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A Study to Compare between Invasive Blood Pressure and Noninvasive Blood Pressure Measurement among

Critically III Children In A Tertiary Care Hospital In Kolkata

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Abstract

Objective: To compare invasive arterial blood pressure with non-invasive arterial bloodpressure in critically ill children. If NIBP can be used interchangeably with IBP to monitor very sick kids

Design: Cross sectional, observational study.

Setting: Tertiary care Pediatric Intensive Care Unit (PICU), From June2015 to May 2017

Participants: Critically ill children aged between one month to twelve year admitted in PICU due to different medical reason.

Study methods: After ethical approval & a valid and written consent, who met the inclusion criteria were included in the study. For each patient noninvasive blood pressure (SBP,DBP, MAP) measurement was performed two hourly. For monitoring of Invasive blood pressure

(IBP) arterial catheter was placed in any peripheral artery of the body (preferably in radial artery or posterior tibial, dorsalispedis artery) under strict asepsis. During measurement of IBP, simultaneous NIBP was also measured by Oscillometric method and recorded in study protocol. Continuous arterial waveform displayed in bed side monitor was checked by one dedicated investigator every 2 hourly to avoid dampening ofarterial wave form. Arterial line was connected with a heparinised normal saline in the infusion pump with a flow rate of 1-2 ml/hr. IBP and NIBP both were recorded every 2 hourly up to first 48 hours of arterial line placement. In cases, where inotropes were used a valid vasoactive –inotrope score (VIS) was calculated and recorded.

Result: Samplet-Test is conducted for the difference between ISBP mean value with the mean NSBP hour, the

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testis significant as the p-value is <0.05. There is low correlation between mean value of ISBP hour with the mean value of NSBP hour and the value is 0.164.Difference between IDBP mean hour with the mean NDBP hour is significant, p-value is<0.05 with low correlation between mean value of IDBP hour with the mean value of NDBP hour, value is 0.165. The p-value is significant (p<0.05)of a one sample t-test which is conducted for the difference between IMAP mean hour with the mean NMAP hour. There is low correlation between mean value of IMAP hour with the mean value of NMAP hour and the valueis0.201.

Conclusion: The differences between blood pressures measured invasively and non –invasivelyfound statistically significant. In most of the cases NIBP was found to be higher than IBP during the periods of hypotension and lower than IBP during the hypertension. Invasive blood pressure co-relates well with the actual blood pressure of the critically ill children. Hence IBP should be monitor in critically ill children for better monitoring which is vital in critical care setting.

Keywords: Non Invasive blood pressures, Invasive blood pressures, critically ill children

Introduction: The assessment of circulatory function is a cornerstone of critical caremedicine. Blood pressure isone of the most important parameters to assess the circulatory status of critically ill children. Generally we used Oscillometric method for measurementof non-invasive blood pressure but these values are not reliable. Inappropriate figure, poor calibration of machine, difference in arm circumference, inter-observervariability can lead to inaccurate and unreliable values of NIBP. For better accuracy, blood pressure can be measured invasively (IBP) by putting a catheter in any peripheral artery and continuous pressure transduction and waveform display. Invasive blood pressure co-relates well with the actual

blood pressureof the critically ill children, hence considered as gold standard for measuring BPin intensive care unit(1-2). Numerousstudies have been conducted across the world comparing non-invasive and invasive method of blood pressure monitoring over last decade(3-7).Maximumstudies were done in adult population, animal model or in post-cardiac surgerypatients. Based on their results it has been difficult to make anyrecommendation regarding superiority of invasive blood pressure (IBP)monitoring in intensive care setting. Beside this paediatric data are also stilllacking. Main objective of our study is to see whether IBPcan give more accurate and reliable blood pressure measurements incompromised hemodynamic status as compared to NIBP.In some clinical settings the ABP technique withmanual aneroid manometers remains the method of choice for BP measurement (8), despite itsinaccuracy in the absence of frequent recalibration (9). IBP monitoring isinstead the reference standard for BP monitoring in intensive care unit (ICU)patients. However, it is expensive, carries an increased risk of complications, and requires more clinical expertise than non-invasive monitoring (10). NIBP monitoring is influenced by factors related to the procedure, to theinstruments themselves, and to interobserver variability (11). Because noninvasivemethods may not be sufficiently accurate in critically ill patients, leading to erroneous interpretations of BP and possible errors in clinical decisions (12), there is a need for validation studies comparing the accuracy and precision of NIBP and IBP monitoring (13). However lack of such studies in eastern Indian paediatric population promptedus to undertake this study.

