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Evaluation of droperidol use in the emergency department: a retrospective analysis of QTc prolongation and adverse events

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Abstract

Background Droperidol is a first-generation antipsychotic medication that has been used for various indications in the emergency department (ED); however, its use has been controversial due to reports of QT prolongation and the risk of torsades de pointes (TdP). The aim of the study is to evaluate the safety of droperidol administration in the ED.

Methods This was a retrospective study, conducted at an academic level I trauma center. System-generated reports were used to identify all droperidol administrations in the ED from the time that droperidol was reintroduced to the institutional formulary on July 1, 2019 through January 31, 2023. The major safety endpoint was a composite of the incidence of QTc interval prolongation, incidence of TdP, ventricular arrhythmia, or hypotension.

Results A total of 327 administrations of droperidol were identified in 245 patients in the ED. The composite safety endpoint occurred in 30 (9.1%) administrations. None of these events were classified as "probable" or "definite" on the Naranjo adverse drug reaction probability scale. No episodes of TdP or serious ventricular arrhythmia were reported. Higher cumulative droperidol dose and creatinine clearance < 60 mL/min were associated with an increased odds of developing QTc prolongation (OR 1.27 [CI 1.04–1.56]) and (OR 1.01 [CI 1.0-1.02]), respectively.

Conclusions The study supports the use of low dose droperidol for various indications in the ED. There were no serious adverse events reported that could be directly attributed to droperidol use; however, it is crucial to consider the potential dose dependent impact on QTc prolongation.

Keywords Droperidol, Emergency department, Drug safety

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Introduction

Droperidol is a first-generation antipsychotic medication that primarily acts as an antagonist at the dopamine-2 receptors, while also inducing mild alpha-adrenergic blockade [1]. Droperidol has been used for various indications in the emergency department (ED), including the management of agitation, nausea and vomiting, and acute migraine headaches; however, its use has been controversial due to reports of QT prolongation and the risk of torsades de pointes (TdP) [2–4]. In response to these reports, the Food and Drug Administration (FDA) issued a boxed warning for droperidol noting an association with QT prolongation and increased risk for TdP in 2001. The warning states that droperidol should be reserved for use only when other acceptable treatments have not provided an adequate response, that all patients should have an electrocardiogram (ECG) prior to administration, and that they should continue to be monitored for arrhythmias after completing treatment [5]. As a result of this warning, there was a substantial decrease in droperidol use in hospitalized patients, and it was removed from drug formularies in many institutions [6].

The primary safety issue regarding droperidol is its potential to prolong the QT interval [2]. The FDA's warning was based on two published studies and data from post-marketing surveillance [3, 4]. It was noted that the droperidol risk of causing QT prolongation is dose dependent and most cases were reported in Europe where higher droperidol doses (25 to 250 mg) were used. These doses are notably greater than those typically administered in the United States (less than 10 mg) [7]. A literature review of the safety of droperidol conducted by the American Academy of Emergency Medicine in 2015 reported that droperidol is safe and effective for the treatment of nausea, headache, and agitation and suggested that ECG monitoring is not necessary for doses under 2.5 mg [5]. As a result, droperidol was reintroduced to the drug formularies in many institutions including ours, which added droperidol back to the formulary in 2019 [8].

There are several studies that have evaluated the safety and efficacy of droperidol for various indications [9–11]; however, it is important to highlight that many of these studies have excluded patients who had risk factors for corrected QT (QTc) prolongation or were taking medications that are known to prolong QTc intervals, highlighting the need for more robust studies [2]. Our study aimed to evaluate the safety and efficacy of droperidol administration in patients located in the ED, including those with risk factors for QTc prolongation.

