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Robustness of Fuzzy Regression Discontinuity Designs under Imperfect Compliance

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Abstract

This paper studies the robustness of fuzzy regression discontinuity designs under imperfect compliance with clinical assignment rules. When treatment assignment based on a biomarker threshold is probabilistic, the cutoff indicator can be interpreted as an instrumental variable identifying a Local Average Treatment Effect. A Monte Carlo simulation calibrated to a cardiovascular risk setting is used to evaluate the local two stage least squares fuzzy regression discontinuity estimator under controlled violations of its identifying assumptions. We consider departures from continuity of potential outcomes at the cutoff, reductions in first stage strength, and violations of monotonicity. The results show that, under approximate continuity and sufficiently strong first stages, the estimator recovers the target local effect with limited bias and near nominal coverage. Weak first stages mainly reduce precision, whereas violations of continuity lead to severe bias even when the instrument is strong. Monotonicity violations increase variability and reduce coverage. Overall, the findings highlight that fuzzy regression discontinuity designs provide reliable local causal inference only under carefully assessed assumptions.

Keywords: fuzzy regression discontinuity, causal inference, instrumental variables, imperfect compliance, sensitivity analysis.

2020 AMS subject classifications: 62J12, 62P10, 62P20.[1]

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1 Introduction

The analysis of complex phenomena in the social, economic, and health sciences is inherently affected by multiple sources of uncertainty. In many empirical settings, uncertainty does not arise solely from randomness, but also from imprecision, vagueness, and partial observability of the mechanisms generating the data. Classical probabilistic models are well suited to represent stochastic variability, but they are often less effective in capturing situations in which concepts, rules, or assignments are not sharply defined.

The theory of fuzzy sets was introduced precisely to address this type of uncertainty, by allowing elements to belong to a set with varying degrees rather than through a crisp binary classification, see Zadeh [1965, 1968, 1975]. Since its introduction, fuzzy logic has provided a flexible conceptual and mathematical framework for representing gradual transitions, linguistic categories, and imprecise rules, and has been extensively developed both from a theoretical and an applied perspective, see Bellman and Giertz [1973], Kosko [1990].

Building on these foundations, several authors have investigated the interaction between fuzziness and randomness, leading to the notion of fuzzy random variables and hybrid probabilistic fuzzy frameworks, see Puri and Ralescu [1986]. This line of research has shown that many empirical processes cannot be adequately described by purely stochastic models or purely fuzzy representations, but require a combination of both to reflect real world complexity.

Fuzzy methods have subsequently been extended to regression analysis and statistical modeling, with the aim of handling imprecise data, vague relationships, and uncertainty in model specification, see Celmins [1987], Diamond [1988]. Further developments have emphasized the role of fuzzy probabilistic approaches for the study of statistical relationships in economic and managerial sciences, where uncertainty often arises from both incomplete information and structural vagueness, see Maturo [2016]. Related contributions have explored fuzzy regression as a tool for addressing causal complexity in social sciences, where deterministic mechanisms are rarely observed, see Maturo and Maturo [2013].

Beyond regression settings, fuzzy concepts have found applications in a wide range of domains, including the modeling of fuzzy events and fuzzy probability in economic and social systems, see Maturo and Maturo [2017], the construction of fuzzy quantities linked to classical probability distributions, see Maturo and Fortuna [2016], and the analysis of complex relational structures such as fuzzy networks and dynamic health monitoring, see Maturo et al. [2020], Porreca et al. [2025]. Together, these contributions highlight the importance of methodological

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frameworks capable of accommodating gradual rules, partial compliance, and non crisp mechanisms in applied statistical analysis.

Within this broader context, the estimation of causal effects in clinical and epidemiological research presents particularly challenging features. Causal relationships are fundamentally counterfactual in nature, since individual outcomes under both treatment and non treatment conditions cannot be simultaneously observed. Randomized Controlled Trials address this problem through exogenous treatment assignment, but their implementation is often constrained by ethical considerations, financial costs, and limited external validity. As a result, causal analyses in medical research frequently rely on observational data, where treatment assignment is potentially endogenous and subject to selection bias.

