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Revised Passing-Bablok Regression Method for Model Comparison

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A B S T R A C T

Type-II regression models are used to compare more than one method that makes the same measurement. The Passing-Bablok regression method, which is one of them, is non-parametric and can yield more successful results than other comparison methods, particularly when there are outliers. In this study, innovations in the calculation of the slope and intercept parameters used in the traditional Passing-Bablok method are proposed. Instead of the median parameter used in the classical model, the use of the trimean parameter is suggested, and the model parameter estimates are adjusted accordingly. The proposed model and classical model predictions were compared on 15 different datasets, eight of which were simulations. It was determined that the proposed model calculations contained fewer errors than the results of the classical method.

1. Introduction

Method comparison studies were conducted to investigate the compatibility between the currently used method and the newly proposed method to evaluate the performance of the new methods. In many subjects obtained by measurements in clinical studies, using a new method that is cheaper and faster than the old method may be the most accurate choice in terms of both cost and measurement accuracy. It is not always possible to obtain complete agreement between the measurements of the different methods used to measure the same parameter. However, it is possible to calculate and compare the differences between new and old methods. If this difference is not at a level that causes problems in clinical interpretation, the new method can be used instead of the old method, or both can be used interchangeably [1]. Different approaches have been suggested in the literature for comparison of methods. These methods are generally referred to as Type II regression analysis methods. While Type I regression methods are applied in cases where the independent variable or variables are assumed to have no measurement error, Type II regression techniques can be defined as regression techniques that obtain results by calculating the measurement errors in the dependent and independent variables simultaneously. These techniques include Orthogonal regression, Deming regression, and York regression techniques, and their derivations under various conditions. Passing-Bablok Regression Technique, on the other hand, can be defined as a non-parametric Type II regression technique. Type-II regression models are typically used in clinical studies.

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2. Method

2.1. Passing-Bablok Regression

When comparing methods measuring the same experimental results, the Altman and Bland plot is an informative way to display the differences between measurements and compare the average differences that may occur between measurements [2]. If it is determined by plotting that the differences do not change with intensity, and the data have a standard normal distribution, the statistical significance of the mean can be tested using the classically paired t-test.

However, quantifying both absolute and proportional bias requires some form of linear regression analysis if the graph shows an increasing deviation of differences from the horizontal with increasing concentration, and the data after conversion to logarithms do not meet some conditions [3]. Since it is assumed that the 'independent' variable is measured without error in the least squares regression analysis, it gives very small slope values and very large intercept values [4]. The question of whether the two analytical methods measure the same parameters is important in the analysis of laboratory data. Therefore, statistical approaches are required to explore and test method equivalence. Passing and Bablok, among others, based their procedure on the used regression modelling [5].

In terms of method comparison, Passing-Bablok regression is a robust, non-parametric method for fitting a straight line to 2-dimensional data where both dependent (Y) and independent (X) variables are measured with error. It comes in handy when you have two instruments that are supposed to provide the same measurements and you want to compare them. This was achieved by estimating a linear regression line and testing whether the cutoff point was zero and the slope was one. This intersection was interpreted as a systematic bias (difference) between the two methods. The slope measures the proportional bias (difference) between the two methods. The Passing-Bablok estimator can also be defined as a variation of the Theil-Sen regression that explains the errors in both variables [6,7].

Based on this estimation principle, the greatest advantage of this method is that it is effective against extreme values. In the case of extreme values, weighting does not work as in methods such as the Weighted Least Squares Method and Weighted Deming Regression Method. The non-parametric approach underlying the Passing-Bablok method allows the modelling of the relationship between laboratory methods in the presence of extreme values. This estimation principle ensures that the method is robust to outliers, which is its primary advantage. Measurement errors were partially considered for both measurement methods. Passing and Bablok claimed that this method can be used when errors are proportional [8]. In the Passing-Bablok method, the slope estimate (β_1) is calculated as the median of all slopes that can be generated from all possible pairs of data points (S_{ij}), which is given in Equation 1 except for pairs that result in a slope of 0/0 or -1:

$$S_{ij} = \frac{y_i - y_j}{x_i - x_j} \tag{1}$$

To correct for prediction bias, because these slopes are not independent, the median is shifted by a factor k, which is the number of slopes less than -1. This created an unbiased estimator. The intercept parameter estimate (β_0) is the median of the inequality calculated from all pairs of observations $Y_i - \beta_1 X_i$.