Materials & Methods: After taking Ethical approval, Critically ill children aged between one month to twelve year, admitted inPICU of our institute and who met the inclusion criteria mentioned above wereincluded in this

study. After admission a valid and written consent form wassigned by the near relatives of the patient. After admission in PICU vitalparameters (heart rate, respiratory rate, spo2, temperature) were monitoredusing Component Monitoring System Intellivue MP30; Philips Healthcare. Noninvasiveblood pressure (NIBP) was measured by standard oscillometricmethod using appropriate size cuff (Happy heart). For each patient noninvasiveblood pressure (SBP,DBP, MAP) measurement was performed twohourly. For monitoring of Invasive blood pressure (IBP) arterial catheter wasplaced in any peripheral artery of the body (preferably in radial artery) understrict asepsis. In those cases where radial artery could not be cannulated we preferred posterior tibial or dorsalispedis artery. Vygon leader flex catheter ofdifferent size was used in our study for monitoring of IBP. During measurementof IBP simultaneous NIBP was also measured by Oscillometric method andrecorded in study protocol. Before taking any measurement of IBP zeroing wasdone. Continuous arterial waveform displayed in bed side monitor waschecked by one dedicated investigator every 2 hourly to avoid dampening of arterial wave form. Arterial line was connected with a heparinized normal saline in the infusion pump with a flow rate of 1-2 ml/hr. Concentration of heparin used in our study was 0.1 ml per 100 ml of normal saline. In case ofdampening of arterial wave form, arterial line was flushed with 5 ml heparinised normal saline and reading of IBP was taken after return of thenormal wave form. IBP and NIBP both were recorded every 2 hourly up to first hours of arterial line placement. In cases, where inotropes were used avalid vasoactive inotrope score (VIS) was calculated and recorded. In cases of discolouration of digits, loss of distal pulsation, any sign of catheterthrombosis, or persistent dampening of arterial wave form, arterial catheterwas removed promptly.

Results: For statistical analysis, data were analysed by SPSS version 23and Graph Pad Prism version5. Data have been summarized as mean and standard deviation for numerical variables and countand percentages for categorical variables. The median and the interquartile range have been stated for numerical variables that are not normally distributed. Student's independent sample's ttest was applied to compare normally distributed numerical variables between groups. The correlation between the SAP, DAP, and MAP alues of the NIBP/IBP comparisons was investigated with line arregression, Pearson's correlation coefficient and a Bland-Altman chart. Explicit expressions that can be used to carry out various *t*-tests are given below. In each case, the formula for a test statistic that either exactly follows or closely approximates a *t*-distribution under the null hypothesis is given. Also the appropriate degrees of freedom are given in each case. Each of these statistics can be used to carry out either a one-tailed test or a two tailed test. Once a t value is determined, a *p*-value can be found using a table of values from Student's t-distribution. If the calculated pvalue is below the threshold chosen for statistical significance (usuallythe0.10,the0.05,or0.01level), then the null hypothesis is rejected in favour of the alternative hypothesis. p-value < 0.05 was considered for statistically significant.

Socio demographic variables

Table 1 gecategory distribution (2-39=1,40-77=2,78-115=3,116-144=4).

	Frequency	Percent	Valid Percent	Cumulative
				Percent
1	27	54.0	54.0	54.0
2	8	16.0	16.0	70.0
3	9	18.0	18.0	88.0
4	6	12.0	12.0	100.0
Valid Total	50	100.0	100.0	

Figure 1:



Comments: Out of 50 children,maximum frequency of children in category1(54%) minimumin category 4(12%). Above table showing the frequency distribution and percent distribution. Pie chart showing percent distribution.

