

Real-world effectiveness of Ruxolitinib: analysis and comparison with COMFORT-II

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Abstract

The analysis included 466 patients with myelofibrosis on treatment with ruxolitinib. The PFS at 12th, 20th, 30th, 40th, and 50th month was 88%, 83%, 75%, 65%, and 61% respectively. Median for PFS was reached at 73.5 months. OS median was reached at 48.2 months. OS at month 12th, 20th, 30th, and 40th month was 87%, 78%, 70%, and 56% respectively. Eligible patients for comparison with COMFORT-II trial after application of inclusion and exclusion criteria were 68, while the clinical trial included 146 patients. The estimated value for PFS at 12th month was 84% and the median PFS was reached at 35.3 months. The values for OS was estimated to be 74% at 12th month and the median of OS was reached at 30th month. The clinical benefit rate from real-world population was estimated at 98%, and objective response rate was estimated at 79.2%, based on 53 patients.

Keywords

Myelofibrosis, ruxolitinib, real-world data, real-world evidence

Introduction

Myelofibrosis (MF) is a myeloproliferative neoplasm (MPN) that can arise de novo (primary MF) or from other myeloproliferative neoplasms, specifically polycythemia vera (PV) and essential thrombocythemia (ET) (Harrison et al. 2020, Arber et al. 2022, Khoury et al. 2022). It is characterized by progressive bone marrow fibrosis, splenomegaly, and constitutional symptoms such as fatigue, weight loss, night sweats, fever and pruritus, which negatively impact the quality of life of patients (Mesa et al. 2016). In addition to the symptom burden MF is related to reduced overall survival (OS) in comparison to the general population and to patients with ET and PV

(Hernández-Boluda et al. 2018, Tefferi 2021). Primary myelofibrosis is classified as a rare disease with reported prevalence of 1–9 per 100 000 (Orphanet n.d.).

The disease pathophysiology is fundamentally driven by constitutive activation of the Janus kinase/signal transducer and activator of transcription (JAK-STAT) signaling pathway (Schieber et al. 2019, Guijarro-Hernández and Vizmanos 2021). Ruxolitinib is an oral JAK1 and JAK2 inhibitor that was approved in 2011 by US Food and Drug Administration (FDA) and in 2012 by European Medicines Agency (EMA) for the treatment of patients with primary myelofibrosis, post polycythemia vera myelofibrosis (PPV-MF) or post essential thrombocythemia myelofibrosis (Post-ET MF) (EMA 2012). The pivotal Phase

III COMFORT-I and COMFORT-II trials established ruxolitinib as the gold standard of care, demonstrating superior efficacy over both placebo and best available therapy (BAT) in achieving a $\geq 35\%$ reduction in spleen volume (SVR35) and significant improvements in total symptom scores (TSS) (Harrison et al. 2012, Verstovsek et al. 2012). Long-term pooled analyses and real-world registries, such as the JUMP and ERNEST studies, have further validated these results, suggesting a durable clinical response and a significant survival advantage, with a reported 30% reduction in the risk of death compared to conventional therapies (Verstovsek et al. 2017, Guglielmelli et al. 2022).

Despite the success of ruxolitinib in controlled clinical environments, its transition to routine practice reveals significant complexities. Clinical trials often employ strict eligibility criteria, typically excluding patients with advanced age, multiple comorbidities, or baseline cytopenias (platelets $< 100 \times 10^9/L$). In real-world populations, however, nearly one-third of patients present with moderate-to-severe thrombocytopenia, which often necessitates dose adjustment and potentially sub-optimal effect (Talpaz et al. 2018, Cervantes et al. 2021). Furthermore, while the therapeutic armamentarium has recently expanded to include second-generation JAK inhibitors such as fedratinib, momelotinib, and pacritinib (EMA application withdrawn in 2017), ruxolitinib continues to be the foundational therapy in global clinical practice. Given this longevity, there is an ongoing opportunity to refine its use through independent, regional real-world evidence (RWE). Such data are essential for characterizing treatment outcomes in heterogeneous patient populations who may present with clinical complexities not fully captured in the original landmark trials (Aruga et al. 2025).

