Point-of-care finger prick test for C-reactive protein and serum infliximab and adalimumab concentrations; P544

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Background

A new point-of-care test (POCT) device (ProciseDx, San Diego, CA, USA) allows more rapid and user friendly measurement of infliximab (IFX) and adalimumab (ADL) serum concentrations and C-reactive protein (CRP), than existing devices.

Aim

We aimed to validate this device by comparing POCT results with conventional laboratory tests for serum CRP, IFX and ADL in patients with inflammatory bowel disease (IBD).

Methods

Design

Prospective validation study

Inclusion criteria

- Adult patients with IBD requiring routine measurement of CRP, ADL or IFX (both trough and intermediate measurements)

Lab measurements

CRP: plasma assay, IFX and ADL: serum enzyme-linked immunosorbent assay (ELISA)

POCT measurement

Add 20µl of capillary whole blood (CWB), obtained with finger prick, and mix with pre-measured buffer in cartridge and place in analyzer device (figure 1), result within 3 minutes.

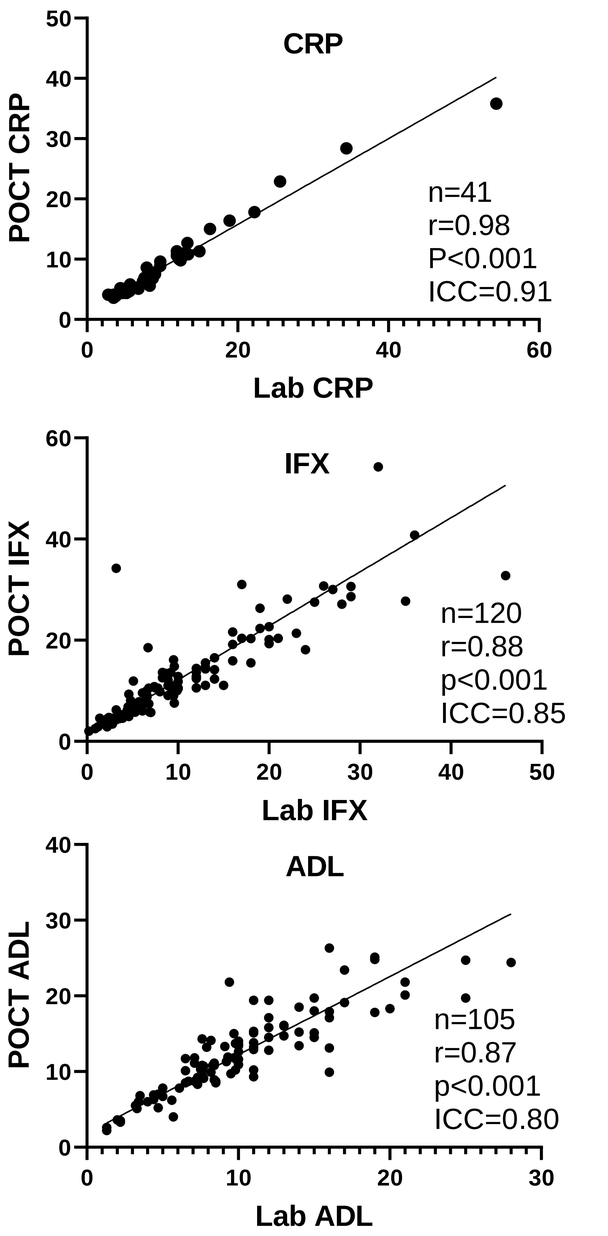
CRP range: 3.6 mg/L – 100.0, IFX and ADL range: 1.3 – 77.2 and 1.3 – 51.5 µg/mL, respectively.

Figure 1: POCT analyzer device and cartridge

Statistics

Visualization on Bland-Altman plot with difference (lab result minus POCT result) on the x-axis, and average of both results on y-axis, mean difference (bias, red line) and upper/lower line of agreement (black dotted line). Deming regression to calculate the intercept and the slope with 95% CI. Intra-class (ICC, two-way mixed, absolute agreement) and Pearson's correlation coefficient. Values outside the assay range were excluded from these analyses

