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Management of Antithrombotic Therapy in Adults with Immune Thrombocytopenia (ITP): A Survey of ITP Specialists and General Hematologist-Oncologists

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Abstract

While patients with immune thrombocytopenia (ITP) and low platelet counts are at risk for bleeding, they are not protected against arterial and venous thrombotic events. Frequently, hematologists are asked to consult on a patient with ITP requiring an antiplatelet (AP) agent or anticoagulant (AC). No direct evidence exists to guide hematologists in weighing the risk of thrombosis against the risk of bleeding in patients with ITP. Therefore, we performed a survey to determine the preferred management of AP/AC therapy in ITP patients. The survey described hypothetical patient scenarios and asked respondents to recommend a minimum platelet count for initiation of AP/AC therapy. We surveyed both hematologists with an international reputation in treatment of ITP (n=48) and also general hematologist-oncologists in Oklahoma (n=97). Response rates were 38/48 (79%) for the ITP specialists and 46/97 (47%) for general hematologist-oncologists. Overall, recommended platelet thresholds for antithrombotic therapy were similar between ITP specialists and general hematologist-oncologists. Although both groups recommended a minimum platelet count of $50 \times 10^9/L$ for AP and AC therapy in most scenarios, there was great variability in individual practice patterns among respondents. This study highlights the need for studies of patients with ITP who require AP/AC therapy to provide high-quality evidence for establishing optimal management strategies.

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Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards or institution and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Keywords

immune thrombocytopenia; ITP; antithrombotic therapy; anticoagulant therapy; antiplatelet therapy

Introduction:

Immune thrombocytopenia (ITP) is an acquired thrombocytopenia caused by autoantibody and T cell-mediated platelet destruction and impairment of thrombopoiesis [1]. Patients with ITP are at risk for bleeding due to thrombocytopenia. Fortunately, life-threatening hemorrhage is uncommon, even with severe thrombocytopenia [2,3]. In a retrospective 10-year study of 310 patients with ITP, only one hemorrhagic death occurred [2]. Furthermore, all major hemorrhagic events occurred at a platelet count of less than $20 \times 10^9/L$ [2]. Thus, treatment for ITP is often reserved for platelet counts below or near this threshold [1].

The thrombocytopenia of ITP does not protect against arterial or venous thromboembolic events [4]. In fact, studies suggest that ITP patients may have a higher incidence of thromboembolism than the general population [5,6]. Because the incidence of ITP in adults increases with age, ITP patients often have comorbidities such as coronary artery disease (CAD), cerebrovascular disease, and venous thromboembolism (VTE) that require temporary or chronic antiplatelet (AP) or anticoagulant (AC) therapy [7–9]. No high-quality evidence exists to guide the management of antithrombotic therapy in patients with ITP. A few experts have proposed a platelet count threshold of $30 \times 10^9/L$ to $50 \times 10^9/L$ based on case reports and small case series [10]. There are no evidence-based guidelines or recommendations for AP therapy in thrombocytopenic patients with CAD because clinical trials of AP agents excluded patients with thrombocytopenia [11].

Given the absence of evidence-based guidelines, we sought to understand the practice of hematologists treating ITP patients with AP/AC therapy. We surveyed ITP specialists and general hematologist-oncologists to assess their recommended minimum platelet counts for initiating AP/AC therapy in a patient with ITP. Compared to general hematologist-oncologists, we hypothesized that ITP specialists would recommend AP/AC therapy at lower platelet counts because of greater familiarity with ITP and its associated bleeding risk.

Methods:

Survey

A survey was sent to ITP specialists and general hematologist-oncologists. The survey described four hypothetical common clinical scenarios in which AP/AC therapy might be considered in a patient with ITP: (1) aspirin for symptomatic stable CAD; (2) dual-antiplatelet therapy for coronary stent placement; (3) anticoagulation for atrial fibrillation; and (4) anticoagulation for VTE (Table 1). For each scenario, we included a history of bleeding that increased in severity from asymptomatic to minor mucocutaneous bleeding to major gastrointestinal (GI) hemorrhage. Respondents were instructed to select the minimum platelet count necessary for approval of the listed AP/AC therapy. The minimum platelet count choices ranged from ‘at least $10 \times 10^9/L$ ’ to ‘at least $100 \times 10^9/L$ ’; alternatively,

respondents could select 'other' and provide a free text response. Respondent demographics were also collected which included: 1) length of time in practice; 2) approximate number of ITP patients seen each year; and 3) approximate number of consults for AP/AC therapy in patients with ITP each year. The survey was pilot tested with 3 ITP specialists and 3 general hematologist-oncologists. Revisions were incorporated into the final version of the survey.

