: a Swedish Stroke Register cohort study. Neuroradiology. 2023 Mar;65(3):479-488. doi: 10.1007/s00234-022-03075-9.

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Manuscripts in preparation

9. The distribution and prognosis of Cerebral amyloid angiopathy probability according to the simplified Edinburgh CT criteria in a large regional ICH population. Amir Hillal, Birgitta Ramgren, Bo Norrving, Johan Wassélius and Teresa Ullberg.
10. Validation of Qure.ER software for detection of large vessel occlusion in brain CT angiography. Helena Mellander, Björn Hansen, Teresa Ullberg and Johan Wassélius.
11. A novel validation platform for automated volume segmentation of chronic subdural hematoma. Drake M, Hall E, Redebrandt-Nittby H, Marklund N, Ullberg T, Wassélius J.

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