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*Original Article*

# Treatment Optimization in Newly Diagnosed Hypertensives using WHO/ISH Cardiovascular Risk Prediction Chart: Findings from 'Great Indian BP Survey', Puducherry

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## ABSTRACT

**Background:** The ever increasing cost of care for Non Communicable Diseases has led to a profound economic impact on healthcare systems especially in Low and Middle Income (LMIC) countries like India. The documentation of total risk approach as a cost effective tool and as a treatment optimization strategy is less. **Objective:** To establish the optimization of treatment using WHO/ISH risk prediction charts among the newly diagnosed hypertensives during the 'Great Indian BP Survey', Puducherry. **Methods:** 'The Great Indian BP Survey' was conducted during September, 2015 on a single day among the adults (≥18 years) including employees, students, patients and public who visited the campus area of a tertiary care institute in Puducherry, India. A standard protocol was used to measure the blood pressure (BP) by 33 different teams. Cardiovascular disease risk assessment was done for those newly diagnosed hypertensive individuals using WHO/ISH chart without cholesterol version for South East Asian region D (SEAR-D). **Results:** Of the total 9906 adults screened, mean (SD) age was 35.5 (13.5) years and 5080 (51.3%) were males. Of them, 2714 (27.4%) were found to have raised BP and out of these 1539 (56.7%) became aware about their raised BP status for the first time. Of the newly diagnosed, only 6% (93/1539) had WHO/ISH risk score of ≥20%. **Conclusion:** The study shows that optimization of treatment using WHO/ISH risk prediction can be a cost-effective approach in LMIC like India.

**Key words:** Hypertension, Newly diagnosed hypertensive, Non Communicable Disease, Treatment optimization, WHO-ISH Risk Score.

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## INTRODUCTION

Hypertension is the most common risk factor for development of cardiovascular disease (CVD).[1] Non communicable diseases account for about 82% of all deaths in low and middle income countries (LMIC); 37% of the mortality being contributed by CVDs alone. The prevalence of high blood pressure (BP) (systolic BP ≥140 and/or diastolic BP ≥90 mm of Hg) in adults aged ≥18 years was around 22% globally in the year 2014.[2] The sixth global target set by World Health Organization (WHO) in their 'Global action plan for prevention and control of NCDs 2013-20' calls for 25% of reduction in the global prevalence of high BP.[3] The eight global target states at least 50% of eligible people should receive drug therapy and counselling (including glycaemic control) to prevent heart attacks and strokes. Proportion of eligible persons aged ≥40 years with a 10-year cardiovascular risk ≥30% receiving drug therapy and counselling is being suggested as the indicator to measure this target.[4]WHO recommends a combination of 'population-wide' and 'individual risk' approach to reduce the CVD burden.[2] In LMIC the total cost of illness due to CVDs is projected to increase from 863 billion US$ to 1044 billion US$ by 2030.[5] This economic impact may be larger in LMIC which are still struggling to tackle the communicable diseases.

WHO guidelines for the primary prevention of CVDs recommend the use of total risk approach rather than individual risk approach especially in high risk groups.[2] As hypertensive are at high risk of developing CVDs and starting drug treatment for all hypertensive can cause a huge economic burden, WHO recommends adopting this strategy for its cost effectiveness. However, the documentation of total risk approach as a cost effective tool and as a treatment optimization strategy is less.

Use of individual risk approach and starting of treatment for all the newly diagnosed patients with hypertension on drug treatment so as to prevent CVDs can lead to profound economic impact. The impact can run across from individual level to family level and can spill over in impacting the health economy of the country. Thus, this paper tries to address this issue with an objective to establish the optimization of treatment using WHO/ISH risk prediction charts (SEAR-D) among the newly diagnosed hypertensive identified during a single day mass screening in a tertiary care institute, South India ('Great Indian BP Survey', Puducherry).

## METHODOLOGY

### *'Great Indian BP Survey'*

To create awareness about raised BP, Cardiology Society of India conducted a marathon BP Awareness and Monitoring Survey – 'The Great Indian BP Survey' on 21st September 2015 to detect high BP across India. As part of it, the Department of Cardiology in collaboration with Department of Preventive and Social Medicine, with the help of all the other Departments of a tertiary care institute, Puducherry, South India recorded the BP of all its employees, students, patients and public who visited the facility on that particular day from 9 am to 5 pm. After obtaining approval from the institute, 33 teams were trained to record BP of all adults (18 years) in a uniform method. BP was measured preferably in right arm after sitting for 3 minutes. The second reading was taken after three minutes only if first BP reading was high (140/90 mmHg). All measurements were done using digital BP measuring apparatus after standardization (Omron Blood Pressure Monitor, HEM-8712). A proforma

was used to collect information after obtaining written informed consent from each participant, on age (single year), gender (male/female), place of stay, history of diabetes (yes/no), heart attack (yes/no), chronic kidney disease (yes/no), elevated cholesterol levels (yes/no) and current tobacco use status (yes/no). All those who were diagnosed to have high BP were referred to Medicine Out Patient Department of the Institute for further management.

