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ASSESSING SENSITIVITY TO AN UNOBSERVED BINARY COVARIATE IN A NO--ETC(U)

JAN 82 P R ROSENBAUM; D B RUBIN

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IN A NONRANDOMIZED EXPERIMENT
WITH BINARY OUTCOME

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and
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ABSTRACT

The results of nonrandomized clinical experiments are often disputed because patients at greater risk may be overrepresented in some treatment groups. This paper proposes a simple technique providing insight into the range of plausible conclusions from a nonrandomized experiment with binary outcome and observed categorical covariate. The technique assesses the sensitivity of conclusions to assumptions about an unobserved binary covariate relevant to treatment assignment, and is illustrated in a medical study of coronary artery disease.

AMS (MOS) Subject Classification: 62P99, 62J05, 62F12, 62F11

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ASSESSING SENSITIVITY TO AN UNOBSERVED BINARY COVARIATE
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Paul R. Rosenbaum* and Donald B. Rubin**

1. INTRODUCTION AND NOTATION

Inevitably, the results of clinical experiments are subject to dispute. In nonrandomized experiments, one basis for dispute is obvious: since patients were not assigned to treatments at random, patients at greater risk may be overrepresented in some treatment groups. This paper proposes a method for assessing the sensitivity of conclusions to an unmeasured patient characteristic relevant to treatment assignment. Despite their limitations, nonrandomized experiments will continue to be performed, and therefore it is prudent to develop appropriate methods of analysis for them.

Our sensitivity analysis consists of the estimation of the average effect of a treatment on a binary outcome variable after adjustment for observed categorical covariates and an unobserved binary covariate u , under several sets of assumptions about u . Both Cornfield, et. al (1959) and Bross (1966) have proposed guidelines for determining whether an unmeasured binary covariate having specified properties could explain all of the apparent effect of a treatment; i.e., whether the treatment effect, after adjustment for u , could be zero. Our method has two advantages: first, Cornfield, et. al.

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(1959) and Bross (1966) adjust only for the unmeasured covariate u , whereas we adjust for measured covariates in addition to the unmeasured covariate u ; second, Cornfield, et. al. (1959) and Bross (1966) only judge whether the effect of the treatment could be zero having adjusted for u , whereas we provide an actual estimate of the treatment effect adjusted for u as well as the observed categorical covariates.

In principle, the i^{th} of the N patients under study has both a binary response r_{1i} that would have resulted if he had received the new treatment, and a binary response r_{0i} that would have resulted if he had received the control treatment. In this formulation, treatment effects are comparisons of r_{1i} and r_{0i} , such as $r_{1i} - r_{0i}$. Since each patient receives only one treatment, either r_{1i} or r_{0i} is observed, but not both. Therefore, comparisons of r_{1i} and r_{0i} imply some degree of speculation. Treatment effects defined as comparisons of the two potential responses, r_{1i} and r_{0i} , of individual patients are implicit in Fisher's (1953) randomization test of the sharp null hypothesis that $r_{1i} = r_{0i}$, $i = 1, \dots, N$. Such definitions are used explicitly by Kempthorne (1952) in his discussion of randomization based inference, and by Rubin (1977, 1978), Hamilton (1979), and Rosenbaum and Rubin (1981) in discussions of observational studies. (The definition does contain some implicit assumptions, such as the assumption of noninterference between patients; see Cox (1958, chapter 2) or Rubin (1978, section 2.3) for discussion.) Here, the N patients in the study are viewed as a simple random sample from some population, and the average treatment effect is defined as

$$E(r_1) - E(r_0) = \text{prob}(r_1 = 1) - \text{prob}(r_0 = 1) = \tau_1 - \tau_2, \text{ say} \quad (1.1)$$

where $E(\cdot)$ and $\text{prob}(\cdot)$ denote expectation and probability, respectively, in the population.

For the i^{th} patient of N patients in the study ($i = 1, \dots, N$) let z_i be the indicator for treatment assignment, and let $z_i = 1$ if patient i is assigned to the new treatment, and $z_i = 0$ if patient i is assigned to the control treatment. Suppose that patients have been stratified or subclassified into one of J strata on the basis of observed covariates, and that patient i falls in stratum s_i . The population model for the stratifying variable s is assumed to be a saturated multinomial.

