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PROSPECTIVE, NON-INTERVENTIONAL, OBSERVATIONAL STUDY ASSESSING THE EFFECTIVENESS OF PERINDOPRIL AND PERINDOPRIL/INDAPAMIDE IN A BANGLADESHI POPULATION OF PATIENTS WITH HYPERTENSION

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ABSTRACT

Background: *In Bangladesh, it has been reported that the age-standardized prevalence of hypertension is 24.4%. The joint BHS/NICE 2011 guidelines for the treatment of hypertension were updated and now recommend that in newly diagnosed patients under 55 years of age, an ACE inhibitor can be used as the first-line treatment. Most recent guidelines for managing arterial hypertension state the combination of ACE inhibitors and thiazide diuretics as preferred combinations when considering two-drug treatment.*

Objective: *To evaluate the effectiveness and tolerability of perindopril and a fixed combination of perindopril/indapamide (4mg/1.25mg) in newly diagnosed and uncontrolled Bangladeshi hypertensive patients with or without diabetes.*

Study design*: The FIRST trial was a prospective, non-interventional, observational, outpatient study involving 76 general practitioners/primary care physicians in 7 divisions of Bangladesh.*

Patients*: Adults aged 40–65 years with newly diagnosed stage-I hypertension (BP ≥140/90 mmHg), newly diagnosed stage-II hypertension (BP ≥160/100 mmHg), or uncontrolled with previous antihypertensive treatment (monotherapy or combined therapy).*

Results: *In total, 2173 patients comprised the ITT population: 39.2. % with newly diagnosed stage- I hypertension; newly diagnosed stage-II hypertension 21.7% and uncontrolled with previous antihypertensive treatment 39.1%. Mean SBP/DBP decreased significantly (-29.29±15.35/- 13.38±8.83 mmHg; p < 0.001) from baseline (158.91±15.76/94.91 ± 9.08 mmHg) over 90 days. BP reduction was also significant in subgroup analysis: in group-I patients (n=751) receiving perindopril 4mg (-22.59±11.26/-11.11 ± 7.02 mmHg; p<0.001) and in group-II patients (n=996) receiving fixed combination of perindopril/indapamide (-34.50 ± 15.66/-14.92 ± 9.20 mmHg; p< 0.001). Treatment with perindopril and a fixed combination of perindopril/indapamide was safe and well-tolerated.*

Conclusion: *Perindopril and fixed combination of perindopril/indapamide were found to be effective and well tolerated antihypertensive treatments in the management of hypertension in Bangladeshi population.*

Keywords: *PERINDOPRIL, HYPERTENSION*

INTRODUCTION:

Hypertension is recognized as a major contributor to disease burden globally. Hypertension and its complications account for an estimated 9.4 million deaths every year.[1] It has become a significant problem in many developing countries undergoing epidemiological transition.[2] The higher the blood pressure, the greater the risks of heart attack, heart failure, stroke and kidney disease.[3] The World Health Organization (WHO) considers hypertension, or high blood pressure, to be the leading cause of cardiovascular mortality.

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The World Health Organization (WHO) raised an alarm against high blood pressure or hypertension on World Health Day-2013, as the disease kills nearly 1.5 million in Southeast Asia. Bangladesh is going through a phase of epidemiological transition from communicable diseases to non-communicable diseases (NCDs) and currently has a double burden of disease.[4] In 2010 WHO survey reports that 12 million or 18 percent of Bangladesh adults aged 25 years or above have high blood pressure, with at least half of them being at risk of grave consequences.[5] One-third of adults in Bangladesh have never got their blood pressure measured in their lifetime.

A recent study conducted in Bangladesh stated that the age-standardized prevalence of prehypertension and hypertension were 27.1 and 24.4%, respectively.(6) Among patients with hypertension, 50.1% were aware of their condition (one in two patients ignore the disease), 41.2% were under treatment, but only 31.4% had controlled hypertension. So, it is clear that hypertension is poorly controlled in Bangladesh.[6] Therefore, it is of interest to study the hypertension control rate in Bangladeshi patients who are already under treatment with any antihypertensive medication.