Materials and methods

Study design, setting and population

This was a single-center, retrospective, observational study, conducted at an 826-bed tertiary, academic medical center and level I trauma center. This study was approved by the Institutional Review Board (protocol # 2022P002473). Data were collected from system-generated reports, which were used to identify all droperidol administrations in the ED from the time that droperidol was reintroduced to the institutional formulary on July 1, 2019 through January 31, 2023. Patients were included if they were at least 18 years of age, received droperidol in the ED for any indication, had a baseline ECG within the prior 6 months, and had at least one ECG documented and interpreted during the index visit. ECGs within 24 h of droperidol administration were reviewed and the computerized Bazett's QTc intervals and cardiac rhythm were recorded [12]. For patients with atrial fibrillation, a pacemaker, bundle branch block, or wide QRS > 120 milliseconds (ms), the Mayo Clinic calculator was used to calculate the QTc [13]. Baseline data collected included demographic information including age, gender and body mass index (BMI); pertinent medical and social history; chief complaint; and admission diagnosis. Drug administration characteristics collected included droperidol dose, frequency, date and time of droperidol administration, and any concomitant QTc prolonging medications (haloperidol, olanzapine, methadone, citalopram, levofloxacin, ciprofloxacin, erythromycin, fluconazole, isavuconazole, voriconazole, amiodarone, metoclopramide, ondansetron, tacrolimus) that were administered 4 h before or 4 h after droperidol use. Known risk factors for QTc prolongation were collected including age greater than 65 years, history of heart failure with reduced ejection fraction, history of myocardial infarction, bradycardia with heart rate < 50 beats per minute, hypokalemia (K < 3.5 mEq/L) and hypomagnesemia (Mg < 1.5 mg/dL) during the index visit [14]. Indications for droperidol administration were categorized based on chief complaint and final diagnosis: abdominal pain, headache, agitation, nausea/vomiting, and cannabinoid hyperemesis syndrome (CHS).

Study endpoints

The major safety endpoint was a composite of the incidence of QTc interval prolongation, incidence of TdP, ventricular arrhythmia, or hypotension. QTc interval prolongation was defined as QTc interval > 60 ms above baseline or QTc interval > 500 ms following droperidol administration. Hypotension was defined as SBP < 90 mm Hg or a reduction of ≥ 30% from baseline SBP within 4 h of droperidol administration [15]. The 4-hour cutoff was chosen based on the effects of droperidol, which may persist for up to 4 h [16]. Hypotension was categorized as requiring one of the following interventions within 4 h of droperidol administration: intravenous fluid bolus, initiation of a vasopressor or inotropic agent, escalation in dose of a previously initiated vasopressor or inotropic

agent, or holding the dose of any antihypertensive medications previously ordered.

The Naranjo adverse drug reaction probability scale was utilized to determine the likelihood that the major endpoint could be attributed to droperidol use. Minor safety endpoints included individual components of the composite endpoint, as well as the incidence of QTc interval > 450 ms for males and > 470 ms for females (in patients with baseline QTc values below these cutoffs), incidence of extrapyramidal adverse effects including akathisia and dystonic reactions collected via nursing chart review and administration of diphenhydramine or benztropine, and incidence of neuroleptic malignant syndrome within 24 h of droperidol use. The safety endpoints were collected by a single reviewer who conducted two rounds of assessments. Any discrepancies in scoring were subsequently resolved through consensus discussions with the study team. The use of concomitant rescue medications within 4 h of droperidol administration was assessed as an efficacy endpoint. Rescue medications included antipsychotics, antiemetics, analgesics and sedatives depending on the indication for droperidol administration. Additional efficacy endpoints included time from admission to discharge from the ED and time from droperidol administration to discharge from the ED.

