

Assessing the Real-World Impact of the FDA Boxed Warning on Breast Implants: A Nationwide Analysis of Reconstructive and Aesthetic Procedural Trends

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Background

- On October 27, 2021, the FDA implemented a boxed warning on breast implants.
- While cross-sectional surveys suggested patients would be less likely to pursue implant-based reconstruction (IBR) or breast augmentation (BA), real-world impacts on procedural volumes remained unknown.

Objectives

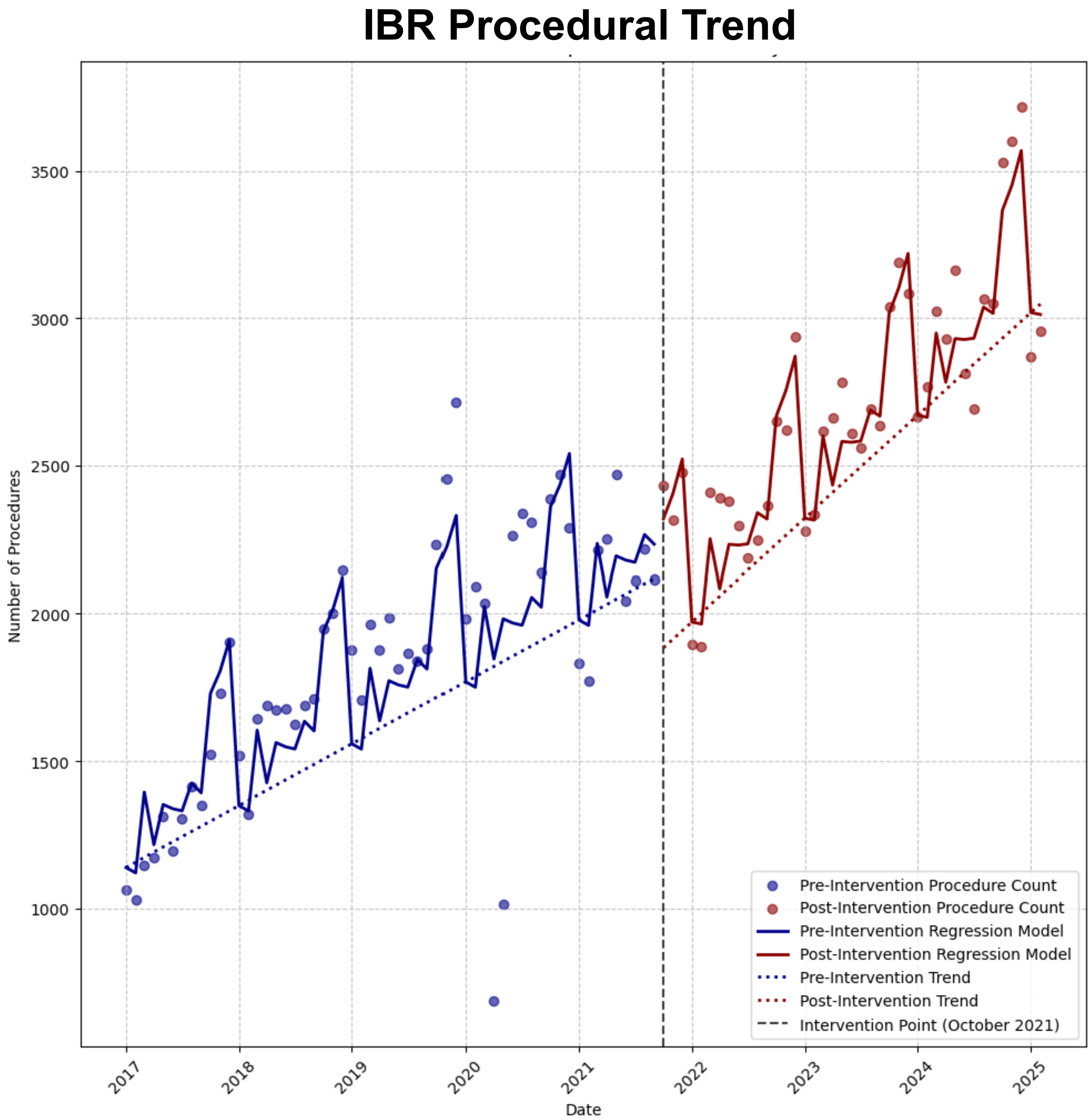
- To quantify changes in IBR and BA trends following the warning.