Table 2 showing the gender distribution (1=BOY ,2=GIRL).

		Frequency	Percent	Valid Percent	Cumulative Percent
ſ	1	21	42.0	42.0	42.0
	2 Valid Total	29	58.0	58.0	100.0
		50	100.0	100.0	

Figure 2



Comments: Out of 50 children, maximum frequency of children are girl(58%). Above table showing the frequency and percent distribution of boys and girl. Pie chart showing the percent distribution.

Table 3. Height category distribution,(55-79=1, 80-104=2,105-129=3, 130-150=4)

	Frequency	Percent	Valid Percent	Cumulative Percent
1	14	28.0	28.0	28.0
2	17	34.0	34.0	62.0
3	12	24.0	24.0	86.0
4	7	14.0	14.0	100.0
Valid Tatal	50	100.0	100.0	

Figure 3

Daughnut diagram shows the distribution of height category



Comments: Out of 50 children, maximum frequency of children incategory 2. Above table showing the frequency and percent distribution of height category. Doughnut diagram showing the percent distribution.

Table 4 showing the distribution of diagnosis

	Frequency	Percent
CCF	5	2.0
hypertention+LVFdrow ning	4	8.0
MAS	1	2.0
meningitis withsensismeningcencenhalitismefrac	2	4.0
torystatusepilepticusseveresepsiswit	7	14.0
hshock spinal muscular atropy status	5	2.0
stroke	2	2.0
TOF withbrainabscess ventricular	15	28.0
tachyarrhythmia Total	1	2.0
	1	2.0
	4	8.0
	1	2.0
	2	4.0
	50	100.0

Figure 4



Comments: Out of 50 children ,maximum frequency of children admitted with sepsis with shock. Above table and bar diagram showing the frequency distribution of diagnosis.

Table 5 showing outcome of patients

	Frequency	Percent
death	25	50.0
discharge	25	50.0
Total	50	100.0

Figure 5



Table 6. showing vaso-ionotropescore distribution,(10-35=1,36-60=2,61-85=3,86-110=4).

	Frequency	Percent
1	19	38.0
2	26	52.0
	1	2.0
3	4	8.0
Valid Total	50	100.0

Figure 6



Comments: Out of 50 children maximum children received ionotope 36-60 (category2) about 52%. Above table showing the frequency and percent distribution of ionotrope. Pie chart showing the percent distribution.

 Table 7: Distribution of MEAN VIS according to

outcome

Outcome	Number	Mean	SD	Minimum	Maximum	Median	p- value
Alive	25	35.7143	20.1424	10.0000	70.0000	30.0000	0.0297
Death D	25 diag	49.2000	20.3961	15.0000	110.0000	50,0000	trong

in relation to out come.



Comments: Above table and diagram showing maximum requirements of ionotrope in death group.

Table 8 shows the ISBP variable One-Sample Statistics

Diff 50 0.440 14.27 2.022	
Din 50 0.440 14.57 2.052	

One-Sample Test

			Test	tValue=0		
			Sig. (2-	Mean	95% Confidence theDifferen	interval of ce
	Т	df	tailed)	Difference	Lower	Upper
Diff	0.216	49	0.830	0.4406	-3.641	4.52

Comment: A one samplet-Test is conducted for the difference between ISBP 0hr. with the mean ISBP hr. The test is in significant as the p-value is >0.05, at 5% level of significance i.e. no difference is accepted.



Figure8: Bland-Altman analysis of the agreement between ISBP 0hr with the ISBP meanhr. methods. Dashed line represents the mean bias; the upper and lower limits of the box represent the1.96 SD limits of agree.

Table9. shows the NSBP variableOne-SampleStatistics.

