Study Quality Form

Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.
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Comparative Effectiveness of Treatments for Chronic Venous Ulcers
Downs and Black Checklist for Measuring Study Quality

REPORTING

1. Is the hypothesis/aim/objective of the study clearly described?

   Yes
   No
   Clear Response

2. Are the main outcomes to be measured clearly described in the Introduction or Methods section?

   If the main outcomes are first mentioned in the Results section, the question should be answered 'no.'

   Yes
   No
   Clear Response

3. Are the characteristics of the subjects included in the study clearly described?

   In trials, inclusion and/or exclusion criteria should be given.

   Yes
   No
   Clear Response

4. Are the interventions of interest clearly described?

   Interventions and controls (where relevant) that are to be compared should be clearly described.

   Yes
   No
   Clear Response

5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?

   A list of principal confounders is provided.

   Yes
   No
   Clear Response

6. Are the main findings of the study clearly described?

   Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).

   Yes
   No
   Clear Response

7. Does the study provide estimates of the random variability in the data for the main outcomes?

   In non-normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered 'yes.'

   Yes
   No
   Clear Response

8. Have all important adverse events that may be a consequence of the intervention been reported?

This should be answered 'yes' if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

- Yes
- No

Clear Response

9. Have the characteristics of subjects lost to follow-up been described?

This should be answered 'yes' where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered 'no' where a study does not report the number of patients lost to follow-up.

- Yes
- No

Clear Response

10. Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?

- Yes
- No

Clear Response

EXTERNAL VALIDITY

11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?

The study must identify the source population for patients and describe how the patients were selected. Subjects would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the subjects are derived, the question should be answered 'unable to determine.'

- Yes
- No
- Unable to determine

Clear Response

12. Were those subjects who were prepared to participate representative of the entire population from which they were recruited?

The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

- Yes
- No
- Unable to determine

Clear Response

13. Were the staff, places, and facilities where the subjects were treated (or where the intervention was implemented) representative of the treatment the majority of subjects receive?

For the question to be answered 'yes' the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered 'no' if, for example, the intervention was undertaken in a specialist center unrepresentative of the hospitals most of the source population would attend.

- Yes
- No
- Unable to determine

Clear Response

INTERNAL VALIDITY-BIAS

14. Was an attempt made to blind study subjects to the intervention they have received?

For studies where the subjects would have no way of knowing which intervention they received, this should be answered 'yes.'

- Yes
- No
- Unable to determine

Clear Response

15. Was an attempt made to blind those measuring the main outcomes of the intervention?

Yes
No
Unable to determine
Clear Response

16. If any of the results of the study were based on "data dredging", was this made clear?

Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer 'yes.'

Yes
No
Unable to determine
Clear Response

17. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients?

Where follow-up was the same for all study participants the answer should be 'yes.' If different lengths of follow-up were adjusted, for example, by survival analysis, the answer should be 'yes.' Studies where differences in follow-up are ignored should be answered 'no.'

Yes
No
Unable to determine
Clear Response

18. Were the statistical tests used to assess the main outcomes appropriate?

The statistical techniques used must be appropriate to the data. For example nonparametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered 'yes.' If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered 'yes.'

Yes
No
Unable to determine
Clear Response

19. Was compliance with the intervention/s reliable?

Where there was non-compliance with the allocated treatment or where there was contamination of one group, the question should be answered 'no.' For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered 'yes.'

Yes
No
Unable to determine
Clear Response

20. Were the main outcome measures used accurate (valid and reliable)?

For studies where the outcome measures are clearly described, the question should be answered 'yes.' For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered 'yes.'

Yes
No
Unable to determine
Clear Response

INTERNAL VALIDITY- CONFOUNDING AND SELECTION BIAS

21. Were the subjects in different intervention groups (trials and cohort studies) recruited from the same population?

For example, subjects for all comparison groups should be selected from the same school. The question should be answered unable to determine for cohort where there is no information concerning the source of subjects included in the study.

Yes
No
Unable to determine
Clear Response

22. Were study subjects in different intervention groups (trials and cohort studies) recruited over the same period of time?

For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

Yes

NA
Unable to determine
Clear Response

23. Were study subjects randomized to intervention groups?

Studies which state that subjects were randomized should be answered yes except where method of randomization would not ensure random allocation. For example alternate allocation would score no because it is predictable.

Yes
No
Unable to determine
Clear Response

24. Was the randomized intervention assignment concealed from both subjects and those conducting the study until recruitment was complete and irrevocable?

All non-randomized studies should be answered 'no.' If assignment was concealed from patients but not from staff, it should be answered 'no.'

Yes
No
Unable to determine
Clear Response

25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?

This question should be answered 'no' for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomized studies, if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered 'no.'

Yes
No
Unable to determine
Clear Response

26. Were losses of subjects to follow-up taken into account?

If the numbers of subjects lost to follow-up are not reported, the question should be answered 'unable to determine.' If the proportion lost to follow-up was too small to affect the main findings, the question should be answered 'yes.'

Yes
No
Unable to determine
Clear Response

POWER

27. Did they report a power calculation?

Yes
No
Clear Response

28. Was the study supported by industry?

Yes (e.g. supported financially by industry, treatment provided by industry, co-author involved with industry)
No (sources of funding provided by non-industry sponsors such as government, etc.)
Not reported
Clear Response

29. Were > 30% of the enrolled patients not analyzed? (e.g. withdrawals, losses to followup)

Yes
No
Not reported
Clear Response

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