Journal of Clinical Neuroscience xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

Journal of Clinical Neuroscience

journal homepage: www.elsevier.com/locate/jocn

Clinical commentary

Minimum Clinically Important Difference of Montreal Cognitive Assessment in aneurysmal subarachnoid hemorrhage patients

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ARTICLE INFO

Article history:
Received 25 May 2017
Accepted 15 August 2017
Available online xxxx

Keywords:
Clinically Important Difference
Montreal Cognitive Assessment
Neurosurgery
Stroke
Subarachnoid hemorrhage

ABSTRACT

Cognitive impairment is a major factor contributing to poor functional outcome after subarachnoid hemorrhage caused by a ruptured cerebral aneurysm (aSAH). Montreal Cognitive Assessment (MoCA) has been shown to be superior to the Mini-Mental State Examination in screening for cognitive domain deficit and correlating to functional outcome in aSAH patients. The aim of the current study was to determine the Montreal Cognitive Assessment (MoCA) score change that was associated with change of health in general in an aSAH patient cohort. We recruited aSAH patients from a regional neurosurgical center over a 3-year period. Patient assessments including MoCA and global rating of change (GRoC) were carried out at at 3 and 12 months after aSAH. Anchor-based and distribution-based approaches were adopted to calculate the Minimum Clinically Important Difference (MID). One hundred and seventy-five aSAH patients completed both 3-month and 1-year assessments and consented for participation. Employing the distribution-based approach for the 3-month and 1-year MoCA scores, the MID estimates equated to a change of 2.0 and 1.1 respectively. Employing the anchor-based approach (with GRoC), the MID estimate of MoCA (median, IQR) was 2, 1–4. In conclusion, we found that the MID of MoCA score associated with change of health in general in aSAH patients was 2. The MID provides guidance for future clinical trial design targeting on cognitive dysfunction after aSAH.

1. Introduction

Subarachnoid haemorrhage from a ruptured aneurysm (aSAH) is a subset of stroke that occurs at a relatively young age compared with other stroke subtypes. The incidence is around nine cases per 100,000 person-years, which has decreased little during the past four decades [1]. Because of the young age and poor outcome, the economic and disease burden of aSAH are considerable, with a total economic burden in the United Kingdom of more than 500 million British pounds per year [2].

Cognitive impairment is a major factor contributing to poor functional outcome after aSAH [3,4]. Identification of aSAH patients with cognitive impairment is important for patient management (medical treatment, cognitive rehabilitation and social arrangements). Montreal Cognitive Assessment (MoCA) has been shown to be superior to the Mini-Mental State Examination (MMSE) in screening for cognitive domain deficit and correlating to excellent outcome in aSAH patients [5,6]. MoCA is highly relevant in aSAH and related to delayed cerebral infarction [7,8]. Therefore, MoCA is an ideal measure for clinical trial aiming to improve outcome after aSAH.

It is imperative to know the clinically important change in MoCA for aSAH patients that is considered meaningful and worthwhile for aSAH patients such that he or she would choose to receive the same treatment again [9]. Statistically significant difference might theoretically be too small to have practical implication to bench mark for more effective treatment [10]. The Minimum Clinically Important Difference (MID) of an instrument such as MoCA associated with change of health in general is important to understand, so as to give meaningful interpretation of assessment results and clinical trials [11].

With these in mind, we designed the current study. The aim of the current study was to determine the MoCA score change that was associated with change of health in general in an aSAH patient cohort.

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http://dx.doi.org/10.1016/j.jocn.2017.08.039
0967-5868/

2. Methods

2.1. Subjects

We carried out the current study in a regional neurosurgical center in Hong Kong over a 3-year period. The study received ethical approvals from the joint Chinese University of Hong Kong and Hospital Authority New Territories East Cluster (CUHK-NTEC) Clinical Ethics Committee and written informed consent was obtained from all participants or their next of kins. The study was conducted in accordance with the protocol, International Conference on Harmonization of technical requirements for registration of pharmaceuticals for human use (ICH) Good Clinical Practice (GCP), ethical principles that had their origin in the Declaration of Helsinki and all applicable local regulations. The investigator assured that the study is conducted in accordance with the provisions as stated in the ICH GCP guidelines and complied with prevailing local laws and customs.

Patient inclusion criteria were: 1) spontaneous subarachnoid hemorrhage with angiography-confirmed etiology of intracranial aneurysms; 2) age between 21 and 75 years; 3) a speaker of Chinese. Patient exclusion criteria were: a) a history of previous cerebrovascular or neurological disease other than unruptured intracranial aneurysm; or b) a history of neurosurgery prior to ictus; or c) known dementia or cognitive impairment prior to ictus; or d) unable to cooperate for assessments (not obeying command or significant dysphasia).

