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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If the study is a clinical investigation involving human participants, use the heading "Patients and Methods." If the study involves animals, cadavers, or in vitro or computer models of any sort, use the heading "Materials and Methods." In general, the Methods section should describe the following elements of the investigation: (1) Aims; (2) Study population; (3) Assessors and other members of the investigational team, population, or sample; (4) Intervention; (5) Endpoints (outcomes); (6) Statistical methods used to determine the meaning of the results.
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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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.

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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.

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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.

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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.

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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.

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Additional references that may be useful in regard to the description of the methods and the presentation of a statistical plan include:


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

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- Consistency and clarity is required when reporting results. As a rule, report means with standard deviations (using the ± symbol) and medians with the range (either minimum and maximum or 25th and 75th percentiles), and always report the proportion of the whole when presenting count data (for instance, “…4 (3.25%) displayed wound dehiscence…”), and report calculations to 2 decimal places.

- It is also crucial that authors remain clear and consistent when they report denominators, with a particular emphasis on clarity in regard to the number of patients versus the number of feet or ankles or extremities, since these numbers vary based on unilateral versus bilateral cases.

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