Ruxolitinib was included in the Positive drug list (PDL) in Bulgaria in 2014 for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis (PPV-MF) or post essential thrombocythaemia myelofibrosis. Inclusion in the PDL for medicinal products deemed as not cost-effective at the time of inclusion puts the product in the therapeutic effectiveness monitoring program, which includes collecting and analyzing real-world data.

This study presents the results of the real-world data analysis of application of ruxolitinib for the treatment of adult patients with primary MF, PPV-MF, and post-ET MF. The results were compared to the COMFORT-II clinical trial results.

Materials and methods

Study design

We performed a retrospective analysis of data from electronic health records for the period 2018–2024. Adult patients on treatment with ruxolitinib were followed up and

their data collected and anonymized. All patients were diagnosed with myelofibrosis with ICD 10 classification code D47.1, and some of them were diagnosed also with PV (ICD 10 classification code D45), essential thrombocythemia (ICD 10 classification code D47.3), and other specified neoplasms of uncertain or unknown behavior of lymphoid, haematopoietic and related tissue (ICD 10 classification code D47.7). The study analyzed the OS, PFS, CBR, and ORR and compared the results with COMFORT-II clinical trial results.

Data source

Data were obtained from healthcare establishments in Bulgaria, where the patients were treated and followed up. The data were extracted from structured and unstructured text through the implementation of LLM algorithms. A sample of the extracted data was manually compared to the original medical documents and validated by two independent Data analysts. Data extraction was found to be at least 95% accurate for the analysed dataset. Data analysis was conducted via the Danny Platform (<https://sqilline.com/products/danny-platform/>), an analytic platform that integrates large amounts of real-world data from EHRs using embedded machine learning and large language model (LLM) algorithms. The results obtained were compared with the results of the COMFORT-II clinical trial, evaluating ruxolitinib versus the best available therapy for the treatment of primary myelofibrosis, myelofibrosis after polycythemia vera, or post-essential thrombocythemia myelofibrosis.

Comparison with clinical trial results

The endpoints reported were overall survival (OS), progression free survival (PFS), clinical benefit rate (CBR), and objective response rate (ORR). PFS was defined as the time from initiation of ruxolitinib treatment to disease progression or death. OS was defined as the time from initiation of ruxolitinib treatment until death. ORR was defined as the proportion of patients achieving partial or complete response to treatment over a specific period of time. CBR was defined as the proportion of patients achieving complete or partial response, or stable disease over a given time. The Kaplan–Meier method was used to estimate PFS and OS from ruxolitinib initiation. The 95% confidence intervals for ORR and CBR were calculated as per the Wilson score method for binomial variables.

For the purpose of aligning characteristics, an Iterative Proportional Fitting (IPF) algorithm was used to adjust real-world data to match the data from the clinical trial. In this way, the progression-free survival (PFS) and overall survival (OS) curves may be more comparable to those from the study. Additional inclusion and exclusion criteria were used in order to ensure comparability and homogeneity between real-world population and COMFORT-II population. There criteria are summarized in Table 1.

Table 1. Inclusion and exclusion criteria for comparison with COMFORT-II.

Inclusion Criteria for comparison	Exclusion Criteria for comparison
Diagnosis code ICD 10 D47.1	Spleen < 5 cm below costal margin
Age ≥ 18 years	Peripheral blasts ≥ 10%
ECOG performance status 0–3	Platelet count < 100 × 10 ⁹ /L
IPSS risk score: Intermediate-2 or High	Absolute neutrophil count ≤ 1 × 10 ⁹ /L

Results

The analysis includes patients (n = 466) diagnosed with myelofibrosis with ICD 10 code D47.1 receiving ruxolitinib. Nine patients were diagnosed with polycythemia vera, 82 with essential thrombocythemia, and 5 were diagnosed with ICD 10 code D47.7 - other specified neoplasms of uncertain or unknown behaviour of lymphoid, haematopoietic and related tissue before or after being diagnosed with myelofibrosis (Table 2).

The PFS at 12th, 20th, 30th, 40th, and 50th month was 88%, 83%, 75%, 65%, and 61% respectively. Median was reached at 73.5 months. (Fig. 1)

The results for OS showed that median was reached at 48.2 months. OS at 12th, 20th, 30th, and 40th month was 87%, 78%, 70%, and 56% respectively. (Fig. 2)

Based on 363 patients the clinical benefit rate is estimated at 96%. The data needed for calculation was not available for all patients.

