Does the Abortion Pill Harm Women? Serious Adverse Events Following Mifepristone Abortion in US Commercial and Medicaid Populations

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BACKGROUND

Mifepristone is a medication used in nearly 63% of all abortions in the United States in 2023.[1] However, due to controversies over its safety profile, access restrictions, and role in abortion care, mifepristone remains at the center of regulatory and political debate.[2,3] Proponents of stricter regulation believe increased restrictions on mifepristone are necessary due to concerns about clinically-important adverse events (AEs).[4] They point to recent real-world data indicating that the rate of clinically-important AEs, including sepsis, hemorrhage, and clinically-important infection, may be much higher than what clinical trials have reported.[4-6] A 2025 study by the Ethics and Public Policy Center reported that approximately 11% of women experienced clinically-important AEs within 45 days of a mifepristone abortion, far higher than rates reported in clinical trials.[7]

OBJECTIVES

To provide robust, risk-adjusted estimates of clinically-important AEs following mifepristone abortion, enabling more accurate comparisons with clinical trial data and informing evidence-based policy decisions.

METHODS

This retrospective study used a closed-claims subset, comprising approximately 172 million commercially insured patients and 60 million Medicaid-insured patients from Kythera Labs Commercial and Medicaid claims files from 01 January 2017, to 15 November 2025.

Mifepristone abortions were identified using a combination of procedure codes, prescriptions, and diagnosis codes for elective termination or unwanted pregnancy, consistent with manufacturer reimbursement guidelines for each state and insurer.

Age, socioeconomic status (SES), and comorbidities were assessed as of the abortion procedure date. Comorbidities potentially associated with poor abortion outcome were selected using International Classification of Disease, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes.

Clinically-important AEs, including sepsis, infection, transfusion, hemorrhage, hospitalization, ectopic pregnancy, life-threatening AEs, repeated surgical abortion, and emergency department (ED) visits occurring within 45 days of abortion were evaluated.

Adverse events were categorized as major if they required hospital admission and minor if they did not require hospital admission. Odds ratios (ORs) and predicted probabilities were estimated across combinations of age, comorbidities, and SES.

RESULTS

Baseline Characteristics

For both payer types, women aged 18 to 34 years, who resided outside high-SES areas and with a greater comorbidity burden were more likely to experience clinically-important AEs (**Table 1**).

Significant variation in clinically-important AE rates was observed across age, SES, and comorbidity groups.

Patients experiencing clinically-important AEs were older, resided in lower socioeconomic areas, and had higher comorbidity burden (p<0.001).

Figure 1. Study Attrition for Women with Abortion

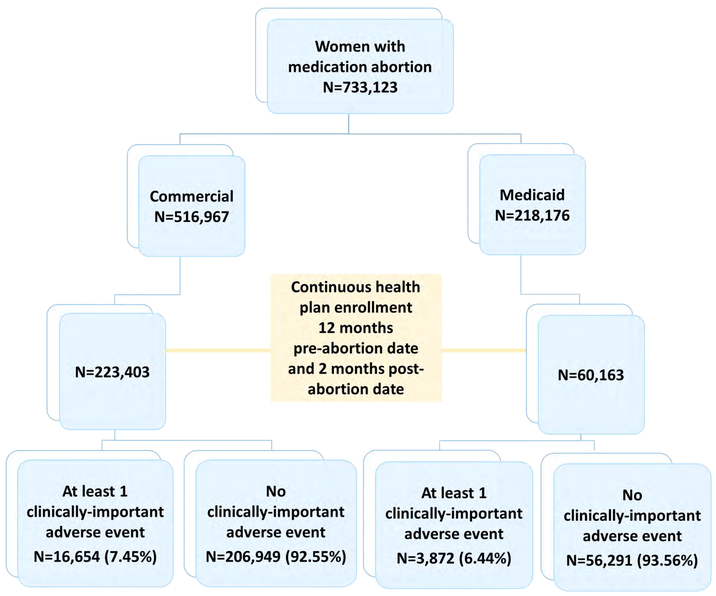

Table 1. Demographic and Clinical Characteristics of Women who Underwent Their First Medication Abortion, With and Without Clinically-Important Adverse Events

