

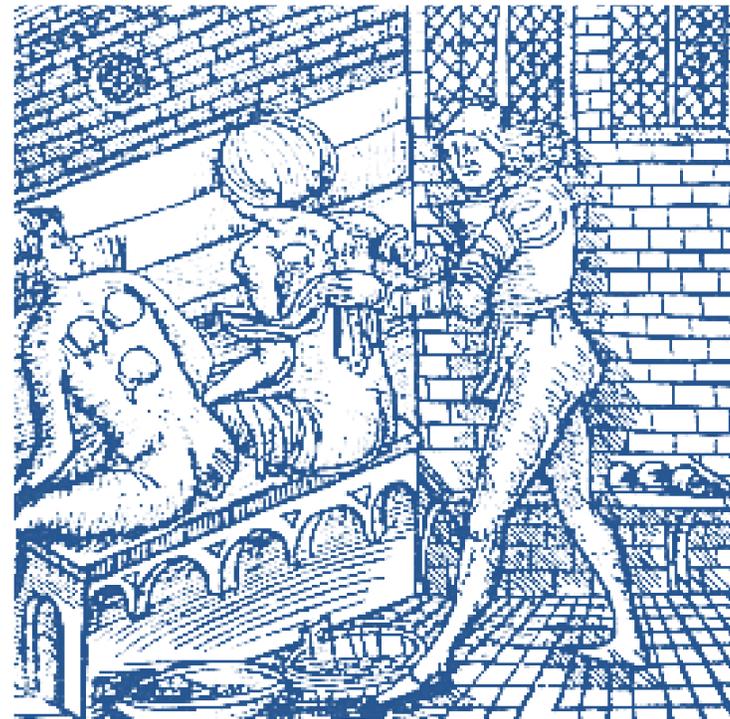
CLINICALLY MEANINGFUL DIFFERENCES IN PAIN AND DISABILITY AFTER CUPPING TREATMENT FOR CHRONIC NECK PAIN – A REANALYSIS OF 4 RANDOMIZED CONTROLLED TRIALS

Lauche R, Dobos GJ, Cramer H

INTRODUCTION

The assessment of clinically meaningful differences in patients self-reported outcomes has become more important when interpreting the results of clinical studies. In conventional medicine these assessments are common however there is still doubt whether these results might apply to trials in complementary medicine.

The aim of this analysis is the determination of minimal clinical important differences (MCID) and substantial clinical benefits (SCB) in patients with chronic non-specific neck pain after cupping treatment. The MCID and SCB for pain intensity (VAS) and neck disability index (NDI) were estimated using common anchor-based method.



METHODS

The data set comprises a total of 200 patients participating in clinical trials on cupping therapy. The MCID and SCB for VAS and NDI were determined using receiver operating characteristic (ROC) curve analysis with an adapted assessment of change in health status (SF36) as an anchor. This item asks the patients how they would rate their health in general now, compared to before treatment. Answer categories ranged from "much better" to "much worse", see on the right. A ROC curve was constructed for each outcome. MCID derived from the ROC was the score with equal sensitivity and specificity to distinguish "somewhat better" from "about the same". The SCB was the score to distinguish "much better" from "somewhat better".

