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# Incidence and clinico-laboratory profile of adult primary immune thrombocytopenia: A retrospective study from 2000 to 2022 in a single teaching hospital

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## Abstract:

**BACKGROUND:** Limited availability of prevalence and clinical epidemiological data on adult primary immune thrombocytopenia (pITP) and the inaccessibility of a gold standard test restricts the veracity of the pITP representation in ASEAN countries, more so in Malaysia.

**OBJECTIVE:** This study aims to ascertain the incidence rate and the relationship between the clinico-laboratory characteristics of adult pITP.

**MATERIALS AND METHODS:** A retrospective study involving a total of 141 adult patients diagnosed with pITP at Hospital Pakar Universiti Sains Malaysia between 2000 and 2022. Incidence rates and clinico-laboratory profiles were established based on findings collected from hospital databases.

**RESULTS:** The annual incidence rate of pITP was 1.2 per 100,000 person-years (95% confidence interval [CI]: 1.0–1.5). A higher incidence was observed in females compared to males (1.8 per 100,000 person-years, 95% CI: 1.4–2.0 vs. 0.7 per 100,000 person-years, 95% CI: 0.5–0.9), with a male-to-female ratio of 1:2.5. The most presented symptoms in pITP patients were cutaneous bleeding (53.2%), gingival bleeding (29.8%) and menorrhagia (19.1%) and they typically occurred in pITP patients with a mean platelet count less than  $50 \times 10^9/L$ . The majority of the patients received first-line therapy (68.8%), whereas 17.7% received no treatment. First-line therapy nonresponders were given second-line therapy (4.2%).

**CONCLUSION:** Our findings highlight the distinctive epidemiological patterns and clinical presentations of pITP in the northeast region of Malaysia, particularly highlighting gender, race, and age-specific variations. Despite comprehensive treatment guidelines, diagnostic challenges remain. Improved diagnostic tools are needed to enhance timely identification and effective management, ultimately improving patient outcomes for pITP.

## Keywords:

Autoimmune disease, cutaneous bleeding, gingival bleeding, incidence, primary immune thrombocytopenia

## Introduction

Immune thrombocytopenia (ITP) is characterized by a low platelet count,

primarily resulting from an autoimmune response in which the immune system mistakenly targets and destroys platelets. The pathophysiology of primary ITP (pITP) involves an autoimmune response characterized by the production

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of autoantibodies, particularly antiplatelet antibodies.<sup>[1]</sup> This leads to an accelerated destruction of platelets and a hindered platelet production process. Despite the exact trigger remaining elusive, it is believed that the immune system mistakenly identifies platelets as foreign entities, tagging them for elimination by macrophages primarily in the spleen and liver.<sup>[1-3]</sup> Platelets coated with antibodies are prematurely removed from circulation, resulting in a reduction in platelet count. While pITP was once considered idiopathic, its complex pathogenesis is emphasized by the interaction of genetic factors, viral infections, and immune dysregulation.<sup>[4,5]</sup>

Globally, the incidence of ITP occurs between 1.9 and 5.00 cases per 100,000 person-years.<sup>[6,7]</sup> In Malaysia, the annual incidence rate is estimated between 0.8 and 9.6 cases per 100,000 person-years.<sup>[8-10]</sup> Moreover, ITP is more common in females and it increases with age.<sup>[11-13]</sup> However, variation in the estimated rate may be attributed to differences in population, demographics, and study methodologies.<sup>[14]</sup> The absence of a gold standard test for diagnosing pITP contributes to underreported cases, thus limiting the availability of comprehensive clinical epidemiology data.<sup>[15]</sup> Moreover, the limited data resources and infrastructure also restrict more accurate representation of pITP in clinical epidemiology studies. Therefore, this retrospective study aims to determine the incidence and epidemiology of pITP in Kelantan, Malaysia.

## Materials and Methods

This retrospective study was conducted on 141 pITP patients diagnosed between January 2000 and December 2022 at Hospital Pakar Universiti Sains Malaysia (HPUSM). The diagnosis of pITP was based on the Malaysian Clinical Practice Guidelines (CPG),<sup>[16]</sup> where there was no gold standard test and the diagnosis was based on clinical data and exclusion of other causes of thrombocytopenia through patient history, physical examination, full blood count, peripheral blood film, autoimmune screen and viral serology tests. Patient data such as sociodemographics, type of bleeding, clinical-laboratory characteristics, and type of management were retrieved from the Haematology Patient Information System and Laboratory Information System databases. The data were tabulated and pre-analyzed in Microsoft Excel.