Characteristics	Commercial					Medicaid				
	≥1 Clinically-important AEs (N=16,654)	No Clinically-important AEs (N=206,749)	*P* Value	OR	95% CI of OR	≥1 Clinically-important AEs (N=3872)	No Clinically-important AEs (N=56,291)	*P* Value	OR	95% CI of OR
Age										
Mean (SD)	27.29 (6.07)	27.85 (18.46)	<0.001	--	--	27.73 (6.50)	27.44 (5.61)	<0.001	--	--
Age 12-17 y, n (%)	278 (1.67%)	3801 (1.84%)	0.116	Ref.	Ref.	34 (0.89%)	598 (1.06%)	0.001	Ref.	Ref.
Age 18-34 y, n (%)	14,090 (84.60%)	168,171 (81.34%)	<0.001	1.16	(1.03, 1.31)	3448 (89.06%)	49,779 (88.43%)	<0.001	1.26	(1.01, 1.57)
Age 35-55 y, n (%)	2269 (13.62%)	34,614 (16.74%)	<0.001	0.92	(0.81, 1.04)	357 (9.22%)	5823 (10.34%)	<0.001	1.25	(0.99, 1.58)
Socioeconomic status, n (%)										
Low and middle tercile	11,290 (67.79%)	133,906 (64.77%)	<0.001	Ref.	Ref.	1331 (34.38%)	18,128 (32.20%)	<0.001	Ref.	Ref.
High tercile	5088 (30.55%)	69,024 (33.39%)	<.001	0.89	(0.86, 0.92)	2440 (63.01%)	36,869 (65.50%)	<0.001	0.98	(0.93, 1.04)
Comorbidity score, mean (SD)										
V-Elixhauser Index <2	14,620 (87.79)	196,985 (92.11)	<0.001	Ref.	Ref.	33,594 (79.07)	266,453 (88.47)	<0.001	Ref.	Ref.
V-Elixhauser Index ≥2	2034 (12.21)	16,884 (7.89)	<0.001	1.62	(1.54, 1.70)	8891 (20.93)	34,714 (11.53)	<0.001	2.18	(2.02, 2.36)
Baseline comorbidities, n (%)										
Diabetes mellitus	545 (3.27%)	6321 (3.06%)	0.122	1.03	(0.94, 1.13)	80 (2.07%)	724 (1.29%)	<0.001	1.08	(0.85, 1.38)
Hypertension	1178 (7.07%)	12,950 (6.26%)	0.027	1.09	(1.02, 1.17)	232 (5.99%)	1933 (3.43%)	<0.001	1.22	(1.05, 1.42)
Obesity	2769 (16.63%)	34,778 (16.82%)	0.949	1.03	(0.98, 1.09)	539 (13.92%)	6454 (11.47%)	<0.001	0.85	(0.76, 0.95)
Cardiomyopathy	36 (0.22%)	330 (0.16%)	<0.001	0.98	(0.68, 1.39)	8 (0.21%)	42 (0.07%)	<0.001	1.5	(0.68, 3.27)
Epilepsy/seizure disorders	222 (1.33%)	1765 (0.85%)	<0.001	1.37	(1.19, 1.59)	51 (1.32%)	319 (0.57%)	<0.001	1.39	(1.02, 1.89)
Asthma	1867 (11.21%)	18,602 (9.00%)	<0.001	1.33	(1.26, 1.40)	510 (13.17%)	3788 (6.73%)	<0.001	1.51	(1.35, 1.68)

AE: adverse event; CI: confidence interval; OR: odds ratio; SD: standard deviation

RESULTS

Clinically-important AEs occurred in 6.71% of commercially-insured patients with abortions vs 6.31% of Medicaid-insured patients (**Table 2**).

