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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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

I would like to thank Kucera and Barna for their correspondence regarding our systematic review (Bleakley et al 2008). They provide clarification on aspects of the treatment intervention used in their high quality randomised controlled trial (RCT) (Kucera 2004), and challenge the PEDro scores that we attributed to the following items: allocation concealment, baseline comparability, and blinding.

Whilst it is possible to implement allocation concealment in every RCT (Schulz et al 1995), without detailed reporting we cannot assume that it is carried out successfully. Although Kucera et al (2004) state that subjects were provided with a randomisation number, there were no further details on the generation and implementation of the random allocation sequence (eg opaque sealed envelopes, or ‘third party’ assignment). Therefore, from the manuscript alone, we could not rule out the possibility of selection bias.

The fourth item on the PEDro scale assesses baseline comparability, and has the lowest inter-rater reliability (Maher et al 2003). Raters score this item based on the between-group comparability, using key prognostic indicators (in this case for ankle sprain recovery) measured prior to intervention. As a minimum, studies must include at least one measure of injury severity and one (different) key outcome. I appreciate that the rater’s definition of ‘comparable’ may be open to subjectivity, and indeed may relate to his/her experience of the injury or condition (Maher et al 2003). Kucera’s study showed clearly that there were no baseline differences in pain and function between the two intervention groups, however we did not feel that there was enough additional information on injury severity and prognostics.

The authors should be commended on the measures they employed to potentially certify participant blinding (ie by ensuring that the intervention medications used in their study were identical in appearance and composition). However, aside from this, few other details were provided in this important area. Describing trials as ‘single blind’, ‘double blind’, or ‘triple blind’ can mean different things to different people, and when they are used without accompanying clarification readers should remain sceptical about the effect on bias reduction (Schulz et al 2002). Kucera and colleagues (2004) described their RCT as ‘double blind’; however, from the manuscript alone, it is difficult to determine if this refers to participants, administrators, outcome assessors, or indeed the data analysts.

Assessing the methodological quality of RCTs is an important and challenging process when conducting a systematic review. We opted to use the PEDro scoring scale based on its acceptable inter-rater reliability (Maher et al 2003), and the discriminative and face validity of its 11 items. In conjunction with the CONSORT guidelines for RCT reporting (Begg et al 1996), the PEDro scale requires that studies provide adequate detail on the most important aspects of study methodology, with scoring based on standardised written criteria. In their correspondence, Kucera and Barna have clarified key details of the methods used in their interesting RCT (Kucera et al 2004), which further highlight the quality of the research. Notwithstanding this, the PEDro scores we attribute must be based on the original manuscript, and cannot be changed in light of this additional information.

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References

A case of near fatal laryngospasm

A 46 year old man was admitted to intensive care with a diagnosis of encephalitis (Glasgow coma scale 12/15) and bronchopneumonia. He had a past history of obesity (BMI 34) and sleep apnoea. He was reviewed for mechanical ventilation but it was requested that the physiotherapy staff continue to manage the chest, including insertion of a nasopharyngeal or Guedels airway if necessary.

The patient then proceeded to have intermittent periods of desaturation to SpO2 89–92%. A junior physiotherapist was paged urgently. On examination, the patient was slumped in supine with nasal prongs in situ (2 l/min), respiratory rate 15 breaths/min, SpO2 94%, and with widespread audible transmitted sounds. He did not cough on command.

It was decided to insert a nasopharyngeal airway and suction the patient. A size 7 Portex® was selected and size checked due to the patient’s nares and tragus. Due to the patient’s body habitus and difficulty in finding a wardsperson, the procedure was completed in a slumped supine position. The airway was lubricated and inserted without difficulty. Suction through the nasopharyngeal airway was applied and a large amount of purulent secretions aspirated. The patient’s SpO2 improved initially to 96–97% and the chest was clearer on auscultation. However, after three minutes, the patient developed a tracheal tug, SpO2 fell to 85%, and respiratory rate rose to 56 breaths/min. Emergency assistance was summoned. The patient continued to deteriorate, and by the time the intubation trolley arrived SpO2 had fallen to 39% and the patient was deep cyanosed.

The patient was given bag and mask ventilation, paralysed with suxamethonium chloride 1.0 mg/kg intravenously, intubated, and ventilated on synchronised intermittent mandatory ventilation (volume cycled). On intubation the vocal cords were noted to be extremely swollen and oedematous and he was noted to have pulmonary oedema.

