



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

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

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}
- 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.

Objective

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

Methods

Study population

- Inpatient EMR data from 7/1/2011- 9/30/2017
- Infants <6 months of age on admission and length of stay >3days
- Included infants <6 months to exclude infants with routine postnatal care

Exposure Assessment

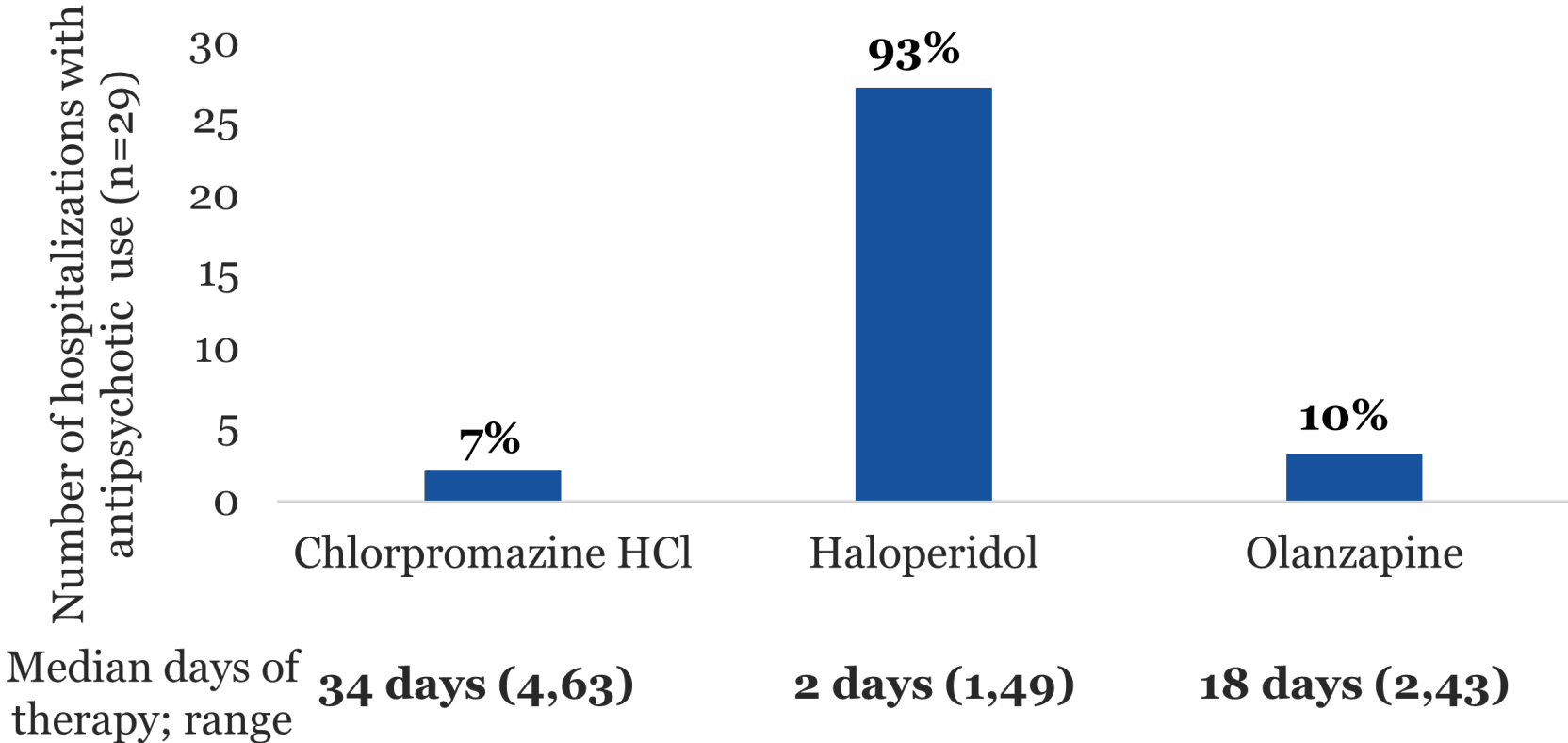
- Defined typical and atypical antipsychotic use
 - Mapped hospital-specific drug mnemonics at each facility
- Estimated distinct dates of AP administration and number of administrations during inpatient stay

Attrition

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 >3days	482,053	471,895	120
Hospitalizations among infants <6 months at admission and LOS >3days, and administered antipsychotics	29	29	4

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



*Percentage of hospitalizations with different AP administrations do not sum to 100% since infants may have received administrations for different AP during the inpatient 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=29	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%

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	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=29	Percent hospitalized infants with atypical AP, %
Hospitalization Characteristics						
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)	-

Conclusions

- 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.



Thank You