### Inclusion and exclusion criteria

#### Inclusion criteria

1. Patients aged 18 years and above
2. Platelet count  $<100 \times 10^9/L$
3. Patients diagnosed as pITP and registered at HPUSM.

#### Exclusion criteria

1. Patients aged below 18 years old
2. Patients diagnosed as sITP for example thrombocytopenia that is associated with autoimmune diseases, viral infections, thrombotic thrombocytopenia, and other clinically apparent conditions.

### Ethical consideration

Ethical approval for this retrospective study was reviewed and granted approval by the Human Research Ethics Committee of Universiti Sains Malaysia (USM/ JEPeM/19090533).

### Statistical analysis

The statistical analysis was performed using IBM-SPSS Statistics version 27.0 (IBM Corp., Armonk, New York, USA). The categorical demographic data were presented as frequency and percentage, whereas numerical variables were expressed as mean with standard deviation or median with interquartile range (IQR). The incidence rates were calculated by dividing the number of pITP cases during the study period by the estimated adult population of the HPUSM catchment area, with an average of 560 thousand people based on population data from the Department of Statistics, Malaysia.<sup>[17]</sup> Incidence was expressed as the number of cases per 100,000 person-years with a 95% confidence interval (CI).

## Results

A total of 141 patients were registered and diagnosed with pITP at Hospital USM for the past two decades. 71.6% of the total patients were female, whereas 28.4% were male, with a male-to-female ratio of 1:2.5. The majority of the patients were Malay (92.9%), followed by Chinese (6.4%) and Indians (0.7%). Patients were aged between 19 and 90 years old, with a median of 44.0 years (IQR: 34.0–61.5) [Table 1]. The frequency distribution of platelet counts among pITPs is shown in Table 2, with a significantly higher number (34.8%) of the patients having a platelet count  $>51 \times 10^9/L$ .

The overall incidence of pITP was 1.2 per 100,000 person-years (95% CI: 1.0-1.5). Females had a higher incidence rate of pITP in comparison to males (1.8 per 100,000 person-years (95% CI: 1.4–2.0) vs 0.7 per 100,000 person-years (95% CI: 0.5–0.9). Furthermore, patients aged 30–39 years old had the highest incidence (2.4 per 100,000 person-years, 95% CI: 1.7–3.2) while those aged between 19–29 had the lowest incidence rate (0.6 per 100,000 person-years, 95% CI: 0.3–0.9) as shown in Figure 1.

The clinical symptoms in adult pITP patients at diagnosis are summarized in Table 3. Cutaneous

**Table 1: Sociodemographic data of adult primary immune thrombocytopenia patients**

	n (%)	Incidence (95% CI)
Gender		
Female	101 (71.6)	1.8 (1.4–2.0)
Male	40 (28.4)	0.7 (0.5–0.9)
Ethnic		
Malay	131 (92.9)	1.9 (1.6–2.2)
Chinese	9 (6.4)	3.5 (1.2–5.7)
Indian	1 (0.7)	5.0 (0.0–14.8)
Age (years)		
19–29	15 (10.6)	0.6 (0.3–0.9)
30–39	38 (27.0)	2.4 (1.7–3.2)
40–49	24 (17.0)	2.1 (1.3–3.0)
50–59	21 (14.9)	2.0 (1.2–2.9)
60–69	18 (12.8)	1.7 (0.9–2.5)
>70	25 (17.7)	2.4 (1.5–3.3)
Median (IQR)	44.0 (34.0–61.5)	

IQR=Interquartile range, CI=Confidence interval

**Table 2: Hematological parameters data of adult primary immune thrombocytopenia patients at diagnosis**

	n (%)
PLT ( $\times 10^9/L$ )	
0–10	37 (26.2)
11–30	34 (24.1)
31–50	21 (14.9)
51–100	49 (34.8)
Median (IQR)	30.0 (10.0–59.0)
Other parameters, median (IQR)	
WBC ( $\times 10^9/L$ )	8.6 (6.5–10.7)
HB (g/dL)	12.2 (11.0–13.8)
ANC ( $\times 10^9/L$ )	4.8 (3.4–6.9)
HCT (%)	35.0 (29.3–40.8)

