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Longitudinal analysis of trends and reporting quality of statistical methods of observational studies published in high-impact urology journals: a protocol for systematic assessment

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Abstract: **Observational studies play an important role in urology research. The quality of statistical reporting can directly affect the reliability of observational studies. According to previous studies, the quality of statistical reporting for published biomedical literature tends to be low. There are no studies on the evaluation of the quality of statistical reports on urological observational studies. The purpose of this study is to investigate the trends and evaluate the reporting quality of statistical methods of observational study published in high-impact urology journals, compare with general medical journals in order to further identify factors related to high quality statistical reporting. This study plans to search the top five journals of urology and top two general medical journals with the highest 5-year impact factor (based on ISI Web of Knowledge Journal Citation Reports) in Pubmed and EMBASE. All observational studies that meet the inclusion criteria will be included. Table "common statistical methods in medical studies" will be used to assess the frequency and trends of statistical methods for observational studies published in urology journals. The quality of statistical reporting for each article will be assessed according to Table "the assessment checklist of the reporting quality of statistical methods". The table consists of 7 items (marked *) that must be reported and 39 items that are subject to selective reporting based on the statistical methods used in the article. The proportion of fully reported items will be calculated based on the type of statistical method used in each article. A logistic regression model will be established to identify factors associated with high-quality statistical reporting. This study will identify major deficiencies of statistical reports, which may provide a reference for authors, reviewers and editors of journals, and help to improve the statistical reporting quality of articles in urological journals.**

Keywords: Checklist; Observational studies; Reporting quality; Statistics; Urology Journals

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1. Introduction

Nowadays, research on the etiology, mechanism and treatment of diseases is developing at an alarming rate, which has made health care professionals and medical researchers increasingly rely on published literature to understand new discoveries. However, more and more medical researchers pay attention to the phenomenon that the main results of research cannot be reproduced[1, 2], and improper use of statistical methods or inadequate statistical reports may be the important reasons for this phenomenon. The low-quality statistical reporting may not make full use of research results, resulting in a waste of valuable information and varying degrees of bias. In addition, it may also make editors and readers unable to measure the reliability of research, and may make readers draw conclusions contrary to those of researchers, thus leading to errors in the secondary studies[3].

The truth is that the poor statistical reporting problem is long-standing, but few people notice it. The first paper on statistical reporting quality of medical literature was published in 1966[4], and dozens of similar studies have been published since then[5-9]. These studies found that although the application of statistical methods is becoming more and more complicated, the problem of insufficient statistical reporting has always existed. To make matters worse, the literature evaluated by these studies is from influential general medical and professional journals.

In 2015, T.A. Lang and D.G. Altman et al. published the "Statistical Analyses and Methods in the Published Literature" (SAMPL) guidelines to improve the quality of basic statistical reporting[10]. The principle of SAMPL is that " authors should describe statistical methods with sufficient detail to enable readers in the professional domain to access raw data to verify the results of the report". In 2017, Pentti Nieminen et al. made the SIMA (Statistical Intensity of Medical Articles) tool and assessed the the statistical intensity in the high impact factor respiratory journal's articles, and they found that approximately one third of the respiratory papers provided incomplete description of their statistical reports[11,12]. Unfortunately, neither has been widely used.

From the design type of medical research, although RCT are generally considered the gold standard for evaluating treatment modalities[13], well-designed observational studies (cohort studies, case-control and cross-sectional studies) are shown to provide similar results[14-16].

Well-produced observational study not only provide a large number of clues for ascertaining the causal relationship between exposure and disease, but also are suitable for investigating long-term or rare side effects of therapies. In fact, observational studies are often used in urology. However, there are few studies have been published on the quality evaluation of statistical reporting for observational studies in urology journals.

Therefore, we intend to carry out this study to describe the frequency and trends of statistical methods used in high-impact urology journals, evaluate the reporting quality of statistical methods of observational study published in urology journals, compare with general medical journals, in order to further identify factors associated with high-quality reporting. It can be expected that this work will identify the major quality deficiencies in the statistical reporting of urological observation studies and promote the improvement of statistical reporting quality of articles in urology journals.

2. Material and Methods

2.1. Journals selection and search strategy

2.1.1. Journals selections

Top two general medical journals (according to 5-year impact factor[17]): New England Journal of Medicine(IF=67.513); Lancet(IF=52.665), and top five urology journals: European Urology(IF=17.581); Journal Of Urology(IF=5.157); BJU International(IF=4.688); Prostate Cancer And Prostatic Diseases(IF=4.099); Prostate(IF=3.820).

