

Benefits of EDTA Chelation Therapy in Arteriosclerosis: A Retrospective Study of 470 Patients

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ABSTRACT: In a retrospective study we report results of EDTA chelation in 470 patients, using a number of parameters, most of them objective. Although the patients acted as their own control, we observed improvement of 80 to 91%, depending upon the measurement used. Of 92 patients referred for surgical intervention, only 10 required ultimate surgery after or during their chelation therapy, thus saving an estimated 3 million dollars of insurance money. Our experience covers a period of 6 years and we saw no severe effects or casualties arising from the treatment. We conclude that EDTA chelation therapy is safe, effective and cost-saving.

Introduction

Intravenous administration of ethylene diamine tetraacetic acid (EDTA) has been used from the beginning of the 1950s by an increasing number of physicians throughout the world for the treatment of arteriosclerosis. In the last few years, there has been increasing criticism of surgical intervention in this disease, since it fails to prolong life, and is a temporary solution in treating a generalized, chronic condition (1). In addition, surgery damages vital tissue by means of reperfusion-released free-radical bursts (2,3). Evidence for effectiveness of EDTA chelation therapy is cumulative over many years (4-9), and the recent association of iron in the etiology of cardiovascular disease (10) makes the technique worthy of complete acceptance today.

It has been proved effective in a number of clinical trials (1 1-16). The impact of oxidative processes on age-related illness is a relatively new science, which began in the late fifties. The impact of oxygen derived free radicals on the occurrence of reperfusion damage is well documented (2-5,8,9). That the method is ignored here in Denmark may be due to Lack of understanding of the importance of these processes.

Another possible explanation may be the harsh attitude of the Danish vascular surgeons from the first. introduction of chelation therapy in Denmark in 1987. A study of 153 patients with claudication was published in three different journals in 1991 and 1992 (1749). This study, which is seriously defective, has been publicly opposed (20,21). It is the only existing study that did not show a significant benefit from EDTA therapy. The results were better in the treatment group, but the effect was reportedly not statistically significant.

Materials and Methods

This study included 470 patients with claudication and/or angina pectoris, who received at least 15 treatments. There were 159 women and 311 men. Of these, 206 were older than 69 years, 92 between 65 and 69, 90 between 60 and 64, and 82 under 60 years. Diagnosis was verified by systolic ankle-arm blood pressure index (Doppler technique), and by stress test on a treadmill. All were interviewed and examined by a physician before and after treatment

Method

All patients were given I.V. infusions of 500 ml sterile water with Na₂EDTA, 50 mg/Kg (Maximum 3 grains) and the infusion included vitamin C, sodium bicarbonate and magnesium as prescribed in the protocol of the American College for Advancement in Medicine (ACAM) (22). In addition, the patients were provided with an oral high dose vitamin/mineral supplementation without iron and copper, 6 tablets a day. Before treatment, a determination was made of blood hemoglobin, erythrocyte sedimentation rate, fasting blood glucose, creatinine, creatinine clearance, total and HDL cholesterol, triglycerides, leucocytes, uric acid, sodium and potassium.

All patients were counseled by both verbal and written communication on the importance of physical exercise, proper nutrition and omitting tobacco. Treatments were administered on an outpatient basis and continued until the patients had a stable clinical situation. This usually required 30 treatments of 3-4 hours duration over a period of 3-4 months. Final assessment was made on completion of treatment and again 2 months later when complete physical examination was repeated.

Patients with claudication had their ankle-arm index, walking distance, foot temperature, pain at rest, skin color of feet and healing of wounds assessed and registered. Subjective judgment of resting pain was rated on a scale from 1-3. Patients with angina pectoris had their working capacity measured on a treadmill, and ST depression by electrocardiogram. Any arrhythmias, blood pressure, body weight and kidney function were noted. The subjective judgment of results was rated on a scale from 1 to 3 with regard to the number of attacks of angina pectoris and consumption of nitroglycerin (1: worse 2: unchanged \pm 10%, and 3: improved). Medications, general state of health, energy level, smoking habits, hearing, visual sense and presence or absence of "dizziness" were recorded.

