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A Comparison of Artificial Intelligence (AI) Based System, Automated Hematology Analyzer, & Manual Method in Platelet Estimation in Peripheral Blood Smear

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ABSTRACT

Introduction: AI based automated peripheral blood smear slide analyzers are tested for in vitro diagnosis that provides morphological analysis as well as quantification of haematology parameters.

Aims & Objectives: The present study aims at determining the correlation between Sysmex XN 1000 & AI based system results of platelet count with the manual method and to assess accuracy, utility & reliability of AI platform in diagnostic hematology.

Material & Method: The study conducted in the department of Pathology, at tertiary care hospital in western India, included 171 patients for platelet count estimation were included in the study after taking written consent from the participants.

Results: There was an acceptable correlation between platelet counts as estimated by AI based system with manual platelet counting with coefficient of correlation .7399. The correlation coefficient for Sysmex XN 1000 platelet count with manual platelet count was .8878. (P value- less than .001, statistically significant) & between AI based system and Sysmex XN 1000 was .7206. The platelet count measurement by Sysmex had higher precision 0.8878 and accuracy 0.9802 in comparison to AI based system where precision was 0.7399 and accuracy stood at 0.8878.

Conclusion: The AI Based system could identify platelet clumps and macro platelet better. Sysmex XN 1000 analyzer has better correlation with manual method of estimation than AI based system with manual count. The advent of new technology needs more studies before they could be used in clinical practice.

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Artificial intelligence (AI) as defined by John Mccarthy the science and engineering of making intelligent machines, especially intelligent computer programs [1]. AI is a field, which combines computer science and robust databases, to enable problem solving. It is worth emphasizing at this point that deep learning and machine learning is not synonyms rather deep learning which comprise of neural networks is a sub field of machine learning. The word 'deep' in deep learning refers to neural network that comprise of more than three layers [2].

The diagnostic relevance of peripheral blood smear examination cannot be overlooked. Platelet count plays pivotal role in patient management and also as diagnostic tool in haematological disorders [3]. It is of paramount importance that platelet counts are performed in an accurate and reliable way. The platelet count estimation by the current generation of haematology automated analyzers use different technologies for platelet counting: impedance method (Beckman Coulter), optical method (Advia-Siemens, Cell dyn sapphire – Abbott diagnostic, Santa Clara, CA USA) and immunofluorescence technique (Sysmex XN instruments - Kobe, Japan, BC-6800 Mindray – Shenzen , China) [4-6].

There are few caveats that every laboratory should be careful while assessing not just platelet counts but all complete blood parameters. The pre-Analytical variables like improper filling of tubes in excess or under filling or insufficient inversion could lead to spurious thrombocytopenia. EDTA anticoagulant is the most common anticoagulant used in hematology for complete blood count, but at times it produces artefactual thrombocytopenia which could be addressed only by peripheral blood smear examination. It is therefore essential that every case of thrombocytopenia is first evaluated to rule out such interferences [7]. The increasing

use of automated hematology analyzer in laboratory medicine has led to heavy reliance on them which at times makes laboratories undermine the utility of peripheral blood smear examination. Now in such scenario with integrated software for auto reporting, which use 'delta check', i.e. correlation with previously reported values of parameters, makes reporting on autopilot mode without intervention of a skilled pathologist. The study by Bret Howen emphasized that a variation in platelet counts exceeding 50% of previous value in adults and 30% in children on delta check needs to be checked manually [8]. Cornet et al in their study showed that manual review is required in fifteen percent or more of blood samples [9]. Blood smear examination is mandatory when an adult present less than 100 X 109 platelets /L in an initial investigations or more than three months after initial result and a child with less than 150 X 109 platelets /L in initial investigations or more than one month after initial result [10,11].

