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(Continued on Additional Information Page)

Mfr. Control Number: 2025AP007268

## **ADDITIONAL INFORMATION**

## 7+13. DESCRIBE REACTION(S) continued

reported.

On an unknown date, the patient intentionally ingested Diphenhydramine, Olanzapine, Acetaminophen, Senna, and Buspirone in a large quantity (dose, frequency, were unknown) for an unknown indication (MULTIPLE DRUG OVERDOSE INTENTIONAL). On an unknown date, the patient presented to the emergency department for anticholinergic toxicity (ANTICHOLINERGIC SYNDROME) with symptoms of tachycardia, agitation and hallucinations with dry skin. The patient received 1 Rivastigmine patch of 9.5 milligram, Lorazepam intravenous (IV) 4 milligram and Midazolam IV 7 milligram for the treatment of anticholinergic toxicity at the discretion of a medical toxicologist. The patients had resolution of anticholinergic symptoms after receiving rivastigmine with no adverse effects.

Action taken with suspect drug was not applicable. Outcome of the event multiple drug overdose intentional was unknown and for the event anticholinergic syndrome was recovered. Dechallenge and rechallenge were not applicable. The seriousness criteria for the events were hospitalization and additionally medically significant for event anticholinergic syndrome.

Author's Comment: Anticholinergic ingestions were all intentionally taken in large quantities and all twelve patients had typical anticholinergic symptoms as noted by the ED team or toxicologist. Table 3: Baseline Characteristics and Results.

Citation: Berg M, Strand A, Garrett ND, Keric A, Wilkinson J. Rivastigmine as an alternative treatment for anticholinergic toxidrome in light of the physostigmine shortage: A case series. American Journal of Emergency Medicine. 2025; 94: 144-147, https://doi.org/10.1016/j.ajem.2025.04.047.

This is 04 of 05 (2025AP007213, 2025AP007266, 2025AP007267, 2025AP007269) cases created from same literature article.

Reporter Comment (500): Anticholinergic ingestions were all intentionally taken in large quantities and all twelve patients had typical anticholinergic symptoms as noted by the ED team or toxicologist. Table 3: Baseline Characteristics and Results.

## 14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1 ) ACETAMINOPHEN (ACETAMINOPHEN)	UNK; Oral use	Product used for unknown	Unknown;
Unknown; Regimen #1		indication (Product used for	Unknown
		unknown indication)	
#2 ) DIPHENHYDRAMINE	UNK; Oral use	Product used for unknown	Unknown;
(DIPHENHYDRAMINE HYDROCHLORIDE)		indication (Product used for	Unknown
Unknown; Regimen #1		unknown indication)	
#3 ) OLANZAPINE (OLANZAPINE) Unknown;	UNK; Oral use	Product used for unknown	Unknown;
Regimen #1		indication (Product used for	Unknown
		unknown indication)	
#4 ) SENNA [SENNOSIDE A+B]	UNK; Oral use	Product used for unknown	Unknown;
(SENNOSIDE A+B) Unknown; Regimen #1		indication (Product used for	Unknown
		unknown indication)	
#5 ) BUSPIRONE (BUSPIRONE) Unknown;	UNK; Oral use	Product used for unknown	Unknown;
Regimen #1		indication (Product used for	Unknown
		unknown indication)	

24d. Report Source Literature

Journal: American Journal of Emergency Medicine

Author: Berg M, Strand A, Garrett ND, Keric A, Wilkinson J.

Title: Rivastigmine as an alternative treatment for anticholinergic toxidrome in light of the physostigmine shortage: A case series

Volume: 94 Year: 2025 Pages: 144-147

25b. Name And Address of Reporters continued M Berg PharmD Regions Hospital 640 Jackson St

## **ADDITIONAL INFORMATION**

St Paul, MN 55101 UNITED STATES

A Strand MD Regions Hospital 640 Jackson St St Paul, MN 55101 UNITED STATES

# **Appendix**

Appendix: 1 Attachment Classification: Source Documentation Attachment Description: A01\_2025AP007268\_FTA

