RATING OF A RESEARCH PAPER

'RANDOMISED CONTROLLED TRIAL TO COMPARE SURGICAL STABILISATION OF THE LUMBAR SPINE WITH AN INTENSIVE REHABILITATION PROGRAMME FOR PATIENTS WITH CHRONIC LOW BACK PAIN: THE MRC SPINE STABILISATION TRIAL'

By: Neti Juniarti, S.Kp., M.Kes., MNurs

Faculty of Nursing

Universitas Padjadjaran

2008

RATING OF A RESEARCH PAPER

'RANDOMISED CONTROLLED TRIAL TO COMPARE SURGICAL STABILISATION OF THE LUMBAR SPINE WITH AN INTENSIVE REHABILITATION PROGRAMME FOR PATIENTS WITH CHRONIC LOW BACK PAIN: THE MRC SPINE STABILISATION TRIAL'

By: Neti Juniarti, S.Kp., M.Kes., MNurs

Faculty of Nursing Universitas Padjadjaran

2008

Acknowledge by,

Dean

Hj. Helwiyah Ropi, S.Kp., MCPN

RATING OF A RESEARCH PAPER

'RANDOMISED CONTROLLED TRIAL TO COMPARE SURGICAL STABILISATION OF THE LUMBAR SPINE WITH AN INTENSIVE REHABILITATION PROGRAMME FOR PATIENTS WITH CHRONIC LOW BACK PAIN: THE MRC SPINE STABILISATION TRIAL'

Introduction

The following essay seeks to critically analysis a research paper by using a rating scale. The paper I have selected is "Randomized controlled trial to compare surgical stabilisation of the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial" by Fairbank et al. (2005). The rating scale I intend to apply to the paper is The PEDro Rating Scale from the physiotherapy department at the University of Sydney. I choose this rating scale because PEDro Rating Scale is a tool that especially made to make critical appraisal of an article that use randomised controlled trials method. It gives details criteria with explanation for each criterion so that it is easier to use and apply to rating RCTs.

The essay has been broken into two distinct parts. Part one discusses the paper appraisal using criteria from PEDro scale. The second part discusses whether the rating scale has assisted with appraisal of the paper.

It is important to distinguish that for the purpose of this essay, the focus of discussion is critical analysis of the paper using PEDro scale from Physiotherapy Evidence Database.

The Paper Appraisal Using PEDro Scale

This paper will appraise by using PEDro rating scale consists of eleven criteria with explanation for each criteria. The following is answers on the questions on PEDro rating scale.

PEDro Scale

ITEMS	ANSWER (YES/NO)
1. Eligibility criteria were specified	Yes
This criterion influences external validity, but not the internal or statistical validity of the trial. This criterion is satisfied because the report describes the source of subjects which fom 15 secondary care orthopedc and rehabilitation centers across the United Kingdom.	
2. Subject were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received).	Yes
Random allocation ensures that (within constraints provided by chance) treatment and control groups are comparable. The report states that randomization was generated centrally by computer program, with minimization for various potential confounding factors.	
3. Allocation was concealed.	No
"Concealment" refers to whether the person who determined if subjects were eligible for inclusion in the trial was aware, at the time he or she made this decision, which group the next subject would be allocated to. The paper describe the eligibility criteria which using the uncertainty of outcome principle to define our entry criteria, but it does not mention about allocation process. Potentially, if allocation is not concealed, the decision about whether or not to include a person in a trial could be influenced by knowledge of whether the subject was to receive treatment or not. This could produce systematic biases in otherwise random allocation.	
4. The groups were similar at baseline regarding the most important prognostic indicators.	No
This criterion may provide an indication of potential bias arising by chance with random allocation. Gross discrepancies between groups may be indicative of inadequate randomization procedure.	