Clinical guidelines represent an important source of quasi experimental variation in such settings. Medical recommendations often prescribe treatment on the basis of a continuous biomarker X_i, where i indexes individuals, relative to a predefined threshold $c \in \mathbb{R}$. This rule generates a binary treatment indicator $D_i \in \{0, 1\}$, where $D_i = 1$ denotes treatment receipt and $D_i = 0$ denotes non treatment. In its idealized form, the guideline induces a deterministic assignment mechanism, which can be written as

$$D_i = \mathbb{1}(X_i \geq c), \tag{1}$$

where $\mathbb{1}(\cdot)$ denotes the indicator function, equal to one if the condition in parentheses is satisfied and zero otherwise. Under this formulation, individuals with biomarker values weakly above the cutoff are assigned to treatment, while those with values below the cutoff remain untreated.

This assignment mechanism defines the Sharp Regression Discontinuity Design. Identification relies on the assumption that individuals located sufficiently close to the cutoff are comparable in both observed and unobserved characteristics, so that any discontinuity in the outcome at c can be attributed to the treatment effect, see Lee and Lemieux [2010]. The validity of this design critically depends on perfect compliance with the assignment rule, meaning that treatment status is fully determined by the threshold.

In applied clinical contexts, however, this assumption is rarely satisfied. Physicians may prescribe treatment to patients whose biomarker values fall below the recommended threshold, based on additional risk factors or clinical judgment. Conversely, some patients who exceed the cutoff may not receive treatment due to contraindications, preferences, or non adherence. As a consequence, treatment assignment becomes probabilistic rather than deterministic, and the sharp design is no longer appropriate.

These deviations from perfect compliance motivate the use of the Fuzzy Regression Discontinuity Design, in which the probability of receiving treatment exhibits a discontinuous jump at the cutoff without reaching zero or one. Formally,

this setting is characterized by

$$\lim_{x \downarrow c} P(D_i = 1 \mid X_i = x) \neq \lim_{x \uparrow c} P(D_i = 1 \mid X_i = x). \tag{2}$$

The discontinuity in treatment probability allows the cutoff indicator to be interpreted as an instrumental variable, identifying a Local Average Treatment Effect for individuals whose treatment status is influenced by the guideline, see Imbens and Lemieux [2008] and Venkataramani et al. [2016].

While the identification strategy underlying fuzzy regression discontinuity designs is well established, applied analyses often rely on strong local assumptions whose empirical plausibility is rarely examined. In particular, continuity of potential outcomes at the cutoff, monotonicity of treatment assignment, and sufficient strength of the first stage are typically assumed without formal assessment. This paper focuses on the robustness of the fuzzy regression discontinuity estimator to controlled violations of these assumptions. Through a simulation framework calibrated to a cardiovascular risk setting, we evaluate how departures from ideal conditions affect bias and variability of the estimated Local Average Treatment Effect, with the aim of providing practical guidance for applied biostatistical research, see [Calonico et al., 2014].

2 Materials and Methods

This section outlines the methodological framework adopted to analyze fuzzy regression discontinuity designs under imperfect compliance. The approach follows the standard instrumental variable interpretation of fuzzy regression discontinuity designs and focuses on the identification and estimation of a local average treatment effect at the cutoff. Particular attention is devoted to the assumptions underlying identification and to their role in the subsequent robustness analysis.

2.1 Identification in Fuzzy Regression Discontinuity Designs

Let X_i denote a continuous forcing variable and c a known cutoff value determining treatment eligibility according to a clinical guideline. Treatment assignment is represented by a binary indicator $D_i \in \{0, 1\}$, and the outcome of interest by Y_i. In a fuzzy regression discontinuity design, crossing the threshold does not deterministically assign treatment, but induces a discontinuous change in the probability of treatment receipt. Formally,

$$\lim_{x \downarrow c} P(D_i = 1 \mid X_i = x) \neq \lim_{x \uparrow c} P(D_i = 1 \mid X_i = x). \tag{3}$$

Under standard assumptions, the discontinuity in treatment probability can be exploited to identify a Local Average Treatment Effect for individuals whose treatment status is influenced by the cutoff. This estimand is defined as the ratio between the discontinuity in the conditional expectation of the outcome and the discontinuity in the conditional expectation of the treatment indicator,

$$\tau_{FRDD} = \frac{\mu_Y^+ - \mu_Y^-}{\mu_D^+ - \mu_D^-,} \tag{4}$$

where μ_Y^+ and μ_Y^- denote the right and left limits of $E(Y_i \mid X_i = x)$ at $x = c$, and μ_D^+ and μ_D^- are defined analogously for D_i. This parameter corresponds to the Local Average Treatment Effect identified by the instrumental variable induced by the cutoff indicator.