Table 1 Baseline Patient Characteristics

Characteristic	(*n* = 245 patients)*†
Age, years	40 [31–58]
Male	101 (41.2)
BMI, kg/m^2	25.8 [22.4–30.2]
CrCl, mL/min	97 [71.5–120]
Pertinent medical/social history	
Atrial fibrillation	10 (4.1)
Bundle branch block	6 (2.5)
On pacemaker	6 (2.5)
Psychological disorders (anxiety/depression/bipolar)	105 (42.9)
Coronary artery disease	21 (8.6)
Cannabis use	93 (37.9)
Other substance abuse	47 (19.2)
Alcohol abuse	47 (19.2)
Baseline QTc, milliseconds	447 [428–465]
QT prolongation predisposing risk factors at baseline	
Age > 65	39 (15.9)
HFrEF	7 (2.8)
Myocardial infarction	13 (5.3)
Bradycardia	22 (8.9)
Hypokalemia	47 (19.1)
Hypomagnesemia	33 (13.4)
Use of QTc-prolonging medications	
4 h before droperidol administration	102 (31.2)
4 h after droperidol administration	45 (13.9)
Indication for droperidol administration#	
Agitation	61 (24.9)
Headache	5 (2)
Nausea/vomiting	122 (49.8)
Cannabinoid hyperemesis syndrome	64 (26.1)
Abdominal pain	86 (35.1)
Other/unknown	1 (0.5)

*data expressed as median [IQR], †data expressed as n (%)

#some patients had more than one indication

Abbreviations: BMI, body mass index; CrCl, creatinine clearance; HFrEF, heart failure with reduced ejection fraction

Statistical analysis

Continuous data were analyzed and expressed as mean ± standard deviation or as median [interquartile range] as appropriate. Categorical features were summarized with frequency counts and percentages. To examine the impact of baseline demographic characteristics, use of QTc-prolonging medications and droperidol dose on the incidence of QTc prolongation, a multivariate logistic regression analysis was performed. These variables were identified a priori which were believed to possibly impact the QTc interval [14, 17]. All variables with a P value < 0.05 from the regression were considered to be associated with a significant impact on the endpoint. All data were analyzed using Stata/SE statistical software Version 15.1 (StataCorp LLC).

Results

A total of 327 administrations of droperidol were identified in 245 patients in the ED over the specified time frame. The baseline characteristics of the patients are provided in Table 1. The median QTc at baseline was 447 ms [428–465] and the most common indication for droperidol was nausea and vomiting (49.8%). Droperidol administration characteristics are described in Table 2. The majority of patients required only one dose of droperidol with a median initial dose of 1.25 mg [1.25–2.5]. Most administrations were via intravenous route (85%) and the remaining 15% were given intramuscularly (Table 2).

The composite safety endpoint occurred in 30 (9.1%) administrations. The majority of these events (60%) were classified as "possible" and none were classified as "probable" or "definite" on Naranjo adverse drug reaction probability scale (Table 3). Overall, QTc prolongation was observed in 19 (7.7%) patients and 23 (7%) administrations. Of these events, the occurrence of both QTc interval > 500 ms and > 60 ms from baseline was observed in 8 (2.5%) administrations. Events with QTc > 60 ms from baseline only were observed in 6 (1.8%) administrations, while QTc interval > 500 ms were observed in 9 (2.7%) administrations. No episodes of TdP or serious ventricular arrhythmia were reported. Two hypotensive events required fluid boluses, no events required initiation or

Table 2 Droperidol Administration Characteristics

Characteristic	(*n* = 327 administrations)*†
Number of administrations of droperidol per patient	245 (74.9)
1	67 (20.5)
2	12 (3.6)
3	3 (0.9)
4	
Dose of droperidol, mg	40 (12.2)
0.625	153 (46.8)
1.25	97 (29.6)
2.5	35 (10.7)
5	2 (0.6)
10	
Route of droperidol administration	278 (85)
Intravenous	49 (15)
Intramuscular	
Cumulative dose per patient before obtaining EKG, mg	2.5 [1.25–2.5]
Total droperidol dose per patient, mg	2.5 [1.25–2.5]

*data expressed as median [IQR], †data expressed as n (%)