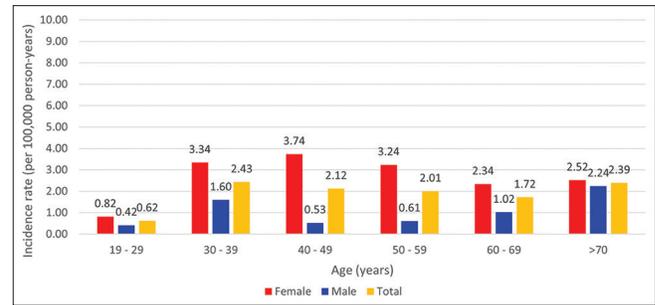
IQR=Interquartile range, WBC=White blood cell, Hb=Hemoglobin, PLT=Platelet, ANC=Absolute neutrophil counts, HCT=Hematocrit

**Table 3: Clinical symptoms of adult primary immune thrombocytopenia at diagnosis**

Clinical symptoms	n (%)	Mean platelet count (SD) ( $\times 10^9/L$ )
Cutaneous bleeding	75 (53.2)	30.8 (27.6)
No symptoms	46 (32.6)	47.1 (30.0)
Gingival bleeding	42 (29.8)	29.6 (29.8)
Menorrhagia	27 (19.1)	27.6 (28.1)
Epistaxis	9 (6.4)	41.4 (42.7)
Upper GIT bleeding*	3 (2.1)	16.3 (22.3)
Hematuria	2 (1.4)	47.5 (16.3)
Hematoma†	2 (1.4)	46.5 (0.7)
Intracranial bleeding	1 (0.7)	57.0
Melena	1 (0.7)	27.0
Subconjunctival bleeding	1 (0.7)	64.0

\*Hematoma including epidural hematoma and hematoma at limbs. GIT=Gastrointestinal, SD=Standard deviation

bleeding was the most presented symptom accounted for 53.2% of the total patients, followed by gingival bleeding (29.8%) and menorrhagia (19.1%). Moreover,



**Figure 1: Annual incidence of primary immune thrombocytopenia in Kelantan by age and gender**

most of the symptoms occurred in patients with a mean platelet count  $<50 \times 10^9/L$ . Meanwhile, the lowest mean platelet count was measured in patients with upper gastrointestinal bleeding ( $16.3 \times 10^9/L$ ).

The initial treatments administered to pITP at diagnosis are presented in Table 4. A total of 82.3% of the patients received treatment, whereas another 17.7% patients of the patients did not require treatment during the initial diagnosis period. Corticosteroids were the most commonly used first-line treatment (58.9%), followed by a combination of intravenous immunoglobulin (IVIg) and corticosteroids (7.1%). Platelet transfusions were administered to 6.4% of the patients as an emergency treatment for severe thrombocytopenia or bleedings. Second-line therapies, including azathioprine, hydroxychloroquine, danazol, and rituximab, were given to patients who did not respond to first-line therapy (4.2%).

## Discussion

Several studies on ITP have been conducted among East Malaysian populations, each contributing to a better insight into its incidence, characteristics, and management in Malaysia.<sup>[8-10]</sup> However, epidemiological studies on pITP have yet to be thoroughly covered, hence, this research further develops the insights from prior studies, emphasizing the distribution of pITP in the northeast region of Malaysia. Through this study, we aim to identify the distinct pITP patterns and trends in Kelantan, paving the way for future investigations which will result in more specialized and efficient management plans.

We discovered that variations observed in the incidence of pITP across genders were consistent with studies performed in Asian countries such as India, South Korea, and Japan.<sup>[11-13]</sup> Specifically, women were twice as likely to be diagnosed with ITP compared to men. Similarly, a higher female incidence rate was also reported among adult South Korean populations (6.0 per 100,000 person-years vs. 4.5 per 100,000 person-years).<sup>[12]</sup> These

findings were further supported by studies from Western countries such as the USA, England, and France as a significantly higher prevalence among adult females was identified.<sup>[18-20]</sup>

In addition, the occurrence of pITP may vary over different age groups. We observed the highest frequency of ITP was among patients aged below 40 years old, followed by elder patients aged more than 70 years old. A similar age distribution trend was noted in studies conducted in China and India, in which women

predominated in the 18–40 age range.<sup>[13,21]</sup> Interestingly, the gender bias patterns could only be observed from those aged 65 and below as the gender-specific differences began to shift to men in 75-year-old and older age groups.<sup>[11,19,22]</sup>

The unique multiracial population in Malaysia provides a setting for the clinical epidemiology study of ITP. Our retrospective study has demonstrated a higher incidence of pITP among Malays as compared to Chinese and Indians. This outcome can be largely attributed to the distribution of ethnic groups in Kelantan, where Malays constitute approximately 70% of the population.<sup>[23]</sup> It is consistent with previous research on ITP conducted in the local regions of Kelantan, Perak, and Selangor, corroborating the finding that the ethnic composition in the region has a substantial influence on the incidence of pITP.<sup>[8-10]</sup>