	N	Mean	Std. Deviation	Std. Error Mean
Diff	50	-4.0224	56.90877	8.04812

One-Sample Test

			Tes	tValue=0		
	Т	df	Sig. (2- tailed)	Mean Difference	95% Confidence theDifferen	Interval of ce
diff	500	49	.619	-4.02238	Lower -20.1957	Upper 12.1509

Comment: A one samplet-Test is conducted for the difference between NSBPOhr. with the mean NSBPhr. The test is n significant as the p-value is >0.05, at 5% level of significance i.e. no difference is accepted



Figure 9: Bland-Altm ananalysis of the agreement between NSBP0hr with the NSBP meanhr. methods. Dashed line represents the mean bias; the upper and lower limits of the box represent the 1.96SD limits of agreement. Table 10 A. shows the ISBP & NSBP variables One-Sample Statistics.

	N	Mean	Std. Deviation	Std. Error Mean
Diff	50	-17.1024	53.44149	7.55777

One-Sample Test

		TestValue=0						
	Т	df	Sig. (2- tailed)	Mean Difference	95% ConfidenceInterval of theDifference			
					Lower	Upper		
diff	-2.263	49	0.028	-17.10239	-32.2903	-1.9145		
Com	comment: A one samplet-Test is conducted for the							

difference between ISBP mean value. with the mean NSBPhr. the testis significantas the p-value is <0.05, at 5% level of significancei.e. no differenceis rejected.



Figure 10: Bland-Altman analysis of the agreement between ISBP mean Hr. With the NSBP mean hr.

Methods. Dashed line represents the mean bias; the upper and lower limits of the box represent the 1.96SD limits of agreement. Correlations (Table 10B).

		ISBPmean	NSBP mean
ISBPmean	PearsonCorrelation	1	.164
	Sig. (2-tailed) N		.255
		50	50
NSBPmean	PearsonCorrelation	.164	1
	Sig. (2-tailed) N	.255	
		50	50

Comment; There is low correlation between mean value of ISBP hr. with the mean value of NSBP hr. The value is 0.164.

Table11. Shows the one samplet-Test for the difference between IDBP0 hr. with the mean IDBPhr. One-Sample Statistics.

	N	Mean	Std. Deviation	Std. Error Mean
Diff	50	1.3898	11.31435	1.60009

One-Sample Test

			Tes	tValue=0		
			Sig. (2-	Mean	95% ConfidenceInterval of theDifference	
	Т	df	tailed)	Difference	Lower	Upper
diff	0.869	49	0.389	1.38980	-1.8257	4.6053

Comment: A one samplet-Test is conducted for the difference between IDBP0hr.with the mean IDBP hr. the test is insignificant as the p-value is >0.05, at 5% level of significancei.e.no bias is accepted.



Figure11: Bland-Altman analysis of the agreement between IDBP 0 hr with the IDBP means hr.methods. Dashed line represents the mean bias; the upper and lower limits of the box representthe1.96SD limits of agreement. Table12.shows the one samplet-Test for the difference between NDBP0hr. with the mean NDBP hr.

One-Sample Statistics

	N	Mean	Std. Deviation	Std. Error Mean
Diff	50	2.5193	12.94275	1.83038

One-Sample Test

		TestValue=0					
			Sig. (2-	Mean	95% Confidencel theDifference	interval of ce	
	Т	df	tailed)	Difference	Lower	Upper	
diff	1.376	49	.175	2.51934	-1.1589	6.1976	

Comment: A one samplet-Test is conducted for the difference between NDBP0hr.with the mean NDBPhr.the test is insignificant as the p-valueis>0.05, at5% level of significancei.e.no bias is accepted.



Figure12: Bland-Altman analysis of the agreement between NDBP0hr with the NDBP means hr. methods. Dashed line represents the mean bias; the upper and lower limits of the box represent the1.96SD limits of agreement. Table13A. Shows the difference of IDBP mean hr. with the NDBP mean hr.

One-Sample Statistics

	N	Mean	Std. Deviation	Std. Error Mean
diff	50	-4.0304	7.94147	1.12309

One-Sample Test

		TestValue=0						
	Т	Df	Sig. (2- tailed)	Mean Difference	95% Confidence theDifferen	interval of ce		
					Lower	Upper		
diff	-3.589	49	.001	-4.03036	-6.2873	-1.7734		

Comment: A one samplet-Test is conducted for the difference between IDBP meanhr. With the mean NDBPhr.the test is significant as the p-valueis<0.05, at5% level of significancei.e.no bias is rejected.