The joint British Hypertension Society (BHS)/NICE 2011 guidelines for the treatment of hypertension were updated and now recommend that in newly diagnosed patients under 55 years of age, an ACE inhibitor can be used as the first-line treatment.[7] Also the 2020 ISH Guidelines for the management of arterial hypertension stated ACE inhibitors and thiazide diuretics combination as a preferred combination when considering two drugs treatment. (8) In these guidelines, large scale clinical trials like PROGRESS[9], ADVANCE[14], HYVET[17], are considered where perindopril and perindopril-indapamide combinations were used.[8] Additionally, data from a number of well-designed randomized clinical studies have demonstrated that the ACE inhibitor perindopril and a fixed-dose combination of perindopril 4mg and indapamide 1.25mg (a thiazide-like diuretic), reduces the blood pressure very effectively, provides end-organ protection and reduces the morbidity and mortality risk significantly in diabetic hypertensive patients.[9]

The FIRST prospective observational study was carried out with the aim to provide data on the antihypertensive effectiveness and tolerability of perindopril and perindopril/indapamide fixed-dose combination in Bangladeshi hypertensive patients in real-world clinical practice settings.

Methods:

Study Design

The FIRST (effect of perindopril and/or perindopril/indapamide on the BP efficacy of a Bangladeshi population of patients with hypertension) study was an observational, multicenter, practice-based, open-label study conducted in Bangladesh and lasting 9 months (March 2015- November 2015). The objective of the study was to record the evolution of the blood pressure of a Bangladeshi hypertensive population, treated with perindopril or perindopril/indapamide. The second objective was to determine the effect of treatment with perindopril or perindopril/indapamide on blood pressure during the 3-month treatment in relation to demographic characteristics, individual patients' medical history and co-administered treatments.

Patients

Men and women who were at least 18 years of age or older were eligible if they had a SBP > 140 mmHg and/or a diastolic BP > 90 mmHg, or if diabetic a SBP>130 mmHg and/or a diastolic BP>80 mmHg), or if elderly (>60 yr.) SBP >150 mmHg). Newly diagnosed stage-I hypertensive patients were defined as having BP ≥140/90 mmHg but <160/100 mmHg and taking no antihypertensive medication and newly diagnosed stage-II hypertensive patients were defined as having BP ≥ 160/100 mmHg but < 180/110 mmHg and taking no antihypertensive medication. Whereas, uncontrolled hypertensive patients were defined as having BP ≥140/90 mmHg even after taking antihypertensive medication (either monotherapy or combination). The need for a prescription of perindopril or perindopril/indapamide had been decided according to the approved Summary of Product Characteristics (SPC), before the inclusion and regardless of the patient perspective to be included in the study. Patients were excluded if they were pregnant or nursing, had severe end-stage diseases or had severe neuropsychiatric diseases, cancer, serious liver, respiratory or renal insufficiency, participated in another study during the previous months, showed low patient co-operation.

A total of 2173 patients were enrolled in the study which was conducted in cardiology hospitals, cardiology clinics, private cardiology offices, and private general practitioner cabinets. A total of 76 physicians were included as investigators.

Study Conduct

Sitting blood pressure was recorded in Case Report Form (CRF) with a mercury sphygmomanometer following the instructions of '2007 ESH/ESC 2013 Guidelines for the management of arterial hypertension. At least two measurements were taken spaced by 1-2 minutes, and additional measurements if the first two are quite different. The average value was recorded. On visit 1 (W0), informed consent, demographic data, cardiovascular disease history, previous antihypertensive

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therapy adverse reactions/events, cause for discontinuation of treatment, and activities were collected as required. A recording and stratification of hypertension was done. Patients were provided with 4 mg perindopril tablets or perindopril/indapamide for 4 weeks and were not to take any other antihypertensive medications. The patients were allowed to take other necessary drugs for cardiovascular indications other than hypertension. During visit 2 (W4); after the BP measurement at this visit, the patient's physician based on clinical judgment decided whether further up-titration of perindopril and Perindopril/Indapamide was needed. Patients deemed by the physician as adequately responsive were maintained on existing medication for additional 8 weeks (a total of 12 weeks). At Visit 3, BP measurements were repeated, and patients returned all remaining study drug.

Patients were followed up and reassessed after 30 (Month 1) and 90 (Month 3) days of treatment.

Efficacy Assessments

BP changes from baseline, BP control (<140/<90 mm Hg) were assessed at week 4 and week 12. At the end of the study (week 12), the treating physician assessed the effectiveness of perindopril or perindopril/indapamide? and entered it into the record as either satisfactory or unsatisfactory. Effectiveness of treatment is considered excellent, good or satisfactory if achieved target BP i.e. SBP <140 and DBP < 90 mmHg

Safety Assessments

All patients were questioned by study personnel regarding the occurrence of adverse events (AEs) at week 4 and week 12.

