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Show-Li Jan, Gwowen Shieh

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The Bland-Altman range of agreement: Exact interval procedure and sample size determination

Show-Li Jan
Department of Applied Mathematics
Chung Yuan Christian University
Taoyuan, Taiwan 32023
Email: sljan@cycu.edu.tw

Gwowen Shieh*
Department of Management Science
National Chiao Tung University
Hsinchu, Taiwan 30010
Email: gwshieh@mail.nctu.edu.tw

Abstract

The Bland-Altman analysis has been widely used to assess the agreement between two quantitative methods of measurement. The range of agreement is thus represented by the designated central proportion of the distribution of the paired differences. This article aims to provide concrete guidance on the use of accurate confidence intervals of the range of agreement. Theoretical examination and numerical comparison are conducted to support the exact approach and to demonstrate the disadvantages of the currently suggested methods for confidence interval estimation of the range of agreement. For the purpose of design planning, the associated sample size calculations for precise interval estimation of the range of agreement are delineated under the expected width and assurance probability considerations. To enhance the utility of the recommended confidence interval and sample size procedures in practical applications, both SAS and R computer algorithms are also developed.

Keywords: limits of agreement; percentile; precision; sample size; tolerance interval

*Corresponding author