Results

Results of the 470 patients completing treatment are shown in Tables 1 through 5. Table 1 shows the sex distribution and results in 265 patients with myocardial ischemia. Of these, 101 over the age of 69 were improved, 6 were the same and one was worse. Of those between 60 and 69 years, 93 were better, 9, unchanged and 1 was worse. Below the age of 60, 47 were better, 7 unchanged and none were worse. The two patients who were worse were the only ones with angina pectoris who received less than 31 treatments.

In the group with claudication, including 262 patients, we found an improvement in 82, distributed according to age and sex as shown in Table 2. Table 3 shows the ankle/arm

ratios which were improved in 82%. Walking distance, which includes both claudication and myocardial ischemia patients, was improved in 87% of the patients.

Figure 1 shows the numbers of patients threatened with amputation or coronary by-pass surgery before and after EDTA chelation therapy. Several of the patients in the claudication group started treatment very late in the course of the illness. Of 44 who had problems with wound healing, 31 improved, 11 were unchanged and 2 became worse. Of 137 who complained of cold feet, 110 improved, 27 were unchanged and none became worse (Table 3)

In the group with angina pectoris, many were so severely disabled that they had been refused bypass surgery, and no other medical treatment was offered. As shown in Table 4, of 253 patients with electrocardiographic S-T depression, 175 showed improvement, 74 were unchanged and 4 had increased S-T depression. The average blood pressure decreased in 109 patients, 37 were unchanged and one had a higher blood pressure. Working capacity was assessed in both myocardial ischemia and claudication patients. This was measured in Joules by computerized ergometry. Of 318 patients undergoing this study, 271 showed improvement (85%).

TABLE 1

This Shows Results of Treatment of 265 Patients with Myocardial Ischemia. Of 65 Patients Referred for Bypass Surgery, 58 did not require it after their course of chelation.

	Worse	Same	Better	% Improved
Sex of Patient:				
Female	-	7	69	91%
Male	2	15	172	90%
Age-groups of patients:				
Over 69 years	1	6	101	93%
65-69 years	-	4	48	92%
60-64 years	1	5	45	86%
Under 60 years	-	7	47	87%
Referred to: Before Chelation By-Pass				
Dilatation	-	1	2	67%
After Chelation By-Pass	1	5	1	0%

Dilatation	-	1	2	67%
No. of Treatments:				
Less than	2	16	144	88%
31-35	-	3	40	93%
36-40	-	1	20	95%
41-50	-	-	30	100%
More than 50	-	2	7	78%

TABLE 2

This Shows Results of Treatment of 262 Patients with Intermittent Claudication. Of the Patients Referred for Amputation, 24 of 27 Legs were Spared Following Their Course of Chelation.

	Worse	Same	Better	% Improved
Sex of Patient:				
Female	2	18	76	77%
Male	1	24	140	84%
Age-groups of patients:				
Over 69 years	2	21	105	80%
65-69 years	1	9	44	80%
60-64years	-	8	39	83%
Under 60 years	-	4	29	88%
Referred to:				
Before:				
Y-Prosthesis	-	2	7	78%
Amputation	-	2	25	92%
After:				

Y-Prosthesis	-	1	2	67%
Amputation	1	-	2	0%
No. of Treatments:				
Less than 3l	3	38	125	73%
31-35	-	4	33	89%
36-40	-	-	25	100%
41-50	-	-	24	100%
More than 50	-	-	10	100%

FIGURE 1

This provides a graphic representation of the data shown in Tables 1 and 2. The first column represents the number of patients referred for surgery. The second column shows the number that required surgery after completing chelation.

