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REVIEW

OFSEP, a nationwide cohort of people with multiple sclerosis: Consensus minimal MRI protocol

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Summary Multiple sclerosis (MS) is most generally considered as a severe disease with high physical and mental risks of disability. Since the end of the 1990s, several high cost long-term disease-modifying treatments provided some clinical efficiency. However, patient's follow-up was needed for the detection and the assessment of their side-effects. The ''Observatoire français de la sclérose en plaques'' (OFSEP) project aims to improve the clinical, biological and imaging systematic longitudinal follow-up of patients. It should increase the quality, efficiency and safety of patients' care, with a unique opportunity of large scale, about 41,000 patients followed in 62 French centers using the European Database for Multiple Sclerosis (EDMUS) software. OFSEP is divided into three working groups (clinical, biological and imaging). The imaging working group defines standards for routine MRI follow-up in the whole cohort and contains three

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Abbreviations: ADC, Apparent Diffusion Coefficient; BBB, blood brain barrier; CSF, cerebrospinal fluid; DTI, Diffusion Tensor Imaging; EDMUS, European Database for Multiple Sclerosis; FLAIR, fluid attenuated inversion recovery; IRC, Imaging Resource Centre; MRI, Magnetic Resonance Imaging; MS, multiple sclerosis; OFSEP, French Observatory of Multiple Sclerosis (''Observatoire français de la sclérose en plaques''); PD, proton density; STIR, Short Tau inversion recovery.

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subgroups: acquisition, workflow, and data processing. A common and feasible brain and spinal cord acquisition protocol has been defined by the acquisition group, and accepted by the OFSEP steering and scientific committees. This protocol can be implemented in all French MRI centers. The major MRI manufacturers have agreed to provide the dedicated collection of sequences as an ''OFSEP box'' with every software upgrade or new MRI machine. The new OFSEP protocol will provide a unique opportunity to study a population-based collection of data from people with MS.

Introduction

Multiple sclerosis (MS) is the first cause of non-traumatic neurological disability in young adults in France [1,2]. It can affect patients' quality of life and is associated with high costs for MS patients, their families, and society as a whole. Indeed, because individuals become symptomatic during their most productive years, the financial cost for the individual and for society can be staggering [3,4]. The pathophysiology of MS is still unknown. However, it is considered as an inflammatory autoimmune neurologic disease with demyelination and axonal injury. It has a prevalence of 1 per 1000 and affects more than 80,000 individuals in France. Simply stated, MS develops early and runs a protracted clinical course so that life expectancy is barely reduced. The clinical features are extremely variable and the prognosis hardly predictable. A detailed knowledge of the overall course and prognosis is therefore desirable for the physician wanting to understand the disease and make it comprehensible to the individual patient facing decisions on personal, family, social or professional involvements and commitments. Furthermore, since new efficient and coasty therapies are now available, indication, efficacy, tolerance, and toxicity should be considered to personalize the treatment.

Magnetic resonance imaging (MRI) has played an increasing role in the diagnosis and management of MS. In 2001, the McDonald criteria for diagnosis were the first to incorporate the central nervous system lesions observed on MRI as a criterion of dissemination in space [5]. The revised 2005 McDonald criteria [6] included the dissemination of MS lesions in time. Swanton criteria [7] were then proposed in 2006 to simplify the diagnosis. Recently, Polman et al. [8] proposed a revision of McDonald criteria that is now used in clinical practice. The high conspicuity of abnormal signal intensities of MS lesions seen on MRI provided the best view yet of tissue injury, lesion activity, and disease accumulation compared to all other imaging modalities. Combined with characteristic symptoms, MRI provides earlier and more confident diagnosis than symptoms alone. It also contributes to our understanding of the pathophysiology and prognosis of MS specially when coupled with contrast agents. The use of these agents offers insights into the pathogenesis of blood-brain barrier (BBB) permeability and improves the monitoring of treatment efficacy.

MRI techniques are quickly evolving. Radiologists are facing several technical issues for good practice such as:

- appropriate magnetic field and sequences including anatomic resolution parameters;
- data reading in comparative manner in a chronic disease with patients having at least one MRI examination per year and where most of patients are under treatment;
- data collection in order to provide any physician with quick, easy and long-term access to the patient's MRI.

Solutions for increasing quality, harmonization and personalized treatment can be:

- to adopt a comprehensive simple MRI protocol, regularly actualized according to the evolution of MR techniques and sequences;
- to determine and regularly actualize the post-processing techniques in order to ensure the reproducibility of longitudinal clinical MRI in single individuals;
- to avoid the data heterogeneity by storing them in a centralized center with high standard quality and security.

As MR imaging in MS evolves, an increasing number of techniques and protocols are adopted. Hence, a great variability in the use of MR imaging among centers (private, general and university hospitals) and among radiologists (sometimes in a same center) is observed. In the face of this growing divergence, experts recognize the importance of standardizing protocols based on evidence of optimal practice [9,10].

In France, there has been since 2001 an effort to standardize clinical data within a network of neurologists using the same software, ''European Database for Multiple Sclerosis'' (EDMUS). This represents all the MS centers including university hospitals and all city-hospital networks devoted to MS care, distributed in 62 clinical centers (http://www.edmus.org) [11]. Thereby, a cohort of more than 41,000 patients with MS, approximatively half the French patients' population, was available in 2014.

This national cohort has been selected in January 2011 for a 10-year tenure as part of the Investments for the Future program of the ''Présidence de la République Française''. Through the systematic longitudinal follow-up of persons with MS and combination of clinical data with biological samples and neuro-images, the Observatoire français de la sclérose en plaques (OFSEP) project aims at improving the quality, the efficacy and the safety of patients' care and fostering clinical, basic and translational research in MS. The OFSEP cohort is open to physicians and researchers, public and private entities, in France and abroad.