2.2 Estimation via Two Stage Least Squares

In empirical applications, treatment assignment is potentially endogenous, as it may depend on unobserved clinical characteristics correlated with the outcome. Estimation is therefore conducted within a Two Stage Least Squares framework, where the cutoff indicator serves as an instrumental variable for treatment receipt.

Let $Z_i = \mathbb{1}(X_i \geq c)$ denote the instrument. The first stage models treatment assignment as

$$D_i = \gamma_0 + \gamma_1 Z_i + f(X_i - c) + \nu_i, \tag{5}$$

where $f(\cdot)$ is a smooth function capturing the relationship between the forcing variable and treatment away from the cutoff. The coefficient γ_1 measures the discontinuous change in the probability of treatment at the threshold and reflects the strength of the first stage.

The second stage relates the outcome to the predicted treatment status,

$$Y_i = \beta_0 + \tau_{FRDD} \hat{D}_i + g(X_i - c) + \epsilon_i, \tag{6}$$

where $g(\cdot)$ is a smooth function analogous to $f(\cdot)$. Under standard regularity conditions, the Two Stage Least Squares estimator of τ_{FRDD} coincides with the Wald estimator defined above.

2.3 Local Polynomial Estimation and Kernel Weighting

Identification in regression discontinuity designs is local in nature and relies on observations in a neighborhood of the cutoff. To emphasize this local structure, estimation is performed using local polynomial regression with kernel weighting.

Observations are weighted according to their distance from the cutoff using a triangular kernel,

$$K(u) = (1 - |u|)\mathbb{1}(|u| \leq 1), \tag{7}$$

which assigns greater weight to observations closer to the threshold. The choice of kernel and bandwidth reflects the standard trade off between bias and variance in local estimation and is held fixed across simulation scenarios to isolate the effects of assumption violations examined in the subsequent analysis.

3 Simulation Design

The simulation study is designed to assess the robustness of the fuzzy regression discontinuity estimator to selected violations of its identifying assumptions, using a deliberately parsimonious Monte Carlo design. Rather than exploring a large grid of parameter combinations, the data generating process focuses on a small set of representative scenarios that isolate the effects of outcome continuity, monotonicity of treatment assignment, and instrument strength. This approach allows a transparent interpretation of bias, variability, and coverage under conditions commonly encountered in applied biostatistical research.

In each Monte Carlo replication, a synthetic population of $N = 2{,}000$ individuals is generated. The forcing variable X_i, representing LDL cholesterol levels, is drawn from a normal distribution,

$$X_i \sim \mathcal{N}(160, 20),$$

and a clinical guideline defines a cutoff at $c = 160$ mg/dL.

Treatment assignment is probabilistic and depends on the position relative to the cutoff. Let p_- and p_+ denote the probabilities of receiving treatment below and above the threshold, respectively. In the baseline configuration,

$$P(D_i = 1 \mid X_i < c) = p_- = 0.15, \qquad P(D_i = 1 \mid X_i \geq c) = p_+ = 0.75,$$

which induces a discontinuity in treatment probability of magnitude $\Delta_D = 0.60$. A weak first stage scenario is obtained by reducing this gap to $\Delta_D = 0.30$, corresponding to $p_- = 0.25$ and $p_+ = 0.55$.

Departures from monotonicity are introduced by allowing a fixed fraction of defiers. In the monotonicity violation scenario, a share of 5% of the population is assigned a treatment status that moves in the opposite direction of the cutoff indicator, while preserving the same marginal probabilities p_- and p_+ as in the baseline configuration.

