Original Research Article

A comparative study on single vs average of three measurements of blood pressure readings on the Omron HEM-7113 and the Microlife Watch BP-Home

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Abstract

Introduction: Hypertension (HT) is the most common comorbidity impacting cardiovascular disease (CVD) and death in the world. Accurate measurement of blood pressure (BP) is imperative for appropriate diagnosis, treatment, CVD risk assessments, management of HT and monitoring of a wide range of clinical conditions. Use of automated BP devices has increased convenience and reduced the expertise required for performing measurements. Additional features such as irregular pulse detection have greatly increased the utility of newer sphygmomanometers. Validation studies and inter-device comparisons are important components of the process that precede regular home use authentication of newer devices. We analysed two oscillometry based digital devices designed for self-blood pressure measurement (SBPM), namely the Omron HEM-7113 and Microlife Watch BP-Home sphygmomanometers in our study. While the former takes single measurements, the latter device automatically measures mean of three readings for higher accuracy. The aim of this study was to evaluate and compare the accuracy of the two sphygmomanometers in normal healthy volunteers. **Materials and Methods:** 92 first year MBBS students attending the department of physiology of SKIMS Medical College, and comprising equal number of participants of either sex, were enrolled in the study. Criteria for exclusion were any history of hypertension, cardiac disease, or endocrine disorders. **Results:** Out of the 92 volunteers, male participants (n=46) had a mean age(±s.d) of 19(±0.91) years while female participants (n=46) had a mean age of 20(±1.01) years respectively. There was no association of age with mean systolic pressure, mean diastolic pressure and BMI. Mean (±s.d.) BP taken with the Omron HEM-7113 which gives single reading of systolic and diastolic BP was 123.82±15.68/76.75±11.37 mmHg. The Microlife Watch BP-Home gave (mean of 3)readings of 121.09±14.18/76.90±10.33 mmHg for systolic/diastolic BP respectively. There was a non-significant difference (p=0.9) between the Microlife's mean diastolic and Omron's single diastolic pressure readings for the individuals under study. The comparison between the Microlife's mean systolic and Omron's single systolic pressure readings indicated that the mean readings are at par with the single pressure reading with a p-value equal to 0.054. The comparison results revealed a non-significant difference in both sexes. **Conclusion:** The study revealed that both the BP measuring apparatus are at par in measuring the BP in young adults.

Keywords: Hypertension, Self-blood pressure measurement, Omron HEM-7113, Microlife Watch BP-Home, sphygmomanometer.

Introduction

Around 18 million deaths are caused every year due to cardiovascular disease (CVD). An important causative (albeit avertible) comorbidity is high blood pressure (BP), also referred to as hypertension (HT). American Heart Association (AHA) in 2017 recommended a threshold of 130/80 mm Hg for diagnosing HT. The condition is normally associated with middle-aged to older adults, but incidence in the the young, including late adolescents and younger adults is increasing. Both Systolic and diastolic BP independently impact CVD risk[1].

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2010 estimates suggest that 1.39 billion adults suffer from HT worldwide, especially so in the lower and middle income countries, which account for 1.04 billion HT sufferers alone[2].

An estimated 46% of adults with HT are unaware that they have the condition. As per the World Health Organization (WHO), 54% of strokes, 47% of ischemic heart disease cases, and 13.5% of cases of all-cause mortality worldwide were attributable to elevated BP[3].

BP measurements include systolic BP which signifies pressure in blood vessels when the heart contracts and diastolic BP which indicates the pressure in the vessels when the heart rests between beats. Hypertension has often been referred to as a "silent killer". Most people with HT are unaware of the problem because of the absence of warning signs or symptoms. Thus, its imperative to measure blood pressure frequently to account for diurnal fluctuations. Certain temporary changes are due to phenomena like extreme heat or cold, physical exertion, stress, and/or pain. Although normally performed by trained personnel, individuals without medical expertise can also measure their own blood pressure using automated devices for readings[4].For more than 100 years the mercury sphygmomanometer has been used as the gold standard noninvasive method of measuring blood pressure. However, increasing awareness about mercury toxicity and potential environmental concerns has led to the replacement of mercury sphygmomanometers with alternative digital sphygmomanometers

