Issues in Research Design and Statistical Methods for Medical Journals

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Background

- Statistical methods are now widely used in medical research , but problems remain with their proper use and with the presentation of research findings.
- The misuse or inaccurate use of statistical methods may point the research in the wrong direction and produce incorrect study results.
- There are many statistical errors medical journals such as: (Altman, 1994)
  - Use the wrong statistical methods
  - Use the right methods wrongly
  - Misinterpret the results
  - Report the results selectively and cite the literature selectively
  - Draw unjustified conclusion

Statistical Errors in Medical Literature

- Of 164 papers with numerical results (66% of 248) published in the British Journal of Psychiatry in 1993, 65 papers (40%) contained statistical errors (McGuigan, 1995)
- Of 145 papers published in the American Journal of Obstetrics and Gynecology in 1994, 46 papers (31.7%) contained statistical errors (Welch and Gabbe, 1996)
- Of 281 randomly selected psychological papers published in 2008, 18% of the papers contained statistical errors (Bakker and Wicherts, 2011)
- Of 1,335 papers in 1998 and 1,578 papers in 2008 from 10 leading Chinese medical journals, statistical errors were contained in 56.3% of the papers in 1998 and 67.9% of the papers in 2008 (Wu et al., 2011)
- Of 139 papers published in Korean Journal of Pain from 2004 to 2008, 20.9% of the papers were free from statistical errors (Yim et al., 2010)

Number of 1993 Papers Published in BJP by Statistical Methods

Statistical Methods	Frequency
Chi-square test	72
Student t-test	46
Correlation	38
Mann-Whitney test	30
ANOVA	29
Confidence intervals	12
Fisher's exact test	8

(Source: McGuigan SM. The use of statistics in the British Journal of Psychiatry. British Journal of Psychiatry. 1995;167:683-688)

Statistical Error Rates Published in BJP in 1977/78 and 1993 Papers

Type of Errors	1977/78 Error rate (1)	1993 Error rate (2)
Randomization	12/49= 24%	25/58=43%
Measures of location	34/139=24%	44/164=27%
Measures of dispersion	16/139=12%	44/164=27%
Student's t-test	13/35=37%	37/46=80%
Chi-squared test	12/48=25%	11/72=15%
Description of methods	18/139=13%	27/164=16%
Statement of results	10/139=13%	28/164=17%
Incorrect analysis	20/139=14%	45/164=27%

1. White SJ. Statistical errors in papers in the British Journal of Psychiatry. British Journal of Psychiatry. 1979;135:336-342.
2. McGuigan SM. The use of statistics in the British Journal of Psychiatry. British Journal of Psychiatry. 1995;167:683-688.

Statistical Errors in 10 Leading Chinese Medical Journals in 1998 and 2008 by Methods

Types of Statistical Methods	Errors in 1998	Errors in 2008	Chi-sq	P value
T-test	305 (62.0%)	253 (44.4%)	32.8	<0.001
1. Multiple comparison	153 (31.1%)	129 (22.6%)	9.7	0.002
2. Non-parametric	89 (18.1%)	60 (10.5%)	12.5	<0.001
3. Paired t-test	73 (14.8%)	60 (10.5%)	4.5	0.034
Contingency tables	154 (58.3%)	169 (32.3%)	21.4	<0.001
1. Small size cell	82 (25.7%)	74 (14.2%)	17.5	<0.001
2. Fisher exact test	52 (16.3%)	53 (10.1%)	6.9	0.009
ANOVA	128 (63.4%)	263 (59.0%)	1.1	0.289
1. Multiple comparison	51 (25.3%)	132 (29.6%)	1.3	0.255
2. Repeated-measures data	45 (22.3%)	63 (14.1%)	6.65	0.010
Non-parametric test	29 (43.3%)	33 (17.7%)	17.57	<0.001

Statistical Errors in 10 Leading Chinese Medical Journals in 1998 and 2008 by Research Design

Types of research design	1998		2008	
	Papers used statistics	Statistical errors	Papers used statistics	Statistical errors
RCT	64 (98.0%)	36 (56.3%)	56 (93.3%)	38 (67.9%)
Clinical trial	82 (91.1%)	47 (57.3%)	58 (95.1%)	34 (67.9%)
Cohort study	47 (79.7%)	28 (59.6%)	80 (92.0%)	17 (21.3%)
Case-control	254 (92.4%)	148 (58.3%)	276 (97.2%)	129 (46.7%)
Cross-sectional	56 (74.7%)	32 (57.1%)	52 (88.1%)	23 (44.2%)
Case study	122 (31.9%)	59 (48.4%)	233 (48.9%)	110 (47.2%)
Basic science	240 (74.1%)	175 (72.9%)	409 (87.4%)	268 (65.5%)
Total	912 (68.3%)	545 (59.8%)	1233 (78.1%)	644 (52.2%)

(Source: Wu S, et al. Misuse of statistical methods in 10 leading Chinese medical journals in 1998 and 2008. Scientific World Journal. 2011;11:2106-2114)

