

Avatrombopag: beyond the approved indications. Experience of a center

Avatrombopag: más allá de la ficha técnica. Experiencia de un centro

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Abstract

Introduction: Avatrombopag, a thrombopoietin receptor agonist, is approved for chronic immune thrombocytopenia (ITP) in adults and in patients with chronic liver disease prior to surgery. However, its “off-label” use has shown promising results in various clinical scenarios where standard options are limited or contraindicated. **Objectives:** Report a single center’s experience with avatrombopag used outside its approved indications, exploring its application in different situations. **Material and method:** A retrospective data collection from electronic medical records, following informed consent. Five detailed clinical cases illustrating the different usage scenarios are presented and analyzed. **Results:** The presented cases demonstrate avatrombopag’s efficacy and good tolerability in “off-label” situations. Rapid and sustained platelet responses were observed in newly diagnosed ITP, maintenance of safe platelet counts in advanced liver disease, successful surgical preparation, and control of thrombocytopenia in clonal cytopenias of undetermined significance, allowing anticoagulation. **Conclusions:** Our experience suggests that avatrombopag may be a promising therapeutic option in complex clinical scenarios where conventional options are limited. Its favorable tolerability and efficacy profile in “off-label” uses warrant further investigation through controlled clinical trials to formally validate these emerging indications.

Keywords: Technical sheet. Thrombocytopenia. Surgery. Oral anticoagulation. Thrombopoietin receptor agonists.

Resumen

Introducción: El avatrombopag, un agonista del receptor de trombopoyetina, está aprobado para trombocitopenia inmunitaria (PTI) crónica en adultos y pacientes con enfermedad hepática crónica antes de cirugía. Su uso «fuera de ficha técnica» ha mostrado resultados prometedores en diversos escenarios clínicos donde las opciones estándar son limitadas o contraindicadas. **Objetivos:** Reportar la experiencia de un centro con el uso de avatrombopag fuera de sus indicaciones aprobadas, explorando su aplicación en diferentes escenarios. **Material y métodos:** Recogida de datos retrospectiva de historias clínicas electrónicas de pacientes, previa obtención de consentimiento informado. Se presentan y analizan cinco casos clínicos en diferentes escenarios de uso. **Resultados:** Los casos presentados demuestran la eficacia y buena tolerancia de avatrombopag en situaciones off-label. Se observaron respuestas plaquetarias rápidas y sostenidas en PTI de nuevo diagnóstico, mantenimiento de recuentos plaquetarios seguros en hepatopatía avanzada, preparación quirúrgica exitosa y control de trombocitopenia en citopenias clonales de significado incierto, permitiendo la anticoagulación. **Conclusiones:** Nuestra experiencia sugiere que el avatrombopag pudiera ser una opción terapéutica prometedora en escenarios clínicos complejos donde las opciones convencionales son limitadas. Su perfil favorable de tolerabilidad y eficacia en usos off-label amerita mayor investigación por medio de ensayos clínicos controlados para validar formalmente estas indicaciones emergentes.

Palabras clave: Ficha técnica. Trombocitopenia. Cirugía. Anticoagulación oral. Agonistas del receptor de trombopoyetina.

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Introduction

Avatrombopag, a second-generation thrombopoietin receptor agonist (TPO-RA), has been approved for the treatment of chronic immune thrombocytopenia, also known as immune thrombocytopenic purpura (ITP), in adults and in patients with chronic liver disease before surgery.¹ The results obtained in these clinical settings are supported both by the clinical development program for the drug² and by reported real-world experience.³ Several authors have even suggested that, compared with other TPO receptor agonists, avatrombopag may be the optimal second-line treatment option for adults with ITP, given that it appears to provide the greatest short-term benefit as second-line therapy, although its ability to achieve complete remission and treatment discontinuation remains to be demonstrated.^{4,5}

Avatrombopag is currently under development for approval in the management of chronic ITP in pediatric patients. In the phase IIIb study by Grace et al.,⁶ avatrombopag was effective and safe in children and adolescents with primary ITP of at least 6 months' duration. A durable platelet response was achieved in 28% of patients and a transient response in up to 81%, compared with 0% in the placebo group. The most common adverse events were mild, including petechiae, epistaxis, and headache, and no thrombosis or severe bleeding was reported. These results support its use as a promising oral therapeutic option in pediatric patients with ITP.