In a stratified randomized trial, treatment assignment z_i and response (r_{1i}, r_{0i}) are known to be conditionally independent given the stratum s_i , or in Dawid's (1979) notation:

$$(r_{1i}, r_{0i}) \perp\!\!\!\perp z_i \mid s_i, \quad (1.2)$$

i.e., within strata, treatment assignment is "random". Condition (1.2) is not known to hold in a nonrandomized experiment. Generally, we shall say treatment assignment is strongly ignorable given some set of covariates v if

$$(r_{1i}, r_{0i}) \perp\!\!\!\perp z_i \mid v_i.$$

For brevity, when treatment assignment is strongly ignorable given the observed covariates (i.e., when as in a randomized experiment, (1.2) holds), we shall say simply that treatment assignment is strongly ignorable.

(Technical Note: If treatment assignment is strongly ignorable, then it is ignorable in Rubin's (1978) sense, which only requires that the probabilities be evaluated at observed outcomes; however, the reverse is not true since strongly ignorable implies the relationship among probabilities must hold for all possible values of the random variables.)

We develop and apply a method to aid in judging the sensitivity of conclusions to certain plausible variations in assumptions about an unobserved binary covariate u . In particular, we assume that treatment assignment is not strongly ignorable given s , but is strongly ignorable given s and

u ; i.e., that (1.2) is false, but instead that

$$(r_{1i}, r_{0i}) \perp\!\!\!\perp z_i \mid s_i, u_i \quad (1.3)$$

is true. If conclusions are insensitive over a range of plausible assumptions about u , the number of interpretations of the data is reduced, and causal conclusions are more defensible.

2. AN EXAMPLE USING DATA ON CORONARY ARTERY DISEASE

Before presenting the model underlying the sensitivity analysis, we show the results of applying it to an example concerning symptomatic relief from coronary artery disease.* Treatment 1 is coronary artery bypass surgery; treatment 2 is medical therapy. The response (r_1, r_0) is functional improvement six months after cardiac catheterization, with $r_t = 1$ signifying improvement under treatment t , $t = 0, 1$, and $r_t = 0$ signifying no improvement.

Here, patients are stratified by the multivariate method described in Rosenbaum and Rubin (1981) that balances 74 observed covariates. The observed proportion improved within each stratum is displayed in Table 1. In examining this table, it must be remembered that there exists evidence for a placebo effect of bypass surgery (Benson and McCalie (1979)).

When treatment assignment is strongly ignorable given the stratum s , then direct adjustment with stratum total weights yields the maximum likelihood estimate of the average treatment effect (1.1) under the saturated multinomial model for s . The directly adjusted proportions improved are .36 for medicine and .67 for surgery, with standard errors .04 and .05 respectively (calculated following Mosteller and Tukey, 1977, ch. 11c).

In order to study the sensitivity of estimates to the assumption of strongly ignorable assignment (i.e. to assumption (1.2)), we now assume that treatment assignment is not strongly ignorable, but rather that treatment assignment is strongly ignorable given s and u (i.e. that assumption (1.3) holds), where u is an unobserved binary covariate. Table 2 displays the sensitivity of the estimate of the average treatment effect to 12 sets of assumptions about u . The method used to derive Table 2, and the symbols that appear in Table 2, will be mathematically defined in the next section.

* The data are used to illustrate methodology, and do not constitute a study of coronary artery disease.

Table 1

Proportion of Patients Improved at 6 Months In Each Stratum

Stratum*	Treatment	Number of Patients	Proportion Improved	Standard Error
1	Medical	277	.35	.03
	Surgical	26	.54	.10
2	Medical	235	.40	.03
	Surgical	68	.70	.06
3	Medical	205	.35	.03
	Surgical	98	.70	.05
4	Medical	139	.30	.04
	Surgical	164	.71	.04
5	Medical	69	.39	.06
	Surgical	234	.70	.03

* The strata were constructed by the method of Rosenbaum and Rubin (1981) in which the conditional probability of surgical treatment given the observed covariates is estimated, and patients with similar estimated probabilities are placed in the same stratum. The strata are predictive of treatment assignments; they are not prognostic strata. This method balances observed covariates within each stratum.

