

EFFICACY OF PAIN SUPPRESSION  
PROPHYLACTIC IN MIGRAINE AND MUSCLE  
CONTRACTION HEADACHE

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## INTRODUCTION

Thirty-six patients were enrolled in a double-blind placebo-controlled study in an effort to evaluate reduction in severity, duration and frequency of headaches. Half the patients used a Sham Pain Suppressor instrument and both groups were subdivided into Inderal-treated, amitriptyline-treated and nonmedication-treated subgroups.

### Results

Of 36 patients enrolled in the study, 32 completed. Of the 4 who did not complete the study 1 was excluded because of violation of protocol and 3 dropped out; all had been in the placebo group (Table 1).

Headache Index (HAI) and Headache Index Ratio (HAR) were calculated for 18 active (pain suppressor treated) and 14 placebo (Sham instrument) patients, by: severe, moderate and dull pain categories (Table 2). In the actively-treated group, the post-treated HAI was found to be significantly lower than the pre-treatment headache group for severe and dull headache categories. No significant changes were seen in the placebo group. The HAR scores of actively-treated patients with severe and dull headaches were significantly better than the matched placebo group categories. No significant changes were noted for moderate headaches in either active or placebo groups (Table 2).

The distribution of improvement was calculated and compared for severe, moderate and dull headaches between active and placebo groups (Table 3). The actively-treated patients with severe headaches scored good to excellent

for 18 active (pain suppressor treated) and 14 placebo (Sham instrument) patients, by: severe, moderate and dull pain categories (Table 2). T-

to an extent significantly greater than the placebo group. While the majority of actively-treated patients with dull headaches experienced 50% - 100% improvement, the result was not significantly better than the placebo-dull headache group. No significant changes were noted for the moderate headache category.

The frequency of patients obtaining a 50 percent or better result was compared between active and placebo status for beta-blocker-treated, amitriptyline-treated and nonmedication-treated patients (Table 4). While numbers were too small for statistical comparison, results showed the following: in the severe headache category 60% of actively-treated patients using beta-blockers and 60% of actively-treated patients using amitriptyline experienced relief (greater than 50%). Of the severe placebo group counterpart, none of 4 patients using beta-blockers and only 20% of those using amitriptyline experienced benefit. In the dull headache category 2/3 patients, actively-treated and using beta-blockers, obtained greater than 50% improvement. This was slightly higher than the placebo counterpart. There appeared to be a similar difference between active and placebo groups where no medications were used. In this non-medication-treated group, actively-treated patients fared better than the placebo group. Also, independent of medication usage, no differences between active and placebo-treated patients were noted in the moderate headache category (Table 4).

Comparing pre-treatment to post-treatment values for 7 biochemical parameters revealed no significant difference among improved resistant placebo categories (Table 5).

amitriptyline experienced benefit. In the dull headache category 2/3 patients,

## DISCUSSION

The results presented indicate that a significant number of patients have obtained a significant level of relief from severe headaches, and to a lesser extent, dull headaches. Since in all cases severe headache attacks represented migraine and dull headaches represented chronic muscle contraction headaches, it would appear that prophylactic use of the Pain Suppressor may beneficially affect the mechanisms responsible for these disorders. A possible clue to the beneficial action of the Pain Suppressor is suggested by the results obtained among concurrently medication-treated patients. Specifically, it was demonstrated that the greatest frequency of response to the Pain Suppressor was among those patients treated with either beta-blockers or amitriptyline. Virtually 60% of these patients experienced a greater than 50% reduction in their severe headaches. This was significantly better than the result for nonmedication-treated active patients. Medication-treated active patients also scored significantly better than the placebo counterpart, while no difference was noted between active and placebo groups in nonmedication-treated patients.

These data suggest that the prophylactic use of Pain Suppressor stimulation may significantly enhance the beneficial effects of either beta-blockers or amitriptyline in migraine and muscle contraction headaches - possibly via central biogenic amine changes. This latter possibility, however, could not be corroborated by analysis of serum amine values obtained before and after single treatments with the Pain Suppressor at the onset and completion of the study trial. This negative finding may have

was significantly better than the result for nonmedication-treated active

been due to an oversight in the design of the protocol whereby post-treatment blood specimens may have been obtained too early, not allowing for latency of effect. Also, serum values of biogenic amines may not be adequately reflected from central changes.