The Passing-Bablok regression also requires the following assumptions [9]:

i. Variables X and Y were highly positively correlated (only for the method comparison).

ii. The relationship between X and Y is linear.

iii. No special assumptions were made regarding the distributions (including the variances) of X and Y.

When the sample size is not large enough, the 95% Confidence Intervals for the intercept and slope parameters will be wide and will likely contain values of 0 and 1. Consequently, method comparison studies based on small sample sizes are biased in concluding that laboratory methods are congruent. Therefore, an accurate and sufficiently large sample size is required. [10] recommended using at least 30 samples to avoid this problem.

It is important to assume a linear relationship between X and Y. [6] tested this assumption by using a modified Cusum test. The Cusum test for the linearity assumption was used to assess how well a linear model fits the data. This test only tested the applicability of the Passing-Bablok method and was not used for interpretation in terms of the comparability of the two laboratory methods. A small significance value (p<0.05) indicates that there is no linear relationship between the two measurements; therefore, the Passing-Bablok method is not applicable.

The average slope $\bar{\beta}$ indicates whether the slope estimate is biased or not. The root mean squared error (RMSE) is an estimate of the total error of the slope and includes both the random error, that is the standard deviation of the dispersion β around the mean β, and the systematic error or bias [8]. In this study, model comparisons were performed using the RMSE formula given in Equation 2.

$$RMSE:\sqrt{\sum u^2 / n} \tag{2}$$

2.2. Proposed Method

In this study, corrections in the calculation procedure for both the β_0 and β_1 parameters were proposed for the Passing-Bablok method. Thus, we aimed to obtain estimates with lower deviations using the revised Passing-Bablok method.

When the slope values of the two highly correlated variables are listed, the effect of the values in the bottom and top slices on the deviations in the data is much greater than that of the median parameter. Therefore, in the estimation of the slope parameter, the effect of the Q_1 and Q_3 quartiles were included in the calculation using the Trimean parameter, which was popularized by [11] instead of the median parameter of the $Y_i - \beta_1 X_i$ values obtained from all the data. Thus, the slope parameter was calculated over a slightly wider range than the bias around the median parameter. The trimean parameter formula is given in Equation 3:

$$Trimean = \frac{Q_1 + 2 \times Q_2 + Q_3}{4} \tag{3}$$

In the Passing-Bablok formulation, the median was shifted by a factor k, which is the number of slopes less than -1, to correct for the estimation bias because the slopes are not independent. In this study, we propose shifting the k factor in the Passing-Bablok formulation as $\sqrt{k}$. The average value obtained by the trimean calculation is located to the right or left of the median value, depending on the excess of extreme values. Instead of shifting the number of S_{ij} less than -1 by k, dimension reduction with square root aims to minimize the difference in bias correction between the calculations obtained with trimean and median parameters. Thus, the slope β_1 is the shifted trimean of S_{ij}, where trimean is shifted to the right $\sqrt{k}$ step.

3. Application

In the application section, the results of the revised Passing-Bablok method introduced above and the classical Passing-Bablok method were compared on 15 different datasets. The RMSE value was used to compare the methods, and model linearity control was performed using the Cusum test recommended by [6]. Passing-Bablok regression analyses were performed using the NCSS 2021 statistical package program, and revised Passing-Bablok method analyses were performed using the R (version 4.3.1) package program. The datasets and sources used in the analysis, the number of observations, and the Cusum linearity test results are listed in Table 1.

The dataset is defined as milk data and fat content of human milk determined by the enzymatic procedure for the determination of triglycerides and measured by the Standard Gerber method (g/100 ml) [1]. The other datasets are hypothetical sets of paired data from which it is possible to establish the method created by the authors and evaluate the agreement. Eight simulation datasets are used in this study. Five of these datasets (with observation numbers of 30 and above) were derived from the distributions of [12], [1], and [13] provided that the sample numbers were equal to the sample numbers in those studies. The other three simulation datasets (with observations less than 30) were derived with different sample sizes and correlation coefficients of 0.99 between variables. All the datasets used in the analysis are provided in the appendix.

In Table 1, the z-values indicate the calculated Cusum test statistic values recommended in the study [6], and the p-values show the probability values given by the NCSS 2021 package program. As shown in Table 1, eight of the datasets were obtained by simulation, and seven of them were used previously studied in the literature. In addition, nine datasets had 30 or more observations. The linearity assumptions of all datasets were also met (p-values greater than 0.05). The parameter estimates and RMSE values obtained from both Passing-Bablok methods are listed in Table 2.