Table 3 Safety Endpoints

Endpoint	(*n* = 327 administrations)*†
Composite safety endpoint#	30 (9.1)
Naranjo doubtful ADR	12 (3.6)
Naranjo possible ADR	18 (5.5)
Overall QTc prolongation	23 (7)
QTc interval > 500 milliseconds and > 60 milliseconds from baseline	8 (2.4)
QTc interval > 500 milliseconds	9 (2.8)
QTc interval > 60 milliseconds from baseline	6 (1.8)
Torsades de Pointes	0
Premature ventricular arrythmia (PVC)	6 (1.8)
Ventricular arrhythmia other than PVC	0
Hypotension	7 (2.1)
Requiring intervention	2 (0.6)
Not requiring intervention	5 (1.5)
QTc interval > 450 milliseconds (male) or 470 milliseconds (female)	26 (7.9)
Extrapyramidal adverse effects	1 (0.3)
Akathisia	6 (1.8)
Dystonia	
Neuroleptic malignant syndrome	1 (0.3)

*data expressed as median [IQR], †data expressed as n (%)

#no reactions were classified as "Probable" or "Definite" on Naranjo adverse drug reaction probability scale

Abbreviations: ADR, adverse drug reaction

escalation of a vasopressor or inotropic agent, and no events required holding antihypertensive medications. There was one akathisia episode and six dystonic reactions reported. One patient experienced neuroleptic malignant syndrome but was unlikely related to droperidol alone as the patient also received high doses of haloperidol.

The findings of the logistic regression evaluating risk factors for QTc prolongation can be found in Table 4.

Table 4 Logistic regression evaluating the impact of different variables on the incidence of QTc prolongation

Variable	OR (95% CI)	*P* value
Age	1.02 (0.99–1.06)	0.14
Male	1.34 (0.48–3.75)	0.56
BMI	0.94 (0.86–1.02)	0.17
CrCl (< 60 mL/min)	1.01 (1.0-1.02)	**0.044**
Atrial fibrillation	0.42 (0.02–6.32)	0.53
Bundle branch block	3.10 (0.24–39.37)	0.38
Has a pacemaker	3.30 (0.30-35.45)	0.32
Psychological disorders	1.18(0.40–3.52)	0.75
Coronary artery disease	1.10 (0.20–5.95)	0.90
Drug abuse	0.60 (0.11–3.11)	0.55
Cannabis use	0.90 (0.25–3.19)	0.87
Alcohol abuse	2.32 (0.59–9.11)	0.22
Has a risk factor for QTc prolongation	2.01 (0.69–5.85)	0.19
Baseline QTc	1.00 (0.98–1.01)	0.709
Cumulative droperidol dose	1.27 (1.04–1.56)	**0.019**
QTc-prolonging medications before droperidol	1.65 (0.62–4.35)	0.312
QTc-prolonging medications after droperidol	1.65 (0.51–5.30)	0.396

Abbreviations: BMI, body mass index; CrCl, creatinine clearance

Droperidol dose and creatinine clearance < 60 mL/min were associated with an increased odds of developing QTc prolongation (OR 1.27 [CI 1.04–1.56]) and (OR 1.01 [CI 1.0-1.02]), respectively. Additional variables were not found to be associated with developing QTc prolongation when controlling for confounders.

Additional endpoints related to droperidol are presented in Table 5. The use of rescue medications within 4 h of the first droperidol administration varied by indication, with the most common indication requiring rescue medication being abdominal pain (*n* = 38, 44.1%).The median time from droperidol administration to rescue medication administration was 138 min [55.5-208.5]. In terms of patient disposition, 77 (31.4%) patients were discharged to home from the ED, with a median time from admission to discharge of 543 min [363-1062.5], and a median time from the first droperidol administration to discharge of 412 min [211-816.2].

