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# Applicability of McDonald 2010 and Magnetic Resonance Imaging in Multiple Sclerosis (MAGNIMS) 2016 Magnetic Resonance Imaging Criteria for the Diagnosis of Multiple Sclerosis in Sri Lanka

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<sup>a</sup>Department of Anatomy, Faculty of Medicine, University of Peradeniya, Peradeniya, Sri Lanka <sup>b</sup>Neurology Unit, Teaching Hospital, Kandy, Sri Lanka <sup>c</sup>Radiology Unit, Sirimavo Bandaranayaka Specialized Children's Hospital, Peradeniya, Sri Lanka <sup>d</sup>Department of Neurology, Karolinska University Hospital, Stockholm, Sweden **Background and Purpose** The magnetic resonance imaging in multiple sclerosis (MAG-NIMS) group recently proposed guidelines to replace the existing dissemination-in-space criteria in McDonald 2010 magnetic resonance imaging (MRI) criteria for diagnosing multiple sclerosis. There has been insufficient research regarding their applicability in Asians. Objective of this study was to determine the sensitivity, specificity, accuracy, positive predictive value (PPV), and negative predictive value (NPV) of McDonald 2010 and MAGNIMS 2016 MRI criteria with the aim of verifying their applicability in Sri Lankan patients.

**Methods** Patients with clinically isolated syndrome diagnosed by consultant neurologists were recruited from five major neurology centers. Baseline and follow-up MRI scans were performed within 3 months from the initial presentation and at one year after baseline MRI, respectively. McDonald 2010 and MAGNIMS 2016 MRI criteria were applied to all MRI scans. Patients were followed-up for 2 years to assess the conversion to clinically definite multiple sclerosis (CDMS). The sensitivity, specificity, accuracy, PPV, and NPV for predicting the conversion to CDMS were calculated.

**Results** Forty-two of 66 patients converted to CDMS. Thirty-seven fulfilled the McDonald 2010 MRI criteria, and 33 converted to CDMS. MAGNIMS 2016 MRI criteria were fulfilled by 29, with 28 converting to CDMS. The sensitivity, specificity, accuracy, PPV, and NPV were 78%, 83%, 64%, 89%, and 69%, respectively, for the McDonald 2010 criteria, and 67%, 96%, 77%, 96%, and 62% for the MAGNIMS 2016 MRI criteria.

**Conclusions** MAGNIMS 2016 MRI criteria were superior to McDonald 2010 MRI criteria in specificity, accuracy, and PPV, but inferior in sensitivity and NPV.

**Key Words** multiple sclerosis, McDonald 2010 magnetic resonance imaging criteria, magnetic resonance imaging in multiple sclerosis 2016 magnetic resonance imaging criteria, McDonald 2017 magnetic resonance imaging criteria, performance, Asia.

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# INTRODUCTION

Multiple sclerosis (MS) is a challenging disease to diagnose despite medical advances due to the complexities of its clinical presentation.<sup>1</sup> MS is heterogeneous in terms of its clinical and radiological manifestations, disabilities, prognoses, and intrathecal antibody responses in different populations of the world,<sup>2-6</sup> making confirmatory diagnoses even more difficult. Early diagnosis is crucial for effective treatment, and magnetic resonance imaging (MRI) plays a major role in the early diagnosis of MS at the stage of clinically isolated syndrome (CIS).

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McDonald 2010 MRI criteria use magnetic resonance imaging in multiple sclerosis (MAGNIMS) dissemination in space (DIS) criteria to identify DIS.7 However, in 2016 the MAGNIMS group proposed altering the MRI guidelines for diagnosing MS based on the intervening developments of MRI techniques and the availability of new data on using MRI to determine dissemination in time (DIT) and DIS criteria.8 The new guidelines proposed modifications to the DIS criteria but not to the DIT criteria, and to include optic-nerve lesions, to increase the number of periventricular lesions from one to three, and to consider cortical and subcortical lesions collectively under one category. That group has also proposed removing the distinction between asymptomatic and symptomatic lesions.8 The latest development is the introduction of McDonald 2017 MRI criteria, which considers the MAGNIMS 2016 MRI criteria and the availability of new data from diverse MS populations. The expert panel aimed to simplify the McDonald 2010 MRI criteria and promote earlier diagnoses while preserving their specificity.9