Results



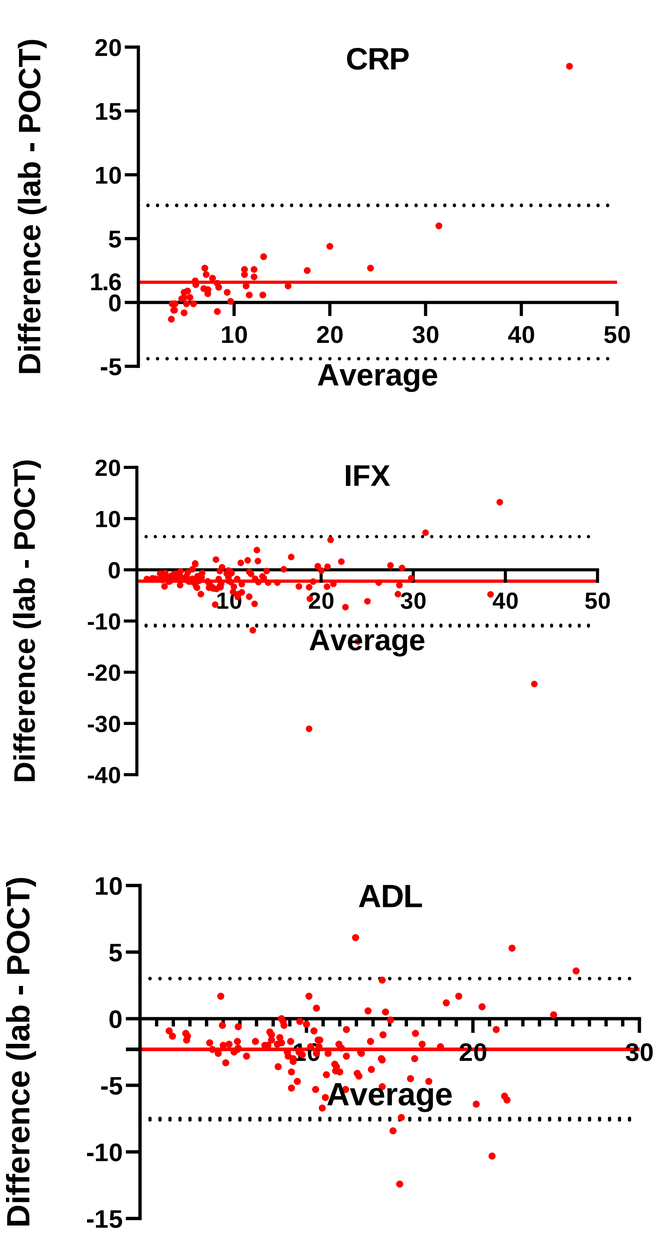


Figure 2: Scatter plot (left) with number, pearson's coefficient and intra-class coefficient. Bland-Altman plot (right) with mean difference (red horizontal line) and upper/lower limit of agreement (black lines), note the different y-axis ranges.

- 66 CRP measurements, 25 excluded because CRP was outside the assay range
- 124 IFX measurements, 4 excluded from analysis because IFX concentration was outside the assay range.
- 109 ADL measurements, 4 excluded because outside of assay range
- Scatter plot and Bland-Altman plot shown in figure 2
- Due to some outliers in the IFX graph, the POCT was repeated on serum samples corresponding with the lab measurement (figure 3)
- Deming regression formulas are shown in table 1 with 95% CI

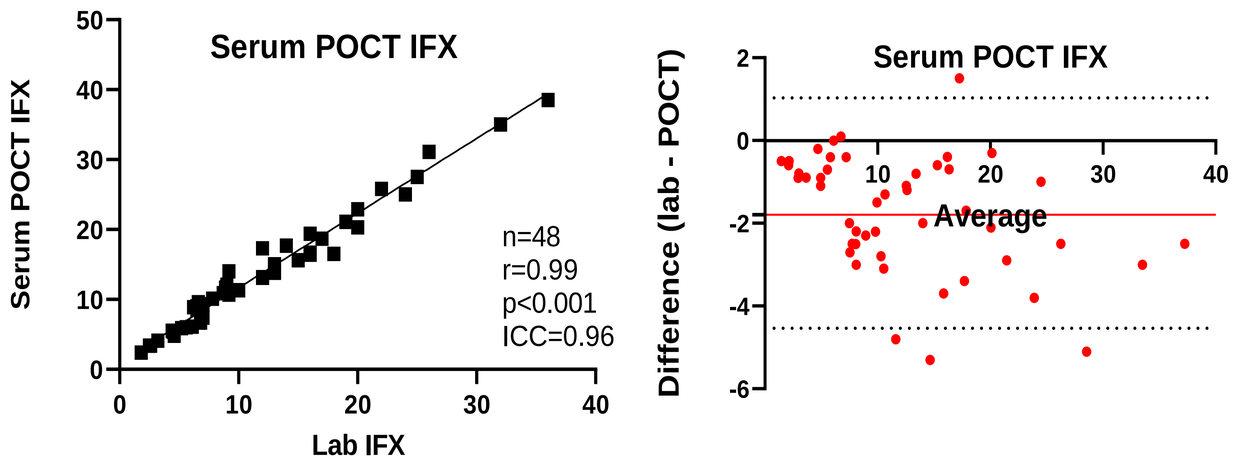


Figure 3: Scatter plot (left) and Bland-Altman plot (right) with mean difference (red horizontal line) and upper/lower limit of agreement (black lines)

	Intercept	*95% CI*			Slope	*95% CI*
POCT CRP =	**1.5**	*-0.4 to 3.5*	+	**Lab CRP** x	**0.71**	*0.5 to 0.9*
POCT IFX =	**1.4**	*-0.5 to 3.4*	+	**lab IFX** x	**1.1**	*0.83 to 1.3*
POCT serum IFX=	**0.95**	*0.4 to 1.5*	+	**lab IFX** x	**1.1**	*1.0 to 1.1*
POCT ADL =	**1.9**	*0.5 to 3.2*	+	**lab ADL** x	**1**	*0.9 to 1.2*

Table 1: deming regression formulas with intercept, slope and 95% confidence intervals (95% CI)

Conclusion

This new analyzer device was reliable, rapid and user friendly than existing devices. Agreement was strongest between serum POCT and serum ELISA IFX, thus revealing a difference between CWB and venous IFX concentrations. Outliers between POCT CWB and serum POCT might be explained by timing errors in which IFX was already infused while performing finger prick for POCT assay. There was a slight underestimation of CRP which was consistent and considered clinically irrelevant.

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Conflicts of interest: this study was funded by ProciseDx. Kurt Bray and Bayda Bahur are currently employed by ProciseDx.