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Reporting Guidelines: The Consolidated Standards of Reporting Trials (CONSORT) Framework

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INTRODUCTION

The Institute of Medicine defines the quality of health care as the "degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[1] 'Yet, only a minority of surgical management decisions have historically been based on randomized controlled trials (RCTs). Fortunately, surgeons are now regularly conducting RCTs and the results are increasingly being translated and implemented into clinical practice.[2] In the past, reporting of RCTs was widely variable and often resulted in an inability to interpret and apply study findings to actual clinical practice.[3] To address inadequate reporting of RCTs, the Consolidated Standards of Reporting Trials (CONSORT) Group first outlined a set of reporting principles in 1996. These original guidelines were updated twice – in 2001 and in 2010.[4] Strict adherence to CONSORT has been widely endorsed by the medical community, including all major medical journals and editorial boards including all JAMA Network journals. In this overview, we describe CONSORT, emphasize several important considerations when using it, as well as point out its limitations.

USE OF THE REPORTING GUIDELINE

In addition to its value in reporting RCT results, the use of the CONSORT checklist is paramount in the design and planning to ensure that all aspects of enrollment, intervention allocation, blinding, follow-up, and analysis are properly addressed. These issues are all pivotal in understanding and interpreting a RCT. For example, describing and ensuring

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proper randomization minimizes confounding by attempting to balance both known and unknown variables, while blinding reduces the likelihood of bias introduced by unsealing the treatment allocation to the investigators.

REQUIRED ITEMS

The checklist is separated into 6 sections: Title and Abstract, Introduction, Methods, Results, Discussion and Other Information. Several essential items from each section should be highlighted.

Title, Abstract, and Introduction

First, the trial must obtain the proper protocol registration and approvals, including with the Institutional Review Board (IRB), Data Safety Monitoring Board (DSMB), if applicable, and clinical trial registry. In addition, the investigators need to explicitly report the funding source and the sponsor's role in the study. The title should identify the study as a randomized trial as well as the intervention(s) evaluated. Since many clinicians only focus on the abstract, it should be accurate with a carefully drafted conclusion.

Methods

Particularly relevant to understanding the quality and rigor of the RCT, the Methods section should include an exact description of the type of trial (e.g., non-inferiority and equivalence trial, etc), the intervention and details of the trial setting, and the primary outcome with a sample size calculation. The CONSORT allows readers to quickly review eligibility criteria and the exclusions that were applied to understand the final study population.[4] The randomization technique, including how concealed allocation was conducted, whether any restrictions on randomization were applied, the use of any stratifying variables, should also be explicitly stated. Additionally, pre-specified subgroup analysis and secondary endpoints must be clearly described. Finally, any interim changes to the study protocol such as the eligibility criteria should be explained.

Results

Several items in the Results section should be highlighted. A flow diagram that describes the number of excluded subjects and the reasons for exclusion, number of subjects in the intervention and control groups, and number lost to follow up should allow for an accurate estimation of the intent to treat and per protocol populations. Demographic and essential baseline data preferred as the first table. This table will demonstrate, among the variables collected, the extent to which randomization succeeded in balancing the intervention and control groups. If the groups appear balanced based on measured variables, it is likely that unmeasured, confounding variables are balanced as well, which is the intent of randomization. If randomization was not achieved, this table provides useful information on what characteristics were different between groups. For each of the pre-specified outcomes, both absolute and relative differences as well as the effect estimates (relative risk, hazard ratio or odd ratio) and the 95%CI should be reported. All other subgroup analyses and adjusted analyses should also be reported and if it is an exploratory analysis, it should be described as such. Adverse effects of the intervention or unintended effects should be clearly

described. If the trial was stopped early (either planned or unplanned) before completing enrollment, reasons should be clearly stated.

Discussion

The Discussion section of the manuscript is key to place the results in the context of the literature and help interpretation. As such, the checklist includes three sections: limitations, generalizability, and interpretation. These topics are certainly relevant for all studies but take on a particularly important role in a study testing efficacy since the impact of the findings can immediately impact patient care. The discussion should include not only what the limitations are, but also what the influence of those limitations could have on the study's findings. The limitations are highly related to the other two items, generalizability and interpretation. Authors must not extend the findings of the study beyond the study population and treatment protocol. The primary outcome is what the study was powered to evaluate, with the other outcomes being more exploratory and hypothesis-generating. Over-interpretation of the results to broader patient populations or clinical settings, can lead to dangerous misuse of an intervention and potential patient harm.

LIMITATIONS OF THE REPORTING GUIDELINE

It is important to understand that these guidelines may not be widely applicable to non-traditional trial designs such as two group parallel design crossover, equivalence, non-inferiority or adaptive trials. This led CONSORT to develop and publish several additional checklists.[4] For example, in adaptive trials, which uses accumulating evidence generated in the trial to modify certain aspects and even interventions in real-time, there are several additional items that must be addressed.[5] Other extensions include those for cluster trials, pragmatic trials, pilot trials, within-person trials, and non-inferiority trials. There are also several extensions that are specific to certain interventions (e.g., herbal interventions) and study types (e.g., health equity, patient-reported outcomes). Investigators should determine the most applicable guideline for their study design to ensure major gaps in the conduct and reporting of the trial are not missed.

CHECKLIST AND FLOW DIAGRAM

Investigators should refer to the CONSORT website (www.consort-statement.org), which contains the flow diagram and other resources including examples, downloads and non-English translations. Additional information can also be found in an important viewpoint describing the reporting and interpretation of RCTs.[6] In addition, investigators should pay particular attention to certain nuances based on journals methodological preferences and statistical philosophies (e.g., frequentist vs. Bayesian theory).

CONCLUSION

With RCTs becoming more frequent in surgical specialties, it is essential that investigators understand and use the CONSORT guidelines at every phase of the RCT, starting with design and inception of the trial, its conduct, and reporting. For each study to live up to its potential, it is important that each item is carefully considered and addressed. Accurate

reporting of RCT results are critical as the findings can have an immediate and lasting impact on patient care.

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SUMMARY BOX:

CONSORT (Consolidated Standards of Reporting Trials)

- WHAT it is used for?
  - RCTs
  - Cluster Trials
  - Pragmatic Trials
  - Crossover Trials
  - Non-inferiority and Equivalence
- HOW it is used?
  - 25-item checklist and flow diagram
- WHY it is used?
  - Identifies pitfalls that may affect validity and reliability of study results
    - Poor selection of endpoints
    - Inappropriate subject selection criteria
    - Insufficient sample size/power
    - Failure to use intention to treat analysis
    - Inadequate randomization, stratification, or blinding
  - Improve design and planning of RCTs
    - Ensure that all aspects of enrollment, intervention allocation, blinding, follow-up, and analysis are properly addressed
  - Standardize quality of RCT reporting
  - Provide a framework for medical journals to evaluate RCTs