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Reducing bias in observational studies

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Editorial

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A randomized controlled trial (RCT) is considered the “gold standard” for clinical studies; however, RCT is not always possible. It would be unethical to expose study participants if there are concerns about negative effects or complications of treatment [1]. Observational studies can be a valuable alternative in such circumstances. With the advent of electronic medical records, some studies may be conducted using existing databases.

However, if the nature of observational data is not from the random group distribution, results in each study can differ due to confounding variables. To control for confounding factors arising from a lack of comparability between groups in observational studies, methods such as matching, stratification, multivariate regression, propensity score (PS), and instrumental variable analysis can be employed [2]. Among them, PS and propensity score matching (PSM) methods are widely used to reduce selection bias. PS represents the probability of the subject belonging to the comparable population based on characteristics. PSM allows unbiased estimation of treatment effect adjusted for confounding factors in observational studies [3]. PSM has become a widely used statistical analysis method in epidemiological or observational studies [4]; a review of the last five years of publications by the *Korean Journal of Anesthesiology* (KJA) reveals that six clinical observation studies describe the application of PSs on real data [5–10].

In the August 2020 statistical round issue of the KJA, De Cassai et al. [11] briefly reviewed the PS. They used simple examples to provide definitions of PS, its adequacy, adjustment methods, and its limitations. Their article has showns an example where results are unreliable because there are significant differences between groups of confounders, which may affect outcomes in the observational study. PSM creates a new population that is not influenced by identified confounders, leading to an unbiased estimation of the treatment effects.

Although PSM is a powerful method to increase the strength of observational studies, it also has many limitations and disadvantages [12]. Firstly, in observational studies, the true PS can never be known and investigators can therefore never be certain that the PSM is accurate. PSM can only be applied on the variables that are collected. There may be residual bias as the remaining uncollected variables could affect treatment assignment. Secondly, the amount of missing data is a major limitation of observational datasets, which can interfere with PS. The number of matched patients may be limited in smaller datasets.

Observational studies can be used in situation which RCTs are inappropriate, but it lack randomization. To overcome this disadvantage, PSM method is widely used. Although PSM has some limitations, it reduces selection bias across many potential differences between groups selected for specific treatment in observational clinical studies.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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