Research Article
Volume 13:1, 2025

Journal of Cardiovascular Diseases & Diagnosis

ISSN: 2329-9517 Open Access

Effects of Ondansetron and Kytril on Cardiac Parameters in Pediatric Patients with Nausea and Vomiting: A Comparative Study

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Abstract

Nausea and vomiting are common symptoms in children, and antiemetic drugs such as ondansetron and Kytril are commonly used to prevent serious complications. However, based on previous research limitations, this study aimed to investigate the changes in cardiac parameters following the administration of these two drugs in pediatric patients.

Methods: This case-control study was conducted on children admitted to Amiralmomenin Hospital in Semnan, Iran, between 2022-2023. Prior to drug administration, Electrocardiograms (ECGs) were obtained. The patients were divided into two groups: Group 1 received Kytril, consisting of 47 male patients (47%) and 53 female patients (53%), while group 2 received ondansetron, consisting of 52 male patients (52%) and 48 female patients (48%). ECGs were obtained again half an hour after drug administration. The collected data, including PR and QTc intervals before and after drug administration, as well as post-drug Heart Rate (HR), were analyzed using SPSS software and statistical tests including *chi-square*, independent t-test, paired-sample t-test, and two-sample t-test.

Results: The two groups were similar in terms of mean age, weight, gender distribution, and mean PR and QTc intervals before drug administration. However, there was a significant increase in the mean PR and QTc intervals after drug administration in both the ondansetron and Kytril groups, indicating their prolonging effect on these intervals. The mean PR and QTc intervals after drug administration were comparable between the two groups, suggesting a similar effect of Kytril and ondansetron in increasing these intervals. The mean HR after drug administration was similar in both groups and within the normal range.

Conclusion: Based on this study, the use of Kytril and ondansetron for the control of nausea and vomiting in pediatric patients is associated with an increase in PR and QTc intervals.

Keywords: Long QT interval • PR prolongation • Ondansetron • Kytril • Antagonist

Introduction

Nausea and vomiting are very common complaints that is been seen every day in emergency department [1]. They can be in different levels and may be caused by different problems like cytotoxic chemotherapy, radiation therapy, and some sort of surgeries. They may be a sign of a major problem and therefore appropriate approach is needed so if they are not properly managed by antiemetic treatments, they may cause severe dehydration which reduces the patient's desire to eat and drink, reduce life quality, threaten the success of therapy, and therefore increase mortality and morbidity [2,3]. With the introduction of 5-HT3 serotonin-receptor antagonist, the management of nausea and vomiting has improved a lot recently. These agents are also called setrons [4]. These drugs are known as the most effective antiemetics and are currently recommended, in combination with corticosteroids, as the first line therapy for nausea and vomiting in most cases [5,6].

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Received: 11 August, 2023, Manuscript No. JCDD-23-110122; **Editor assigned:** 14 August, 2023, PreQC No. JCDD-23-110122 (PQ); **Reviewed:** 29 August, 2023, QC No. JCDD-23-110122; **Revised:** 22 January, 2025, Manuscript No. JCDD-23-110122 (R); **Published:** 22 January, 2025, DOI: 10.37421/2329-9517.2025.13.637

Ondansetron affects both central and peripheral nervous systems to control nausea and vomiting. Central effects are made by controlling the 5-HT3 serotonin receptors in the area postrema. This area is located on the fourth ventricle floor and contains the "chemoreceptor trigger zone." This zone senses neurotransmitters like serotonin, toxins, and other signals and plays a role in mediating the sensation of nausea and subsequent vomiting. the peripherally effects are made by affecting the vagus nerve. It works on the 5-HT3 receptors which are located at the vagus nerve terminals. The vagus nerve can sense nausea and vomiting triggers within the GI tract, such as stomach irritants. It forms synapses within the nucleus tractus solitarius of the brainstem, another region important in vomiting. It is believed that most of the effects of ondansetron are a result of peripheral actions [7,8]. Granisetron (kytril) is also a very powerful and highly selective 5-HT3-receptor antagonist which has little or no affinity for other 5-HT receptors, or dopaminergic, adrenergic, benzodiazepine, histaminic, or opioid receptors [9]. Other 5-HT3-receptor antagonists have effects on other receptors as for ondansetron it also binds to 5-HT1B, 5-HT1C, α1-adrenergic and μ-opioid receptors [10]. Recent researches have shown selective 5-HT3-receptor antagonists significantly affect QT intervals and affect it as further studies show ondansetron can prolong QT up to 120 ms [11,12]. Prolongation of the QT interval associated with polymorphic ventricular tachycardia or torsades de pointes has been the most important reason that some medications, which already entered the market, were withdrawn or restricted later [13,14].

In this study we tried to evaluate the difference in ECG findings specially QT prolongation difference between patients administrated ondansetron and kytril which can be very useful in future studies and administration of this drugs.

Materials and Methods

This cross-sectional hospital-based study was conducted over a period of 6 months, 2022 to 2023, in the Paediatric Emergency Department at Semnan University, Amir al-momenin Hospital. The study included a total of 200 patients between the ages of 2 and 15 years who presented with complaints of vomiting. Patients who did not provide consent and those with known cardiac disease or dysrhythmias were excluded from the study.

ECG recordings were obtained from 100 patients before and after intravenous administration of ondansetron at a dose of 0.15 mg/kg for vomiting, and from another 100 patients before and after intravenous administration of Kytril at a dose of 10 mic/kg for vomiting.

Data collection involved filling out a checklist for all enrolled patients. The checklist included information such as age, sex, and weight of the patients.