Figure13: Bland-Altman analysis of the agreement between IDBP meanhr with the NDBP means hr.methods. Dashed line represents the mean bias;the upper and lower limits of the representthe1.96SD limits of agreement. Fig. showing wide range of agreement.

Correlations (Table 13B).

		IDBPmean	NDBPmean
	Pearson Correlation	1	.165
IDBPmean	Sig. (2-tailed) N Pearson Correlation		.224
		50	50
NDBPmean	Sig. (2-tailed) N	.165	1
		.224	
		50	50

Comment; There is low correlation between mean value of IDBP hr. with the Mean value of NDBP hr. The value is 0.165.

Table 14.shows IMAP variable

One-Sample Statistics

	N	Mean	Std. Deviation	Std. Error Mean
diff	50	1.2059	11.40167	1.61244

One-Sample Test

		TestValue=0						
	Т	df	Sig. (2- tailed)	Mean Difference	95% Confidence theDifferen	Interval of ce		
					Lower	Upper		
diff	0.748	49	0.458	1.20591	-2.0344	4.4462		

Comment: A one samplet-Test is conducted for the difference between IMAP 0hr.with the mean IMAP hr. the test is significant as the p- value is<0.05, at5% level of significance i.e.no bias is rejected.



Figure14: B1 and-Altm ananalysis of the agreement between IMAP0hr with the IMAP meanhr. methods. Dashed line represents the mean bias; the upper and lower limits of the box represent the 1.96 SD limits of agreement.

Table15.shows NMAP variable

One-Sample Statistics

	N	Mean	Std. Deviation	Std. Error Mean
diff	50	2.6045	13.60218	1.92364

One-Sample Test

		TestValue=0					
	Т	df	Sig. (2- tailed)	Mean Difference	95% ConfidenceInterval of theDifference		
					Lower	Upper	
diff	1.354	49	0.182	2.60450	-1.2612	6.4702	

Comment: A one samplet-Test is conducted for the difference between NMAP 0hr.with the mean NMAPhr.the test is significant as the p-valueis <0.05, at5% level of significancei.e.no bias is rejected.



Figure 15: Bland-Altmananalys is of the agreement between NMAPOhr with the NMAP mean hr.methods. Dashed line represents the mean bias; the upper and lower limits of the box represent the1.96SD limits of agreement. Table 16A. Shows difference of IMAP meanhr. With the NMAP mean hr. One-Sample Statistics.

	N	Mean	Std. Deviation	Std. Error Mean
DIFF	50	-5.6614	9.21953	1.30384

One-Sample Test

	TestValue=0					
	Т	df	Sig. (2- tailed)	Mean Difference	95% ConfidenceInterval of theDifference	
					Lower	Upper
DIFF	-4.342	49	0.000	-5.66141	-8.2816	-3.0412

Comment: A one samplet-Test is conducted for the difference between IMAP mean hr. with the meanNMAP hr. the test is significant as the p-value is<0.05,at5% level of significance i.e.no bias is rejected.



Figure16 : Bland-Altman analysis of the agreement between IMAP mean hr with the NMAP mean hr .methods. Dashed line represents the mean bias; the upper and lower limits of the box represent the1.96 SD limits of agreement.

Fig. showing wide range of agreements.

Correlations (Table 16B)

		IMAP mean	NMAP mean
	PearsonCorrelation	1	.201
IMAP mean	Sig. (2-tailed) N		.089
	PearsonCorrelation	50	50
NMAP mean	Sig. (2-tailed) N+	.201	1
		.089	
		50	50

Comment; There is low correlation between mean value of IMAP hr. With the mean value of NMAP hr. the value is 0.201.

