Adherence to recommended cardiac monitoring in breast cancer patients prescribed ribociclib



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Background

- Ribociclib is a cyclin-dependent kinase (CDK) 4/6 inhibitor used to treat hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer
- Ribociclib has serious adverse effects necessitating close monitoring of electrocardiograms (ECG) assessing QT intervals (QTc)
- QTc can be calculated several ways, the most popular using the Bazett formula (QTcB), but with this formula, there have been known inaccuracies, including overestimating the number of patients with potentially dangerous QTc
- Currently, it is recommended to use the Fridericia formula (QTcF) when calculating a patient's QTc for ribociclib use
- A previous study noted 17.9% of clinical changes associated with prolonged QTc were deemed inappropriate when using QTcF

Objective(s)

- Primary objective: Evaluate adherence to recommended QTc monitoring in patients taking ribociclib
- Secondary objective: Describe risk factors for QTc prolongation in patients taking ribociclib

Methods

Design: Retrospective chart review

Inclusion:

- ≥ 18 years old
- •ICD diagnosis code of breast cancer
- •One or more ribociclib orders between Jan. 1st, 2021 and Sept. 30th 2024
- •Ribociclib prescribed by a West Virginia University (WVU) Medicine provider

Exclusion

Off-label schedule

Discussion

<u>Limitations include</u>: variability in where QTc measurements were documented in the EMR, off-label dosing, ribociclib orders may represent patients stable on therapy, difficulty determining start date, and lack of reporting of concomitant QTc prolonging drugs

Dose changes, holds, and discontinuations captured in the study appeared to be based on QTcB calculations instead of the recommended QTcF measurement

Ribociclib monitoring recommendations: Age (years) Monitor ECG prior Repeat ECG on Median (Range) 47 (28-88) to treatment approximately day 14 of cycle initiation Sex Patients that received recommended 77 (97%) **Female** cardiac monitoring for ribociclib (n=79) **atients** 60 50 Race 75 (95%) White 40 ð 3 (4%) Other 30 51 Number 10 0 Hispanic/ 1 (1%) 27 Latino ECG prior to ECG after ECG prior to Starting dose ribociclib order* ribociclib and after 400 mg 22 (88%) ribociclib order order** Completed ECG monitoring 57 (72%) 600 mg

Results / Conclusion

Most patients included in the study were female (97%) and white (95%)

Only 12 patients (15.2%) with a ribociclib order received the cardiac monitoring recommended in the package insert. Further, these patients had QTcB measurements documented in the electronic medical record (EMR) rather than the recommended QTcF

The most common cardiac-related diagnoses was cardiac arrythmia

Reference(s)

Parish PC, Muluneh B, Hicks C, Jensen B, Zeidner JF, Richardson DR. Prevalence of discordant QTc values among cancer patients by the Bazett, Fridericia, and Framingham formulae: Evidence for Kisqali (ribociclib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; September 2024.

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Disclosure

No disclosures