Sentinel Pregnancy in Women with Heart failure: A Cross-Sectional Study in the Sentinel System

Presented at ICPE 2021 All Access

Yan Li¹, Austin Cosgrove², Efe Eworuke¹, Catherine Corey¹, Joy Kolonoski², Mayura Shinde²

¹ Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD, USA

² Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, USA

BACKGROUND

- Given the increase in blood volume and cardiac output, pregnancy poses significant risk of morbidity and mortality in women with underlying heart diseases, including heart failure (HF).
- Prior epidemiological studies concerning HF and pregnancy have mostly focused on HF-related encounters during peripartum and postpartum periods.
- An analysis of the Nationwide Inpatient Sample (NIS) suggested HF diagnoses existed in about 0.1% of all pregnancy related hospitalizations in the United States from 2001 to 2011, and a large proportion of these diagnoses represented newonset HF and occurred during the postpartum period (Mogos, Circ Heart Fail, 2018).
- Without information on patients' medical history in the NIS database, the rate of pregnancy among HF women could not be determined.

OBJECTIVES

• To estimate the prevalence of HF in women of childbearing age and the number of live birth and stillbirth pregnancies among these women.

METHODS

- Childbearing age women (i.e., 15 to 54 years) with live birth or stillbirth deliveries were identified in the FDA's Sentinel System from January 2010 to February 2020 (Figure 1).
- We used ICD-9 and ICD-10-CM diagnosis and procedure codes to identify live birth and stillbirth deliveries. Women were required to be continuously enrolled ≥ 480 days prior to delivery. To identify pregnancies among women with HF, we required evidence of qualifying HF diagnoses during the 180-day pre-pregnancy period or the first trimester, because newonset HF in pregnant women rarely occurs during the first trimester.
- To understand the background rate of pregnancy in women with HF, we identified all childbearing age women with qualifying HF diagnoses in the database regardless of pregnancy status. Results were stratified by age group and calendar year. This analysis was designed on Sentinel Query Request Package (QRP) version 9.7.0.

