TBL Guide for Critical Appraisal Summaries

Expected summary structure

The TBL summaries have adapted over time, as the editorial group have learned what works and what doesn't. Not all summaries will therefore match this expected structure. If you have a good reason to deviate from this structure, the editors will listen to your idea.

Copyright laws prevent you from copying "significant or substantial work" from the original paper. Please do not take screenshots from the paper, and paraphrase any elements you wish to copy. Do not directly copy any quotes.

Examples to look at are:

HARP2 summary

TRISS summary

PROPPR summary

All text in the sections will be styled with bullet points for consistency when published. Short, bulleted lines or paragraphs are encouraged for easy reading. Sub-bullets up to three levels deep are allowed when it helps to contextualise meaning or content.

Title

The title of the original paper as published.

Reference

The study should be referenced in a modified Vancouver format. Give only the first author. Abbreviate journals using common standards. Format the citation as "year; volume (issue if applicable): page range" without spaces between.

- Nielsen. NEJM 2013;369:2197–206.

Follow this by the DOI of the online article:

- DOI:10.1056/NEJMoa1310519

Clinical question

Define the clinical question that the study aimed to investigate. Try to keep this is a PICO(T) format: population, intervention, control, outcome, and timing when applicable.

- In adults that suffer an out-of-hospital (OOH) cardiac arrest of presumed cardiac cause, does induced therapeutic hypothermia targeting 36°C compared to 33°C reduce mortality or reduce neurological deficit?

Design

Outline the type of study, the methodology and key features that allow assessment of common biases. Examples include randomisation method, concealment and blinding. Comment on notable deviations from typical designs. Describe the power calculation so that the target sample size can be compared to the results.

- Randomised, controlled clinical trial
- Central randomisation using computer-generated sequence
- Permuted block of varying size stratified according to clinical site
- Single blinded: clinicians were aware, neuro-prognosticating physicians (outcome assessors) and statisticians were blinded
- Manuscript written by blinded authors prior to revealing group assignment
- 900 patients required to power the study at 90% to detect a 20% reduction in hazard ratio for death in the 33°C group compared with the 36°C group, assuming 55% mortality in the 36°C group, with an alpha level of 0.05

Setting

Describe the number of centres and their locations

Outline the recruitment time period accurate to the month where this is available.

- 36 intensive care units
- Europe and Australia
- November 2010 to January 2013

Population

List inclusion criteria followed by exclusion criteria. This can be in a semi-colon separated list in a sentence or a bulleted list – which ever you feel is clearer. It is acceptable to simplify the terminology or leave out minor, rare, or obvious criteria.

The importance of this section is for readers to understand whether the study can be applied to the patients under their care.

Describe the patient numbers, with additional information such as the number screened for enrolment or exclusion numbers where this adds something to the summary.

It may be useful to provide a short summary of the patient demographics, to illustrate the population in which this study was performed. For example, details regarding age, gender, ethnicity, illness acuity or chronic health may be relevant. Any differences between the groups are worth including if you feel it reduces the internal validity.

- Inclusion: adult patients who were unconscious (GCS < 8) on admission to hospital after OOH cardiac arrest of presumed cardiac cause
- Exclusion: > 6 hours from ROSC to enrolment screening; unwitnessed arrest with asystole; hypothermia < 30°C; suspected or known intracranial haemorrhage
- 950 patients enrolled

Intervention

Describe the intervention in simple terms, but with enough detail that a reader could repeat it in their clinical practice.

Outline any notable deviations.

> - 28 hours of temperature management with a target of 36°C using invasive or surface cooling, followed by gradual warming to 37°C at 0.5°C per hour and avoidance of pyrexia for 72 hours from randomisation.
> - 4 patients did not receive this intervention as assigned

Control

Describe the control, in a format as similar as possible to the intervention for easy comparison. If it was identical placebo given in an identical manner, then just write 'identical placebo'.

> - 28 hours of temperature management with a target of 33°C using invasive or surface cooling, followed by gradual warming to 37°C at 0.5°C per hour and avoidance of pyrexia for 72 hours from randomisation
> - 3 patients did not receive this control as assigned

Common Management

At this point in the summary, management that is common to both groups may be included. The peer-review editor will include this in a position and format that allows easy reading.

Outcome

Since studies use a variety of styles and statistics to report outcomes, this section is flexible. Generally, a summary will have 'primary outcome' and 'secondary outcomes'. Other sub-sections might be 'sub-groups', 'tertiary descriptive data' or 'post-hoc analyses'.

The first line of each should be the outcome in words, which can make read easily.

