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Can we accurately assess MS disease activity using automated methods in large real-life MRI databases? Insights from the OFSEP HD database

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Background: The systematic collection of MRI scans associated with large real-life clinical databases (DB) is still rare but offers the opportunity to directly extract a wide range of imaging metrics through the use of AI-based tools. **Objective:** To compare the performance of an automatic tool that detects new lesions on FLAIR images vs radiological data entered in the clinical DB to classify MS patients as "active" or "inactive" in a large multicenter real-life DB.

Methods: We included **1412 pairs of brain MRI scans** with both FLAIR images available in the French OFSEP HD multicentric imaging DB at two time points, and the radiological comparison captured in the OFSEP HD clinical DB. The data was heterogeneous (FLAIR images acquired on 35 different types of scanners from 5 manufacturers). An automated tool was used to detect new lesions. A ground truth for 160 pairs of MRIs was built from two experts and differences in sensitivity, specificity and accuracy between the two methods were assessed.

Results:

Figure 1: Overall, 222 out of 1412 (16%) intervals were considered active from the clinical DB, compared to 467 (35%) from the automated method. **Figure 2:** The clinical DB was more specific, but the automated method was more sensitive and accurate (p<0.001) to classify MS patients. **Figure 3:** Under simplified assumptions, we extrapolate a sensitivity, specificity and accuracy of about 0.69, 0.99 and 0.92 for the clinical DB and 0.99, 0.95 and 0.96 for the automated method.

Figure 1: Creation of the ground truth from 160 intervals for which the clinical database and the automatic method disagree

Figure 2: Relative performance of the automatic tool versus the clinical database on the disagreement data set (N=160 intervals) and p-values for equality of sensitivity, specificity and accuracy.

What is the sensitivity, specificity and accuracy of the two methods ?

Figure 4: Examples of false negatives generated by the clinical database (A, B) and false positives generated by the automatic tool (C, D). A: patient with 1 new lesion detected by the automatic tool and classified as inactive in the database; B: patient with 21 new lesions detected by the automatic tool and classified as inactive in the database; C: patient correctly classified as inactive in the database but where changes in image characteristics between two acquisitions leads to false detection of a new lesion by the automatic tool; D: patient correctly classified as inactive in the database but where image artifacts leads to false detection of two new lesions by the automatic tool.

Conclusion: The automated analysis of images collected in large reallife databases increases the accuracy of MS patient classification as active or inactive compared to the clinical database and offers the possibility to extract other metrics such as lesion number or volume. These results should encourage us to develop the systematic collection and re-analysis of real-life imaging data linked to large clinical databases, in order, for example, to evaluate the effectiveness of treatments in real life.

Figure 3: Specificity, sensibility and accuracy as computed i) by using the Bayesian Model assuming that the outcomes of the two classification methods (the clinical database and the automatic tool) are independent conditionally to the actual patient activeness and ii) by considering that when the two methods agreed, the patient was correctly classified.

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