The outcome variable Y_i, representing systolic blood pressure, is generated according to

$$Y_i = \alpha + \beta(X_i - c) + \tau D_i + \delta \mathbb{1}(X_i \geq c) + \eta_i + \epsilon_i, \tag{8}$$

where $\alpha = 120$, $\beta = 0.1$, and $\tau = -10$ is the true treatment effect. The parameter δ introduces a direct discontinuity in untreated potential outcomes at the cutoff and is set to $\delta = 5$ in the continuity violation scenario, while $\delta = 0$ in all other configurations. Individual heterogeneity is modeled through $\eta_i \sim \mathcal{N}(0, 5)$, and $\epsilon_i \sim \mathcal{N}(0, 2)$ represents idiosyncratic noise.

Estimation is conducted using a local linear fuzzy regression discontinuity design with triangular kernel weighting and a fixed bandwidth of $h = 10$. The Local Average Treatment Effect is estimated via two stage least squares using the cutoff indicator as an instrumental variable. For each scenario, $B = 150$ Monte Carlo replications are performed, and performance is evaluated in terms of bias, standard deviation, root mean squared error, and empirical coverage of nominal 95% confidence intervals.

4 Results

The simulation study considers four configurations, namely a baseline scenario, a continuity violation scenario, a weak first stage scenario, and a monotonicity violation scenario. Table 1 reports the Monte Carlo performance of the local two stage least squares fuzzy regression discontinuity estimator and of a naive ordinary least squares benchmark. Graphical evidence supporting the main findings is provided in Figures 1, 2, 3, and 4.

4.1 First Stage Behavior and Local Sample Size

Figure 1 displays the empirical first stage in the baseline scenario, plotting binned treatment probabilities against the forcing variable. A clear discontinuity is observed at the cutoff $c = 160$, with treatment probabilities increasing from values close to 0.15 below the threshold to approximately 0.75 above it. This jump visually confirms the presence of a strong first stage induced by the guideline rule.

In the baseline configuration, the corresponding discontinuity in treatment probability is $\Delta_D = 0.60$. Consistently, the empirical first stage diagnostic is large, with mean $\widehat{F}_Z \approx 94.24$, and the average number of locally weighted observations within the bandwidth is about 766. This combination ensures reliable local identification of the causal effect.

In the weak first stage configuration, where $p_- = 0.25$ and $p_+ = 0.55$, the discontinuity decreases to $\Delta_D = 0.30$. Although the local sample size remains

Table 1: Monte Carlo performance of the fuzzy regression discontinuity estimator and naive OLS across simulation scenarios

Scenario	Method	Mean	Bias	SD	RMSE	Coverage
Baseline	FRDD local 2SLS	-10.09	-0.09	1.44	1.43	0.95
	Naive OLS	-9.97	0.03	0.29	0.29	0.95
Weak first stage	FRDD local 2SLS	-10.05	-0.05	3.07	3.06	0.97
	Naive OLS	-9.98	0.02	0.25	0.25	0.95
Monotonicity violation	FRDD local 2SLS	-9.85	0.15	1.73	1.73	0.90
	Naive OLS	-10.00	0.00	0.28	0.28	0.97
Continuity violation	FRDD local 2SLS	-1.72	8.28	1.58	8.43	0.00
	Naive OLS	-8.58	1.42	0.26	1.45	0.00

comparable, about 763, the first stage diagnostic drops markedly to a mean value of $\widehat{F}_Z \approx 17.66$. This reduction in instrument strength is not associated with a systematic change in bias but leads to a substantial loss of precision in the fuzzy regression discontinuity estimator, as documented below.

4.2 Reduced Form and Local Average Treatment Effect

Figure 2 shows the reduced form relationship between systolic blood pressure and LDL cholesterol in the baseline scenario. The outcome exhibits a smooth increasing trend in the forcing variable, together with a visible downward shift at the cutoff. This discontinuity represents the intent to treat effect, which combines the true treatment effect with the incomplete compliance induced by the guideline.

In the baseline scenario, the local fuzzy regression discontinuity estimator is centered close to the true effect $\tau = -10$. The Monte Carlo mean is $\bar{\hat{\tau}} \approx -10.09$, with bias about -0.09, standard deviation about 1.44, and empirical coverage close to the nominal level, approximately 0.95. Figure 3 summarizes this behavior by reporting the mean estimate and dispersion across scenarios, together with a reference line indicating the true parameter value.