AI based automated peripheral blood smear slide analyzers are tested for in vitro diagnosis that provides morphological analysis as well as quantification of haematology parameters like WBC, RBC and platelet count, analysis of RBC shapes like elliptocytosis, target cells, schistocytes, W B C differential counts and platelet clumps [12]. The artificial intelligence -based deep learning machines have both hardware and software. The instrument used in present study had light microscope and cell phone constituting the hardware component [13,14]. The rear camera captures images of different parts of the peripheral blood smear into sixty image capture and a one twenty image capture. Prior to the image capture the system identify cells in mono layer and in case of poor smear quality where monolayer is not detected the slide is rejected. Thereafter the images are uploaded on cloud server and analysis of images is done with the results available within five minutes. The image capture is done from areas with minimal overlapping of cells and where RBC was just touching each other. The robotic system captured that field of view with at least single WBC.

The present study aims at determining the correlation between Sysmex XN 1000 & AI based system results of platelet count with the manual method and to assess accuracy, utility & reliability of AI platform in diagnostic hematology.

Material & Methods

The objectives of the study were to compare platelet count by automated platelet analysis and AI based system with manual count. We also studied accuracy of AI based system for identification of platelet clumps and utility of giant platelets in making diagnosis of underlying disease. The study comprises of random sampling selection of cases which included samples with or without thrombocytopenia.

The investigation was routine complete blood count which included RBC, WBC, Platelet cell counts and other parameters which were reported as per department standard operating procedures. AI based system analysis for platelet count was not incorporated in reporting for platelet count and was only for research analysis. There was no extra cost bearing on patients or the hospital as the study used peripheral blood smear glass slide that are routinely prepared for Complete blood analysis. The study was a single time capture of platelet count and therefore no follow up of patients was required.

Staining

The smears for AI based system were prepared using auto spreader provided and smears were stained by Leishman Stain. The study was done in blinded manner where Sysmex XN 1000 analyzer, AI based system run and manual platelet check was done independently. The mean value of platelet count by two Pathologist was taken as final manual count and were used as gold standard.

The study was conducted in the Department of pathology in a tertiary care hospital in India over six months period June 2021 to December 2021. The retrospective study was done after institution ethics committee approval. Samples received from the in-house admitted patients for platelet count estimation were included in the study after anonymization. A total of 171 patients were included in the study. The study was done in a blind fashion and takes it comes what done by two independent pathologists. The objectives of the study were to evaluate the accuracy of AI based system for platelet analysis and computing correlation coefficient between:

- Sysmex XN 1000 with manual count
- AI based system with manual count

The platelet output is extracted as platelets, large platelets and platelet clumps. AI based system uses deep neural network models trained with several images and 120 images were captured per sample. The number of images and selection of field of view on slide was done.

Results

The retrospective study was conducted in the department of Pathology, at tertiary care hospital in western India, included 171 patients for platelet count estimation.

The mean age of study group was 40.75 years (SD±17.29) with minimum age- 1 year and maximum – 91 years. The male to female ratio was 1.3:1. The mean platelet count by Sysmex XN 1000 analyzer was 1, 38,836/cumm, (SD±170815) with minimum platelet count measured 5000/ cumm and maximum 11, 03,000/ cumm. The mean platelet counts by AI based system 2, 40,536/ cumm, (SD±140000) with minimum platelet count measured zero and maximum 18, 60,000/ cumm. The mean platelet count by manual method was 1, 73,000/cumm, (SD±178640) with minimum platelet count measured 10000/ cumm and maximum 11, 86,000/ cumm. (Table -1) There were 11 (6.43%) cases where Sysmex analyzer noted clumps of platelets (Table-2).