American Journal of Emergency Medicine 94 (2025) 144-147



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# Rivastigmine as an alternative treatment for anticholinergic toxidrome in light of the physostigmine shortage: A case series



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Keywords: Rivastigmine Anticholinergic toxicity Physostigmine Acetylcholinesterase inhibitor

## ABSTRACT

Introduction: Physostigmine is an acetylcholinesterase inhibitor historically used for the treatment of anticholinergic toxicity. Supply of physostigmine has been limited as the US manufacturer recently stopped production. Rivastigmine, a long-acting acetylcholinesterase inhibitor FDA-approved for the treatment of Alzheimer's and Parkinson's disease dementia, is a potential alternative to physostigmine. There are few case reports and case series demonstrating the safe and effective use of both oral and transdermal rivastigmine for anticholinergic toxicity. The objective of this study was to describe the effects of rivastigmine in patients with anticholinergic toxicity. Methods: A retrospective case review of patients that received rivastigmine at a metropolitan level-1 trauma center between January 2022–January 2024 resulted in 12 patients who met inclusion/exclusion criteria and were included in this analysis. Data collected included xenobiotic ingested, co-ingestions, symptoms on presentation, rivastigmine capsule and/or patch administration, adverse events, benzodiazepine administration, disposition, ICU and hospital length of stay.

Results: Of 12 patients, 9 had co-ingestions of other prescription or over-the-counter medications. 2 of 12 patients received both rivastigmine patches and capsules, 8 of 12 received only patches, and 2 of 12 received only capsules. The average dose of rivastigmine patches was 8.66 mg and average capsule dose was 6 mg. None of the patients experienced adverse effects from rivastigmine use. Length of stay ranged from 2 to 9 days with an average of 3.6 days.

*Conclusion:* Our study shows that rivastigmine is a reasonable alternative to physostigmine based on the lack of adverse events reported and symptom relief.

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## 1. Introduction

Anticholinergic toxicity can occur from intentional or unintentional large ingestion of anticholinergic medications, such as antidepressants, antipsychotics, and antihistamines [1]. When large amounts of anticholinergics are introduced into the body, the drug competitively inhibits acetylcholine at the muscarinic receptor, causing symptoms ranging from dry secretions, tachycardia, and altered mental status to Qtc prolongation and seizures [2]. Physostigmine, an acetylcholinesterase inhibitor, is an FDA-approved antidote for anticholinergic toxidromes. Over the last several years, physostigmine has been in shortage due to the discontinuation of its manufacturing in the United States. Rivastigmine, another centrally-acting acetylcholinesterase inhibitor used for the treatments of Alzheimer's and Parkinson's related dementia, has been proposed as an alternative option (see Table 1). The aim

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of our study was to describe the effects of rivastigmine in patients with anticholinergic toxicity.

There is limited data on the safety and efficacy of using rivastigmine for anticholinergic toxicity. In 2020, two case reports were published that showed promising use of rivastigmine as an alternative to physostigmine. In the first case report, a patient ingested a large amount of procyclidine and presented with severe anticholinergic symptoms and altered mental status [3]. The patient received 1.5 mg of oral rivastigmine with improved symptoms after 6 h, then another 1.5 mg 12 h after the first dose. This resulted in the resolution of symptoms within 24 h of starting the rivastigmine and the patient was able to discharge the next day. Rivastigmine was continued 1.5 mg twice daily for 7 days after presentation to prevent relapse of symptoms.

A second case report came out shortly after in response to the first case report explaining a physician's experience with a patient who overdosed on diphenhydramine and presented with typical anticholinergic symptoms in addition to severe agitation not managed with benzodiazepines [4]. The patient received 3 doses of 3 mg of rivastigmine capsules within 2 h, which brought her RASS score from 3 to 1 in that

https://doi.org/10.1016/j.ajem.2025.04.047

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**Table 1**Package insert information for Physostigmine salicylate, Rivastigmine tartrate capsule and Rivastigmine patch.

