Costs of dose escalation among patients with inflammatory bowel disease treated with vedolizumab and ustekinumab in Portugal

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1 Background and Objectives

Background

- Inflammatory bowel disease (IBD), which includes both ulcerative colitis (UC) and Chron's disease (CD), is a chronic and progressive condition that causes inflammation in the gastrointestinal tract[1].
- Patients with moderate to severe CD and UC are treated with biologic therapies, which include anti-tumor necrosis factor therapies, anti-integrin agents such as vedolizumab, and anti-interleukin 12/23 agents like ustekinumab[1,2].
- These treatments tend to lose their effectiveness over time, with some patients undergoing a dose intensification or an increase in the dosing frequency [2] .
- The aforementioned dose escalation has the potential to affect the cost of treating these patients, generating a critical need to understand how physicians use targeted immunomodulators to manage patients with IBD in clinical practice in Portuguese hospitals

Objectives

- The present work aims to assess the treatment costs of vedolizumab and ustekinumab therapies based on the real-life dosages administered to IBD patients in Portugal

2 Methods

- A set of 16 Portuguese public hospitals (~59% representativeness) provides clinical data to IQVIA on a monthly basis, reporting all the products consumed by patients within the hospital scope. The data provided is anonymized at the hospital and it is not possible to identify patients. The present work does not display any individual data, only aggregated results.
- For this retrospective study, patients with vedolizumab and/or ustekinumab treated in gastroenterology departments were selected. Of these, those who started maintenance treatment from January 2020 onwards and who completed at least one year of maintenance were included in the analysis. Induction consumptions were identified and removed from the analysis.
- To assess the real-life costs of vedolizumab and ustekinumab the following metrics were developed:

1 — Annual maintenance dosage & Patient Equivalence

- The annual maintenance dosage per patient was obtained by summing all doses consumed over a one-year period (excluding induction phase). The obtained results were compared to the annual standard dose according to the summary of product characteristics (SmPC). This allowed for the identification of how many patients underwent dose escalation in their first maintenance year. Dose escalation prevalence and magnitude were used to quantify the equivalent patient treatment rate representing the number of patients per 100 that could have been treated with standard dosing, given the prevalence of dose escalation in the treated population

2 — Annual maintenance units

- The annual maintenance dosage was converted to units by dividing the annual dosage for each pack strength

3 — List Price

- The list prices without VAT, in force in 2023, of vedolizumab (1 343,23 €) and ustekinumab (2 144,01 €) were used to calculate the annual costs of these therapies. Although the analysis timeframe is from 2020 to 2022, the current prices were applied, since the dynamics remain constant

4 — Annual maintenance costs

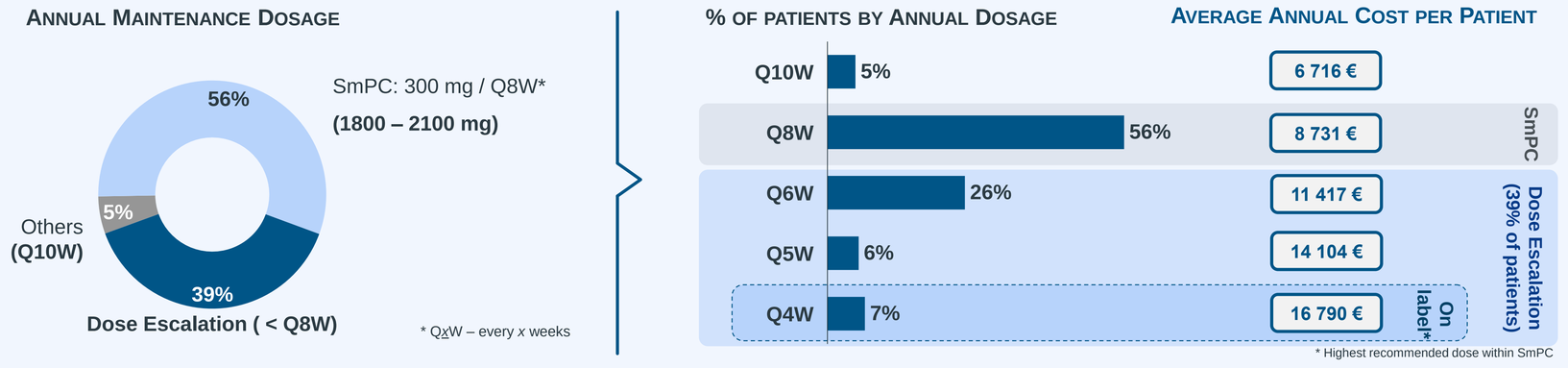
- For both molecules, the annual treatment cost for each annual dosage was determined by multiplying the number of units consumed by the list price previously mentioned The average weighted annual costs of vedolizumab and ustekinumab therapies were calculated considering the number of patients consuming each annual dosage. The obtained results were compared to the annual treatment costs if the defined SmPC dosages were followed