A 12-lead ECG was performed on all children with vomiting before and after 30 minutes of receiving ondansetron at a dose of 0.15 mg/kg or Kytril at a dose of 10 mic/kg. The electrocardiograms were reviewed, and descriptive reports were created.

The following variables were determined: Heart rate, PR interval, QRS duration, and QT interval. The QT interval was measured from the onset of the QRS complex to the end of the T wave, which was defined by the return of the terminal T wave to the isoelectric T-P baseline. The corrected QT interval (QTc) was calculated using Bazett's formula, taking into account the heart rate. Interpretation of the ECG findings was conducted using specific centile tables for normal values of ECG waves and intervals based on age.

Data analysis

The collected data were coded, processed and analyzed using the SPSS stoical software, chi square, independent T test, paired sample T test and two sample T test was analyzed.

Results

Sexual distribution of patients under consideration

Total of patients were 200 and they were separated 2 group. Group 1; ondansetron (100 patients, include 52 females and 48 male) received. Group 2; kitril received (include 100 patients, 47 males and 53 female) (Figure 1).

Rows: ANTIEMETIC Columns: SEX

	1	2	All
1	53	47	100
	50.50	49.50	
2	48	52	100
	50.50	49.50	
All	101	99	200

Cell Contents
Count
Expected count

Chi-Square Test

	Chi-Square	DF	P-Value
Pearson	0.500	1	0.479
Likelihood Ratio	0.500	1	0.479

Figure 1. Sexual distribution of patients with antiemetic values.

P-value count by *chi square* test was 0.479. Both of group were similar to in term of mean of count female or male (Figure 2).

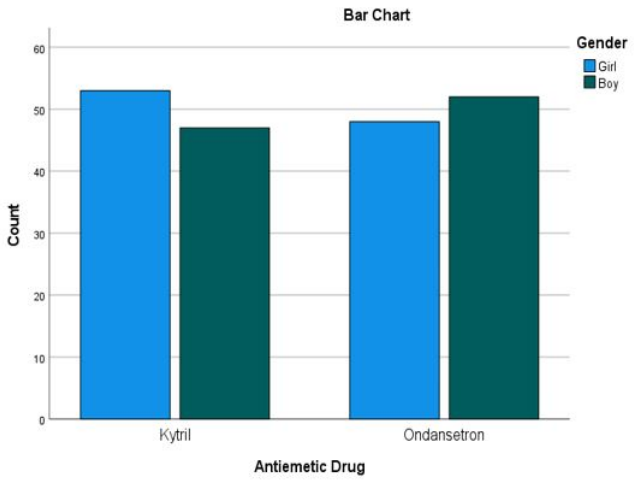

Figure 2. Bar chart of the antiemetic drug and count.

The average age of patients

Average age of ondansetron group; 87/2 ± 81/6. The average age of the kitril group; 88/2 ± 24/6 (Figure 3).

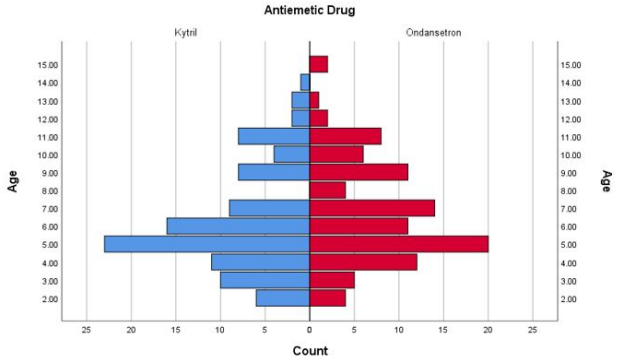

Figure 3. The average age of patients and drugs.

P-value count by indecent T test was; 0/164. The two groups were similar in age.

Average weight of patients

Average weight of ondansetron group; 14/8 ± 80/24. The average weight of the kitril group; 00/8 ± 22/2 (Figure 4).

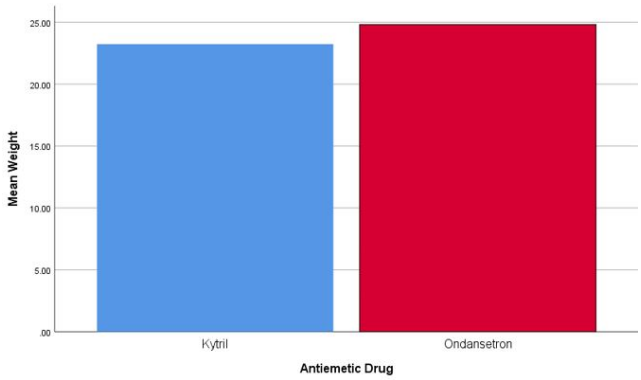

Figure 4. Average weight of patients.

P-value by independent T test was; 0/166. The two groups are similar in weight.

PR interval before and after received drug

In kitril group before received drug (pre-drug) was: 28/19 ± 3/148, and after revived drug was: 07/20 ± 80/151. According to the level of confidence of 95% and p-value was 0/000 by paired sample T-test, the null hypothesis is false and it accepts kitril can prolong the PR interval (Figures 5-8).