**TABLE 2**

MEAN HEADACHE INDEX(HAI)+AND HEADACHE INDEX RATIO(HAR)++  
OF SEVERE,MODERATE AND DULL HEADACHES FOR ACTIVE  
AND PLACEBO GROUPS

GROUPS	_N	HEADACHE INDICES AND INDEX RATIOS		
		SEVERE	MODERATE	DULL
ACTIVE	18			
<b>PRE-TREATMENT</b>		.035	.023	.008
POST-TREATMENT		.017	.026	.004
(HAR)		.486	1.13	.500
(%)IMPROVEMENT+++		(51.4)	(-13.0)	(50.0)
PLACEBO	14			
PRE-TREATMENT		.025	.039	.009
POST-TREATMENT		.034	.040	.007
(HAR)		1.360	1.026	.778
(%)IMPROVEMENT		(-36.0)	(-2.6)	(22.2)

+ HAI=FREQ. X DURATION ÷ TOTAL DAYS  
++HAR=POST-TREATMENT HAI ÷ PRE-TREATMENT HAI  
% IMPROVEMENT = (1.0-HAR) (100)

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TABLE 3

DISTRIBUTION OF IMPROVEMENT AMONG ACTIVE AND PLACEBO GROUPS BY HEADACHE INTENSITY CATEGORY

<u>INTENSITY</u>	<u>GROUP</u>	N	<u>% IMPROVEMENT</u>				
			<u>0-24</u>	<u>25-49</u>	<u>50-74</u>	<u>75-100</u>	<u>GOOD-EXCELLENT</u>
SEVERE	ACTIVE	17	7(41.2)	2(11.8)	1(5.9)	7(41.2)	47.1 %
	PLACEBO	13	9(69.2)	3(23.1)	0(0)	1(7.7)	7.7 %
MODERATE	ACTIVE	18	13(72.2)	3(16.7)	2(11.1)	0(0)	11.1 %
	PLACEBO	14	9(64.3)	2(14.3)	2(14.3)	1(7.1)	21.4 %
DULL	ACTIVE	16	5(31.3)	2(12.5)	4(25.0)	5(31.3)	56.3 %
	PLACEBO	14	9(64.3)	0(0)	4(28.6)	1(7.1)	35.7 %

AMONG  
INTEN.

% IMPROVEMENT

50-100%

1 (5.9%)

0 (0%)

2 (11.1%)

2 (14.3%)

4 (25.0%)

4 (28.6%)

TABLE 4

SIGNIFICANT IMPROVEMENT AMONG MEDICATION AND NON-MEDICATION TREATMENT CATEGORIES IN ACTIVE AND PLACEBO GROUPS >50%

MEDICATION CATEGORY	<u>SEVERE</u>			<u>MODERATE</u>			<u>DULL</u>		
	<u>N</u>	<u>N</u>	<u>(%)</u>	<u>N</u>	<u>N</u>	<u>(%)</u>	<u>N</u>	<u>N</u>	<u>(%)</u>
$\beta$ - BLOCKER									
ACTIVE	5	3	(60.0)	5	0	(0)	3	2	(66.7)
PLACEBO	4	0	(0)	4	1	(25.0)	4	2	(50.0)
AMITRIPTYLINE									
ACTIVE	5	3	(60.0)	5	1	(20.0)	5	2	(40.0)
PLACEBO	5	1	(20.0)	5	1	(20.0)	5	2	(40.0)
NO MEDICATION									
ACTIVE	7	2	(28.6)	8	1	(12.5)	8	3	(37.5)
PLACEBO	4	0	(0)	5	1	(20.0)	5	0	(0)

3 MED  
ACTIV

MODEL

N

0

1

1

1

1

1

TABLE 5

## MEAN BIOCHEMICAL VALUES OF STUDIED GROUPS

	RANGE		IMPROVED		RESISTANT		PLACEBO		DIED
	PRE-TX.	POST-TX.	PRE-TX.	POST-TX.	PRE-TX.	POST-TX.	PRE-TX.	POST-TX.	
ENDORPHIN	4.7-11.8	5.0-12.9	8.3	8.9	10.1	8.28	7.5	6.9	RES
CORTISOL	6.4-15.5	5.2-12.0	13.9	8.1	9.2	7.7	10.0	7.9	RE-TX
ACTH	18.2-112.	20.1-105.	52.3	46.6	67.2	59.8	58.6	59.7	LO.1
5-HT	29-102.	15.0-67.0	50.3	43.5	47.7	55.0	58.8	39.3	9.2
TRYPTOPHAN	18-63.0	18-61.0	41.0	38.2	53.3	46.3	46.6	39.5	57.2
NOR-EPI	139-491	109-425	282.0	194.0	398.0	263.0	321.0	295.0	47.7
DOPA	20-120	17-138	64.7	56.2	106.0	61.7	77.9	81.7	53.3