Assessment of QTc-interval Prolonging Medication Utilization and Associated Potential Drug-Drug Interactions in Hospitalized Cardiac Patients: A Cross-**Sectional Study in Cardiology**

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ABSTRACT

Background: Several medications are linked to QTc-interval prolongation and torsades de pointes (TdP), a risk that is more common among hospitalized patients due to polypharmacy and associated QTc-interval-prolonging drug-drug interactions (QTc-pDDIs).

Objective: This study aimed to identify the prevalence of QTc-interval-prolonging drug (QTc-Drug) utilization and QTc-pDDIs among postoperative cardiac patients admitted to the National Institute of Cardiovascular Diseases (NICVD).

Method: We conducted a cross-sectional study at the NICVD, reviewing patients' medication charts for the use of QTc-Drugs and QTc-pDDIs. The CredibleMeds list was used to identify drugs associated with QTc-interval prolongation, while Micromedex Drug-Int.® and Lexicomp Interact® were utilized to screen for QTc-pDDIs.

Results: A total of 384 patients, with an average age of 48.9 ± 13.9 years, were included in the study. On average, patients used 10.3 ± 1.7 medications. Of the 3,956 medications prescribed, 22.9% were QTc-Drugs. The most frequently used QTc-Drug classes were diuretics (69.3%), anti-emetics (61.5%), and proton pump inhibitors (51.0%). Overall, 99.7% of patients received at least one QTc-Drug. The most frequent QTc-pDDI was ciprofloxacin-domperidone (7.6%), classified as major by Micromedex and a category B interaction by Lexicomp. Conclusion: The prevalence of QTc-Drugs was very high among postoperative cardiac patients, with nearly all patients (99.7%) receiving at least one QTc-Drug. The most common QTc-pDDI was ciprofloxacin-domperidone (7.6%), identified as a major interaction by Micromedex and a category B interaction by Lexicomp. Category X (contraindicated) QTc-pDDIs should be avoided in hospitalized patients.

Keywords: QTc-interval prolonging drugs; Polypharmacy; Torsade de pointes; Potential drug-drug interaction; cardiovascular diseases: Pakistan.

INTRODUCTION

Each year, around six million people die from sudden cardiac death (SCD) related to ventricular tachyarrhythmias

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thepharmacistguru@gmail.com Accepted: 18/05/2024. [1]. A prolonged QTc interval is associated with torsades de pointes (TdP), a potentially life-threatening polymorphic ventricular tachycardia [2]. While cardiovascular arrest due to TdP is rare, it can be devastating for hospitalized patients. QTc prolongation is defined as a value greater than 460 ms for men and 470 ms for women [3].

Several factors can cause the QTc interval to be prolonged, with polypharmacy playing a significant role

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[4]. Polypharmacy is defined as the concurrent use of five or more medications, while hyper-polypharmacy refers to the use of ten or more medications simultaneously [5]. In addition to polypharmacy, potential drug-drug interactions associated with QTc-interval prolongation (QTc-pDDIs) are a risk factor for prolonged QTc intervals. The risk of TdP is significantly higher when a OTc-intervalprolonging drug is involved in potential drug-drug interactions (pDDIs) [6]. OTc-Drugs may cause pharmacodynamic interactions with additional therapies, exacerbating the prolongation of the OTc interval [7]. Adding new drugs to a patient's ongoing treatment regimen may increase the risk of pDDIs in hospitalized patients [8, 9]. Beyond QTc-interval prolongation and the consequent risk of TdP, pDDIs can result in serious outcomes, which may prompt consultants to take risks due to the lack of evidence supporting adverse effects [10].

There is a relationship between geriatric patients, females, electrolyte imbalances, bradycardia, hereditary heart abnormalities, and the likelihood of developing QTc-interval prolongation. Several drugs can prolong the QTc interval, a phenomenon known as drug-induced QTc-interval prolongation [11]. The Arizona Center for Education and Research on Therapeutics (AZCERT) has identified over 220 drugs linked to QTc-interval prolongation on CredibleMeds®. To demonstrate the level of assurance regarding TdP risk, AZCERT has categorized QTc-interval-prolonging medications into four groups: known risk of TdP, possible risk of TdP, conditional risk of TdP, and drugs to avoid in congenital long QT syndrome (cLQTS) patients. It has been identified that more than 50 drugs are associated with a known risk of TdP [1].