Table 1: Summary Statistics

	Mean	Median	Mode	SD	Min value	Max value
Age (Years) (n-177)	40.75	42	50	17.3	1	91
Sex (n-177)	1.3:1					
Sysmex count (/cumm) (n-177)	138836	79000	18000	170815	5000	1103000
Sysmex clumps (n=11)	1.73	1	1	1.19	1	4
AI based system Count (/ cumm) (n-177)	240536	140000	271603	170815	0	1860000
AI based system Giant platelet	14.56	5	0	33.45	0	282
Manual count (/ cumm) (n-177)	173000	140000	150000	178640	10000	1186000

Table 2: AI based System-SYSMEX Clumps Analysis 2x2

	AI based system		
SYSMEX CLUMP	Yes	No	Grand Total
Yes	12	11	23
No	14	140	154
Grand Total	26	151	177

The chi-square statistic is 29.6404. The p-value is < 0.00001. Significant at $p < .05$

Table 3: shows correlation between platelet count measured by Sysmex XN (Figure-1) and AI based system

Table 3: Correlation Between Different Methods

	AI based system - Manual platelet count	SYSMEX - Manual platelet count	AI based system - SYSMEX platelet count
Sample size	177	177	177
Correlation coefficient r	0.7399	0.8878	0.7206
Significance level	P<0.0001	P<0.0001	P<0.0001
95% Confidence interval for r	0.6649 to 0.8001	0.8519 to 0.9154	0.6413 to 0.7847

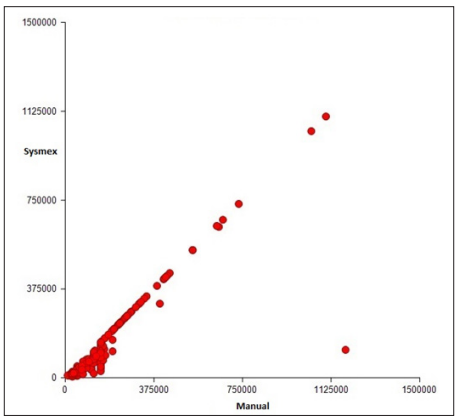

Figure 1: Correlation Sysmex XN 1000- Manual Method

(Figure-2) with manual method as gold standard. There was an acceptable correlation between platelet counts as estimated by AI based system with manual platelet counting with coefficient of correlation .7399. The correlation coefficient for Sysmex XN 1000 platelet count with manual platelet count was .8878. (P value- less than .001, statistically significant).

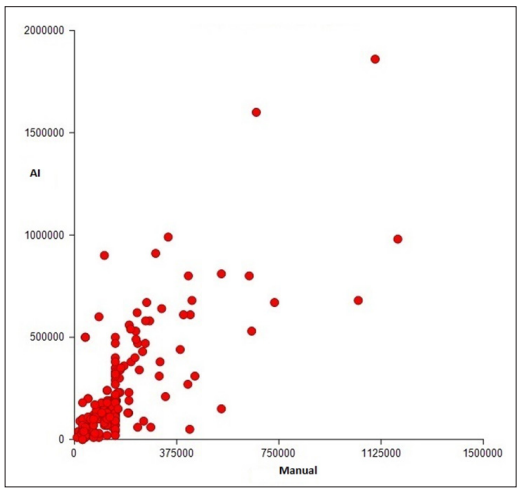

Figure 2: Correlation AI-Manual Method

(Figure 3) Shows correlation between AI based system and Sysmex XN 1000 which was .7206.

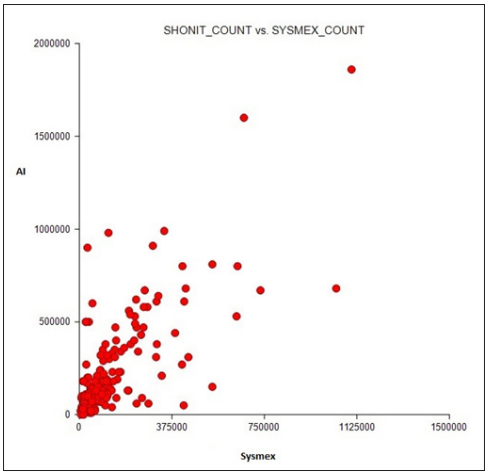

Figure 3: Correlation AI-Sysmex XN 1000

We also computed concordance correlation coefficient for AI based system and Sysmex XN 1000 platelet counts which was 0.6511 for AI based system and 0.8702 for Sysmex respectively. The platelet count measurement by Sysmex had higher precision 0.8878 and accuracy 0.9802 in comparison to AI based system where precision was 07399 and accuracy stood at .8878. (Table-4,5,6,7,8).