Roughly speaking, α is the increase in the log odds of surgery associated with $u = 1$ rather than $u = 0$; δ_t is the increase in the log odds of improvement under treatment t associated with $u = 1$; and π defines the marginal distribution of u by $\pi = p(u=0)$.

In Table 2, the estimates of the proportion improved vary from .34 to .38 for medicine and from .63 to .70 for surgery; this range of values is about the same as the standard error of the directly adjusted proportions (i.e., .04 for medicine, .06 for surgery). Consequently, we see that this hypothetical, unobserved covariate u , which has defied the cardiologists' attempt to record all variables used in assigning treatments, would have to more than triple the odds of surgery and more than triple the odds of improvement, before altering the conclusion that the proportion improved under surgery far exceeds the proportion improved under medicine. Although this difference may reflect a placebo effect of surgery, the difference does not seem to be easily explained as the result of an imbalance due to the nonrandomized nature of the study.

Another way of describing this analysis is to say that we have explored the extent to which the data might be an example of Simpson's paradox. For discussion from this perspective, see Lindley and Novick (1981).

Table 2

Effects of an Unobserved Two-Category Variable u on the Probability of Substantial Improvement at 6 Months for Medical (M) and Surgical (S) Patients

Effect of u=1 vs u=0 on Treatment Assignment z Effect of u=1 vs u=0 on Improvement r_t .1 .5 .9 (t.e. =)

doubles the odds of surgery	halves the odds of improvement	M .36 S .67	M .35 S .68	M .36 S .68
$\exp(\alpha) = 2$	$\exp(\delta_t) = .5$			
..	doubles the odds of improvement	M .36 S .66	M .37 S .65	M .36 S .66
	$\exp(\delta_t) = 2$			
triples the odds of surgery	reduces by 2/3 the odds of improvement	M .35 S .68	M .34 S .70	M .35 S .69
$\exp(\alpha) = 3$	$\exp(\delta_t) = 1/3$			
	triples the odds of improvement	M .37 S .66	M .38 S .63	M .37 S .65
	$\exp(\delta_t) = 3$			

3. THE MODEL AND THE MAXIMUM LIKELIHOOD ESTIMATE

This section describes the model underlying the sensitivity analysis in Table 2; section 4 describes computational procedures. The principal result of this section is the derivation of the maximum likelihood estimate of the average treatment effect (1.1).

Assume treatment assignment is strongly ignorable given s and u (i.e., assume (1.2)). Let π define the marginal distribution of the unobserved covariate u by

$$\begin{aligned} p(u=0) &= \pi \\ p(u=1) &= 1 - \pi \end{aligned}$$

where for convenience u is assumed independent of s ; i.e.,

$$u \perp\!\!\!\perp s. \quad (3.1)$$

As stated previously, the population distribution of the stratifying variable is assumed to be a saturated multinomial for the J possible values of s .

Assume, for treatment assignment

$$p(z|s,u) = \frac{\exp\{z(\gamma_s + \alpha u)\}}{1 + \exp\{\gamma_s + \alpha u\}}, \quad (3.2)$$

and assume for response under treatment t , $t = 1, 2$

$$p(r_t=1|s,u) = \frac{\exp\{r_t(\beta_{st} + \delta_t u)\}}{1 + \exp\{\beta_{st} + \delta_t u\}}, \quad (3.3)$$

where $\gamma_s, \beta_{st}, s = 1, \dots, J, t = 0, 1$, are parameters to be estimated, and $\alpha, \delta_0, \delta_1, \pi$ are parameters assigned values for the sensitivity analysis.

In words, the parameter α defines the relationship between the unobserved covariate u and treatment assignment z ; the parameter δ_t defines the relationship between u and the response r_t to treatment t , $t = 0, 1$. Within every stratum, $u = 1$ increases the log odds of receiving treatment 1 by the same amount α . Similarly, within every stratum, $u = 1$ increases the log odds of improvement under treatment t (i.e., of $r_t = 1$) by the same amount δ_t . (The development below can also be immediately applied to the case where π , δ_t and α are replaced by stratum dependent parameters π_s , δ_{st} , and α_s , which, in particular, do not satisfy assumption (3.1); however, this more general formulation introduces too many sensitivity parameters for many practical applications.)

