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Semipersonalized Psychological Evaluation of Quality of Life of Hypertensive Patients in a trial with two Calcium Antagonists: a Multicenter Latinamerican Study (Lastlhy)

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ABSTRACT

The main objective of this study was to evaluate well being and physical activity of two hundred and forty eight hypertensive patients, of which, one hundred and seventy seven were female, who had previously finished the Latin Amerícan Study on Lacidipine in Hypertension (LASTLHY). This was an open study carried out in twelve clinical centers situated in Argentina, Brazil, Colombia, Mexico and Venezuela, to compare, over a period of sixteen weeks, the antihypertensive actions of fixed-dose once daily oral monopharmacotherapy of 4 rng of lacidipine (n = 120) patients VS. 30 mg of nifedipine (n = 128) patients aged between 40-65 years old, with mild to moderate hypertension beginning at the end of a four weeks placebo run-in (end of week -1). Well being and physical activity were assessed through an experimental single questionnaire, which was administered taking into consíderation the physical and cultural diversities amongst the clinical centers and patients. The questionnaire included thirteen multiple-choice and eight contingent open questions. The score to each question was multiplied by a coefficient according to the importance of each question for each patient (semipersonal ization); the coefficient was evaluated from cultural and socioeconomic information collected at the time of enrollment. The semipersonalization was carried out by a blind psychological study with respect to the medication and had a high repeatability in the assignment of personalized coefficients to the score of each question. The scores of each question were added to obtain an overall weil being and activity scoring. The possible theoretical range for the overall scoring in this study was 10- 124.

Key Words: Arterial blood pressure, Semipersonalized, Hypertension, Lacidipine, Nidedipine.

INTRODUCTION

Usually, the psychological evaluations related to the quality of life during antihypertensive therapy are in disagreement due to the differences between patients[1,2,3,4]. Moreover, it has also been demonstrated that lacidipine is about 10 times more potent than nifedipine in reducing the vasoconstrictor response induced by sympathetic stimulation of the rat smooth muscle; this action is not accompanied by cardiodepression[6].

Lacidipine has an antiatherosclerotic effect, and also, it protects the smooth muscle from damage produced by hypertension at the therapeutic doses used in humans[7,8]. It has been demonstrated in recent studies that lacidipine improves the sensibility to insulin in patients with type II diabetes[9].

MATERIALS AND METHODS

This study was performed in twelve clinical centers of five different countries: Argentina, Brazil, Colombia, Mexico and Venezuela. Range ages of patients were between 40–65 years old with diastolic blood pressure between 100 –115 mmHg after one week of placebo period. Arterial blood pressure was measured in the supine position using a sphygmomanometer. The active treatment was performed during 16 weeks. Non pharmacological treatment and a low sodium diet was prescribed at the beginning of the study. Nifedipine was prescribed to 128 hypertensive patients in daily doses of 30 mg and lacidipine (4 mg) was administered in a similar manner to 120 hypertensive patients during 16 weeks.

Semipersonalized psychological assay of quality of life

The psychological semipersonalized score was named PSS. After adding the score of each question, this result was multiplied by the personalized coefficient. A theoretic range for this study was established between 10 –124, establishing that a high score of PSS reflect a good quality of life and physical activity.

Table 1: Eleven Symtoms Improved in at Least one Treatment Group

	PREVALENCE				**WITHIN-GROUP CONTRAST**	
SYMPTOM	**LACIDIPINE**		**NIFEDIPINE**		**(Two-side p from Friedman's test)**	
	WEEK -1	**MIN**	**WEEK** -1	**MIN**	**LACIDIPINE**	**NIFEDIPINE**
Dizziness	19	9	22*	9	< 0.0001	< 0.01
Headache	57*	33	59*	30	< 0.0001	< 0.0001
Flushing	28	24	39*	24	n.s.	< 0.001
Blurred Vision	28*	18	30*	18	< 0.01	< 0.001
Visual darkning	25*	11	20*	9	< 0.001	< 0.05
Constipation	21*	8	16	9	n.s.	< 0.001
Palpitations	31	12	30	19	< 0.001	< 0.05

Cold Hands	9	4	16*	2	n.s.	< 0.0001
Tiredness	52*	35	48*	34	<0.0001	< 0.05
Malaise	20	12	19	12	<0.05	n.s.
Memory loss	47	32	42*	27	<0.05	< 0.001

