

A Retrospective Observational Study of Ibrutinib in Real- Life Settings in France, Using the SNDS Database (OSIRIS)

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BACKGROUND

Ibrutinib is a Bruton's Tyrosine Kinase Inhibitor indicated in the treatment of several B-cell malignancies: in first line (L1) and relapse/refractory (R/R) Chronic Lymphocytic Leukemia (CLL), in R/R Mantle Cell Lymphoma (MCL) and in L1 and R/R Waldenström's Macroglobulinemia (WM) [1]. Since August 1, 2017, ibrutinib is reimbursed in specific indications and is available in community pharmacies and hospital pharmacies in France.

AIM

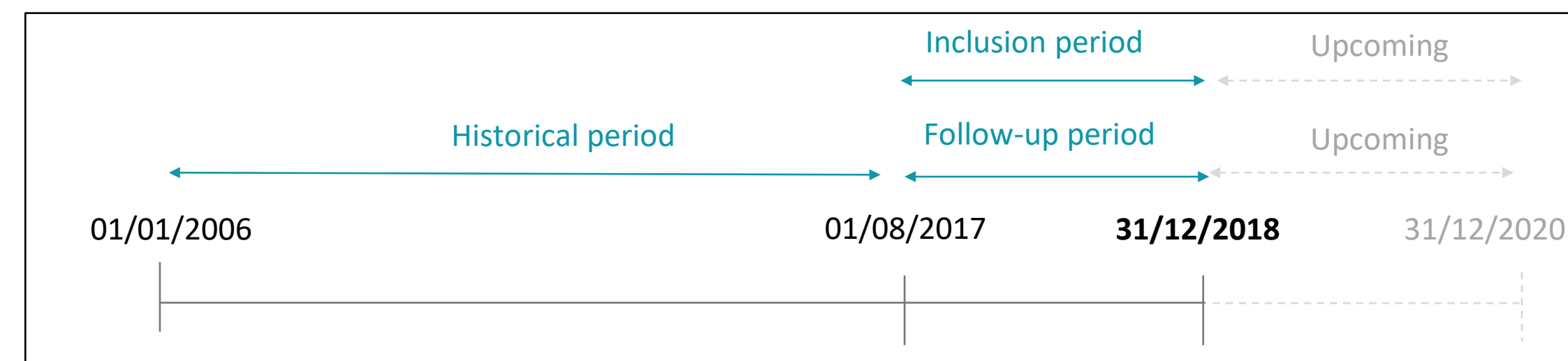
This study aims to describe the characteristics of patients treated by ibrutinib and their medical resources use and associated costs.

METHODS

Design

- This is a retrospective observational cohort study of patients affiliated to the general scheme (around 80% of the French population)* with an ibrutinib initiation from August 1, 2017 (date of reimbursement in France) to December 31, 2018 identified in the French national health insurance database (SNDS – a comprehensive in- and out-patient healthcare consumption database).
- Indications for which ibrutinib was assumed to be used were defined by an algorithm. This algorithm is based on ICD codes to understand the disease (CLL, MCL or WM), CIP and UCD codes of dispensed drugs before and during ibrutinib's exposure to understand lines of treatments (first line, second or more) and treatment pattern (monotherapy or associated with bendamustine and rituximab or other treatment patterns).

Figure 1. Study Design



Statistical Analysis

- Comorbidities were defined according to algorithms based on ICD codes of hospital and Long Term Disease diagnoses. They were evaluated using Charlson comorbidity score.
- The number and percentage of patients with at least one care of each item of Medical Resource Utilization (MRU) were described during follow-up period.
- Costs were described per month from a collective perspective for each indication and by categories (medications, hospitalizations and others).

CONCLUSION

- This is the first study estimating the costs for patients with CLL, MCL and WM, treated with ibrutinib in France. However, no distinction could be made between costs specific to the management of these diseases and those related to comorbidities.
- The highest monthly costs were for patients with MCL representing a total cost of 8,600€ while they were around 6,000€ for the other patients. Cancer treatment costs accounted for about 90% of the total cost.
- Future analyses with data from 2019 and 2020 will be conducted to update these results.