2.1.2. Search strategies

We searched the relevant studies in the PubMed, Web of Science and Embase databases. The search strategy was ("N Engl J Med"[Journal]) AND ((("cross-sectional studies") OR "case-control studies") OR “cohort studies”) without other restrictions and the journals mentioned above were searched in turn.

2.2. Articles selection

Articles that meet the following criteria will be selected: (1) Observational studies, including cross-sectional studies, case-control studies, and cohort studies; (2) Original articles; (3) Studies on humans, including both adults and children. The exclusion criteria are as follows: (1) Review articles; case reports; quasi-randomized trial; randomized controlled trials and other interventional studies. (2) Unpublished data and published abstracts only.

2.3. Screening process

The articles retrieved will be preliminarily reviewed according to titles and abstracts by two investigators (Dai and Li) independently. If the consistency of screening results is less than 95%, the screening will be repeated until 95%. Any disagreement will be resolved by consulting with senior authors (Zhou).

After the initial screening, the full text of relevant research will be searched, and two investigators (Dai and Li) determine the final literature to be evaluated based on inclusion and exclusion criteria.

2.4. Trends and assessment of reporting quality of statistical methods

2.4.1. The frequency and trend of statistical methods

Table 1 will be used to assess the frequency and trends of statistical methods for observational studies published in urology journals. Table 1 is based on Emerson's study[18], and the original study divided statistical methods into 21 categories. All 20 categories, with the exception of benefit analysis, have been incorporated into our checklist with slightly modified. An entry containing the following information has also been added to the checklist: Multiple comparisons, repeated measurement data analysis, consistent measurement, Bayesian analysis. The absence or presence of statistical methods in each article will be recorded by this table. If the statistical method is used in the article, tick a” √ ” in the blank box after the method. The frequency and trend of each statistical method used in every journal will be described on the basis of records.

Table 1. Common statistical methods in medical studies

Method		
Descriptive statistics		
	Means (standard deviation)	□ Yes
	Median (interpercentile range)	□ Yes
	Proportion	□ Yes
	Rate (e.g. incidence rate, survival rate)	□ Yes
	Ratio (e.g. odds ratios, relative risk)	□ Yes
Ancillary analyses		

	Variable transforms	□ Yes
	Variable constructs	□ Yes
	Standardizing	□ Yes
	Matching	□ Yes
	Propensity score methods	□ Yes
	Sensitivity analysis	□ Yes
	Stratification or sub-group analyses	□ Yes
Student *t*-test		
	One sample *t*-test	□ Yes
	Paired/matched *t*-test	□ Yes
	Two independent samples *t*-test	□ Yes
	Z test	□ Yes
Analysis of variance(ANOVA)		
	Completely random design ANOVA	□ Yes
	Randomized block design ANOVA	□ Yes
	Factorial design ANOVA	□ Yes
	Cross-over ANOVA	□ Yes
	Analysis of covariance	□ Yes
	Multivariate Analysis Of Variance	□ Yes
Multiple comparisons		
	Students-Newman-Keuls method	□ Yes
	Bonferroni method	□ Yes
	Dunnett method	□ Yes
	Duncan's method	□ Yes
	LSD method	□ Yes
	Tukey method	□ Yes
	Sidak method	□ Yes
	Scheffe method	□ Yes
	FDR (false discovery rate)	□ Yes
Repeated measurement data		
	Repeated measurement data ANOVA	□ Yes
	GEE (Generalized estimating equation)	□ Yes
	MMRM (Mixed-effect models for repeated measures)	□ Yes
	GLMM (generalized linear mixed models)	□ Yes
Non-parametric test		
	Sign test	□ Yes
	Wilcoxon signed-rank test	□ Yes
	Mann-Whitney test	□ Yes
	Kruskal-Wallis *H* test	□ Yes
	Friedman test	□ Yes
	Kolmogorov-Smirnov test	□ Yes
	Median test	□ Yes
Contingency tables		
	Chi-square test	□ Yes
	McNemar’s test	□ Yes
	Fisher’s exact test	□ Yes
Correlation analysis		
	Pearson correlation coefficient	□ Yes
	Spearman correlation coefficient	□ Yes
	Kendall’s tau_b correlation coefficient	□ Yes
	Trend test	□ Yes
	Partial correlation coefficient	□ Yes
	Multiple correlation coefficient	□ Yes
Multiple regression		