Physostigmine	Rivastigmine
FDA approved to treat anticholinergic toxicity	FDA approved for treatment of Lewy body, Parkinson-related, and vascular dementias
Onset: 3–8 min	<ul> <li>Onset: 1 h (oral/transdermal patch)</li> </ul>
• Duration: up to 60 min	• Duration: 10 h (oral); 24 h (trans- dermal patch)
<ul> <li>Dosing/Formulation: 0.02 mg/kg IV/IM (max 0.5 mg/dose); repeat every 5–15 min for max of 2 mg</li> <li>Side Effects: gastrointestinal upset, bradycardia, seizures (administration rate dependent)</li> </ul>	<ul> <li>Dosing/Formulation: oral capsule (twice daily) and transdermal patches (24 h)</li> <li>Side Effects: gastrointestinal upset, bradycardia</li> </ul>

timeframe. They received an additional 3 mg after those doses for a total of 12 mg of rivastigmine. It was noted that her symptoms completely resolved within 24 h of receiving rivastigmine with no adverse effects from its use and the patient was able to be discharged the day after presentation.

In 2023, a case series including 22 patients looked at length of stay, time to symptom resolution, and side effects noted from rivastigmine use [5]. Patients received either patches only (15 patients) or a combination of the patches and capsules (7 patients). It was found that the median length of stay was 2 days, no adverse events were reported from using the rivastigmine, and time to symptoms resolution was 5 h in the patch-only group, and 2 h for the combination group. Compared to physostigmine studies, the length of stay (2–3 days) and time to symptom resolution (30 min-2 h) is similar to this rivastigmine study [6].

Due to the limited data on the safety and efficacy of rivastigmine for anticholinergic toxicity with an ongoing critical shortage of physostigmine, the aim of our study was to describe the effects of rivastigmine in patients with anticholinergic toxicity.

## 2. Methods and patient population

A retrospective case series was performed using medication IDs for every administration of rivastigmine between January 2022 and January 2024 from a metropolitan level 1 adult and pediatric trauma center with 534 staffed hospital beds and 72 Emergency Department (ED) beds, with approximately 97,000 ED visits per year. The ED is staffed by an in-person medical toxicology service during daytime hours with oncall consultation available 24/7. Inclusion criteria included patients of any age who received either rivastigmine patches and/or capsules for the treatment of anticholinergic toxicity at the discretion of a medical toxicologist. Of the 101 orders identified, twelve patients met the full inclusion/exclusion criteria; cases were excluded if rivastigmine was not given for anticholinergic toxicity and in a single case where a patient was transferred to an outside hospital after receiving a single dose of rivastigmine. Notes, medication administration records (MARs), and vital signs were individually reviewed. Data including patient demographics, drug ingested, symptoms of anticholinergic toxicity, dose and route of rivastigmine, adjunct medications, adverse reactions to rivastigmine, and length of stay were recorded in a secure spreadsheet. The research protocol was approved in 2023 by our Institutional Review Board prior to data collection and informed consent was waived.

## 3. Outcomes

Our primary outcome was side effects experienced after receiving rivastigmine. Adverse effects monitored for were bradycardia and gastrointestinal upset. Secondary outcomes included length of stay, resolution of symptoms, rescue benzodiazepine use, and disposition after the ED. These outcomes were pulled from chart notes, medication administration records, and vitals charts.

#### 4. Results

The patient population ranged from 22 to 59 years of age (median age of 30.5 years) and there was an equal number of males and females. Anticholinergic ingestions were all intentionally taken in large quantities and all twelve patients had typical anticholinergic symptoms as noted by the ED team or toxicologist. 7 of the 12 (58.3 %) patients ingested 2 or more anticholinergics before presentation and 5 of the 12 (41.7 %) had co-ingestions of non-anticholinergic agents. Table 2 lists the toxins ingested.

There were no adverse events noted from rivastigmine use. Of the 12 patients in the study, eight were able to be monitored on the general medicine floors after presentation to the ED, while three patients were monitored in the ICU. One patient was discharged from the ED to an outpatient treatment facility. All patients were transferred to our inpatient psych unit after being deemed medically stable, except for the one patient who was transferred to an outpatient treatment facility after being medically cleared from the ED. The average length of stay from admission to before an inpatient psych unit stay was 3.6 days (range: 2–9 days; median: 3 days).

