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POSTER ABSTRACTS

311.DISORDERS OF PLATELET NUMBER OR FUNCTION: CLINICAL AND EPIDEMIOLOGICAL

Evaluation of Bleeding Self-Assessments By Patients with Immune Thrombocytopenia (ITP): An Agreement Study

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Introduction. Immune thrombocytopenia (ITP) is an autoimmune condition that causes an increase in the risk of bleeding. Bleeding is a patient-important outcome; however, timely and complete assessments of bleeding are time- and labour-intensive. ITP bleeding measurements may be simplified with patient self-assessments. We designed this study to compare the agreement of bleeding assessments done by ITP patients and by trained research staff.

Methods. All patients were identified from the McMaster ITP Registry, a longitudinal registry study of consecutive adult patients with thrombocytopenia followed at the McMaster University Medical Centre, a tertiary referral clinic. A modified version of the ITP Bleeding Scale was used for all bleeding assessments, which captured the patients' worst bleeding event at each of 9 anatomical sites - skin, mouth, epistaxis, gastrointestinal, genitourinary, gynecological, pulmonary, ocular or intracranial - graded from 0 (no bleeding) to 2 (severe bleeding) from the time of the last assessment (typically 6 months prior). Patients were provided with instructions on how to use the scale and asked to complete bleeding self-assessments using an online tool. Once the patients completed their self-assessments, a trained research staff member contacted the patient to repeat the bleeding assessment by telephone. Chance-corrected interrater agreement was determined using the kappa statistic for 2-way agreement (Grade 2 vs. Grade 0 or 1 bleeding) and for 3-way agreement (Grade 0 vs. Grade 1 vs. Grade 2). Chance-independent 2-way agreement was also measured using the phi statistic. The primary analysis was the 2-way kappa, since the detection of Grade 2 bleeds is clinically important.

Results. We enrolled 108 consecutive patients with ITP from the McMaster ITP Registry who had duplicate bleeding assessments done. The median time between assessments was 3 days (IQR, 2-5). Median age of patients in the study was 53 years (IQR, 38-64), 64% were female. The worst bleeding events, as determined by research staff, were Grade 0 (n=22, 20.4%), Grade 1 (n=34, 31.5%) or Grade 2 (n=52, 48.1%). There was perfect agreement for bleeding assessments at all anatomical sites for 44 patients (40.7%). There were no intracranial hemorrhages and no Grade 2 genitourinary or pulmonary bleeds were reported. Chance-corrected 2-way agreement was excellent for gynecological (k=0.86, 95% CI 0.71-1.02), gastrointestinal (k=1), genitourinary (k=1), pulmonary (k=1) and intracranial (k=1) bleeds (**Table**). Agreement was good for skin (k=0.68, 95% CI, 0.54-0.82), oral (k=0.76, 95% CI, 0.53-0.98) and ocular (k=0.66, 95% CI, 0.04-1.28) bleeds, and moderate for epistaxis (k=0.58, 95% CI, 0.21-0.95). Results of chance-independent agreement and 3-way agreement were similar.

Conclusions. Bleeding self-assessments by ITP patients yielded comparable results to trained research staff. Agreement for skin and epistaxis was lower than for other sites, suggesting that additional instructions or prompts may be needed for these categories. Bleeding self-assessments could simplify data collection in research and in clinical practice.

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Table. Agreement on bleeding assessments done by patients and research staff (N=108)

Bleeding site	2-way agreement		3-way agreement
	Kappa (κ), 95% CI (95% CI)	Phi (Φ),	Weighted Kappa (κ_w) (95% CI)
Skin	0.68 (0.54, 0.82)	0.68	0.69 (0.58, 0.81)
Oral	0.76 (0.53, 0.98)	0.78	0.70 (0.57, 0.83)
Epistaxis	0.58 (0.21, 0.95)	0.59	0.53 (0.38, 0.69)
Gastrointestinal	1*	1	0.77 (0.58, 0.95)
Genitourinary	1**	1**	0.56 (0.11, 1.01)
Gynecological	0.86 (0.71, 1.02)	0.87	0.87 (0.72, 1.01)
Pulmonary	1**	1**	1*
Ocular	0.66 (0.04, 1.28)	0.70	0.73 (0.49, 0.96)
Intracranial	1**	1**	n/a

Abbreviations and symbols: n/a – not evaluable as values were unavailable; * – Ward’s confidence interval did not allow for appropriate calculation; ** – Kappa/Phi calculated by replacing 0 by 0.01 in zero cells for agreement. 2-way agreement considers Grade 2 vs. Grade 0 or 1 bleeds, 3-way agreement considers Grade 0, 1 or 2 bleeds.

Figure 1

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