Table 4: Concordance Correlation Coefficient with Manual Method

	AI BASED SYSTEM	SYSMEX COUNT
Sample size	177	177
Concordance correlation coefficient	0.6511	0.8702
95% Confidence interval	0.5752 to 0.7159	0.8303 to 0.9012
Pearson ρ (precision)	0.7399	0.8878
Bias correction factor Cb (accuracy)	0.8800	0.9802

Table 5: Bland Altman Analysis

Bias and Limits of Agreement for SYSMEX_COUNT and Manual platelet count					
Parameter	**Count**	**Value**	**Standard deviation**	**95.0% LCL**	**95.0% UCL**
Bias (Difference)	177	-34163.84	83113.98	-46492.96	-21834.72
Lower Limit of Agreement	177	-197067.2	10696.66	-218177.5	-175957
Upper Limit of Agreement	177	128739.6	10696.66	107629.3	149849.8
Bias and Limits of Agreement for AI Based System and Manual Platelet Count					
Parameter	**Count**	**Value**	**Standard deviation**	**95.0% LCL**	**95.0% UCL**
Bias (Difference)	177	67536.73	184076.9	40230.77	94842.68
Lower Limit of Agreement	177	-293254	23690.46	-340007.9	-246500.1
Upper Limit of Agreement	177	428327.5	23690.46	381573.5	475081.4
Bias and Limits of Agreement for AI Based System and SYSMEX_COUNT					
Bias (Difference)	177	101700.6	189951.8	73523.13	129878
Lower Limit of Agreement	177	-270605	24446.55	-318851.1	-222358.9
Upper Limit of Agreement	177	474006.1	24446.55	425760	522252.2

Table 6: Clumps on AI Based System with Platelet Count

AI BASED SYSTEM CLUMP	High Platelet	Low Platelet	Normal platelet	Grand Total
0	8	83	60	151
1	1	5	3	9
2		2	2	4
3			3	3
4			3	4
5			1	1
6			2	2
7			1	1
8			1	1
16			1	1
61		1		1
Grand Total	9	91	77	177

Table 7: Clumps on AI Based System with Platelet Count

AI BASED SYSTEM CLUMP	Normal platelet count	Low platelet count	Grand Total
N	140	11	151
Y	25	1	26
Grand Total	165	12	177

Table 7: Challenge Test

	Platelet count Manual	Platelet count Sysmex	Platelet count AI based system
1	10000	2000	8000
2	100000	46000	80000
3	500000	450000	80000
4	150000	20000	150000 (Clumps)

Table 8: Giant Platelets on AI Based System

AI BASED SYSTEM RANGE MACROPLATELET (%)	H	L	N	Grand Total
0-5	8	47	44	99
5-10	1	17	20	38
10-15		12	6	18
15-20		3	5	8
20-25		7	1	8
25-30		1		1
30-35		1	1	2
>40		3		3
Grand Total	9	91	77	177

The Bland Altman analysis for the three platelet estimation methods show that Sysmex XN 1000 analyzer has better correlation with manual method of estimation than AI based system with manual count. (Figure 4,5,6)