McDonald 2010 MRI criteria have been developed using data gathered from adult Caucasians of European and North American populations and there has been less research and practical experience regarding their application in Asian populations. The need for new research in this area has been repeatedly emphasized by experts<sup>7,10</sup> since the criteria were published in 2010. However, in the latest McDonald 2017 MRI criteria it is stated that the applicability of the McDonald 2010 MRI criteria has been studied in MS patients from Canada, Italy, the Netherlands, Spain, and Russia.9 A few studies conducted in East Asia, Russia, and Argentina have concluded that McDonald 2010 MRI criteria can also be applied to these populations with significant confidence.<sup>11-14</sup> In addition, studies of the applicability of the 2010 McDonald MRI criteria in Asian, Middle Eastern, and Latin American populations have been reported since 2010. Even though these studies were small, all of them have concluded that Mc-Donald 2010 MRI criteria are applicable to these diverse MS populations.9

Research on the applicability of MAGNIMS 2016 and Mc-Donald 2017 MRI criteria in diverse populations is highlighted as a major requirement for future revisions of the Mc-Donald 2017 MRI criteria.<sup>9</sup> One recent study in South Korea evaluated the performance of MAGNIMS DIS criteriain CIS patients.<sup>15</sup> A study in the USA evaluated the performance of both criteria in a cohort of primary progressive MS patients.<sup>16</sup> In addition, a multicenter European study reported in early 2018 compared the prediction of MS diagnosis in CIS patients using McDonald 2010 and MAGNIMS 2016 MRI criteria.<sup>17</sup> However, there have been no studies of the applicability of the McDonald 2010 and MAGNIMS 2016 MRI criteria in South In this background, the present study assessed the sensitivity, specificity, accuracy, positive predictive value (PPV), and negative predictive value (NPV) of McDonald 2010 MRI criteria and proposed MAGNIMS 2016 MRI criteria with the objective of determining their applicability in the Sri Lankan MS population.

## **METHODS**

Patients with CIS diagnosed by consultant neurologists were recruited for the study from 2012 to 2015 from five major neurology referral centers in Sri Lanka. Ethical approval for the study was granted by the Ethical Subcommittee, Faculty of Medicine, University of Peradeniya, Sri Lanka (IRB No. 2012/ EC114). All of the included patients provided informed written consent to participate in the study. The following inclusion criteria were applied: 1) CIS with clinical features suggestive of MS, 2) aged 18-60 years, since MS rarely presents in the childhood and elderly periods and may be challenging to diagnose,<sup>9,18</sup> 3) follow-up period of at least 2 years, 4) availability of spinal-cord MRI data if presenting with spinal-cord syndrome, and 5) negativity for aquaporin-4 immunoglobulin. The exclusion criteria were 1) receiving disease-modifying treatment (DMT), 2) having neuromyelitis optica spectrum disorder as defined by the 2015 neuromyelitis optica spectrum disorders criteria,<sup>19</sup> and 3) presence of atypical clinical features suggestive of other demyelinating disorders that mimic MS, including intractable hiccup, nausea, vomiting for more than 2 days, febrile illness preceding the onset of symptoms, myelopathy associated with spinal-cord lesions involving more than three spinal segments and the central part of the spinal cord on axial sections, severe bilateral optic neuritis associated with swollen optic-nerve chiasma lesion, presence of space-occupying lesions, or contrast enhancement of all the lesions.

Baseline brain and spinal-cord MRI was performed with T1-weighted, T2-weighted, and FLAIR pulse sequences and contrast enhancement within 3 months from the initial presentation of the disease. The follow-up MRI scans were performed within 1 year from the baseline MRI.

All patients were followed up for at least 2 years to assess the conversion to clinically definite multiple sclerosis (CDMS), defined as at least two typical MS attacks and clinical evidence of at least two lesions (CDMS A1) according to the Poser criteria.<sup>20</sup> The initial CIS patient recruitment and assessment of conversion to CDMS were performed by two experienced consultant neurologists. Both McDonald 2010 MRI criteria<sup>7</sup> and MAGNIMS 2016 MRI criteria<sup>8</sup> were applied retrospec-

tively to all MRI scans by a single experienced investigator who was not blinded of the clinical presentation of the patient, since it is recommended that MRI scans be interpreted by an experienced person who is aware of the patients clinical and laboratory findings.<sup>10</sup> The sensitivity, specificity, accuracy, PPV, and NPV of both McDonald 2010 and MAG-NIMS 2016 MRI criteria for predicting the conversion to CDMS were calculated at the end of the follow-up period as follows:

 $Sensitivity=[TP/(TP+FN)]\times 100$   $Specificity=[TN/(TN+FP)]\times 100$   $Accuracy=\left[\frac{(TP+TN)}{(TP+FP+TN+FN)}\right]\times 100$   $PPV=[TP/(TP+FP)]\times 100$   $NPN=[TN/(TN+FN)]\times 100$ 

True positive (TP), true negative (TN), false positive (FP), false negative (FN). All descriptive statistics were analyzed using GraphPad Prism software (GraphPad Software, La Jolla, CA, USA).