Methods

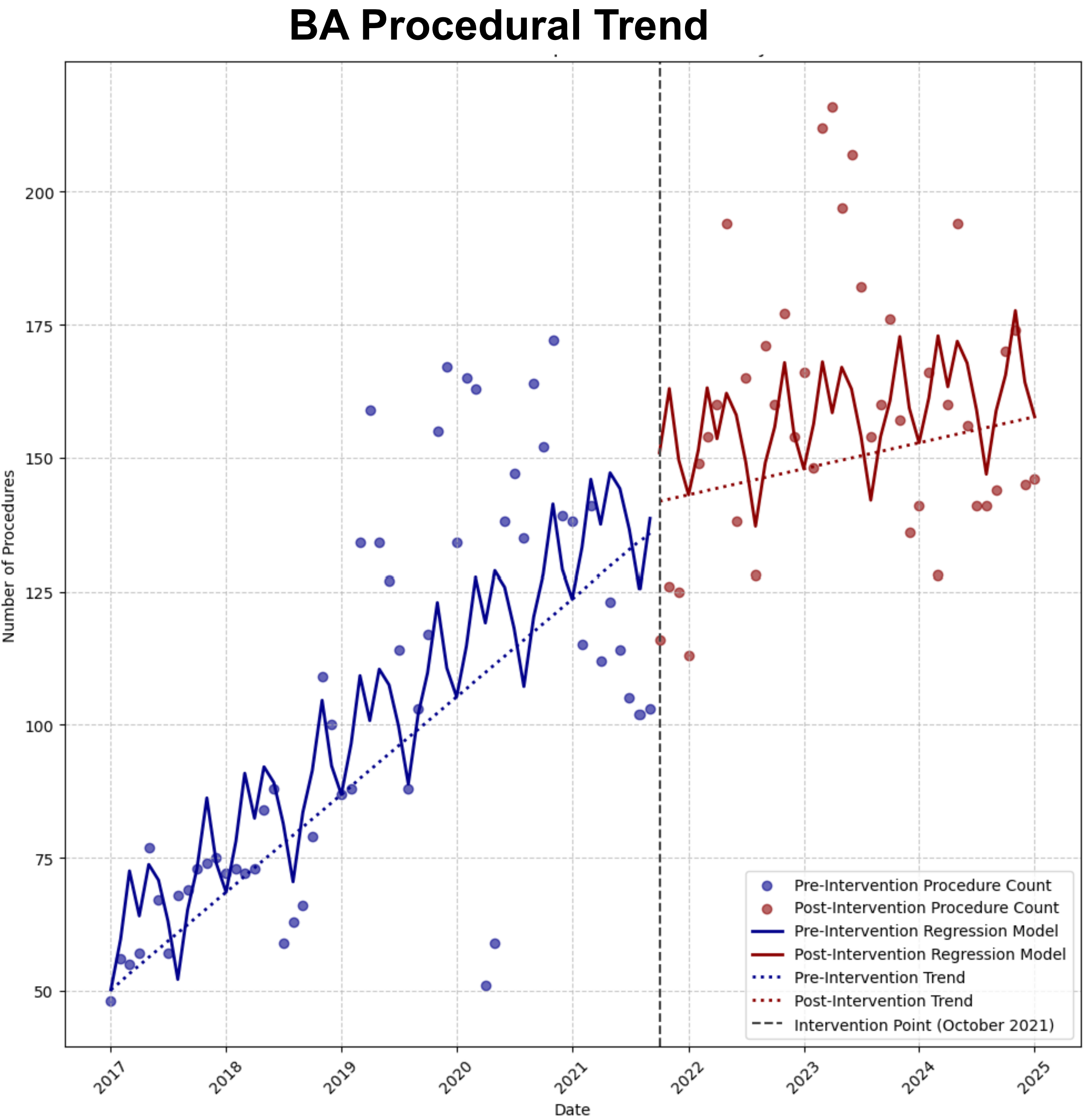
- Interrupted Time Series Analysis (ITSA)
- Monthly procedural rates of IBR (CPT 11970, 19340, 19342) and BA (CPT 19325) were retrieved from Epic Cosmos database from January 2017 through January 2025.
- ITSA using segmented regression identified immediate and gradual shifts in procedural trends, controlling for seasonality.

Results

- 211,849 IBR and 12,206 BA procedures across 177 healthcare centers.
- Prior to the boxed warning, monthly IBR increased steadily by 17.5 procedures per month (PPM) (95% CI, 13.9–21.2, $p<0.001$), while BA increased at 1.5 PPM (95% CI, 1.1–2.0, $p<0.001$).
- ITSA demonstrated a significant immediate decline in monthly IBR of 251.9 procedures (95% CI, 65.2–438.5, $p<0.01$) following the FDA boxed warning, representing **10.4%** of October 2021 procedural volume. Subsequently, procedural growth increased by 11.6 PPM (95% CI, 4.6–18.6, $p=0.0016$), representing a **66.2%** increase in slope compared to the pre-intervention trend.
- Conversely, BA declined in growth rate by 1.1 PPM (95% CI, 0.3–2.0, $p<0.01$), reduced to **27.8%** of the pre-intervention trend.



	Procedure Data	95% CI	p
October 2021 (Proc)	2431	-	-
Pre-Warning Trend (PPM)	17.51	(1.86, 21.15)	< 0.001
Post-Warning Level Change (Proc)	-251.86	(-438.48, -65.23)	< 0.01
Post-Warning Slope Change (PPM)	+11.58	(+4.60, +18.55)	0.001



	Procedure Data	95% CI	p
October 2021 (Proc)	116	-	-
Pre-Warning Trend (PPM)	1.53	(1.11, 1.95)	< 0.001
Post-Warning Level Change (Proc)	+ 4.45	(-17.49, 26.39)	0.690
Post-Warning Slope Change (PPM)	-1.12	(-1.95, -0.29)	< 0.01

References

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Conclusions

- This study provides the first quantitative evidence that FDA boxed warnings substantially influence surgical practice patterns.
- Important differences were noted in the impact of FDA actions on procedural volume of IBR compared to BA
 - While both declined after the warning, this decrease was transient for IBR but sustained for BA.
- As it is unclear whether this variation reflects true differences in patient preferences based on indication or variation in how risk is conveyed in physician-patient interactions, this study highlights the importance of effective risk communication in aligning procedures with patients' unique care goals.
- These results establish an evidence-based foundation to guide future FDA policy on risk communication, underscoring their potential to transform clinical practice patterns and improve shared decision-making between patients and physicians.

Risk communications should be evaluated on several dimensions. Areas for further inquiry:



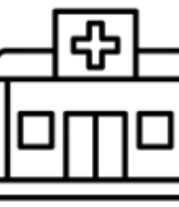
Are current checklists effective at producing lasting, comprehensive educational benefit?



Do FDA actions improve adherence to screening guidelines?
Existing studies demonstrate as low as 6% compliance.



How does media affect efficacy and validity of risk communication?



Were independent, private practice settings affected similarly to large healthcare organizations?