In recent years, several successful experiences with off-label avatrombopag use have been reported. For example, in 2022, Cui et al.⁷ reported the results of an open-label, multicenter study involving patients with solid tumors who developed chemotherapy-induced thrombocytopenia (CIT). Avatrombopag significantly increased platelet counts, with treatment success – defined as a platelet count $\geq 50 \times 10^9/L$ – achieved in 70.3% of cases at 4 weeks, with good tolerability. Galamaga et al.⁸ reported their clinical experience in 6 patients with CIT treated with avatrombopag after failure of, or the need for alternatives to, other treatments such as eltrombopag. In all cases, avatrombopag enabled platelet recovery and continuation of chemotherapy without interruptions or clinically meaningful dose reductions. No serious adverse events related to avatrombopag were reported. These findings suggest that avatrombopag may be an effective and safe option for the management of CIT in patients with solid tumors.

Successful experiences have also been reported in cases of nonsevere aplastic anemia or aplastic anemia induced by chemoradiotherapy,^{9,10} as well as in a case of postchemotherapy amegakaryocytosis successfully treated with a combination of avatrombopag and cyclosporine.¹¹ Of particular interest is the study by Virk et al.¹² on the use of avatrombopag as first-line therapy. This multicenter observational study evaluated the safety and efficacy of avatrombopag in 75 adults with ITP, comparing patients in early disease phases – newly diagnosed or persistent ITP – with those with chronic ITP. Platelet response rates, defined as $\geq 50 \times 10^9/L$, and complete response rates, defined as $\geq 100 \times 10^9/L$, were high and similar in both groups, at 91 vs. 96% and 86 vs. 81%, respectively. No major bleeding or thromboembolic events were observed in the early ITP group, compared with 4 major bleeding events and 1 thromboembolic event, respectively, in the chronic ITP group. The discontinuation rate due to lack of efficacy was identical in both groups, at 13%. The safety profile was favorable and comparable between disease phases. These findings support the effective and safe use of avatrombopag even in nonapproved disease phases and suggest that it may be a valid therapeutic option for newly diagnosed ITP.

Endpoints

To report our center's experience with off-label avatrombopag use and the reasons that led to its administration. Four clinical scenarios were considered: newly diagnosed ITP, thrombocytopenia in the setting of advanced liver disease, surgical preparation in a patient with ITP, and management of thrombocytopenia in the setting of myelodysplastic syndrome.

Method

We present a retrospective case series of patients treated at the Hematology and Hemotherapy Service of Hospital Universitario Álvaro Cunqueiro, Vigo, between 2022 and 2025. Patients who had received avatrombopag for an indication not included in the current prescribing information were identified consecutively. Clinical data, including underlying diagnosis, comorbidities, previous treatments, avatrombopag dose and schedule, serial platelet counts, response, and adverse events, were obtained from the electronic medical record system, lanus® (SERGAS).

Platelet response was defined as attainment of a platelet count $\geq 50 \times 10^9/L$, and complete response as

a platelet count $\geq 100 \times 10^9/L$. Safety was assessed by recording clinical and laboratory adverse events during follow-up. All patients provided informed consent before inclusion.

Case presentation

Cases 1 and 2

A 66-year-old woman with newly diagnosed ITP and multiple comorbidities, including arterial hypertension and overweight, had a history of corticosteroid-induced psychosis, which contraindicated their use. Because of a platelet count of $18 \times 10^9/L$ and mild bleeding symptoms consisting of scattered petechiae, first-line treatment with avatrombopag at a dose of 40 mg/day was initiated. A rapid response was achieved, with a platelet count of $220 \times 10^9/L$ after 7 days. The dose was progressively reduced and treatment was discontinued after sustained remission was achieved 7 months after initiation (Fig. 1). Treatment was well tolerated, with only mild initial headache.

Although the use of TPO-RAs such as avatrombopag as first-line therapy has not been formally approved, it may be justified in selected patients such as this one and is supported by recent literature.^{12,13} Avatrombopag also offers advantages over other TPO-RAs, including oral administration, absence of hepatotoxicity, and no dietary restrictions. According to the recommendations of GEPTI,¹⁴ individualized treatment in older patients or those with comorbidities is essential, and avatrombopag may represent a safe and effective option in these settings.