Table 1. Information on the data used in the analysis

			Cusum Linearity Test	
Data Name	**Source**	**Observation**	**z-value**	**p-value**
Data Set-1	[14]	8	0.8944	>0.3
Data Set-2	Simulation	10	0.8165	>0.3
Data Set-3	Simulation	14	0.7071	>0.3
Data Set-4	[15]	16	1	0.2848
Data Set-5	[16]	18	12.649	0.0809
Data Set-6	Simulation	20	1.206	0.1088
Data Set-7	[14]	30	0.75	>0.3
Data Set-8	[12]	30	1.25	0.0873
Data Set-9	Simulation	30	1	0.2848
Data Set-10	Simulation	30	0.75	>0.3
Data Set-11	[1]	45	0.8341	>0.3
Data Set-12	Simulation	45	10.911	0.1887
Data Set-13	[13]	50	0.9806	>0.3
Data Set-14	Simulation	50	0.5883	>0.3
Data Set-15	Simulation	50	0.58	>0.3

Table 2 shows that the RMSE results obtained from the proposed method had lower values than the classical results. Low RMSE values indicate that the revised model fits the data well (albeit slightly) and estimates with a lower variance. Using quartile parameters instead of the median parameter of the slopes that can be created from all pairs of data points of two highly correlated variables is more compatible with the data in the revised model and has more precise estimates.

Table 2. Results of model parameter estimates and RMSE values of the data sets

	PB Regression			Revised PB Regression		
Data Set	β_0	β_1	**RMSE**	β_0	β_1	**RMSE**
Data Set-1	1.881	0.8033	0.57725	2.0097	0.7884	***0.56899***
Data Set-2	-0.0845	10.514	0.133	-0.06694	1.046192	***0.129***
Data Set-3	-0.0689	10.898	0.1648	-0.06251	1.08388	***0.1622***
Data Set-4	-1.96964	1.21428	0.7619	-1.35104	1.16667	***0.7476***
Data Set-5	-33.61792	1.12735	39.441	-26.6671	1.089674	***38.044***
Data Set-6	-0.0264	11.075	0.0946	0.004677	1.103448	***0.0872***
Data Set-7	-0.0092	0.9986	2.2184	0.008166	0.998217	***2.2181***
Data Set-8	7.0819	1.0553	31.706	9.28846	1.05384	***31.689***
Data Set-9	-0.135	1.1111	0.038	0.11229	0.90804	***0.032***
Data Set-10	-0.6284	1.0364	0.408	0.71761	0.93939	***0.379***
Data Set-11	0.0556	0.9759	0.0786	0.071476	0.973293	***0.0775***
Data Set-12	-0.0886	10.374	0.4809	0.176602	0.940171	***0.4305***
Data Set-13	-0.141522	1.012121	0.3604	0.00625	1	***0.3567***
Data Set-14	-0.1416	1.0579	0.2041	0.1862	0.8958	***0.1408***
Data Set-15	1.5223	0.9362	0.9877	1.889204	0.90909	***0.9837***

4. Conclusion

The Passing-Bablok regression method is a non-parametric method used to compare two different measurement methods for the same measurement. The main idea of this method is to examine the agreement of two different concentrations with a regression model to be created with the help of the median parameter of all slopes that can be calculated between two variables. In this study, suggestions were made for the parameter calculations of the classical Passing-Bablok method. First, the use of the trimean parameter instead of the median parameter used in classical model calculations is proposed, and second, $\sqrt{k}$ correction is proposed in the k-factor shift used in the slope parameter calculation. The prediction results obtained using the new calculation method were compared with those obtained using the classical method.

According to the results obtained, the revised Passing-Bablok model prediction results give fewer erroneous prediction results compared to the classical results. For the parameter estimations performed on 15 different data sets, 8 of which are simulation data sets and 7 of which are data sets studied in the literature, effective results were obtained even below the number of observations suggested in [10]. Thus, the slope scores calculated with the trimean parameter, in which the effects of the first and third quartile values in the data were also included in the average, made calculations with less error.