[5]. In the hospital/emergency department, there is a physiological phenomenon known as 'White-coat hypertension' wherein patients experience anxiety and an increased blood pressure, by upto 30 mmHg or even more, with systolic showing elevations upto 50-60 mmHg. This is not seen in the newer user-friendly digital sphygmomanometers which do away with the need for specialized personnel to perform the blood pressure measurements[6]. Such Self-blood pressure measurement (SBPM) devices can be used on the wrist or upper arm. In certain cases of arrythmias and arteriosclerosis, digital meters tend to be less accurate. Newer devices have irregular pulse measuring gadgetry and some may detect certain types of arrythmias. Validation of newer BP measuring devices is vital. It is very crucial and important to measure the variability in two BP measurement methods[7]. Instruments are to be checked, standardized, and calibrated by experts as per acceptable standards such as those of the European Society of Hypertension (ESH) and/or the International Organization for Standardization (ISO)[8].

Materials and Methods

The study was conducted after obtaining permission from institutional ethics committee. The written consent of every individual was obtained. The study was done on the first year students of SKIMS Medical College Srinagar attending the department of physiology. Both male as well female students were enrolled equally (m=46, f=46). Students with history of hypertension, cardiac disease, endocrine disorders were excluded from the study. The instruments used for this study included Digital Microlife Watch BP-Home which gives mean of 3 readings and the Omron HEM-7113 digital sphygmomanometer which gives single reading of systolic and diastolic BP. The Microlife Watch BP-Home device is a highly validated apparatus and utilises an oscillometric mechanism in accordance with recommendations of ESH, AHA and the British Hypertension Society (BHS), with the added advantage of detecting pulse irregularity of atrial fibrillation. It has a blood pressure and pulse rate range of 30-280 mmHg and 40-200 beats/min respectively. The accuracy as per manufacturer is ±3 mmHg pressure and ±5% pulse rate. An automatic electric pump is utilized for inflation while an automatic pressure release valve triggers deflation[9]. The Omron HEM-7113 is also based on oscillometric principle with a pressure and heart rate range of 0–299 mmHg and 40–180 beats/min respectively. The manufacturer specified accuracy is similar to the Microlife Watch BP-Home. Fuzzy-logic algorithms are used for inflation system and deflation is achieved by an automatic pressure release valve. Although we could not find validation studies for this particular model, several studies of closely related models such as the HEM-7130 and HEM-7134 E attested to the accuracy and reliability as per ESH standards[10][11]. In both the Microlife Watch BP-Home and Omron HEM-7113, the systolic, diastolic blood pressure as well as heart rate are displayed on a liquid crystal display (LCD). The students were given a rest of 5-10 minutes before recording the blood pressure. The student were made to sit comfortably in a chair with the arm resting on a table which was kept at the level of heart. The interval of 2 minutes was given between recording with either of the two sphygmomanometers included in our study.

Results

In our study, males and females were present in equal numbers (n=46 each) with mean age (±s.d) 19 (±0.91) years for males and and 20(±1.01) years for females.

