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Clinical Study

Clinically important difference of Stroke-Specific Quality of Life Scale for aneurysmal subarachnoid hemorrhage

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ABSTRACT

Health-related quality of life measurements, are commonly used to quantify burden of disease, to evaluate treatment method, and to facilitate benchmarking. The aim of the current study was to determine the Clinically Important Difference (CID) for a Chinese version of Stroke-specific Quality of Life (SS-QOL) in an aneurysmal subarachnoid hemorrhage (SAH) patient cohort. The study recruited SAH patients in a neurosurgical unit in Hong Kong. SAH patients who completed both 3-month and 1-year assessments were included in the analysis. The study received ethical approvals from the joint CUHK-NTEC Clinical Ethics Committee and written informed consent was obtained from all participants or their next of kins. Over a 2-year period, 65 eligible patients were included in the study. Employing the anchor-based approach with global rating of change, the CID estimate of SS-QOL total score was 4.7 (95% confidence interval [CI]: 2.5–5.3), the CID estimate for SSQOL physical subscore was 2.1 (95% CI: 0.3–2.4), and the CID estimate for SS-QOL psychosocial subscore change was 2.8 (95% CI: 1.8–3.7). In conclusion, our study defined the CID for SS-QOL applied to SAH patients and should be further validated in another SAH patient population.

1. Introduction

Subarachnoid hemorrhage (SAH) from a ruptured intracranial aneurysm accounts for approximately 5% of all strokes, occurs at a relatively young age, and carries a worse prognosis, despite improvement in medical care with time [1–3]. Moreover, quality of life is often decreased in SAH survivors, as confirmed in reported case series and our Asia–Pacific cohorts [4,5]. Health-related quality of life is perceived as a better measure of outcome, especially in SAH patients [6–8]. Health-related quality of life measurements, are commonly used to quantify burden of disease, to evaluate treatment method, and to facilitate benchmarking. For outcome research, a combination of generic (allows comparisons across different disease populations) and disease-specific (sensitive to disease-specific problems) measures is recommended [9].

Stroke-specific Quality of Life Scale (SS-QOL) is one of the commonest disease-specific quality of life measures initially developed and validated for ischemic stroke patients in 1999 [10], and subsequently, in mixed ischemic and hemorrhagic stroke patients in 2007 [11]. For SAH, Dutch version SS-QOL was first validated in 2010 using a Dutch version [3]. Our group had subsequently validated the Chinese Version of SS-QOL in a local SAH population [12]. Our analysis suggested a different dichotomization of physical (upper extremity, vision, work productivity, energy, family roles, mobility, self-care) and psychosocial (personality, thinking, mood, language, social role) subscores, which may reflect cultural differences. Moreover, cognitive impairment and psychiatric dysfunction are common in local and international studies [13–18]. A clinically important change refers to a difference that is considered meaningful and worthwhile by the patient such that he or she would choose to receive the same treatment again [19]. Statistically significant difference might theoretically be too small to have practical implication to benchmark for more effective treatment [20]. The clinically important difference (CID) of an instrument such as SS-QOL for SAH is important to understand, so as to give meaningful interpretation of assessment results and interpret clinical trials. Before the application of SS-QOL to evaluate

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disease burden and as tool for clinical trial to seek effective treatment, CID of SS-QOL in SAH population should be established.

With these in mind, we designed the current study. The aim of the current study was to determine the CID for a Chinese version of SS-QOL in a SAH patient cohort.

2. Materials and methods

2.1. Patients

We carried out the current study in a regional neurosurgical center in Hong Kong over a 2-year period [16]. The study received ethical approvals from the joint 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, ICH 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 SAH 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 aneurysmal SAH.

2.3. Delayed cerebral infarction and delayed ischemic neurological deficit

Delayed cerebral infarction (DCI) was diagnosed by interval computed tomography (CT) brain scan, as compared to post-treatment CT brain scan, 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) DCI, unrelated to surgery/intervention, rebleed, hydrocephalus, infection, electrolyte or metabolic disturbance.

2.4. Instruments

Disease-specific Quality of Life Measure: Stroke-specific Quality of Life Scale (SS-QOL) Chinese Version [12].

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

2.5. Generic Quality of Life Measure: Short Form-36 (SF-36)

SF-36 is a 36-item generic general health questionnaire that yields scores on eight health subscales relating to physical health and social and mental well-being. The Chinese version has previously been validated, and population-based norms are available [21,22]. The scores of the various scales are combined to form physical health and mental health component scores. The procedures for scoring and the computation of the scale and component scores of SF-36 have been applied previously using norms for the Hong Kong population to a multicenter trial managed by our group [5].

2.6. Activity of daily living: Chinese Lawton instrumental activity of daily living (IADL) scale [23]

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. The Chinese version was validated and used previously [23].

2.7. Global rating of change [24,25]

At 1 year, the global rating of change (GRoC) scale is administered and is composed as the following questions:

Compared to last assessment at 3 months, how would you rate your health in general now?

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

2.8. Statistical analyses

Statistical analyses are performed with the assistance of IBM SPSS Statistics 20 (SPSS, Chicago, IL, USA). Numerical variables were compared with unpaired t tests and categorical variables were compared with Chi Square tests. $P < 0.05$ was considered statistically significant.

The CID, 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" [26–28].

The distribution-based and anchor-based approaches were both used to determine the CIDs of the SS-QOL total scores and subscores [29]. The distribution-based CID (CIDdist) estimate was determined using the Cohen effect-size benchmark [30]. We used results of previous work [33,34] to determine that dividing the standard deviations (SD) of 3-month score and subscores by 5 would establish 0.2 SD estimates. AN effect size of 0.2, indicating small but important change, was used to establish the minimal threshold. The anchor-based CID (CIDanch) 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 Chinese version of SS-QOL is reversed i.e. multiplied by −1. The means were calculated for each subscores and total score differences.

Correlations of SSQOL scores with SF-36 and IADL were assessed with Spearman's rank order correlation coefficients.

3. Results

Sixty-five aneurysmal SAH patients completed both 3-month and 1-year assessments battery for inclusion into current study. 77% (50) were women aged 54 ± 11 years. World Federation of Neurosurgical Societies grade was I–II in 83% (54) of patients. 86% (56) had ruptured anterior circulation aneurysms, and 40% (26) had clipping. 17 (26%) had DIND and 16 (25%) had DCI. At