For fixed values of the sensitivity parameters, α , δ_0 , δ_1 , π , the maximum likelihood estimates (mle's) of the $3J$ parameters γ_s , β_{s0} , β_{s1} , $s = 1, 2, \dots, J$, do not have a simple, closed form. However, there are $3J$ parameters that are a 1-1 function of γ_s , β_{s0} , β_{s1} that do have simple, explicit mle's, namely, $p(z=0|s)$, $p(r_0=0|z=0,s)$ and $p(r_1=0|z=1,s)$. We first derive the relationship between these two sets of parameters, then display the explicit mle's for the second set of parameters, and finally describe how to solve for the mle's of γ_s , β_{s0} , β_{s1} . Section 4 provides details for computing these solutions.

For $s = 1, \dots, J$,

$$\begin{aligned}
 p(z=0|s) &= \pi p(z=0|s, u=0) + (1-\pi)p(z=0|s, u=1) \\
 &= \frac{\pi}{1+\exp[\gamma_s]} + \frac{(1-\pi)}{1+\exp[\gamma_s+\alpha]} \quad (3.3)
 \end{aligned}$$

Furthermore, using assumption (1.3) we have

$$\begin{aligned}
 p(r_t=0|z=t, s) &= & (3.4) \\
 p(r_t=0|s, u=0)p(u=0|z=t, s) \\
 &+ p(r_t=0|s, u=1)p(u=1|z=t, s) \\
 &= \frac{w_{sz}}{1+e^{\beta_{st}}} + \frac{1-w_{sz}}{1+e^{\beta_{st} + \delta_t}}
 \end{aligned}$$

$$\begin{aligned}
 w_{sz} = p(u=0|z, s) &= \frac{\frac{\pi \exp[z\gamma_s]}{1 + \exp[\gamma_s]}}{\frac{\pi \exp[z\gamma_s]}{1 + \exp[\gamma_s]} + \frac{(1-\pi) \exp[z(\gamma_s + \alpha)]}{1 + \exp[\gamma_s + \alpha]}} & (3.5) \\
 &= \frac{\pi}{\pi + (1-\pi) \frac{e^{z\alpha} [1+e^{\gamma_s}]^{\gamma_s}}{1 + e^{\gamma_s + \alpha}}}
 \end{aligned}$$

Note that the w_{sz} 's define the conditional distribution of the unobserved covariate u given the observed treatment assignment.

Since r_{ti} is observed only if $z = t$, the likelihood of the observed data is

$$\prod_{i=1}^N p(r_{ti}|z_i = t, s, \gamma_s, \beta_{st})p(z_i = t|s, \gamma_s)p(s) .$$

For specified $(\alpha, \delta_0, \delta_1, \pi)$, the model is saturated, so the mle's of $p(r_{ti}|z_i = t, s, \gamma_s, \beta_{st})$, $p(z_i = t|s, \gamma_s)$ and $p(s)$ are the corresponding observed proportions: the mle of $p(s = j)$ is the proportion $\hat{p}(s=j)$ of patients in stratum j , the mle of $p(z=0|s)$ is the observed proportion $\hat{p}(z = 0|s)$ of patients receiving treatment 0 in stratum s , and for $t = 0$

and 1, the mle of $p(r_t=0|z=t,s)$ is the observed proportion $\hat{p}(r_t = 0|z = t, s)$ of patients with response $r_t = 0$ among patients who received treatment $z = t$ in stratum s .

For each stratum s , equation (3.3) with $\hat{p}(z = 0|s)$ substituted for $p(z = 0|s)$ may be solved for the mle of γ_s , without reference to any other equation. Having found $\hat{\gamma}_s$ and calculated \hat{w}_{st} , equation (3.4) with $\hat{p}(r_t = 0|z = t,s)$ substituted for $p(r_t = 0|z = t,s)$ may be solved for $\hat{\beta}_{st}$ without reference to any other equation. Since equations (3.3) and (3.4) are of the same general form, a single one dimensional Newton-step algorithm yields maximum likelihood estimates of the parameters $\gamma_s, \beta_{s0}, \beta_{s1}$, $s = 1, \dots, J$.