Most of the pITP patients had platelet counts of more than  $30 \times 10^9/L$  at the diagnosis. This finding diverges from what had been reported in prior studies which demonstrated a higher incidence of patients having platelet counts  $<30 \times 10^9/L$ .<sup>[11,13,21]</sup> The research also noted a decreasing trend in the frequency distribution of platelet counts over age groups. The differences in findings can be due to the variability in the age-sex distribution, clinical presentation, and regional factors.<sup>[20,24,25]</sup>

**Table 4: Treatment of adult primary immune thrombocytopenia at diagnosis (n=141)**

Treatment	n (%)
No treatment	25 (17.7)
Platelet transfusion	9 (6.4)
First-line therapy	
IVIg	7 (5.0)
Corticosteroids	83 (58.9)
IV dexamethasone	2 (1.4)
IVIg+corticosteroids	10 (7.1)
Second-line therapy	
Azathioprine	2 (1.4)
Danazol	1 (0.7)
Hydroxychloroquine	2 (1.4)
Rituximab	1 (0.7)

IVIg=IV immunoglobulin, IV=Intravenous

**Table 5: Comparison of the epidemiology of primary immune thrombocytopenia across the world**

Year	Authors	Country	Percentage (%)*	Male-to-female ratio	Incidence†	Clinical symptoms (%)
2024	This study	Kelantan, Malaysia	0.039	1:2.53	1.24	Cutaneous bleeding (53.2) No symptoms (32.6) Gingival bleeding (29.8)
2022	Doobaree <i>et al.</i> <sup>[28]</sup>	England	0.048	1:1.37	4.20–6.40	NA
2020	Bekadja <i>et al.</i> <sup>[29]</sup>	Algeria	0.006	1:3.39	0.85	Severe haemorrhages (34.7) Ecchymotic (33.5) No symptoms (31.8)
2020	Weycker <i>et al.</i> <sup>[20]</sup>	United States of America	0.009	1:1.31	6.10	NA
2019	Christiansen <i>et al.</i> <sup>[27]</sup>	Scandinavia	0.042	1:1.38	1.80–2.80	NA
2018	Wu <i>et al.</i> <sup>[25]</sup>	Taiwan	0.005	1:1.99	1.86	NA
2017	Lee <i>et al.</i> <sup>[12]</sup>	South Korea	0.021	1:1.30	3.70	NA
2017	Rao <i>et al.</i> <sup>[13]</sup>	India	NA	1:1.86	NA	Cutaneous bleeding (45.0) Gingival bleeding (20.0) Menorrhagia (17.5)
2015	Ni <i>et al.</i> <sup>[21]</sup>	China	0.033	1:1.80	NA	Haemorrhage (72.16) Fatigue (16.89)
2014	Moullis <i>et al.</i> <sup>[19]</sup>	France	0.002	1:0.81	2.90	Cutaneous bleeding (96.6) Oral bullae (86.2) Epistaxis (51.7)
2013	Pamuk <i>et al.</i> <sup>[26]</sup>	Turkiye	0.035	1:2.80	2.92	NA
2012	Galdarossa <i>et al.</i> <sup>[22]</sup>	Italy	0.002	1:1.09	2.60	Minor haemorrhages (57.5) No symptoms (32.5) Grade 2 haemorrhages (7.5)
2011	Kurata <i>et al.</i> <sup>[11]</sup>	Japan	0.008	1:1.70	2.20	Cutaneous bleeding (62.8) Gingival bleeding (19.9) Epistaxis (10.0)

\*Percentage of pITP over the population, †Per 100,000 person-years. NA=Not applicable, pITP=Primary immune thrombocytopenia

Moreover, we calculated the incidence rate of adult pITP patients among the northeast Malaysian population based on 20 years of data and the findings suggest the annual incidence is less than two cases per 100,000 person-years. However, a range of incidence rates of pITP were observed in several continents might be due to various factors, including population density, age distribution, geographical disparities, and heterogeneity inherent in study designs. As shown in Table 5, studies in Asia such as in Turkiye, Taiwan, China, Korea, and Japan had noted the incidence rates of pITP patients were about 1.9–3.7 cases per 100,000 person-years.<sup>[11,12,21,25,26]</sup> On the other hand, a much wider range of incidence rates was observed among the Western population with 1.8–6.4 cases per 100,000 person-years.<sup>[19,20,22,27,28]</sup> To illustrate more, we also assessed the percentage of pITP occurrence in a few studies that we had come across by calculating the number of pITP patients per total population. As a result, we could observe that a study from England has the highest percentage of occurrence (4.2–6.4 cases per 100,000 person-years) compared to studies from other countries.<sup>[28]</sup>