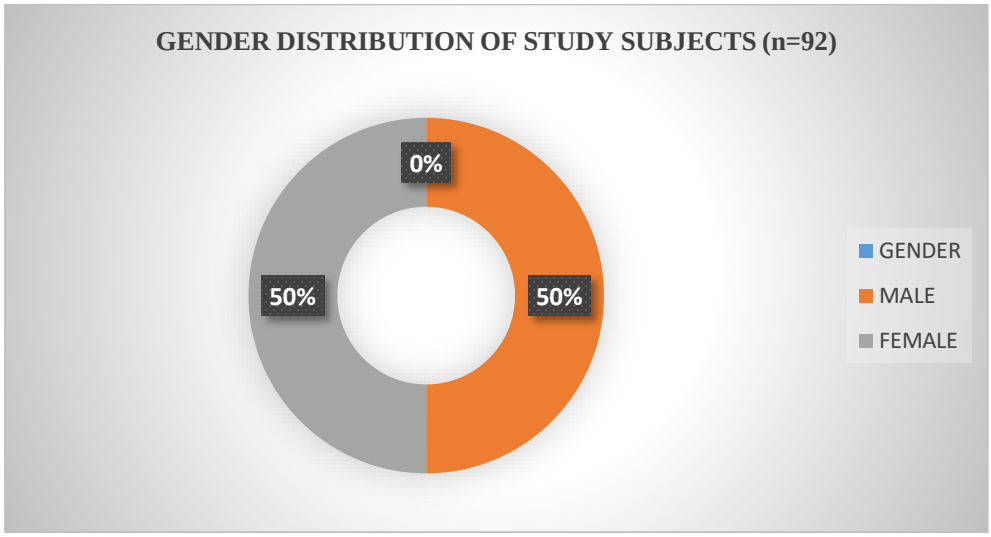
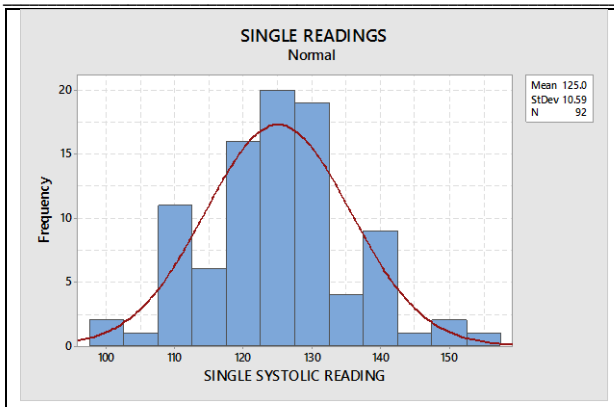


Fig 1: **Gender distribution of the study population**

Individual readings taken on the Omron HEM-7113 as well as the average of three for systolic and Diastolic BP taken on the Microlife Watch BP Home are displayed as frequency histograms (Figures 2 and 3) for the participants under study.



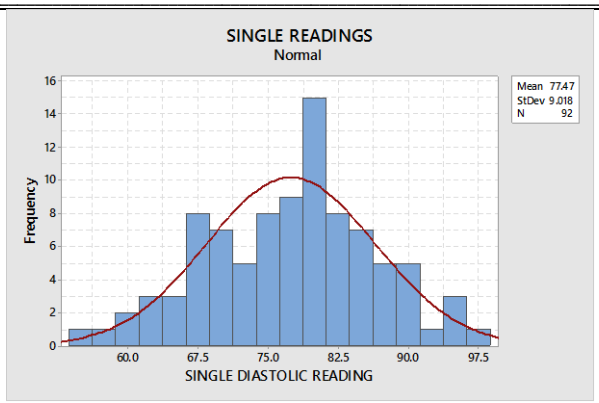
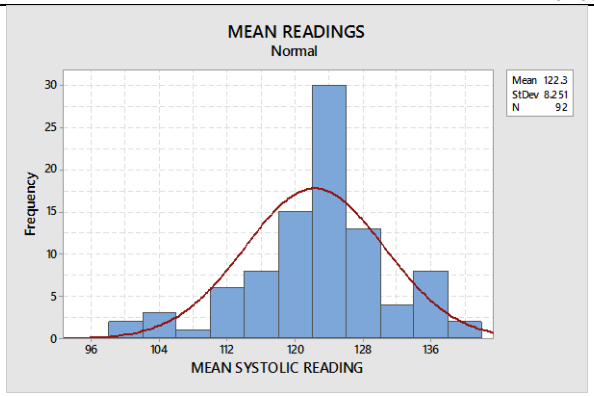


Fig 2: Histograms displaying the frequency for the Omron HEM-7113's single systolic and diastolic readings of the participants under study



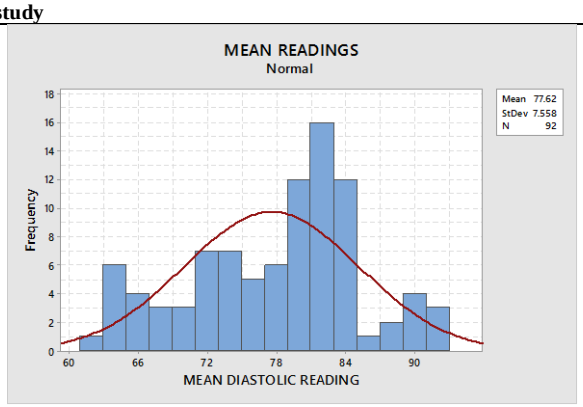


Fig 3: Histograms displaying the frequency for the Microlife Watch BP-Home's mean systolic and mean diastolic readings of the participants under study

The chi-square test was used to ascertain the association between the age of the individuals and the parameters recorded like mean systolic pressure, mean diastolic pressure and BMI. But since more than 20% of the cells had an expected count less than 5, instead of the Pearson chi-square, the likelihood ratio was taken as a measure to analyse the association between the Age and other parameters. Eventually, it was found that there was no association of age with Mean Systolic Pressure, Mean Diastolic Pressure and BMI. In other words the parameters are independent of the age of the individuals. This could be attributed to the small age range of ~3 years.

