APPLICATION OF THE JMF 10 WARNING SIGNS FOR EARLY DETECTION OF PRIMARY IMMUNODEFICIENCY AMONG CHILDREN WITH RECURRENT INFECTIONS IN INDONESIA

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Abstract

Introduction: Limited awareness and diagnostic resources contribute to delayed recognition of primary immunodeficiency (PID). The Jeffrey Modell Foundation (JMF) 10 warning signs have been widely used for screening. However, their diagnostic performance has not been validated in Indonesia. **Objective:** To evaluate the diagnostic performance of the JMF 10 warning signs for early detection of PID among children with recurrent infections in Indonesia. **Methods:** This multicentre cross-sectional study was conducted across 10 hospitals in Jakarta involving 254 children aged 0–18 years who met the severe, persistent, unusual, and recurrent (SPUR) infection criteria. The diagnosis of PID was established based on clinical diagnosis by the European Society for Immunodeficiencies (ESID) Registry Working Definitions. Analysis was performed to determine the sensitivity, specificity, predictive values, and accuracy of the JMF 10 warning signs. **Results:** Diagnostic performance for PID improved with the number of warning signs, with overall accuracy increasing from 15% (1 sign) to 86.2% (≥5 signs). A total score of ≥3 signs was associated with higher occurrence of PID (PR 2.63; 95% CI 1.23–5.60; p = 0.008), providing an optimal balance of 75.7% sensitivity and 48.9% specificity. The two most specific indicators were recurrent severe sinus infections (99.5%) and ear infections (95%). All PID subjects required IV antibiotics. **Conclusion:** The JMF warning signs remain a valuable clinical screening tool for early detection of PID among Indonesian children. A threshold of three or more warning signs provides reasonable accuracy for screening and referral of PID in resource-limited settings.

Keywords: primary immunodeficiency, JMF warning signs, recurrent infection.

Introduction

Primary immunodeficiency (PID) is one of the underlying conditions for recurrent infections that is commonly missed, especially in developing countries. This condition is primarily caused by limited physician awareness and the limitations of available diagnostic tests.[1-3] In general, the incidence of PID is estimated at 1 per 2,000 to 1 per 10,000 live births, with a male-to-female ratio of 5:1.[4,5] However, in Indonesia, merely 70 cases of PID were recorded in the national registry in 2021.[6] Delay in PID diagnosis contributes to increased morbidity and mortality, as well as a reduced quality of life. Existing data indicate that the diagnostic interval typically ranges from approximately 3 months to 5 years.[7-16] However, diagnostic delay in Indonesia may extend to 10 years.[6] Different sets of warning signs aimed at improving the early recognition of PID have been developed worldwide.

One of the instruments used globally as a screening tool is the Jeffrey Modell Foundation (JMF) 10 warning signs, which has been translated into over 50 languages, including Indonesian. These warning signs include four or more new ear infections within one year, two or more sinus infections within one year, two or more months on antibiotics with little effect, two or more pneumonia within one year, failure of an infant to gain weight or grow normally, recurrent, deep skin or organ abscesses, persistent thrush in mouth or fungal infection on skin, need for intravenous antibiotics to clear infections, two or more deep-seated infections including septicemia, and a family history of PID.[17,18]

The overall JMF 10 warning signs score has shown differences in sensitivity and specificity across various studies. Studies from Germany, the United States, Egypt, and Turkey have reported sensitivity values ranging from 30% to 94% and specificity values ranging from 16% to 93%.[19-23] However, their diagnostic performance has yet to be evaluated in Asian developing countries, such as Indonesia. This study aimed to determine the performance of JMF 10 warning signs for PID in identifying PID cases among Indonesian children.

Materials and Methods

A cross-sectional study was conducted from July 2024 to September 2025 at 10 hospitals in Jakarta, including dr. Cipto Mangunkusumo Hospital, Harapan Kita Children and Women's Hospital, Fatmawati Hospital, Persahabatan Hospital, Sulianti Saroso Hospital, Universitas Indonesia Hospital, Budhi Asih District Hospital, Koja District Hospital, Tebet District Hospital, and Pasar Rebo District Hospital. The inclusion criteria were children aged 0-18 years with severe, persistent, unusual, and recurrent (SPUR) infections. Children who received chemotherapy, long-term steroids, immunosuppressants, and biological agents were excluded from the study. Severe infection was defined as a life-threatening infection or an infection requiring intensive care management. Persistent infection was defined as an infection with a history of an inadequate response to standardized therapy. Unusual infection was defined as an infection occurring at atypical sites or caused by uncommon

pathogens. Recurrent infection was defined as an infection occurring more frequently than expected in an immunocompetent child (e.g., upper respiratory infections occurring more than 8 times per year, or diarrheal episodes occurring more than 3 times per year).