Cardiovascular disease risk assessment was done for those newly diagnosed hypertensive individuals using WHO/ISH chart for South East Asian Region D (SEAR-D). Among the two types of charts available, we have used the SEAR-D WHO/ISH charts without cholesterol version for risk stratification as we were not able to measure any blood investigations during the mass screening.[6] A previous study among rural Indian population shows there is a difference in predicting CVD risk between these two available charts.[7] However, for a lower and middle income country like India without cholesterol chart is a feasible and cost effective tool for risk stratification.CVD risk is categorized into five categories as follows: 0–9%; 10–19%; 20–29%, 30–39% and ≥ 40%. Although CVD risk calculation is appropriate for age more than 40 years in WHO/ISH risk chart, in this study newly diagnosed patients between the age of 18 and 40 years were assumed to have similar risks as that of the 40 year old person.[6]Also, we have used tobacco use as a variable rather than smoking status as given in the WHO/ISH charts for risk prediction. This modification was done keeping in the view that tobacco use in any form is hazardous and is a risk irrespective of it been smoke form or smokeless form. Also, as majority of the tobacco users in India use smokeless forms irrespective of the gender unlike smoking; this adjustment was made to predict a more accurate risk scoring. Current tobacco user was defined as those who had used tobacco at least once in the last one month prior to the survey date. Status of diabetes was captured as self-reported. To check optimization of treatment, cut off was selected at both 20% and 30% risk score. As mentioned in the practice notes given in WHO/ISH risk chart booklet, we also used one more cut off which included all those ≥20% and also BP ≥160/100 mm Hg as high risk group.[6]

The Number of people Needed to Screen was calculated as the proportion of the newly identified persons with high BP to the total number of screened subjects who had no history of high BP (rounded off to the nearest whole number). The diagnosis gap was also calculated as the proportion of the difference between the 'number of screened subjects who had no history of high BP and the newly detected persons with high BP to that of the total number of screened subjects who had no history of high BP expressed as percentage.

## DATA ENTRY AND ANALYSIS

Data were entered and analysed using IBM developed SPSS software version 20.0. Age was expressed as mean ±SD. Self-reported morbidity, gender, age categories, tobacco use, WHO/ISH risk categories; Number of people Needed to Screen and Diagnosis gap was expressed using proportions.

## RESULTS

A total of 9906 adults aged ≥18 years were screened. After scrutinising the raw data 9897were included in the final analysis. The mean ± SD age of the participants was 38.5 ± 13.5 years and 51% were males. About 5523 (55.8%) were below 40 years of age. It was revealed from mass screening that 1175 (11.9%) and 933 (9.4%) individuals had self-reported hypertension and diabetes during screening. Around 521 (5.3%) reported about their high cholesterol status. Tobacco use was reported in 904 (9.1%) of the subjects (Table 1).

Out of total 9897 individual screened, 2714(27.4%) were found to be having raised blood pressure from the survey result. Out of these, 43.3% (1175/2714) had self-reported hypertension i.e. already diagnosed and 1539 (56.7%) became aware about their raised BP status for the first time during survey (Table 2). In order to initiate treatment for these newly diagnosed hypertensivesas per predicted "total cardiovascular risk approach", risk scores were calculated using WHO/ISH chart (Table 3).

Out of 1539 newly diagnosed individuals, 883 (57.3%) were ≥40 years of age. Assuming those below 40 years would have same risk as that of a 40 year old person; total cardiovascular risk score were calculated. Majority of the individuals (86%) were having CVD risk <10% (Table 3). Only 93 (6%) individuals had their risk score more than 20%.

After stratifying the risk scores based on the hypertension category (cut off of BP ≥160/100 mm Hg), only105 (6.8%) individuals had BP ≥160/100 mm Hg. But, taking into account the risk prediction, 65 out of 105 (61.9%) had less than 20% cardiovascular risk (Table 4).

