

Study Quality

Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.

Rethnam U, Yesupalan RS, Sinha A.

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Troponin EPC Downs and Black Checklist for Measuring Study Quality

REPORTING

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

- Yes
 No

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

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

4. Are the tests of interest clearly described?

Tests results (where relevant) that are to be compared should be clearly described.

- Yes
 No

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

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

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

8. 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

9. 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

10. 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

11. 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

12. Were the staff, places, and facilities where the subjects were treated/tested representative of the testing the majority of subjects receive?

For the question to be answered 'yes' the study should demonstrate that the testing was representative of that in use in the source population. The question should be answered 'no' if, for example, the testing 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

13. Was an attempt made to blind those measuring the main outcomes of the testing strategy?

- Yes
 No
 Unable to determine
 Not feasible
Clear Response

14. 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

15. 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
 Not applicable (i.e. no followup for this type of study)
Clear Response

16. 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

17. 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

18. Were the subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control 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

19. Were study subjects in different testing groups groups (trials and cohort studies) or were the cases and controls (case-control 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
- No
- Unable to determine

Clear Response

20. 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" for adjusted for all major confounders (demographic and common comorbidities) and "Yes, some" if some, not all major confounders were adjusted for.

- Yes (adjusted for all confounders)
- Yes, some (adjusted for some confounders)
- No (did not adjust for confounders)
- Unable to determine
- Not applicable (i.e. diagnostic test paper)

Clear Response

21. 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
- Not applicable (i.e. no followup period such as KO1)

Clear Response

POWER

22. Did they report a power calculation?

- Yes
- No

Clear Response

23. 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

24. What was the overall quality of the study?

- **Good** (low risk of bias). These studies had the least bias, and the results were considered valid. These studies adhered to the commonly held concepts of high quality, including the following: a clear description of the population, setting, interventions, and comparison groups; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; a low dropout rate; and clear reporting of dropouts.
- **Fair**. These studies were susceptible to some bias, but not enough to invalidate the results. They did not meet all the criteria required for a rating of good quality because they had some deficiencies, but no flaw was likely to cause major bias. The study may have been missing information, making it difficult to assess limitations and potential problems.
- **Poor** (high risk of bias). These studies had significant flaws that might have invalidated the results. They had serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.

- Good
- Fair
- Poor

Clear Response

25. For Questions 1-9, how many were answered "no"?

26. Is the number in question 25 greater than or equal to 5?

- Yes (sum is 5 or more)
 No (sum is 4 or less)
Clear Response

27. For questions 10-12, how many questions were answered "no"?

28. Is the number in question 27 greater than or equal to 2?

- Yes (sum is 2 or more)
 No (sum is 1 or 0)
Clear Response

29. For questions 13-22, how many were answered "no"?

30. Is the number in question 29 greater than or equal to 5?

- Yes (sum is 5 or more)
 No (sum is 4 or less)
Clear Response

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