

Selection Bias Adjustment: Root Canal Therapy and Self-reported Oral Health

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ABSTRACT

Observational studies allow evaluation of treatments for which randomization is not possible, but may yield biased estimates of treatment effects. Sample selection modeling was developed in economics, to adjust for bias due to observed and unobserved variables that are related both to selection into a particular treatment group and to the outcome measure. Originally, this method was limited to the analysis of a single continuous outcome measure in cross-sectional study designs, but has been extended to binary and longitudinal outcomes. The effect of adjustment for sample selection bias was evaluated for a specific treatment, root canal therapy, on a range of oral health outcomes, using data from 24 months of follow-up in the Florida Dental Care Study. Results of analyses with and without bias adjustment were compared. Statistically significant bias was found in 11 of 18 analyses, but adjustment changed the statistical decision for treatment in only two analyses..

INTRODUCTION

Traditionally, the randomized clinical trial has been considered the gold standard for evaluating the outcomes of medical treatment. However, this type of study may not always be the protocol of choice, for reasons based on either practical or ethical constraints, and a non-randomized observational study design may provide the only option for conducting the research. In human subjects research, randomization may not be possible. This is often the case if subjects self-select into groups which are not subject to randomized assignment, such as smoking or non-smoking status. Even if it is possible to identify a group of subjects who could be randomized to groups based on criteria that are typically self-determined, such as receiving or declining a particular dental treatment, this pool of potential subjects may be systematically different from the population that is actually of interest. For example, the results of some clinical trials that are of direct relevance to dental practice have received criticism that care is delivered under ideal, atypical conditions¹, and that exclusion criteria eliminate “many if not most of the types of patients treated in the real world of clinical practice”². These criteria have typically excluded population groups that dental research should make a point of including: diverse groups with high levels of disease and/or its consequences. We also note conclusions from two separate studies published recently in the *New England Journal of Medicine*: 1) “The results of well-designed observational studies (with either a cohort or a case-control design) do not systematically overestimate the magnitude of the effects of treatment as compared with those in randomized, controlled trials on the same topic”³; and 2) “We found little evidence that estimates of treatment effects in observational studies reported after 1984 are either consistently larger than or qualitatively different from those obtained in randomized, controlled trials”⁴.

In a review of research needs, it was concluded that “The number of untested interventions is too large to rely on traditional randomized clinical trials to assess efficacy as a first step in determinations of effectiveness, so this usual sequence may be shortened by initiating direct tests of effectiveness in quasi-experimental large-scale studies”¹. We judge that this is especially true for diverse population groups of special relevance to oral health disparities, such as African-Americans, persons of low socioeconomic status, and subjects whose approach to use of dental services is problem-oriented rather than based on regular attendance. For these reasons, non-randomized observational studies remain an important tool in dental research, and may provide an alternative to an elusive gold-standard design. This project is intended to contribute to improving the utility of non-randomized observational studies, by evaluating and adjusting for bias that may occur due to the self-selected nature of the comparison groups.

Observational studies present estimation and analysis issues in addition to those present in randomized studies. Because subjects are not randomly assigned to receive treatment or not, observed group effects are likely to be confounded by characteristics, observed or not observed, other than the group difference that is of interest. This confounding leads to a potential for biased estimation of treatment differences. The bias resulting from this confounding is known as “sample selection bias.”⁵ Having been developed in the econometrics literature⁶, the conception and analysis of sample selection bias is surprisingly under-studied in the health research literature. The only reports evaluating or adjusting for selection bias in the dental literature are from the Florida Dental Care Study (FDCS), which provides the data set for the current grant application.

The field of oral health and dental care offer major advantages for research in this methodologic area, providing ideal scenarios in which to investigate the effect of selection bias. The dental care sector itself comprises a significant part of the overall health care market (approximately \$66 billion in 2001⁷). Additionally, the dental care sector treats multiple types of diseases and conditions, which range from those that would be apparent to patients, to those that

would only be evident to a clinician^{8,9,10,11}. Dental care also comprises multiple types of diagnostic and treatment services, which range from treatment choices that all clinicians would agree upon (e.g., excision of a pathologic lesion), to multiple treatment options for the same clinical circumstance (e.g., options to restore missing teeth), to treatment that is done for entirely discretionary reasons (e.g., for esthetic reasons).