More recently, a second patient, an 83-year-old man with arterial hypertension and diabetes, had ITP requiring treatment because of a platelet count of $18 \times 10^9/L$ and minimal bleeding symptoms. Avatrombopag was initiated at 20 mg/day. After 7 days, his platelet count had increased to $169 \times 10^9/L$, and the dose was adjusted. After 6 weeks of treatment, he was receiving 80 mg/week of avatrombopag, with a most recent platelet count of $115 \times 10^9/L$. Avatrombopag has been well tolerated.

Case 3

A 45-year-old man with severe hemophilia A, factor VIII activity $< 1\%$, carrying an intron 22 inversion and without an inhibitor, was receiving prophylaxis with pegylated recombinant factor VIII, turoctocog alfa pegol. His comorbidities included human immunodeficiency virus infection, diagnosed in 1985 after receipt

of contaminated blood products, for which he was receiving Juluca® with an undetectable viral load. He also had chronic hepatitis C virus infection, genotype 1b, with sustained virologic response since 2014.

He had advanced liver cirrhosis, with FibroScan® stiffness of 21 kPa and grade 4 fibrosis, portal hypertension, congestive splenomegaly, and secondary severe thrombocytopenia, with platelet counts $< 30 \times 10^9/L$ due to chronic liver disease. He also had grade II esophageal varices. The patient had previously received avatrombopag in preparation for multiple dental extractions.¹⁵ He had previously received eltrombopag to maintain platelet counts $> 50 \times 10^9/L$ while undergoing hepatitis C virus eradication therapy.

Because of progressive worsening of thrombocytopenia, with persistent platelet counts $< 20 \times 10^9/L$, and given that he had severe hemophilia, avatrombopag was initiated at reduced doses of 40–60 mg/week. Platelet counts were maintained between 30 and $60 \times 10^9/L$ and consistently $> 30 \times 10^9/L$, which was considered the safety threshold (Table 1 and Fig. 2).

Although this individualized chronic use may be debatable, in our opinion it is consistent with the pathophysiology of thrombocytopenia in liver disease, including reduced endogenous TPO production, increased platelet consumption through mixed mechanisms, immune destruction, and hypersplenism. It is also supported by accumulated clinical experience and the need to minimize cumulative bleeding risk in such a vulnerable patient. After 6 months of treatment, avatrombopag was well tolerated, with no notable adverse effects.

Case 4

A 72-year-old woman with chronic ITP had platelet counts ranging from 35 to $50 \times 10^9/L$. She had never received treatment for ITP because there had previously been no indication. Her comorbidities included arterial hypertension and overweight.

She was scheduled to undergo arthroscopic meniscectomy and attended the outpatient clinic 2 weeks before the procedure. A complete blood count showed a platelet count of $39 \times 10^9/L$. The surgical preparation protocol used for patients with chronic liver disease was applied in this case.^{1,16} Avatrombopag was administered at 40 mg/day for 5 days. A complete blood count on day +8 showed a platelet count of $109 \times 10^9/L$. The patient underwent surgery on day +12 without complications and received antithrombotic prophylaxis at discharge with enoxaparin sodium 40 mg/day for 2 weeks.