The medication was purchased by the patients from the retail pharmacy. Adherence to treatment was assessed at each follow-up visit: the investigator interviewed each patient regarding the continuation of their treatment, inquired about missed doses, if any since the last visit, and ensured that the patients took their medication as prescribed on a daily basis. On the follow-up visit day, the investigator documented the time the study medication was taken a day prior to the visit date.

Statistical Analysis

The efficacy and adverse event analyses were performed on the intent-to-treat (ITT) population. Treatment adherence rates were calculated for those completing the study per protocol (the per protocol set). Data are expressed as mean ±SD or as the number and proportion of patients [n (%)]. The significance of changes in quantitative variables was tested using the standard error of difference of the means. Significant differences were defined as those with a p-value of <0.05.

Results

Patient Disposition

In total 2173 patients were enrolled into the study and comprised the ITT population. Among 2173 hypertensive patients, 851 were newly diagnosed stage-I, 472 were newly diagnosed stage- II and 850 were uncontrolled according to the criteria of ESH/ESC hypertension guidelines 2013. 2005 patients completed the study. The remaining 168 patients did not complete the study due to adverse events (n=107) or being lost to follow up (n= 61).

Baseline Characteristics

In the ITT patient population (n=2173), the mean (SD) age was 52.82±12.28 years. Patients were equally distributed by gender: male 1080 (49.7%) and female 1093 (50.3%). A total of 730 (33.6%) patients were reported to have Type 2 Diabetes. Among them, some had a significant risk of cardiovascular diseases; these include high salt intake (5.5%), acute myocardial infarction, MI (0.5%), stroke or transient ischemic attack (2.1%), Chronic Kidney Disease, CKD (1.2%), smoking (7.5%), and known family history of cardiac disease (4.8%). Among these ITT patients 297 (13.7%) had known family history of hypertension. Of these, 851 (39.2%) patients were newly diagnosed stage-1, 472 (21.7%) were newly diagnosed stage-2 and 850 (39.1%) were treated but uncontrolled. The baseline mean (SD) sitting SBP and DBP of ITT patients was 158.91 ± 15.76mmHg and 94.91 ± 9.08 mmHg respectively (shown in table-1). The mean baseline SBP/DBP was 158.91 ± 15.76/94.91 ± 9.08mmHg in overall population.

Table-1: Types of hypertensive patients (n=2173)

Type of hypertensive patients	Frequency (n)	Percentage (%)
Newly diagnosed stage-I	851	39.2
Newly diagnosed stage-II	472	21.7
Treated but Uncontrolled	850	39.1

Table-2: Baseline characteristics (n=2173)

	Frequency (n)	Percentage (%)
Age in years (mean±SD)	52.82±12.28	
Gender		
Male	1080	49.7
Female	1093	50.3
Known hypercholesterolemia	222	10.2
Known hypertriglyceridemia	143	6.6
Known family history of stroke	92	4.2
Known family history of	105	4.8

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cardiac disease		
High Salt intake	119	5.5
Diabetes	730	33.6
Smoking	162	7.5
Infarct	31	1.4
Coronaropathy	10	0.5
Heart failure	13	0.6
Betel quid chewing	52	2.4
Would you say you have enough physical activity?	20	0.9
Do you eat 5 servings or more of fruit/vegetable per day?	14	0.6
Other	61	2.8
Known family history of hypertension	297	13.7
Known family history of infarct	24	1.1
Known arsenic intoxication (water supply)	1	0.05
Compliant with diabetes therapy	74	3.4
Sedentary life style	173	8.0
Stroke/TIA	45	2.1
Acute MI (Acute myocardial Infarction)	10	0.5
Chronic kidney disease	25	1.2

Effect on blood pressure

Mean SBP and DBP values in the overall population and in each subgroup decreased progressively from baseline during the 90-day treatment period (figures 1 and 2).

Overall, there was a mean reduction in SBP of 29.29±15.35 mmHg at day 90 (to 129.57±8.56 mmHg; $p < 0.001$ vs baseline). Similarly, mean DBP decreased by 13.38±8.83 mmHg, to 81.49±5.18 mmHg ($p < 0.001$) (Fig-1).

