

Peer reviewer checklist

Peer reviewer checklist:

Validating the clinical question of the study

Is there a clear, focused, and answerable [study question](#)? see [PICO](#)

Is the study question [innovative](#) or [relevant](#)?

Does the [manuscript](#) present an updated [literature](#)? [MESH](#)

Has the question already been answered in the literature?

Does the study have the potential to advance scientific knowledge, influence clinical management and health policy, or provide some directions to future research?

Does it matter?

What relevant information will the study add to the literature?

Is the paper clearly written and well organized?

PICOT: Patient, Intervention, Comparative, Outcome, Timing, and Type of study

Are the eligibility criteria for inclusion and exclusion broad and clearly stated?

Is the condition used in the selection clear: tests, scores, signs, and symptoms?

Is the group homogeneous?

Are the characteristics of the patients representative of those of the clinical question?

Are the baseline characteristics reported?

Were patients similar at baseline in terms of demographics and comorbidity?

Regulatory approval

If humans, human tissues, or animals are involved, has [ethics approval](#) been obtained and is the study ethical?

Is the paper in agreement with the standards of medical ethics?

Is informed consent applied?

Is the study registered?

Are there any conflicts of interest from the authors?

Sample size calculation

<https://www.surveysystem.com/sscalc.htm#one>

Did the authors perform a sample size calculation?

Do the authors mention the power of their study?

What level of significance do they calculate (in %)?

Are the clinical parameters used to calculate clinical significance?

Allocation

Are patients allocated randomly to trial groups?

Is the randomization described and detailed enough to verify its adequacy?

Can you think of any way in which someone could get around the randomization process described in the article?

PICOT: “Intervention” and “Comparative”

Do the authors adequately describe the treatment (including postoperative protocol) for each treatment arm?

Are the intervention and comparison sufficiently detailed to ensure their applicability?

Is the comparison useful for the clinical question?

Maintenance

Are patients treated equally and comparable apart from the intervention group?

How many patients dropped out during the study?

What is the dropout rate?

Are the losses equally distributed and do they have similar characteristics?

How many patients completed all the evaluations?

How many patients crossed over during the study?

Is there a flow diagram reporting the quantity of patients eligible and included in the study, the number of subjects in each treatment arm, and how the study ended, by presenting the number and the reasons why patients left the study at various points in time?

PICOT: “Outcome”

Are the outcomes clinically relevant or important to the patients?

Are the instruments or questionnaires for measurement objective?

Are the instruments or questionnaires for measurement well described in the literature to enable a correlation of the results?

Are patient-reported outcomes used or just physiological or radiographic measures?

Are the evaluation instruments appropriate for the study and validated for the language of the country where they will be applied?

Is the outcome assessor (evaluator) blinded?

How is the data collection performed (prospectively or retrospectively)?

How many follow-up visits are performed and how many time points are used to measure the outcomes?

Masking or blinding techniques

Is blinding used?

If there is blinding, who is blinded?

Has the blinding process been described?

Would it have been possible for the blinded person to realize which intervention was performed?

If no blinding is reported, can you think of a way in which blinding could have been done in the study (e.g., blinding the outcome assessor, etc.)?

PICOT: “Time of follow-up”

Was the timing for observation adequate to detect differences between the groups?

PICOT: “Type of study”

What was the type of study?

Was the study design appropriate for the research question?

Statistical analysis and data presentation

Did the authors describe the statistical software used?

Did the authors explain what statistical models were used?

Did the authors provide sufficient numerical information for someone to check the statistics that were calculated?

Are patients analyzed as randomized (intent to treat) or according to the treatment (as treated)?

Could presentation of the results be improved and do they answer the question?

How large is the treatment effect?

How precise is the estimate of the treatment effect?

Is the baseline information table described?

Do the figures and tables have important information and describe the data accurately?

Are they consistent, e.g., are bars in charts the same width, are the scales on the axes logical?

Internal validity Was the study performed according to the original protocol?

Are the results valid and near the truth?

Are there selection systematic errors or bias?

Are there allocation systematic errors or bias?

Are there treatment systematic errors or bias?

Are there measurement systematic errors or bias?

Are there many confounding factors?

Are there sample size calculation, adequate allocation, good study design, blinding techniques, intention-to-treat analysis, and completeness of follow-up?

Are the methods described clearly enough for other researchers to replicate?

Are the study limitations described in the discussion?

Do the data justify the conclusions?

External validity

Does the study evaluate efficacy or effectiveness of a technique or product?

Is there enough information to reproduce the study elsewhere?

Can I see the limitations and strengths if I decide to reproduce the study?

Are the results applicable, easy to implement, and can they probably modify the evolution of diseases?

Can I generalize this study to my everyday work and my patients?

Will the results help me in caring for my patient?

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