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New software for computation sensitivity analysis to detect hidden bias for partially order set test statistic in observational studies

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Abstract

In observational studies, subjects are not randomly assigned to treatment or control, so they may differ in their chances of receiving the treatment. In this study we designed new software for a method is developed and demonstrated for displaying the sensitivity of conventional two-unmatched group permutation inferences to departures from random assignment of treatments for partially order set test statistic in observational studies. We designed an algorithm with visual FORTRAN (SENPOSET) program for calculating the sensitivity analysis for detects hidden biases in observational studies. The method embeds the usual randomization reference distribution in a one-parameter family of departures involving an unobserved covariate that would have been controlled by adjustments had it been observed. As this parameter is varied, the sensitivity of permutation significance levels and confidence intervals is displayed. This program indicates that the proposed algorithm performs well in identifying sensitivity to unobserved biases and comparisons vary considerably in their degree of sensitivity.

Keywords: sensitivity analysis, hidden biases, observational studies, computational statistics;

1. Introduction

Randomized controlled trials (RCTs) provide the strongest evidence for the efficacy of preventive and therapeutic procedures in the clinical setting.1 In RCTs, subjects are randomized to a treatment or control group. By the very nature of chance, random assignment tends to balance covariates, so that there are not systematic differences (bias) in measured and unmeasured covariates between subjects assigned to treated and control group [1]. If there are unobserved variables that simultaneously affect assignment into treatment and the outcome variable, a hidden bias might arise to which matching estimators are not robust [2]. Since estimating the magnitude of selection bias with no experimental data is not possible, we address this problem with the bounding approach proposed by Rosenbaum [2].The basic question is whether unobserved factors can alter inference about treatment effects. One wants to determine how strongly an unmeasured variable must influence the selection process to undermine the implications of the matching analysis. Sensitivity analyses provide evidence on the degree to which any significance results hinge on this untestable assumption. If the results turn out to be sensitive, the researcher might have to think about the validity of his identifying assumption and consider other estimation strategies.

DiPrete and Gangl [3] provide an ado-file (rbounds) that lets the researcher test sensitivity for Wilcoxon rank test as well as Becker and Caliendo[4] introduced sensitivity analysis for binary outcome(mbounds), whereas our

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command SENPOSET focuses on rank test for Partially Ordered Outcomes , which are often used to test the null hypothesis of no treatment effect against the alternative that treated units tend to have higher responses than controls in the sense of partial order on the outcomes. You can find this approach in [5] and [2]. I outline this approach briefly in section 2 and 3. Section 4 presents the options of SENPOSET and, we illustrate the command with some examples.

2. Methodology*:*

Rosenbaum's method of sensitivity analysis in observational study relies on the sensitivity parameter Γ that measures the degree of departure from random assignment of treatment. Two subjects with the same observed characteristics may differ in the odds of receiving the treatment by almost a factor of Γ . In a randomized experiment, randomization of the groups ensures that $\Gamma = 1$. In an observational study ,if $\Gamma =2$, and two subjects are same on observed covariates then one might be twice as likely as the other to receive the treatment because they differ in terms of an unobserved covariate[6]. If a study is free of hidden bias, then the probability π_j , that unit j receives the treatment is a function of the observed covariates x_j that describe unit j. There is hidden bias if two units with the same values on x have differing chances of receiving the treatment, that is, if $x_J = x_K$ but $\pi_i \neq \pi_k$ for some j and k. In a sensitivity analysis, we ask how large the difference sin π would need to be to change our basic inference. We do this through the use of the odds ratio. The odds that units j and k receive the treatment are, respectively, $\pi_j /(1-\pi_j)$, and the same being true for unit k. imagine that we knew that this odds ratio for units with the same x was at most :

$\frac{1}{\Gamma} \leq \frac{\pi_j(1-\pi_j)}{\pi_k(1-\pi_k)} \leq \Gamma$ for all j,k with $x_J = x_K$.

If the value for Γ is one then this implies that the odds ratio of treatment is the same and the study would be free of hidden bias. If $\Gamma = 2$ then two units that have the same values of x could differ in their odds of receiving treatment by as much as a factor of 2. Therefore one unit would be twice as likely to receive the treatment as the other unit. In sensitivity analysis, Γ is a measure of the degree of departure from a study that is free of bias. Therefore the sensitivity analysis will consider several values of Γ and describe how the inference might change.
Another way to think about this is in terms of an unobserved covariate. Characteristics that are not in x were not controlled for when we matched. We might call this unobserved covariate u. We can change the model above in terms of this unobserved covariate. Suppose that unit j has observed covariates x and an unobserved covariate u_j .

We can write a logit form linking treatment assignment to the covariates (x_j, u_j) , namely:

$$\log\left(\frac{\pi_j}{1-\pi_j}\right) = k(x) + \gamma u_j \qquad 0 \leq u_j \leq 1$$

Where, $k(.)$ is an unknown function and γ is an unknown parameter [2, 5].

If unit's j and k have the same observed covariate x then $x_j = x_k$ and we can write the ratio of the odds that unit's j and k receive the treatment $\frac{\pi_j /(1-\pi_j)}{\pi_k /(1-\pi_k)} = \exp\{\gamma(u_j - u + k)\}$.

Here two units with the same x values differ in their odds of receiving the treatment by a factor that involves the parameter γ and the difference in the unobserved covariate. Rosenbaum [2] showed that the two statements of unobserved bias are the same. Therefore we can think if Γ as the size of log of the coefficient for the unobserved covariate u . The larger it is the more likely our inference will change due to the magnitude of the hidden bias. Under this model, sharp bounds on the significance level ($p-value$) ,may be obtained given our uncertainty about the unobserved u .for Γ =1,the upper and lower bounds are both equal to the conventional randomization significance level, but as Γ increases, the bounds move apart, reflecting uncertainty about u . Therefore, we can also see how the magnitude of the treatment effect changes with an increasing Γ .Each sensitivity test is built to one a