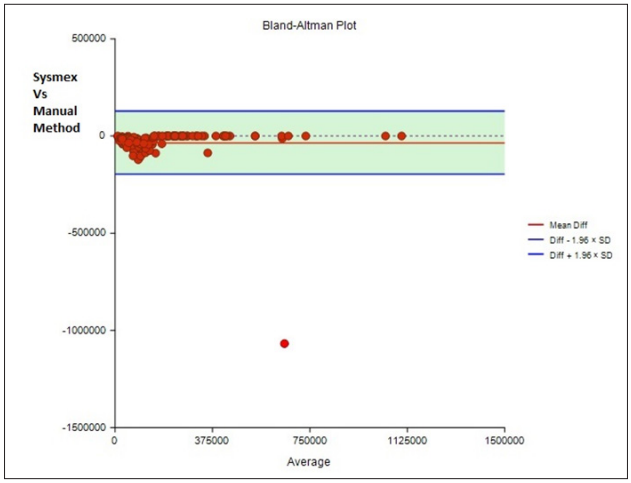

Figure 4: Bland Altman-Sysmex XN1000- Manual

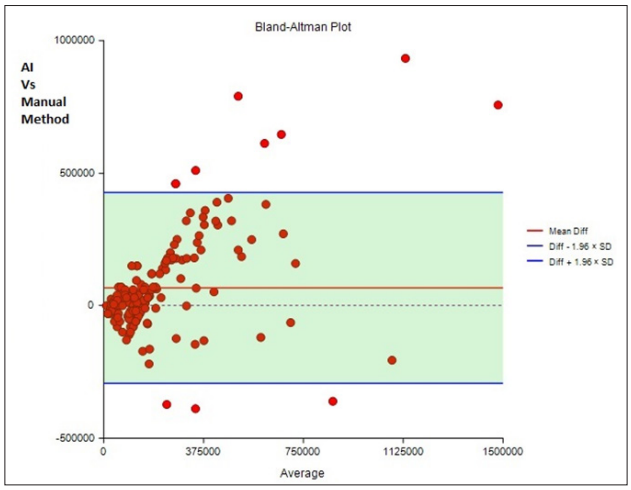

Figure 5: Bland Altman AI- Manual Method

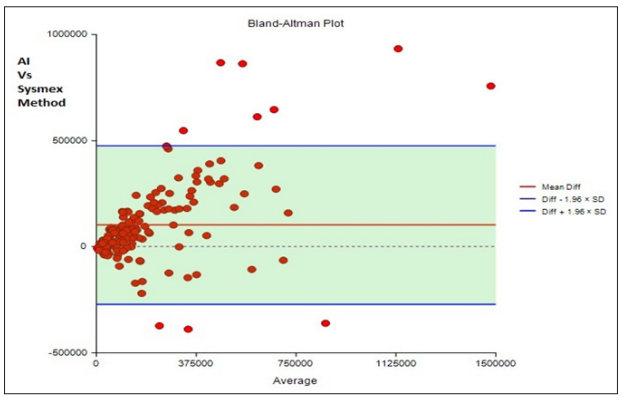

Figure 6: Bland Altman AI-Sysmex XN 1000 Method

Discussion

The present study evaluates AI based system a cloud-based machine learning artificial intelligence system for platelet count and morphology. It classified platelets as normal or giant platelets as well as detected clumps. The platelet count estimation by AI based system was in correlation with Sysmex XN 1000 analyzer. In comparing with the manual count AI based system count had correlation coefficient .7399 whereas the Sysmex XN 1000 platelet analyzer count with manual count was .8878. It implies that Sysmex platelet count correlated more with the

manual count in comparison to the AI based system count. It is prudent to make differentiation between AI based system with any automated analyzer as the AI system is for peripheral blood smear examination and not for counting based on impedance or flow cytometry. AI relies on morphological assessment and intended to find application where facilities of a trained pathologist are lacking [3]. AI offers blood smear examination from samples from far off remote places as the image of the slides is uploaded on cloud interface. In addition, AI system captures multiple images that are large in number than those seen by pathologist and also removes subjectivity in analysis or bias [15]. The detection systems have evolved from rudimentary form. The earliest development of such analyzers includes Cell scan, Hematrak and Cydac (cydec scanning microscope system) but were slow and hence found of limited utility in terms of automated slide examination [16-19].

The advantages of automated slide examination by AI based system include correct identification of cells as there is simultaneous display of cells that helps in identification [20,21]. The slides are traceable and easily retrieved for review or second opinion [22, 23].