FUNDING

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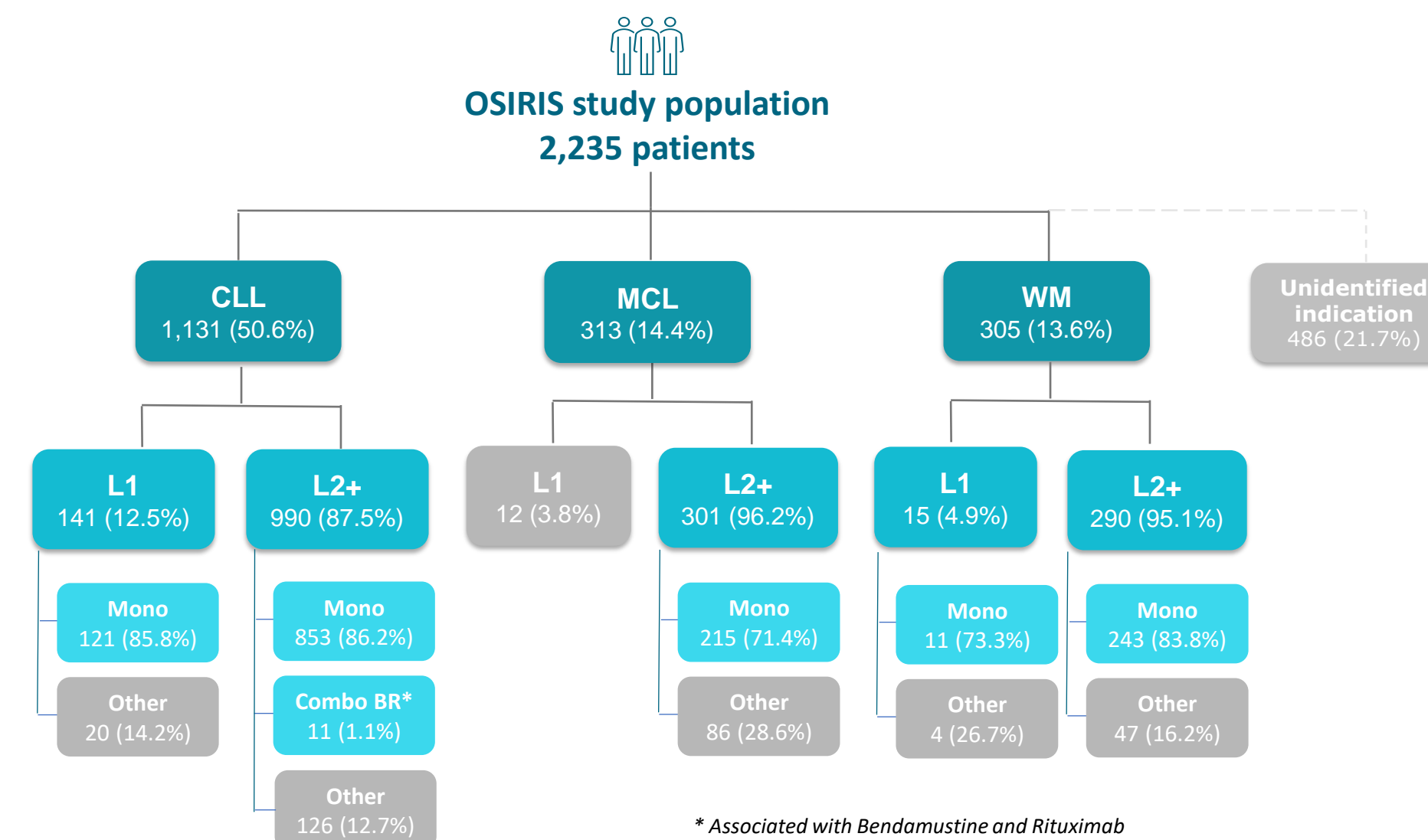
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*are not affiliated (around 20% of the French population) : official, farmers, independent, soldiers and fairground merchant

