Wall analysis, embryologic, molecular development studies, and computer modeling.

References


Letter to the Editor

An attempt at data verification in the EACTS Congenital Database: data before and after verification differ significantly

Markus Neuhauser*, Nils Lehmann, Michael Nonnemacher, Jürgen Stausberg
Institute for Medical Informatics, Biometry and Epidemiology, University Hospital Essen, Hufelandstr. 55, D-45122 Essen, Germany

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Maruszewski et al. [1] reported on a data verification in the EACTS Congenital Database. Using Source Data Verification, 100% of the 2003 records for nine fields have been checked at five of the largest volume participating centers. Note that ‘data verification is essential to reliability of the database and is best accomplished by Source Data Verification’, as Jacobs [2] pointed out in an editorial comment. Maruszewski et al. [1] reported that no statistically significant differences were found between verified and unverified data. However, on the one hand, the absence of a significant difference is no reason to conclude that there is no difference. In order to demonstrate the absence of a relevant difference one has to reverse the traditional hypotheses in an equivalence test [3].

On the other hand, the main flaw in the statistical analysis of Maruszewski et al. [1] is that tests for the comparison of two independent samples, such as Welch’s t-test, were applied. Obviously, the data before and after verification are paired samples and, consequently, other statistical methods are appropriate.

More than 10% of the deaths (7 out of 68) were missed. With the number of patients of 1703 the proportion of correct entries is (1703−7)/1703 = 0.9999. The corresponding 95% confidence interval for this proportion [4] is 0.9915−0.9983. Since this interval does not include 1 the found proportion is significantly different from a completely correct registration of deaths.

Beside the mortality, the length of hospital stay is another important variable [2]. The comparison of data before and after verification should be performed with a paired t-test rather than Welch’s t-test. Unfortunately, the raw data necessary to carry out the paired t-test are not available. However, the values given in Table 5 [1] enable a power calculation. With the observed difference of approximately 0.5 days (15.782−15.276) and the observed standard deviation of approximately 23 days the power of a paired t-test (two-sided, significance level 0.05) to detect a difference is 80% under the assumption that the correlation between the values before and after verification is 0.95. Hence, it is very likely that there is a significant difference between the data before and after verification in length of stay. Three out of the other five variables reported in Table 5 [1] have, based on the observed differences and a correlation of 0.95, a power of even more than 80%. These three variables are aortic cross-clamp time, circulatory arrest time, and cardiopulmonary bypass time. Only the demographic variables age and body weight have a power lower than 80%.

Moreover, in our opinion, it would be important to know how large the proportion of errors is for the continuous variables, and how the errors are distributed. This information may help to detect systematic errors.

In summary, there is some evidence that the comparison pre-verification versus post-verification would be significant with regard to mortality and some operative details when appropriate statistical methods were applied. This has important consequences on the reliability of the database.

References


* Corresponding author. Tel.: +49 201 723 4462; fax: +49 201 723 5933. E-mail address: markus.neuhaeuser@uk-essen.de (M. Neuhaeuser).

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