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# EFFICACY AND COMPLIANCE OF PRESCRIBING 9 DAYS CYCLIC MENUS TO SELECTED STAGE 1 AND STAGE 2 HYPERTENSIVESUBJECTS (40-70 YEARS)

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**ABSTRACT : Objective** To assess efficacy and compliance of prescribed 9 days cyclic menu on hypertensive subjects (40 to 70 yr) of urban Baroda.

Method Sixty four confirmed hypertensive subjects were purposively selected. Anthropometry and baseline blood pressure values were measured on basis of which subjects were divided into stage 1 and stage 2 hypertensive categories. Subjects were then divided into experimental and control group after matching for age, initial blood pressure levels and body mass index. Experimental group was given 9 days prescribed cyclic menus (low sodium<3 gm/day, high potassium-4gm/day, calcium-1200mg/day, magnesium-500 mg/day with partial substitution of LONa salt) earlier checked for acceptability, while control group did not receive any of these. Compliance of diet was checked using compliance card. Post intervention data - blood pressure and weight of subjects was collected after 12 weeks of intervention.

**Result** Experimental group subjects belonging to Stage 1 and Stage 2 category demonstrated fall in mean blood pressure levels by 4/1.13 mm Hg and 5/1.13–1.97 mm Hg respectively and a mean weight reduction of 1kg and 0.5 kg respectively. In contrast, control group subjects showed little change in blood pressure values and no change in mean weight.

**Conclusion** Prescription of low sodium, high potassium diet proved to be effective in reducing blood pressure levels of hypertensive subjects and the resulting positive changes in their weight and blood pressure serve to encourage them to adopt the healthy diet on long term basis.

Key words: Hypertension, Sodium, Cyclic menu, Intervention

### INTRODUCTION

Developing countries, now and in the future will have to deal with the growing burden of diet related non communicable diseases because evidences show that the major global burden of chronic non communicable diseases in adult life, amenable to dietary modifications affects the developing world more than the developed countries. The escalating death rates from non communicable diseases often occur in adults, making a particularly valuable contribution to the economy of a developing society. Mortality, morbidity and disability caused by major non-communicable diseases account for about 60% of all deaths & 47% of the global burden of disease and these rates are expected to rise further (Ghaffar, et.al., 2004). Hypertension is the leading risk factor for non communicable diseases and continues to be a common finding in the developing and developed world. Being one of the leading risk factors for development of cardiovascular diseases makes it even more essential to take public health measures to bring awareness about this diet related non communicable disease for better livelihood and to avoid future unnecessary social and economic burden. According to a study involving 5022 confirmed hypertensive subjects, although hypertension treatment (84.4% of those aware of hypertension) was high, awareness (51.8% of those having hypertension) and control (27.1% of hypertension on treatment) was low (Yi, et.al., 2009). According to WHO, by 2030, almost 23.6 million people will die from CVDs, mainly from heart disease and stroke and these are projected to remain the single leading causes of death (WHO, 2011). JNC VII recommends that dietary modifications is the first line of treatment to be advocated in hypertensive subjects who have no complications and only when these fail to control B.P., pharmacological therapy may be initiated (Seventh Report of the Joint National Commission, 2003). Even in patients who are on drugs, dietary modification enhances the effect of drugs in controlling B.P.



Hence dietary modification represents the cornerstone in the prevention and management of hypertension, irrespective of other types of treatment prescribed for hypertension. The findings of an interventional study carried out to assess the impact of dietary sodium intervention on hypertensive subjects clearly indicate that hypertensive individuals have increased sensitivity towards dietary sodium intervention and low dietary sodium intake may be effective in reducing BP among them (He, et.al., 2009).

Keeping the above points in mind the present study was planned with the broad objective:

To study the efficacy and compliance of the 9 days cyclic menus prescribed to selected hypertensives for 12 weeks by :

- 1. Recording change in blood pressure from baseline over a period of 12 weeks.
- 2. Assessing the change in anthropometric status after 12 weeks of intervention.
- 3. Evaluating the compliance card given to the patients.

