

Review Form 1.7

Journal Name:	Asian Journal of Probability and Statistics
Manuscript Number:	Ms_AJPAS_111609
Title of the Manuscript:	On the Confidence Intervals in Bioequivalence Studies
Type of the Article	Original Research Article

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PART 1: Review Comments

	Reviewer's comment	Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
<p>Compulsory REVISION comments</p> <ol style="list-style-type: none"> 1. Is the manuscript important for scientific community? (Please write few sentences on this manuscript) 2. Is the title of the article suitable? (If not please suggest an alternative title) 3. Is the abstract of the article comprehensive? 4. Are subsections and structure of the manuscript appropriate? 5. Do you think the manuscript is scientifically correct? 6. Are the references sufficient and recent? If you have suggestion of additional references, please mention in the review form. <p><u>(Apart from above mentioned 6 points, reviewers are free to provide additional suggestions/comments)</u></p>	<ol style="list-style-type: none"> 1. Maybe. 2. Yes. 3. No. 4. No. 5. Yes. 6. Yes. <p>Additional Comments:</p> <ol style="list-style-type: none"> 1. The paper effectively explains the preference for the geometric mean in bioequivalence studies due to the log-normal distribution of pharmacokinetic parameters. However, it would be beneficial to provide more detailed examples or data to substantiate this point. A comparative analysis showing the impact of using geometric mean versus arithmetic mean on study outcomes could offer clearer insights. 2. The rationale behind the specific bioequivalence limits (0.8, 1.25) and their asymmetry around 1 is well-explained in terms of accommodating variability and error rates. Nonetheless, the paper could be strengthened by including more detailed statistical justifications or historical context on how these limits were established and their evolution over time. 3. The explanation that the product of the BE limits equals 1 to ensure an unbiased ratio on the scale is clear. However, the paper would benefit from a deeper exploration into how this impacts the overall design and interpretation of bioequivalence studies, possibly with illustrative examples or simulations. 4. The paper briefly discusses the intersection-union test theory as the basis for the TOST approach. Expanding on this theory with more mathematical rigor and examples could provide readers with a better understanding of its significance in bioequivalence testing. 5. The paper touches on the power of TOST but does not fully explore scenarios where TOST may not be the most powerful test. A comparison with other statistical tests in terms of power, especially in different sample sizes or variance conditions, could be very enlightening. 6. The distinction between these two confidence interval approaches in bioequivalence testing is a crucial point in the paper. A more detailed mathematical and statistical explanation, perhaps with graphical representations, would aid in understanding why one method is preferred over the other in certain scenarios. 7. The paper provides a comprehensive overview of bioequivalence studies, but the flow 	

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	<p>between sections could be smoother. A more structured approach, leading the reader from basic concepts to complex theories, would enhance readability and understanding.</p> <p>8. While the paper references important studies and guidelines, a broader literature review covering recent advancements and debates in bioequivalence study methodologies could provide a more robust context for the paper's contributions.</p> <p>9. The paper is strong in theory but lacks a discussion on practical implications. Case studies or real-world examples of bioequivalence studies that have employed these statistical methods would greatly enhance the paper's relevance and applicability.</p> <p>10. Finally, it would be beneficial to include a section on future research directions in bioequivalence studies, particularly focusing on emerging challenges and potential methodological innovations.</p> <p>Overall, the paper is well-positioned to make a significant contribution to the field, and addressing these points would greatly enhance its value and impact.</p>	
<p>Minor REVISION comments</p> <p>1. Is language/English quality of the article suitable for scholarly communications?</p>	<p>Yes.</p>	
<p>Optional/General comments</p>		

PART 2:

	Reviewer's comment	Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
<p>Are there ethical issues in this manuscript?</p>	<p><i>(If yes, Kindly please write down the ethical issues here in details)</i></p>	

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