The mle of the average response to treatment t in stratum s is

$$\begin{aligned} \hat{p}(r_t=0|s) &= \hat{p}(r_t=0|s, u=0)\pi + (1-\pi)\hat{p}(r_t=0|s, u=1) \\ &= \frac{\pi}{1+e^{\hat{\beta}_{st}}} + \frac{1-\pi}{1+e^{\hat{\beta}_{st}+\delta_t}} \end{aligned}$$

Thus, the mle of the average response τ_t to treatment t is given by the directly adjusted rate

$$\hat{\tau}_t = \sum_{j=1}^J \hat{p}(r_t=0|s=j)\hat{p}(s=j) \quad (3.6)$$

where $\hat{p}(s=j)$ is the proportion of patients in stratum j . Values of the estimator $\hat{\tau}_t$ are displayed in Table 2 for our data and various assumptions about the sensitivity parameters $(\pi, \alpha, \delta_1, \delta_2)$.

4. MAXIMUM LIKELIHOOD COMPUTATIONS

Equations (3.3) and (3.4) are both of the form

$$p = \frac{a}{1+e^{\theta}} + \frac{1-a}{1+e^{\theta+b}} \quad (4.1)$$

To find θ for fixed a, b and p , we use the following Gauss-Newton iteration

$$\theta_{n+1} = \theta_n + \frac{\frac{1-a}{1+e^{\theta_n+b}} + \frac{a}{1+e^{\theta_n}} - p}{\frac{(1-a)e^{\theta_n+b}}{\theta_n+b^2} + \frac{ae^{\theta_n}}{\theta_n^2}} \quad (4.2)$$

The iteration (4.2) can be easily programmed on a pocket calculator.

To calculate $(\hat{\gamma}_s, \hat{\beta}_{s0}, \hat{\beta}_{s1})$ for fixed $(\pi, \alpha, \delta_1, \delta_2)$:

- a) Solve (3.3) for $\hat{\gamma}_s$ using (4.2) with $p = \hat{p}(z=0|s)$, $a = \pi$, $b = \alpha$.
- b) For $t = 0, 1$ find \hat{w}_{st} using (3.5).
- c) For $t = 0, 1$ solve (3.4) for $\hat{\beta}_{st}$ using (4.2) with $p = \hat{p}(r_t=0|z=t, s)$, $a = \hat{w}_{st}$, $b = \delta_t$.

Steps a, b, and c are repeated for $S = 1, \dots, J$ and the results combined using (3.6).

Although the iteration (4.2) can easily be performed using a hand calculator, a simple closed form approximation is convenient for obtaining a good starting value, especially if many sensitivity analyses are to be performed. Specifically, the solution θ of equation (4.1) can be closely approximated by a Taylor approximation, providing $.05 < p < .95$.

Define L as the logit

$$L = \log_e \frac{1-p}{p}$$

so

$$\frac{1}{1+e^L} = p$$

Equation (4.1) may be rewritten

$$0 = \frac{a}{1+e^\theta} + \frac{1-a}{1+e^{\theta+b}} - \frac{1}{1+e^L} \quad (4.3)$$

Implicit differentiation (e.g., Hildebrand (1962), page 339) of (4.3) yields

$$\frac{\partial \theta}{\partial p} = \frac{\frac{e^L}{(1+e^L)^2}}{\frac{ae^\theta}{(1+e^\theta)^2} + \frac{(1-a)e^{\theta+b}}{(1+e^{\theta+b})^2}}$$

At $\theta = 0$, p equals

$$\frac{a}{2} + \frac{1-a}{1+e^b} = p_0, \text{ say}$$

and therefore L equals

$$\log_e \frac{1-p_0}{p_0} = L_0, \text{ say}.$$

Expanding around L_0 yields the closed form approximation

$$\theta = \frac{\frac{e^{L_0}}{(1+e^{L_0})^2}}{\frac{a}{4} + \frac{(1-a)e^b}{(1+e^b)^2}} (L-L_0) \quad (4.4)$$

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