Paired T-Test and CI: PR-pre, PR-post

Descriptive Statistics

Sample	N	Mean	StDev	SE Mean
PR-pre	100	0.14830	0.01928	0.00193
PR-post	100	0.15180	0.02007	0.00201

Estimation for Paired Difference

Mean	StDev	SE Mean	95% Upper Bound for μ_difference
-0.003500	0.006256	0.000626	-0.002461

μ_difference: population mean of (PR-pre - PR-post)

Test

Null hypothesis	H_0: μ_difference = 0
Alternative hypothesis	H_1: μ_difference < 0

T-Value	P-Value
-5.59	0.000

Figure 5. In kitril group before (pre-drug) and after (post-drug) received drug.

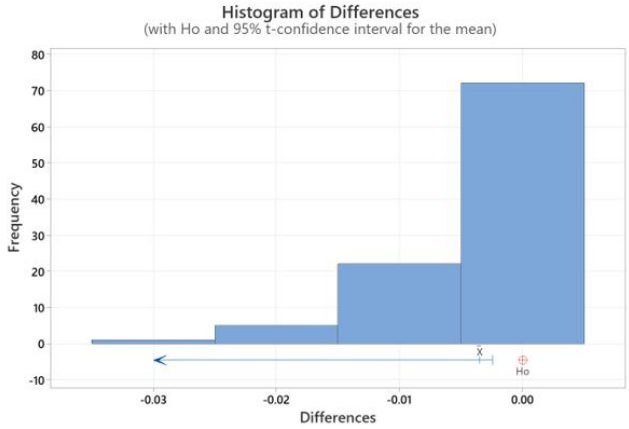

Figure 6. Histogram differences of the kitril.

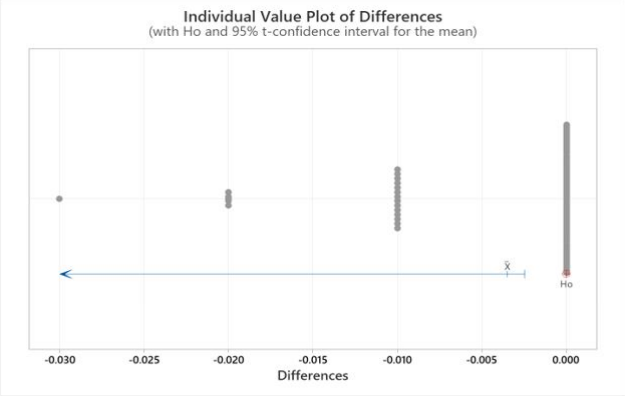

Figure 7. Individual value of plot differences of kitril.

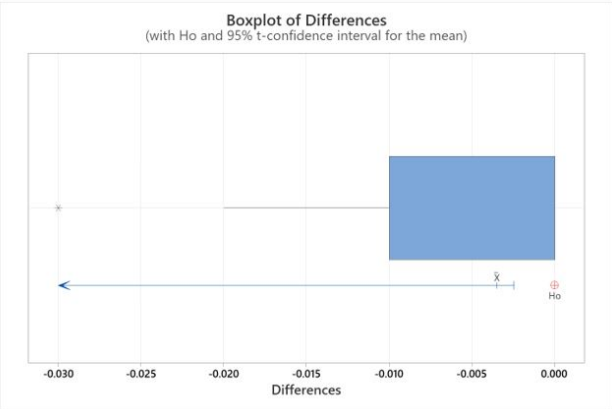

Figure 8. Boxplot differences of the kitril.

In ondansetron group before received drug (pre-drug) was: 33/18 ± 8/151 and after revived drug (post-drug) was: 50/18 ± 50/154.

According to the level of confidence 95% and p-value was 0/000 by paired sample T-test, so the null hypothesis is false and it accepts ondansetron can prolong the PR interval (Figures 9-12).

Paired T-Test and CI: PR-pre, PR-post

Descriptive Statistics

Sample	N	Mean	StDev	SE Mean
PR-pre	100	0.15180	0.01833	0.00183
PR-post	100	0.15450	0.01850	0.00185

Estimation for Paired Difference

Mean	StDev	SE Mean	95% Upper Bound for μ_difference
-0.002700	0.005478	0.000548	-0.001790

μ_difference: population mean of (PR-pre - PR-post)

Test

Null hypothesis H_0: μ_difference = 0
Alternative hypothesis H_1: μ_difference < 0

T-Value	P-Value
-4.93	0.000

Figure 9. In ondasetron group before (pre-drug) and after (post-drug) received drug.

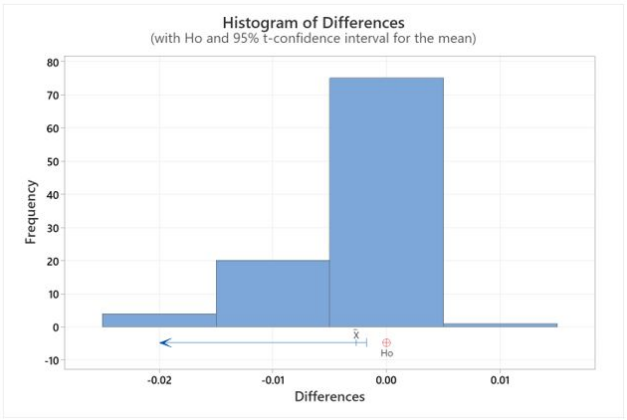

Figure 10. Histogram differences of the ondansetron.

