

Percutaneous Transluminal Septal Myocardial Ablation and Common Procedural Complications: a Descriptive Study

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INTRODUCTION

- Dehydrated alcohol is used in percutaneous transluminal septal myocardial ablation (PTSMA), a procedure for the treatment of left ventricular outflow tract obstruction in patients with hypertrophic obstructive cardiomyopathy.
- The first dehydrated alcohol product, Ablysinol, was approved by the U.S. Food and Drug Administration (FDA) on June 21, 2018.
- Prior to June 21, 2018, data on the frequency of PTSMA and suspected post-PTSMA complications are limited.

METHODS

- Identified patients undergoing their first qualifying PTSMA in inpatient and outpatient care settings between January 1, 2014 and June 21, 2018 in the Sentinel System.
- Followed patients after index PTSMA for common complications such as: permanent pacemaker placement (PPP), ventricular arrhythmia, heart failure, as well as septal myectomy and repeat PTSMA for up to 365 days after PTSMA. Atrioventricular (AV) block was assessed in the 30 days after PTSMA (**Figure 1**). Patients were followed using an intention to treat (ITT) approach until the outcome, death, or disenrollment.
- Calculated the rate of complications per 1,000 person-years and the proportion of patients who experienced each outcome separately by care setting.

RESULTS

- We identified 376 inpatient PTSMA procedures and 852 outpatient procedures, and the number of procedures increased over time (**Table 1**).
- Compared to outpatients, inpatients were younger (mean age 69.2 vs 72.1), more likely to be male (38.3% vs. 27.3%) and had a lower mean combined comorbidity score (4.0 vs. 4.5) (**Table 1**).
- In both care settings, the most common complication was AV block, followed by heart failure (**Table 2**).
- Ventricular arrhythmias were more common after inpatient procedures than outpatient procedures (**Table 2**).

	Inpatient Procedures		Outpatient Procedures	
	N/Mean	%/Std Dev ¹	N/Mean	%/Std Dev ¹
Number of Unique Patients	376		852	
Demographics				
Mean Age	69.2	11.2	72.1	10.6
Age: 18-64 Years	123	32.8%	148	17.4%
Age: 65-74 Years	119	31.6%	337	39.6%
Age: 75+ Years	134	35.6%	367	43.1%
Gender (Female)	232	61.7%	619	72.7%
Gender (Male)	144	38.3%	233	27.3%
2014	29	7.7%	159	18.7%
2015	65	17.3%	150	17.6%
2016	113	30.1%	176	20.7%
2017	118	31.4%	238	27.9%
2018	51	13.6%	129	15.1%
Medical conditions				
Charlson/Elixhauser Combined Comorbidity Score ²	4.0	2.4	4.5	2.7
Acute Myocardial Infarction	14	3.7%	45	5.3%
Atrial Fibrillation	99	26.3%	267	31.3%
Ischemic Heart Disease	230	61.2%	567	66.5%
Heart Failure	169	44.9%	440	51.6%
Diabetes	82	21.8%	202	23.7%
Health Service Utilization				
Mean Number of Ambulatory Encounters	18.6	14.4	19.4	16.5
Mean Number of Inpatient Hospital Encounters	0.6	1.1	0.8	1.2
Mean Number of Unique Drug Classes	9.0	4.5	9.5	4.8

¹Value represents standard deviation where no % follows the value
²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during the 183 days prior to PTSMA

