

Antipsychotic Medication Use among Hospitalized Infants Using Inpatient Data in FDA's Sentinel System

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INTRODUCTION

- The Sentinel System is the U.S. Food and Drug Administration's (FDA) active safety surveillance system that uses routine querying tools and pre-existing electronic healthcare data to monitor safety of medical products.
- In 2016, the FDA expanded the Sentinel network of Data Partners to include inpatient electronic medical record (EMR) data from HCA Healthcare (HCA).
- At the time of this analysis, the HCA database available to Sentinel included approximately two million hospitalizations per year.

BACKGROUND

- The extent of antipsychotic (AP) use among infants admitted to neonatal intensive care units (NICUs) is unknown.
- Two published case reports have described use of APs to treat delirium in four infants admitted to NICUs,^{1,2} and no observational studies have examined AP utilization among hospitalized infants.

¹Groves A, Traube C, & Silver G. Detection and management of delirium in the neonate unit: a case series. *Pediatrics*. 2016; 137(3).
²Edwards LE, et al. A case of infant delirium in the neonatal intensive care unit. *J Neonatal Perinatal Med*. 2017;10(1):119-123.

OBJECTIVES

To quantify the frequency of typical and atypical AP administrations among hospitalized infants.

METHODS

- Data:** This was a retrospective descriptive study among infants hospitalized between 7/1/2011 – 9/30/2017. During the study period, 173 facilities contributed to the HCA database, and we identified typical and atypical AP administrations using inpatient pharmacy data.
- Study Population:** In order to exclude infants with routine postnatal care, we included infants <6 months of age on admission and with a length of stay (LOS) of >3 days. We also examined a cohort of infants <6 months of age on admission in a sensitivity analysis.
- Exposure Assessment:** We used generic name, brand name, and National Drug Codes (NDC) to define typical and atypical AP.
 - We mapped hospital-specific drug mnemonics at each facility and estimated days of AP use using distinct dates of administration of AP during the inpatient stay.
 - Further, we also examined number of administrations per inpatient stay, including multiple administrations of the APs given on the same day.
- Data Analyses:** We conducted descriptive analyses estimating the frequency of any AP use by exposure type: typical or atypical, and AP generic drug.
 - We examined demographics (e.g., age, sex), hospitalization characteristics (e.g., admission year, LOS) and facilities with NICU care.

RESULTS

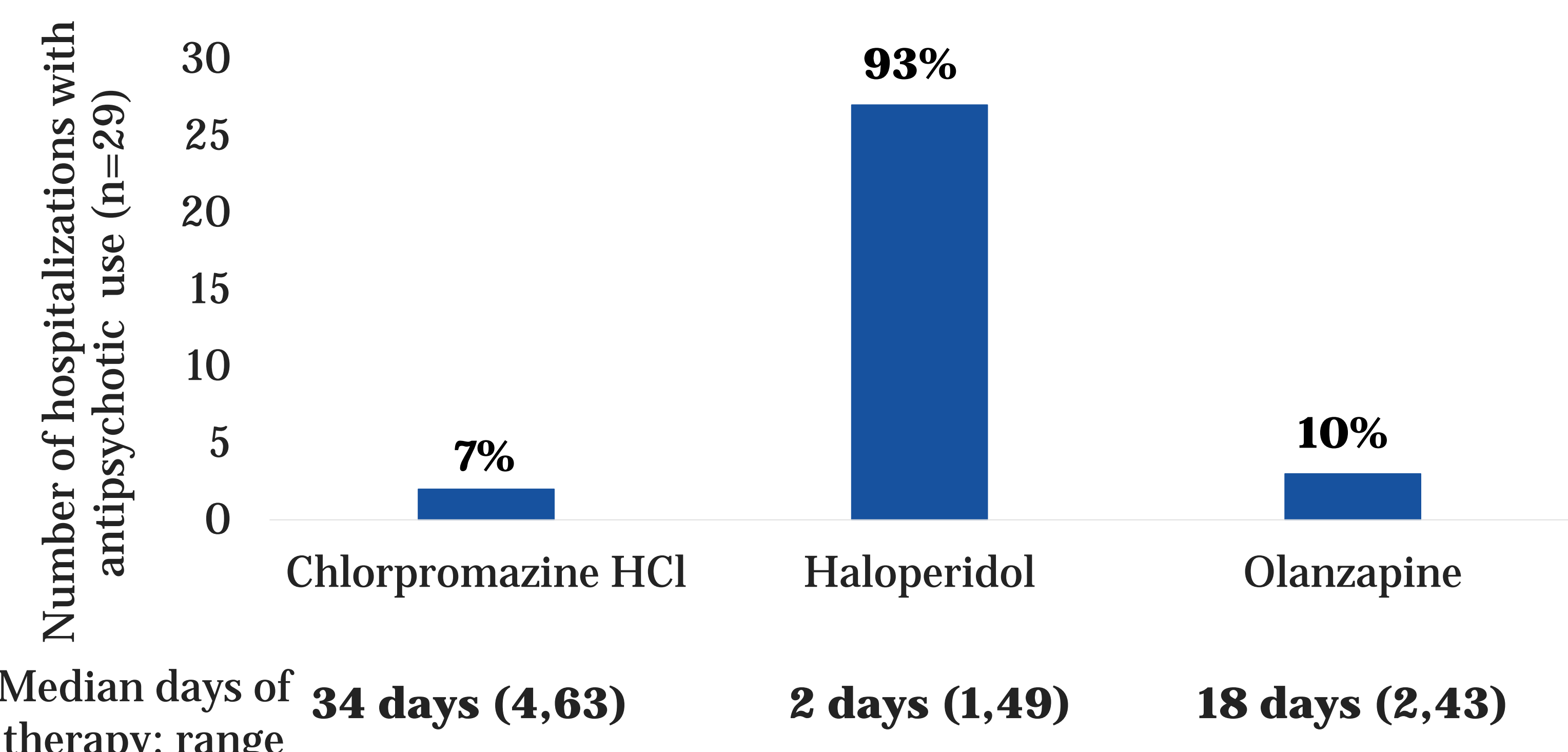
- We identified 29 infants with AP administrations among 482,053 eligible hospitalizations in infants during the study period, representing a rate of 6.0 per 100,000 hospitalizations.
- Infants with APs administrations were identified in only four out of 120 facilities contributing to our analysis, of which two facilities had level III and two had level IV NICUs.
- All 29 infants received typical AP, but 3 also received atypical AP during their stay.
- Haloperidol was the most commonly administered AP among hospitalized infants.

