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144. Drug Shortage Outcomes and Solutions Reported to the ToxIC Registry over a 22-Month Period

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Background: Drug shortages have become increasingly common and often involve antidotes. Data describing the impact of antidotal shortages on patients, and mitigation strategies clinicians and hospitals employ, are limited.

Hypothesis: Antidotal shortages adversely affect poisoned patients.

Methods: This is an analysis of data reported to the Drug Shortage Supplemental Registry within the Toxicology Investigators Consortium (ToxIC) Core Registry. This supplemental registry was created in January 2023 and prospectively tracks shortage mitigation strategies and outcomes including level of care, length of stay, morbidity, and mortality. Cases affected by a drug shortage were queried from January 1, 2023 through November 7, 2024. Rates of shortage, mitigation strategies, and adverse outcomes were described.

Results: Fifty-seven poisoned or envenomated patients whose care involved a shortage were identified, representing 0.4% of all patients reported to the ToxIC Core Registry during the period. Drugs implicated were physostigmine (N= 48, 84% of all cases), calcium disodium edetate (N = 4, 7%), Latrodectus mactans antivenom (N = 2, 3.5%), dimercaprol (N = 1, 1.75%), glucagon (N = 1, 1.75%), and lorazepam (N = 1, 1.75%). Physostigmine shortage was reported in 35 cases after an imported German product became available in November 2023. Physostigmine shortage was mitigated by substitution in 40/48 (83%) cases: 35 patients received rivastigmine, four received benzodiazepines, and one received dexmedetomidine. Calcium disodium edetate shortage necessitated inter-institutional sharing, compounding, succimer substitution, and emergent drop shipment. Shortages adversely impacted 65% (37/57) of patients: 30 had increased length of stay, seven required a higher level of care, and three were intubated. Delay to chelation was reported in three cases. Excessive somnolence from dexmedetomidine was the only adverse reaction from drug substitution described. No adverse effects from oral and/or transdermal rivastigmine use, including in combination with physostigmine, were reported. No deaths occurred due to shortage.

Conclusion: Antidote shortages did not affect the management of most poisoned or envenomated patients using data obtained from medical toxicology consultations across the United States. However, adverse outcomes were reported in the majority of patients whose treatment was impacted by shortage. Shortages predominantly involved calcium disodium edetate and physostigmine, despite FDA-facilitated physostigmine importation. Adverse effects from rivastigmine substitution were not reported. These findings should inform treatment and importation protocols during antidote shortages.