TABLE OF CONTENTS

- Description  p.1
- Audience  p.1
- Impact Factor  p.1
- Editorial Board  p.1
- Guide for Authors  p.3

DESCRIPTION

The Journal of Foot & Ankle Surgery is the leading source for original, clinically-focused articles on the surgical and medical management of the foot and ankle. Each bi-monthly, peer-reviewed issue addresses relevant topics to the profession, such as: adult reconstruction of the forefoot; adult reconstruction of the hindfoot and ankle; diabetes; medicine/rheumatology; pediatrics; research; sports medicine; trauma; and tumors.

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**The Building Blocks of Good Clinical Evidence**

(1) Explicitly defined research question, population, and endpoints; (2) Randomized treatment allocation and intention-to-treat analysis; (3) Participants and outcomes assessors blind to treatment allocation; (4) Use of a valid health measurement (quality of life) instrument; (5) Power and sample size determined a priori; (6) Statistical analyses compatible with type and distribution of the data; (7) Point estimate and 95% confidence interval reported. (From Turlick MA, Kushner D, Stock D. J Am Podiatri Med Assoc 93:392-398, 2003.)

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Describe members of the investigational team in regard to their participation in the study: (1) If they served as outcome assessors. (2) If they performed an intervention. (3) If they abstracted data from medical records, in the case of a retrospective study.

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At this point in time, however, IRB approval is not required for publication, although it is required that the author disclose whether or not IRB approval was obtained.

**Study Population**
The Methods section provides readers with an explicit description of the participant/patient population and the time period from which they were selected. The time period should delineate the month, year that the period started and the day, month, and year that the period ended (MM/DD/YYYY-MM/DD/YYYY). If the specific day is not know, it is acceptable to just use the month.

For Case Reports and Series and Cohort Studies, state whether or not the participants were enrolled consecutively, and clearly indicate inclusion and exclusion criteria.

Refer to subjects as "participants" if the diagnostic test or intervention is experimental and not yet approved for use by the US FDA. Refer to participants as "patients" for all other tests or interventions that are already known to be therapeutic, safe, and efficacious.

**Intervention**
Explicitly describe the intervention in any investigation.

If participants were randomized to an active therapy that was compared to standard therapy or to a placebo, you must describe each treatment arm.

Avoid presenting a detailed narrative report of an operative intervention for a standard procedure. Instead, cite a reference for that standard procedure. Describe variations on the procedure.

Thoroughly describe all novel interventions, notable variations on standard procedures, decision points related to an intervention, and adjunct procedures.

Use generic drug names where possible. When a brand name is used, include the name, city, state, country of the manufacturer in parentheses immediately after the proprietary name. Whenever medication use is described, provide complete dosing information: dose, method of administration, frequency of use, duration of use.

**Endpoints (Outcomes)**
Explicitly define outcome measures in terms of (1) how the variable was measured, (2) who made the measurement, and (3) whether or not the assessor was blind to the interventional (for an intervention trial).

Clearly state if outcomes were based on physical examination, chart review, telephone interview, questionnaire, radiographic films, or some other method.

Consider for analysis any variable that you consider to be important in regard to the treatment of patients, as it pertains to the investigation

"Hard" endpoints such as analytical measurements, clinical and microbiology laboratory results, and other specific measurements are preferred to "soft" endpoints. If "soft" endpoints such as quality of life (QOL) or foot-related QOL are used, it is preferred that health measurement instruments that have been previously shown to be reliable and provide valid information be used.

A health measurement instrument is not in and of itself valid, although the information gained from the use of the health measurement instrument should be used. QOL instruments should be specific to the foot and ankle (e.g., ACFAS, AOFAS, Bristol Foot Score, Foot Function Index).

Describe an investigator-derived questionnaire in terms of reliability and validity if such testing was undertaken by the investigators or if the questionnaire has been described in a previous publication.

For scales that rank categories (e.g., mild, moderate, severe), use an aggregate score. For measurements of pain, the 10-cm visual analog scale (VAS) is recommended.

**Statistical Methods**
Clearly describe the statistical plan. Include, at minimum, descriptive and inferential statistical analyses. Ideally, also include univariate and multiple variable statistical analyses.