Rivastigmine doses and formulation varied among patients due to the inconsistency of strengths carried in our pharmacy and the toxicologist recommendation. Most patients received the 9.5 mg/24 h patch strength and all patients received a dose of 6 mg if given capsules (Table 3). Some patients were able to take the patch off before 24 h and 2 patients needed extra doses of the patch after receiving the patch for 24 h.

Although we were unable to quantify how long it took for patients to experience symptom relief, all patients had resolution of their anticholinergic symptoms as mentioned in notes in patient charts. Of the 12 patients, 10 patients received additional benzodiazepines for symptomatic relief of agitation and/or anxiety (up to the discretion of the nursing staff). Benzodiazepine timing, types, amounts, and frequency varied by patient depending on prescriber preference, stock, and patient factors (intubation, co-ingestions, and anticholinergics ingested). 6 of 9 patients received IV benzodiazepines within 2 h of rivastigmine patch placement. Of the 4 patients with documented urinary retention, 3 were treated with a foley catheter.

## 5. Discussion

Based on this case series reporting no adverse events, rivastigmine is a safe and reasonable alternative to physostigmine. Additionally, the patient length of stay was roughly the same as those for patients treated

 Table 2

 List of anticholinergic and non-anticholinergic drugs consumed in patient cohort.

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**Table 3**Baseline Characteristics and Results.

Patient	Medications ingested	Symptoms	Rivastigmine Patch Received** $n = 10 \text{ patients}$	Rivastigmine Capsule Received $n = 4$ patients	Additional Benzodiazepine Given (total)	Adverse Events following Rivastigmine
1	Diphenhydramine	Tachycardia, delirium, dry mouth, urinary retention	Patch: 9.5 mg x1	Capsules: 6 mg x1	Lorazepam IV 2.5 mg	None
2***	Venlafaxine, hydroxyzine, ibuprofen, and prednisone	Seizure, dry mouth, tachycardia, slurred speech	Patch: 9.5 mg x1	Capsules: None	Diazepam oral 32.5 mg Diazepam IV 45 mg Midazolam IV 9 mg	None
3	Quetiapine, hydroxyzine, gabapentin, and valium	Tachycardia, AMS (somnolence/agitation), dry mucous membranes	Patch: 9.5 mg x1	Capsules: None	Midazolam IV 2 mg	None
4	Quetiapine	Tachycardia, urinary retention, dry mouth, agitation, delirium	Patch: 9.5 mg x3 (worn consecutively; first for 16 h, then 24 h x2)	Capsules: None	Lorazepam IV 16.5 mg Lorazepam 2 mg oral	None
5	Quetiapine and ibuprofen	Dry mucous membranes, flushing, urinary retention, tachycardia, agitation, delirium	Patch: 9.5 mg x2 at the same time	Capsules: None	Midazolam IV 23 mg	None
6***	Promethazine and hydroxyzine	Delirium, agitation, dry mucous membranes, mydriasis	Patch: 9.5 mg x1	Capsules: None	Diazepam IV 25 mg Midazolam IV 3 mg Lorazepam oral 1 mg	None
7	Quetiapine	Dry mouth, delirium and carphologia	Patch: 9.5 mg x1	Capsules: None	None	None
8	Diphenhydramine	Delirium, hallucinations, diaphoresis, urinary retention, tachycardia	Patch: 4.6 mg x3 at the same time	Capsules: 6 mg x1	Diazepam IV 15 mg	None
9	Diphenhydramine, olanzapine, senna, buspirone, and acetaminophen	Tachycardia, agitation and hallucinations with dry skin	Patch: 9.5 mg x1	Capsules: None	Lorazepam IV 4 mg Midazolam IV 7 mg	None
10*	Quetiapine, benztropine, and hydroxyzine	Delirium, agitation, dry mucous membranes, tachycardia, urinary retention	Patch: 13.3 mg x2 (worn consecutively for 24 h each)	Capsules: none	Midazolam IV 6 mg	None
11	Quetiapine and valproic acid	Tachycardia, diaphoresis	Patch: None	Capsules: 6 mg x1	None	None
12****	Venlafaxine, quetiapine, lamotrigine, diazepam, cocaine, and alcohol	Diaphoresis, sedation, tachycardia	Patch: None	Capsules: 6 mg x1	Diazepam IV 40 mg Diazepam oral 50 mg Lorazepam IV 3 mg Lorazepam oral 10 mg Midazolam IV 5 mg	None

<sup>\*</sup> Patient that was given physostigmine and rivastigmine.

with physostigmine (2–3 days) as well as for other documented cases of rivastigmine treatment (about 1–3 days) [3–6].