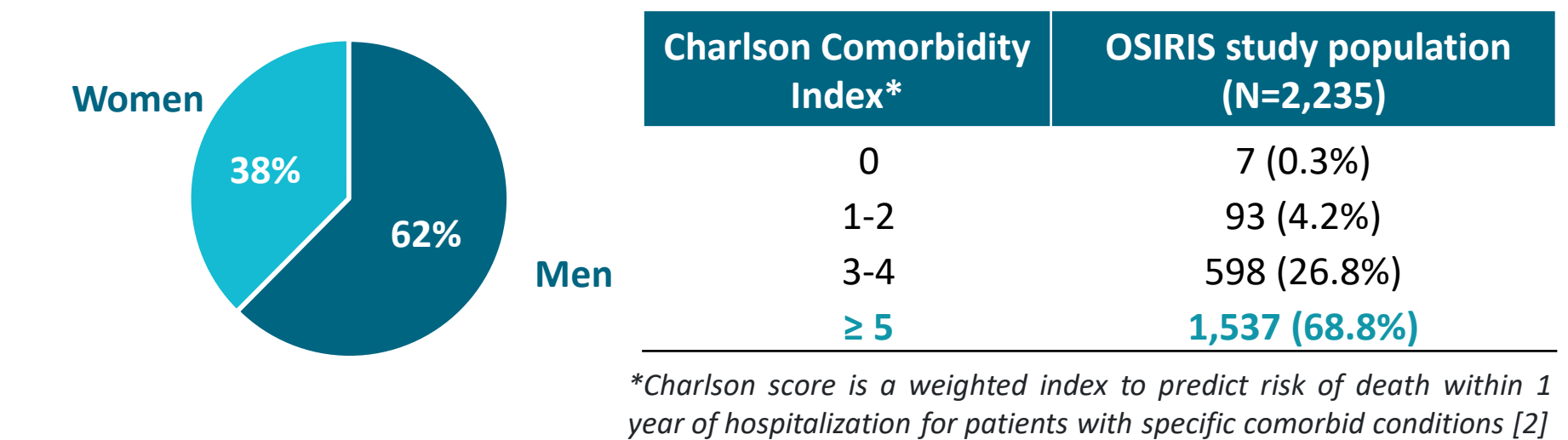
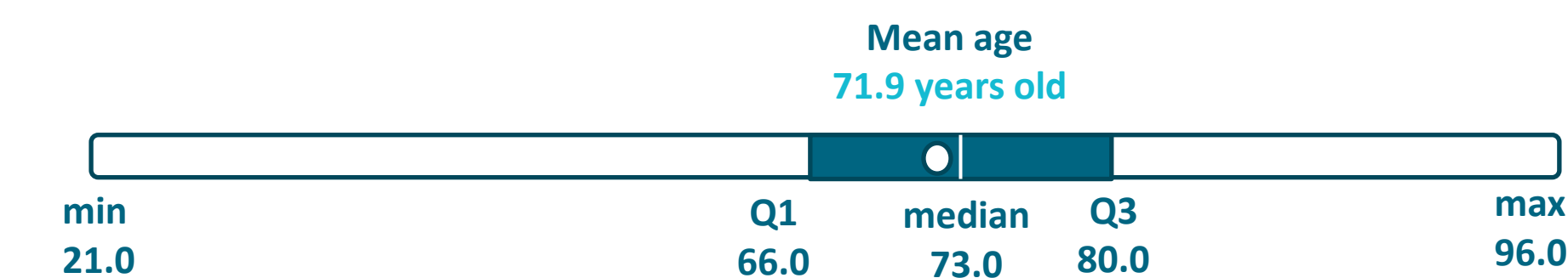
RESULTS

Study Population



Half of patients initiated ibrutinib had a CLL diagnosis (50.6%). The profile of Ibrutinib users were in accordance with the marketing authorization and reimbursement [1].