Prescribing drugs that prolong QTc intervals requires prescribers to weigh the risks against the potential therapeutic benefits. Dhanani and colleagues highlighted the importance of clinical pharmacists in prescribing and managing medications across a clinical healthcare system [12]. Managing daily clinical risks is challenging due to the lack of specific guidelines for reducing QTc-interval

prolongation. According to Tisdale et al. and Vandael et al., a risk score can be used to predict the risk of QTc prolongation, with scoring systems developed based on observational studies. Tisdale et al. classified QTc prolongation risk groups into low, moderate, and high by calculating a summated risk score [13]. Vandael et al. developed the RISQ-PATH score, based on a systematic review of observational studies, which aids in clinical decision-making and facilitates the prescribing process for QTc-drugs [14].

There is relatively little published data about QTc-pDDIs and QTc-Drugs. In cardiac tertiary care units, only a few studies have focused on overall pDDIs or interactions that may lead to QTc-interval prolongation [15]. In developing countries, particularly Pakistan, data on this topic are limited. Therefore, research in this demographic is recommended. Additionally, many limitations in relevant studies, such as small sample sizes, retrospective approaches, a restricted scope focusing solely on pDDIs, and the use of diagnostic instruments, suggest that more thorough investigations are needed [4].

Thus, this study evaluated the prevalence of QTc-Drug usage, QTc-pDDIs, and the AZCERT classification of drugs associated with QTc-interval prolongation.

METHODOLOGY

Setting and Design of Study

A cross-sectional study was conducted over six months at the NICVD in Karachi, Pakistan, from November 2021 to April 2022. We collected data using approved data collection forms from patient records, including information on patients' demographics, diagnoses, and prescribed medications. All patients in our study were aged 18 years or older and had received at least two medications, regardless of the route of administration. Patients under 18 years of age were excluded from the study.

The sample size was calculated using Daniel's formula, $n=Z^2P\ (1-P)/d^2\ [16]$. A total of 384 patients were included in our study based on this formula. Ethical

approval for our study was obtained from the Ethical Review Committee (ERC), Clinical Research Department, NICVD, Karachi, Pakistan (ERC-117/2021).

Data Analysis

Each patient's list of dispensed medications was analyzed for QTc-pDDIs using Micromedex DrugReax® and Lexicomp Interact® [17]. Drugs associated with QTc-interval prolongation were assessed using the AZCERT QTc-Drugs lists and were categorized based on their TdP risks [18]. Data were collected in an MS ExcelTM spreadsheet, which was checked for accuracy and completeness by the co-supervisor. All statistical analyses

were performed using SPSS (version 25.0).

RESULTS

Among the 384 patients, 70.1% were male. The mean age of the patients was 48.9 ± 13.9 years, with the majority (46.4%) aged between 46 and 60 years. Patients with a single co-morbidity accounted for 34.9%, those with more than one co-morbidity accounted for 35.9%, and those without any known co-morbidity comprised 29.2%. The most common surgery was Coronary Artery Bypass Grafting (CABG), performed in 54.2% of the patients (Table 1).

Table 1: Baseline Characteristics of total patients

Variables	% (n)
Gender	
Male	70.1 (269)
Female	29.9 (115)
Age	
Mean±SD	48.9 ± 13.9
18-30 years	12.8 (49)
31-45 years	21.1 (81)
46-60 years	46.4 (178)
Above 60 years	19.8 (76)
Co-Morbidities	
Single Co-morbidity	34.9 (134)
More than one co-morbidity	35.9 (138)
NKCM (No Known Co-Morbidities)	29.2 (112)
Commonest Procedures/Surgeries	
Coronary artery bypass grafting (CABG)	54.2 (208)
Mitral Valve Replacement (MVR)	15.1 (58)
Aortic Valve Replacement (AVR)	10.2 (39)
Double Valve Replacement (DVR)	5.5 (21)
Atrial Septal Defect (ASD) Closure	5 (19)
Wound Debridement	6.5 (25)
Excision of Myxoma	1.8 (7)

The study analyzed 3,956 drugs prescribed to 384 patients, of which 906 (22.9%) were identified as QTc-Drugs, with a mean of 2.36 ± 0.85 per patient. The minimum number of drugs administered to patients was five, while the maximum was fifteen. The average number of medications administered per patient was 10.3 ± 1.7 , as shown in Table

2. Overall, 99.7% of patients received at least one QTc-Drug of any class, with 16.1% receiving a single QTc-Drug, 39.6% receiving two QTc-Drugs, 35.7% receiving three QTc-Drugs, 8.1% receiving four QTc-Drugs, and 0.3% receiving five QTc-Drugs (Table 2).