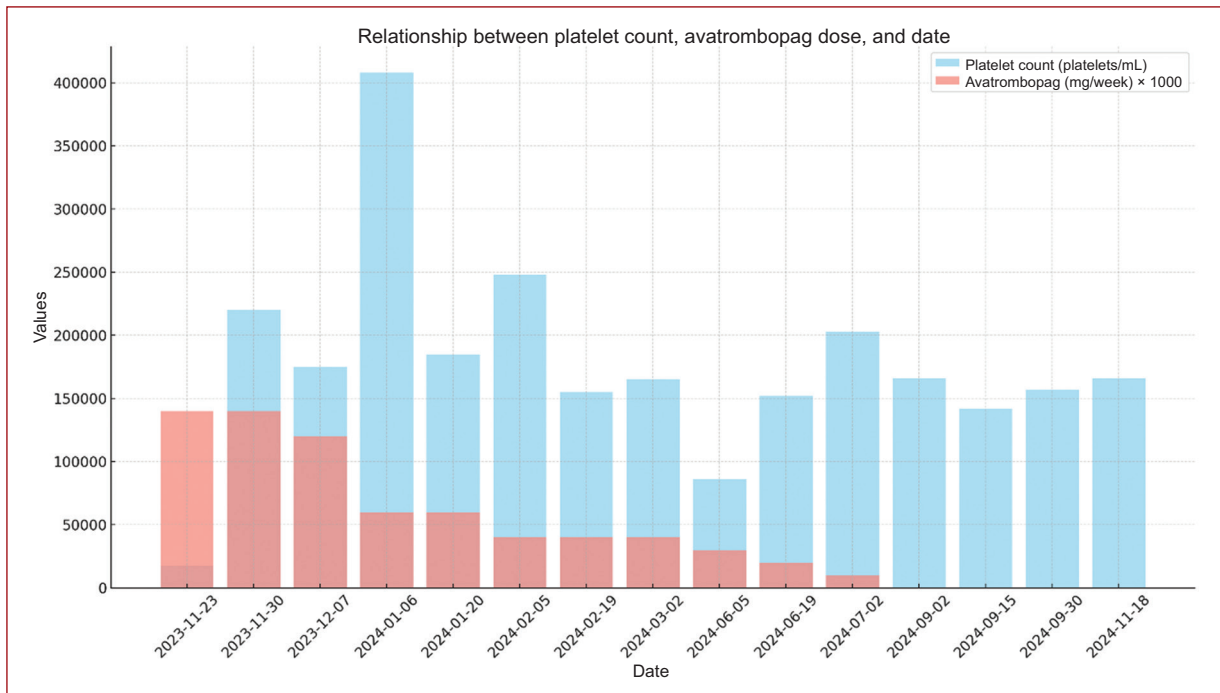


Figure 1. Relationship between platelet count and avatrombopag dose.

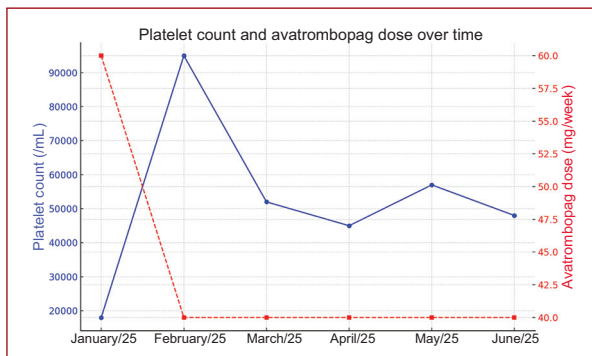


Figure 2. Case 3. Platelet count over time in chronic liver disease.

Table 1. Case 3. Platelet count over time in a patient with chronic liver disease

Date	Platelet count (× 10 ⁹ /L)	Avatrombopag dose (mg/week)
January 2025	18	60
February 2025	95	40
March 2025	52	40
April 2025	45	40
May 2025	57	40
June 2025	48	40

On day +19, the platelet count was $96 \times 10^9/\text{L}$, and 2 months later it was $55 \times 10^9/\text{L}$ (Fig. 3). Three months later, the same regimen was repeated in preparation for scheduled laparoscopic cholecystectomy, with similar results. In both situations, avatrombopag was effective, safe, and well tolerated.

Given the nature of the thrombocytopenia and the absence of liver involvement, it is foreseeable that, just as avatrombopag proved effective in the ADAPT-1 and ADAPT-2 studies, it may also be effective in preparing patients with ITP for surgery. This approach may avoid

the risks associated with platelet transfusions, including alloimmunization and infection, as well as the risks associated with corticosteroids or immunoglobulin therapy, while reducing costs compared with the latter.