RESULTS

| Outcome | Anchor status (GHO) | No. | Pre treatment mean ± SD | Post treatment mean ± SD | Change mean ± SD | Change in % mean ± SD | MCID (Sens., 1-Spec.) | Area under the ROC (95% CI) | p | SCB (Sens., 1-Spec.) | Area under the ROC (95% CI) | p |
|--------------------------|---------------------|-----|-------------------------|--------------------------|------------------|-----------------------|-----------------------|-----------------------------|--------|----------------------|-----------------------------|--------|
| Pain VAS | "much better" | 22 | 52.3 ± 24.4 | 11.8 ± 15.3 | -40.5 ± 21.8 | -78.3 ± 20.0 | | | | -26.5 (0.68, 0.33) | 0.79 (0.67-0.92) | <0.001 |
| | "somewhat better" | 41 | 45.0 ± 16.8 | 26.3 ± 17.1 | -18.7 ± 13.5 | -45.4 ± 25.9 | -8.0 (0.78, 0.22) | 0.88 (0.81-0.94) | <0.001 | -66.8 (0.77, 0.23) | 0.85 (0.75-0.95) | <0.001 |
| | "about the same" | 74 | 41.7 ± 16.6 | 42.5 ± 16.5 | +0.7 ± 14.0 | +6.1 ± 34.7 | -21.3 (0.80, 0.19) | 0.89 (0.83-0.96) | <0.001 | | | |
| Neck Disability Index | "much better" | 21 | 27.6 ± 12.9 | 16.4 ± 12.1 | -11.2 ± 10.1 | -41.0 ± 35.0 | | | | -8.44 (0.57, 0.42) | 0.65 (0.49-0.80) | 0.06 |
| | "somewhat better" | 41 | 27.7 ± 10.1 | 21.6 ± 9.7 | -6.2 ± 7.3 | -21.8 ± 25.0 | -3.0 (0.71, 0.27) | 0.73 (0.63-0.83) | <0.001 | -29.0 (0.57, 0.44) | 0.66 (0.51-0.82) | 0.04 |
| | "about the same" | 73 | 28.8 ± 10.1 | 27.8 ± 9.5 | -0.8 ± 5.7 | -0.1 ± 22.2 | -9.8 (0.71, 0.30) | 0.75 (0.65-0.85) | <0.001 | | | |
| SF-36 Bodily Pain | "much better" | 22 | 41.1 ± 16.3 | 66.1 ± 22.6 | +25.0 ± 21.9 | +79.3 ± 87.4 | | | | +15.5 (0.50, 0.49) | 0.62 (0.46-0.78) | 0.13 |
| | "somewhat better" | 41 | 42.1 ± 12.3 | 57.7 ± 15.0 | +15.6 ± 14.3 | +45.9 ± 54.5 | +10.0 (0.72, 0.30) | 0.76 (0.67-0.86) | <0.001 | +43.1 (0.55, 0.44) | 0.61 (0.46-0.77) | 0.15 |
| | "about the same" | 73 | 41.9 ± 11.4 | 44.7 ± 12.2 | +2.8 ± 11.3 | +11.0 ± 33.6 | +20.5 (0.69, 0.31) | 0.73 (0.63-0.83) | <0.001 | | | |
| SF-36 Physical Component | "much better" | 22 | 40.0 ± 9.9 | 47.3 ± 7.4 | +7.4 ± 7.1 | +25.2 ± 37.8 | | | | +5.1 (0.55, 0.46) | 0.61 (0.46-0.76) | 0.17 |
| | "somewhat better" | 40 | 41.0 ± 7.2 | 45.6 ± 7.6 | +4.4 ± 5.7 | +11.5 ± 14.3 | +2.6 (0.62, 0.39) | 0.68 (0.57-0.78) | 0.003 | +12.9 (0.55, 0.46) | 0.60 (0.45-0.75) | 0.21 |
| | "about the same" | 70 | 40.7 ± 6.7 | 41.7 ± 7.0 | +1.1 ± 5.8 | +4.0 ± 15.6 | +7.7 (0.62, 0.36) | 0.67 (0.56-0.77) | 0.004 | | | |

Table: Pre and post treatment scores, absolute and percentage changes as well as estimated minimal clinical important differences (MCID) and substantial clinical benefit (SCB) for pain intensity (VAS), neck disability index, SF-36 subscale Bodily Pain and the Physical Component Score. MCID and SCB were anchored using the General Health Outcome (GHO) item of the SF-36.

CONCLUSIONS

MCID and SCB for VAS in cupping trials are comparable to conventional trials although absolute and relative changes were slightly different. For NDI absolute and relative changes are smaller than in other trials, which might be due to the fact that scores were low in general. Altogether results support the assumption that patients' perceptions of treatment benefits in complementary trials are largely comparable to those in trials using conventional therapy.

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Corresponding author: Romy Lauche, r.lauche@kliniken-essen-mitte.de