Table 2:Polypharmacy and Types of QTc-Drugs as per CredibleMeds Classification [27].

Variables	% (n)
Polypharmacy	
Total Drugs (n=384)	3956
$Min - Max (Mean \pm SD)$	5 - 15 (10.31 ± 1.7)
QTc-Drugs	
Total (n=384)	22.9 (906)
$Min - Max (Mean \pm SD)$	$0 - 5 (2.36 \pm 0.85)$
Known risk of TdP	
Total (n=384)	34.5 (313)
$Min - Max (Mean \pm SD)$	$0 - 2 (0.82 \pm 0.58)$
Possible risk of TdP	
Total (n=384)	2.9 (26)
$Min - Max (Mean \pm SD)$	$0 - 2 (0.07 \pm 0.27)$
Conditional risk of TdP	
Total (n=384)	60.9 (552)
$Min - Max (Mean \pm SD)$	$0 - 3 (1.41 \pm 0.59)$
Drugs to avoid for cLQTS patients	
Total (n=384)	1.6 (15)
$Min - Max (Mean \pm SD)$	$0 - 2 (0.04 \pm 0.2)$
No. of QTc-Drugs per patient	
1	16.1 (62)
2	39.6 (152)
3	35.7 (137)
4	8.1 (31)
5	0.3 (1)
Patients received QTc-Drugs	99.7 (383)

Table 3 presents the prevalence of QTc-Drugs along with their associated TdP risks. The most frequently used QTc-Drugs in postoperative cardiac patients were furosemide (69.3%), domperidone (61.5%), omeprazole (51%), ciprofloxacin (14.3%), tramadol (6.3%), and

amiodarone (4.7%). This table provides valuable insights into the prevalence of drug utilization and the TdP risk classifications across different therapeutic categories, aiding healthcare providers in making well-informed decisions regarding medication selection for their patients.

Table 3: Drug Classification of QT Drugs and CredibleMeds Category [27]

Drug Class	QTc-Drugs	% (n)	TdP Risk Category
Diuretic	Furosemide	69.3 (266)	Conditional risk of TdP
Gastrointestinal Agent/Anti-Emetic	Domperidone	61.5 (236)	Known risk of TdP
Gastrointestinai Agent/Anti-Emetic	Ondansetron	0.3(1)	Known risk of TdP
Proton Pump Inhibitor	Omeprazole	51 (196)	Conditional risk of TdP
	Ciprofloxacin	14.3 (55)	Known risk of TdP
Antibiotics	Moxifloxacin	0.8(3)	Known risk of TdP
	Piperacillin-Tazobactam	0.8(3)	Conditional risk of TdP
	Co-trimoxazole	0.8(3)	Drugs to avoid for cLQTS patients
Anti-Arrhythmic	Amiodarone	4.7 (18)	Known risk of TdP
Opioid Analgesic	Tramadol	6.3 (24)	Possible risk of TdP
Bronchodilator	Salbutamol (Albuterol)	2.6 (10)	Drugs to avoid for cLQTS patients
Beta-Agonist	Adrenaline	1 (4)	Drugs to avoid for cLQTS patients
Deta-Agonist	Norepinephrine	0.5(2)	Drugs to avoid for cLQTS patients
Calcium Channel Blocker	Diltiazem	0.3(1)	Conditional risk of TdP
Hyperpolarization-activated Cyclic Nucleotide-gated (HCN Blocker)	Ivabradine	0.3(1)	Conditional risk of TdP
	Levosulpiride	0.3(1)	Known risk of TdP
Antipsychotic	Quetiapine	0.8(3)	Conditional risk of TdP
	Risperidone	0.3(1)	Conditional risk of TdP
Anticonvulsant	Levetiracetam	0.3(1)	Possible risk of TdP

Table 4 shows the drug-drug interaction pairs (Micromedex DrugReax®) involved in QTc-pDDIs and their associated TdP risks. The most frequent pairs were domperidone-ciprofloxacin (7.6%), domperidone-amlodipine (4.4%), domperidone-amiodarone (1.6%), and amiodarone-ciprofloxacin (0.8%).