The study was approved by the institutional review board at the University of Oklahoma Health Sciences Center (OUHSC). Each respondent gave passive consent by completing the survey.

Study population

ITP specialists were defined as hematologists with an international reputation for focusing on ITP. Authors (AC, DC, MM, JG) initially identified 23 ITP specialists and then each specialist was asked to identify two additional ITP specialists based on their knowledge of the active researchers and clinicians in the field. Excluded were ITP specialists who exclusively treated pediatric ITP patients.

General adult hematologist-oncologists were identified using previously established methodology [12,13]. We searched the Oklahoma Board of Medical Licensure and the Oklahoma Osteopathic Association websites for all physicians certified in hematology/oncology, hematology, or oncology. General hematologist-oncologists were included if they had an active Oklahoma license and were currently treating hematology-oncology patients in Oklahoma as of June 2016. Current practice was confirmed by contacting the hematologist-oncologists' offices. Physicians whose careers were devoted to full-time research or administration, who did not have an active Oklahoma license, who exclusively treated pediatric patients, or who were not currently treating hematology patients in Oklahoma were excluded. Also excluded were physicians who listed hematology (pathology) or gynecologic, radiation or surgical oncology as a specialty. Additionally, general hematologist-oncologists were excluded if they reported that they did not see ITP patients on the returned completed survey.

Data Collection

Surveys were sent between July 2016 and January 2017. Surveys were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at OUHSC. REDCap is a secure, web-based application designed to support data capture for research studies [14]. All ITP specialists were emailed a link to the survey. The general hematologist-oncologists received the survey in a variety of ways according to their preferred method of contact (email, fax, or postal mail). Reminders were sent every week until a response was received or a maximum of five attempts at contact had been made. No compensation or incentives were provided.

Statistical Analysis

Descriptive statistics were calculated to describe demographics of the physicians. A chi-square or Fisher's exact was used to compare minimum platelet count categories (at least $10 \times 10^9/L$, $20 \times 10^9/L$, and $30 \times 10^9/L$ versus at least $50 \times 10^9/L$, $70 \times 10^9/L$ and $100 \times 10^9/L$)

by physician classification (ITP specialist vs. general hematologist-oncologist) for each scenario. To examine changes in the recommendation for minimum platelet count within each scenario based on bleeding severity, we categorized responses as ‘minimum platelet count decreased’, ‘minimum platelet count increased’ or ‘minimum platelet count stayed the same’ and the proportion of respondents who changed their threshold was compared using a binomial test. An alpha of 0.05 was used and all tests were two-sided. SAS version 9.4 (Cary, NC) was used for all analyses.

The pre-determined classification of physicians (ITP specialist vs general hematologist-oncologist) was based on reputation rather than standardized formal criteria. As a result, it is possible that physicians were placed into the incorrect category which then introduced a bias (misclassification). To assess for misclassification of physicians, we performed a sensitivity analysis reclassifying the physicians based on self-reported number of ITP patients seen per year and self-reported number of consults on AP/AC therapy in ITP patients. For the purpose of this sensitivity analysis, ‘ITP specialists’ were defined as physicians who reported both 11 ITP patient consults per year and 7 ITP consults involving AP/AC per year and ‘general hematologist-oncologists’ were defined as physicians who did not meet those criteria.

Results:

Response rates were 38/48 (79%) among ITP specialists and 46/97 (47%) among general hematologist-oncologists. ITP specialists represented hematologists practicing in United States, United Kingdom, Germany, Canada, Italy, Australia, France, Mexico, Austria, Japan, Spain, and Sweden. As expected, 79% of ITP specialists saw >20 ITP patients per year compared to 7% of general hematologist-oncologists. A consult for administration of AP/AC for a patient with ITP was received >12 times per year by 29% of ITP specialists compared to 4% of general hematologist-oncologists. Furthermore, 53% of ITP specialists had been practicing over 20 years compared to 20% of general hematologist-oncologists (Table 2).

Minimum Platelet Count Recommendations for AP/AC therapy—The minimum platelet count recommendations were compared between ITP specialists and general hematologist-oncologists (*Online Resource 1*). Scenario #1 and #2 describe patients with ITP and CAD requiring low-dose aspirin (#1) or dual antiplatelet therapy (#2). When the patient had no bleeding history, the minimum platelet count recommendations of ITP specialists for aspirin or dual-antiplatelet therapy ranged from at least $20 \times 10^9/L$ to at least $100 \times 10^9/L$. Similarly, the recommendations of general hematologist-oncologists ranged from at least $10 \times 10^9/L$ to at least $70 \times 10^9/L$ for aspirin or to at least $100 \times 10^9/L$ for dual antiplatelet therapy. Scenario #3 and #4 describe ITP patients requiring AC for atrial fibrillation (#3) and VTE (#4). Without a history of bleeding, the recommendations in both physician groups ranged from a minimum platelet count of at least $20 \times 10^9/L$ to at least $70 \times 10^9/L$ for atrial fibrillation. With AC for VTE, the responses were from at least $10 \times 10^9/L$ for both groups up to at least $70 \times 10^9/L$ (ITP specialists) or $100 \times 10^9/L$ (general hematologist-oncologists).