Table 1: Measure of association for age and other recorded parameters

	Mean Systolic Pressure		Mean Diastolic Pressure		BMI	
	Likelihood Ratio	**p-value**	**Likelihood Ratio**	**p-value**	**Likelihood Ratio**	**p-value**
Age	21.573	0.364	8.009	0.784	14.043	0.296

Mean (±s.d.) BP taken with the Omron HEM-7113 which gives single reading of systolic and diastolic BP was 123.82±15.68/76.75±11.37 mmHg. The Microlife Watch BP-Home gave (mean of 3) readings of 121.09±14.18/76.90±10.33 mmHg for systolic/diastolic BP respectively. The collected data was analysed in R-studio software using ggplot-2 package and the data was compared using two sample z test. The results revealed a non-significant difference (p=0.9) between the Microlife's mean diastolic and Omron's single diastolic pressure readings for the individuals under study. Similar results were obtained while comparing the mean systolic and single systolic pressure readings (P=0.054) indicating that the mean readings obtained on Microlife's Watch BP-Home are at par with the single pressure readings obtained on the Omron HEM-7113 as shown in Figures 4 and 5.

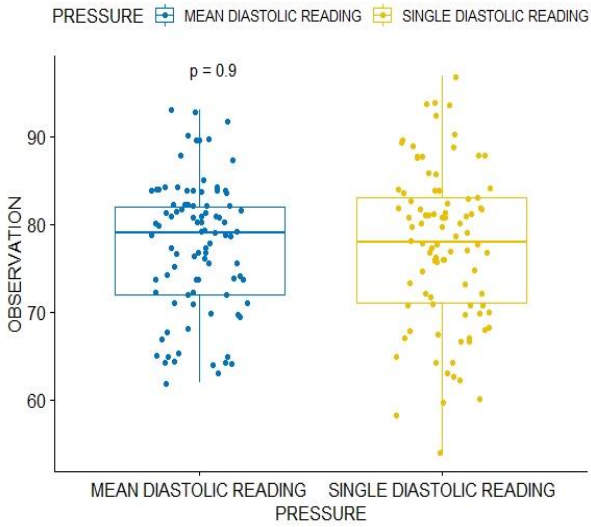


Fig 4:Boxplots along with the significance levels for comparing the mean diastolic reading with single diastolic reading

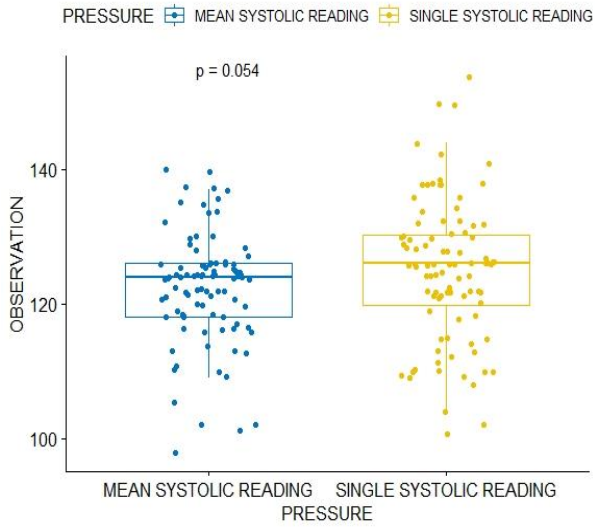


Fig 5:Boxplots along with the significance levels for comparing the mean systolic reading with single systolic reading

The Omron HEM-7113 showed mean systolic/diastolic readings of 125.78 ± 11.91 mmHg and 78.67 ± 9.13 mmHg for females and124.24 ± 9.15 mmHg and 76.26 ± 8.84 mmHg for males. The Microlife Watch BP-Home gave mean systolic/diastolic readings of 121.78 ± 9.83 mmHg and 79.19 ± 8.46 mmHg for females and 122.80 ± 6.35 mmHg and 76.04 ± 6.22 mmHg for males.