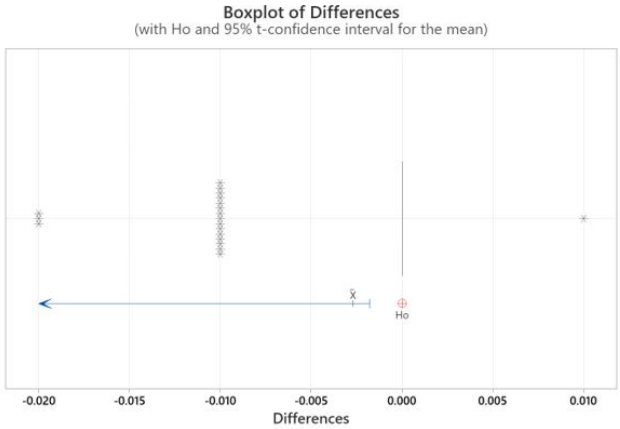

Figure 11. Boxplot differences of the ondansetron.

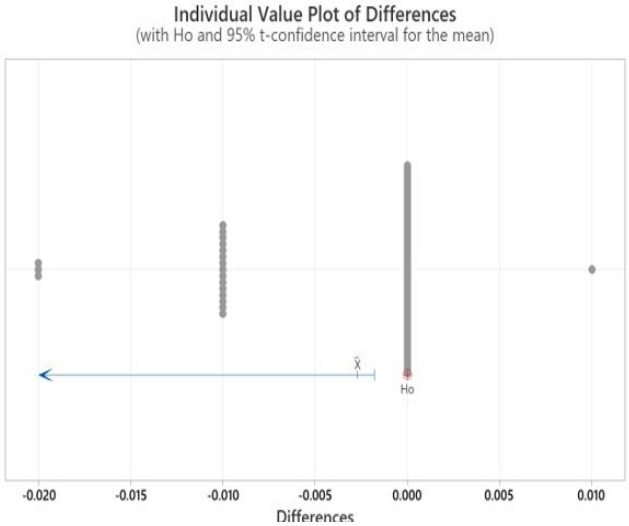

Figure 12. Individual value of plot differences of ondasetron.

Both 2 groups according to the level of confidence of 95% and p-value of 0/19 (two sample T-test); these two groups have an equal average PR interval before receiving the drug (Figures 13-15).

Two-Sample T-Test and CI: PR-pre, ANTIEMETIC

Method

μ_1: population mean of PR-pre when ANTIEMETIC = 1
μ_2: population mean of PR-pre when ANTIEMETIC = 2
Difference: $\mu_1 - \mu_2$

Equal variances are not assumed for this analysis.

Descriptive Statistics: PR-pre

ANTIEMETIC	N	Mean	StDev	SE Mean
1	100	0.1483	0.0193	0.0019
2	100	0.1518	0.0183	0.0018

Estimation for Difference

Difference	95% CI for Difference
-0.00350	(-0.00875, 0.00175)

Test

Null hypothesis H_0: $\mu_1 - \mu_2 = 0$
Alternative hypothesis H_1: $\mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
-1.32	197	0.190

Figure 13. Two sample T-test; and confident intervals of PR-pre *vs.* anti-emetics.

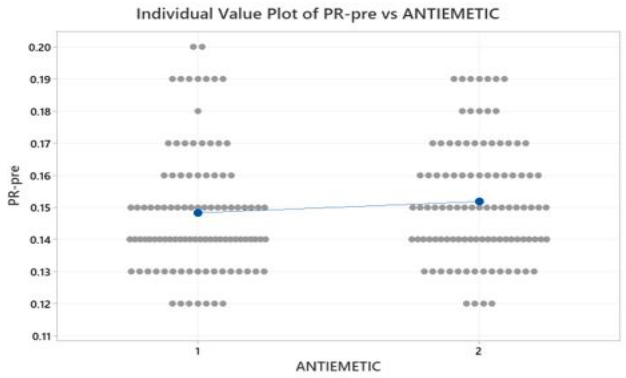

Figure 14. Individual value plot of PR-pre *vs.* antiemetics

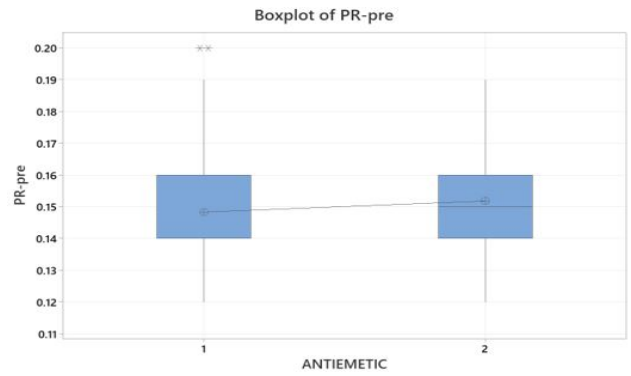

Figure 15. Boxplot of PR-pre *vs.* antiemetics.

Both 2 groups according to the level of confidence 95% and p-value of 0/324 (two sample T test), these two groups have an equal average PR interval after receiving drug (Figures 16-18).

Two-Sample T-Test and CI: PR-post, ANTIEMETIC

Method

μ_1: population mean of PR-post when ANTIEMETIC = 1
μ_2: population mean of PR-post when ANTIEMETIC = 2
Difference: $\mu_1 - \mu_2$

Equal variances are not assumed for this analysis.

Descriptive Statistics: PR-post

ANTIEMETIC	N	Mean	StDev	SE Mean
1	100	0.1518	0.0201	0.0020
2	100	0.1545	0.0185	0.0018

Estimation for Difference

Difference	95% CI for Difference
-0.00270	(-0.00808, 0.00268)

Test

Null hypothesis H_0: $\mu_1 - \mu_2 = 0$
Alternative hypothesis H_1: $\mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
-0.99	196	0.324

Figure 16. Two sample T-test and confident intervals of PR-post *vs.* anti-emetics.