Comparison with COMFORT-II

Eligible patients for comparison with COMFORT-II trial after application of inclusion and exclusion criteria were 68, while the clinical trial included 146 patients.

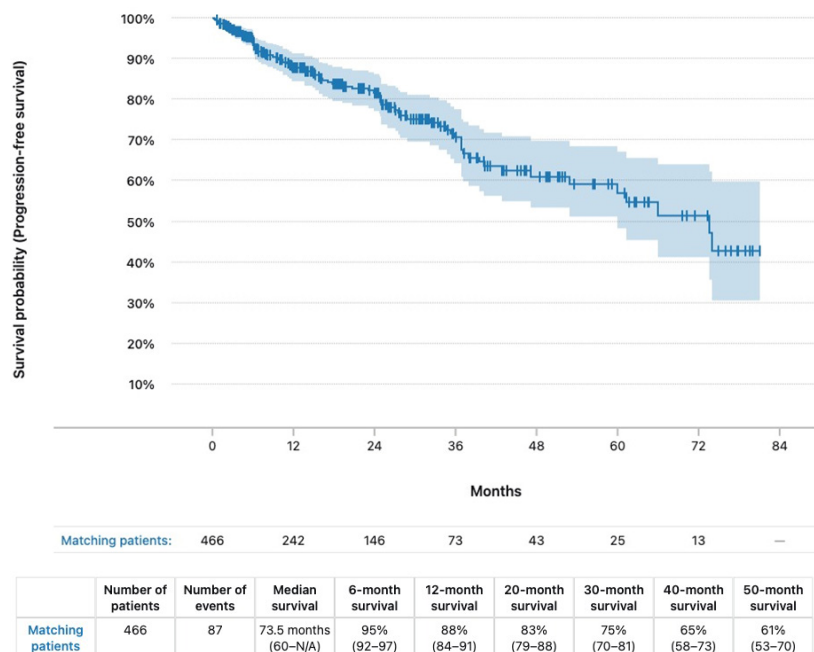
Table 2. Demographics and clinical characteristics.

Disease	ICD-10 code	n	%
PV	D45	9	2%
ET	D47.3	82	18%
Other	D47.7	5	1%
CMD	D47.1	466	100%
Sex		n	%
Female		220	47%
Male		246	53%
Age		Value	± SD
Average		68.9	± 10.1
Median		71	
ECOG score		Value	
0		23	
1		196	
2		98	
3		21	
4		3	
N/A		125	

That allows for statistically significant results up to the 12th month time point. Not all of the clinical trial criteria were applied when selecting eligible patients from the real-world population, as the necessary data were not available for every patient and doing so would have resulted in too small a sample size for meaningful comparison.

Progression-free survival (PFS)

The estimated value for PFS at 6th month and 12th month was 93% and 84% respectively with the median PFS reached at 35.3 months. Data for PFS from COMFORT-II was not reported (Fig. 3).

**Figure 1.** Progression-free survival in all patients on ruxolitinib.

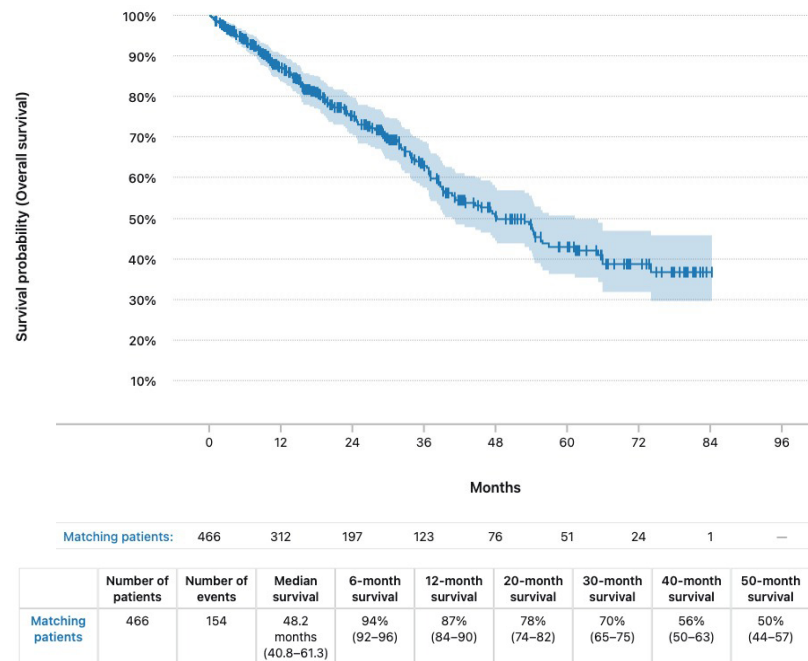


Figure 2. Overall survival in all patients on ruxolitinib.