	Linear regression	□ Yes
	Curve estimate	□ Yes
	Path analysis	□ Yes
	Nonlinear regression	□ Yes
	Logistic regression	□ Yes
	Poisson regression	□ Yes
	Negative binominal	□ Yes
	Spline regression	□ Yes
	Other regression model	□ Yes
Survival analysis		
	Kaplan-Meier estimate	□ Yes
	Life-table method estimate	□ Yes
	Log-rank test	□ Yes
	Breslow test	□ Yes
	Tarone-Ware test	□ Yes
	Cox proportional hazards model	□ Yes
	Other survival model	□ Yes
Consistency measurement		□ Yes
Principal component analysis		□ Yes
Factor analysis		□ Yes
Discriminant analysis		□ Yes
Cluster analysis		□ Yes
Log-linear models		□ Yes
Structural equation modeling (SEM)		□ Yes
Multilevel modeling		□ Yes
Multi dimensional scaling analysis		□ Yes
Bayesian analyses		□ Yes
Other statistical methods		□ Yes

2.4.2. The checklist of statistical reporting quality assessment

The quality of statistical reports within each article will be assessed according to Table 2. This checklist was established based on the SAMPL guideline and other previously published studies[10, 19-21], and the items were modified to be listed in Table 2 in a simple and readable manner. All of the logistic regression items in table 6 are droved from Zhang's research[22], and Cox regression items are all from Zhu's research[23].

The list consists of 7 items (marked *) that must be reported and 39 items that are subject to selective reporting based on the statistical methods used. A score of “1” represents the answer "yes", while “0”represent the answer "no".

The proportion of items that are adequately reported in the statistical methods used in the study will be calculated for each article. For example，multiple linear regression and Student t- test were used in one article, there are 17 items should be reported (7 items that must be reported，8 items for multiple linear regression, and 2 items for Student t-test), 9 items (4 items that must be reported ,4 items for multiple linear regression, and 1 items for Student t- test) have been adequately reported, then the proportion of statistical report of this article is about 0.53 (9/17).

Table 2. The assessment checklist of the reporting quality of statistical methods

Item	Content	
Preliminary analysis		
*	1. Sample calculation / Power analysis	□ Yes □ No
*	2. Whether there were outliers in an article	□ Yes □ No

	3. Report how any missing data were treated, if applicable.	□ Yes □ No
If the mean with standard deviation, median with interpercentile range and proportion were reported in an article, item 4, 5, 6 are considered applicable items.	4. Mean and standard deviation with examine for normality	□ Yes □ No
	5.Median and interpercentile range with explaining reason (non-normality, ordinal data, quantitative variable without exact data at either end)	□ Yes □ No
	6. Proportion (report numerator and denominator)	□ Yes □ No
*	7. Name of statistical package or program reported	□ Yes □ No
*	8. Report the alpha level (e.g. 0.05) that defines statistical significance	□ Yes □ No
*	9. Report one or two tailed for test. (Justify the use of one-tailed tests.)	□ Yes □ No
*	10. Exact P-values for test (e.g. P=0.23)	□ Yes □ No
*	11. Confidence intervals	□ Yes □ No

Statistical methods

If the following statistical methods are recorded in Table one, the specific items in each statistical method are considered applicable items.