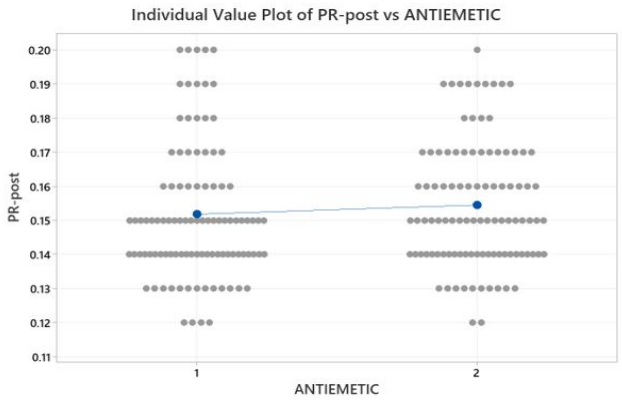

Figure 17. Individual value plot of PR-post *vs.* anti-emetics.

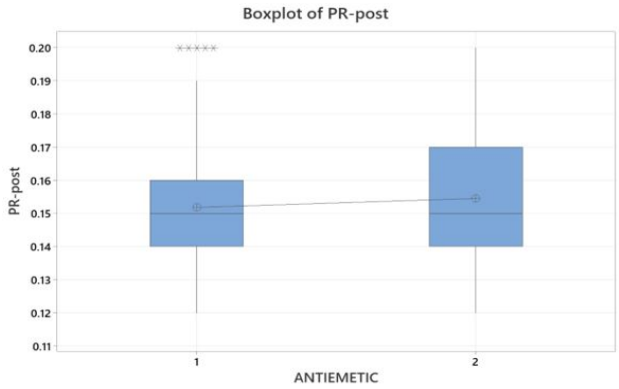

Figure 18. Boxplot of PR-post *vs.* anti-emetics.

QT corrected before and after receiving the drug

In kitril group before received drug: QT=382/40 ± 26/40, and after received drug: 50/388 ± 57/27.

According to the level of confidence 95% and p-value of was: 0/000 (paired sample T test), so the null hypothesis is rejected, and as a result, the drug kitril led to an increase in QTc interval (Figures 19-22).

Paired T-Test and CI: QTc-pre, QTc-post

Descriptive Statistics

Sample	N	Mean	StDev	SE Mean
QTc-pre	100	0.38240	0.02640	0.00264
QTc-post	100	0.38850	0.02757	0.00276

Estimation for Paired Difference

Mean	StDev	SE Mean	95% Upper Bound for μ_difference
-0.00610	0.01091	0.00109	-0.00429

μ_difference: population mean of (QTc-pre - QTc-post)

Test

Null hypothesis	H_0: μ_difference = 0
Alternative hypothesis	H_1: μ_difference < 0

T-Value	P-Value
-5.59	0.000

Figure 19. Paired T-test and confidence intervals QTc-pre and QTc-post of the kitril.

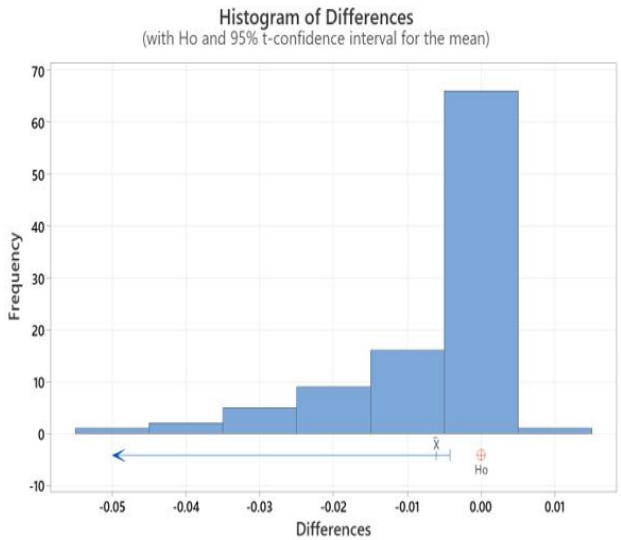

Figure 20. QTc-pre and QTc-post of kitril histogram of differences.

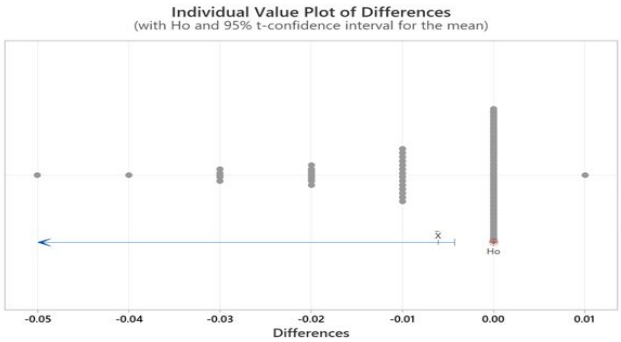

Figure 21. QTc-pre and QTc-post of kitril individual value plot of differences.