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Appendix

Data Set-1

Y	7.9	8.2	9.6	9	6.5	7.3	10.2	10.6
X	7	8.3	10.5	9	5.1	8.2	10.2	10.3

Data Set-2

Y	1.055	1.115	1.075	1.025	1.02	1.025	1.085	5.215	1.93	1.085
X	1.115	1.105	1.1	1.035	1.07	1.055	1.13	5.06	1.735	1.135

Data Set-3

Y	3.11	3.23	3.15	3.05	3.04	3.05	3.17	11.51	4.87	3.17	11.37	9.03	3.57	3.07
X	3.23	3.21	3.2	3.07	3.14	3.11	3.26	11.2	4.48	3.27	10.78	8.31	3.43	3.1

Data Set-4

Y	10.1	11.4	10.8	11.3	11.8	12.1	12.3	13.60	14.2	14.4	14.6	15.3	15.5	15.8	16.2	16.5
X	9.8	9.7	10.7	10.9	12.4	12.5	12.8	12.85	12.9	13.3	13.4	13.5	13.7	14.9	15.2	15.5

Data Set-5

Y	371	283	373	341	353	454	214	230	510	295	286	453	114	328	109	203	305	154
X	347	249	369	286	329	410	267	295	500	286	271	506	117	329	132	274	277	198

Data Set-6

Y	0.89	5.61	4.52	0.09	0.05	0.05	0.04	0.05	0.09	0.03
X	0.71	5.18	4.15	0.12	0.04	0.045	0.07	0.07	0.11	0.05
Y	2.27	1.5	5.05	0.22	2.13	0.05	4.09	1.46	1.2	0.02
X	2.08	1.21	4.46	0.25	1.93	0.08	3.61	1.13	0.97	0.05

Data Set-7

Y	69.1	26.7	61.4	51.2	34.7	88.5	57.9	45.1	33.4	60.8	66.5	48.2	88.3	29.3	96.4
X	69.3	27.1	61.3	50.8	34.4	92.3	57.5	45.5	33.3	60.9	56.3	49.9	89.7	28.9	96.3
Y	77.1	82.7	78.9	51.6	28.8	97.3	68.4	84.2	98.6	56.6	69.7	61.8	12.7	67.1	96.8
X	76.6	83.2	79.4	51.7	32.5	96.9	68.2	86.8	99.1	56.6	69.8	61.5	14.2	67.5	96.7

Data Set-8

Y	8	16	30	24	39	54	40	68	72	62	122	80	181	259	275
X	1	5	10	20	50	40	50	60	70	80	90	100	150	200	250
Y	380	320	434	479	587	626	648	738	766	793	851	871	957	1001	960
X	300	350	400	450	500	550	600	650	700	750	800	850	900	950	1000

Data Set-9

Y	1.06	1.32	0.82	1.33	1.21	0.82	0.89	1.56	0.83	1.85
X	1.03	1.04	0.87	1.57	1.31	0.87	0.79	1.26	0.9	1.9
Y	1.34	1.39	0.89	1.26	1.27	1.27	0.91	1.27	2.45	1.21
X	1.3	1.54	0.79	1.12	1.29	1.29	0.86	1.21	2.36	1.13
Y	1.07	0.68	1.39	1.56	0.87	0.97	0.8	0.87	1.66	1.56
X	1.25	0.73	1.54	1.26	0.82	1.13	1.12	0.82	1.33	1.26

Data Set-10

Y	6.6	4.55	16.9	12.25	8.85	10.3	6.65	4.7	5.85	6
X	5.2	4.3	17.1	11.8	9.45	10.4	5.65	5.1	6.5	5.55
Y	6.35	8.3	5.85	6.05	4.1	7.6	3.5	16.9	5.35	5.4
X	6.05	6.65	4.3	6.55	4.35	7.2	2.8	17.1	4.95	5.55
Y	5.5	4.45	4.15	5.1	7.6	6.35	5.05	5.5	4.8	7.05
X	4.8	3.95	4.5	4.6	7.2	6.45	4.1	4.8	4.7	5.7

Data Set-11

Y	0.96	1.16	0.97	1.01	1.25	1.22	1.46	1.66	1.75	1.72	1.67	1.67	1.93	1.99	2.01
X	0.85	1	1	1	1.2	1.2	1.38	1.65	1.68	1.7	1.7	1.7	1.88	2	2.05
Y	2.28	2.15	2.29	2.45	2.4	2.79	2.77	2.64	2.73	2.67	2.61	3.01	2.93	3.18	3.18
X	2.17	2.2	2.28	2.43	2.55	2.6	2.65	2.67	2.7	2.7	2.7	3	3.02	3.03	3.11
Y	3.19	3.12	3.33	3.51	3.66	3.95	4.2	4.05	4.3	4.74	4.71	4.71	4.74	5.23	6.21
X	3.15	3.15	3.4	3.42	3.62	3.95	4.27	4.3	4.35	4.75	4.79	4.8	4.8	5.42	6.2