Table 5 presents the drug-drug interaction pairs (Lexicomp Interact®) involved in QTc-pDDIs and their

TdP risks. The most frequent pairs were domperidone-ciprofloxacin (7.6%), domperidone-salbutamol (1.8%), domperidone-amiodarone (1.6%), and amiodarone-ciprofloxacin (0.8%). Category X (contraindicated) pairs, such as domperidone-amiodarone and domperidone-verapamil, were labeled as major interactions in Micromedex DrugReax®.

Table 4:QTc-pDDIs pairs as per Micromedex Screening

QTc-pDDIs	% (n)	Severity	Onset	Documentation	Mechanism
Domperidone-Ciprofloxacin	7.6 (29)	Major	Not Specified	Fair	Pharmacokinetic
Domperidone-Amlodipine	4.4 (17)	Major	Not Specified	Fair	Pharmacokinetic
Domperidone-Amiodarone	1.6 (6)	Major	Not Specified	Fair	Pharmacokinetic
Domperidone-Quetiapine	0.8(3)	Major	Not Specified	Fair	Pharmacodynamic
Amiodarone-Ciprofloxacin	0.8(3)	Major	Not Specified	Fair	Pharmacodynamic
Domperidone-Diltiazem	0.3(1)	Major	Not Specified	Fair	Pharmacokinetic
Domperidone-Ticagrelor	0.3(1)	Major	Not Specified	Fair	Pharmacokinetic
Domperidone-Alprazolam	0.3(1)	Major	Not Specified	Fair	Pharmacokinetic
Domperidone-Verapamil	0.3(1)	Major	Not Specified	Fair	Pharmacokinetic

Table 5: QTc-pDDIs pairs as per Lexicomp Screening

QTc-pDDIs	% (n)	Risk Rating	Mechanism
Domperidone-Ciprofloxacin	7.6 (29)	В	Pharmacokinetic
Domperidone-Salbutamol	1.8 (7)	В	Pharmacokinetic
Domperidone-Amiodarone	1.6 (6)	X	Pharmacokinetic
Domperidone-Quetiapine	0.8(3)	D	Pharmacodynamic
Amiodarone-Ciprofloxacin	0.8(3)	С	Pharmacodynamic
Domperidone-Diltiazem	0.3(1)	X	Pharmacokinetic
Domperidone-Verapamil	0.3(1)	X	Pharmacokinetic
Furosemide-Ivabradine	0.3(1)	С	Pharmacodynamic
Amiodarone-Salbutamol	0.3(1)	С	Pharmacodynamic

DISCUSSION

According to this study, postoperative cardiac inpatients exhibited a high prevalence of QTc-interval prolongation. Our research aimed to determine both the prevalence of QTc-Drugs and QTc-pDDI prescribing patterns simultaneously. Multiple comorbid conditions likely contribute to the high prevalence of QTc-interval prolongation risk factors. Postoperative patients frequently

experience polypharmacy, which may be attributed to comorbid illnesses [19]. Our findings suggest that polypharmacy may be associated with the use of drugs that prolong the QTc interval and with QTc-pDDIs. Postoperative patients are highly likely to experience QTc-pDDIs, which can lead to severe arrhythmias and sudden death [20]. Our analysis revealed that most patients frequently used QTc-Drugs, increasing the risk of TdP and

prolonged QTc intervals.

Additionally, a study conducted in a medical ward found extensive use of QTc-Drugs [21]. Many postoperative inpatients suffer from chronic illnesses that may necessitate long-term medication use. To minimize risks, it is essential to consider alternative treatments for patients on QTc-Drugs [18]. Data on QTc-interval prolongation risk factors in postoperative patients are limited. However, several studies have documented QTc-interval prolongation in intensive care units (ICUs), where there is a relatively high prevalence of QTc-Drugs [3, 13, 22].

A study indicated a significant correlation between polypharmacy and QTc-interval prolongation [23]. There was also a substantial correlation between QTc-pDDIs and drug classes such as antimicrobials and anti-emetics. The combination of these medications with others may increase the risk of QTc-interval prolongation and subsequent TdP [18]. Among the drug-interacting pairs, the most common was domperidone-ciprofloxacin (a pharmacokinetic interaction), and the most critical interactions were with amiodarone, domperidone, and ondansetron, known to cause TdP. Patients experiencing these interactions must be closely monitored to prevent potentially harmful effects [24].