Case 5

A 90-year-old woman had a diagnosis of clonal cytopenia of undetermined significance (CCUS) and mild splenomegaly measuring 15 cm on abdominal ultrasonography. Fluorescence in situ hybridization showed deletion of 20q12 in 62% of cells, an abnormality that,

Day	1	2	3	4	5			11	12			19		24					60
Platelet count/mL	39000								109000			96000							55000
									SURGERY										
Avatrombopag dose (mg)	40	40	40	40	40														
Antithrombotic prophylaxis								x	x	x	x	x	x	x	x				

Figure 3. Case 4. Preparation for meniscectomy.

in the absence of other criteria, is not diagnostic of myelodysplastic syndrome (MDS) and may be present in older individuals.

Her medical history included arterial hypertension, dyslipidemia, and non-ST-segment elevation acute coronary syndrome in 2005. Platelet counts had remained consistently between 35 and 47 × 10⁹/L for years. She had initially been diagnosed with ITP, but the absence of response to 3 cycles of dexamethasone, the subsequent development of other cytopenias – including anemia with hemoglobin levels around 11 g/dL and neutropenia with counts around 1.2 × 10⁹/L – and splenomegaly prompted diagnostic reassessment.

Two years previously, she had experienced an episode of atrial fibrillation with an indication for oral anticoagulation, based on a CHA₂DS₂-VAsC score of 4. Because platelet counts were < 50 × 10⁹/L and therefore contraindicated anticoagulation,¹⁷ avatrombopag was initiated at 20 mg/day. The platelet count increased, allowing anticoagulation with dabigatran etexilate to be started.

In November 2024, after an episode of lower gastrointestinal bleeding, dabigatran was discontinued and prophylaxis with low-molecular-weight heparin was initiated. During 2 years of avatrombopag treatment, platelet counts remained between 40 and 90 × 10⁹/L, with dose adjustments to the current dose of 40 mg/day. Treatment was well tolerated, with no adverse events, worsening cytopenias, or clonal progression (Table 2 and Fig. 4).

Nevertheless, CCUS is associated with a high risk of clonal progression to MDS or acute myeloid leukemia (AML). This risk ranges from 10–20% in the short term but may exceed 50% at 10 years when certain high-risk genetic criteria are present.^{18,19} In contrast, current evidence suggests that TPO-RAs in MDS do not clearly increase the risk of transformation to AML. A meta-analysis comparing patients with MDS treated with romiplostim or eltrombopag versus placebo found no

significant increase in progression to AML (RR, 1.04; 95% CI, 0.81–1.34; p = 0.75).²⁰

It is reasonable to assume that avatrombopag would not behave differently, although its potential efficacy and safety require appropriate validation in controlled clinical trials. In our patient, it allowed resolution of a difficult clinical situation, given that without anticoagulation she had an estimated annual risk of stroke or transient ischemic attack of approximately 4%.

Discussion

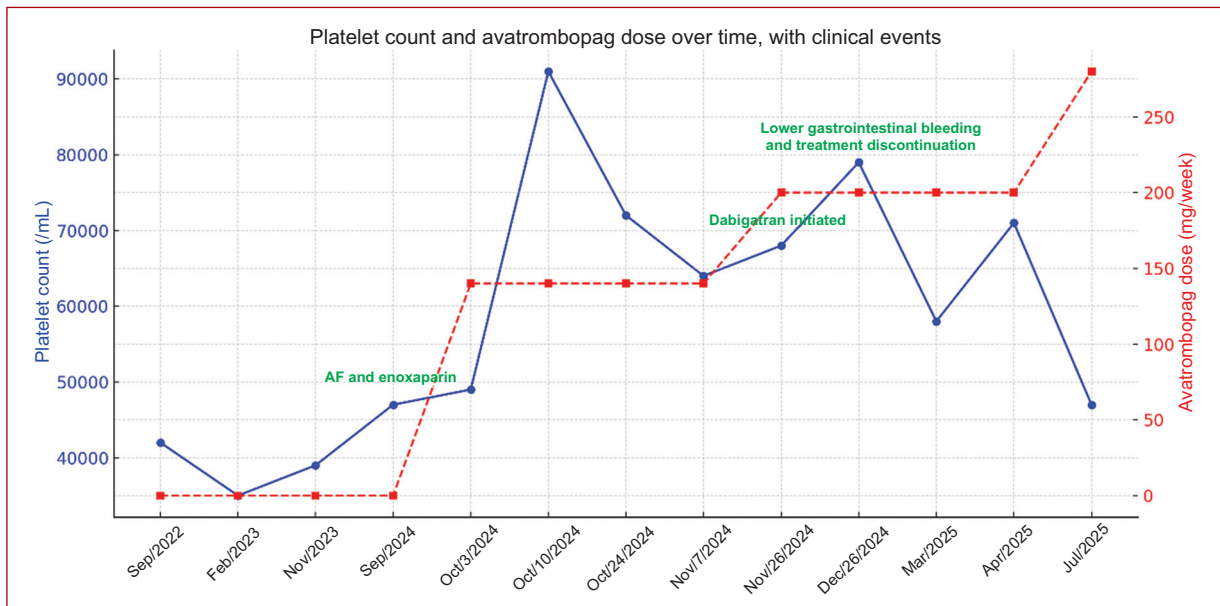
Off-label use of avatrombopag has attracted increasing clinical interest because of the need for safer, more effective, and better-tolerated alternatives to conventional treatments for thrombocytopenia. The 5 cases presented illustrate 4 distinct scenarios – newly diagnosed ITP, advanced chronic liver disease, surgical preparation, and CCUS – that share the need to increase platelet counts in settings where available alternatives are limited, contraindicated, or associated with greater risk. This series provides real-world experience that adds to the growing body of evidence regarding emerging indications for the drug.