Data Set-12

Y	3.99	3.69	2.37	4.68	5.31	2.43	4.47	3	10.14
X	4.71	3.87	2.37	3.78	5.67	3.9	4.83	2.49	10.26
Y	3.93	2.04	3.81	5.31	3.21	3.93	10.14	5.31	3.81
X	4.32	2.19	3.63	5.67	3.75	3.45	10.26	5.67	3.87
Y	2.55	2.46	3.3	3.93	5.16	2.49	2.46	10.14	2.7
X	3.18	2.61	3.51	3.45	4.68	2.7	2.37	10.26	2.46
Y	6.84	2.88	2.67	3.21	2.82	5.16	2.67	2.1	3.3
X	6.75	2.64	2.37	3.75	3.06	4.68	2.61	2.34	3.63
Y	2.37	2.46	3.69	6.84	4.77	2.88	3.18	3.06	5.16
X	2.37	2.31	3.18	6.75	5.64	2.64	3.84	2.76	5.64

Data Set-13

Y	10.1	10.6	13.1	8.7	11.5	10.4	9.9	11.3	7.5	11.9	7.8	9.7	9.9	16.2	9.8	11.8	8.7
X	10.1	10.5	12.8	8.7	10.8	10.6	9.6	11.3	7.7	11.5	7.9	9.9	9.3	16.3	9.4	11	9.1
Y	11.9	12.6	9.5	9.1	9.2	8.7	9.7	13.1	9.1	9.6	11.3	14.8	9.3	16.5	8.6	8.1	9.6
X	12.2	13.4	9.2	8.8	9.3	8.5	9.6	13.5	9.4	9.5	10.8	14.6	9.7	16.4	8.1	8.3	9.5
Y	20.4	8.5	8.8	8.7	9.9	8.1	9	17	10	9.8	6.6	7.6	10.7	14.1	12.7	9.4	
X	20.3	8.6	9.1	8.8	9.2	8.1	9.2	17	10.2	10	6.5	7.9	11.3	14.2	11.9	9.9	

Data Set-14

Y	0.82	1.83	1.39	0.81	1.72	3.23	1.23	1.37	1.72	0.96
X	0.79	1.62	1.36	1.3	1.88	3.35	1.06	1.34	1.56	0.94
Y	0.76	1.15	0.95	1	1.52	1.56	2.45	1.85	0.89	0.82
X	0.69	1.16	0.71	0.83	1.44	1.26	2.36	1.9	0.95	0.77
Y	1.01	0.96	3.38	1.31	1.1	1.26	1.15	1.2	1.01	1.33
X	0.82	0.88	3.42	1.15	0.96	1.12	1.02	1.29	0.87	1.13
Y	0.87	1.66	1.41	1.08	1.17	1.77	1.33	1.23	1.21	1.2
X	0.82	1.33	1.14	0.93	1.09	1.89	1.57	1.29	1.13	1.11
Y	1.49	0.89	1.09	1.03	1.07	0.89	1.39	0.96	1.06	1.17
X	1.61	0.79	1.19	0.96	1.25	0.87	1.36	0.86	1.03	0.86

Data Set-15

Y	10.2	20.3	15.9	10.1	19.2	34.3	14.3	15.7	18.2	11.6
X	9.9	19.2	15.6	12.1	20.8	35.5	12.6	15.4	17.6	11.4
Y	9.6	13.5	11.5	12	17.2	17.6	26.5	20.5	10.9	10.2
X	8.9	13.6	9.1	10.3	16.4	14.6	25.6	21	11.5	9.7
Y	12.1	11.6	35.8	15.1	13	14.6	13.5	14	12.1	15.3
X	10.2	10.8	36.2	13.5	11.6	13.2	12.2	14.9	10.7	13.9
Y	10.7	18.6	14.1	12.8	13.7	19.7	16.3	14.3	14.1	14
X	10.2	17.3	13.4	11.3	12.9	20.9	17.7	14.9	13.3	13.1
Y	16.9	10.9	12.9	12.3	12.7	10.9	15.9	11.6	12.6	11.7
X	18.1	9.9	13.9	11.6	13.5	10.7	15.6	10.6	12.3	10.6