The prognosis of pITP is influenced by the spectrum and severity of the clinical symptoms, notwithstanding the elusive nature of its pathophysiology. The presentation of hemorrhagic manifestations in pITP patients is notably high, encompassing a range of symptoms such as cutaneous bleeding, oral hemorrhage, gastrointestinal bleeding, menorrhagia, and haematuria.<sup>[11,13,19,21,22,26,29]</sup> Notably, cutaneous bleeding emerges as the most common clinical symptom, a finding that aligns with research conducted in Japan, India, and France as shown in Table 3.<sup>[11,13,19]</sup> In addition, a higher frequency of cutaneous bleeding spots was observed among females compared to males, contrary to a study in India.<sup>[13]</sup> Approximately one-third of the patients diagnosed with pITP were asymptomatic. This observation reflects similar findings with Italian and Algerian studies, which reported a comparable proportion of asymptomatic cases (31.8%–32.5%).<sup>[22,29]</sup>

Furthermore, we also attempted to evaluate the association between clinical symptoms and mean platelet counts, and we discovered that most of the clinical features were presented in patients with mean platelet counts  $<50 \times 10^9/L$ . In contrast to our study results, other studies by Rao *et al.* and Wong *et al.* reported that patients with haematuria had a platelet count  $<5 \times 10^9/L$ .<sup>[13,30]</sup> Essentially, platelets play a crucial role in maintaining vascular integrity by providing a surface for coagulation proteins and adhering to the vessel wall at sites of endothelial injury. It is estimated that about  $7-8 \times 10^9/L$  platelets are needed to maintain vascular hemostasis.<sup>[2,3]</sup> Thus, significant bleedings are rare when platelet counts are above  $30 \times 10^9/L$  and usually only occur when counts drop below  $10 \times 10^9/L$ .

This relationship has been observed in both adults and children with chronic ITP.<sup>[11,31-33]</sup> However, there's significant variability in bleeding risk across patients, and a long-term study would be required to establish the correlation between very low platelet counts and bleeding within and between patients.<sup>[34]</sup>

In this cohort, 50% of the pITP patients presented with platelet count  $<30 \times 10^9/L$  received first-line treatments such as corticosteroids and IVIg.<sup>[16]</sup> These treatment patterns are aligned with established practices in countries such as Japan, India, and South Korea.<sup>[11-13]</sup> Moreover, a small portion of second-line treatment were prescribed to patients with serious hemorrhagic symptoms and non-responsive to steroids. This includes immunosuppressive drugs and thrombopoietin receptor agonists (TPO-Ras).<sup>[11-13,19,21]</sup> Comparable observations have been documented in previous studies, wherein fewer than 30% of patients were given second-line therapy at the time of diagnosis.<sup>[8,9]</sup> Nevertheless, longitudinal data indicate that the requirement for second-line treatment increases substantially over time, with up to two-thirds of patients which may be due to relapse, refractory disease, or corticosteroid dependence.<sup>[15,27]</sup> Surgical interventions like splenectomy may also be suggested for refractory ITP patients with platelet counts  $<30 \times 10^9/L$  and active bleeding.<sup>[19]</sup> Nevertheless, there was a significantly reduced in the amount of splenectomies performed in the recent years primarily due to the advancement in the treatment and the COVID-19 pandemic.<sup>[35,36]</sup> The Malaysian CPG adopts a tiered personalized approach to treatment. However, the effective management of ITP is often hindered by diagnostic challenges.

This study is subject to certain limitations, including the absence of pediatric data. As a result, the findings reflect only the adult population, omitting an important demographic also affected by ITP. Furthermore, the study was conducted at a single healthcare center in Kelantan, which may limit the generalizability of the results to other regions of Malaysia due to variations in sociodemographic factors, healthcare infrastructure, and disease reporting practices. In addition, the diagnosis of pITP was based on clinical judgment and exclusion, which may introduce diagnostic variability. Finally, the study lacked longitudinal follow-up data, restricting the assessment of disease chronicity and treatment response over time.

## Conclusion

Our findings highlight the distinctive epidemiological patterns and clinical presentations of pITP in the northeast region of Malaysia, particularly highlighting gender, race, and age-specific variations. Despite comprehensive

treatment guidelines, diagnostic challenges remain. Improved diagnostic tools are needed to enhance timely identification and effective management, ultimately improving patient outcomes for pITP.

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### Conflicts of interest

There are no conflicts of interest.

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