Patients' characteristics at Ibrutinib Initiation



Patients' comorbidities at Ibrutinib Initiation

- 48.1% cardiovascular diseases or marker (i.e. use of antiplatelet drugs and/or anticoagulant agent and/or pacemaker)
- 24.6% solid tumors (two most frequent: skin cancer and prostate cancer)
- 9.4% severe chronic respiratory failure
- 7.6% chronic kidney disease
- 2.2% chronic disease of the liver and cirrhosis

Main Medical Resource Utilization during follow-up period

Main MRU, n(%)	CLL L1 mono (N=121)	CLL L2+ mono (N=853)	MCL L2+ mono (N=215)	WM L2+ mono (N=243)
Hematologic cancer treatments in pharmacies				
Ibrutinib	121 (100.0%)	853 (100.0%)	215 (100.0%)	243 (100.0%)
Other targeted therapy	2 (1.7%)	14 (1.6%)	4 (1.9%)	2 (0.8%)
Medical or paramedical contacts				
Medical visits to private general practitioner	108 (89.3%)	743 (87.1%)	180 (83.7%)	208 (85.6%)
Nurse visits	109 (90.1%)	729 (85.5%)	191 (88.8%)	209 (86.0%)
Medical visits to public or private hospital practitioner	106 (87.6%)	691 (81.0%)	179 (83.3%)	183 (75.3%)
Visits to emergency room	29 (24.0%)	138 (16.2%)	33 (15.3%)	42 (17.3%)
Medical visits to private hematologists	6 (5.0%)	39 (4.6%)	12 (5.6%)	19 (7.8%)
Medical procedures in outpatient settings				
Imaging (e.g., CT scans of nervous system)	22 (18.2%)	137 (16.1%)	26 (12.1%)	27 (11.1%)
ECG	20 (16.5%)	115 (13.5%)	31 (14.4%)	35 (14.4%)
Medical procedures during hospitalization				
Imaging (e.g., CT scans of nervous system)	41 (33.9%)	210 (24.6%)	70 (32.6%)	58 (23.9%)
Blood transfusion	28 (23.1%)	136 (15.9%)	29 (13.5%)	42 (17.3%)
ECG	27 (22.3%)	129 (15.1%)	41 (19.1%)	34 (14.0%)
Lab tests in private activity				
Blood tests	91 (75.2%)	623 (73.0%)	182 (84.7%)	202 (83.1%)
Hospitalizations				
Related to CLL, MCL, WM	24 (19.8%)	123 (14.4%)	44 (20.5%)	38 (15.6%)
Related to session of treatment	5 (4.1%)	36 (4.2%)	15 (7.0%)	8 (3.3%)
Medical transportations	65 (53.7%)	465 (54.5%)	137 (63.7%)	135 (55.6%)

- The mean number of visits to general practitioner was 1 visit per month.
- The mean number of visits to nurses was 5 visits per month.
- On average, patients had about one ECG procedure per quarter and at least one imaging procedure every 2 months (0.5 in patients CLL L1 and 0.8 procedures in the other subgroups).
- The mean number of hospitalizations was less than one per month and the mean length of stay was less than one day per month.

Cost of patients using Ibrutinib

Mean monthly cost (SD) from collective perspective (in euros)	CLL L1 mono (N=121)	CLL L2+ mono (N=853)	MCL L2+ mono (N=215)	WM L2+ mono (N=243)
Hematologic cancer treatments	5,685.3 (2,813.0)	5,878.4 (3,098.7)	7,491.0 (3,850.7)	5,931.3 (3,984.4)
Medications in addition of the cancer treatment	160.8 (332.6)	253.1 (512.1)	184.8 (376.3)	192.0 (378.9)
Medical or paramedical contacts	131.0 (217.4)	116.5 (189.2)	141.2 (204.7)	91.5 (150.8)
Medical procedures, lab tests and medical devices	10.7 (9.8)	13.0 (25.9)	22.9 (74.5)	12.8 (13.0)
Hospitalizations	757.8 (1,140.3)	1,249.4 (1,894.0)	2,742.7 (2,842.2)	810.8 (881.1)
Medical transportations	94.4 (143.4)	118.1 (166.2)	134.9 (148.1)	127.7 (185.1)
Total	6,203.3 (2,822.2)	6,526.0 (3,253.9)	8,579.3 (4,221.3)	6,432.3 (3,971.7)

The total cost of patients was mainly driven by the hematologic cancer treatments costs (91.6%, 90.1%, 87.3% and 92.2% of total cost of patients CLL L1 mono, CLL L2+ mono, MCL L2+ mono and WM L2+ mono, respectively), followed by hospitalizations costs.

The cancer treatment cost of patients with MCL is higher than the other groups due to the difference in dosage (4 capsules per day versus 3).