In the weak first stage scenario, the estimator remains approximately unbiased on average, with $\bar{\hat{\tau}} \approx -10.05$ and bias about -0.05. However, dispersion increases substantially, with standard deviation about 3.07 and mean standard error about 3.20. This pattern is clearly visible in Figure 3, where the confidence band widens markedly relative to the baseline. Empirical coverage remains close to nominal, about 0.97, reflecting the larger uncertainty induced by the weaker first stage.

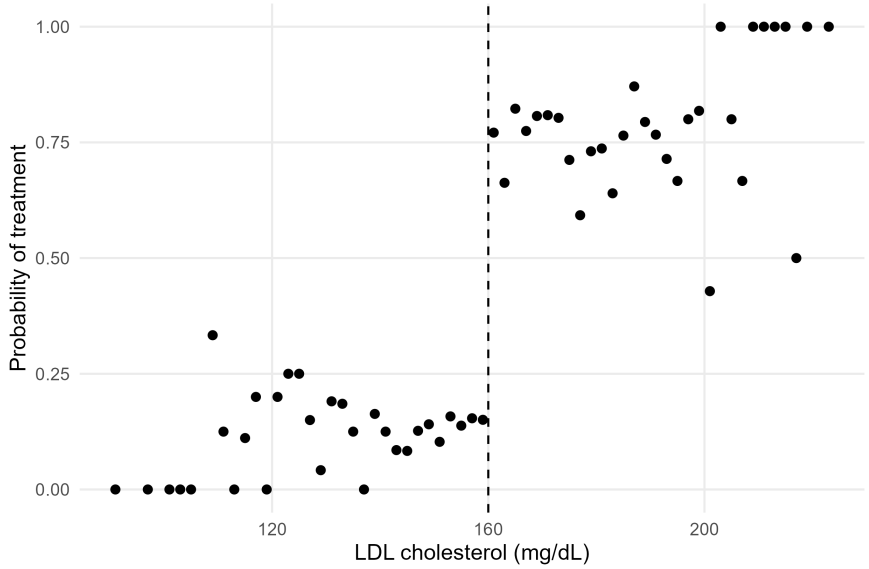

Figure 1: First stage in the baseline scenario. Binned treatment probabilities are plotted against LDL cholesterol. The vertical dashed line marks the cutoff $c = 160$.

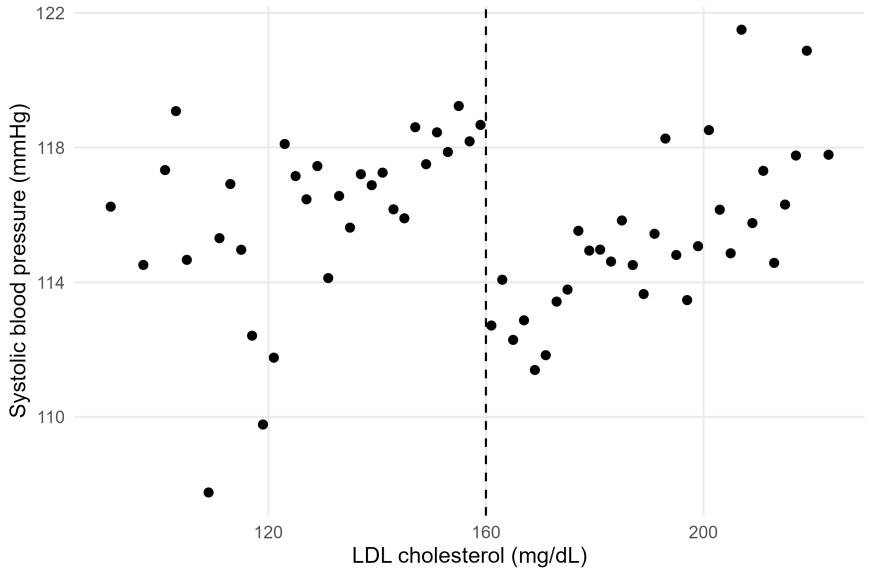

Figure 2: Reduced form in the baseline scenario. Binned averages of systolic blood pressure are plotted against LDL cholesterol. The vertical dashed line marks the cutoff $c = 160$.

