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EDITORIAL

Understanding the Uniformity in Scientific Publications on Blood Pressure Device Validation

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The Role of Standardized Protocols in Study Design

The cornerstone of blood pressure (BP) device validation studies lies in their compliance with the international standard ISO 81060-2, and particularly its 2020 amendment (ISO 81060-2:2018/AMD 1:2020). This universal protocol defines the study design in precise terms, allowing no deviations to ensure consistency and comparability of results across devices. Consequently, all validation studies inherently share identical designs.

For instance, the protocol mandates that the validation be a non-interventional, non-randomized study using a specified number of paired BP measurements from both the tested device and a reference method (typically a mercury sphygmomanometer or equivalent). It further dictates the sequence of BP measurements, the rest periods between readings, and the conditions under which measurements must be taken (eg, same-arm, supported at heart level). These rigid requirements ensure that every study adheres to the same scientific rigor, but they also result in a lack of variability in study design.

This strict standardization is crucial for achieving reliable and reproducible outcomes. Any deviation from the protocol could compromise the validity of the results, rendering the study ineligible for regulatory approval or professional endorsement and publication. Consequently, the similarity in study designs across validation studies is not a matter of choice but an obligation to meet international standards.

Similarity in Study Populations

Another source of uniformity in BP device validation studies arises from the stringent requirements for participant characteristics set forth by the ISO protocol. The protocol specifies not only the total number of participants (usually at least 85) but also their distribution across predefined subgroups. For instance, the population must represent a balanced mix of males and females, specific age ranges, and diverse BP levels. Additionally, it requires participants with varying arm or wrist circumferences to ensure that the device is tested across its intended operational range.

This meticulous stratification ensures that the validation study provides comprehensive data on the device's performance in different demographic and physiological conditions. However, it also leads to the inclusion of highly similar populations across studies, as researchers must recruit participants to fit the same rigid criteria. This uniformity is not a reflection of unoriginality but a necessary step to guarantee that the results are representative and comparable across devices.

Standardized Statistical Analysis and Evaluation Criteria

The ISO 81060-2 protocol also prescribes the statistical methods to be employed and the criteria by which device accuracy is evaluated. The protocol specifies two primary criteria:

Criterion 1: The mean difference between the test device and reference measurements must not exceed ±5 mmHg, with a standard deviation of ≤ 8 mmHg.

Criterion 2: For each individual, the standard deviation of the mean BP differences must fall within specified limits.

These criteria form the cornerstone of the validation process, ensuring a uniform standard of accuracy for all devices. Researchers are required to calculate these metrics using predefined formulas and report them in a prescribed format.

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Additionally, the protocol recommends the use of Bland-Altman scatter plots and specific tabular presentations to visualize and summarize the data.

As a result, the statistical analyses and their presentation in BP validation studies follow a consistent pattern. This uniformity is a direct consequence of the protocol's requirements, which aim to provide transparency and comparability, rather than an indication of a lack of originality or academic misconduct.

Standardized Presentation of Results

The ISO protocol goes beyond defining the study design and analysis; it also dictates the format in which results must be presented. It specifies the type of tables, figures, and even the content to be included in each section of the manuscript. For instance, the results section must include tables summarizing participant demographics, BP ranges, and device accuracy relative to the reference method. Figures such as Bland-Altman plots are mandated to graphically represent the agreement between the test device and the reference method.

The aim of this standardized presentation is to facilitate the interpretation and comparison of results across studies. By adhering to a uniform format, researchers ensure that stakeholders—including regulatory authorities, healthcare professionals, and consumers—can easily assess whether a device meets the required standards. While this standardization might lead to similarities in the visual and textual presentation of results, it enhances the scientific value of these studies by promoting clarity and consistency.

Standardized Reporting of Articles

In addition to prescribing the study design and analysis, the ISO 81060-2 protocol provides detailed guidelines for reporting validation studies. It even includes a recommended template for structuring the corresponding article. This template specifies what information should appear in each section, from the introduction and methods to the results and discussion. The goal is to ensure that all relevant details are reported systematically, leaving no room for ambiguity or selective reporting.

For example, the methods section must detail the study design, population characteristics, and measurement procedures in alignment with the protocol. The results section must present accuracy data in a format that directly corresponds to the evaluation criteria. The discussion should contextualize the findings within the framework of the protocol's requirements.

By adhering to this standardized reporting format, researchers produce articles that are inherently similar in structure and content. This uniformity is not indicative of plagiarism but reflects a commitment to rigorous reporting standards essential for scientific transparency and reproducibility.

Addressing Misconceptions About Plagiarism

Critics who label the similarities in BP device validation articles as plagiarism overlook the unique context of these studies. Unlike other fields where researchers have greater flexibility in designing studies and reporting findings, BP device validation is governed by strict international standards. The uniformity observed in these articles is a testament to the rigorous standardization required to ensure the reliability and comparability of results, not an indication of academic misconduct.

Moreover, the ISO protocol's guidelines for reporting studies serve as a template rather than a prescriptive script. While researchers are required to include specific content, they retain the freedom to discuss their findings and contextualize their results within the broader literature. This balance between standardization and originality ensures that articles maintain scientific rigor without compromising intellectual contribution.

Conclusion

The apparent similarities in articles on BP device validation are a natural consequence of the strict adherence to the ISO 81060–2 protocol, which governs every aspect of these studies, from design and population characteristics to statistical analysis and reporting. Far from being a limitation, this uniformity is a strength that ensures the reliability, transparency, and comparability of validation studies across devices.

Accusations of plagiarism fail to account for the unique requirements of this field, where standardization is not only expected but essential. By following the prescribed guidelines, researchers contribute to the collective goal of ensuring that BP measuring devices meet the highest standards of accuracy and reliability. This commitment to standardization ultimately benefits patients and healthcare providers, fostering trust in the tools used for the critical task of BP measurement.

Disclosure

Professor Asmar is the Editor in Chief of the *Vascular Health & Risk Management* journal and Chairman of the Foundation-Medical research Institutes (F-MRI), Geneva, Switzerland.