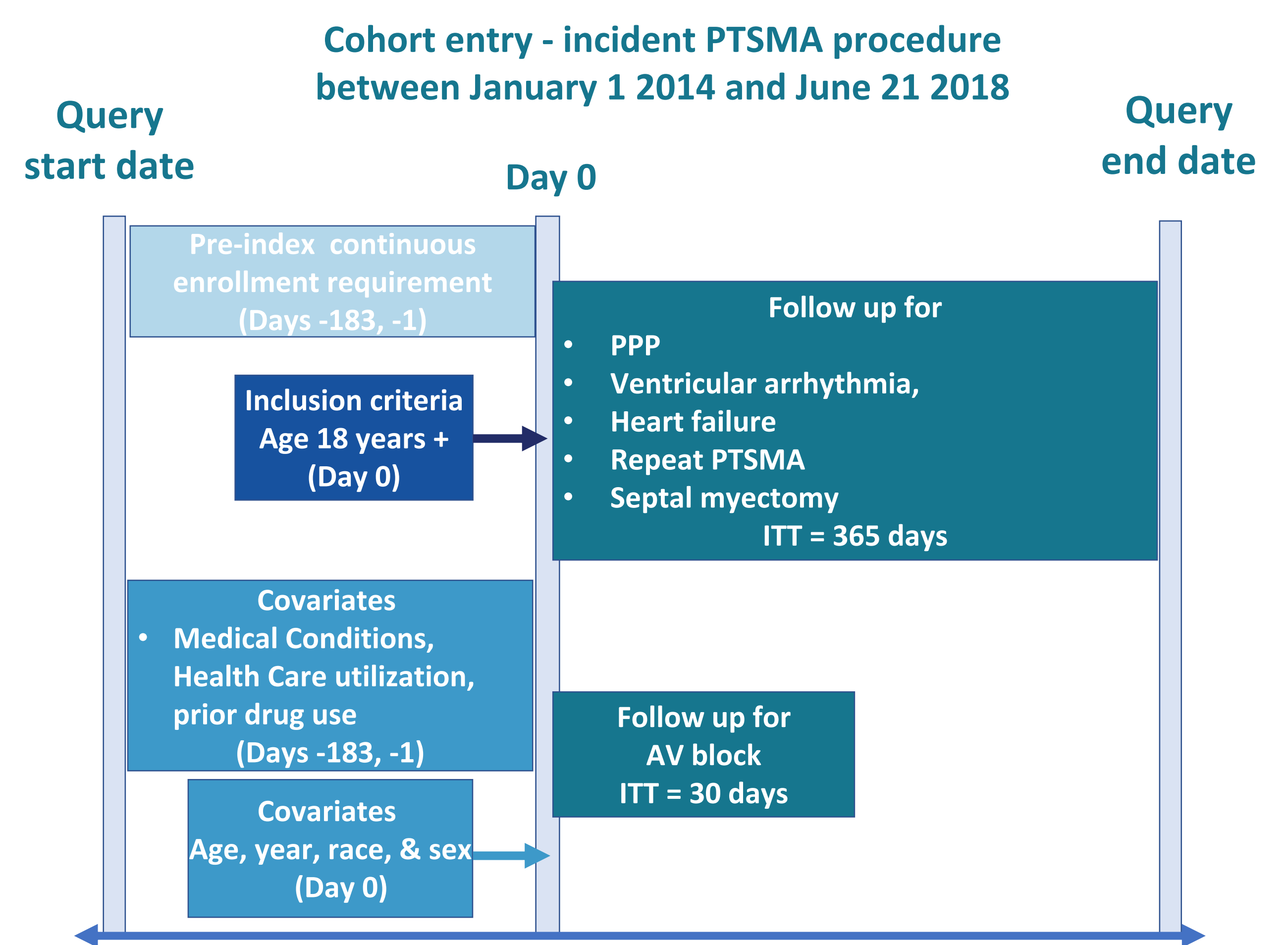
DISCUSSION

- PTSMA procedures increased over time, except for 2018 where data were incomplete. More PTSMA procedures were conducted in outpatient than inpatient settings in the Sentinel system.
- Suspected complications of PTSMA, such as AV block, heart failure, and PPP were common following the procedure, in both settings, with AV block occurring in almost 50% of patients.
- Further work will examine changes in the number of PTSMA procedures conducted and the post-PTSMA suspected complication rate after FDA approval of Ablysinol using interrupted time-series analyses.

OBJECTIVE

To estimate the frequency of PTSMA and the rate of common suspected complications following PTSMA prior to the approval of dehydrated alcohol in the Sentinel System.

Figure 1. Study Design Diagram



- Repeat PTSMA within 365 days was more common after inpatient procedures (10.4%) than outpatient procedures (4.9%) (**Table 2**).
- 51 patients with an outpatient procedure (6%) experienced both AV block and permanent pacemaker placement, the most commonly co-occurring complications after outpatient PTSMA.
- 35 patients with an inpatient procedure (9%) experienced both ventricular arrhythmia and heart failure, the most commonly co-occurring complications after inpatient PTSMA.

	Patients with PTSMA	New Episodes with Outcome	Incidence Rate per 1,000 Person-Years at Risk	Proportion of Patients with Outcome During Follow-Up ¹
Inpatient PTSMA Procedures				
Permanent pacemaker placement	376	115	561.80	30.9%
Ventricular arrhythmia	376	123	614.69	33.2%
Heart failure	376	183	1,132.43	49.7%
Atrioventricular block	376	140	7,106.60	47.3%
Repeat PTSMA	376	.	.	10.4%
Septal myectomy	376	*****	10.65	*****
Outpatient PTSMA Procedures				
Permanent pacemaker placement	852	268	600.22	32.0%
Ventricular arrhythmia	852	143	254.63	17.5%
Heart failure	852	368	894.07	45.3%
Atrioventricular block	852	317	7,254.00	48.2%
Repeat PTSMA	852	.	.	4.9%
Septal myectomy	852	11	16.91	1.5%

¹Reflects the proportion of patients who experienced the outcome during the specified follow-up period, without regard for censoring
*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

CONFLICTS OF INTEREST AND ACKNOWLEDGEMENTS

- The authors have no conflicts of interest to disclose and thank the Sentinel Data Partners who provided data used in the analysis.
- This poster includes the personal views and opinions of the co-authors and is not intended to convey official FDA policy, and no official support or endorsement by the FDA is provided or should be inferred.
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