TRIAL OF PROCAINE IN OLD AGE AND CHRONIC DEGENERATIVE DISORDERS

BY

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Procaine hydrochloride (H3) has been claimed by Aslan (1960) to possess such remarkable rejuvenating properties when given to persons with degenerative disorders that it was felt a double-blind trial for a year was warranted, particularly as she also gave evidence which suggested that it had a favourable effect on the growth of tissue cultures and bacteria. A recent assessment in this country (Cashman and Lawes, 1961), though adequately controlled, was open to the criticism that the agent was given for only one month, whereas Aslan treated her patients for three months at least.

Procedure

Forty women aged 50 and over, 20 each from the long-stay wards of two chronic hospitals, were selected by two of us because of their poor general condition, as any change in this would be obvious, because they seemed likely to live for more than a year, and because their disease was stable.

The projected course of treatment and the nature of the experiment were explained to them, or their relatives if they could not understand. Only those who volunteered were accepted. Some, having read the

newspapers, were most interested to take part. These patients were divided by the third member into two groups of similar diagnostic composition and average age (Table I). The choice regarding which received procaine and which the control injections of saline was made randomly by a fourth person.

Sterile 5-ml. ampoules of 2% procaine hydrochloride at a pH of 3.3-4 and similar 5-ml. ampoules of normal saline at the same pH were prepared at the central pharmacy. These were randomly numbered so that they bore no relation to the procaine and control groups, and monthly supplies were sent to each hospital, so that those who administered the injections and those who assessed the patients did not know what was being given.

A questionnaire was prepared to assess the subject's mental and physical powers on a points system (Table II); this was done before the injections were started. The patients were weighed on accurate chair scales, care being taken to ensure that they were in the same

TABLE II

Bedfastness	Points	Intellect	Points
Totally bedfast	0	Reads books and papers { Yes 1 No 0	
Ambulant with assistance { To chair only 1 To toilet 2		Capable of understanding simple instructions { Yes 1 No 0	
Ambulant	3	Capable of recognizing staff and or relatives { Yes 1 No 0	
Incontinence		Knowledge of day or week { Yes 1 No 0	
Continent	4	Memory of date of birth { Yes 1 No 0	
Incontinent { Intermittent 2 Continuous 0		Memory of last address { Yes 1 No 0	
Emotion			
Laughs cries, or { Yes 0 rages inappropriately { No 1			
Need of sedation { Yes 0 No 1			

TABLE I

Procaine Group		Control Group	
Age	Diagnosis	Age	Diagnosis
52	Disseminated sclerosis	50	Rheumatoid arthritis; cerebral haemorrhage (right hemiplegia)
59	Cerebrovascular disease; hypertension; Parkinsonism	67	Rheumatoid arthritis; Parkinson's disease
61	" " "	67	Osteoarthritis of spine; generalized arteriosclerosis
63	Parkinson's disease	69	Diabetes mellitus
67	Cerebral thrombosis (right hemiplegia)	71	Cerebral arteriosclerosis (right hemiplegia)
67	Cerebral haemorrhage (left hemiplegia)	72	Disseminated sclerosis
68	Rheumatoid arthritis	76	Hypertension; senility
72	Cerebral arteriosclerosis; Parkinsonism	76	Senile dementia; hypertension
73	Cerebral arteriosclerosis; hypertension	76	Cerebral arteriosclerosis; Parkinsonism
73	Diabetes mellitus; hypertension; generalized arteriosclerosis	76	Cerebral arteriosclerosis (left hemiplegia)
78	Diabetes mellitus; hypertension; osteoarthritis of hips	77	Cerebral thrombosis (right hemiplegia)
78	Cerebral arteriosclerosis; hypertension; Parkinsonism	77	Senile dementia
79	Senile dementia; diabetes mellitus	77	Cerebral arteriosclerosis
80	Senile dementia	79	Senile dementia
82	Old carcinoma left breast	81	Senility; osteoarthritis of right hip-joint
84	Senile dementia	82	Cerebral arteriosclerosis
85	" "	83	Senile dementia
85	Senility; duodenal ulcer	84	" "
87	" fractured neck of femur	87	" "
91	Senile dementia	93	Cerebral arteriosclerosis

clothes each time they were weighed. Their power of grip was tested with a sphygmomanometer cuff tightly rolled. A little air was pumped in and the manometer scale adjusted to zero by varying the tension on the cuff. The patient was then encouraged to squeeze the cuff as hard as she could, and only the sustained pressure was noted. This method was adopted because the majority of the patients could not use the normal type of grip meter.

Patients were given 5 ml. of the prepared solutions twice a week by intramuscular injection for 12 weeks, followed by 12 days' rest; then the cycle was repeated. This was continued for one year.

The assessment of the patients by the prepared questionnaire, weight, and grip was done once monthly and the report posted to the third member, who stored