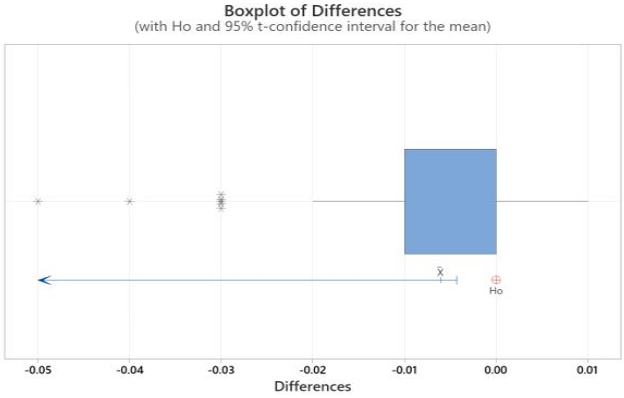

Figure 22. Boxplot differences of QTc-pre and QTc-post of kitril.

In ondansetron group before received drug: QT=380/20 ± 24/04, and after received drug: 385/60 ± 26/26.

According to the level of confidence 95% an p-value of was:0/000 (paired sample T test), so the null hypothesis is rejected, and as a result, the drug ondansetron led to an increase in QTc interval (Figures 23-26).

Paired T-Test and CI: QTc-pre, QTc-post

Descriptive Statistics

Sample	N	Mean	StDev	SE Mean
QTc-pre	100	0.38020	0.02404	0.00240
QTc-post	100	0.38560	0.02626	0.00263

Estimation for Paired Difference

Mean	StDev	SE Mean	95% Upper Bound for μ_difference
-0.005400	0.009148	0.000915	-0.003881

μ_difference: population mean of (QTc-pre - QTc-post)

Test

Null hypothesis	H_0: μ_difference = 0
Alternative hypothesis	H_1: μ_difference < 0

T-Value	P-Value
-5.90	0.000

Figure 23. Paired T-test and confidence intervals QTc-pre and QTc-post of the ondasetron.

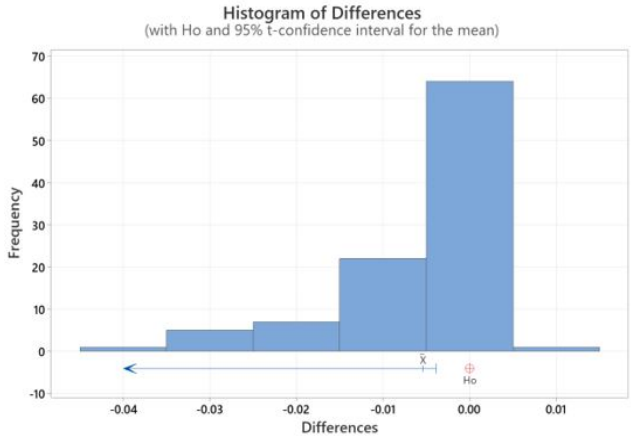

Figure 24. QTc-pre and QTc-post of ondasetron histogram of differences.

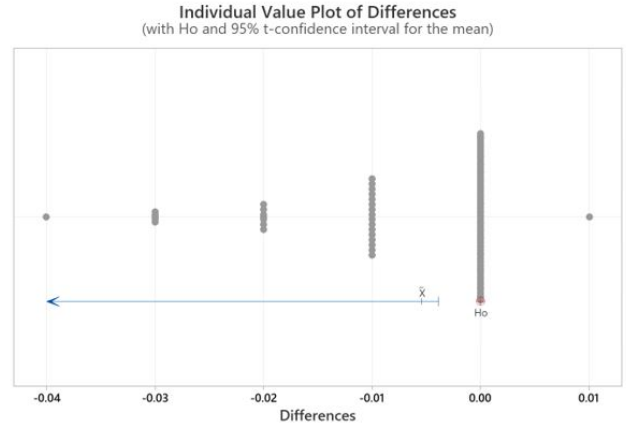

Figure 25. QTc-pre and QTc-post of ondasetron individual value plot of differences.

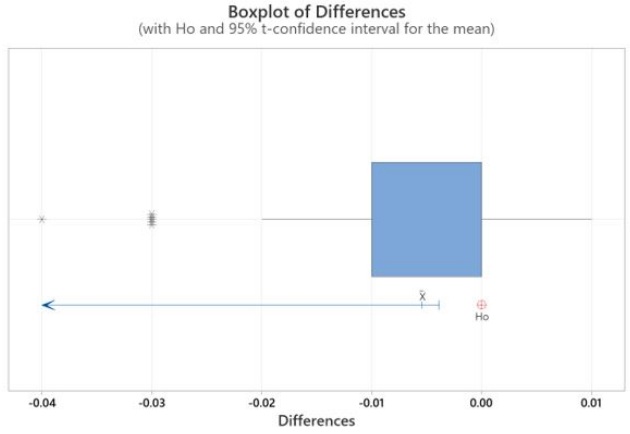

Figure 26. Boxplot differences of QTc-pre and QTc-post of ondasetron.

Both 2 groups According to the level of confidence of 95%a p-value of 0/539 (two sample T-test); these two groups have an equal average QT interval before received the drug (Figures 27-29).

