The New England Journal of Medicine

©Copyright, 1975, by the Massachusetts Medical Society

Volume 292

JANUARY 16, 1975

Number 3

1-PHENYLALANINE MUSTARD (L-PAM) IN THE MANAGEMENT OF PRIMARY BREAST CANCER

A Report of Early Findings

Bernard Fisher, M.D., Paul Carbone, M.D., Steven G. Economou, M.D., Robert Frelick, M.D., Andrew Glass, M.D., Harvey Lerner, M.D., Carol Redmond, Sc.D., Marvin Zelen, Ph.D., Pierre Band, M.D., Donna L. Katrych, R.N., Norman Wolmark, M.D., and Edwin R. Fisher, M.D. (and Other Co-operating Investigators)

Abstract Prolonged I-phenylalanine mustard (L-PAM) administration as an adjuvant to mastectomy in the management of patients with primary breast cancer and pathologically positive axillary nodes was evaluated by a prospective, randomized, clinical trial.

Treatment failures occurred in 22 per cent of 108 patients receiving placebo and 9.7 per cent of 103 women given L-PAM (p = 0.01). A statistically significant difference (p = 0.02) existed in favor of L-PAM relative to disease-free interval.

In premenopausal women, the difference with re-

spect to disease-free interval of treated and control groups was highly significant (p=0.008). A treatment failure occurred in 30 per cent of premenopausal patients receiving placebo and 3 per cent of those treated with L-PAM (p=0.008). Whereas a similar trend was observed in postmenopausal patients, the difference is not statistically significant. Thus, L-PAM has been demonstrated to be effective in the treatment of women with primary breast cancer, particularly those who are premenopausal. Results were achieved with minimal undesirable side effects. (NEnglJ Med 292:117-122, 1975)

Table 3. Proportion of Failures, Average Follow-up Time and Failure Rates According to Menopausal Status. FAILURE STATUS PROPORTION AVERAGE OF FAILURES RATE FOLLOW-UP

Penion

	PATIENT		
		mo	×10 ²
Premenopausal:	11 of 37=0 30	8.6	0.30/8.6=3.5

Premenopausal:			
Placebo	11 of 37=0.30	8.6	0.30/8.6 = 3.5
L-PAM	1 of 30=0.03	9.3	0.03/9.3 = 0.4
p value	0.008		0.008
Postmenopausal			

Premenopausal:			
Placebo	11 of 37=0.30	8.6	0.30/8.6 = 3.5
L-PAM	1 of 30=0.03	9.3	0.03/9.3 = 0.4
p value	0.008		0.008
Postmenopausal			
Placebo	13 of $63=0.21$	8.3	0.21/8.3 = 2.5
L-PAM	7 of 66=0.11	8.8	0.11/8.8 = 1.2

p value	0.008		0.008
Postmenopausal			
Placebo	13 of $63=0.21$	8.3	0.21/8.3 = 2.5
L-PAM	7 of 66=0.11	8.8	0.11/8.8 = 1.2
p value	0.15		0.17
Intramenopausal:			
.			

Placebo	13 of $63 = 0.21$	8.3	0.21/8.3 = 2.3
L-PAM	7 of 66=0.11	8.8	0.11/8.8 = 1.2
p value	0.15		0.17
Intramenopausal:			
Placebo	0 of 8 = 0	9.2	_

p value	. 0.15		0.17
Intramenopausal:			
Placebo	0 of 8 = 0	9.2	_
L-PAM	2 of 6 = 0.33	11.0	0.33/11.0=3.0

pa aoai,			
Placebo	0 of 8 = 0	9.2	_
L-PAM	2 of 6 = 0.33	11.0	0.33/11.0=3.0
p value	0.16		_

L-PAM	2 of 6 = 0.33	11.0	0.33/11.0=3.0
p value	0.16		

=0.02

p value for all menopausal groups