FIGURE 1

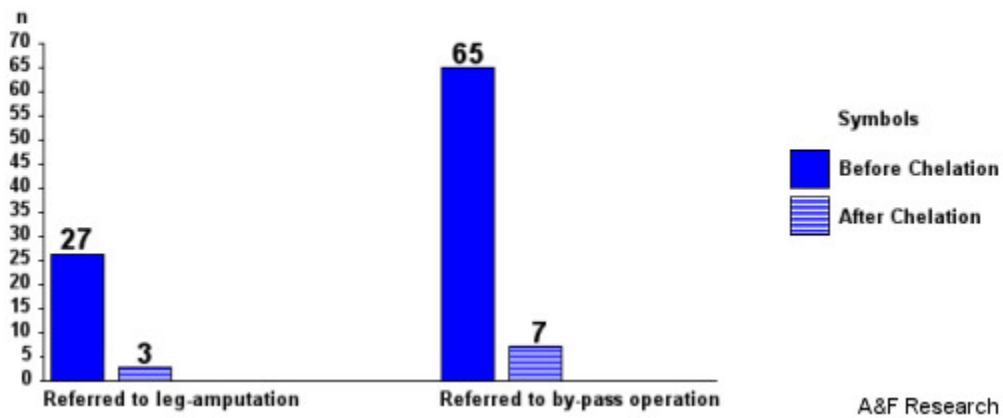


TABLE 3

This is Primarily to Show Results in the 262 Patients with Intermittent Claudication. However, "Walking Distance" Includes some Patients with Angina.

	Worse	Same	Better	% Improved
Ankle/Arm BP Ratios	3	42	217	82%
Wound-healing	2	11	31	66%

Rest-pain	1	15	87	83%
Foot-temperature	-	27	110	80%
Skin colour of feet	1	19	64	75%
Walking Distance	3	33	272	87%

FIGURE 2

Claudication. This is a graphic presentation of the same data as revealed in Table 3,

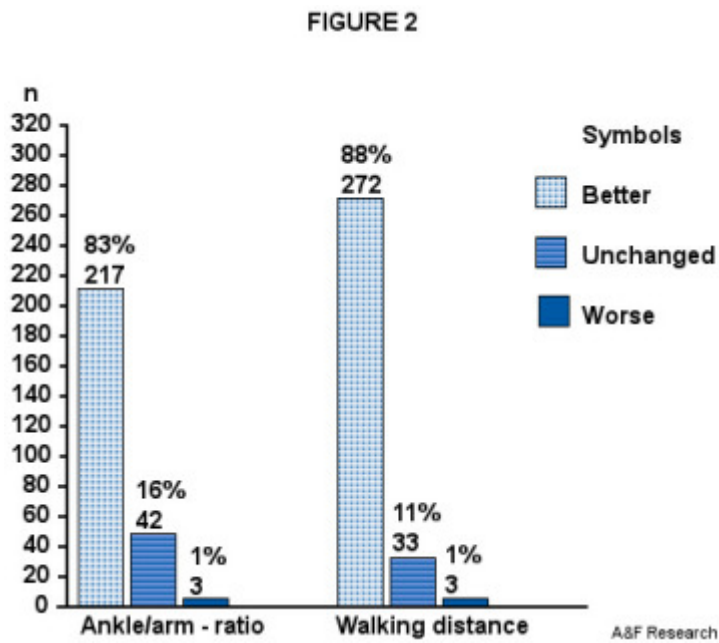


TABLE 4

Working Capacity, Tested by Computerized Ergometry, Refers to both Patients with Angina and Intermittent Claudication who were Tested by this Method. The Rest of the Table Refers to Those with Coronary Heart Disease.

	Worse	Same	Better	% Improved
ST-Depression	4	74	175	69%
Arrhythmia	-	24	39	62%
Blood pressure (mean)	1	37	109	73%
Angina Pectoris	2	22	241	91%
Nitroglycerin Demand	2	16	189	91%

Working Capacity (objective)	4	43	271	85%
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FIGURE 3

Myocardial. This is a graphic presentation of the same data as revealed in Table 4.