2.2. Assessors and time points of assessments

Patient assessments were carried out at 3 and 12 months after aSAH.

2.3. Delayed cerebral infarction (DCI) and delayed ischemic neurological deficit (DIND)

Delayed cerebral infarction (DCI) was diagnosed by interval computed tomography of brain, as compared to post-treatment computed tomography of brain, typically 12–24 h after clipping or coiling. Presence of delayed ischemic neurological deficit (DIND): was defined as (i) clinical vasospasm as manifested by a fall of two or more points on the modified Glasgow Coma Scale, and/or new focal neurological deficit lasting more than 2 h, and/or CT perfusion evidence of cerebral ischemia, and/or (ii) delayed cerebral infarction, unrelated to surgery/intervention, rebleed, hydrocephalus, infection, electrolyte or metabolic disturbance.

2.4. Instruments

2.4.1. Cognitive Outcome: Montreal Cognitive Assessment (MoCA) [12]

The MoCA is a one-page, 30-point test that is usually administered within 15 min and evaluates the following six subtests: visuospatial/executive functions, naming, attention, abstraction, recall, and orientation. One point is added for participants with less than 12 years of education. We has reported the application of the Hong Kong version of MoCA in SAH patients [5–7].

2.4.2. Disease-specific quality of life measure: Stroke-specific Quality of Life Scale (SS-QOL) Chinese Version [13]

The Chinese version has had been previously validated in a local SAH population [13]. It comprises comprised 49 items in 12 domains, with two subscores and a total score. Completion of the questionnaire takes took about 15 min.

2.4.3. Modified Rankin Scale (mRS)

mRS is a seven point scale measuring disability and death after stroke and aSAH.

2.4.4. Activity of daily living: Chinese Lawton Instrumental Activity of Daily Living (IADL) scale [14]

The Lawton IADL Scale is an appropriate instrument to assess independent living skills. Items that are assessed include ability to use the telephone, go shopping, prepare food, do the housekeeping, and do the laundry, mode of transportation, responsibility for own medications, and ability to handle finances.

2.4.5. Global rating of change [15,16]

At one year, the global rating of change (GRoC) scale is administered and is composed as the following questions:

Compared to last assessment at three months, how would you rate your health in general now?

5. Much better now
4. Somewhat better now than last assessment at three months
3. About the same
2. Somewhat worse now than last assessment at three months
1. Much worse now

2.5. Statistical analyses

Statistical analyses were performed with the assistance of IBM SPSS Statistics 23 (SPSS, Chicago, IL, USA). $P < 0.05$ was considered statistically significant. The Minimum Clinically Important Difference (MID), from the patient perspective, was defined as "the smallest difference in scores which patients perceive as beneficial and which would mandate a change in the patient management if feasible" [17–19]. The distribution-based and anchor-based approaches were both used to determine the MIDs of the MoCA score to overall improvement of health in general [20]. The distribution-based MID (MIDdist) estimate was determined using the Cohen effect-size benchmark [21]. We used results of previous work to determine that dividing the standard deviations (SD) of 3 month score by 5 would establish 0.2 SD estimates [22,23]. An effect size of 0.2, indicating small but important change, was used to establish the minimal threshold [22,23]. The anchor-based MID (MIDanch) estimate was calculated by considering patients whose GRoC scores are 4 or 2 as having experienced some change equivalent to CID. In patients experienced a worsening (GRoC score 2), the change in MoCA is reversed i.e. multiplied by −1. The mean was calculated for score difference.

Correlations of MoCA score change with other one-year outcomes were assessed with Spearman's rank order correlation coefficients. Multiple regression analysis was performed to determine the clinical factors associated with MoCA score change using the enter method, with the F probability of entry set at 0.05 and that of removal set at 0.10. Tolerance value (TV) is an indicator of the extent to which the variance of the specified independent variable is not explained by the other independent variables in the model and is calculated using the formula 1-R squared for each variable. A very small value (less than 0.10) indicates that the multiple correlation with other variables is high, suggesting the possibility of multicollinearity. The other value is the variable inflation factor (VIF), which is the converse of the tolerance value. Similarly, VIF values above 10 indicate multicollinearity. All analyses had TV larger than 0.10 and VIF less than 10, which indicated no multicollinearity. The independent variables considered included age, years of formal education, admission World Federation of Neurosurgical Societies (WFNS) grade, mode of treatment of the aneurysm, acute hydrocephalus requiring external ventricular drain insertion, delayed cerebral infarction, and chronic hydrocephalus requiring ventriculo-peritoneal shunt insertion.

Please cite this article in press as: Wong GKC et al. Minimum Clinically Important Difference of Montreal Cognitive Assessment in aneurysmal subarachnoid hemorrhage patients. J Clin Neurosci (2017), http://dx.doi.org/10.1016/j.jocn.2017.08.039