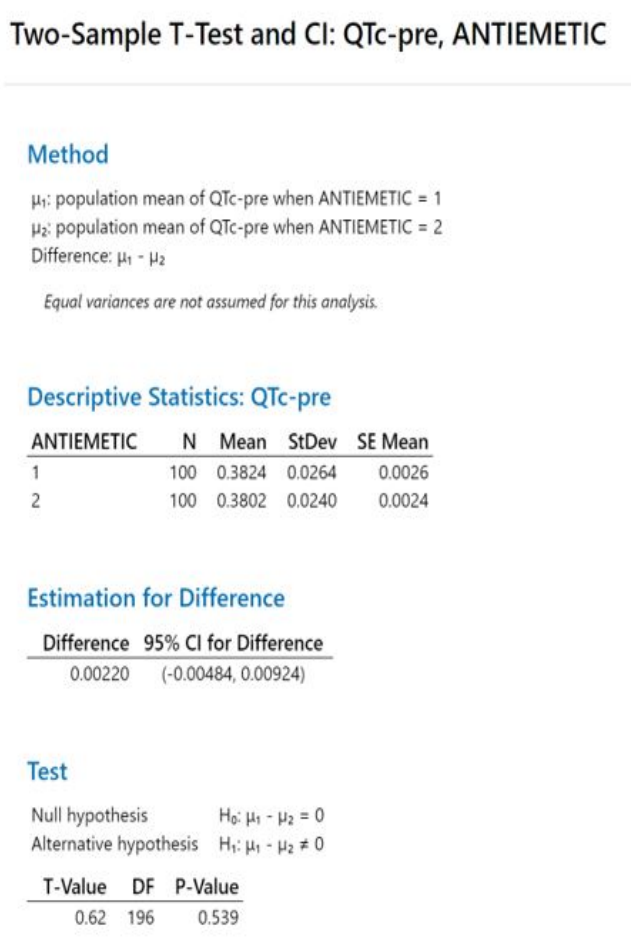

Figure 27. Two sample T-test and confidence intervals of QTc-pre *vs.* anti-emetics.

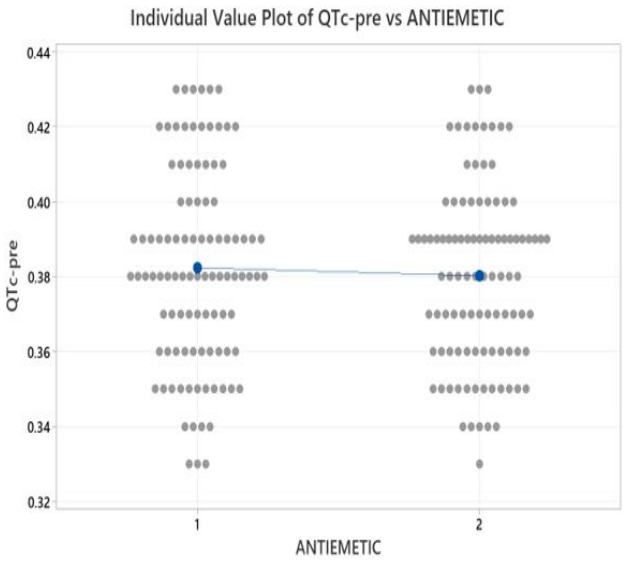

Figure 28. Individual value plot of QTc-pre *vs.* antiemetics.

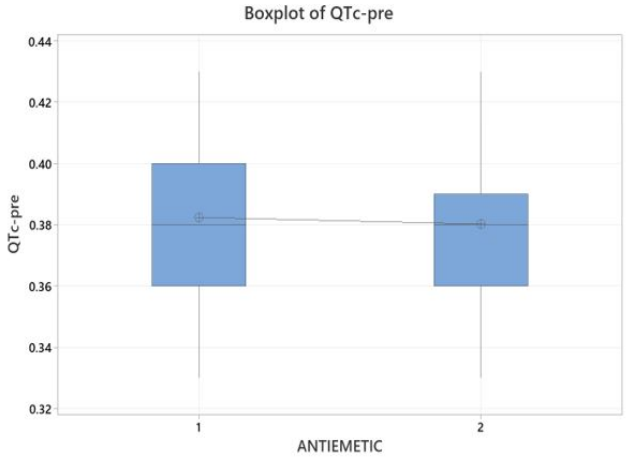

Figure 29. Boxplot QTc-pre.

Both 2 groups according to the level of confidence of 95% and p-value of 0/447 (two sample T-test); these two groups have an equal average QT interval after receiving the drug (Figures 30-32).

Two-Sample T-Test and CI: QTc-post, ANTIEMETIC

Method

μ_1: population mean of QTc-post when ANTIEMETIC = 1
μ_2: population mean of QTc-post when ANTIEMETIC = 2
Difference: $\mu_1 - \mu_2$

Equal variances are not assumed for this analysis.

Descriptive Statistics: QTc-post

ANTIEMETIC	N	Mean	StDev	SE Mean
1	100	0.3885	0.0276	0.0028
2	100	0.3856	0.0263	0.0026

Estimation for Difference

Difference	95% CI for Difference
0.00290	(-0.00461, 0.01041)

Test

Null hypothesis H_0: $\mu_1 - \mu_2 = 0$
Alternative hypothesis H_1: $\mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
0.76	197	0.447

Figure 30. Two sample T-test and confidence intervals of QTc-pre *vs.* antiemetics.

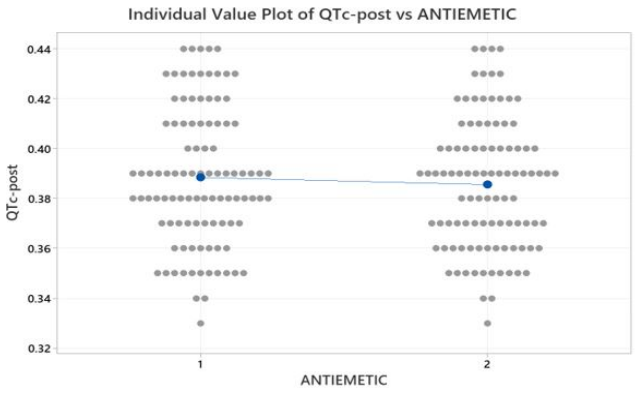

Figure 31. Individual value plot of QTc-pre *vs.* antiemetics.