Discussion

In this retrospective analysis of parenteral droperidol administration in the ED, we evaluated the safety and efficacy of this medication after it was reintroduced to our institution. Notably, droperidol was utilized at a range of doses for various indications in the ED which highlighted the importance of our study. There were no clinically significant arrhythmias attributable to droperidol administration. The overall incidence of QTc prolongation occurred in 7% of the administrations, which is comparable to what has been reported in previous

Table 5 Efficacy endpoints

Endpoint	(*n* = 245 patients)*†
Number of patients required repeat droperidol dose	67/245 (27.3)
Use of concomitant rescue medications within 4 h of first droperidol administration[#]	
Acute agitation (*n* = 61)	21/61 (34)
Headache (*n* = 5)	1/5 (20)
Nausea/vomiting (*n* = 122)	16/122 (13.1)
CHS (*n* = 64)	28/ 64 (43.7)
Abdominal pain (*n* = 86)	38/86 (44.1)
Time to first rescue medications after droperidol, minutes	138 [55.5-208.5]
Disposition	
Floor	60 (24.4)
ICU	17 (6.9)
Home	77 (31.4)
Facility	14 (4.2)
Time from admission to discharge from the ED, minutes	543 [363-1062.5]
Time from droperidol administration to discharge from the ED, minutes	412 [211-816.2]

*data expressed as median [IQR], †data expressed as n (%)

#some patients had more than one indication

Abbreviations: CHS, cannabinoid hyperemesis syndrome; ICU, intensive care unit

studies that reported incidences ranging from 2.6 to 7.5% [18, 19]. Our study differs from the work by Gaw et al., which included 5,784 patients and primarily focused on mortality within 24 h of droperidol administration. In that study, approximately 66% of patients did not have a baseline ECG; among those who did, only 77 had elevated QTc, and 73.7% did not have a follow-up ECG after droperidol administration. In our population, the median baseline QTc interval was 447 ms, which is higher than that reported in other studies [18, 19]. This higher baseline QTc may have contributed to the slightly increased incidence of QTc prolongation in our findings, especially since a QTc interval > 500 ms and an increase of > 60 ms from baseline were observed in only 2.4% of the administrations. Furthermore, variations in the definitions of QTc prolongation across these studies could explain the differences in incidence. Additionally, a large percentage of our patients had at least one QT prolongation predisposing risk factor or had received a known QTc-prolonging medication within 4 h of droperidol use. It important to highlight that, while QTc prolongation was observed, the absence of TdP or significant ventricular arrhythmias suggests that the clinical risk of these events remains low. Furthermore, our logistic regression analysis showed the cumulative droperidol dose to be an independent risk factor for QTc prolongation. This study highlights the importance of considering the cumulative dose of droperidol when evaluating the need for additional pharmacologic therapy. Our study also showed that reduced renal function may be associated with an increased risk of QTc prolongation. Droperidol package insert emphasizes using caution in patients with impaired renal function despite the lack of specific dosing recommendations [20]. This study emphasized the need for careful consideration and monitoring when administering droperidol in this patient population.

Additional adverse effects associated with droperidol occurred at similar rates in our population as compared to previous studies [18, 21]. The rate of hypotension was slightly higher (2.8%) than what was reported in other studies (1–2%) [18, 21]. One potential explanation is that we were assessing the incidence of hypotension within 4 h of droperidol administration while the other studies chose 60 min as a cut-off for evaluating hypotension. Only two episodes of hypotension required interventions with fluid bolus administration and none required initiation of vasopressor therapy. Attributing hypotension to droperidol administration only is challenging given potential confounding factors such as underlying conditions, volume status, and concomitant medications, which could have contributed to the incidence of hypotension. The rate of extrapyramidal adverse effects was low; we noted one episode of akathisia and six episodes of dystonia and all of which resolved with diphenhydramine. There was one episode of suspected neuroleptic malignant syndrome that was observed in one patient after receiving concomitant high dose of haloperidol (> 30 mg), which made it difficult to establish an association with droperidol use. It is noteworthy to highlight that the exact incidence of these side effects is unknown in the literature, and there is a paucity of evidence on their prevalence.

