Implementing ODA from Within Stata: Identifying Structural Breaks in Single-Group Interrupted Time Series Designs (Invited)

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In this paper, I describe how to determine if any structural breaks exist in a time series prior to the introduction of an intervention using the new Stata package for implementing ODA. Given that the internal validity of the design rests on the premise that the interruption in the time series is associated with the introduction of the intervention, treatment effects may seem less plausible if a parallel trend already exists in the time series prior to the actual intervention.

Prior papers¹⁻⁶ introduced the new Stata package called **oda**⁷ for implementing ODA from within the Stata environment. This package is a wrapper for the MegaODA software⁸, and therefore the MegaODA.exe file must be loaded on the computer for the **oda** package to work (MegaODA software is available at https://odajournal.com/resources/). To download the **oda** package, at the Stata command line type: "ssc install oda" (without the quotation marks).

In this paper, I demonstrate how the **oda** package can be used to examine whether or not structural breaks exist in a time series prior to the initiation of an intervention in a single-group interrupted time series analysis (ITSA).

ITSA is an increasingly popular study design for evaluating the effectiveness of large-

scale interventions and policy changes, ⁹⁻¹¹ in which a single aggregate entity (e.g., hospital, county, or state) is the treatment unit, and accordingly, the outcome of interest is reported serially over time at the aggregate level (e.g., morbidity or mortality rates). The design is called an *interrupted time series* because the intervention is expected to "interrupt" the level and/or trend of the outcome variable subsequent to its introduction. ¹²

The validity of ITSA when used for making causal inferences has begun to receive attention in the literature, specifically the importance of testing for interruptions in the time series that occur prior to the actual initiation of the intervention. ¹³⁻¹⁶ The assumptions necessary for causal inference in the single-group ITSA may seem plausible when the pre-intervention

trend is followed by a statistically significant change in the trend of the outcome variable immediately following the introduction of the intervention, and sustained over some meaningful period of time. In contrast, these assumptions seem less plausible if a parallel trend already exists in the time series prior to the initiation of the intervention. Linden¹³ suggests conducting an iterative sensitivity analysis involving testing each pre-intervention time period treated as a "pseudo-intervention" period. This approach is consistent with regressionbased structural break analysis commonly used in time series econometrics. The underlying assumptions of the single-group ITSA may be challenged if interruptions in the level or trend of the outcome variable are found to exist at other time points prior to the actual initiation of the intervention.

Following Linden¹³, in **oda** we test for structural breaks in a time series prior to the initiation of an intervention by specifying, in turn, each "pseudo-intervention" indicator (representing a "pre-pseudo- intervention" and "post-pseudo-intervention" period for each pre-intervention year) as the *class* variable and the outcome variable as the *attribute*.

Methods

Data

I examine data from the 1988 voter-initiated Proposition 99, a widespread effort in California to reduce smoking rates by raising the cigarette excise tax by 25 cents per pack and to fund antismoking campaigns and other related activities throughout the state. Per capita cigarette sales (in packs) serves as the aggregate outcome variable under study, measured annually at the state level from 1970 until 2000 (with 1989 representing the first year of the intervention). The current study limits analysis to cigarette sales in only the pre-intervention years between 1970 and 1988 to determine if there are addi-

tional interruptions in the time series prior to actual initiation of the intervention in 1989.

While a comprehensive discussion on the use of ODA for evaluating structural breaks in single-group interrupted time series is available elsewhere, ¹⁶ here the discussion is limited to its implementation using the **oda** package.

Analytic process

Using the "pseudo-intervention" year as the class variable and the outcome as the attribute, **oda** is implemented with the following syntax (see the help file for **oda** for a complete description of the syntax options):

oda tx79 cigsale if inrange(year, 1970,1988), pathoda("C:\ODA\") store("C:\ODA\output") iter(25000) loo sidak(18) seed(1234)

The above syntax is explained as follows: The variable "tx79" (representing the pseudo-intervention for the year 1979) is the class variable; the outcome "cigsale" is the attribute; we use the "if inrange" statement to limit the data to the pre-intervention years of 1970-1988; the directory path where the MegaODA.exe file is located on my computer is "C:\ODA\"; the directory path where the output and other files generated during the analysis should be stored is "C:\ODA\output"; the number of iterations (repetitions) for computing a permutation P-value is 25,000; a leave-one-out analysis is requested; a Sidak adjustment for multiple testing of 18 comparisons is specified; and we set the seed to 1234 to allow us to replicate the permutation results (any integer value can be used in the seed).

The **oda** package produces an extract of the total output produced by the ODA software (the complete output is stored in the specified directory with the extension ".out").

