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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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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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.

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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.

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

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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.

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