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Bioequivalence Confidence-Interval Interpretation

Practical 19 - Clinical pharmacy case practical

Aim

To interpret a bioequivalence confidence interval with the applicable decision rule.

Principle

A conventional average-bioequivalence analysis uses log-transformed exposure endpoints and back-transformed confidence intervals for test/reference geometric mean ratios. Product-specific or narrow-therapeutic-index requirements can differ.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Verify design, endpoint, analysis population, period/sequence handling and missing-data rules.
4. Review the log-scale treatment estimate, standard error and appropriate confidence interval under the prespecified model.
5. Back-transform and compare the entire interval with the applicable limits for every required endpoint.
6. Explain why a point estimate inside the limits is insufficient.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Calculations

- Geometric mean ratio = exp(log-scale treatment difference)

• Back-transformed CI = exp(lower log limit) to exp(upper log limit)

Worked Example

Illustrative geometric mean ratio 0.98 with 90% CI 0.92 to 1.04 meets a conventional 0.80 to 1.25 interval rule for that endpoint. Ratio 1.00 with CI 0.78 to 1.28 does not.

Apply the actual product and jurisdiction requirements rather than assuming these limits fit every study.

Result and Interpretation

• Deliver endpoint-level interval decisions, model assumptions and the overall evidence gaps.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Why log transform?

Exposure ratios and multiplicative variation are often modelled on the log scale.

Does a nonsignificant difference prove equivalence?

Equivalence needs the prespecified interval within its limits.

Why assess all required endpoints?

Passing one exposure measure may be insufficient.

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