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Clinically meaningful differences in pain, disability and quality of life for chronic nonspecific neck pain — A reanalysis of 4 randomized controlled trials of cupping therapy

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Cupping;
Chronic neck pain;
Minimal clinically important difference;
Substantial clinical benefit

Summary

Objectives: The assessment of clinically meaningful differences in patients' self-reported outcomes has become increasingly important when interpreting the results of clinical studies. Although these assessments have become quite common there are hardly any data for nonspecific neck pain, especially in the context of complementary and alternative medicine. The aim of this analysis is the determination of minimal clinically important differences (MCID) and substantial clinical benefits (SCB) in patients with chronic nonspecific neck pain after cupping treatment.

Methods: The data set comprised a total of 200 patients with chronic nonspecific neck pain participating in clinical trials on cupping therapy. The MCID and SCB for pain intensity (VAS), neck disability index (NDI) and the subscale bodily pain (SF-36-BP) as well as physical component summary (SF-36-PCS) of the SF-36 were determined using receiver operating characteristic (ROC) curve analysis with an adapted assessment of change in health status (SF-36), i.e. a 5-point Likert scale ranging from ''much better'' to ''much worse'', as anchor. MCID derived from the ROC was the score to distinguish ''somewhat better'' from ''about the same'', and the SCB was the score to distinguish ''much better'' from ''somewhat better''.

Results: The calculated MCIDs were: −8 mm (−21%) for VAS, −3 points (−10.2%) for NDI, +10 points (+20.5%) for SF-36-BP and +2.6 points (+7.7%) for SF-36-PCS. The SCBs were: −26.5 mm (−66.8%) for VAS, −8.4 points (−29%) for NDI, +15.5 points (+43.1%) for SF-36-BP and +5.1 points (+12.9%) for SF-36-PCS. Accuracy of the estimations was good for MCID in general and for SCB regarding VAS and NDI.

Conclusions: The results support the assumption that patients' perceptions of treatment benefits measured by VAS in these trials might be comparable to others in conventional therapies.

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For NDI and SF-36-PCS the estimated differences were smaller than in previous reports indicating that context factors such as patient characteristics and specific treatment conditions might play an important role. Further studies on MCIDS and SCBs for chronic nonspecific neck pain seem warranted.

Introduction

Neck pain is the second most common condition for which complementary therapies are used.[1] In the US, more than half of patients suffering from neck pain use complementary therapies. An increasing number of clinical studies and systematic reviews investigated complementary and alternative therapies for the treatment of chronic neck pain.[2–6] Outcomes are commonly judged by statistical significance and only few studies compared the impact of observed changes in terms of clinically important differences (CID), which according to Jaeschke et al.[7] is ''the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side-effects and excessive cost, a change in patient's management''. Only when taking CID into account the true effectiveness of a treatment can be evaluated.

Although the assessment of clinically important differences is more common nowadays only a few recommendations regarding chronic nonspecific neck pain are available. Studies have so far only provided estimations for pain intensity on a numeric rating scale (NRS) and the neck disability index (NDI).[8] Clinically important differences were defined as changes on NRS between 1.5 and 2.5 points and on NDI between 3.5 and 7.5 points on a 0—50 scale.[9–11] No estimations have been found for pain intensity measured by the visual analogue scale (VAS) or for quality of life (SF-36).

Given the fact that clinical outcomes and judgement of symptom changes might depend on context variables,[12] the caring and empathic environment of complementary and alternative medicine (CAM) and the focus on coping and acceptance may play an important role in weighing therapy induced improvements, especially since they might not only influence symptoms but also psychosocial wellbeing.[13,14]

One of the many complementary treatment options frequently employed for chronic pain conditions is cupping, an ancient medical technique of European, Asian, and Middle Eastern cultures.[15,16] Cupping in general utilizes a glass cup to create suction over a painful area. With dry or fire cupping the cups are applied to the intact skin, in cupping massage the cup is drawn along major back muscles. In so-called wet or bloody cupping the skin is incised before the cups are applied. Cupping is mainly applied to increase the local circulation of blood and lymph and to relieve painful muscle tension.[17] In clinical practice cupping is regularly observed to bring about pain relief and to increase a patient's general feeling of wellbeing.[16,17]

We recently conducted 4 trials on cupping therapy for the treatment of chronic nonspecific neck pain.[18–21] Results of the study indicate that cupping might be an effective treatment improving symptoms, disability and quality of life. This study merged the data of these 4 trials in order to estimate the minimal clinically important difference (MCID) and the substantial benefit (SCB) in patients with chronic nonspecific neck pain after cupping therapy.

Methods

Study design

Data were pooled from 4 randomized waitlist controlled trials on cupping therapy for chronic nonspecific neck pain. Patients in the treatment group were treated with either a single wet cupping treatment[19] or five applications of dry cupping,[20] pulsating cupping[18] or cupping massage[21] whereas patients in the waiting list control groups received no treatment. Before treatment and 4 days after the last treatment patients filled in questionnaires regarding pain intensity (VAS), neck disability (NDI) and quality of life (SF-36).

All patients provided written informed consent, and the institutional review board approved all protocols, which were developed in accordance with the ethical standards of Good Clinical Practice and the Declaration of Helsinki. Further details about the studies can be found in the published study reports.[18–21]

Patient population

Patients were between 18 and 75 years of age, male or female with chronic nonspecific neck pain. All patients were included according to the study protocol if they suffered from neck pain for at least the previous 3 months at least 5 days a week. The average neck pain intensity had to be at least 40 mm on a 100 mm visual analogue scale (VAS). Exclusion criteria were neck pain due to specific causes (disc protrusion, radicular syndrome, whiplash, congenital deformity of the spine, spinal canal stenosis and neoplasm), inflammatory rheumatic disease, active oncologic disease, severe affective disorder, addiction and psychosis. Further criteria can be found in the published studies.[18–21]

MCID/SCB assessment

The visual analogue scale for pain intensity (VAS),[22] the neck disability index (NDI)[8] and the subscale bodily pain (SF-36-BP) as well as the physical component score (SF-36-PCS) of the SF-36 as a measure of health-related quality-of-life[23] were used to determine the minimal clinically important difference (MCID) and the substantial clinical benefit (SCB). The absolute and relative differences between pre and post treatment assessment scores were calculated for each outcome. Receiver operating characteristic (ROC) curve analysis[24] was utilized with an adapted assessment of change in health status (SF-36-CHS) as an anchor. The SF-36-CHS asks the patients how they would rate their health compared to before treatment. Answer categories ranged from