## RESULTS

This study included 66 patients, of which 42 (64%) converted to CDMS during the follow-up period of  $2.2\pm0.4$  years (mean±SD). The female-to-male ratio was 2.2:1, and the

Table 1. Demographic characteristics of the patients

| Follow-up period (years)                       | 2.2±0.4     |
|--|-------------|
| Conversion to CDMS                             | 42 (64)     |
| Time for conversion to CDMS (days)             | 356±30      |
| Female-to-male ratio                           | 2.2:1       |
| EDSS (range)                                   | 2.0 (1–3.5) |
| Time of baseline MRI from disease onset (days) | 69±20       |
| Time of follow-up MRI from baseline MRI (days) | 283±46      |
| Number of attacks during follow-up (range)     | 3 [2–7]     |
| CIS  |             |
| After first 3 months (%)                       | 57 (86)     |
| After follow-up period (%)                     | 24 (36)     |

Data are n (%), mean±SD, mean (range), or median [range] values. CDMS: clinically definite multiple sclerosis, CIS: clinically isolated syndrome, EDSS: Expanded Disability Status Scale, MRI: magnetic resonance imaging. mean age at onset was 33.2 years (Table 1).

Periventricular lesions were the most common in both baseline and follow-up MRI, followed by juxtacortical, infratentorial, and spinal-cord lesions (Table 2).

Of the 66 patients, 37 fulfilled McDonald 2010 MRI criteria, most (89%) of whom converted to CDMS during the follow-up period. TP and TN for the McDonald 2010 MRI criteria were 50% and 30%, respectively. Similarly, 44% of patients fulfilled the MAGNIMS 2016 MRI criteria, with all but one of them converting to CDMS. TP and TN for the MAGNIMS 2016 MRI criteria were 42% and 35%, respectively (Table 3).

The sensitivity and NPV were higher for McDonald 2010 MRI criteria than for MAGNIMS 2016 MRI criteria, while MAGNIMS 2016 MRI criteria had higher specificity, accuracy, and PPV (Table 4).

Example MRI scans of TP, FP, and FN patients when applying McDonald 2010 MRI criteria are shown in Fig. 1. Both McDonald 2010 TP and TN patients predominantly presented with cerebral motor manifestations, followed by optic neuritis and cerebral sensory manifestations, while both FP and FN patients predominantly had cerebral sensory manifestations in their first presentation, followed by cerebral motor and cerebellar manifestations. The MAGNIMS 2016 TP group mainly presented with optic neuritis manifestations, whereas most of the MAGNIMS 2016 TN patients had cerebral motor manifestations at their presentation. The single MAGNIMS 2016 FP patient had optic neuritis, whereas

 Table 2. Central nervous system lesion characteristics in baselineand follow-up MRI

| Typical neuroanatomical<br>lesion location | Baseline<br>MRI | Follow-up<br>MRI |
|--|-----------------|------------------|
| Periventricular                            | 44 (67)         | 51 (77)          |
| Juxtacortical                              | 38 (57)         | 50 (76)          |
| Infratentorial                             | 33 (50)         | 39 (59)          |
| Spinal cord                                | 12 (18)         | 19 (29)          |
| Optic nerve                                | 9 (13)          | 17 (26)          |
| DIS fulfillment (McDonald 2010)            | 54 (81)         | 59 (89)          |
| DIS fulfillment (MAGNIMS 2016)             | 48 (73)         | 53 (80)          |

Data are *n* (%) values. Dissemination in time fulfillment is the same for both McDonald 2010 and MAGNIMS 2016 MRI criteria.<sup>8</sup>

DIS: dissemination in space, MAGNIMS: magnetic resonance imaging in multiple sclerosis, MRI: magnetic resonance imaging.

Table 3. Results of application of McDonald 2010 and MAGNIMS 2016 MRI criteria after 2 years of follow-up

|                            | Positive | Negative | True positives | False positives | True negatives | False negatives |
|----------------------------|----------|----------|----------------|-----------------|----------------|-----------------|
| McDonald 2010 MRI criteria | 37 (56)  | 29 (44)  | 33 (50)        | 4 (6)           | 20 (30)        | 9 (14)          |
| MAGNIMS2016 MRI criteria   | 29 (44)  | 37 (56)  | 28 (42)        | 1 (2)           | 23 (35)        | 14 (21)         |

Data are n (%) values.