Although there was wide variation among individual responses, a minimum platelet count of $50 \times 10^9/L$ was the modal response in the majority of scenarios, irrespective of bleeding severity, for both ITP specialists and general hematologist-oncologists. The exception among general hematologist-oncologists was AP in an ITP patient with a history of major GI bleeding (*modal response: at least $100 \times 10^9/L$*). Among ITP specialists, the exceptions were AC for VTE without a bleeding history (*modal response at: $30 \times 10^9/L$*) as well as for AC for VTE with a history of minor bleeding (*bimodal response: at least $30 \times 10^9/L$ and at least $50 \times 10^9/L$*).

We compared the percentage of respondents recommending a platelet count of at least $50 \times 10^9/L$ for each scenario between ITP specialists and general hematologist-oncologists (Figure 1). There was a significant difference in only one scenario (#4a-patient with venous thromboembolism and no bleeding history). In this scenario, significantly more general hematologist-oncologists suggested a platelet count of at least $50 \times 10^9/L$ compared to ITP specialists ($p=0.05$). Because there were no significant differences in recommendations between ITP specialists and general hematologist-oncologists for the other 11 scenarios, the responses on all scenarios were combined for the “change in minimum platelet count recommendation for increase in bleeding severity” analysis.

Additionally, a sensitivity analysis was done comparing responses between those physicians re-classified as ‘ITP specialists’ based on reported experience (physicians who reported both 11 ITP patient consults per year and 7 ITP consults involving AP/AC per year) vs the ‘general hematologist’ being those physicians with self-reported less experience. Results from the sensitivity analysis did not significantly change results of any of the above analyses.

Change in Minimum Platelet Count Recommendation for Increase in Bleeding Severity—The percent of all respondents who changed the minimum platelet count for AP/AC therapy based on the severity of bleeding history (no symptoms vs minor mucocutaneous bleeding; no symptoms vs major GI bleeding) is displayed in Figure 2. Among respondents who changed the minimum platelet count recommendation, the trend was to increase the minimum platelet count threshold as bleeding severity increased ($p<0.01$).

When considering aspirin for symptomatic CAD (scenario #1), 44% (36/81) of respondents increased to a higher platelet threshold for a history of minor mucocutaneous bleeding and 74% (55/74) increased the threshold for a history of GI bleeding. For dual antiplatelet therapy in the setting of coronary artery stenting (scenario #2), 21% (17/81) of respondents increased the minimum platelet threshold for minor mucocutaneous bleeding and 51% (40/79) for GI bleeding. The percentage of respondents who increased the minimum platelet threshold for AC with a history of minor mucosal bleeding for atrial fibrillation (scenario #3) or VTE (scenario #4) was similar at 23% (19/83) and 19% (16/84), respectively. A higher percentage of respondents recommended an increase in the minimum platelet for patients with a history of GI bleeding who required AC for atrial fibrillation (56%, 42/75), or VTE (43%, 34/79).

Discussion:

Antithrombotic therapy in ITP patients is challenging, and no guidelines exist to aid clinical decision-making. We present the first study describing the recommendations of individual practicing hematologists for minimum platelet count thresholds in patients with ITP who require antithrombotic therapy. Our study did not affirm our hypothesis that ITP specialists would recommend AP/AC therapy at a lower platelet threshold. Both ITP specialists and general hematologist-oncologists responded with a wide range of acceptable minimum platelet counts for antithrombotic therapy from $10 \times 10^9/L$ or $20 \times 10^9/L$ to $70 \times 10^9/L$ or $100 \times 10^9/L$ in the majority of hypothetical patient scenarios. Notwithstanding this variation among respondents, as a group, a platelet count of $50 \times 10^9/L$ was the most frequent response for aspirin, dual antiplatelet therapy, and therapeutic intensity anticoagulation. A significant number of respondents increased their minimum platelet count recommendations based on bleeding severity history.

There are no published studies in ITP to suggest a platelet count of $50 \times 10^9/L$ should be the minimum platelet count recommended for antithrombotic therapy. Notably, another survey study found the majority of malignant and non-malignant hematologists also recommended a minimum platelet count of $50 \times 10^9/L$ for therapeutic anticoagulation in patients with chemotherapy-induced thrombocytopenia [15]. This is consistent with the International Society on Thrombosis and Haemostasis (ISTH) guidelines for a minimum platelet count of $50 \times 10^9/L$ for therapeutic AC in patients with chemotherapy-induced thrombocytopenia, although this recommendation based on low quality evidence and expert opinion [16].

