FDA INSIGHTS

Optimizing Registry Data Presentation

Understanding and following these guidelines will facilitate appropriate assessment.

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Presentation of data from clinical studies, whether from a single-site experience, a multicenter study, or a national or international registry, should include the basic information needed to clearly describe the strengths and limitations of the database and the data analyses. Without this information, it is not possible to assess the level of certainty that can be associated with the proposed conclusions.

Because national and international registries tend to include relatively large numbers of patients, reports from these databases are often used to address questions of a global nature. Therefore, reports from registries can potentially have a significant impact on the assessment and application of a technology. This article provides a reminder of the types of information that should be included with such reports.

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INFORMATION ON AUTHORS

Ideally, registry data should be analyzed and presented by individuals with minimal bias—possibly those in academia. Of note is that bias can be based on more than just conflicts of interest, such as financial incentives. Geographical influences, such as the proximity to urban areas, the preference for the use of devices from a particular device manufacturer, and one's medical specialty and clinical experience may all influence perception and thus the interpretation of information by an individual. Because it is rare that an author has no financial interest, has no preference for using any particular device, is board certified in multiple medical specialties (as well as having a degree in biostatistics), is proficient in noninvasive, minimally invasive and surgical treatment, and is both a novice and seasoned clinician, bias in authorship cannot be eliminated. Therefore, sources of potential bias should be acknowledged for every publication and/or presentation.

REGISTRY DESIGN

In publications and presentations, it is important to review the purpose of the registry and its design. For example, the following information should be provided: a description of the patient population that was to be enrolled in the registry; the reporting mechanism, including whether routine patient follow-up was required versus only capturing events when patients sought medical attention; the primary and secondary endpoints that were to be the focus of the registry; the duration of anticipated follow-up; and how the data were to be audited.

RESULTS

An adequate description of the baseline characteristics of patients is needed to allow for consideration of the applicability and scope of any conclusions reached from the registry data. This information is typically included in the presentation of data from nonregistry clinical studies, but is not uncommonly omitted in the presentation of registry data.

Often lacking in the presentation of registry data is a description of the amount of follow-up for the patients enrolled in the study. Ideally, registries would have complete follow-up data for each patient ever treated with the device of interest. Unfortunately, it is more common

		Patient follow-up # (%)			Patients with adequate imaging to assess the parameter # (%)				Events occurring before next visit # (%)			
Time of visit	Eligible for visit	Followed	CT	X-ray	Size Increase	Endoleak	Migration	Fracture	Conversion	Death	LTF	Not due for next visit
0			N/A	N/A	N/A							
30 day												
6 month												
1 year												
Additional years												

Figure 1. An example of an endovascular graft study with scheduled patient follow-up.

to have significant amounts of missing data for the relatively small percentage of patients who are ultimately included in the registry. As such, it is imperative that information be provided on the number of patients with data related to each endpoint analyzed.

As an example, for an endovascular graft study with scheduled patient follow-up, the following information should be provided, preferably in tabular form as illustrated in Figure 1: the patients eligible for a visit; the patients seen at the scheduled time; those with CTs and those with x-rays; patients with adequate imaging or paired imaging, as necessary, to assess important parameters such as aneurysm size increase, endoleak, device migration and metallic fractures; patients who were converted to open surgical repair or who died before their next scheduled visit; the patients lost to follow-up; and the patients who are not yet due for their next scheduled visit. The total number of patients who would be available for follow-up at each scheduled visit would be the number who survived since the last scheduled visit without being converted or lost to follow-up and who had been implanted long enough to be due for the visit. Presenting such detail avoids any confusion as to the appropriate denominator in calculating event rates.

ANALYSES

Analyses of registry data that were not specified prior to the start of the trial should be identified as exploratory in the reporting of results. Such notification allows the findings to be viewed with appropriate caution. Given the many variables in typical registries, such as the inclusion of multiple devices and patients with different operative risk levels, subgroup analyses are often warranted. When comparisons between treatment groups are being made, propensity score analyses may be of use in addressing the inherent differences in the groups being compared.

For endovascular graft registries, it is important that data be stratified by device type, regardless of whether the manufacturers or device names are identified. In addition, the author should acknowledge whether there appeared to be important differences in outcomes between devices.

CONCLUSIONS FROM ANALYSES

Recommendations stemming from analyses of registry data should include acknowledgement of the limitations of the analyses. Fair representation of the data and analyses is critical to avoid misinterpretation and possibly inappropriate reactions. For example, it would be unfortunate for a clinician to deny endovascular treatment to all patients with large neck diameters based on a report from a registry that concluded that such individuals were likely to suffer migration of their devices, only to find that the analysis did not take into consideration the sizes of devices available for use at the time of the study. The migrations observed could have been due to undersizing. Alternatively, the difference in rates for patients with large diameter necks as compared to those with smaller diameter necks could have been due to closer surveillance of these patients, or to a small number of such patients being enrolled.

SUMMARY

This article is not intended to be a criticism of the recommendations that have been presented from analyses of registry data. However, the provision of adequate information that would allow an appropriate assessment of study results has been too uncommon. Authors need to be particularly mindful of the potential impact of their recommendations on patient care, and at times, even the regulation of and/or the reimbursement for devices. ■

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