Table 2. Rates of Clinically-Important Adverse Events Associated with Medication Abortion

Clinically-important Adverse Events	Commercial (N=307,932), n (%)	Medicaid (N=78,140), n (%)
Sepsis	374 (0.12%)	94 (0.12%)
Infection without sepsis	436 (0.14%)	101 (0.13%)
Hemorrhage without transfusion	1811 (0.59%)	465 (0.60%)
Ectopic pregnancy	1114 (0.36%)	265 (0.34%)
Transfusion	212 (0.07%)	74 (0.09%)
ED visit (related to abortion)	12,744 (4.14%)	2979 (3.81%)
Incomplete medical abortion requiring surgical intervention	1317 (0.43%)	354 (0.45%)
Other abortion-related complications	2639 (0.86%)	601 (0.77%)
Total	**20,647 (6.71%)**	**4933 (6.31%)**

ED, emergency department

AE-Related Hospitalization

Among hospitalized patients, clinically-important AEs occurred in 0.38% of commercial abortions and 0.39% of Medicaid abortions. Sepsis was associated with the highest hospitalization rate (58.29% commercial; 59.57% Medicaid), followed by transfusion (34.43% commercial; 32.43% Medicaid; **Table 3**).

Table 3. Hospitalization Rates Related to Clinically-Important AEs following Medication Abortion

Clinically-important Adverse Events	Commercial			Medicaid		
	Total, n	Hospitalized, n (%)	Not Hospitalized, n (%)	Total, n	Hospitalized, n (%)	Not Hospitalized, n (%)
Sepsis	374	218 (58.29%)	156 (41.71%)	94	56 (59.57%)	38 (40.43%)
Infection without sepsis	436	42 (9.63%)	394 (90.37%)	101	19 (18.81%)	82 (81.19%)
Hemorrhage without transfusion	1811	155 (8.56%)	1656 (91.44%)	465	43 (9.25%)	422 (90.75%)
Ectopic pregnancy	1114	131 (11.76%)	983 (88.24%)	265	23 (8.68%)	242 (91.32%)
Transfusion	212	73 (34.43%)	139 (65.57%)	74	24 (32.43%)	50 (67.57%)
ED visit (related to abortion)	12,744	423 (3.32%)	12,321 (96.68%)	2979	96 (3.22%)	2883 (96.78%)
Incomplete medical abortion requiring surgical intervention	1319	39 (2.96%)	1280 (97.04%)	355	12 (3.38%)	343 (96.62%)
Other abortion-related complications	2639	92 (3.49%)	2547 (96.51%)	601	30 (4.99%)	571 (95.01%)
Total	**20,649**	**1173 (5.68%)**	**19,476 (94.32%)**	**4934**	**303 (6.14%)**	**4631 (93.86%)**
Total abortions	**307,932**	**0.38%**	**6.32%**	**78,140**	**0.39%**	**5.93%**

ED: emergency department

Limitations

Directly comparing clinical trial results with real-world data comes with significant limitations.[8,9] Clinical trials are conducted in highly controlled settings; therefore, the incidence of clinically-important AEs observed may not be generalizable to broader patient populations.[10,11] Further, clincial trials use randomization to minimize bias and ensure comparability between groups,[12,13] whereas real-world studies often involve heterogeneous comparison groups managed in heterogeneous settings.[14] Consequently, higher rates of AEs observed in real-world settings, often cited in support of increased regulation, may be attributable to population heterogeneity rather than the effects of the medication. By controlling for demographic and clinical characterstics, researchers can strengthen the evidence base needed to guide policy decisions on appropriate restrictions for mifepristone.

CONCLUSION

Real-world rates of clinically-important AEs following mifepristone abortion were higher than those reported in clinical trials, but ~75% lower than recent public policy estimates. Our findings demonstrate that clinically-important AEs following medication abortion were rare, with <1% of abortions leading to AEs requiring hospitalization.

Additional restrictions on mifepristone, especially post-*Dobbs v Jackson Women's Health Organization,* may further limit abortion access and disproportionately impact women in US states with abortion bans who must travel for care. Transparent, real-world data are essential for guiding evidence-based policy decisions and ensuring that abortion regulations are proportionate to measured clinical risks.

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