Table 2: Descriptive statistics for Single readings for Female and Male participants on the Omron HEM-7113

Variable	Sex	N	Mean	SE Mean	SD	Minimum	Q1	Median	Q3	Maximum
Single systolic reading (mmHg)	F	46	125.78	1.76	11.91	101.00	118.00	126.00	136.00	154.00
	M	46	124.24	1.35	9.15	104.00	119.5	126.00	130.00	150.00
Single diastolic reading (mmHg)	F	46	78.67	1.35	9.13	60.00	71.00	79.50	86.00	97.00
	M	46	76.26	1.30	8.84	54.00	70.75	77.00	82.00	94.00

Table 3: Descriptive statistics for Mean readings for Female and Male participants on the Microlife Watch BP-home

Variable	Sex	N	Mean	SE Mean	SD	Minimum	Q1	Median	Q3	Maximum
Mean systolic reading (mmHg)	F	46	121.78	1.45	9.84	98.00	118.00	124.00	126.00	140.00
	M	46	122.80	0.937	6.35	110.00	118.00	124.00	126.00	140.00
Mean diastolic reading (mmHg)	F	46	79.20	1.25	8.46	62.00	73.50	81.00	84.00	93.00
	M	46	76.043	0.918	6.23	64.000	71.750	76.500	81.000	88.000

The results revealed a non-significant difference (p>0.01) between the Omron HEM-7113's single systolic, single diastolic, and the Microlife Watch BP-Home's mean systolic and mean diastolic BP in both males and females as depicted from the boxplots (Figure 6 & 7).

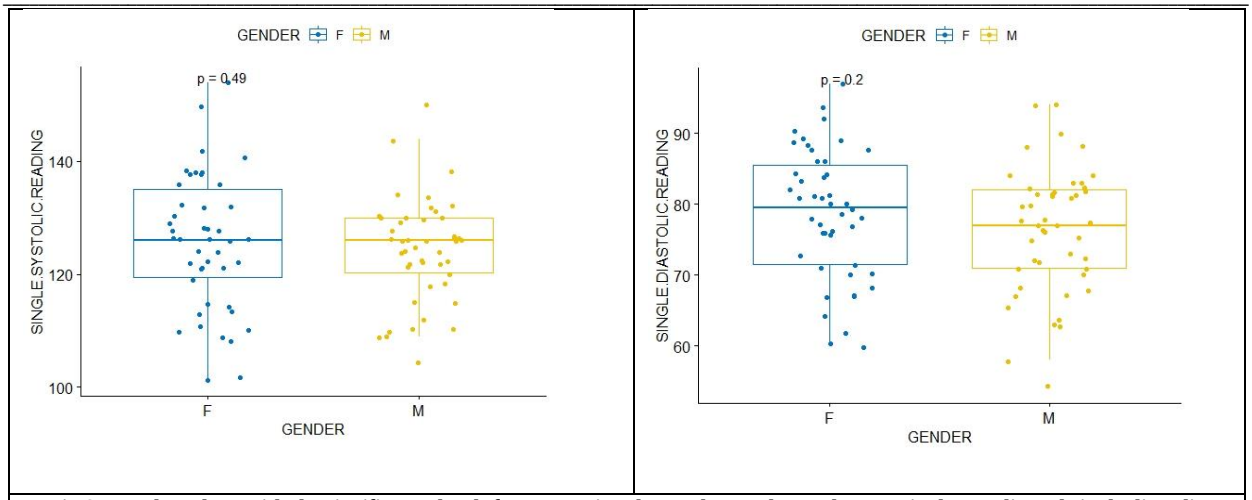


Fig 6: Boxplots along with the significance levels for comparing the genders under study w.r.t single systolic and single diastolic reading utilising the Omron HEM-7113.