Our study has several limitations. The response rate among general hematologist-oncologists was low (47%) but compares favorably with other survey studies of physicians [17]. All of the general hematologist-oncologists practice in a single state, and thus it is possible that their practice patterns are not generalizable outside of Oklahoma. However, the ITP specialist group in our study represents an international community and their recommendations were largely similar to those of the Oklahoma hematologist-oncologists. Additionally, we relied on reputation rather than formal criteria to define ITP specialists, an approach that could have led to misclassification bias. Reassuringly, ITP specialists saw more ITP patients and consulted on AP/AC therapy in ITP patients more often than general hematologist-oncologists. We also conducted sensitivity analyses in which respondents were grouped according to number of ITP patients and number of AP/AC consults per year. Results of these sensitivity analyses mirrored those of the primary analysis, arguing against the presence of substantial misclassification bias. An additional limitation of our study is that there are numerous complexities and nuances that may inform real-life clinical decision-making but are difficult or impossible to capture in a hypothetical scenario with multiple choice responses. Such factors include patient values and preferences, responsiveness to and tolerability of ITP therapy, comorbidities, and adherence. Survey respondents were permitted to respond “other” and include additional thoughts on management, which was chosen by a small number of respondents.

Our study is the first to assess clinical practice patterns of individual hematologists on the use of AP/AC therapy in patients with ITP. The variation in responses we observed, both

among specialists and generalists, highlights a lack of consensus and the need for future studies. A multicenter study of bleeding events among ITP patients receiving antithrombotic therapy by severity of thrombocytopenia should be performed. Such a study could help guide safe antithrombotic therapy recommendations.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Key Points:

- A platelet count of $50 \times 10^9/\text{L}$ was the most commonly recommended minimum platelet count for patients with ITP who require antithrombotic therapy.
- There is a wide variation among individual practicing hematologists in the minimum platelet count recommended for patients with ITP who require antithrombotic therapy.
- There were no differences in recommended minimum platelet counts between ITP specialists and general hematologist-oncologists.

Fig. 1.

Percent of ITP specialists versus general hematologist-oncologists recommending a platelet count of at least $50 \times 10^9/L$ by scenario

Fig. 2.
Percent of all respondents who changed the minimum platelet count for antithrombotic therapy due to severity of bleeding history.

Table 1

Summary of the clinical scenarios in the survey

Scenario #	Clinical Vignette	Recommended antiplatelet/anticoagulant therapy
1A-C	67-year old female with chronic ITP presenting with dyspnea on exertion with coronary atherosclerosis on CT coronary angiography with no indication for revascularization	Aspirin (81–100 mg)
2A-C	72-year old male with chronic ITP presenting with acute ST segment elevation myocardial infarction requiring coronary angiography and drug-eluting stent placement	Dual antiplatelet therapy
3A-C	78-year old with chronic ITP presenting with atrial fibrillation and TIA two days prior with a history of previous ischemic infarcts	Anticoagulant therapy
4A-C	57-year old male with chronic ITP presenting with acute pulmonary embolism and lower extremity deep vein thrombosis	Low molecular weight heparin or Unfractionated heparin (therapeutic dose)

For all scenarios: Scenario A—no signs or symptoms of bleeding, Scenario B—petechiae 1–2 times per year and occasional epistaxis, Scenario C—gastrointestinal bleeding with a hemoglobin drop of 2g/dL one year ago *CT* computed tomography, *TIA* transient ischemic attack

Table 2.

Demographics of survey respondents

	ITP specialists n=38 n (%)	General hematologist–oncologists n=46 n (%)
How long have you been practicing hematology?		
< 5 years	1 (23%)	18 (39%)
5–20 years	17 (45%)	19 (41%)
>20 years	20 (53%)	9 (20%)
Approximately how many ITP patients do you see each year?		
0	0 (0%)	0 (0%)
<5	0 (0%)	17 (37%)
5–10	1 (3%)	18 (39%)
11–20	7 (18%)	7 (15%)
>20	30 (79%)	3 (7%)
Missing	0	1 (2%)
Approximately how often are you asked to consult on administering AP/AC therapy to ITP patients?		
0 times per year	0 (0%)	5 (11%)
1–3 times per year	9 (24%)	28 (61%)
4–6 times per year	10 (26%)	7 (15%)
7–12 times per year	8 (21%)	4 (9%)
>12 times per year	11 (29%)	2 (4%)