Data on demographics, clinical characteristics, and basic laboratory findings were collected from medical records and parents' interviews. A 6-milliliter blood sample was collected from each subject to measure lymphocyte subsets, immunoglobulin levels, the dihydrorhodamine (DHR) test, C3, C4, and HIV antibody. All laboratory tests were conducted at the Clinical Pathology Laboratory of dr. Cipto Mangunkusumo Hospital, except for the HIV antibody test, which was performed at each respective hospital.

We calculated the total number of the 10 JMF warning signs for each subject. The criteria "family history of PID" were modified to "family history of PID or early death related to infection in family", because of the limited confirmed PID cases in Indonesia. The diagnosis of PID was established based on the European Society for Immunodeficiencies (ESID) Registry Working Definitions. Statistical analysis was performed using STATA version 16.1. The chi-square test or Fisher's exact test was used for categorical variables, as appropriate. A p-value <0.05 was considered statistically significant. The study was approved by the Ethics Committee of the Faculty of Medicine, Universitas Indonesia - Dr. Cipto Mangunkusumo Hospital.

Results

This study included 254 subjects, with 53% males, slightly higher in the PID group than in the non-PID group (60.61% vs 52.04%), but not significantly different. The median age at disease onset also did not differ between the two groups (9 months in the PID group vs 8 months in the non-PID group). There were 33 (13%) subjects in the PID group, and the others were in the non-PID group. Most subjects (98%) fulfilled at least 1 JMF 10 warning sign, with the highest number (7) observed in a subject with Hyper-IgE syndrome. The presence of three or more signs was associated with a significantly increased likelihood of PID, and the strength of association increased with each additional warning sign (Table 1).

Among the 10 JMF criteria, the most common parameters were the need for IV antibiotics to clear infection (93.31%), followed by failure to thrive (50.79%), and recurrent pneumonia (49.61%). We calculated each JMF criterion's performance to identify which signs were the strongest predictors. Out of the JMF 10 warning signs, 4 signs were associated with higher PID occurrence: two or more months of antibiotic use with little effect (PR 2.65, p=0.002), recurrent skin or organ abscesses (PR 2.99, p=0.002), persistent fungal infections on mouth or skin (PR 3.38, p<0.0001) and family history of primary immunodeficiency or early death related to infection (PR 3.73, p<0.0001).

Table 1. Characteristics of Subjects Based on the JMF 10 Warning Signs

Parameter	Total (n=254)	PID (n=33)	Non-PID (n=221)	Prevalence ratio (95%CI)	p value
Number of JMF 10 warning signs, n (%)					
≥1 sign	249 (98.03%)	33 (100.00%)	216 (97.74%)	-	-
≥2 signs	220 (86.61%)	31 (93.94%)	189 (85.52%)	2.40 (0.60–9.56)	0.187
≥3 signs	138 (54.33%)	25 (75.76%)	113 (51.13%)	2.63 (1.23–5.60)	**0.008**
≥4 signs	38 (14.96%)	14 (42.42%)	24 (10.86%)	4.19 (2.30–7.62)	**<0.001**
≥5 signs	12 (4.72%)	5 (15.15%)	7 (3.17%)	3.60 (1.69–7.66)	**0.013**
JMF 10 Warning Signs*, n (%)					
≥ 4 new ear infections within 1 year	12 (4.72%)	2 (6.06%)	10 (4.52%)	1.30 (0.35–4.82)	0.694
≥ 2 serious sinus infections within 1 year	2 (0.79%)	1 (3.03%)	1 (0.45%)	3.94 (0.95–16.39)	0.060
≥2 months of antibiotic treatment with little effect	50 (19.69%)	13 (39.39%)	37 (16.74%)	2.65 (1.42-4.97)	**0.002**
≥ 2 episodes of pneumonia within 1 year	126 (49.61%)	14 (42.42%)	112 (50.68%)	0.75 (0.39-1.43)	0.380
Failure of an infant to gain weight or grow normally	129 (50.79%)	16 (48.48%)	113 (51.13%)	0.91 (0.48-1.76)	0.777
Recurrent, deep skin or organ abscesses	21 (8.27%)	7 (21.21%)	14 (6.33%)	2.99 (1.48-6.05)	**0.002**
Persistent thrush in the mouth or fungal infection on the skin	22 (8.66%)	8 (24.24%)	14 (6.33%)	3.38 (1.73-6.57)	**<0.001**
Need for intravenous antibiotics to clear infections,	237 (93.31%)	33 (100.00%)	204 (92.31%)	-	-
≥ 2 deep-seated infections, including septicemia	34 (13.39%)	6 (18.18%)	28 (12.67%)	1.44 (0.64-3.23)	0.379
Family history of PID / early death related to infection in the family	30 (11.81%)	11 (33.33%)	19 (8.60%)	3.73 (2.02-6.92)	**<0.001**