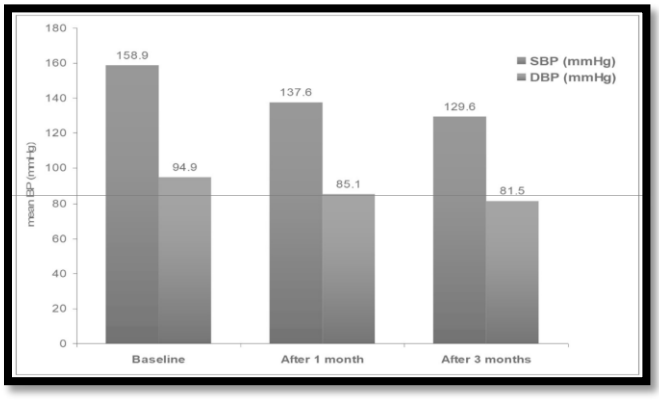

Fig-1: Bar diagram showing the mean blood pressure at baseline and at follow up visits (N=2173)

Group I and Group II Patients

Group I included the patients (n=751) who received perindopril 4 mg till the final visit and Group II included the patients (n=996) who received perindopril/indapamide. In both groups, a statistically significant (<0.001)) reduction in mean sitting BP was observed at week 12 compared with baseline. The baseline BP was 150.44/91.89 mmHg and 163.86 /96.52 mmHg for group-I & II respectively. The BP reduction was 22.59/11.11 mmHg and 34.50 /14.92 mmHg for group-I & II respectively. In both groups BP reduction was significant ($p<0.001$).

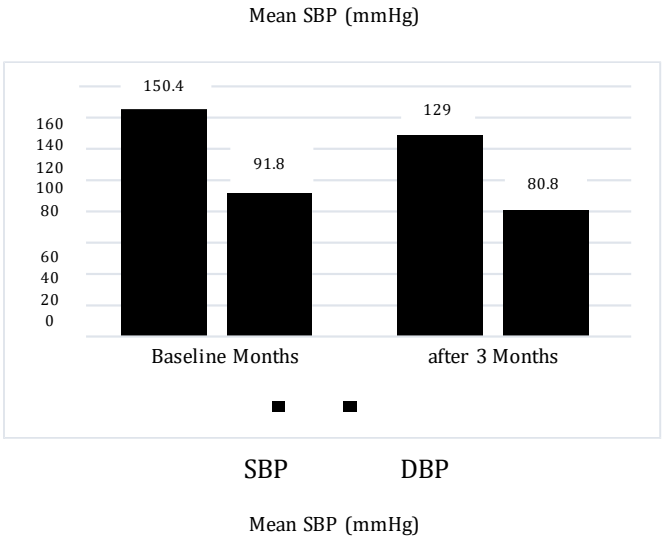

Fig-3: Bar diagram showing changes in blood pressure from baseline (Group-I patients).

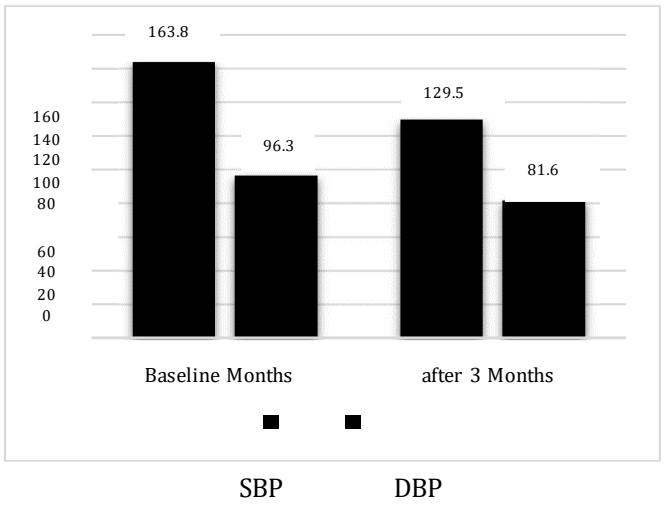

Fig-4: Bar diagram showing changes in blood pressure from baseline (Group-II patients).