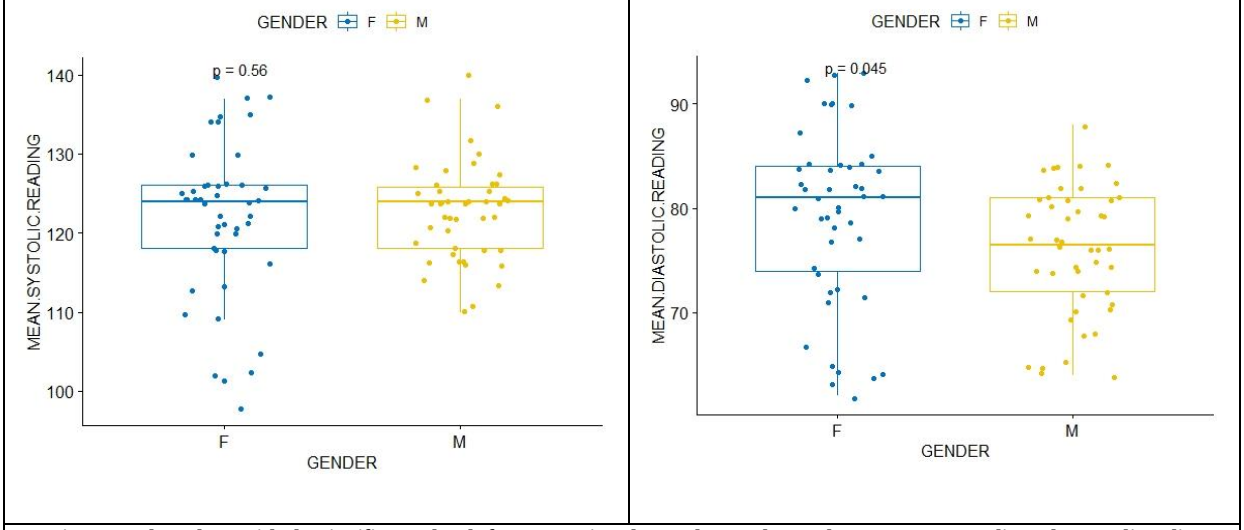


Fig 7:Boxplots along with the significance levels for comparing the genders under study w.r.t mean systolic and mean diastolic readings utilising the Microlife Watch BP-home

Discussion

Patients in the hypertensive/pre-hypertensive categories and varying levels of cardiovascular compromise require regular BP monitoring. A reliable, accurate and user-friendly sphygmomanometer which can be used with minimal assistance greatly improves ease of monitoring and simplifies medication adjustments. Several guidelines have been published with the aim of improving the accuracy of BP measurements by standardized procedures[12]. Independent validation is a pre-requisite as per European society of Hypertension (ESHA) recommendations. As per recommendations, studies on the accuracy and reliability of these devices must be published in peer-reviewed journals. ESHA were also skeptical about utility of oscillometric techniques in all situations such as in arrhythmias with a rapid ventricular response. Physician tend to be suspicious about trusting the manufacturer's largely secretive algorithmic methods utilized in designing digital devices. ESHA infact recommended retaining mercury sphygmomanometer as a gold standard in designated laboratories for validation studies[6]. Nonetheless, the previously published encouraging studies of digital Microlife Watch BP-home alleviated our concerns of using the mercury devices as standards[13]. The highly beneficial atrial fibrillation detection mechanism in Microlife's BP device has also been validated. Concomitantly, in our study, no statistically significant difference was found between the BP recordings taken using Omron HEM-7113 digital sphygmomanometer which gives single reading of systolic and diastolic BP and Microlife watch BP-Home sphygmomanometer which gives mean of 3 readings. Similar results for the blood pressure readings were observed separately for each gender. There was no statistically significant difference between the males and females for the single and the mean of 3 readings respectively.

Conclusion

There is no significant variation in the blood pressure readings recorded with the Omron HEM-7113 and Microlife Watch BP-Home sphygmomanometer. Since the systolic and diastolic blood pressure readings measured by both the devices were comparable, they can be used interchangeably in daily clinical practice as well as for SHBP. Both the devices are highly portable, and the results can be stored electronically. However, while the Microlife watch BP-Home sphygmomanometer has greater utility as it gives the mean of 3 readings, thus eliminating observer bias with the added advantage of detection of atrial fibrillation, the Omron HEM-7113 performs equally and is a more affordable option with basic features of irregular pulse detection.

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Ethical Considerations
This study has been approved by the Institutional ethical committee of SKIMS Medical college.

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