Student *t*- test		
	1. Assessing assumptions for *t*-test	□ Yes □ No
	2.Report the type of *t*-test (e.g. one sample, two independent samples, paired/matched)	□ Yes □ No
ANOVA/ANCOVA		
	1. Assessing assumptions for ANOVA /ANCOVA	□ Yes □ No
	2. Report the type of ANOVA (e.g. one way, randomized block design, factorial design, repeated measure design, cross-over design etc.)	□ Yes □ No
	3. Interaction among independent variables (containing more than two independent variables)	□ Yes □ No
Chi-square test		
	1. Report the type of Chi-square test (Pearson Chi-square test, continuity correction Chi-square test, McNemar's test or Fisher's exact test)	□ Yes □ No
Non-parametric test		
	1.Provide reasons (continuous variable with non-normality, ordinal data, quantitative variable without exact data at either end)	□ Yes □ No
	2. Report the type of non-parametric test (e.g. sign test, Wilcoxon signed-rank test, Mann-Whitney test, Kruskal-Wallis H test, Friedman's test)	□ Yes □ No
Linear correlation		
	1.Report the type of correlation coefficient, with confidence intervals (e.g.pearson, spearman, Kendall's tau_b correlation or trend test) and provide reasons (continuous variable with non-normality, ordinal variable)	□ Yes □ No
Multiple linear regression		
	1. Conformity with a linear gradient	□ Yes □ No
	2. Reason of selection of variables (e.g. based on published literatures, professional knowledge, results of univariate analysis or decision of the researcher)	□ Yes □ No
	3.Methods for variable selection (all possible subsets selection, forward selection, backward selection, stepwise selection)	□ Yes □ No
	4. Interactions among independent variables	□ Yes □ No
	5. Colinearity of independent variables	□ Yes □ No
	6. Coding of variables	□ Yes □ No

	7. Validation of the statistical model	□ Yes □ No
	8. Goodness of fit test (e.g. coefficient of determination, r^2)	□ Yes □ No
Multiple Logistic regression		
	1.Sufficient events (>10) per variable (the ratio of outcome events to independent variables)	□ Yes □ No
	2.Conformity with linear gradient for continuous or rank variables	□ Yes □ No
	3. Reason of selection of variables (e.g. based on published literatures, professional knowledge, results of univariate analysis or decision of the researcher)	□ Yes □ No
	4.Methods for variable selection (forward selection, backward selection, stepwise selection)	□ Yes □ No
	5. Interactions between independent variables	□ Yes □ No
	6.Colinearity of independent variables	□ Yes □ No
	7.Coding of variables	□ Yes □ No
	8.Validation of the statistical model (e.g. likelihood ratio test, Wald test, score test)	□ Yes □ No
	9.Goodness of fit test	□ Yes □ No
Survival analysis		
	1. Identify dates or events marking the beginning and the end of the time period analyzed	□ Yes □ No
	2. Report follow-up information (e.g. the mean of follow-up time, the median of follow-up time, the average of follow-up, the range of follow-up, person-years)	□ Yes □ No
	3. Survival rate or survival function	□ Yes □ No
	4. Report the circumstances under which data were censored	□ Yes □ No
If comparative analysis was applied		
	1. Report the statistical methods applied to compare two or more survival curves.	□ Yes □ No
	2. Report median survival time	□ Yes □ No
If Cox model was applied		
	1. Reported assumption of proportional hazard (assumption of PH) for Cox proportional hazards regression model (Cox model)	□ Yes □ No
	2. Conformity with a linear gradient for continuous or rank variables for Cox model	□ Yes □ No
	3. Interactions between independent variables for Cox model	□ Yes □ No
	4. Colinearity of independent variables for the Cox model	□ Yes □ No
	5. Reason of selection of variables (e.g. based on published literature, professional knowledge, results of univariate analysis or decision of the researcher) for Cox model	□ Yes □ No
	6. Methods for variable selection (forward selection, backward selection, stepwise selection) for Cox model	□ Yes □ No
	7. Coding of variables for Cox model	□ Yes □ No

***: The items that must be reported for each article.**

2.4.3. Reporting quality assessments

Two reviewers (Dai, Li) will apply the checklist independently to appraise the statistics reporting quality of included studies. After the evaluation is completed, the evaluations of the two reviewers will be compared. If two investigators argued over the evaluation of an article, it will be resolved by discussion with the third person until consensus was reached. For articles that cannot get the full text, we will try to contact the authors of the study to obtain full text or details of their statistical analysis of their study.

2.5. Data collection

Two investigators will extract data independently from the included articles. Discrepancies will be resolved by discussion between two investigators (Dai and Li). Statistical methods used in the article and general characteristics were extracted, including the year of publication, impact factors of journals, study design, the number of authors and country of corresponding author, participation of statisticians, the number of affiliations ,the number of times cited ,financial support, etc.