Table 1. Total Eligible Hospitalizations among Infants <6 months old and Length of Stay >3 days, July 2011 – September 2017

	Number of hospitalizations	Number of patients	Number of facilities
Total hospitalizations	12,145,437	7,535,580	173
Hospitalizations among infants <6 months at admission and LOS >3 days	482,053	471,895	120
Hospitalizations among infants <6 months at admission, LOS >3 days, and administered antipsychotics	29	29	4

- Infants with AP administrations generally had longer median LOS than among all hospitalized infants (114 days vs 4 days).
- In hospitalized infants receiving any AP during their stay, median days of therapy was 4 days (range, 1 to 63 days), with a median of 5 (range 1, 160) administrations per hospitalization.

Figure 1. Proportion of Hospitalized Infants* with Atypical and Typical Antipsychotics Administrations by Medication Type, July 2011 – September 2017



*Infants were less than 6 months of age on admission, and were required to have a LOS of >3 days.

**Percentage of hospitalizations with different AP administrations do not sum to 100% since infants may have received administrations for different AP during the encounter stay.

Table 2. Characteristics of Hospitalizations among Infants <6 months old and LOS >3 days and those with Atypical and Typical AP Use, July 2011 – September 2017

	Hospitalized infants, N=482,053	Percent hospitalized infants, %	Hospitalized infants with typical AP, N=29	Percent hospitalized infants with typical AP, %	Hospitalized infants with atypical AP, N=3	Percent hospitalized infants with atypical AP, %
Demographics						
Age at admission (days)						
0-10	450,236	93%	12	42%	1	33%
11-60	16,173	4%	1	3%	1	33%
61-179	15,644	3%	16	55%	1	33%
Sex						
Female	223,491	46%	13	45%	2	67%
Male	258,164	54%	16	55%	1	33%
Unknown	398	0%	0	0%	0	0%
Hospitalization characteristics						
Admission year						
2011	38,660	8%	0	0%	0	0%
2012	78,325	16%	1	3%	1	33%
2013	75,736	16%	3	10%	0	0%
2014	78,089	16%	7	24%	0	0%
2015	79,221	16%	3	10%	0	0%
2016	77,694	16%	11	38%	2	67%
2017	54,328	11%	4	14%	0	0%
Median length of stay; range (in days)	4 (4,484)	-	111 (5,408)	-	132 (5,215)	-
Days of therapy during inpatient stay						
Median days of therapy; range (in days)	-	-	3 (1,63)	-	18 (2,43)	-
Number of antipsychotic administration during inpatient stay						
Median; range	-	-	5 (1,160)	-	18 (3, 53)	-

CONCLUSION

- Overall, AP administration among hospitalized infants was rare.
- This is the first assessment examining the frequency of AP use among infants using inpatient data from the Sentinel System. Our findings are limited to only four facilities that noted AP use in infants.
- Future work may include assessment of indications for AP use among infants, as well as examining potential medication related adverse effects. Further, researchers may also consider exploring the extent of AP use across other hospital networks in the US.

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- The views expressed in this poster represent those of the author(s) and do not necessarily represent the official views of FDA, HCA Healthcare, or any of its affiliated entities.