MAGNIMS: magnetic resonance imaging in multiple sclerosis, MRI: magnetic resonance imaging.

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cerebral sensory manifestations predominated in the MAG-NIMS 2016 FN group.

The majority of patients across all the categories had typical periventricular lesions in MRI, followed by cortical/subcortical, infratentorial, and optic-nerve lesions, respectively (Fig. 2).

 Table 4. Validation parameters of McDonald 2010 and MAGNIMS

 2016 MRI criteria for the diagnosis of multiple sclerosis

|                           | McDonald 2010    | MAGNIMS 2016     |  |
|---------------------------|------------------|------------------|--|
|                           | MRI criteria (%) | MRI criteria (%) |  |
| Sensitivity               | 78.5             | 66.7             |  |
| Specificity               | 83.4             | 95.8             |  |
| Accuracy                  | 63.7             | 77.2             |  |
| Positive predictive value | 89.0             | 96.5             |  |
| Negative predictive value | 68.9             | 62.1             |  |

MAGNIMS: magnetic resonance imaging in multiple sclerosis, MRI: magnetic resonance imaging.

# DISCUSSION

This study found that all of the performance parameters (i.e., sensitivity, specificity, accuracy, PPV, and NPV) had high values when the McDonald 2010 and MAGNIMS 2016 MRI criteria were applied to Sri Lankan patients, which confirms the validity of both MRI criteria in our setting.

A similar study involving a Russian MS cohort found that a sensitivity of 74% for McDonald 2010 MRI criteria,<sup>14</sup> while Swanton et al.<sup>21</sup> found a sensitivity of 77%, and the sensitivity was 68% in a study of Taiwanese MS patients.<sup>12</sup> Thus, the sensitivity of McDonald 2010 MRI criteria in the present Sri Lankan MS cohort (78.5%) appears to be higher than that in Taiwanese patients and lower than that in Russian patients. The accuracy of McDonald 2010 MRI criteria was considerably lower in the present study (64%) than those in the studies of Belova et al.<sup>14</sup> (82%), and Swanton et al.<sup>21</sup> (86%), and Hsueh et al.<sup>12</sup> (73.8%).

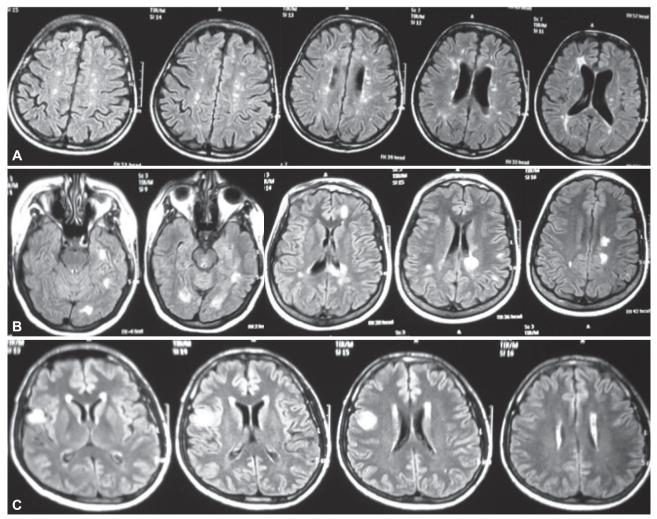


Fig. 1. Magnetic resonance imaging scans of McDonald 2010 true-positive (A), false-positive (B), and false-negative (C) patients.

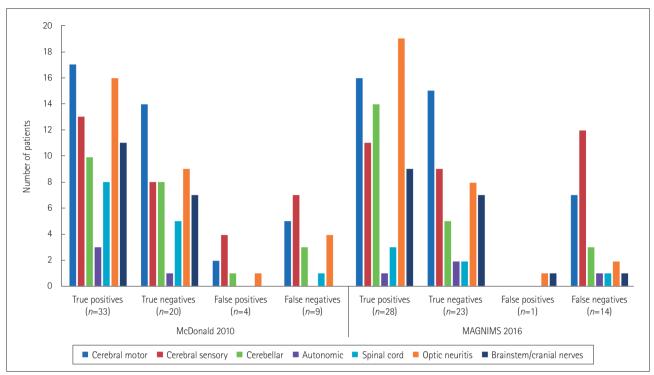


Fig. 2. Presenting clinical manifestations in the study population. MAGNIMS: magnetic resonance imaging in multiple sclerosis.