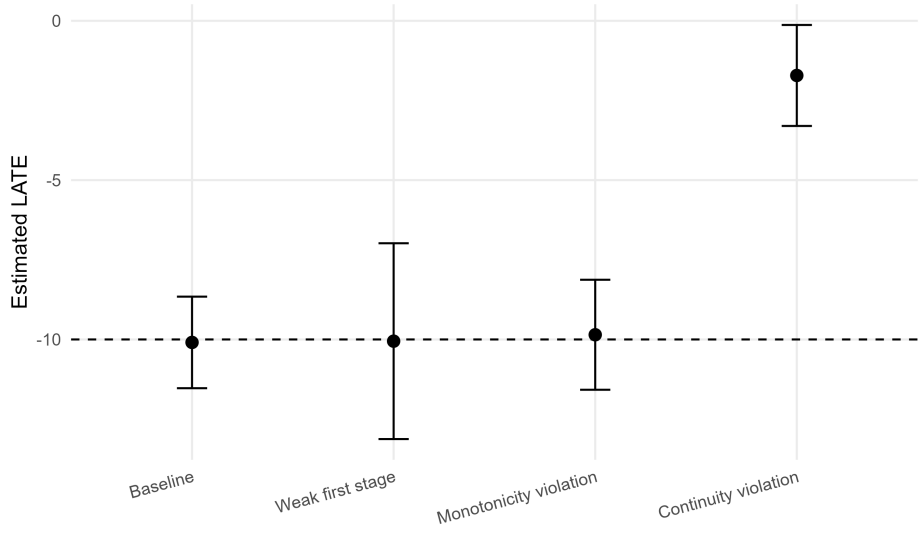

Figure 3: Monte Carlo mean and dispersion of the FRDD local 2SLS estimator across simulation scenarios. Points represent mean estimates, vertical bars represent one Monte Carlo standard deviation, the horizontal dashed line indicates the true effect $\tau = -10$.

A markedly different behavior emerges under violations of outcome continuity at the cutoff. In the continuity violation scenario, where untreated potential outcomes feature an additional discontinuity modeled through $\delta = 5$, the fuzzy regression discontinuity estimator becomes severely biased. The Monte Carlo mean is $\bar{\hat{\tau}} \approx -1.72$, with bias about 8.28, and empirical coverage collapses to zero. This failure occurs despite a very strong first stage, with mean $\widehat{F}_Z \approx 102.89$, indicating that instrument strength cannot compensate for violations of the continuity assumption. This result is clearly reflected in Figure 3, where the estimated effect lies far from the true value.

Finally, under monotonicity violations implemented through a defier share equal to 0.05, the fuzzy regression discontinuity estimator remains close to the true effect on average, with $\bar{\hat{\tau}} \approx -9.85$ and bias about 0.15. However, variability increases relative to the baseline, with standard deviation about 1.73, and empirical coverage decreases to approximately 0.90. The first stage remains strong, with mean $\widehat{F}_Z \approx 102.24$, suggesting that the observed degradation is driven by departures from monotonicity rather than by weak instrument behavior.

4.3 Coverage and First Stage Strength

Figure 4 relates empirical coverage of nominal 95% confidence intervals to the magnitude of the treatment probability discontinuity. Coverage remains close to the nominal level when the first stage gap is moderate or large, while it deteriorates sharply in the presence of continuity violations, even under strong instruments. This figure highlights that correct inference in fuzzy regression discontinuity designs depends jointly on instrument strength and on the validity of the underlying identification assumptions.

