Was the PEDro rating accurate?

The systematic review of Bleakley and colleagues (2008) on some effective conservative strategies added to controlled mobilisation with external support after acute ankle sprain provides a most welcome overview of the treatment options for acute ankle sprain. In fact the results reflect our experience in sports medicine.

As the authors of one of the cited trials we feel that some details regarding the studies on the application of topical comfrey preparations warrant a comment. Whereas Koll et al (2004) in fact used comfrey root extract, our study was not performed with comfrey roots, but a topical preparation containing an extract from the flowering herb of a special comfrey cultivar devoid of pyrrolizidine alkaloids (Kucera et al 2004). Against the background of muscle pain and broken skin (abrasions) that are regularly encountered in sports injuries, such as ankle sprains, we have recently demonstrated that comfrey herb cream possesses additional benefits for application in sports injuries. Comfrey herb extract has distinct muscle pain relieving (Kucera et al 2005) and wound healing properties (Barna et al 2007), proven both statistically significant and clinically relevant in randomised double-blind trials.

The PEDro score attributed to our study also requires a small correction: even though this was not explicitly mentioned in the publication, the group allocation was in fact concealed, and assessor blinding was ensured throughout the trial period. Both conditions must usually be met in clinical double-blind trials relevant for drug registration, and both are part of the ICH guidelines for clinical testing. They are therefore usually not mentioned specifically in trial protocols. In addition, group similarity at baseline was denied in Table 1 of the review (Bleakley et al 2008), which does not reflect the study results. In fact, the primary and secondary parameters were not statistically different between groups at baseline.

In conclusion, we think the PEDro score should total 10 points, not 7 as indicated in Table 1.

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References

PEDro scale can only rate what papers report

Complete reporting of randomised controlled trials (RCT) in peer reviewed journals is important for physiotherapists who use trials to inform clinical practice.

In their published report, Kucera et al (2004) use the term ‘double blind’ to describe the study design. It is not possible to determine who was blinded to group allocation from this ambiguous terminology. The ambiguity of the term ‘double blind’ is illustrated by a survey of 91 physicians and 25 textbooks which provided 17 and 9 definitions of the term ‘double blind’ respectively (Devereaux et al 2001).

As described in the Editorial for the Vol 54 No 3 issue of Australian Journal of Physiotherapy (Vaarbakken et al 2008), explicit reporting of RCTs is encouraged by the Consolidated Standards of Reporting Trials (CONSORT) Group (http://www.consort-statement.org/). Both the original CONSORT Statement (Altman et al 2001) and the extension for herbal interventions (Gagnier et al 2006) recommend that trial reports provide details on concealed allocation and blinding of participants, therapists, and assessors.

The PEDro ratings challenged by Kucera and Barna in their correspondence were generated by the authors of the systematic review (Bleakley et al 2008). However, like the CONSORT Statement, the Physiotherapy Evidence Database (PEDro) scale requires authors to describe explicitly concealment and exactly who was blinded when they report trials (Maher et al 2003).

For randomised controlled trials indexed on PEDro we have provided a mechanism to dispute ratings and had the trial by Kucera et al (2004) been indexed on PEDro the authors could have requested that the rating be reviewed. However the trial is not eligible for indexing on PEDro because it does not evaluate a physiotherapy intervention. Users of the PEDro database are also invited to contact PEDro (PEDro@george.org.au) if they disagree with the rating of a particular trial. We assess all disputed ratings, and amend the PEDro ratings if indicated. However, ratings are always based on the original report, not on additional information provided by authors after publication. The dispute mechanism is one strategy that ensures the quality of ratings indexed on PEDro.

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References