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The findings of this study suggest that appropriate measures should be taken for postoperative cardiac patients to avoid adverse outcomes caused by QTc-Drugs and QTc-pDDIs. Electrocardiographic (ECG) monitoring, including manual measurement of the QTc interval, should be a standard part of clinical practice, especially for patients with risk factors and those taking OTc-prolonging medications. It is recommended to perform an ECG 8-12 hours after initiating or increasing a high-risk OTcprolonging medication [25]. Drug selection for these patients should be based on a risk-benefit analysis [26]. Pharmacists should be well-educated about QTc-interval prolongation when conducting drug reviews. Implementing pharmacist-driven QTc-interval monitoring can help reduce the risk of OTc-interval prolongation [1].

CONCLUSION

In postoperative cardiac patients, there is a high prevalence of QTc-Drugs. QTc-pDDIs categorized as Category X should be avoided in these patients. Healthcare professionals, especially clinical pharmacists, must understand ECG interpretation, QTc-pDDIs, and their associated risks. Risk assessment tools should be implemented to reduce the risk of QTc prolongation and TdP.

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تقييم استخدام الأدوية التي تطيل فترة QTc والتفاعلات المحتملة بين الأدوية المرتبطة بها لدى المرضى القلبية المقيمين في المستشفى: دراسة عرضية في مجال القلب

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ملخص

الخلفية :ترتبط العديد من الأدوية بإطالة فترة QTc وتورساد دي بوانت(TdP) ، ويكون ذلك أكثر شيوعًا بين المرضى المقيمين في المستشفى بسبب التعددية الدوائية والتفاعلات بين الأدوية التي تؤدي إلى إطالة فترة.(QTc (QTc-pDDIs)

الهدف :ضممت هذه الدراسة لتحديد انتشار استخدام أدوية إطالة فترة QTc (QTc-Drugs) والتفاعلات بين الأدوية التي تؤدي إلى إطالة فترة QTc (QTc-pDDIs) بين المرضى القلبية بعد الجراحة الذين تم إدخالهم إلى المعهد الوطني للأمراض القلبية الوعائية. (NICVD) تم مراجعة سجلات أدوية المرضى للتحقق الطريقة :أجرينا دراسة عرضية في المعهد الوطني للأمراض القلبية الوعائية .(NICVD) تم مراجعة سجلات أدوية المرضى للتحقق من استخدام أدوية إطالة فترة .QTc (QTc-pDDIs) والتفاعلات بين الأدوية التي تؤدي إلى إطالة فترة .CredibleMeds استخدام قوائم CredibleMeds لتحديد الأدوية المتعلقة بإطالة فترة .QTc وتم استخدام هوائم المتفاعلات بين الأدوية.

النتائج :شملت الدراسة 384 مريضًا بمتوسط عمر 48.9 ± 13.9 عامًا. في المتوسط، استخدم المرضى 38.4 ± 1.7 أدوية. من بين 3956 دواءً موصوفًا، كانت (22.9% منها أدوية إطالة فترة .(QTc (QTc-Drugs) كانت الفئات الأكثر استخدامًا من أدوية QTc عام، تلقى ومضادات القيء بنسبة 61.5%، ومثبطات مضخة البروتون بنسبة 51.0%. بشكل عام، تلقى QTc هي المدرات بنسبة واحدًا على الأقل من أدوية QTc كانت التفاعلات الأكثر شيوعًا بين أدوية QTc هي السيبروفلوكساسين Agre ومبيريدون بنسبة 7.6%، والتي تم تصنيفها كأدوية رئيسية بواسطة Micromedex وتصنيف والسطة. Acciomp

الاستنتاج :كان انتشار أدوية إطالة فترة (QTc (QTc-Drugs) مرتفعًا جدًا بين المرضى القلبية بعد الجراحة. تلقى تقريبًا جميع المرضى (99.7%) دواءً واحدًا على الأقل من أدوية QTc وكانت التفاعل بين الأدوية الأكثر شيوعًا هو السيبروفلوكساسين-دومبيريدون بنسبة 7.6%، والذي تم تصنيفه كدواء رئيسي بواسطة Micromedex وتصنيف B بواسطة . (الممنوعة) في المرضى المقيمين بالمستشفى.

الكلمات الدالة: أدوية إطالة فترة QTc؛ التعددية الدوائية؛ تورساد دي بوانت؛ التفاعلات المحتملة بين الأدوية؛ الأمراض القلبية الوعائية؛ باكستان.

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