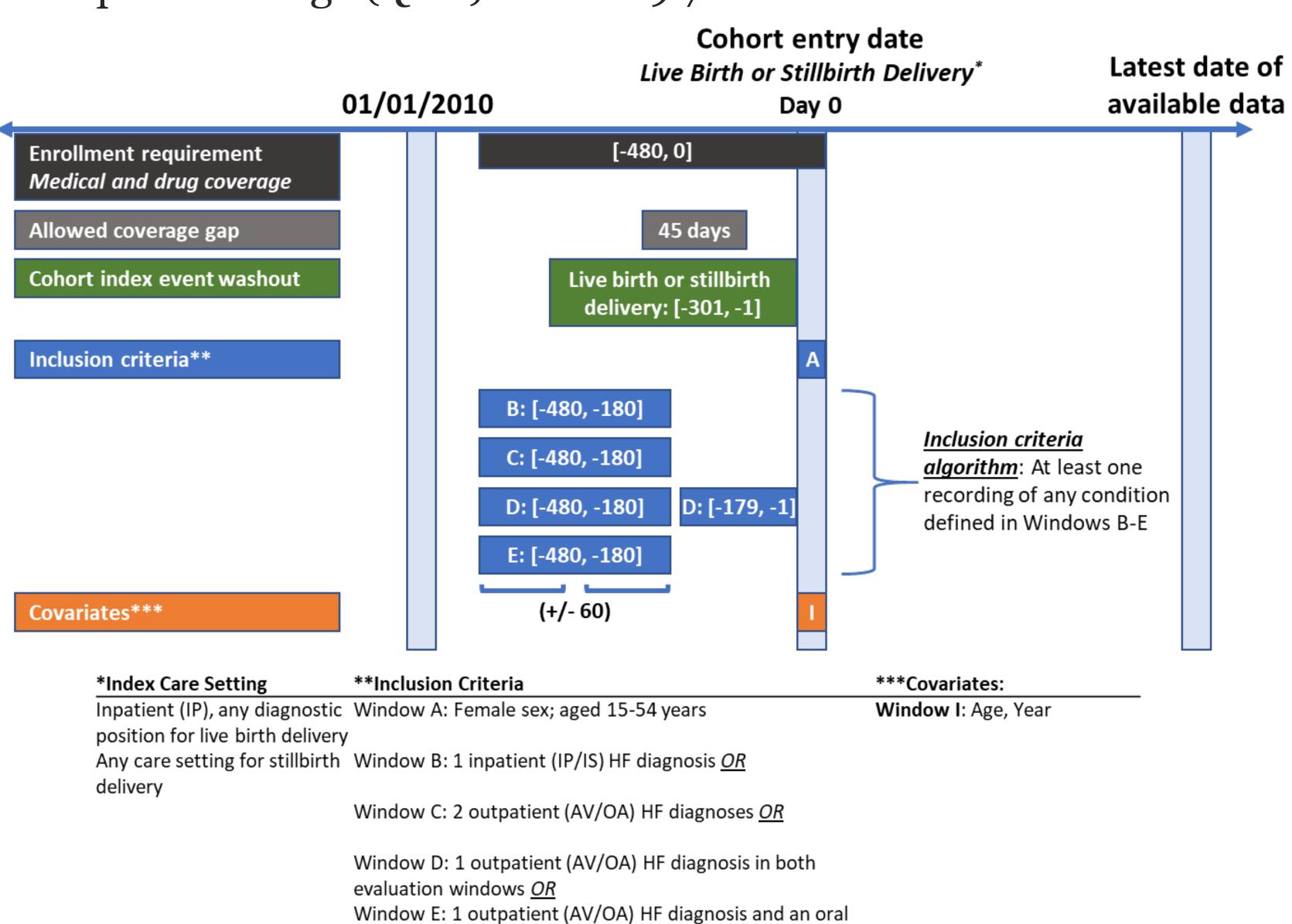


Figure 1. Graphic illustration of study design

HF-related medication dispensed (+/- 60 days) of diagnosis

Contact email: yan.li@fda.hhs.gov

RESULTS

- As shown in Table 1, among 29.6 million women of child-bearing age in the database, we identified 144,162 HF cases (prevalence, 0.5%). Within this HF cohort, there were 813 women with 822 pregnancies ending in live birth deliveries (5.6 live birth deliveries per 1,000 women with HF).
- The prevalence of HF increased monotonically with age which reached 1.2% in the 50-54 years group. The majority of live birth deliveries occurred among younger patients, with the 25-29 years group having the highest proportion (34.7 live birth deliveries per 1,000 women with HF).
- Across the study period, the prevalence of HF remained stable (~0.3%), as did the rate of deliveries (Table 1).
- Including stillbirth deliveries barely changed the observed trends.

Table 1. Live Birth or Stillbirth Deliveries among Women with Heart Failure (HF) in the Sentinel System between January 2010 and February 2020

	# of eligible women	# of women with HF	Prevalence of HF, %	# of live birth deliveries	# of live birth deliveries per 1,000 women with HF	# of live birth or stillbirth deliveries	# of live birth or stillbirth deliveries per 1,000 women with HF
Total	29,535,188	144,162	0.5%	822	5.6	846	5.8
Age group							
15-19	4,651,623	1,735	0.04%	11	6.3	11	6.3
20-24	5,033,406	3,133	0.06%	81	25.5	84	26.5
25-29	5,673,276	4,932	0.09%	171	34.7	172	34.9
30-34	5,514,271	9,177	0.2%	247	26.8	255	27.6
35-39	5,477,578	14,853	0.3%	211	14.1	215	14.4
40-44	5,518,878	24,418	0.4%	65	2.6	68	2.7
45-49	5,780,940	42,013	0.7%	21	0.5	22	0.5
50-54	5,885,323	69,710	1.2%	15	0.2	19	0.3
Year							
2010	9,417,397	28,772	0.3%	84	2.9	87	3.0
2011	8,951,714	26,969	0.3%	94	3.5	96	3.6
2012	8,647,256	25,475	0.3%	78	3.1	79	3.1
2013	8,546,556	24,680	0.3%	72	2.9	73	3.0
2014	9,189,860	26,571	0.3%	83	3.1	86	3.2
2015	9,667,980	29,132	0.3%	88	3.0	92	3.2
2016	9,899,429	31,321	0.3%	91	2.9	96	3.1
2017	10,133,960	31,827	0.3%	84	2.6	84	2.6
2018	9,658,004	28,371	0.3%	72	2.5	74	2.6
2019	9,248,525	27,637	0.3%	72	2.6	75	2.7
2020 ¹	3,875,117	8,116	0.2%	< 5	N/A	< 5	N/A
	-	.		3			

¹ The 2020 data ended in February, resulting in irregularly small counts

CONCLUSION

• HF is rare among women of childbearing age and pregnancies only occurred in a small number (<0.6%) of these women. Further study is needed to understand characteristics and outcomes of pregnancies among women with HF.

LIMITATIONS

- Underestimation of the overall pregnancy rate as a result of missing spontaneous or induced abortions
- Algorithms to identify HF diagnoses are not fully validated; therefore, potential misclassification of HF cases

ACKNOWLEDGEMENTS/DISCLOSURES

- The views expressed in this poster represent those of the presenters and do not necessarily represent the official views of the U.S. FDA.
- This project was supported by Task Order 75F40119F19001 under Master Agreement 75F40119D10037 from the US Food and Drug Administration (FDA).
- Many thanks are due to data partners who provided data used in the analysis.
- The authors have no conflicts of interest to disclose.