FIGURE 3

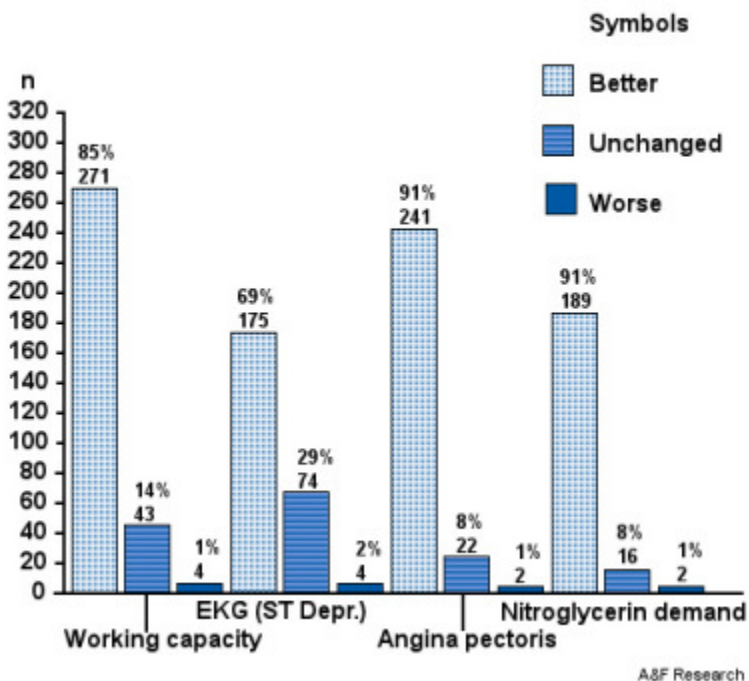


TABLE 5

This Shows the Results of Evaluating Subjective Symptomatology in the Entire Group of 470 Patients. Renal Function was judged by Creatinine Clearance.

	Worse	Same	Better	% Improved
General Wellbeing	4	41	371	88%
Working Capacity (subjective)	6	42	363	87%
Energy/Initiative	7	38	319	86%
Vertigo	4	13	71	76%
Memory	2	19	48	67%
Medicine Consumption	5	98	212	66%
Hearing	2	60	121	65%
Visual Sense	5	22	54	60%

Renal Function	8	13	100	48%
Smoking Habit	2	84	61	40%
Overweight	13	107	36	1%

Of 207 patients using nitroglycerine, 189 reduced their consumption. Most of them were able to discontinue its use altogether. However, 16 continued with the same dose as before and 2 had to increase their dose.

No morbidity or serious side effects directly due to the treatment were reported in the clinics from 1987 to 1993. Table 5 shows the benefits in other parameters as well as it shows the difficulty in handling the problems of smoking and excess body weight. Fortunately only 147 of the 470 were smokers initially and 86 of them continued to smoke during the treatment.

Subjective improvement in coldness of feet, increased energy and work capacity, together with striking improvement in general condition were noted by most patients. Several of the male patients reported improved sexual potency, improved sight and hearing, and symptoms like migraine and tinnitus disappeared as an unexpected bonus for many patients. Although a placebo effect could not be ruled out, of course, the degree of improvement was remarkable and exceeds our previous experience with similar patients. Of 65 patients who were referred for coronary by-pass surgery, 58 did not require it after chelation therapy. Of 27 patients awaiting amputation as the only surgical offer of treatment, 24 avoided surgery.

Discussion

In our view, the beneficial results that we observed were far in excess of the 10-15% improvement that is usually seen in the placebo group of a controlled study. Same patients with claudication who were unable to walk more than 100 feet could walk painlessly for 2 miles or ride several miles on a bicycle after their treatment. We found convincing evidence that EDTA infusion therapy is effective in treating arteriosclerosis. Our results are identical with those of other similar studies (12,16). Although the study registration was done in two sections, one in March 1991, and one in April 1993, the results are the same. It is evident that results are reproducible from patient to patient, from clinic to clinic and internationally.

Such results have led to a worldwide increase in interest in chelation therapy in medical circles familiar with the theoretical principles of oxygen & rived free radical pathology. This interest has resulted in an increased scientific effort by a number of investigators (4,12-16,23. 26)

On the basis of such well published data, it seems to us that it is unethical to wait for a randomized, double blind, cross-over study to approve EDTA chelation for the treatment of arteriosclerosis, though we admit that such a FDA approved study would act the seal

on this therapy if it were to be as successful as we believe it would be, based on our results and those already published. Since there is massive evidence that the spontaneous development of arteriosclerosis is the number one killer disease in the Western World, there is every reason to hasten to increase our efforts to bring this important therapy into mainstream medicine as soon as possible.

Conclusion

In spite of the weakness and possibility of bias in a retrospective study without a control group, the historical record for treatment of this disease is poor. We find it difficult not to conclude that EDTA chelation therapy is a safe, effective and cost-saving method of improving angina pectoris and intermittent claudication. We urge a massive and concerted effort to study the method further.

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