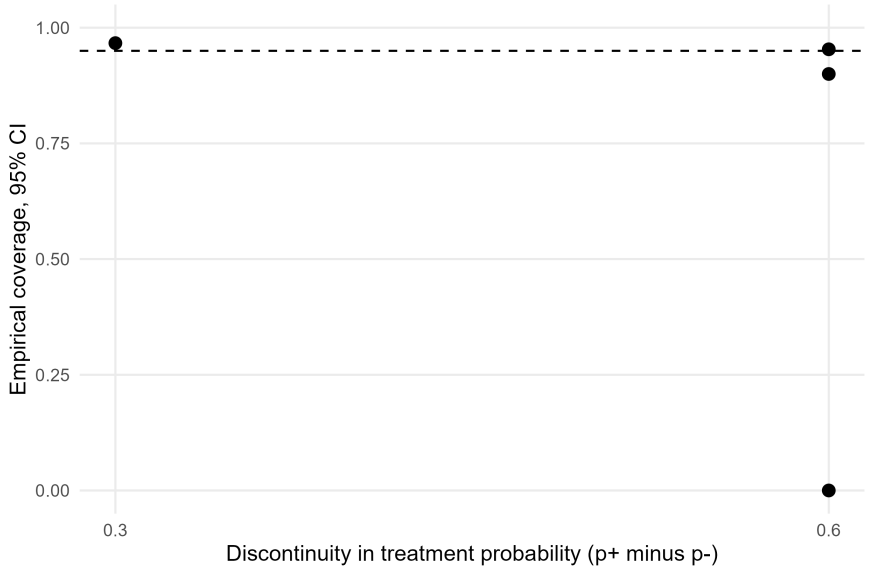

Figure 4: Empirical coverage of nominal 95% confidence intervals as a function of the discontinuity in treatment probability. The horizontal dashed line marks the nominal coverage level.

5 Discussion and Conclusions

The simulation results provide a systematic assessment of the robustness properties of fuzzy regression discontinuity designs under departures from their key identifying assumptions. The graphical evidence reported in Figures 1, 2, 3, and 4 complements the numerical results in Table 1 and helps clarify the mechanisms underlying estimator performance.

In the baseline configuration, the probability of treatment exhibits a clear discontinuity at the cutoff, as shown in Figure 1, and untreated potential outcomes are continuous. Under these conditions, the local two stage least squares estimator

recovers the target Local Average Treatment Effect with negligible bias and coverage close to the nominal level. Figure 2 illustrates how the reduced form discontinuity reflects an attenuated version of the true treatment effect, which is correctly rescaled by the fuzzy regression discontinuity estimator. The corresponding point in Figure 3 lies close to the true value $\tau = -10$, confirming the validity of the design in this idealized setting.

Weakening the first stage by reducing the discontinuity in treatment probability primarily affects precision rather than bias. In the weak first stage scenario, the estimator remains centered near the true effect, but its dispersion increases markedly, as clearly visible in Figure 3. This behavior is consistent with the instrumental variable nature of the estimator, since lower compliance reduces the amount of exogenous variation available for identification. Figure 4 shows that coverage remains close to nominal despite the weaker first stage, reflecting appropriately wider confidence intervals rather than systematic distortion.

The most critical failure mode emerges under violations of continuity of potential outcomes at the cutoff. In the continuity violation scenario, the estimator becomes severely biased and empirical coverage collapses to zero, even though the first stage remains strong. This breakdown is clearly illustrated in Figure 3, where the estimated effect departs substantially from the true parameter, and in Figure 4, where coverage drops to zero despite a large treatment probability discontinuity. These results emphasize that instrument strength alone is insufficient for valid causal inference, since the local exclusion restriction implied by continuity of untreated outcomes is essential.

Violations of monotonicity generate a different pattern of sensitivity. When a nonzero share of defiers is introduced, the estimator remains approximately centered on the true effect, but variability increases and coverage deteriorates relative to the baseline. This behavior, visible in Figure 3, indicates that departures from monotonicity complicate finite sample performance and blur the interpretation of the estimated Local Average Treatment Effect, even when the first stage remains strong.

Overall, the results highlight that fuzzy regression discontinuity designs can provide reliable local causal inference in clinical and epidemiological applications only under a restricted set of conditions. Approximate continuity of potential outcomes at the cutoff and sufficient compliance are crucial, while violations of continuity lead to severe bias and loss of inferential validity. The proposed simulation framework, together with the accompanying graphical diagnostics, offers a practical tool to assess the plausibility and consequences of these assumptions in applied settings.

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Data availability statement

The dataset used in the empirical application is not publicly available. It can be provided by the author upon reasonable r ::contentReference[oaicite:0]index=0

Author Contributions

Both authors jointly contributed to the conception and design of the study, methodological development, programming and data analysis, manuscript writing and revision, responses to reviewers, and approved the final version of the manuscript.

Use of Generative AI in Scientific Writing

The authors used *AI* to improve the English language in preparing this work. They reviewed and edited the content as needed and took full responsibility for the publication's content.

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