2.6. Statistics analysis

2.6.1. Descriptive analysis

Initially, descriptive analysis of the characteristics of the included articles will be conducted. Continuous variables with normal distribution will be described by mean ± standard deviation (SD), as medians (interquartile range) with non-normal variables, and as frequency (percentage) for categorical variables. The comparison of means between the two groups will be performed by independent student's t-test, with multiple factors being analyzed by one-way analysis of variance (ANOVA), and SNK post hoc test will be used for comparisons between two groups. The Mann-Whitney U test and Kruskal-Wallis H test were used to analyze variables for skewness distribution. Differences in categorical variables were explored using the $\chi 2$ test or Fisher exact test. According to a cutoff value of the 75 percentile of the statistical reporting quality score will be divided into high and low quality groups. Univariate and multivariate logistic regression analysis will be performed to identify the factors affecting reporting quality. All variables with a $P < 0.1$ for univariate comparison between high- and low-quality reporting will be included in the model. We will examine the interaction between variables and whether there is collinearity. The Kappa index was used to measure the consistency of two reviewers'results.

2.6.2. Subgroup analyses

Analysis of the subgroup of studies with higher reported strength of association (odds ratio of >2 or <0.5) between exposure and outcome.

2.6.3. Sensitivity analyses

Delete the medical journals and urology journals with the least number of observational studies, and repeat the analysis. Observing whether the overall quality of the report is improved when the journals with low publication rates are deleted.

2.7. Outcomes

We will describe the types of statistical method used in each study, the frequency of statistical methods adopted in urology and general medical journals, and their change trends over time will also be described. The types and frequency of statistical methods between urology and general medical journals will be compared. A composite score based on the proportion of items that have been adequately reported within the relevant statistical domains used in a given study will be calculated for each article. The items that are more likely to be reported/omitted will be identified among statistically significant study results. The predictive factors associated with high quality statistical reporting will be explored.

3. Discussion

At present, few articles have been published on the quality of urology statistical reporting. According to articles we have reviewed so far, there are many statistical problems in the field of urology research. Scales et al. evaluated the accuracy of statistical methods used in the urology literature[24]. They found that 71% of articles had at least one statistical error, including using the wrong test for the data type (28%), and inappropriate use of a parametric test (22%) and misinterpretation of multiple comparisons (65%). K. Afshar et al. analyzed the use of statistical methods in articles on urology and found that 40% of articles did not clearly describe statistical methods used[25]. Both two studies have pointed out that the articles on urology have relatively large statistical defects, but these two articles only pay attention to whether the use of statistical methods is correct, and do not concern the quality of statistical reporting.

Standardized statistical reports of medical papers not only help editors or reviewers better understand research design to improve the quality of Journal papers, but also enable readers in related fields to better understand the content and results of research to enrich their professional knowledge. Vickers, A. J's research provided a statistical reporting guidelines for articles published or intended to be published in the European Urology[26], but it was not suitable for evaluating the quality of statistical reporting.

The purpose of this study is to describe the frequency and trends of statistical methods.The results can suggest that doctors and medical students in the field of urology should pay more attention to which statistical method of learning. Another important purpose is to assess and compare the quality of statistical reporting of the article in general medical journals and urological journals and further identify the most frequently omit areas of statistical reporting and identify factors related to the quality of high statistical reports. It is expected that the main defect in the statistical reporting will be identified, and provides references for authors, readers, commentators, and journal editors to improve the quality of statistical reporting in urology.

We considered the SAMPL and SIMA evaluation forms at the beginning of the study, but we did not use them in the formal study. Although SAMPL can evaluate the quality of reports in most statistical methods in more detail, it has limitations in some aspects. A major limitation of SAMPL is too complicated to be implemented in actual work. The main limitation of SIMA is that SIMA is used to describe the intensity of the statistical method in the article, but the intensity of the statistical method is not equal to the quality of the statistical report. Our checklist is complemented and optimized on the basis of SAMPL, SIMA, and other previously published studies, not just the repetition of these studies. While the checklist that is proposed in this work is not validated, it is important to emphasize that no validated instrument currently exists.

The strength of our checklist is to absorb the advantage of SAMPL, SIMA and other studies. It cannot only assess the quality of various statistical methods in observational studies in detail, but also be easy to operate in practical work. However, the limitations of our research should be considered. One limitation of our research is that our research is only aimed at the quality of statistical reporting of observational studies, and whether it can be extended to other types of studies remains to be studied. Besides, only the most commonly used statistical methods are included in our checklists, and some rarely used statistical methods are not included.

We hope that the findings of this study will provide urology researchers and journal editors with an opportunity to better understand the most commonly used statistical methods in urology, and call for more transparent reporting of statistical methods to improve the quality of statistical analysis.

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