Limitations

The annual dosage analysis corresponds to the average annual consumption of the eligible patients and does not consider the moment from which each patient undergoes a dose escalation. The list price used for the annual treatment cost calculation does not consider any discounts or confidential pricing that may be offered to the hospitals, thus the need to perform a sensitivity analysis.

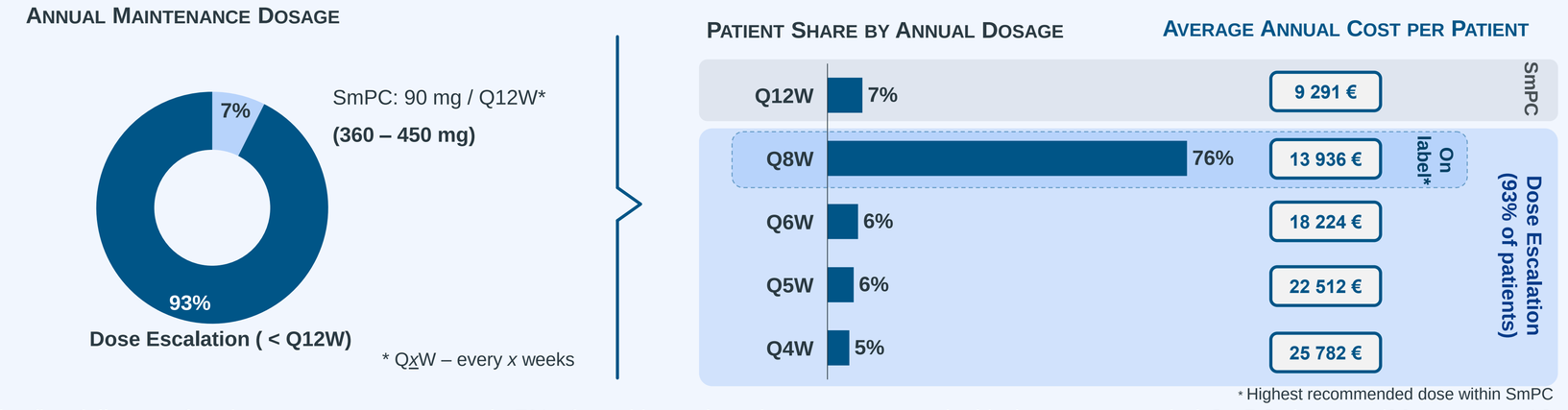
3 Results and Discussion

Vedolizumab (N = 170)