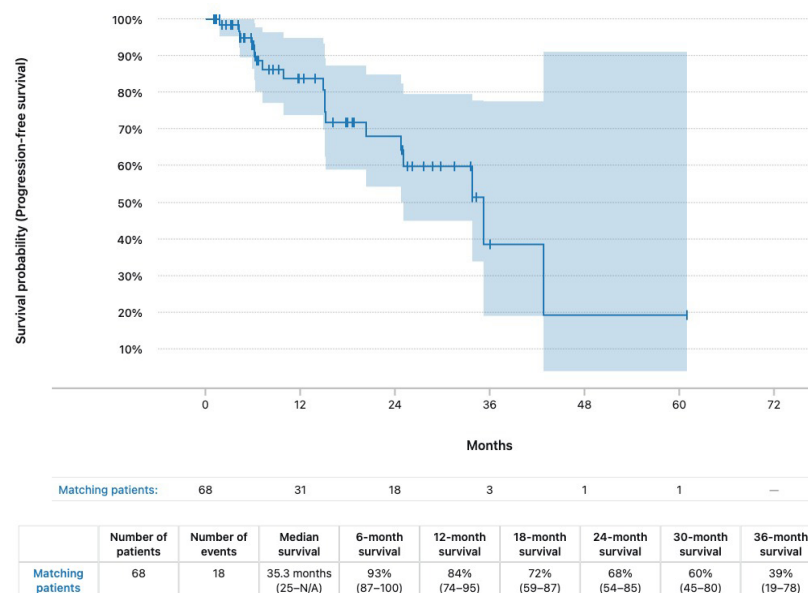


Figure 3. Progression-free survival in patients after IPF.

Overall survival (OS)

The values for OS for the real-world population was estimated to be 90% at 6th month, 74% at 12th month, and 59% at 18th month, while COMFORT-II reports 97%, 95%, and 88% for the same time points respectively. The median of OS in real-world population was reached at 30th month, while it was not reached in COMFORT-II trial (Fig. 4).

Clinical benefit rate (CBR) and objective response rate (ORR)

The clinical benefit rate from real-world population was estimated at 98%, and objective response rate was

estimated at 79.2%, based on 53 patients. These parameters were not reported in COMFORT-II and thus comparison can not be made.

Discussion

In this real-world data study a total of 466 patients were followed up and their data analyzed. The median for PFS was reached at 73.5 months, however enough patients for statistical significance were available until 55th month. The estimated progression-free survival in our cohort closely corresponds to the reported PFS data from JUMP – 83% (95% CI, 79–88%) at 20th month vs 81% (95% CI,

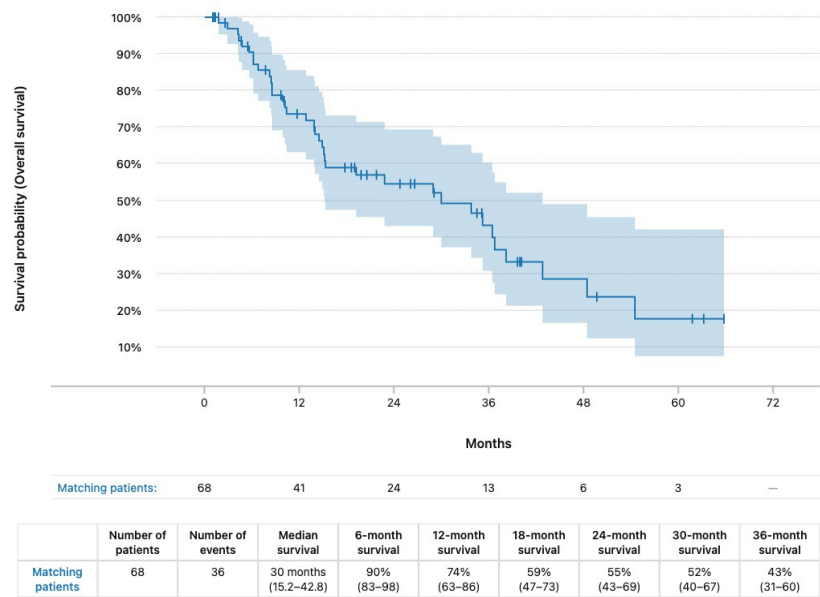


Figure 4. Overall survival in patients after IPF.