#### **METHODS**

**Sample selection**: Sixty four confirmed hypertensive subjects (40-70 years), were purposively selected from a local clinic in Baroda after obtaining informed consent from them to participate in the study. Patients having their Systolic Blood Pressure (SBP) >140 mm Hg and/or Diastolic Blood Pressure (DBP) >90 mm Hg for 3 consecutive times were selected for the study. Only those subjects who had no other health complications except hypertension and whose drug and dosage would remain unchanged during study period were enrolled as study subjects.

**Study plan:** The study subjects were kept under observation for a period of one month during which their blood pressure was measured every week for 4 consecutive weeks at the same time of the day. The mean of these 4 readings was taken as the baseline blood pressure value. On the basis of the blood pressure measurements, the subjects were divided into 2 categories:

Stage 1 hypertensives- those having SBP (140-159 mm Hg) or DBP (90-99 mm Hg) and Stage 2 hypertensives- those having SBP (160-179 mm Hg) or DBP (100-109 mm Hg).

Anthropometric measurements of the subjects were taken at the time of enrollment. The subjects were matched for age, initial mean blood pressure levels and body mass index and then divided into experimental group (n=34) and control group (n=30). The subjects belonging to experimental group received 9 days prescribed menu – a diet having low sodium < 3 gm/day, high potassium - 4 gm/day, calcium - 1200mg/day, magnesium - 500 mg/day with LoNa salt advised for partially substituting the common salt (LoNa, British health foods). The diet was planned according to the daily dietary requirement and nutritive value of foods given in the book 'Nutritive Value of Indian Foods' by C.Gopalan. The method of preparation of recipe given in the menus and Compliance card were distributed to the subjects 1 week prior to intervention phase. Monitoring of the patients for the compliance of the prescribed diets during the intervention phase of 12 weeks was done by random checks during lunch and dinner hours. Compliance of the diets was checked through Compliance card. At the end of the intervention phase, baseline parameters of weight and blood were repeated on experimental group as well as control group to assess the effect of intervention on the subjects. After the 12 weeks of intervention were completed, the blood pressure of the subjects belonging to both groups was measured every week at same time of the day for a period of 4 weeks. The mean of these values was taken as the final value of blood pressure of subjects.

#### Tools used for data collection:

**Blood pressure** was measured using a sphygmomanometer as recommended by WHO study group (1978). Measurements were taken by the investigator using stethoscope and sphygmomanometer only after the doctor certified the investigator's preparedness to measure the blood pressure correctly and accurately.

**Weight** measurement was done using standardized weighing scale – DETECTO. The machine was set to zero before each measurement, weight was measured to nearest 0.5 kg.

## Nine days cyclic menu

The review of literature suggested that for hypertension, sodium restriction accompanied by increased intake of minerals like potassium, calcium and magnesium may be implicative in lowered blood pressure. The nine days diets were thus planned by Tuteja et al (1999), along a set of following considerations, in order to meet the increased allowances of potassium, calcium & magnesium and restrict sodium:



- 2000 kcal diet for adult sedentary man having no health complication other than hypertension.
- Liberal fruit intake and more amount of whole pulses in diet (rich sources of potassium, poor source of sodium).
- Fair amount of low fat milk and milk products (to meet the increased calcium needs).
- Moderate amount of vegetable A (low calorie vegetables) and cereals.
- Low amount of vegetable B (high sodium content).
- Small amount of nuts (high magnesium content).
- 3 gm sodium provided by the diet in a day (NaCl + LONa).

The menu was then tested for its efficacy in reducing blood pressure levels of hypertensives.

#### Statistical analysis

The data which was collected was statistically analyzed using appropriate statistical methods. Mean scores were calculated for data regarding weight and blood pressure measurements of the subjects and percent change in the pre and post intervention mean values of the same were calculated.

#### RESULTS

# Impact of 12 weeks of intervention on systolic and diastolic blood pressure levels of the subjects in experimental and control group

As shown in Table 1, Stage 1 category hypertensives belonging to experimental group showed a mean fall of 4 mm Hg in SBP and 1.13 mm Hg in DBP. The control group showed an increase in the mean SBP values by 0.35 mm Hg while their mean DBP value remained unchanged after the intervention. In Stage 2 category, after intervention, blood pressure levels were lower in experimental group as compared to control group. Comparison of percent change in mean SBP and DBP before and after intervention within the two groups showed a fall of 5 mm Hg in SBP and 1.97 mm Hg in DBP (Table 1). When percent fall in mean blood pressure levels of the two categories of hypertension (stage 1 and stage 2) were compared it was seen that percent fall in subjects belonging to stage 2 category was higher (SBP 2.9% and DBP 1.9%) as compared to that of subjects belonging to stage 1 category (SBP 2.6% and DBP 1.2%). The data clearly demonstrates a significant beneficial effect of the nine days prescribed menus on blood pressure levels of the hypertensive subjects. No change was observed in the blood pressure levels of two subjects who themselves reported non compliance on account of being out of station.