*A subject can present with more than one warning sign

Diagnostic performance for PID improved with the number of warning signs, with overall accuracy increasing from 15% (1 sign) to 86.2% (≥5 signs). We found that a total score of ≥3 signs provided an optimal balance of 75.7% sensitivity and 48.9% specificity (Table 2).

Table 2. Performance of the Number of JMF 10 Warning Signs in Identifying PID

Number of the JMF 10 warning signs	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
≥1 sign	100	2.3	13.3	100	15.0
≥2 signs	93.9	14.5	14.1	94.1	24.8
≥3 signs	75.7	48.9	18.1	93.1	52.4
≥4 signs	42.4	89.1	36.8	91.2	83.1
≥5 signs	15.2	96.8	41.7	88.4	86.2

PPV: positive predictive value; NPV: negative predictive value.

The need for IV antibiotics, failure to thrive, and recurrent pneumonia were the most sensitive parameters for identifying PID, with sensitivities of 100%, 48.48%, and 42.42%, respectively (Table 3). Severe recurrent sinus infections, ear infections, recurrent

abscesses, and persistent fungal infections had the highest specificities (99.5%, 95%, 93.67%, and 93.67%, respectively). Overall diagnostic accuracy was highest for severe recurrent sinus infection, persistent fungal infection, and recurrent abscesses (87.01%, 84.65%, and 84.25%).

Table 3. Performance of Each Parameter of the JMF Criteria in Identifying PID

JMF 10 Warning Signs	Sensitivity(%)	Specificity(%)	PPV (%)	NPV (%)	Accuracy (%)
≥ 4 new ear infections within 1 year	6.06	95.48	16.67	87.19	83.86
≥ 2 serious sinus infections within 1 year	3.03	99.55	50.00	87.30	87.01
≥2 months of antibiotic treatment with little effect	39.39	83.26	26.00	90.20	77.56
≥ 2 episodes of pneumonia within 1 year	42.42	49.32	11.11	85.16	48.43
Failure of an infant to gain weight or grow normally	48.48	48.87	12.40	86.40	48.82
Recurrent, deep skin or organ abscesses	21.21	93.67	33.33	88.84	84.25
Persistent thrush in the mouth or fungal infection on the skin	24.24	93.67	36.36	89.22	84.65
Need for intravenous antibiotics to clear infections,	100	7.69	13.92	100	19.69
≥ 2 deep-seated infections, including septicemia	18.18	87.33	17.65	87.73	78.35
Family history of PID / early death related to infection in the family	33.33	91.40	36.67	90.18	83.86

PPV: positive predictive value; NPV: negative predictive value.

Discussion

The JMF 10 warning signs have been used globally as a screening tool for identifying PID. In this study, we found that the presence of three or more signs was associated with a higher likelihood of PID. The majority of subjects required intravenous antibiotics to eradicate infections, followed by failure to thrive or poor weight gain in infancy, and two or more episodes of pneumonia within one year. Similar findings were reported in Egypt, where the most frequent PID warning sign was the need for intravenous antibiotics, followed by failure to thrive in infancy and recurrent pneumonia among subjects with severe, unusual, and recurrent infections.[22] Meanwhile, a study from India reported that the most common warning sign among subjects evaluated for PID was the requirement for intravenous antibiotics, followed by severe infections including sepsis, prolonged antibiotic use without clinical improvement, and recurrent pneumonia.[24] Although the most common presentation among the JMF 10 warning signs in this study was the need for IV antibiotics, it did not differ between the two groups. These findings may be explained by the fact that subjects in this study are predominantly those presenting with severe infections that need intravenous antibiotic therapy to clear the infection.