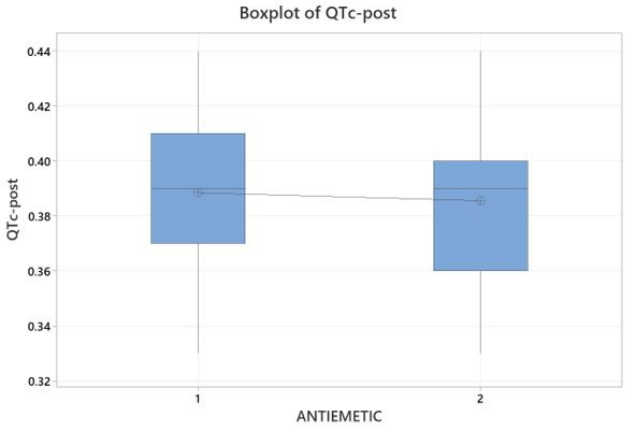

Figure 32. Boxplot of QTc-post.

Average of HR in patient

The average HR after receiving ondansetron was: 90/15± 16/90. The average HR after receiving ondansetron was: 46/19 ± 73/91. Both 2 groups according to the level of confidence of 95% and p-value of 0/533 (two sample T-test), these two groups have an equal average HR after receiving the drug (Figure 33).

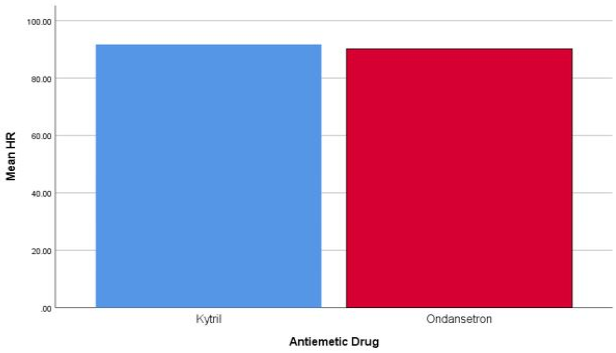

Figure 33. Two groups have an equal average HR after receiving the drug.

Discussion

This case-control study was conducted on 200 children admitted to Amirul Al-Mominin Hospital in Semnan in 2022-2023. The patients included two groups receiving Kytril and receiving Ondansetron. These two groups were similar in terms of average age, weight and gender. This similarity shows that these factors have no effect on the results of the research and the results are only related to the drugs themselves. An ECG was taken from the patients before receiving the drug. Considering the half-life of these drugs and previous researches that the effects of these two drugs on the ECG are removed in less than 24 hours, in this study, the ECG of the patients was examined only half an hour after receiving the drug.

These two groups were similar in terms of the average PR interval and the average QTc interval before receiving the drug, which indicates that the two groups have a similar situation in terms of the risk of increasing these intervals.

The difference in the average PR interval and QTc interval before and after receiving the drug indicates the effect of increasing these intervals by both drugs ondansetron and kytril.

These two groups were similar in terms of the average PR interval and the average QTc interval after receiving the drug, which indicates the same effect of Kytril and Ondansetron in increasing these intervals.

According to a strip study, 5-HT3 receptor antagonists block potassium and sodium channels in the cardiac myocyte membrane and thus lead to an increase in PR and QTC intervals.

Few articles have addressed the ECG changes [15,16]. In Pinarelli's article, it was mentioned about the decrease in heart rate and in article about the lack of changes in HR. In this study, only HR was measured after drug administration. The average HR of the two groups after receiving the drug is similar and is within the normal range.

The advantage of this study compared to previous studies is the appropriate amount of samples and the study of the age group of children. In other studies, the sample size was small [17,18] and few studies investigated the age group of children, and these studies were also on children undergoing chemotherapy and it was not determined that the drugs Whether chemotherapy is effective or not.

Among the articles that investigated the effects of ondansetron or kytril on ECG, all of them mentioned the QTc interval, but few of them also discussed the PR interval. In Pinarelli's article, significant shortening of PR90 interval and QRS24 complex duration and QTCa 90 prolongation were seen in the kitril group, and no changes were observed for the ondansetron group, which contradicts the results of Pinarelli's article and this study as well.

In this article, the control group was not used, because we cannot prohibit the patient from receiving the medicine for ethical reasons.

Conclusion

The results of this study indicate that the administration of kytril and ondansetron in children for the management of nausea and vomiting leads to an increase in the PR and QTc intervals within half an hour of drug administration. Considering the potential risk of arrhythmias associated with prolonged QTc intervals, caution should be exercised when prescribing these medications to children who are already taking drugs known to prolong QTc or have risk factors for QTc prolongation. Close cardiac monitoring for at least thirty minutes is recommended in such cases.

However, it is important to note that the use of kytril and ondansetron as agents for nausea and vomiting control in other children without pre-existing risk factors for QTc prolongation appears to be safe. Overall, individual patient characteristics and medical history should be carefully considered when prescribing these medications to children, and close monitoring is crucial to ensure their safety and minimize the risk of adverse cardiac effects.

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How to cite this article: Hooshmandi, Soodeh, Amir Khaujuei, Hamed Abbasizade Ghoroghchi and Farideh Moakkedi, et al. "Effects of Ondansetron and Kytril on Cardiac Parameters in Pediatric Patients with Nausea and Vomiting: A Comparative Study." *J Cardiovasc Dis Diagn* 13 (2025): 637.