In newly diagnosed ITP, although TPO-RAs are not recommended as first-line treatment in current guidelines, some patients with contraindications to corticosteroids, comorbidities, or increased risk of adverse effects may benefit from early treatment with avatrombopag. In older patients with multiple comorbidities and polypharmacy, avatrombopag or other TPO-RAs may represent a valid first-line treatment option for ITP.

The rapid aging of the global population should also be considered. The number of people older than 65 years is expected to increase from 461 million in 2004 to approximately 2 billion in 2050, making it likely that ITP will increasingly become a disease of older adults.²¹ The 2 cases presented may support this

Table 2. Case 5. Platelet count over time

Date	Platelet count ($\times 10^9/L$)	Avatrombopag dose (mg/week)	Bleeding symptoms
September 2022	42.000	0	No
February 2023	35.000	0	No
November 2023	39.000	0	No
September 2024	47.000 AF CHADS2 score 4 Enoxaparin sodium 60 mg/day	0	No
October 3, 2024	49.000	140 mg	No
October 10, 2024	91.000	140 mg	No
October 24, 2024	72.000	140 mg	No
November 7, 2024	64.000	140 mg	No
November 26, 2024	68.000 Dabigatran etexilate 110 mg every 12 hours, orally	200 mg	No
December 26, 2024	79.000 Dabigatran discontinued Prophylaxis with enoxaparin sodium resumed	200 mg	Lower gastrointestinal bleeding
March 2025	58.000	200 mg	No
April 2025	71.000	200 mg	No
July 2025	47.000	280 mg	No

**Figure 4.** Case 5. Platelet count over time.

potential use, consistent with recent studies suggesting high response rates and a favorable safety profile even in early disease phases.¹²

In the patient with advanced liver disease, chronic low-dose use, although off-label, represented a clinically adapted strategy in a setting with no safe

alternatives. Evidence supporting short-term avatrombopag use in chronic liver disease and its favorable safety profile supported this individualized decision.

It should be taken into account that chronic liver disease is also associated with reduced levels of natural anticoagulants, which may partially offset the increased bleeding tendency. Nevertheless, the ADAPT-1 and ADAPT-2 studies, together with guidelines such as those issued by the International Society on Thrombosis and Haemostasis in 2022,²² support the use of avatrombopag in chronic liver disease, including repeated administration, with a low thrombotic risk when platelet counts are maintained within a safe range, although only in the perioperative setting.

Regarding surgical preparation, extrapolation of the liver disease regimen to patients with ITP or thrombocytopenia secondary to other conditions was effective in the cases described. This approach may avoid transfusions or the use of intravenous polyclonal immunoglobulins, thereby reducing associated costs and risks.

