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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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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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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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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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.

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