Preliminary evidence from the Florida Dental Care Study (FDCS) suggests that selection bias differs for at least one aspect of oral health-related quality of life; namely, recovery from chewing difficulty¹². A variety of dental symptoms and characteristics were evaluated as predictor variables, with and without adjustment for selection bias. The amount of bias that was found differed considerably among the different predictor variables. Selection bias may also differ by type of treatment and by the particular oral health outcome being evaluated. The FDCS provides a data set that is particularly suited to evaluating selection bias, due to the wide range of treatment types, oral health outcomes and potentially confounding variables that are included in the data set.

The goal of this study was to describe an adaptation of Heckman's adjustment for selection bias for use with longitudinal binary outcomes and to illustrate the use of this technique to evaluate the effect of a single dental treatment, root canal therapy (RCT), on a range of self-reported dental care outcomes.

SAMPLE SELECTION MODELS

Sample selection modeling provides a method to assess and to adjust for sample selection bias when comparing treatment effects. This technique is somewhat similar to propensity score analysis, in that both methods include an initial stage of regression modeling to estimate the probability of selection into a particular group. Propensity score analysis estimates the conditional probability of group membership based on a set of observed covariates. Treatment comparisons are then made within subsets of the observations with similar propensity scores^{5,12}. Analysis using instrumental variables is an alternative methodology that may be used to adjust for confounding by unobserved characteristics that differ between the treatment groups. The instrumental variable technique requires the identification of a surrogate for one or a set of covariates that is highly correlated with the covariates that it replaces, but is not correlated with the dependent variable, conditional on the observed values of the covariates. In the oral health context, as in many other contexts, it may not be possible to find a variable (instrument) that is strongly correlated with receipt of treatment but is not also correlated with the health outcome, adjusted for the covariates. In the current context, this may be due to an adverse selection phenomenon in which those most in need of care are also those least likely to receive it. This is one aspect of what we have come to refer to as the "paradox of dental need", which has been one of the fundamental contributions to the literature made by the FDCS⁸.

Sample selection modeling was initially developed by Heckman⁶ for applications in economics. Its application to medical outcomes was recently reported by Crown⁵. The method is intended to adjust for bias due to unobserved variables that are related both to selection into a particular treatment group and to the outcome measure⁵. The original application of this method was typically limited to the analysis of a single continuous outcome measure in cross-sectional study designs. Shelton, et.al., extended the methodology, using the FDCS¹², to outcomes that are binary and longitudinal in nature. The proposed study will utilize this extension of sample selection model methodology to evaluate treatment effects and bias relative to a variety of oral health outcome measures.

Sample selection models are two-stage models. In the first-stage, an effect of being self-selected into comparison groups is estimated for each subject, based on a set of covariates. This subject-specific estimate, represented by the Inverse Mills Ratio (IMR), is then entered into a second-stage model as a covariate whose corresponding regression coefficient can be interpreted as the amount of bias present in estimating the probability of a specific health outcome.

The IMR reflects an individual subject's probability of not being selected into a particular group, given the probability of selection into that group, based on the subject's levels of variables in the selection pathway. If the predicted probability of membership in a particular group is high based on observable variables, then the influence of unobservable variables is small, and the bias, and consequently the IMR, is small. Thus, assuming that the observed variables provide an adequate characterization of the selection equation, including the IMR as a covariate in the analysis provides a method of adjustment for bias due to unobserved variables that have an effect on selection into comparison groups. This adjustment does not, of course, remove the possibility of bias in the second stage model, if important predictors of the outcome are excluded from the model⁵.

Extending sample selection models to accommodate longitudinal binary outcomes explicitly requires that both stages incorporate a time component, because both outcomes and comparison group (or 'treatment') status can change. In the first stage, which is referred to as the 'choice' stage, interval-specific probabilities that a subject will select into a specific treatment group are modeled as a function of observed covariates that are also believed to be associated with the selection process. Estimates of the IMR in each interval are then entered as an interval-varying (or time-varying) covariate into the second-stage model. Treatment group status is also entered as a time-varying covariate,

because seeking dental services can vary from interval to interval. Generalized Estimating Equations (GEE) are used to estimate a probit regression model in both stages, in order to model the longitudinal outcomes and time-varying covariates.

THE FLORIDA DENTAL CARE STUDY

The FDACS combines the following types of measures into one study: 1) a comprehensive set of clinical measures; 2) a comprehensive set of self-reported measures of oral health and OHRQOL, derived from a theoretical model of oral health that has been extensively validated^{11,13-18}; 3) self-reported 6-monthly incident use of specific dental services and the reason(s) for that use; 4) incident use of specific services as determined by abstraction from the actual dental records; and 5) characteristics and treatment tendencies of these dentists and dental practices. Moreover, of this information was gathered from a racially, socio-economically, and dentally diverse sample of adults, and 6-year longitudinal observations were collected.

