STATISTICAL DATA AND REPORTING GUIDELINES: IMPORTANT TO GET YOUR PAPER PUBLISHED

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None to declare
Statistical and data reporting guidelines for the *European Journal of Cardio-Thoracic Surgery* and the *Interactive CardioVascular and Thoracic Surgery*

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SUMMARY

- Existing recommended guidelines [1] for data reporting were published in 1988!

Currently 5 statistical consultants on the editorial board

Guidelines developed based on experience of all consultants to make clear expectations to those submitting research, and highlight common errors

Approximately 1 in 4 manuscripts submitted to EJCTS are referred for statistical review

Areas considered:

1. Was there a clear study design and the objectives well formulated?
2. Were the statistical analysis methods clearly described?
3. Were the statistical methods appropriate for the study/data?
4. Were the data appropriately summarized?
5. Were the statistical results adequately reported and inferences justified?
1. EXISTING REPORTING GUIDELINES

EJCTS Guidelines **supplement** existing reporting statements—not replace them!
1. STUDY DESIGN: CORE REQUIREMENTS

- Objective / hypothesis and type of study
- Data acquisition methods (incl. post-discharge follow-up)
- Inclusion and exclusion criteria
- Sample size rationale – calculations should be reproducible
- Randomization and blinding (if relevant)
- Potential sources of bias → statistical adjustment methods used
1. STUDY DESIGN: DEFINITIONS

- Explicitly define outcomes, e.g.
  - ‘(Peri-)operative mortality’ – in-hospital or 30-day?
  - Time origin for time-to-event variables – surgery, randomisation, discharge, etc.?
  - All-cause or cause-specific mortality?

- Use accepted definitions where available

- Avoid ambiguous or undefined study variables
  - E.g. ‘normal’ vs. ‘abnormal’ white cell count

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2. DESCRIPTION OF STATISTICAL ANALYSIS

- A description of statistical methods used, and when they were used
- Additional information request for advanced statistical methods
- Handling of missing data
- Phrasing and terminology, e.g. incidence vs. prevalence or multivariate vs. multivariable
2. DESCRIPTION OF STATISTICAL ANALYSIS: REGRESSION MODELS

- Inclusion of adjustment covariates
  - Univariable screening
  - Stepwise regression methods (details of algorithm required)
  - Covariates forced into model
  - All covariates included
  - Consideration to over-fitting and stability?
- Functional form of continuous covariates (e.g. transformations, dichotomization)
2. DESCRIPTION OF STATISTICAL ANALYSIS: PROPENSITY SCORE MATCHING

Limited guidance, but recommendations in literature [1] include:

- Evaluate balance between baseline variables using standardised difference, not just hypothesis tests

- Provide details of matching algorithms used (incl. caliper details, match ratio, with/without replacement) – not just software!

- Lack of balance requires further iterations of propensity score model building (e.g. interaction terms) – don’t stop at first attempt!

- Describe statistical methodology used to estimate treatment effects in the matched data

3. APPROPRIATE METHODS

- Regression models should have assumptions checked, and if necessary be assessed using suitable diagnostics and goodness-of-fit tests
  - E.g. Proportional hazards assumption for Cox regression models
- Correct statistical model / methodology for data
  - E.g. using logistic regression when a Cox model should have been used
  - E.g. independent samples test for paired data
- Multivariable models should have an adequate event-per-variable ratio
  - E.g. fitting a logistic regression model with 7 covariates to data with 20 events and 1000 subjects using maximum likelihood would be inappropriate
3. PRESENTING DATA GRAPHICALLY

Anscombe's quartet *

- Same number of points
- Same Pearson sample correlation coefficient
- Same linear regression line fit
- Same marginal means and standard deviations