Incidence of Inferential Statistics in 119 Papers Published in the Korean Journal of Pain

Statistical Methods	2004	2005	2006	2007	2008	Total
Student t-test	9	13	14	9	8	53 (21.0)
Chi-square test	9	8	9	8	6	40 (15.9)
One way ANOVA	5	7	4	5	4	25 (9.9)
Mann-Whiney test	3	4	7	3	6	23 (9.1)
Paired t-test	7	4	3	3	5	22 (8.7)
Repeated measures ANOVA	6	6	2	0	4	18 (7.1)
Fisher's exact test	2	2	6	3	1	14 (5.6)
Wilcoxon signed rank test	3	0	5	0	2	10 (4.0)
Kruskal-Wallis test	2	1	1	2	3	9 (3.6)
Total	53	47	64	46	42	252 (100)

(Source: Yim KH, et al., Analysis of statistical methods and errors in the articles published in the Korean Journal of Pain. 2010;23(1):35-41)

Statistical Errors in the Papers Published in the Korean Journal of Pain from 2004 to 2008

Types of Errors	2004	2005	2006	2007	2008	Total
Nonparametric test	12	21	9	6	8	56 (33.9)
Inadequate dispersion	8	7	5	5	10	35 (21.2)
Chi-square test	5	5	3	6	5	24 (14.5)
Multiple comparison	2	4	1	6	2	15 (9.1)
Ignoring data characteristics	4	2	2	1	3	12 (7.3)
Paired t-test	0	4	3	2	0	9 (5.5)
Illogical conclusion	4	2	0	0	1	7 (4.2)
Total	36	47	25	27	30	165 (100)

(Source: Yim KH, et al., Analysis of statistical methods and errors in the articles published in the Korean Journal of Pain. 2010;23(1):35-41)

Types of Statistical Errors in Medical Journals by Review Categories

Category	Statistical Errors
Design	Failure to use randomization in controlled trial Use of an inappropriate control group Inadequate sample size
Analysis	Unpaired method for paired data Wrong unit of analysis Wrong assumptions Categorization of continuous variable Use of parametric methods for non-normal data
Presentation	Giving SE instead of SD to describe data Results given only as p-values
Interpretation	Concluding causation from an observed association Interpreting a poor study (e.g. small sample, case study)

(Source: Altman DG. Statistical reviewing for medical journals. Statistics in Medicine, 1998;17:2661-2674)

Check-lists for 100 Papers Reviewed for the British Medical Journal during 1991-1993

Check-list	Yes	Unclear	No
Objective clear?	83	6	11
Appropriate study design	72	25	3
Source of subjects?	83	6	10
Sample sized calculation?	0	0	63
Satisfactory response rate?	49	23	2
Methods described adequately?	47	-	53
Statistical analyses appropriate?	41	37	22
Statistical presentation satisfactory?	14	-	86
Confidence intervals given?	51	-	41
Conclusion justified?	40	49	11
Paper statistically acceptable?	4	-	96

(Source: Altman DG. Statistical reviewing for medical journals. Statistics in Medicine, 1998;17:2661-2674)

Suggestions for Researchers

- Planning for research
  - Decide what questions you will be studying
  - Consult with statistician about study design before you gather data because the design affects what method of analysis is appropriate
- Analyzing data
  - Ask whether or not model assumptions are plausible to the data
  - Plot the data to get additional checks on model assumptions
  - Identify the variables used in the analysis and summarize each with descriptive statistics
  - Consult with statistician about analytic methods to find the best methods for your data
- Writing up research
  - Aim for transparency and reproducibility
  - Include discussion of why the analyses used are appropriate

Suggestions for Editors and Referees

- More extensive refereeing of paper by statisticians
- The refereeing of study protocols, rather than completed research (McGuigan, 1995)
- Statistical reviewers should be included in the editorial boards of the journals
- Statistical guidelines for authors should be developed and authors encouraged to follow them (Altman, 1998; Lang et al., 2013)

Guidelines for Reporting Statistical Results

- Descriptive Statistics
  - Summarize data that are approximately normally distributed with mean and standard deviation (not standard error)
  - Summarize data that are not normally distributed with medians and inter-percentile ranges or ranges
- Hypothesis Testing
  - Report whether the test was one- or two-tailed and for paired or independent samples
  - Do not report "NS" or inequalities; give the actual p-value
- Regression Analysis
  - Confirm that the assumptions of the analysis were met
  - Report whether the variables were assessed for colinearity and interaction
  - Describe the variable selection process (e.g. forward-stepwise)

(cont.)

- Analysis of Variance (ANOVA) or Covariance (ANCOVA)
  - Confirm that the assumptions of the analysis were met
  - Select the appropriate covariate in ANCOVA

  (Reference: Lang T, Altman D. Basic statistical reporting for articles published in clinical medical journals: the SAMPL Guidelines. In: Smart P, Maisonneuve H, Polderman A (eds). *Science Editors' Handbook, European Association of Science Editors, 2013)*

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