A telephone survey methodology¹⁹ was used that employed both listed numbers and random digit dialing to identify dentate persons 45 years old or older and to oversample African Americans, poor persons, and residents of nonmetropolitan counties. The objective was to construct a sample of community-dwelling adults, but simultaneously to insure inclusion of adequate numbers of those with characteristics of interest (dentate status, race, age group, rural/urban residence, and poverty status). A total of 873 subjects participated for a baseline in-person interview and clinical exam. Unlike most community-based studies, participation was actually highest among African Americans and poor individuals. The sample obtained was diverse, representative of the population of interest, and generalizable to persons who meet eligibility criteria (age, race, dentate status, etc.)¹⁹.

Data collection was done at 6-monthly intervals. In-person interviews and clinical exams were conducted at baseline and at months 24, 48 and 72. Telephone interviews were conducted at months 6, 12, 18, 30, 36, 42, 54, 60 and 66. A very low attrition rate was achieved in the FDACS, with 714 (82%) of the original 873 participants remaining in the study at the 48-month follow-up. Most attrition was due to death or medical problems. A total of 873 individuals participated between August, 1993, and April, 1994, for a baseline in-person interview and clinical exam. After 24 months of follow-up, 764 persons (unweighted n; weighted n=788) remained in the study. This report includes analysis of data collected through the 24-month follow-up interview and examination.

A comprehensive array of oral health and dental care measures was gathered. Clinical measures included tooth loss, coronal caries and restorations, root caries and restorations, bulk restoration fractures, cusp/incisal edge fractures, root surface defects, tooth mobility and periodontal attachment level. Information on a broad array of self-reported dimensions of oral health was collected, including measures of self-rated oral health, oral disadvantage due to oral disease or tissue damage, oral disadvantage due to oral pain, oral disadvantage due to oral function decrements, oral functional limitation, oral pain and discomfort, and self-reported oral disease and tissue damage. Predisposing and enabling characteristics measured for each participant include age, sex, race, approach to dental care (regular attendance versus problem-oriented attendance), dental attitudes, oral hygiene behavior, household income, present financial situation, ability to pay an unexpected \$500 dental bill, and having dental insurance. Information on the dental visits made by each FDACS participant was collected, including dates of the visits, reasons for the visits, specific dental services used at each visit, treatment alternatives, and names of each dentist who provided care. Additionally, ADA codes for all procedures received and characteristics of the practices and of the individual dentists were collected. Furthermore, the self-reported dental care use was complemented by documenting exact dental procedures from dental records of practices that served FDACS participants.

A consistent finding of the FDACS to date has been the value of understanding participants' typical approach to dental care, which not only predicts subsequent dental utilization, but also is associated with dental disease, self-reported oral health problems, dental attitudes, dental self-care, dental self-extractions, and use of tobacco products²⁰⁻²³. At baseline, participants were asked to describe their "approach to dental care" as: (1) "I never go to a dentist"; (2) "I go to a dentist when I have a problem or when I know that I need to get something fixed"; (3) "I go to a dentist occasionally, whether or not I have a problem"; or (4) "I go to a dentist regularly". Those who responded number 1 or 2 were classified as "problem-oriented attenders", and those who responded number 3 or 4 were classified as "regular attenders".

STATISTICAL ANALYSIS

The dental treatment that was evaluated in this analysis was RCT. Information on receipt of a root canal was obtained by clinical examination, by self-report at the telephone interviews, and by abstracting procedure information from records of dental practices that served FDACS participants.

Sample selection models were used to estimate the effect of RCT for ten self-reported dental health outcome

measures, presented in Table 1. For each of the outcome variables, separate analyses were conducted for onset of and recovery from the outcome. The models were implemented using two-stage logistic regression models for each of the binary outcomes, incorporating the longitudinal nature of the FDCS data.

Generalized estimating equations (GEE) were used to implement two-stage longitudinal models incorporating Shelton's extension of Heckman's sample selection bias adjustment (Shelton et al., 2003) to model the longitudinal outcomes and time-varying covariates. The unit of observation was the person-interval, consisting of one subject participating in a single 6-month follow-up period. Correlations between the non-independent observations made during multiple intervals on each subject were incorporated into the analysis using an autoregressive covariance structure, in order to reflect higher correlations between measurements made closer together in time than between those made farther apart in time.

The first-stage model estimated an effect of self-selection into the respective treatment groups (received RCT; did not) for each participant as a function of observed covariates believed to be associated with the selection process. The probability that an individual will select into a specific treatment group was estimated, and was used to calculate a subject- and interval-specific IMR value for each observation interval. The IMR was then entered into the second-stage model as a time-dependent covariate. The regression coefficient for IMR in the second-stage model can be interpreted as the amount of bias present in the treatment effect estimate.