So what occurred with this patient? It was hypothesised that the extremely swollen vocal cords and subglottic oedema noted on intubation were due to laryngospasm. This patient had not been intubated previously and had been suctioned only once. Therefore, there was no other reason for the swollen cords.

As the patient exhibited pulmonary oedema on intubation this also supported the diagnosis of laryngospasm, as negative pressure involved in obstruction of the airway can precipitate pulmonary oedema. It was fortunate that this patient was in intensive care at the time of the incident. Any further delay in intubation may have proven fatal.

Why did laryngospasm occur? Laryngospasm is most commonly precipitated by direct airway stimulation (airway manipulation, blood or secretions in the pharynx) (Visvanathan et al 2005). Therefore the insertion of a nasopharyngeal airway or suction catheter may have initiated the laryngospasm.

In this patient, the incorrect sizing of the nasopharyngeal airway may have increased the amount of direct airway stimulation. When inserted correctly, the nasopharyngeal airway should lie approximately 10 mm above the epiglottis. If the airway is too short it will fail to separate the soft palate from the posterior wall of pharynx. If the airway is too long it can pass into the larynx or into the vallecula (a blind-ended pouch at the root of the tongue (Stoneham 1993), or it can cause airway obstruction if it is pressed against soft tissues.

Selection of the correct size of nasopharyngeal airway is controversial (Roberts et al 2005). Current methods taught include matching the nasopharyngeal airway length with the distance between the nose and ear (nares-tragus); correlating the size of the nostril with a patient’s little finger width and matching a patient’s height with the length of the nasopharyngeal airway. The former two methods were used with this patient. However, no correlation has been found between nares-epiglottis and nares-tragus distance in adults (Stoneham 1993) and measurements of little finger width frequently over estimate nasopharyngeal airway size (Roberts and Porter 2003). Use of these methods may have increased the likelihood of direct airway stimulation.

A number of other factors may have also been responsible for an inaccurate estimation of the nasopharyngeal airway size:

- A slumped supine position may have shortened the nares-epiglottis distance.
- Patients who are obese with a ‘bull neck’ are recognised as having a short ‘chin to larynx distance’ (Frerk et al 1996). Anaesthetic guidelines for determining airway anatomy recommend estimating ‘thyromental distance’ ie the space between the thyroid cartilage and floor of mouth (Magboul 2005). If this distance is less than two fingers it indicates the patient has an unusually short distance between the mouth and larynx.
- Patients with established obstructive sleep apnoea are at higher risk of laryngospasm and pulmonary oedema on insertion of definitive airways ie naso/endo tracheal tubes (Lorch and Sahn 2008).

So what should be done differently? Nasopharyngeal and oropharyngeal airways are usually inserted temporarily as a mechanism of halting progressive respiratory deterioration and avoiding intubation and the subsequent complications; but they can potentiate serious problems. It is important that clinicians are aware of factors that determine the appropriate sizing of an airway, which patients are more likely to constitute a difficult airway, and the potential complications related to airway insertion and suctioning. This should be incorporated into current undergraduate teaching.

The length, not the diameter of a nasopharyngeal airway is the most important measurement when choosing the correct airway. The correct estimation of nares-epiglottis distance is best based upon a patient’s height, rather than nares-tragus or little finger width measurements (Roberts and Porter 2003, Stoneham 1993). Additional factors may impact on this estimation (eg patient position, airway anatomy). In this case study, the patient’s position could have been improved prior to suction, but was difficult at the time.

Laryngospasm is a recognised risk of airway suctioning due to direct airway stimulation. The risk may be decreased by selecting an accurate nasopharyngeal airway size and
where possible, inserting suction catheters until a cough is stimulated and not through or beyond the larynx.

It is important for clinicians to be aware of the signs and symptoms of laryngospasm and the management required. The type of laryngospasm that occurred in this incident involved subglottic oedema. Laryngospasm of this type is more dangerous and is different to the usual post extubation stridor we often observe in intensive care. Subglottic oedema is quieter and the airway is obstructed more quickly. Treatment for this type of laryngospasm requires immediate paralysis, bag mask ventilation, and intubation.

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**References**


