Safety of Ribociclib for patients with hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative Breast Cancer: The Royal Marsden experience

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Introduction

Ribociclib is approved in combination with an aromatase inhibitor (AI) or fulvestrant for patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer, and more recently has been approved as an adjuvant treatment in combination with an AI for patients with HR-positive, HER2-negative early breast cancer at higher risk of recurrence.

Evaluating its safety profile in a less selected patient population in the real world is key. We aimed to evaluate it in patients treated at our Institution.

Methods and Materials

We retrospectively identified patients with HR-positive, HER2-negative breast cancer who received Ribociclib between December 2017 and February 2024 at our institution. The only exclusion criteria was Ribociclib given within clinical trials. Demographics, disease characteristics, blood tests and toxicities were recorded for 90 patients. Simple statistics were used as appropriate.

Results

Figure 1. Demographics, Disease and Treatment Characteristics

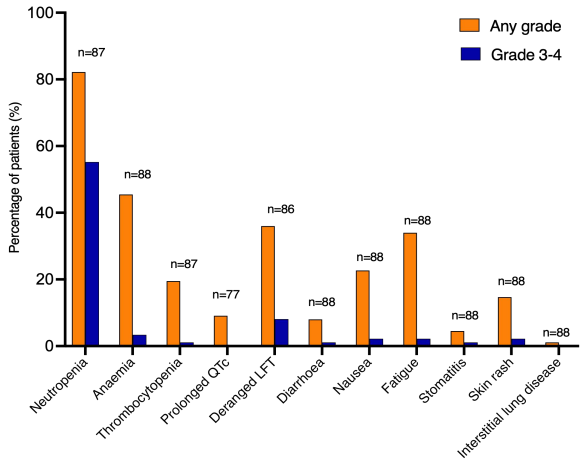
Characteristic	Category	n (%)	Characteristic	Category	n (%)
Age (n=90)	<50	27 (24.3%)	**Treatment intent (n=90)**	Palliative	77 (85.5%)
	≧50	63 (75.7%)		Curative	13 (14.4%)
Sex (n=90)	Female	90 (100%)	**Endocrine agent (n=90)**	Tamoxifen	1 (1.1%)
	Male	0 (0%)		Aromatase inhibitor	75 (83.3%)
Ethnicity (n= 90)	White	50 (55.6%)		Fulvestrant	14 (15.6%)
	Black	6 (6.7%)	**Ovarian function suppression (n=90)**	No	60 (66.7%)
	Asian	14 (15.6%)		Yes	30 (33.3%)
	Mixed	3 (3.3%)	**Metastatic Sites[a] (n=77)**	Visceral metastasis	46 (59.7%)
	Others	17 (18.8%)		Bony metastasis	74 (96.1%)
ECOG Performance Status (n=84)	0	47 (55.9%)		Nodal metastasis	56 (72.7%)
	1	31 (36.9%)		Chest wall metastasis	9 (11.7%)
	2	5 (6.0%)	**Disease Progression (n=85)**	No	46 (54.1%)
	3	1 (1.2%)		Yes	39 (45.9%)
Menopausal Status (n=89)	Pre-menopausal	26 (29.2%)	**Treatment after ribociclib (n=58)**	Chemotherapy	30 (51.7%)
	Peri-menopausal	7 (7.9%)		Endocrine	21 (36.2%)
	Post-menopausal	56 (62.9%)		Trial	2 (3.5%)
Grade (n=83)	Well differentiated	4 (4.8%)		No further treatment	5 (8.6%)
	Moderately differentiated	34 (41.0%)			
	Poorly differentiated	45 (54.2%)			

[a] Patients could have more than 1 metastatic site

Results

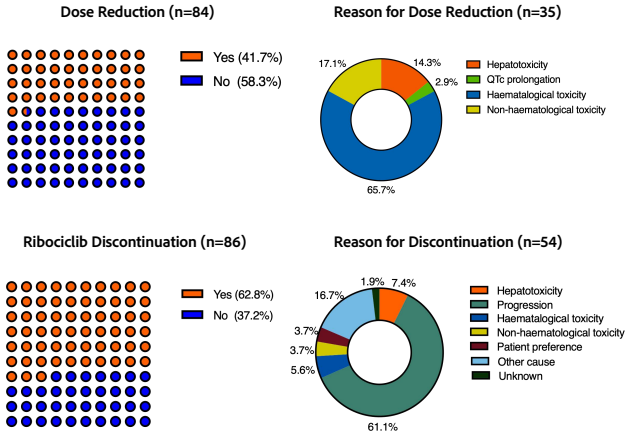
Among patients with complete safety data, 72 (82.8%) had any grade of neutropenia (grade 3-4 in 48 [55.2%]), 31 (36.0%) had any grade of deranged liver function (grade 3-4 in 7 [8.1%]), 40 (45.5%) had any grade of anaemia, 20 (22.7%) had any grade of nausea, 30 (34.0%) had any grade of fatigue, 13 (14.7%) had any grade of skin rash and 1 (1.1%) had any grade of interstitial lung disease; seven patients (9.1%) had QTc prolongation (grade 1 in all patients). Three patients (3.4%) had an infection requiring antibiotics within the first 28 days. Ribociclib was dose reduced in 35 patients (41.7%) and discontinued in 54 patients (62.8%): due to progression in 33 (61.1%), hepatotoxicity in 4 (7.4%), haematological toxicity in 3 (5.6%) and patient preference in 2 (3.7%).

Figure 2. Frequency of Adverse Events (Any Grade vs. Grade 3-4)



Results

Figure 3. Rates of dose reduction and discontinuation and their causes



Conclusions

Our analysis of the safety profile of ribociclib in this population confirms a similar neutropenia and dose reduction rate compared with published trials findings. However, rates of anaemia and deranged liver function of any grade were higher in our patient population, though the frequency of grade 3-4 deranged liver function tests aligns with existing literature. These findings are key to inform decision-making in a less selected patient population in the real world, especially ahead of the increasing use of ribociclib also in the curative setting.

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We acknowledge funding from the Patricia McGregor Travel Fellowship Fund and Royal Marsden Cancer Charity, and support from the NIHR RM/ICR BRC

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