Table 1 - Impact of 12 weeks of intervention on systolic and diastolic blood pressure levels of the subjects in experimental and control group

Experimental group (EG) Control group (CG) N = 34N = 30Mean + SEMean + SECategory of hypertension Diastolic Systolic B.P. Systolic B.P. Diastolic B.P. B.P. mm Hg mm Hg mm Hg mm Hg STAGE 1 151.90+0.90 93.00+0.47 93.18+0.44 151.65+0.92 Baseline (B) 147.9+1.00 92.05+0.41 152.00+0.89 93.00+0.49 Final (F) ↓4 ↓1.13 ↑0.35 Change in BP (B v/s F) ↓2.6 ↓1.2 ↑0.2 Percent change (%) STAGE 2 104 80+0 64 172.16+1.77 172 00+1 85 105.00+0.70 Baseline (B) 167.16+1.99 172.20+1.75 102.83+0.64 105.00+0.75 Final (F) ↓5 ↓1.97 ↑0.20 Change in BP (B v/s F) 12.9 ↓1.9 ↑0.1

- **↓** Indicates fall in blood pressure
- ↑ indicates rise in blood pressure

**B.P.** – **Blood pressure** 

Percent change (%)

#### Impact of 12 week intervention on weight of subjects in experimental and control group

In stage 1 category of hypertension, on comparing percent changes in mean weight from baseline, it was revealed that there was a reduction of 1 kg in the experimental group, while no change was noticed in control group from its baseline values.

Similar results were obtained in the subjects belonging to stage 2 category of hypertension where mean weight reduction of 0.5 kg was observed in the experimental group, while no change was noticed in the control group from its baseline values. Stage 1 hypertensives showed a greater weight reduction (1 kg) compared to stage 2 hypertensives (0.5 kg) in the experimental group (Table 2).

Table 2 - Impact of 12 weeks of intervention on weight of the subjects in experimental and control group

Category of hypertension	Experimental group (EG)	Control group (CG)		
	N = 34	N = 30		
	Mean ± SE	Mean <u>+</u> SE		
	Weight in kg			
	Mean $\pm$ SE			
STAGE 1				
Baseline (B)	78.00 <u>±</u> 2.00	78.00 <u>+</u> 2.00		
Final (F)	77.00 <u>±</u> 2.00	78.00 <u>+</u> 2.00		
Change in BP (B v/s F)	↓ 1.00	-		
Percent change (%)	↓ 1.3	-		
STAGE 2				
Baseline (B)	62.50 <u>±</u> 1.50	63.10 <u>+</u> 1.50		
Final (F)	62.00 <u>±</u> 1.43	63.10 <u>+</u> 1.50		
Change in BP (B v/s F)	↓ 0.5	-		
Percent change (%)	↓ 0.8			

**↓ - Indicates fall in blood pressure** 

Impact of weight reduction on blood pressure levels of subjects who reduced their weights (responders) compared to those who did not lose weight (non responders) belonging to stage 1 and stage 2 category of hypertension in the experimental group

In the stage 1 category, when the mean baseline blood pressure levels of the experimental group subjects who responded to weight reduction (Responders) and those who did not respond to weight reduction (Non responders) were compared it was found that the Responders showed a mean fall of 5.35 mm Hg in SBP and 1.55 mm Hg in DBP. In the same category, the Non responders showed a mean reduction of 3.84 mm Hg in SBP and 1.2 mm Hg in DBP from its baseline value. Similar results were observed for subjects belonging to stage 2 category of hypertension. While the Responders showed a fall of 2.75 mm Hg in mean SBP and 2 mm Hg in mean DBP values, the Non Responders showed a lower fall in their mean blood pressure levels (Table3).