TABLE III.—Monthly Average Weight, Grip, and Points Scored

Month	Procaine Group					Controls				
	No.	Weight		Power of Grip (mm. Hg)	Points	No.	Weight		Power of Grip (mm. Hg)	Points
		lb.	kg.				lb.	kg.		
0	19	115.8	52.5	68.4	7.7	20	111.1	50.4	49.0	7.0
1	10	96.4	43.7	72.0	5.6	10	107.9	48.9	28.0	4.3
2	19	116.2	52.7	73.6	8.3	19	112.8	51.2	48.2	6.1
3	18	114.4	51.9	57.3	7.6	17	115.3	52.3	49.3	5.8
4	18	113.1	51.3	49.9	8.2	15	116.7	52.9	42.5	6.7
5	17	110.7	50.2	59.8	8.5	14	122.5	55.6	56.4	6.9
6	17	111.1	50.4	48.1	7.9	14	121.5	55.1	60.3	6.8
7	16	110.2	50.0	46.6	6.3	13	122.3	55.5	45.0	7.1
8	15	108.3	49.1	57.6	7.7	12	121.3	55.0	44.3	6.7
9	15	109.6	49.7	63.0	6.3	12	122.4	55.5	51.6	6.9
10	14	106.3	48.1	52.1	6.9	12	121.4	55.1	49.2	5.9
11	14	106.5	48.3	64.6	7.6	12	121.7	55.2	47.1	6.5
12	9	94.3	42.8	46.7	4.4	8	105.7	47.9	42.5	4.4

them until the end of the experiment. Thus the observers had to make a fresh assessment each month. One observer was on holiday when the time came for the second set of observations.

Results

After one year the patients were separated into the two groups, and the average weight, grip, and points score calculated for each group monthly are given in Table III.

Twelve patients died during the investigation—five in the procaine group and seven in the control group (Table IV).

TABLE IV.—Deaths

Procaine Group			Controls		
Month	Age	Cause of Death	Month	Age	Cause of Death
3	73	Gangrene left leg; arteriosclerosis; diabetes mellitus	3	93	Congestive cardiac failure; ischaemic heart disease
			3	50	Cerebral haemorrhage
			3	77	Bronchopneumonia
			4	67	Parkinson's disease
			4	71	Acute cystitis; senile brown atrophy of heart; hemiplegia due to cerebral thrombosis
5	78	Coronary artery occlusion; ischaemic heart disease			
7	87	Hypostatic pneumonia	7	81	Congestive cardiac failure; ischaemic heart disease
8	82	Congestive cardiac failure; hypertension	7	67	Bronchopneumonia
10	59	Left lower lobar pneumonia; upper respiratory infection; paralysis agitans			

Summary

Twenty women patients aged over 50, suffering from various disorders, mostly of a degenerative nature, received procaine hydrochloride for one year, according to Aslan's technique. There was no evidence from this double-blind trial that these patients benefited from this therapy. There was no significant difference between the trend of this group and that of a control group of 20 similar patients.

Our thanks are due to Mrs. H. M. Hewines, late matron of St. Mary's Hospital, Launceston, Cornwall, and to Sister D. Wyatt, of the medical ward at Wolseley Home, Plymouth, and their staffs, who gave the injections and weighed the patients; and to Mr. L. H. Bryan, M.P.S., and his staff, who prepared the injection solutions.

REFERENCES

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In response to a request from those responsible for the care of elderly people and invalids, the British Standards Institution technical committee, which recently revised the British Standard for cast iron baths (B.S. 1189), added a rectangular, shallow bath to the existing range of patterns. It is hoped that in future this type of bath will become a standard fixture in old people's residential and nursing-homes, and in dwellings built specially for the elderly. Copies of this Standard may be obtained from the British Standards Institution, Sales Branch, 2 Park Street, London W.1, price 6s. each. (Postage will be charged extra to non-subscribers.)

A CLINICAL TRIAL OF PROCAINE HYDROCHLORIDE

BY

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The postponement and the reversal of the effects of ageing have interested physicians for many centuries, long before the alchemists bankrupted themselves in the search for the elixir of life. It was therefore to be expected that Professor Anna Aslan's claims for procaine hydrochloride (Aslan, 1957, 1960) would arouse much interest. She described eutrophic and rejuvenating effects on all systems of the body, and, after treating 5,000 patients, proposed that it be dignified as a new vitamin—H3—its components, para-aminobenzoic acid and diethylaminoethanol, taking the names H1 and H2.

She visited this country in 1959 (*Brit. med. J.*, 1959a; Droller, 1960), and gave lectures which aroused much interest—lay, professional, and commercial (*Brit. med. J.*, 1959b)—and gave rise to some criticism (*Brit. med. J.*, 1959c) in that there were no satisfactory controls among her many cases.

It was felt that a properly controlled trial of this material was needed.

Design and Procedure

The generality of Professor Aslan's claims dictated the form of the trial as a strictly controlled double-blind, the basic criteria of assessment being purely clinical, although weight, haemoglobin, blood urea, and blood-pressure could be treated numerically as parameters of general health. It appeared from the literature that the serum cholesterol rose after two months' treatment (Droller, 1960).

The criteria for entry to the trial were: (1) all patients were in-patients of this unit, though some were later transferred to our halfway house; (2) the prognosis regarding life was at least one year so far as could be estimated; and (3) the patients' general and medical condition would be stable, or they would have been in-patients for at least one month, whichever was the longer. It was explained to each patient on entry that a new drug was to be used, which might or might not help him, and all agreed to collaborate.

On entry to the trial each patient was given a number which controlled his allocation to the treated or control group according to a sheet of random numbers which was held in confidence by the hospital pharmacist, who then dispensed an individually labelled bottle for each patient. The material used was a 2% solution of procaine hydrochloride in sterile water. An ampoule of Professor Aslan's material, supplied by Dr. Woodford Williams, showed no buffer on analysis, though Professor Aslan had laid some emphasis on a pH of 3 to 5 in various papers. Lüth (1960) confirms that she uses ordinary adrenaline-free procaine. The control material was sterile water. Intramuscular injections of 5 ml. were given thrice weekly for four weeks, with a rest period of 10 days between each course of 12 injections. Other treatment was given without reference to the trial, except that injections were avoided whenever possible.