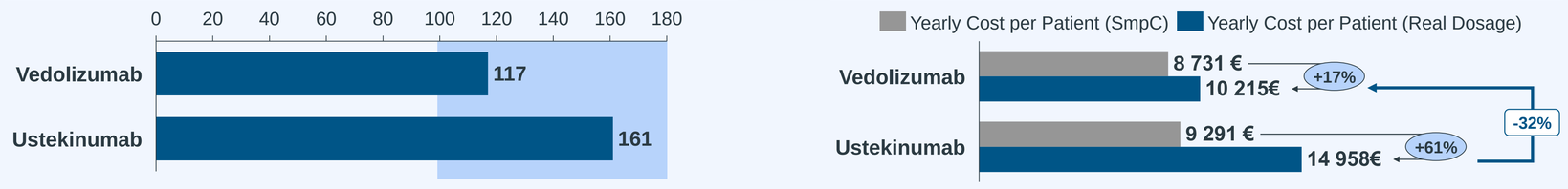
- In the first full year of maintenance treatment, a significant share of vedolizumab patients (56%) were treated according the standard dose recommended within the SmPC (300 mg every 8 weeks), with each patient costing a total of 8 731 € per year. 39% of patients undergo a dose escalation in the first maintenance year, with the annual treatment costs ranging from 11 471 € to 16 790 € per patient. Despite the dosage escalation observed, it doesn't surpass annual standard dose (QW4) according to the SmPC.

Ustekinumab (N = 108)



- In the first full year of maintenance treatment, only 7% of ustekinumab patients were treated with the recommended SmPC dosage (90 mg every 12 weeks). Each of these patients has a total annual cost of 9 291 €. The remaining patients undergo a dose escalation, with 17% of them reaching off-label dosage, presenting annual treatment costs ranging from 13 936 € to 25 782 € per patient

Comparative Analysis



- Ustekinumab has the highest patient equivalence, with the real-world dosing of 100 patients being equivalent to treating 161 patients if the recommended SmPC dosage was followed. For vedolizumab, the real-world dosing of 100 patients is equivalent to treating 117 patients with the recommended SmPC dosage, a much lower value when compared to ustekinumab.
- If the SmPC defined dosage was administered, a patient treated with vedolizumab would cost 8 731 € per year. However, according to real-life dosages a vedolizumab patient costs 10 215 € per year, an increase of 17% (+ 1 484 €). For ustekinumab patients, this cost difference is much higher, with a difference of + 61% (+ 5 667 €). These results also make clear the significant difference in treatment costs, where the annual average treatment cost vedolizumab (10 215€) is 32% less expensive than ustekinumab (14 958 €).

Sensitivity Analysis

Vedolizumab Discount \ Ustekinumab Discount	Yearly Cost per Patient	0%	2%	4%	6%	8%	10%	12%	14%	16%	18%	20%	22%	24%	26%	28%	30%	32%	34%	36%	38%	40%
		14 892	14 594	14 297	13 999	13 701	13 403	13 105	12 807	12 510	12 212	11 914	11 616	11 318	11 020	10 722	10 425	10 127	9 829	9 531	9 233	8 935
0%	10 205																			VDZ > UST		
2%	10 001																					
4%	9 796																					
6%	9 592																					
8%	9 388																					
10%	9 184																					
12%	8 980																					
14%	8 776																					
16%	8 572																					
18%	8 368																					
20%	8 164																					
22%	7 960																					
24%	7 755																					
26%	7 551																					
28%	7 347																					
30%	7 143																					
32%	6 939																					
34%	6 735																					
36%	6 531																					
38%	6 327																					
40%	6 123																					

VDZ < UST

vedolizumab Patient Cost < ustekinumab Patient Cost vedolizumab Patient Cost > ustekinumab Patient Cost

- The sensitivity analysis shows that results are consistent, regardless of possible ranges of confidential agreements.

4 Conclusion

- Patients treated with vedolizumab or ustekinumab undergo dose escalation in the first year of maintenance. This is much more evident in ustekinumab patients, where 93% experience a dosage increase *vs* 39% for vedolizumab
- The dose escalation is greater in ustekinumab patients, with the real-life dosage of 100 patients being equivalent to treating 161 patients if the standard dosage was followed. Vedolizumab has a much lower patient equivalence (117). The greatly higher percentage of ustekinumab patients who undergo dose escalation as well as the magnitude of this escalation, affects the annual treatment costs, causing a 61% increase. For vedolizumab this cost increase is 17%.
- The real-life annual treatment cost of a vedolizumab patient is 32% less expensive than the annual treatment cost of an ustekinumab patient, highlighting the significant difference between this two therapies.
- These dose escalations observed, may have deep economic implications resulting in unexpected increased drug costs to payers in Portugal.

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