Table 3 - Impact of weight reduction on blood pressure levels of stage 1 and stage 2 hypertensive subjects in experimental group who reduced their weights (responders) compared to those who did not (non responders)

to those who are not (non-responders)						
Category of hypertension	Responders 'R'		Non Responders 'NR'			
	N=14		N = 20			
	Mean $\pm$ SE		Mean $\pm$ SE			
	Systolic B.P.	Diastolic B.P.	Systolic B.P.	Diastolic B.P.		
	(mm Hg)	(mm Hg)	(mm Hg)	(mm Hg)		
STAGE 1						
Baseline (B)	153.55 <u>+</u> 0.96	93.15 <u>+</u> 0.62	150.67 <u>+</u> 1.34	93.20 <u>+</u> 0.61		
Final (F)	148.20 <u>+</u> 1.42	91.60 <u>+</u> 0.61	146.83 <u>+</u> 1.32	92.00 <u>+</u> 0.55		
Change in BP (B v/s F)	↓ 5.35	↓ 1.55	↓ 3.84	↓ 1.20		
Percent change (%)	↓ 3.5	↓ 1.7	↓ 2.5	↓ 1.3		
STAGE 2						
Baseline (B)	172.25 <u>+</u> 2.38	106.50 <u>+</u> 0.83	170.12 <u>+</u> 2.11	104.00 <u>+</u> 0.70		
Final (F)	169.50 <u>+</u> 2.77	104.50 <u>+</u> 0.83	169.00 <u>+</u> 2.55	103.00 <u>+</u> 0.70		
Change in BP (B v/s F)	↓ 2.75	↓ 2.00	↓ 1.12	↓ 1.00		
Percent change (%)	↓ 1.6	↓ 1.9	↓ 0.7	↓ 0.96		

↓ - Indicates fall in blood pressure



#### **DISCUSSION**

In the present study, there was reduction in the mean blood pressure of experimental group subjects belonging to both stage 1 and stage 2 hypertension category. The results of a meta-analysis of 11 randomized controlled trials conducted to know the effect of long term modest salt reduction on blood pressure reported that a modest reduction in salt intake for a duration of 4 or more weeks has a significant and, from a population viewpoint, important effect on blood pressure in both individuals with normal and elevated blood pressure (He and MacGregor, 2004). Another meta analysis including 58 randomized trials of Caucasians with elevated blood pressure, low sodium intake reduced SBP by -4.18 mm Hg (CI: -5.08; - 3.27) (p < 0.0001) and DBP by -1.98 mm Hg (CI: -2.46; -1.32) (p < 0.0001) as compared to high sodium intake (Jurgens and Graudal, 2004) . Among the subjects belonging to experimental group, stage 1 hypertensives showed less reduction in mean blood pressure values (4 mm Hg in SBP and 1.13 mm Hg) in DBP as compared to the stage 2 hypertensive subjects (5 mm Hg

in SBP and 1.97 mm Hg in DBP) i.e. the subjects having a higher mean blood pressure at baseline showed a greater reduction in the post intervention values. The results of an interventional study conducted to know the response of confirmed hypertensives to reduced dietary sodium intake and potassium supplementation show that both systolic and diastolic BP responses to dietary interventions were higher for individuals who had higher baseline blood pressure levels (He, et.al., 2009). It was also observed in the present study that stage 1 hypertensives showed greater weight reduction (1 kg) as compared to the stage 2 hypertensives (0.5 kg) which could be attributed to the higher mean weight of the stage 1 hypertensive subjects at baseline. Also, Responders (those who lost weight) in both stage 1 as well as stage 2 hypertensives showed greater reduction in mean blood pressure levels as compared to the Non Responders. Obesity is strongly associated with hypertension and cardiovascular disease (Rahmouni, et.al., 2005). These findings clearly point out to the relation of overweight & obesity with hypertension. Higher response seen Responders as compared to Non responders clearly indicates the potential of weight reduction as a strategy for B.P. control along with reducing the intake of sodium and increasing potassium, calcium and magnesium levels. Thus, the marked fall in mean blood pressure levels of Responders can be attributed to additional impact of weight reduction. Thus, prescribing these diets for hypertensive subjects as a ready reckoner in terms of following healthy diets may help in reducing incidence and prevalence of hypertension worldwide.

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