Our findings showed that only 67 patients (27.3%) required additional droperidol. An observational study that evaluated droperidol for agitation reported that 14.3% patients required a repeated dose of droperidol, which is lower than our study; however, they evaluated droperidol as part of combination therapy with midazolam, which could justify the lower rate compared to our study [22]. The use of concomitant rescue medications within 4 h of droperidol administration was not uncommon in our patients and was higher to what has been reported in another study, which assessed the use of rescue medications within 30 to 60 min of droperidol administration [18]. Notably, the median time to first rescue medication after droperidol was 138 min, which, given the half-life of 2–3 h, may explain the higher rates of rescue medication in our analysis [20]. The median time to discharge from the ED from droperidol administration was higher (412 min) than what has been reported in another study (137 min) [23]. However, our study included patients who received droperidol for various indications, including agitation, which may require a

prolonged ED stay whereas the other study only included patients with CHS.

The limitations of this study include its observational retrospective design, single-center nature, and the possibility that it may be underpowered to detect rare events, such as TdP and ventricular arrythmia due to relatively small sample size, which may limit the generalizability of our findings to other institutions. It is noteworthy that the use of composite safety endpoint was intended to capture a broad spectrum of adverse effects, including rare and severe events such as TdP and ventricular arrythmias. However, the incidence of the composite safety endpoint in our study was primarily driven by QTc prolongation with no instances of TdP or ventricular arrythmia recorded. Thus, the generalizability of these findings including the risk for severe arrhythmic events is limited. Additionally, potential cofounders for hypotension, including underlying conditions, concomitant medications, and volume status were not collected, which could have impacted the incidence of hypotension. Symptom response to droperidol was not consistently recorded or measured using a formal rating scale in all cases; however, we were able to evaluate the potential efficacy of droperidol based on ED length of stay and a decreased use of concomitant rescue medications among patients who received droperidol treatment. Another limitation of our study is the fact that it is difficult to account for the contribution of droperidol administration to the development of adverse effects given the common practice of administering multiple medications in the ED; however, we were able to use the Naranjo adverse drug reaction probability scale to determine the likelihood that the adverse event could be attributed to droperidol use. While helpful for confirming adverse drug events, the Naranjo adverse drug reaction probability scale is limited in its ability to distinguish causality among multiple agents with similar mechanisms, such as other QTc-prolonging agents. About one-third of patients were discharged home after administration, making it challenging to assess any additional safety outcomes. However, our findings primarily reflect the immediate safety profile of low-dose administrations for 1–2 doses in the ED, with no clinically significant adverse effects observed within this narrow timeframe. Despite these limitations, our study provides real-world data on droperidol use for various indications in the in the ED. Furthermore, there were no instances of TdP or serious arrhythmias reported after using droperidol including patients who had risk factors for QTc prolongation, had elevated QTc at baseline or were on a known QTc prolonging medication. Future research should aim to increase sample size, potentially by including cases from pre-shortage periods, or through prospective studies focused on higher-risk population. Additionally, future studies should consider evaluating efficacy of droperidol.

Conclusion

Our study supports the use of droperidol for various indications in the ED at a low dose. There were no serious adverse events such as TdP or arrhythmias requiring intervention reported that could be directly attributed to droperidol use; however, it is crucial to consider the potential role of renal function and the dose dependent impact on QTc prolongation. Future prospective research with a larger sample size is needed.

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Author contributions
AMA, KEC, JCR and KEL were responsible for planning the study. AMA performed statistical analyses and was responsible for drafting the manuscript, with substantial contributions from KM, CSK, JCR, KEL and KEC. AMA and KEC processed the available data for statistical analysis. KEC and KM supervised the authors throughout the whole project. All authors read and approved the final version of the manuscript.

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Data availability
The data supporting the findings of this study will be made available by the corresponding author, upon request.

Declarations

Ethics approval and consent to participate
This study was approved by the Institutional Review Board of the Mass General Brigham (protocol # 2022P002473)). Due to the retrospective nature of the study, the ethics committee have waived the necessity of informed consent.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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