**Table 1: Socio-demographic characteristics and risk factor status of study participants (N=9897)**

| Study Characteristic | | Total, n (%) |
|---|---|---|
| Gender* | | |
| | **Male** | 5080 (51.3) |
| | **Female** | 4813 (48.6) |
| **Age category** | | |
| | **18 – 29** | 3006 (30.4) |
| | **30 – 39** | 2517 (25.4) |
| | **40 – 49** | 2116 (21.4) |
| | 50 – 59 | 1464 (14.8) |
| | **60 – 69** | 595 (6.0) |
| | **≥70** | 199 (2.0) |
| **Self-reported morbidities** | | |
| | **Hypertension** | 1175 (11.9) |
| | **Diabetes** | 933 (9.4) |
| | Heart attack | 778 (7.9) |
| | **Kidney disease** | 170 (1.6) |
| | **High cholesterol** | 521 (5.3) |
| **Personal habits** | | |
| | **Smoker** | 598 (6.0) |
| | **Tobacco chewer** | 306 (3.1) |

*Four of them were classified as others and none of them had high BP

**Table 2: Result of blood pressure measurement status distributed across hypertension status among the total population screened (N=9897)**

| | | H/O Hypertension | | Total |
|---|---|---|---|---|
| | | No | Yes | |
| **Result of Screening** | **Normal** | 7183 | 607 | 7790 |
| | **High BP (≥140/90)** | 1539 | 568 | 2107 |
| **Total** | | 8722 | 1175 | 9897 |

**Table 3: Distribution of WHO/ISH risk grading across different age groups and gender (n=1539)**

| (N=1539) | Total, n (%) | <10% risk, n (%) | 10 to <20% risk, n (%) | 20 to <30% risk, n (%) | 30 to <40% risk, n (%) | ≥40% risk, n (%) |
|---|---|---|---|---|---|---|
| **Age Category (in years)** | | | | | | |
| **18 – 39** | 656 (42.6) | 647 (98.6) | 5 (0.8) | 4 (0.6) | 0 | 0 |
| **40 – 49** | 412 (26.8) | 392 (95.2) | 8 (1.9) | 9 (2.2) | 3 (0.7) | 0 |
| **50 – 59** | 307 (19.9) | 277 (90.2) | 15 (4.9) | 2 (0.7) | 9 (2.9) | 4 (1.3) |
| **60 – 69** | 120 (7.8) | 18 (15.0) | 56 (46.7) | 40 (33.3) | 1 (0.8) | 5 (4.2) |
| **≥70** | 44 (2.9) | 0 | 28 (63.6) | 12 (27.3) | 2 (4.5) | 2 (4.5) |
| **Gender** | | | | | | |
| **Male** | 1036 (67.3) | 896 (86.5) | 78 (7.5) | 43 (4.2) | 10 (1.0) | 9 (0.9) |
| **Female** | 503 (32.7) | 438 (87.1) | 34 (6.8) | 24 (4.8) | 5 (1.0) | 2 (0.4) |
| **Total** | **1539 (100)** | **1334 (86.7)** | **112 (7.3)** | **67 (4.3)** | **15 (1.0)** | **11 (0.7)** |

**Table 4: Distribution of WHO/ISH risk grading with blood pressure cut-off at ≥160/100**

| (N=1539) | Total, n (%) | <10% risk, n (%) | 10 to <20% risk, n (%) | 20 to <30% risk, n (%) | 30 to <40% risk, n (%) | ≥40% risk, n (%) |
|---|---|---|---|---|---|---|
| **<160/100** | 1434 (93.2) | 1285 (89.6) | 95 (6.7) | 45 (3.1) | 3 (0.2) | 5 (0.3) |
| **≥160/100** | 105 (6.8) | 49 (46.7) | 16 (15.2) | 22 (21.0) | 12 (11.4.) | 6 (5.7) |
| **Total** | **1539 (100)** | **1334 (86.7)** | **112 (7.3)** | **67 (4.3)** | **15 (1.0)** | **11 (0.7)** |

*SBP →Systolic Blood Pressure, DBP→Diastolic Blood Pressure

## DISCUSSION

This study is one among the first to investigate optimization of initiation of hypertension treatment using WHO/ISH predictive risk score in India. This study shows about 27% of individuals is having hypertension based on history and result from blood pressure measurement. This is in agreement with another study done in Puducherry, India during 2015 (24%).[8] However, the study done in Puducherry was limited to those aged above 40 years and living in a rural area. But, current study was a screening survey and included people mostly from Tamil Nadu and Puducherry attending tertiary care institute on a particular day.

### *Screening*

This single day mass survey showed that about 17.6% of people who were not aware of their BP status had raised blood pressure; giving the number needed to screen to detect one unknown case of raised BP to be 'six'. This number needed to screen may be more if done in a community setting. This mass survey also found that about 48% of the already diagnosed hypertensive are having uncontrolled BP. This is in concordance with the findings from the Chennai Urban Rural Epidemiology Study (CURES–52) done in South India (54%).[9]

As the screening of hypertension involves minimal extra marginal cost in an already established set ups like the Primary Health Centres in India; this kind of mass screening surveys can be carried out at least once in a year. Although in community settings, the number needed to screen may be on the higher side than what has been found in the current study; the feasibility of this type of mass screening for hypertension is definitely a possibility followed up with effective management using total CVD risk approach.