Present appropriate plots of your data when possible

4. DATA REPORTING

- Include summary table of patient/surgical characteristics, stratified by treatment groups if a comparison study.
- Location statistics (e.g. mean, median) should always be reported with appropriate measure of variability (e.g. median, IQR).
- Always report what summary statistics are reported.
  - “average age was 65 years (41-79) years” – is it mean and range, median and (1st, 3rd) quartiles?
### 4. DATA REPORTING: AVOIDABLE ISSUES

**Table 1.** Patient and operative characteristics data by CPB technique with statistical comparison.

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>On-pump</th>
<th>Off-pump</th>
<th>$\Delta$ (%)</th>
<th><strong>P</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number</td>
<td>$n=3402$</td>
<td>$n=1173$</td>
<td>$n=2229$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Logistic EuroSCORE (%)</td>
<td>$2.4 \pm 2.5$</td>
<td>$2.4 \pm 2.8$</td>
<td>$2.3 \pm 2.3$</td>
<td>$1.8$</td>
<td>0.965</td>
</tr>
<tr>
<td>Age (years)</td>
<td>$61.7 \pm 10.6$</td>
<td>$61.1 \pm 10.3$</td>
<td>$61.9 \pm 10.7$</td>
<td>$-8.1$</td>
<td>0.026</td>
</tr>
<tr>
<td>BMI (kg/m$^2$)</td>
<td>$28.5 \pm 4.6$</td>
<td>$28.7 \pm 4.7$</td>
<td>$28.4 \pm 4.5$</td>
<td>$6.1$</td>
<td>0.090</td>
</tr>
<tr>
<td>Female</td>
<td>$880$</td>
<td>$325$</td>
<td>$555$</td>
<td>$6.4$</td>
<td>0.083</td>
</tr>
<tr>
<td>Preoperative AF</td>
<td>$69$</td>
<td>$28$</td>
<td>$41$</td>
<td>$2.8$</td>
<td>0.242</td>
</tr>
<tr>
<td>Urgent</td>
<td>$733$</td>
<td>$271$</td>
<td>$462$</td>
<td>$5.7$</td>
<td>0.119</td>
</tr>
<tr>
<td>NYHA III/IV</td>
<td>$645$</td>
<td>$225$</td>
<td>$420$</td>
<td>$0.9$</td>
<td>0.846</td>
</tr>
<tr>
<td>History of neurological</td>
<td>$53$</td>
<td>$25$</td>
<td>$28$</td>
<td>$6.8$</td>
<td>0.070</td>
</tr>
<tr>
<td>dysfunctions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. DATA REPORTING: CHARTS

- Statistical figures are for summarizing complex data
- Readers will be drawn to them, so make them intuitive, sensible and clear

https://www.biostat.wisc.edu/~kbroman/topten_worstgraphs/
5. RESULTS

- $P$-values alone $\neq$ results $\rightarrow$ effect sizes and confidence intervals
- Full regression models should be reported – not just significant terms
- Details of any deviations from the planned study
- $P$-values and statistics reported to appropriate precision
5. RESULTS: PRESENTING PLOTS

An unacceptably presented Kaplan–Meier graph

An acceptably presented Kaplan–Meier graph

Log–rank test \( P = 0.001 \)
5. DISCUSSION & CONCLUSIONS

- Association ≠ causation
- \( P \)-values ≠ probability null hypothesis is true
- Absence of evidence ≠ evidence of absence, e.g. \( P=0.60 \) only tells us there is insufficient evidence for an effect, which might be due to:
  - No effect being present
  - Large variability
  - Insufficient information in the data due to small sample size
- Statistical significance ≠ clinical significance
- Study weaknesses should go beyond commenting on the sample size and observational data
CONCLUSIONS

- EJCTS & ICVTS Statistical and Data Reporting Guidelines inform authors on what statistical reviewers are looking for.
- A well analyzed study allows reviewers to focus on what is important—the science!
- It is advised that a biostatistician be involved in the analysis.
- Correct and well-reported (and correct) statistical analysis essential to getting your paper published!
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