Both the first- and second-stage models were based on the logit link function, to facilitate interpretation of results as odds ratios. All analyses included sampling weights to reflect the design of the FDCS.

Variables used in the first-stage model were hypothesized predictors of receiving RCT. Race, gender and regular or problem-oriented approach to dental care (APPROACH) were included in this model. Age was initially included, but was not significant in any of the models, and was removed from further consideration.

The second-stage models included potential confounders of the association between the treatment and the outcome variables. Race, gender, PAY500, and RCT were included as independent variables in these models, the subject-specific IMR value. Treatment group status was included as a time-dependent variable, because seeking dental services can vary from interval to interval.

Second-stage models were run twice, once with and once without the adjustment, so that the effect of adjustment for selection bias could be evaluated. Differences in the parameter estimates and significance levels for RCT between the two models as well as the statistical significance of the IMR term in the bias-adjusted model were considered as evidence of the presence of selection bias.

The following self-reported oral-health outcomes were evaluated: Sore gums, bleeding gums stained teeth, bad breath, sensitive teeth, avoided smiling or laughing, embarrassed by appearance, self-rated oral health, satisfaction with appearance, perceived need for dental care. Onset of and recovery from each of the outcome variables was coded, and separate analyses were run for each of these.

The first-stage models were estimated using a logistic regression model, implemented with SAS® PROC GENMOD.

```
proc genmod data=stage1 desc; weight nml_wt ;  
class id t1approach gender race ;  
model canal=t1approach race gender age/ dist=bin link=logit ;  
repeated subject=id / type=AR corrw;  
output out=out1 xbeta=eta pred=hat reschi=resid3;  
title 'First stage equation for estimating IMR-logit model'; run;
```

The parameter estimates obtained in the first-stage model were used to calculate IMR separately for those who received a root canal and for those who did not.

```
data imr; set out1;  
if canal=1 then  
    lambdaT=(1/sqrt(2*3.141592654)*exp(-1*eta**2/2))/probnorm(eta);  
else if canal=0 then  
    lambdaT=(1/sqrt(2*3.141592654)*exp(-1*eta**2/2))/probnorm(eta) - 1;
```

```
else lambdaT=.; run;
```

IMR values calculated in the first stage were then merged with the main data set.

```
proc sort data=imr; by id; run;
data stage2; merge stage1 imr(keep= id lambdaT hat resid3); by id ;
format race race. gender sex. t1pay500 canal yesno.;
run;
```

The second-stage model was run with and without bias adjustment. Odds ratios and 95% confidence intervals were calculated.

```
%let yvars = onset_soregums recov_soregums onset_bleed recov_bleed onset_stained
recov_stained
            onset_badbreath recov_badbreath onset_sens recov_sens onset_avsmile recov_avsmile
            onset_embar recov_embar onset_oralrate recov_oralrate onset_satapp recov_satapp
            onset_pneed recov_pneed;

%macro stage2;
    %do m=1 %to 20;
        %let yvar= %scan (&yvars,&m);
    proc genmod data=stage2 descending;
        weight nml_wt;
        class id race gender t1pay500 canal ;
        model &yvar = race gender t1pay500 canal/dist=binomial link=logit waldci;
        repeated subject=id / type=ar corrw;
        estimate 'LogOR' canal 1 -1 /exp;
        title "Second stage modeling for &&yvar - LOGIT model";
    run;
    proc genmod data=stage2 descending;
        weight nml_wt;
        class id race gender t1pay500 canal ;
        model &yvar = race gender t1pay500 lambdaT canal / dist=binomial
link=logit waldci;
        repeated subject=id / type=ar corrw;
        estimate 'LogOR' canal 1 -1 /exp;
        title "Second stage modeling for &&yvar w/ IMR - LOGIT model";
    run;

quit;
%end;
%mend;

%stage2;
```

RESULTS

Table 1 shows the results of the unadjusted and bias-adjusted regression models. The regression parameter for IMR was significant in nine of ten models for the onset variables and for two of seven recovery variables, indicating the existence of significant sample selection bias for these outcomes. Two of the models for recovery variables, embarrassed by appearance and perceived need for care, failed to converge. The statistical decision for the effect of RCT was changed in two of ten models for onset variables, dental sensitivity and infected/sore gums. None of the statistical decisions were changed by the adjustment for the recovery models.