In September of 2023, the FDA announced that United States hospitals were able to temporarily obtain physostigmine directly from Germany-based drug manufacturers [7]. Although our hospital decided to capitalize on this opportunity and purchase this antidote to use in our ED, we are limited in how much we can obtain from the source depending on supplies. Therefore, rivastigmine is a relevant and important treatment option or necessary alternative for our anticholinergic toxicity patients.

Importantly, there is a large cost difference between rivastigmine and physostigmine. At our hospital, we are currently able to obtain physostigmine 2 mg/5 mL ampules for about \$125 each. Most patients receive 1–3 doses of physostigmine, which can cost patients hundreds of dollars for treatment. In comparison, rivastigmine 3 mg capsules are

about \$0.08- \$0.50 each and the 13.3 mg patches cost about \$1.22-\$10.94 per patch, all depending on manufacturer and their purchasing costs. Even if patients need multiple doses of rivastigmine, there is a significant cost savings when compared to even a single dose of physostigmine.

As a retrospective case series and chart review with a small cohort of patients, this analysis cannot speak on the efficacy of rivastigmine in treating anticholinergic toxicity. Over half of our patient population co-ingested other non-anticholinergic medications, which could have affected outcomes, such as benzodiazepine use, disposition postemergency department admission, and length of stay. Lastly, we were unable to reliably obtain timestamps of when patient symptoms resolved, making it difficult to determine the time to resolution of symptoms. This factor, in addition to lack of a control group, made it difficult to know if the resolution was due to the rivastigmine or the natural

<sup>\*\*</sup> For patients who received more than one patch, whether the patient received multiple patches concurrently or consecutively is documented.

<sup>\*\*\*</sup> One night ICU stay.

<sup>\*\*\*\* 7</sup> day ICU stay. Treated for suspected alcohol and benzodiazepine withdrawal.

resolution of anticholinergic symptoms after 24–48 h. Therefore, we were unable to draw any concrete conclusions about the efficacy of using rivastigmine in this patient population. However, the symptom relief experienced in our patient population was clinically significant and noteworthy. This, combined with the cost savings and unpredictability of receiving physostigmine from German manufacturers warrants further study into the efficacy of using rivastigmine as a treatment option for anticholinergic toxicity.

### 6. Conclusion

Our outcomes were similar to what is seen in not only past rivastigmine studies, but also past physostigmine studies. Rivastigmine appears to be a safe alternative to physostigmine based on the lack of adverse events reported in our study. As for the efficacy of using rivastigmine for anticholinergic toxicity, because our conclusions were only based on symptom relief noted in patient charts with no timestamps as to when patients' symptoms resolved, it is difficult to make a conclusion on this outcome. Larger studies with statistical analysis to derive statistical significance from their safety and efficacy outcomes would be needed to be more conclusive about using rivastigmine in this patient population. Overall, rivastigmine is a reasonable alternative to physostigmine and could also be considered as an adjunctive agent to physostigmine.

## Previous presentation of data

Midwest Pharmacy Residency Conference (MPRC) May 9th, 2024.

## **CRediT authorship contribution statement**

**M. Berg:** Writing – review & editing, Writing – original draft, Resources, Project administration, Methodology, Investigation, Data curation. **A. Strand:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Data curation, Conceptualization. **N.D. Garrett:** Writing – review & editing, Writing – original draft, Resources. **A. Keric:** Writing – review & editing, Supervision, Conceptualization. **J. Wilkinson:** Writing – review & editing, Supervision, Conceptualization.

## **Funding**

None.

## **Declaration of competing interest**

No COI to discuss.

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