** Also the maximal prevalence (week - 1 to week 16) n.s. = not significant. p > 0.05*

Table 2: Eight Symptoms Improved by Lacidipine Treatment and Three Symptoms Improved by Nifedipine Treatment

SYMPTOM	**LACIDIPINE**		**NIFEDIPINE**		**(Two-side p from Friedman's test)**	
	WEEK -1	**MIN**	**WEEK** -1	**MIN**	**LACIDIPINE**	**NIFEDIPINE**
Impaired concentration	37*	26	38*	23	< 0.05	< 0.0001
Headache	52*	39	48*	41	< 0.0001	n.s.
Sleep disturbances	24	20	31*	18	n.s.	< 0.01
Nightmares	6	4	15	5	n.s.	< 0.01
Effort dyspnea	22*	8	23*	9	< 0.0001	< 0.0001
Orthopnea	9*	3	14*	5	n.s.	< 0.05
Nicturia	49*	37	44	40	< 0.05	n.s.
Cough	20*	4	16*	8	< 0.0001	n.s.
Facial redness	11	22[a]	14	20[a]	< 0.01[b]	n.s.
Dry mouth	22	18	28	23	n.s.	n.s.
Ankle edema	15	11	23	18	n.s.	n.s.

** Also the maximal prevalence (week - 1 to week 16)*

n.s. = not significant. p > 0.05

[a] Maximal prevalence

b Impairment

Table 3: Decrease of Nervousness after Lacidipine or Nifedipine Treatment

End of study week	**LACIDIPINE**				**NIFEDIPINE**			
	0	1	2	3	0	1	2	3
-5	47	53	19	1	45	55	20	8
-3	57	48	12	3	53	52	18	5
-1	57	50	12	1	63	43	15	4
1	58	46	14	2	70	49	7	2
2	57	48	14	1	73	49	4	2
4	67	43	9	1	70	48	9	1
6	66	46	7	1	75	49	4	0
8	67	45	7	1	72	52	4	0

10	70	40	9	1	69	50	9	0
12	70	44	5	1	71	49	7	1
14	67	44	7	2	75	44	6	3
15	73	40	7	0	74	48	6	0
16	69	44	5	2	75	48	4	1

p* < 0.0001 >0.05

Values represent number of patients without (0) or with mild (1), moderate (2), or important (3) nervousness Contrast between groups (nervousness absent or present, Fisher's test): > 0.05 in all instances

**Contrast within groups including weeks -1 to 16 (Friedman's non parametric two-way analysis of variance)*

STATISTICS

Once established the size of the sample and the real value of the psychological semipersonalized score (PSS), this variable was considered as a metrical variable and was used statistically as they are used in psychological studies (Repeated measured ANOVA and Dunnet test).

Characteristic considered for the calculation of the score in the semipersonalized questionnaire

1. Age

2. Gender

3. Degree of education

4. Economical status: Whether or not the patient is economically independent, Responsibilities, economic income.

5. Daily activity: Type of work, leisure and its type, Familial commitment and their type, Daily average of sleep time (hours), Time (s) of the day at which the patient sleep.

6. Number of person with whom the patients live: Degrees of relativeness, Age, Gender.

7. Feeding: Number of daily meals,Who prepares the meals, Whether meals are prepared using fresh ingredients or consume rapid food.

DISCUSSION

Semipersonalized psychological studies evaluating the quality of life and the side effects produced by two calcium channel blockers such as lacidipine and nifedipine in hypertensive patients have not yet been performed. In previous work of phase II in 2000 hypertensive patients was reported a relative incidence of the following side effects: headache, vomit, edema, dizziness, palpitations, fatigue and gastric disorders[10].

In the present prospective study we observed a significant decrease in the side effects reported for lacidipine, this absence of side effects make this drug with an excellent tolerance and at the same time the quality of life of the hypertensive patients improve in a significant manner. However, this is not the case for nifedipine, although the questionnaire of the side effects was not in a spontaneous manner, in which we could not differentiate the score very good.

We also observed a significant decrease of the nervousness with lacidipine but not with nifedipine, which in turn give a better improvement in the daily activity and also in the quality of life and possibly at the end of the treatment the arterial blood pressure for the group of hypertensive patients treated with lacidipine will be lower than for the group treated with nifedipine.

In conclusion, our study reveal that the administration of calcium channel blockers such as lacidipine and nifedipine, and specifically, lacidipine produced less incidence of side effects and because of that also improve the quality of life.

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