Subsequent sub-bullets can be the data in numbers. The effect size and accuracy should be demonstrated. This may be a mean difference or ratio of proportions for example, and 95% confidence intervals can be used to demonstrate the accuracy and inference to the bigger population. Absolute differences should be used where possible, and relative differences should be avoided (outcomes have been shown to be perceived as more substantial when quoted as relative values, which can mislead readers). P-values can be used for hypothesis-based conclusions, but the 'statistical significance' use of p-values is discouraged.

> - Primary outcome: There was no difference in all-cause mortality through to the end of the trial (mean follow-up period was 256 days).
> - 48% had died in the 36°C group and 50% had died in the 33°C group.
> - The hazard ratio for death was 1.06 for cooling to 33°C (CI 0.89 to 1.28; p=0.51)
> - Secondary outcome: There were no differences between the groups regarding their neurological status (modified Rankin scale or Cerebral Performance Category).

A data table can sometimes summarise in-depth data much better than words. Authors will be provided with a Microsoft Excel datasheet that they can adapt to display relevant data. Please see the notes within that datasheet for guidance.

Authors' Conclusions

Paraphrase a short conclusion that the paper's authors have drawn. This is usually a one, or at most two, sentence.

- This trial does not provide evidence that targeting a body temperature of 33°C confers any benefit for unconscious patients admitted to the hospital after out-of-hospital cardiac arrest, as compared with targeting a body temperature of 36°C.

Strengths

The strengths should be demonstrated here. These can be single lines or, if unique and interesting, more in-depth explanations.

These points should demonstrate why you think internal validity (accuracy of the result) and the external validity (generalisability of the result) are acceptable.

- Highly relevant clinical question
- Well designed, pragmatic methodology
- Objective outcomes assessed by blinded external physicians
- Intention-to-treat analysis with minimal drop-out / loss-to-follow-up

Weaknesses

In a similar style, these points can be simple or more in-depth. Again, try to relate these weaknesses to the internal or external validity.

These need to be objective and as factual as possible.

If you are commenting on a weakness that may bias the result in one direction or another, comment on what sort of bias it is, which was it may have affected the result and to what extent. Is this just note-worthy, or has the bias potentially led to unacceptable doubt over the internal validity?

- Not generalisable to arrests with long or unknown 'down-time'
- Unwitnessed arrests with systole as initial rhythm were excluded
- 90% had bystander witness; 73% had bystander CPR
- Median time to basic life support was 1 minute!
- Median time to advanced life support was 9 and 10 minutes
- Median time to ROSC was 25 minutes
- Follow-up was relatively short-term; unclear if 36°C confers long-term neurological benefit or harm.
- Wide confidence intervals: with 95% certainty, true hazard ratio for 33°C could be anywhere between 0.89 (strong benefit) and 1.28 (strong harm).

The Bottom Line

This should be your conclusion, having considered

a) The internal validity – how accurate are the results?
b) The effect size of the intervention over the control – what do the results show?
c) The external validity – how generalisable are the results?

Try to be objective. Where there may be different ways to interpret the study, and you are including your personal opinion of how you have chosen to interpret the study, state that it's your opinion.

> - This trial has a negative outcome, and fails to show any benefit of therapeutic hypothermia at 36°C over 33°C after OOH cardiac arrest. Not everyone agrees this is the same as "36°C is equivalent to 33°C".
> - My conclusion: if cooling a patient to the conventional 33°C induces unwanted effects, aim for 36°C instead and it *probably* will make no difference to the patient's outcome.

External Links

Provide up to four references to online material that complement this study or your summary. TBL encourage open access material; so only include restricted access material if it is strongly relevant. Examples may be commentary from other sites, podcasts on the study or related topics, explanatory notes for the topic or statistical methods used.

The fifth link will be a link to the paper on PubMed.

This example is adapted from the RESTORE trial summary, not the TTM trial as the previous examples have been!

> - [abstract] Protocolized sedation vs usual care in pediatric patients mechanically ventilated for acute respiratory failure: a randomized clinical trial by Martha Curley et al
> - [editorial] Protocolized sedation in critically ill children by Sabgeeta Mehta
> - [commentary] Sedation protocol does not reduce time of respiratory support from HealthManagement.org

Please include the type of material you are linking to, the title of the material, the author or name of the website, and the URL address for the material.

Metadata

Please provide your name, the date you wrote this summary and your professional Twitter username. TBL encourage engagement in Twitter, where these summaries are shared and discussed. Furthermore, TBL feel it is important to be transparent: anonymous Twitter accounts are not encouraged.