78–83%) at week 96 (Al-Ali et al. 2020). The median for OS was reached at 48.2 months. The results from COMFORT trials showed that ruxolitinib was associated with significant improvement of OS compared to placebo or best available treatment (Verstovsek et al. 2017). Overall survival in patients with MF who received ruxolitinib compared with control populations, was evaluated in few real-world studies. Analysis of data from ERNEST study revealed that OS was significantly longer in ruxolitinib treated patients with MF in comparison to patients receiving hydroxyurea (Median: 6.7 years vs 5.1 years; $p = 0.001$) (Guglielmelli et al. 2022). A multicenter, retrospective chart review, including 469 patients from six countries reported median survival from ruxolitinib initiation was 44.4 months (95% CI, 38.8–50.2 months) (Passamonti et al. 2022). (Stoeva et al. 2023) reported significant improvement in overall survival in Bulgarian patients population treated for MF with ruxolitinib compared with BAT, estimating that 75% of patients on ruxolitinib would live for at least 80 months. Although real-world studies are associated with inherent limitations including limited data, limited number of patients, and risk of bias, and results vary, the findings are consistent and in agreement with prolonged OS in ruxolitinib treated patients in COMFORT trials.

The IPF algorithm was applied to allow more precise comparison between our data and COMFORT-II data. This resulted in lower number of patients eligible for inclusion in the analysis compared to the entire population, 68 out of the 466. An additional limitation is that complete data were not available for every patient, owing to the nature of the data source, which consists of documents containing free-text entries and non-mandatory fields. There are differences in the criteria used to select patients from clinical practice compared to the criteria used in the clinical trial. Only a subset of the inclusion criteria was implemented in real-world practice to enable

the inclusion of a larger study population. The number of patients in the clinical trial (146) is significantly higher than the number of patients in real-world practice (68). Consequently, the real-world data is sufficient for statistically significant conclusions only up to approximately the 12th month. The clinical trial does not present data for PFS (Progression-Free Survival). The overall survival values in real-world practice compared to the clinical trial were as follows: 90% vs. 97% at 6th month, 74% vs. 95% at 12th month, and 59% vs. 88% at 18th month. The median OS in real-world practice was reached at 30th month, whereas in the clinical trial, it was not reached. The CBR (Clinical Benefit Rate) for ruxolitinib in clinical practice was 98% (52 out of 53 patients). The ORR (Overall Response Rate) was 79.2% (42 out of 56 patients). There is no available data from the clinical trial to perform a direct comparison for these metrics. These results are consistent with the results from COMFORT-II and other real-world studies (Harrison et al. 2012, Meckstroth et al. 2021, Al-Ali et al. 2025).

Conclusions

Despite their limitations, real-world studies in MF are essential for the better understanding of the disease, treatment effectiveness and safety. Ruxolitinib remains the standard of care first line treatment for MF. Our findings affirm that ruxolitinib is a valuable treatment option for patients with MF and are consistent with other real-world studies and COMFORT-II clinical trial results.

Additional information

Conflict of interest

The authors have declared that no competing interests exist.

Ethical statements

The authors declared that no clinical trials were conducted in the present study.

The authors declared that no experiments on humans or human tissues were performed for the present study.

The authors declared that no informed consent was obtained from the humans, donors or donors' representatives participating in the study.

The authors declared that no experiments on animals were performed for the present study.

The authors declared that no commercially available immortalised human and animal cell lines were used in the present study.

This study was based on secondary usage of anonymized data. Ethics committee approval or patient-informed consent were not required for this type of research as per local Bulgarian regulations.

Use of AI

No use of AI was reported.

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Data availability

All of the data that support the findings of this study are available in the main text.

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