Platelet clumps were well picked up by AI based system. It detected clumps in 26/177 (14.69%) whereas SYSMEX in 12/177(6.78%) cases, 25 cases were in addition to those detected by AI based system out of which 8 had normal platelet count while 1 had higher count. The definition of platelet lump more than or equal to 5 platelets it is to emphasize here that the AI system at places have considered clump of platelet comprising of just three platelets [24]. The platelet clumps are considered where 5 or more platelets are seen in groups as defined in standard hematology textbooks, whereas AI based system has considered group of 3 platelets as clump, this needs to be established by more studies. The literature studies by Gulati et al using CELL VISION reported failure of AI system in detecting platelet clumps [25]. Billiard et al in their study did not obtain satisfactorily results for platelet clumps as the platelet clumps were found outside area screened by CELL VISION [21]. The findings of current study are comparable to Gao et al who analyzed peripheral blood smear with manual microscopy, automated hematology analyzer, cell vision and found similar results with Bland Altman analysis plot showing no bias like in the current study [26].

In terms of macro platelet those with >25% macro platelet has lower platelet count on manual method. As a challenge test known cases of idiopathic thrombocytopenic purpura ITP were used in the study and macro platelets were picked up by AI based system, the macroplatelet percentage was 66% in that case. These macro platelets can be used to protect Pro thrombotic potential.

There were 2 cases where Sysmex platelet count was zero, AI based system on the other hand estimated 7000 & 17000 respectively while manual counts were 30000. There was some degree of underestimation of platelet counts by AI based system [27].

The Bland Altman analysis showed acceptable measurements between automated, AI based system and manual estimation where the results are acceptable for platelet values below 50,000/ cumm. One of the advantages of artificial intelligence-based platelet counting is that more field areas wars selected therefore increasing the sensitivity of the counting method.

In our study we found that AI based system was easy to operate, required minimum maintenance, minimum technical expertise for running the samples and took approximately 6 to 7 minutes for each smear for screening. The 120 images captured were transmitted on cloud and interpretation was done within 2 minutes. The total time taken for each slide varied from 7 to 10 minutes but it is expected that in future better, quick and fast processing will be achieved. The success of the system relies on good quality peripheral blood smears where the cells are in monolayer like the thin smears. The instrument comes with a manual spreader which could be employed for smear preparation as suggested by the manufacturer. The review speed for similar AI based instrument CELL VISION was 30 slides per hour comparable to our study [28].

The AI system could be used in remote areas where there is lack of availability of a trained pathologist that is telemedicine telepathology. There is no doubt that AI will boast diagnostics and provide morphological evaluation where there is lack of trained pathologists. In terms of TAT and cutting short of reporting time the system needs to be faster. The biggest advantage of AI based system is that it provides standardized, reproducible, morphological assessment which isn't dependent on human eye or subjectivity. It has a greater potential in research and educational use as well.

Conclusion

The AI Based system could identify platelet clumps and macro platelet better than automated or manual method. Sysmex XN 1000 analyzer has better correlation with manual method of estimation than AI based system with manual count. However as on now with the available technology AI system has to go long way in terms of improvement where it can substitute a trained pathologist, but in present times relying beyond limits on AI would be apocalypse.

The advent of new technology needs more studies before they could be used in clinical practice.

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Conflict of Interest: Nil.

Concordance Correlation Coefficient

The concordance correlation coefficient ρ_c (Lin, 1989 & 2000) evaluates the degree to which pairs of observations fall on the 45° line through the origin. It contains a measurement of precision ρ and accuracy C_b:

$\rho_c = \rho\ C_b$

where

- ρ is the Pearson correlation coefficient, which measures how far each observation deviates from the best-fit line, and is a **measure of precision**, and
- C_b is a bias correction factor that measures how far the best-fit line deviates from the 45° line through the origin, and is a **measure of accuracy**.

Descriptive Scale

McBride (2005) suggests the following descriptive scale for values of the concordance correlation coefficient (for continuous variables):

Value of ρ_c	Strength of agreement
< 0.90	Poor
0.90 - 0.95	Moderate
0.95 - 0.99	Substantial
>0.99	Almost perfect

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