There is no data regarding the diagnosis gap in hypertension available in public domain from SEAR countries. The current study has found that there is a high diagnosis gap (56.7%) in detecting hypertension cases in India. This gap was found to be higher than Cambodia (45.4%) but lesser than Mongolia (65.8%).[10] This calls for an assessment in screening strategies adopted in LMIC like India.

### *Treatment Optimization*

If the individual risks approach is practiced, considering the cut-off of 140 mm of Hg for systolic BP and/or 90 mm of Hg for diastolic BP, all the 1539 newly diagnosed patients need to be started on anti-hypertensive medications. But, if the total CVD risk approach with ≥30% cut-off as suggested by WHO is used then only 26 (1.7% ) of the newly detected cases needs drug treatment. Even with stringent cut off of ≥20%, the number of them to be started on drugs will be only 93 (6%). If we include the patients with those ≥160/100 mm of Hg irrespective of their WHO/ISH risk score on treatment and with also keeping the higher cut-off of 20%, still 158 (10.3%) of them only need to be started on drug treatment.

With WHO/ISH risk cut-off of ≥20%, studies done in rural India showed a varied range of risk ranging from 9.2% to 11.3%.[8-11-12] Another study done in rural Bangladesh showed that 11.1% had CVD risk of ≥20%.[13] Study done among those aged between 40 and 64 years in Cambodia, Malaysia and Mongolia showed a risk of 1.3%, 2.3% and 6% respectively (with ≥20% as cut-off).[14] But, all these studies have calculated the risk in general population, which merely serves as a reporting but do not have any practical implications. The current study was designed to show the optimization of treatment with risk scoring done only in those who are having high BP. Thus, the risk proportion is considerably low due to elimination of already diagnosed cases and who are on treatment for hypertension.

Thus, the current study shows that use of total CVD risk approach has actually reduced the proportion of people to be started on drug treatment to around 10% of all the newly diagnosed cases. This reduction has a lot of economic implication in LMIC like India which has high out of pocket expenditure. These economic benefits go beyond the direct expenditure on drugs. It also reduces the major burden of indirect expenditure occurred mostly due to visits to the health facilities for collection of drugs and also loss of daily wages.

This study has few strengths. This is one of the first studies from LMIC to use WHO/ISH risk prediction for optimization of treatment in hypertension. This is the first study from India to have estimated the diagnosis gap in hypertension. The study reports data from a large mass survey done on a single day with uniform methodology. We have extrapolated the WHO/ISH risk prediction score to those who were less than 40 years of age, considering they would have had the same risk as that of a 40 year old person. This could have overestimated the finding in this age category. However, as the more stringent cut-off was used and due to shift of hypertension to the younger population the risk prediction would serve as a major advantage in starting of drug treatment. Considering tobacco use instead of only smoking in classification of risk status in India where there is a significant number of people use smokeless tobacco in different forms would have captured a better CVD risk in present study.

The study also has few limitations. A major limitation is that the status of diabetes was from self-reporting. As BP was measured on a single visit during survey it may overestimate population of people being classified as hypertensive. The questionnaire used did not capture the data regarding any end organ damage. This could have led to an underestimate of our study findings.

This study has few implications. The study establishes a large diagnosis gap and calls for change in screening strategies adopted in the country thus far. Initiation of drug therapy as well as follow up can be optimized using total CVD risk approach. This strategy will enhance the cost effectiveness of CVD prevention in public health programs and can be considered to implement in primary health care in LMIC like India. As present study suggests total risk approach, drug management policy for high risk groups like hypertension need to be revamped considering other risks of CVD as an integrated approach. Although it's a snap shot survey, the present study also highlights poor controlled status among known hypertensive. Thus, adherence to appropriate cost effective management of hypertension is the call of hour in LMIC like India in presence of other competing health priorities. This study establishes the need to formulate uniform guidelines regarding the screening, counselling, management and follow-up of Non Communicable diseases (NCD)in a single framework in LMIC like India.

## CONCLUSION

Optimization of treatment using WHO/ISH risk prediction can be a cost-effective approach for LMIC like India. The study highlights the diagnosis gap in hypertension and the need for effective screening strategy. There is a need for development of guidelines in screening and follow-up of people detected with hypertension based on total CVD risk approach in India. Further implementation research is the need of the hour to assess the effectiveness of this approach in the programmatic mode.

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## CONFLICT OF INTEREST

The authors declared that there is no conflict of interest in this study.

## ABBREVIATION USED

**CVD:** Cardiovascular Disorder; **WHO:** World Health Organization; **ISH:** International Society of Hypertension; **BP:** Blood Pressure; **SEAR:** South East Asia Region.

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