Four warning signs differed between the two groups. They were associated with higher PID occurrence: two or more months of antibiotic use with little effect, recurrent skin or

organ abscesses, persistent fungal infections on the mouth or skin, and a family history of primary immunodeficiency or early death related to infection. The findings of this study differed from those of previous studies.[22,23,25] The differences may be attributed to variations in study populations, the spectrum of infections, and the prevalent PID type in each population. For example, recurrent pneumonia and failure to thrive are significant predictors of PID in the Western studies; however, these parameters could not differentiate the PID group from the non-PID group in our study. This finding may be explained by the high burden of respiratory infections and malnutrition in Indonesia, which limits the ability of these parameters to distinguish PID from other conditions.

The JMF 10 warning signs that have been most consistently associated with PID across multiple studies were a positive family history of PID, which has been identified as the strongest predictor.[2,22,24,26] In this study, a modification was made to the original PID warning sign regarding family history, as obtaining information on diagnosed PID within families is challenging, given the limited number of PID diagnoses in Indonesia. Therefore, this warning sign was modified to include a family history of primary immunodeficiency or early childhood death due to infection. This modification facilitated the assessment of family history. Early childhood death due to infection can act as an important clue, especially when similar types of infections and immunological laboratory patterns are observed among siblings. This finding is supported by a study from Turkey, which demonstrated a higher rate of sibling mortality among subjects with PID.[23]

The best cutoff for further PID evaluation varied among countries. The sensitivity and specificity of the JMF 10 warning signs in this study were lower than those reported in other studies in Egypt, Turkey, and the United States. [22,23,26] A study in Egypt found that two or more signs gave 94% sensitivity and 64% specificity, while three or more signs gave a more balanced 77% sensitivity and 86% specificity.[22] Another study in Turkey reported that the cutoff of 1.5 signs provided 92% sensitivity and 93.5 specificity.[23] Meanwhile, a study in the United States reported that the cutoff of 2 signs was associated with a 56% chance of identifying PID in children.[26] However, the sensitivity of JMF 10 warning signs in this study is higher than in a study in Germany, but with lower specificity. These differences may be due to differences in the study population, higher disease severity, and infection burden in our study locations. As the majority of subjects were referred from a tertiary hospital, the burden and severity of the disease were higher than in population-based or primary health care cohorts.

In this study, 2% of the subjects did not present with any of the JMF 10 warning signs. A study conducted in the United States reported that among 141 subjects evaluated for PID, 24% did not show the JMF warning signs. Further evaluation revealed that 32% of these subjects were finally diagnosed with PID.[21] Another study from Poland showed that 20.4% of PID subjects had no warning signs.[27] This finding emphasized the importance of not relying solely on the JMF 10 warning signs for PID screening. A subject with hyper-IgE

syndrome exhibited the highest number of warning signs, with up to seven signs identified. This is consistent with findings from a study in the United States, which reported that subjects with hyper-IgE syndrome had the greatest number of PID warning signs [26]

The performance of each warning sign in this study differed from that reported in a Polish study. The need for intravenous antibiotics showed the highest sensitivity in both studies; however, the magnitude of the difference was marked, with 100% in our study compared with only 33.8% in the Polish study. Another study from Turkey showed that the need for intravenous antibiotics also had the highest sensitivity (82.65%).[23] This is because most of the subjects need intravenous antibiotics to clear infections. The family history of PID had the highest specificity in the Polish study (98.7%).[27] Although it was not the most specific parameter in our study, its specificity was comparable at 91.4%. In the Turkish study, most parameters had high specificity (>85%), and only 1 parameter, family history of PID, had a specificity of 75%.[23] In this study, overall diagnostic accuracy was highest for severe recurrent sinus infection, persistent fungal infection, and recurrent abscesses. These findings differed from another study, which reported that the need for intravenous antibiotics, ≥2 months of antibiotic treatment with little effect, and failure to gain weight or grow normally were the three parameters with the highest diagnostic accuracy.[23] This suggests that the performance of the JMF 10 warning signs differs across populations, and that the burden, severity, and type of infections in each population should be taken into account when using these warning signs.

Conclusions

Our study revealed that a total score of three or more of the JMF 10 warning signs provided an optimal balance of sensitivity and specificity for identifying PID. Warning signs criteria, including two or more months of antibiotic use with little effect, recurrent skin or organ abscesses, persistent fungal infections of the mouth or skin, and a family history of primary immunodeficiency or early death related to infection, were more strongly associated with PID. The JMF 10 warning signs remain useful as a screening tool for identifying PID in Indonesia.

Competing Interests

We declare no competing interests.

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