Section 8-
Reporting Results
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- Participant discussion of 9Jan97 NEJM articles using the checklist
- Review Checklist for Writing Manuscript
Checklist for Manuscripts

_________ **Title Page**
_________ Title: short, descriptive, catchy, jargon-free
_________ Authors: full names and degrees
_________ Institutional affiliation for all authors
_________ Funding: all sources of support for the research, including grant numbers
_________ Address for correspondence and reprints, including telephone and fax #s, e-mail

_________ **Structured Abstract**
_________ Followed specifications of the target publication: format and length
_________ May need Condensed Abstract of ~100 words

_________ **Introduction**
_________ Identified the problem
_________ Described the problem: scope, history, prior solutions
_________ Stated the primary and secondary hypotheses of your study
Methods

Detailed enough so that another can reproduce the results

Patients: inclusion/exclusion criteria, informed consent, IRB approval
Account for all registered patients
Comparability of treatment groups in relevant patient characteristics

Sites: any criteria (volume of operations, size etc.)

Study Design: abbreviated if details have already been published.
Otherwise, identify:
blinding method if blinded, randomized
random allocation of pts, details of randomization design
generation of random assignment, retrospective, consecutive, etc.
Treatment arms and ancillary treatments or procedures
Patient compliance
Physician compliance
Summary of actual vs planned treatment
Proportion of pts who completed treatment if longterm

Toxicity, side effects and complications

Important dates listed (study open, last pt entered, last time of f.u.

Monitoring: Planned formal monitoring of the data, interim analyses

Sample size: Planned and actual. Discussion if different. Statement of power or precision if a negative study.

Endpoints: Primary and secondary. Identified other endpoints. Gave definitions of “soft” endpoints like angina, indices such as for bleeding, and composites.

Follow-up,
Accounting of pts were lost to fu
Descriptions of how drop-outs are treated in analyses
Description of censoring
Some measure(s) of the duration of f.u.
Identified any core laboratories.

Statistical Analyses: Indicated how continuous and categorical variables were summarized. Identified all specific comparisons made, method of analysis for each comparison, and criteria for significance. Detail any modeling that was done (univariable, multivariable). Discuss all assumptions that are relevant for the tests used and show that they are justified. Give enough detail to enable a reader to reproduce the results if the data were available.

Results

Disposition of patients: numbers enrolled, excluded, lost to follow-up if not given above

Baseline demographic and relevant clinical characteristics (usually a table), discussed major (clinical or statistical) similarities and differences

Primary endpoint analyses: presented positive and important negative findings, used tables/figures to display data efficiently

Secondary and other endpoint analyses
Discussion

Identified the primary finding, validation of primary hypothesis?

Discussed how this adds to previous knowledge - similarity or contrast

Discussed reasons (methodological, clinical, pathophysiological) for different results compared with prior studies (or why they are similar)

Discussed secondary findings

Discussed limitations of the study

Discussed additional analyses that would be helpful

One- or two-sentence summary

References

Avoided using abstracts, personal communications, unpublished data

Figure Legends

Identified the data that are being displayed (axes, units)

Defined all symbols and abbreviations

Define chart so clearly that all data presented can be understood

Tables

Gave each a short title

Defined all symbols and abbreviations

Presented only data relevant to the analyses