DISCUSSION

The iterative estimation algorithm of PROC GENMOD failed to converge for two of the analyses, so no effect estimates are available for these outcomes. These failures to converge were likely due to reduced sample sizes for the recovery variables. In order for a subject to show recovery, the subject would have had to report having the condition during interval t and not having the condition during interval $t + 1$. This definition requires that the maximum sample size for a recovery variable during an interval is the number of subjects who reported having a particular condition during the previous interval. Collinearity between IMR and the second-stage variables might also contribute to this occurrence, since there is considerable commonality between the first- and second-stage variables. Also, intervals with identical information for some participants are relatively common in this sample. This results from there being no change in the reported outcome or predictor variables across multiple intervals. This increases the dimensionality of the estimation problem without providing additional information.

Some cautions regarding the use of this approach are appropriate. First, the Heckman sample selection model, and in particular the use of IMR as the bias adjustment, was based on the assumption that the data follow a normal distribution⁶. Other adjustments may be appropriate, such as bias adjustment using residuals from the first-stage model instead of the IMR²⁴. Problems with two-stage bias adjustment have been reported, in which the adjustment may yield parameter estimates that are more biased than the unadjusted estimates, or that precision of estimation may be reduced by collinearity induced by the adjustment²⁵. Further research will be necessary to more fully evaluate the performance of selection bias adjustment and its potential role in health services research.

CONCLUSION

The results of this study show little effect of adjustment for sample selection bias on the estimates of the effect of RCT. Selection bias adjustment may be warranted in some situations, but further research is needed in order to establish the suitability of adjustment methods for particular data characteristics.

Table 1. Results of Unadjusted and Bias-Adjusted Models

OUTCOME	UNADJUSTED MODEL			BIAS-ADJUSTED MODEL			
	Odds Ratio	95% CI	p-value	BIAS (IMR) p-value	Odds Ratio	95% CI	p-value
<i>Infected /sore gums</i>							
Onset	2.82	(1.09, 7.28)	0.0320	0.0313	2.11	(0.71, 6.32)	0.1804
Recovery	0.28	(0.02, 4.44)	0.3635	0.2785	0.36	(0.01, 9.57)	0.5450
<i>Bleeding gums</i>							
Onset	1.67	(0.44, 6.43)	0.4533	0.0302	1.19	(0.35, 4.04)	0.7858
Recovery	0.28	(0.02, 3.57)	0.3291	0.0884	0.21	(0.02, 2.36)	0.2067
<i>Stained teeth</i>							
Onset	1.05	(0.34, 3.25)	0.9275	<.0001	0.44	(0.14, 1.38)	0.1594
Recovery	NA	NA	NA	NA	NA	NA	NA
<i>Bad Breath</i>							
Onset	0.94	(0.22, 4.03)	0.9341	0.0033	0.65	(0.14, 3.11)	0.5944
Recovery	1.13	(0.35, 3.59)	0.8402	0.2287	1.38	(0.46, 4.14)	0.5674
<i>Dental Sensitivity</i>							
Onset	2.41	(1.05, 5.53)	0.0374	0.0206	2.04	(0.82, 5.08)	0.1273
Recovery	0.45	(0.19, 1.07)	0.0713	0.9060	0.44	(0.19, 1.03)	0.0587
<i>Avoided laughing / smiling</i>							
Onset	0.83	((0.15, 4.70)	0.8364	<.0001	0.21	(0.04, 1.23)	0.0830
Recovery	0.71	(0.17, 3.05)	0.6504	0.3181	0.54	(0.22, 1.35)	0.1890
<i>Embarrassed by Appearance</i>							
Onset	2.08	(0.52, 8.39)	0.3038	<.0001	0.77	(0.14, 4.23)	0.7660
Recovery	NA	NA	NA	NA	NA	NA	NA
<i>Self-rated oral health (good)</i>							
Onset	1.39	(0.27, 7.25)	0.6902	0.1570	1.14	(0.15, 8.65)	0.9000
Recovery	2.16	(0.72, 6.51)	0.1698	<.0001	0.79	(0.21, 2.89)	0.7163
<i>Satisfaction with dental appearance</i>							
Onset	1.02	(0.21, 4.89)	0.9768	0.0172	1.12	(0.26, 4.75)	0.8772
Recovery	0.42	(0.09, 1.88)	0.2567	<.0001	0.19	(0.04, 0.86)	0.0315
<i>Perceived need for care</i>							
Onset	0.57	(0.09, 3.42)	0.5413	<.0001	0.25	(0.04, 1.50)	0.1304
Recovery	NA	NA	NA	NA	NA	NA	NA

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