This criterion is not satisfied because from two key outcome, only Oswestry disability index that has similar baseline while shuttle walking test in meters did not have similar baseline and big difference in standard deviation.	
5. There was blinding of all subjects.	No
Blinding of subjects involves ensuring that subjects were unable to discriminate whether they had or had not received the treatment. The paper does not state that there was blinding of all subjects, therefore the reader can not be satisfied that the apparent effect (or lack of effect) of treatment was not due to placebo effects or Hawthorne effects (an experimental artifact in which subjects responses are distorted by how they expect the experimenters want them to respond).	
6. There was blinding of all therapists who administered the therapy.	No
The paper states that the researchers were not able to blind the trial research therapists to patient allocation after the baseline assessment, therefore the reader can not be satisfied that the apparent effect (or lack of effect) of treatment was not due to the therapists' enthusiasm for the treatment or control condition.	
7. There was blinding of all assessors who measured at least one key outcome.	No
The paper does not state that there was blinding of all assessors, therefore the reader can not be satisfied that the apparent effect (or lack of effect) of treatment was not due to the assessors' biases impinging on their measures of outcomes.	
8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups.	No
This criterion is not satisfied because the report explicitly states that a key outcome have been measured in less than 85% of subjects at one of those points in time which is only 79% patients receive surgery treatment while 87% patients receive rehabilitation treatment. This condition would increase potential bias because the magnitude of the potential bias increases with the proportion of subjects not followed up.	
9. All subjects for whom outcome measures were available received the	No

treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”.	
This criterion is not satisfied because the report explicitly states that 21% of surgery group and 13% of rehabilitation group did not received treatment or control conditions as allocated. Moreover, forty eight (28%) patients randomized to rehabilitation had surgery by two years and seven (4%) patients randomized to surgery had rehabilitation instead of surgery.	
10. The results of between-group statistical comparisons are reported for at least one key outcome.	Yes
The comparison in this paper is in the form of an estimate differences from available cases and from multiple imputation analyses with p-value and 95% confidence interval.	
11. The study provides both point measures and measures of variability for at least one key outcome.	Yes
The treatment effect in this paper described as a difference in outcomes in each of groups between 0 – 24 months. Measures of variability include standard deviations, 95% confidence intervals, and p-value.	

Discussion of whether the PEDro Rating Scale has Assisted with Appraisal of the Paper

The PEDro rating scale has assisted with appraisal of the paper. This rating scale is easy to use and provide clear explanation and example how to rate certain criteria. However, i

t does not give clear criteria about how to make conclusion whether the paper is good evidence or not after rated all criteria. Therefore it makes confusion for user to make decision about the paper. For instance in above appraisal, there are four items with answer “yes”, and seven items with answer “no”. The confusion might be happen because the purpose of the PEDro scale is to help the users to identify rapidly which of the research paper are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11), and

could have external validity or “generalisability” or “applicability” of the trial (criterion 1) (PEDro Scale, 1999).

The Physiotherapy Evidence Database website said that the PEDro scale should not be used as a measure of the “validity” of a study’s conclusions. In particular, the website caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. In the end it is up to user to decide whether to use the evidence from the article or not based on previous knowledge, risk and benefit of the evidence to apply, and patients preferences.

Conclusion

Over all, the paper “Randomized controlled trial to compare surgical stabilisation of the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial” by Fairbank et al. (2005) is a good paper which showed that no clear evidence that primary spinal fusion surgery is better than intensive rehabilitation. The research has external validity or “generalsability” or “applicability” of the trial because it was randomized all subjects and also have sufficient statistical information to make the result interpretable. However, the evidence from this paper seems does not strong enough to apply because this paper does not give the exact type of surgery and the intensive rehabilitation method apply to patients. More over, the research paper are not likely to be internally valid because groups were not similar at baseline particularly in shuttle walking test, there were not blinding of all subjects, all therapists, and assessors; there are a key outcome have been measured in less than 85% of subjects at one of those points in time which is only 79% patients receive surgery treatment while 87% patients receive rehabilitation treatment and some of participant in rehabilitation group also use surgical method so that it will be difficult to compare the outcomes from each treatment group.

Reference List

Fairbank, J, Frost H, Wilson-MacDonald J, Ly-Mee Y, Barker K, Collins R. 2005. Randomized controlled trial to compare surgical stabilisation of the lumbar spine

with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial. *British Medical Journal 330 (7502):1233-1240*. Available from http://www.bmj.com/cgi/content/full/330/7502/1233.

Physiotherapy Evidence Database. 1999. *PEDro Scale*. Available from www.fhs.usyd.edu.au/scale_item.html