A diagnostic tool with a high specificity will tend to exclude FP cases.<sup>12</sup> The specificity of McDonald 2010 MRI criteria was 83% in our study population, which is higher than those of MS patient populations in Argentina<sup>13</sup> (80%) and Taiwan<sup>12</sup> (80%), but lower than that reported in central Russia<sup>14</sup> (93%).

The PPV of McDonald 2010 MRI criteria in the present cohort of Sri Lankan MS patients is comparable but slightly lower than the values reported in the literature for other MS populations, such as 94% for central-Russia MS patients<sup>14</sup> and 96% for Argentinian MS patients.<sup>13</sup> The NPVs of these two MS patient samples were 70%<sup>14</sup> and 46%<sup>13</sup> respectively, indicating that the NPV of McDonald 2010 MRI criteria for the present Sri Lankan MS patients was higher than that for central-Russia patients but lower than that for Argentinian patients.

This is the first study to have determined the applicability of the new MAGNIMS 2016 MRI criteria in a South Asian MS patient population. A multicenter European study that evaluated the prediction of an MS diagnosis in CIS patients concluded that McDonald 2010 and MAGNIMS 2016 MRI criteria provide similar accuracy.<sup>17</sup> In the present study, the sensitivity of MAGNIMS 2016 MRI criteria (66.7%) was lower than that of McDonald 2010 MRI criteria (78.5%), whereas the specificity was higher for MAGNIMS 2016 MRI criteria (95.8% vs. 83.4%). These results are consistent with Lamas Pérez<sup>22</sup> finding that MAGNIMS 2016 MRI criteria had better specificity than McDonald 2010 MRI criteria in a group of 161 CIS patients. The lower sensitivity and higher specificity of MAGNIMS 2016 MRI criteria in both of these studies may be attributable to the required number of periventricular lesions increasing from one to three. However, in another recent study of 170 Korean patients with CIS, the sensitivity of new MAGNIMS DIS criteria was found to be superior to that of McDonald 2010 MRI criteria, whereas the specificity was lower than that of McDonald 2010 MRI criteria. The diversity of the findings for CIS cases might be attributable to differences in study methodologies. The total rate of conversion to CDMS was higher in the present study (64%) than in these two previous studies. This difference might have been due to our CIS patients not receiving DMT until they experienced their second clinical episode, whereas proportion of the patients in both of the other studies were receiving DMT. This would have affected the conversion rate to CDMS since DMT slows the development of CDMS.<sup>15</sup> This aspect may have also affected the differences in performance parameters. Furthermore, it is recommended for interpreters of MRI scans to be aware of the clinical findings of patients to ensure accurate MRI interpretations in MS,10 and so the investigator who applied MRI criteria was not blinded of the clinical features and investigation findings of the patients in the present study, which contrasts with the approach taken by Hyun et al.<sup>15</sup>

The present study has the limitation of its sample being smaller than those in both previous studies. This is mainly

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due the expected low prevalence of MS in the South Asian region. The sample size was further restricted by the high cost and limited availability of MRI facilities. In addition, in revisions of McDonald 2010 MRI criteria it was suggested to perform spinal-cord MRI both in patients with spinal-cord syndrome, as well as those who present with non-spinal-cord CIS when their brain MRI did not fulfill the DIS criteria.<sup>7</sup> Although spinal-cord MRI scans were available in patients with spinal-cord MRI in all other patients due to facility and financial limitations.

This study found that TP MS cases could be diagnosed more accurately using McDonald 2010 MRI criteria than new MAGNIMS 2016 MRI criteria in a cohort of Sri Lankan MS patients. However, the specificity, accuracy, and PPV were higher for the MAGNIMS 2016 MRI criteria. The very high specificity and PPV indicate that the new MAGNIMS consensus guidelines are more effective in excluding MS that mimics MRI lesions than are the McDonald 2010 MRI criteria. Thus, the new MAGNIMS consensus guidelines decreased the probability of false diagnoses of MS in our study sample, and their high PPV further improves the ability to select a well-refined sample of true MS patients.

Thus, new MAGNIMS consensus guidelines had better specificity, accuracy, and PPV than McDonald 2010 MRI criteria in our sample of the Sri Lankan MS population. However, McDonald 2010 MRI criteria had superior sensitivity and NPV compared to MAGNIMS 2016 MRI criteria in this population.

#### Conflicts of Interest

The authors have no financial conflicts of interest.

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