As shown in the **oda** output, the ODA model is interpreted as follows: "if cigarette sales <= 120.6, then predict that the pseudo-intervention period is 1 (post-pseudo-

intervention). If cigarette sales are > 120.6, then predict that the pseudo-intervention period is 0 (pre-pseudo-intervention)." The effect strength for sensitivity (ESS) is labelled in the output as "Effect Strength PAC". The ESS is 100.00% (perfect effect strength) in the training analysis and 78.89% (strong effect strength) in LOO. ¹⁷ The permutation P-value for the training sample was statistically significant P < 0.0001 (P = 0.0007 when Sidak adjusted), and P = 0.001 for LOO (P = 0.0176 when Sidak adjusted).

```
ODA model:
IF CIGSALE \leftarrow 120.6 THEN TX79 = 1 IF 120.6 \leftarrow CIGSALE THEN TX79 = 0
Summary for Class TX79 Attribute CIGSALE
Performance Index
                                      Train
                                                  L00
Overall Accuracy
                                     100.00%
                                                89.47%
PAC TX79=0
PAC TX79=1
                                     100.00%
                                                88.89%
Effect Strength PAC
PV TX79=0
PV TX79=1
                                     100.00%
                                                78.89%
                                     100.00%
                                                90.00%
88.89%
                                     100.00%
Effect Strength PV
Effect Strength Total
Monte Carlo summary (Fisher randomization):
Iterations: 25000
Estimated p: 0.000040
Sidak Adjusted (18) p: .00071976
Results of leave-one-out analysis
19 observations
Fisher's exact test (directional) classification table p = .000985 Sidak Adjusted (18) p for LOO: .01758233
```

In summary, ODA was able to discriminate perfectly between a "pre-pseudo-intervention period" and a "post-pseudo-intervention period" that occurred in 1979—which is 10 years prior to the introduction of the actual intervention (Proposition 99)!

The Table presents the annual actual cigarette sales per capita, the ODA derived cutpoint on cigarette sales for predicting belonging to the pre- and post-pseudo-intervention periods, and reliability and accuracy measures (*P* values and ESS) for training and LOO analysis for all pre-intervention years (1970-1988). While no ODA model could be obtained for 1988, and no LOO model could be obtained for 1970, 1987,

or 1988, ODA identified statistically significant structural breaks (i.e., generalized P < 0.05) for all years between 1975 and 1986 based on the analyses involving the total sample (training analysis), and between 1976 and 1985 when considering LOO cross-validation. When considering only structural breaks meeting the more stringent Sidak adjusted P values, then all years between 1977 and 1985 meet the experimentwise criterion for the training analysis, and 1979 through 1983 and 1985 met the experimentwise criterion in LOO cross-validation analysis. ESS values ranged from 53% to 100% for the training analysis (representing relatively strong to perfect effect strength), and from 28% to 100% for LOO analysis (representing moderate to perfect effect strength).

When considering Sidak-adjusted P values, ESS, and type of analysis (training and LOO) together, perfect structural breaks (i.e., the ESS in training and in LOO analysis are both 100%, and have experimentwise P < 0.05) are identified for the years 1983 and 1985, and strong, reproducible, statistically reliable structural breaks are identified for the years 1979 through 1982.

Discussion

The ODA-based approach described here provides a robust framework for analyzing structural breaks in single-group interrupted time series designs. ODA should be considered the preferred approach over other commonly-used parametric models because ODA avoids the assumptions required of parametric models, is insensitive to skewed data or outliers, and has the ability to handle any variable metric including categorical, Likert-type integer, and real number measurement scales.8 Moreover, in contrast to conventional statistical models, ODA also has the distinct ability to ascertain where optimal (maximum-accuracy) cutpoints are on the outcome variable, which in turn, facilitates the use of measures of predictive accuracy.

			Training Set		LOO Analysis	
Year	Per capital sales	Predict intervention	P value	ESS	P value	ESS
1970	123.00	122.45	0.8474	61.11%		
1971	121.00	120.60	0.5262	52.94%	0.3217	47.06%
1972	123.50	120.60	0.2956	56.25%	0.1703	50.00%
1973	124.40	120.60	0.1530	60.00%	0.3329	28.33%
1974	126.70	120.60	0.0686	69.23%	0.1842	37.14%
1975	127.10	120.60	0.0204*	75.00%	0.0914	44.87%
1976	128.00	120.60	0.0069*	81.82%	0.0399*	52.38%
1977	126.40	120.60	0.0018**	90.00%	0.0149*	60.23%
1978	126.10	120.60	0.0003**	90.91%	0.0045*	68.89%
1979	121.90	120.60	0.0001**	100.00%	0.0010**	78.89%
1980	120.20	119.40	0.0001**	100.00%	0.0002**	87.50%
1981	118.60	117.00	0.0001**	100.00%	0.0003**	85.71%
1982	115.40	113.10	0.0001**	100.00%	0.0006**	83.33%
1983	110.80	107.80	0.0003**	100.00%	0.0001**	100.00%
1984	104.80	103.80	0.0007**	100.00%	0.0158*	68.33%
1985	102.80	101.25	0.0020**	100.00%	0.0010**	100.00%
1986	99.70	98.60	0.0122*	100.00%	0.2047	44.12%
1987	97.50	93.80	0.1053	100.00%		
1988	90.10					

Notes:

ESS = effect size sensitivity (0 = chance accuracy, 100 = perfect accuracy)

LOO = leave-one-out (jackknife) cross-validation

Moreover, ODA can perform cross-validation using LOO which assesses the cross-generalizability of the model to potentially new study participants or non-participants.¹⁸

Finally, the findings continue to support our recommendation to employ the ODA and CTA frameworks to evaluate the efficacy of health-improvement interventions and policy initiatives. ¹⁹⁻³⁸

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⁻⁻⁻ No ODA model possible

^{**} Experimentwise P < 0.05; * Generalized P < 0.05

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Author Notes

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