Finally, the case involving CCUS illustrates a rational use of avatrombopag to increase platelet counts and permit safe anticoagulation. Although deletion of 20q12 alone does not define MDS, CCUS carries an intermediate-to-high risk of progression to MDS or AML. Our experience, although subject to understandable caution, showed hematologic stability and no evidence of progression. Prospective studies are nevertheless required to establish the long-term safety of avatrombopag and other TPO-RAs in this setting.

The efficacy of avatrombopag in CIT and in certain contexts involving myelodysplastic syndromes, although off-label, is consistent with its central mechanism of stimulating megakaryopoiesis. This suggests that it may have broader usefulness in thrombocytopenic states beyond immune-mediated platelet destruction, providing a production-targeted approach in situations in which other therapeutic strategies may be less effective or associated with greater patient risk.

Overall, this experience suggests that rational and closely monitored use of avatrombopag beyond its approved indications may provide effective and safe solutions in complex clinical settings in which standard options are limited or inadvisable. Compared with other agonists, avatrombopag offers advantages such as convenient oral administration, lack of food interactions, and no requirement for liver function monitoring.

Beyond quantitative improvements in platelet counts, these characteristics contribute substantially to greater patient convenience and satisfaction, as observed in our cases. This is consistent with recent findings suggesting improved satisfaction among patients switching

from other TPO-RAs to avatrombopag, potentially resulting in better adherence and overall well-being.²³ Whether these advantages are transferable to other clinical settings remains to be determined.

The present series has the limitations inherent to this type of design, including a small sample size, retrospective nature, absence of a control group, and heterogeneity of the clinical scenarios, which preclude conclusions regarding comparative efficacy. However, the diversity of the situations addressed and the consistency of the responses observed in each case support the biologic plausibility of avatrombopag use beyond its approved indications.

These findings should be interpreted as hypothesis-generating rather than definitive evidence and underscore the need for prospective controlled studies to formally validate efficacy and safety in each of the clinical settings described.

Conclusions

The efficacy of avatrombopag in the treatment of ITP is well established. In our limited experience, its off-label use was useful across several clinical scenarios, with good tolerability and efficacy.

Our findings suggest that avatrombopag may represent a promising therapeutic option in selected clinical settings in which standard treatments are limited or contraindicated. Its favorable tolerability profile and the efficacy observed in our pilot cases warrant further investigation in controlled trials.

First-line use in ITP, although still off-label, may be justified in selected patients, particularly those with contraindications to corticosteroids or comorbidities that may be worsened by their use, especially older individuals. In advanced liver disease, chronic low-dose administration may help prevent bleeding and maintain a safe platelet threshold without notable adverse effects, particularly in patients with cirrhosis and portal hypertension.

In the perioperative preparation of patients with thrombocytopenia, avatrombopag may represent an effective and safe alternative to other treatments, with advantages in logistics, tolerability, and costs, while also facilitating more efficient use of Blood Transfusion Service resources.

In CCUS or low-risk MDS, avatrombopag may enable key clinical decisions such as anticoagulation, although its use should be individualized and maintained under close hematologic monitoring.

Although our findings are encouraging, the imperative need for prospective controlled clinical trials to

formally validate these off-label uses and precisely define the role of avatrombopag in these emerging indications should not be underestimated. Such studies should focus on long-term safety, comparative efficacy, and cost-effectiveness.

It would also be useful to report cases involving the use of avatrombopag or other TPO-RAs in situations for which they are not approved, as has already been done in CIT. This would contribute to the accumulation of real-world evidence, inform complex clinical decisions, and support the evolution of treatment guidelines.

As the population ages and patients present with increasingly complex clinical conditions, the flexibility and favorable profile of avatrombopag suggest that it may play an increasingly relevant role in the comprehensive and personalized management of thrombocytopenia across a range of circumstances beyond its current indications.

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Conflicts of interest

The authors declared no conflicts of interest whatsoever.

Ethical considerations

Protection of humans and animals. The authors declare that no experiments involving humans or animals were conducted for this research.

Confidentiality, informed consent, and ethical approval. The authors followed the protocols of their healthcare center or institution for access to medical record data. Informed consent was obtained from the patients, and approval was granted by the Ethics Committee. The recommendations of the SAGER guidelines were followed.

Declaration on the use of artificial intelligence. The authors declare that ChatGPT 4o was used to create the figures.

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