State of the Literature in Foot and Ankle

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I. EBM is Here to Stay
A. FAI began rating all clinical papers as to their level of evidence (I-V)
B. Levels of Evidence, FAI 2008
C. Level I study is the gold standard for clinical research
   - Level I study is increasingly difficult.
   - JBJS in January 2009 instituted new policy where all randomized controlled trials must be
     registered in a public trials registry acceptable to the International Committee of Medical
     Journal Editors (ICMJE)
   - Recommend that authors follow CONSORT (Consolidated Standards of Reporting Trials)
     with primary results based on intention to treat analysis including accounting for all
     randomized patients.
   - However in today's clinical research environment, Levels II-V still play an important role.
   - IRB approval, especially academic medical centers, have been increasingly onerous due
     to past abuses of the research process (at my institution it is approximately 15 page blank
     application)

II. Scrutiny of Research – Peer Review Process
A. Caveat – Podium presentations are minimally peer reviewed prior to meeting
   - Only abstract is available for program committee to review to decide upon whether to
     have paper presented. No input by program committee as to content as in journal
     submission where authors respond to reviewers queries.
B. Journal Peer Review Process
   - All papers peer review with some rejected upon submission due to lack of
     clinical relevance or Level V papers with no impact other than interesting case.
   - Essentially all papers go through one revision with increasing number going 3
     or 4 submissions.
   - All papers copyedited by editor-in-chief which can lead to further queries or
     modification of language of paper.
   - Ultimately editor-in-chief is responsible for all content of journal.

III. Influence of Industry
   - Authors have been required to declare industry support whether research funding or
     payments directly to any of the authors.
   - Not unusual for authors to claim no industry sponsorship and yet implants for
     biomechanical studies were provided which leads to change in the authors initial
     declaration that they received no research support.
   - Clearly, support from industry influences outcomes overtly or subconsciously and it is up
     to both reviewers/editor-in-chief and readers to decide the level of potential bias.
   - Industry support however is essential to get high quality studies done as there are
     inadequate funds to support high quality research projects.

IV. Many Level IV and V papers still are important and deserve publication.
   - Level IV papers continue to be the most common papers to be published today; if
     properly designed can add to a body of literature.
   - Caveat - no conclusions on best treatment can be made based on Level IV or V study.
   Authors can simply state that the method worked but can not make conclusions regarding
   efficacy vs other treatments. They can discuss their opinions regarding the advantages
of their technique but can not make any solid conclusions.

V. Lack of negative results – virtually all papers report favorable results.
- Unfavorable or poor results should also be published. Only situation where poor results may not merit publication is if an operation or data analysis was performed improperly. (see references below on ankle in high risk population and hallux MP preservation surgery in RA)
- Most surgeons hate dealing with failures clinically and I believe few are interested in “airing their dirty laundry” for fear of others thinking they are “bad surgeons.” It is essential to report bad outcomes if they follow initial favorable publication, however there is no way to “police” this.

VI. Peer Review Process for FAI is as un-biased as possible
A. I personally have had 2 papers rejected for publication over the past year. One was published in May 2010 American Journal of Orthopaedics on syndemosis fixation survey and the other one was rejected for poor results on calcaneocuboid distraction arthrodesis where reviewers felt that it added nothing new to literature.

References

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