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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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.

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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.

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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:

Results: The results section should provide quantitative information about the data collected, in the form of descriptive and inferential statistics.

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