Discussion: There are different methods available to measure arterial systolic, diastolic, and mean BP, which rely on the detection of different physical events. IBP monitoring is commonly used in the ICU and normally consists of a column offluid directly connecting an arterial catheter to a pressure transducer, whichconverts the pressure waveform into an electrical signal. The signal is processed, amplified, converted, and displayed as BP value and graphic wave form. In the absence of technical errors (e.g. kinking, bubbles or clots inthe cannula/tubing,

and wrong positioning of the transducer) IBP is considered the golden standard for BP measurement in the ICU. It provides several advantages over less invasive methods: it allows quick and easy bloodsampling, it ensures close monitoring through continuous beat-to-beat BP measurement, its readings remain reliable in obese, burned. hemodynamically neonate. unstable. or arrhythmic patients, and it generates wave forms that allow pulse contour analysis .Oscillometric devices record the oscillations of pressure in a sphygmomanometer cuff during its progressive deflation: the maximal detected oscillation corresponds to MAP, while SAP and DAP are estimated according to various empirical algorithms usually not disclosed by manufacturers that may result in dramatically different accuracy levels (14). Moreover, the amplitude of the oscillations may depend on factors other thanBP, that is, the stiffness of the arteries and the site of measurement, becausein more distal arteries SAP tends to increase and DAP to decrease (15). Additionally, since the cuffs deflate at a manufacturer-specific speed that assumes a regular pulse, OBP is unreliable in arrhythmic patients. A large number of studies have demonstrated that OBP measurements obtained by wrist finger, or brachial oscillometric devices do not achieve adequate accuracy in either adult or paediatric critically ill patients (16-24). Only in a few studies from paediatric populations were the BP measurements obtained by wrist devices consistent with those recorded by IBP (25-26). Previous study shows that non-invasive methods was inaccurate amongs critically ill patients and leads to erroneous interpretations of blood pressure in particular non- invasive methods are extremily imprecise in measuring SAP(27-29). Our study shows, that there is significant statistical difference inmean SBP in between invasive and non- invasive group(p < 0.05). Our study correlates well with above study. In a study from Takci et al. (23) where IBP

monitoring was compared to OBP in critically ill preterm infants, oscillometric MAP was found to be significantly higher in the presence of hypotension (p < .0.05), while no statistically significant difference was shown for normal or high pressure values. Holt et al. (21) compared IBP with OBP and sphygm/Doppler ultrasound BP measurements in 40 paediatric ICU patients and found that OBP was higher during hypotension and lower during hypertension. A retrospective study by Wax and colleagues in anesthetized patients found that the BP values from OBP were higher than those recorded by IBP monitoring during periods of hypotension but lower during periods of hypertension (30). In our study, Figure 10,13,16 may suggest that the largest betweentechnique differences wereoutside normal BP values, there were statistically significant wide range of agreement there was poor correlation between these differences (in table10B,13B,16B) but BP values detected. oscillometric methods was often unpredictably very different from the IBP. For this reason, we suggest that Oscillometric techniques cannot be regarded as reliable alternatives to IBP specially in critical care unit.

Conclusions: This study has some limitations. First of all, the patients included in this study differed in terms of their main diagnosis. However, data from previous studies have demonstrated that underlying diseases do not contribute to the differences between different methods (31). Second, we were able to include only a few patients with BP values outsidethe normal range; more research is needed in hypotensive and hypertensivepatients, where the decision-making is particularly important but, at the sametime, the vital information may be especially in accurate.Thirdly, the mortality statistics in this study are not representative of over all ICU mortality, but reflect the outcomes of patients with invasive IAP monitoring, which selects for a hemodynamically unstable cohort with high

expected mortality. Despite these limitations, we believe our findings are important and may have valuable clinical implications for the care of critically ill patients. We found statistically significant differences between blood pressures measured invasively and non -invasively. There is wide range of agreement which is statistically significant. In most of the cases NIBP was found to be higher than IBP during the periods of hypotension and lower than IBP during the hypertension. Invasive blood pressure co-relates well with the actual blood pressure of the critically ill children. Hence IBP should be monitor in critically ill children for better monitoring which is vital in critical care setting.A larger sample size collected several centers would have been across more representative.

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