In the descriptive statistical analysis, define parameters such as the measure of central tendency (mean or median average) and measures of dispersion (standard deviation or range).
Select the parameter, as well as the statistical test, based on the type and distribution of data.

Continuous numeric data that are normally distributed are suitable for representation using the mean and standard deviation and may be analyzed using mean-based statistical tests such as Student's t test.

Categorical data and data that are non-normally distributed are suitable for representation using the median and range and may be analyzed using median-based (nonparametric) methods such as the Wilcoxon matched-pairs signed-ranks test, sign test, Wilcoxon rank-sum test, and the Kruskal-Wallis equality-of-populations rank test and other null hypothesis tests and methods of estimation.

Use univariate analyses to describe the association of independent variables with the outcome of interest (dependent variable). Use multiple variable analyses to describe the association of all of the clinically important variables with the outcome of interest.

Present results with only as much precision as is of scientific value. For example, report measures of association (e.g., odds ratios, relative risks, risk differences) to 2 significant digits. Reserve the terms significant and significantly for when describing statistical differences. Do not make the statement "no significant difference was found" between 2 or more groups unless a power analysis was done and the value of alpha (level of significance typically 5% or p value < .05) or beta (the power to detect a statistically significant difference, usually 80% or 90%) is reported. Denote the probability of the null hypothesis using a lowercase italic p separated from the word "value" by a hyphen (specifically p value).

Use of the word “significant” requires reporting of a p value (probability) or, preferably, the 95% confidence interval about a point estimate. 95% confidence intervals are preferred whenever the results of survivor analyses are given in the text, tables, or graphs. Except when 1-sided tests are required by study methodology, such as in noninferiority trials, 2-sided p values should be reported. By convention, Report p values > .01 to 2 decimal places, p values between .01 and .001 to 3 decimal places, and p values < .001 as p < .001. Probabilities should never be reported as p = .000. Furthermore, use of the word “correlation” or the phrase “correlates with” requires that a correlation coefficient be calculated and reported, otherwise terms such as “association” or “associated” should be used.

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The results of a sensitivity analysis, such as that described by Greenland (Maldonado G, Greenland S: Simulation study of confounder-selection strategies. Amer J Epidemiol. 1993; 138: 923–936.), or that described by Rosenbaum (Rosenbaum PR. Sensitivity analysis for matched case-control studies. Biometrics. 1991 Mar; 47(1): 87-100; and, Rosenbaum PR. Discussing hidden bias in observational studies. Ann Intern Med. 1991 Dec 1; 115(11): 901-5.), should be presented for retrospective studies where unmeasured independent variables may have potentially influenced the results.

Additional references that may be useful in regard to the description of the methods and the presentation of a statistical plan include:
Results: The results section should provide quantitative information about the data collected, in the form of descriptive and inferential statistics.

· Relevant information on the study population includes demographic information for each subgroup (control group and study groups), exclusions and attrition. Inferential statistics should be used to compare groups using appropriate statistical tests based on the size of the study population, type of variables under study (discrete vs. categorical), and the distribution of the data collected.

Quantitative information should be summarized in the text, and readers should be referred to relevant tables for more detailed information. As a rule, a minimum of three results tables should be presented, and designated Tables 1, 2, and 3. Table 1 typically depicts the baseline demographic characteristics of the sample population, often categorizing the patients/participants by intervention or outcome, and showing whether or not statistically significant differences existed between the groups. For randomized controlled trials, it is not necessary to depict statistically significant differences at baseline, since randomization distributes the characteristics by chance. Table 2 generally depicts the results of the univariate analyses, and Table 3 generally depicts the results of the multiple variable analyses. All tables must denote the sample size, or subgroup sizes, in the parentheses at the end of the title, or in parentheses in the column heading for each specific group heading. Use upper case "N" for the total, or overall sample size, and lower case "n" for subgroup sizes. For example, a table title might say: "Table 1 A statistical description of the cohort (N = 78 feet in 76 patients)." Or, if subgroups are being described, column headings might say; "Control group (n = 28)" and "Intervention group (n = 34)." Always keep track of denominators when denoting sample sizes. It is very important to include the sample size information in each and every table and figure title or column headings, since readers must be able to determine sample sizes just by looking at the figures and tables.

· For randomized controlled trials, the first figure should be the study flow chart.

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