Tolerability and Treatment Adherence

The overall treatment was well tolerated over the entire study duration. A total of 168 patients did not complete the study. Reasons for withdrawal during the 90-day study were loss to follow- up (n = 61), and adverse events

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(n = 107). 4.83% patients experienced the dry cough (n=105) which was the major adverse event for discontinuation. Loss to follow-up in this study comprised patients who did not attend the next scheduled visit, for reasons that were unknown, but likely included change of residence, change of doctor, and the patient feeling better, etc. All patients who completed the study (n = 2005 [92.26%]) adhered to their treatment protocol in accordance with the methods described earlier for assessment of treatment adherence.

Discussion

The main finding of the FIRST study is that the antihypertensive efficacy of monotherapy and combination therapy demonstrated in randomized controlled trials can be observed in the 'real world' setting of daily clinical practice, at least in the short term. Thus, the FIRST study a significant reduction in BP was observed in patients treated with perindopril 4mg or fixed combination of perindopril/indapamide once daily for 90 days in a primary healthcare setting. Patients with stage-I, Stage-2 and uncontrolled hypertension at baseline all responded well.

In our study, up-titration of the perindopril dose was left to the physicians' decision, and no specific target goals were preset. This permitted us to gain some insight into physicians' adherence to hypertension treatment guidelines. This large study established that overall patients tolerated perindopril and fixed combination of perindopril/indapamide well with a low withdrawal rate due to AE (4.92 %). Cough was reported in 4.83% an incidence similar to others in its class13.

The strength of this study is the large sample size and prospective design. However, this study has limitations due to the lack of control group and its nonrandomized design, although comparison of age, race, and gender breakdown of the sample suggests that the sample was representative. Due to the short duration of the study, long-term effects could not be assessed. A limitation of a study of this size is management (monitoring and data collection) of the study, which corresponded to some unavoidable loss of data from patients. In addition, the study design did not include a wash-out period, which could have compromised baseline BP due to influence of previous antihypertensive.

Chazova I, Mychka V, Kirilova M, et.al.15 studied the efficacy of Perindopril in patients with arterial hypertension in Russia. The study included 2,200 patients. The average age was 56.2 ± 0.2 years, and 42.6% were men and 57.4% were women. In the study patients, the incidence of metabolic syndrome was 44.3%, family history of cardiovascular diseases was 18.3%, and diabetes mellitus was 13.2%. Most (83.2%) patients were previously treated but had uncontrolled blood pressure. Among the study population, 538 patients have treated with Perindopril 4mg for the first 2 weeks, afterward up titrated to perindopril 8mg, and continued treatment for 16 weeks. After dosing up-titration to perindopril 8mg, the mean reduction in SBP/DBP reached -29.4/-13.3 mmHg. In our study, the mean BP reduction was 29.3/13.38 mmHg. The study differs from our study in some contexts like baseline BP was less than 1 mm hg in our study (158.86/ 8.6 versus 159.8/94.9 mmHg) and treatment duration of our study was less (12 weeks versus 16 weeks).

T. A. Netchessova, A. P. Shepelkevich et.al.16 studied the efficacy of the fixed combination of perindopril+indapamide in patients with both hypertension and type 2 diabetes were enrolled in this multicenter, prospective, open clinical study. Single-pill perindopril/ indapamide was either prescribed on its own (started or switched to from previous treatment) or added to previous therapy. Perindopril/indapamide dosage could be increased, from 4/1.25 mg to 8/2.5 mg once daily, if blood pressure (BP) was uncontrolled. BP and tolerability were assessed at 4 visits over 6 months. 397 patients were analyzed (age 57.6 ± 9.4 years, men 46 %). At baseline, systolic blood pressure (SBP) was 160.0 ± 14.3 mmHg, diastolic blood pressure (DBP) 95.2 ± 8.3 mmHg. After 6 months, SBP fell by 30 mmHg, DBP by 14 mmHg, and pulse pressure by 16 mmHg (all p\0.0001). In our study, the mean BP reduction was 34.50/14.92 mmHg. The study differs from our study in some contexts like several patients (2173 vs 397) and treatment duration of our study was less (12 weeks vs 24 weeks) and patient type (Stage-II and uncontrolled vs diabetic hypertensive patients). The antihypertensive efficacy of perindopril/indapamide in type 2 diabetes has already been established in a large-scale, randomized, morbi-mortality trial featuring 11,140 patients14.

Conclusion:

Our findings in a hypertensive population of Bangladesh suggest that perindopril 4mg and perindopril/indapamide (4/1.25) fixed combination are effective, safe, and well-tolerated antihypertensive treatments.

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