THE EFFECT OF EDTA CHELATION THERAPY PLUS MULTI-VITAMIN/TRACE MINERAL SUPPLEMENTATION UPON VASCULAR DYNAMICS (ANKLE/BRACHIAL SYSTOLIC BLOOD PRESSURE)

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Summary

A study of 117 limbs in 77 elderly males and females with vascular stenosis as judged by the Doppler method revealed that EDTA chelation therapy with supportive multivitamin/trace mineral supplementation reduced vascular insufficiency significantly in approximately 60 days with 26 infusions. This, as far as we can determine, is the first such demonstration.

Bernstein and his contributors (1), in their monumental Noninvasive Diagnostic Techniques in Vascular Disease make four cogent points. First, noninvasive diagnostic instrumentation and interpretation have now reached an opertional state of excellence. Second, some of the procedures are simple and practical enough to warrant their use in the general private practice environment. Third, of all of the possible available single diagnostic parameters, the ankle/brachial systolic blood pressure is preferred. Fourth and lastly, these diagnostic and predictive measures can be employed to monitor surgical and even medical treatment. Surprisingly, no mention is made of the possible therapeutic potential of EDTA chelation.

The uniqueness of this study lay in the fact that it utilizes a noninvasive method in a general private practice atmosphere with emphasis on the ankle/brachial systolic blood pressure before and after the administration of EDTA chelation therapy in conjunction with multivitamin and trace mineral support.

Review of the Literature

There is general agreement that the presence of occlusive arterial disease may be ascertained in a large percentage of patients by means of a careful history and physical examination. There is also no question that more precise information about the location and severity of the lesion(s) may be derived by angiography. Clinical assessment is obviously highly subjective; angiography is invasive. The quantification of blood pressure can be derived by noninvasive techniques easily, repeatedly, quantitatively, and with objectivity and so provide a reasonable sensitive index of the occlusive process.

It is true that segmental blood pressure readings at various levels in the limbs provide valuable information. However, for routine assessment of the occlusive state in the lower limbs, the ankle has been commonly used since it reflects, better than any other single reading, the overall state in the proximal vessels (2, 3, 4).

The ankle/brachial relationship has been studied in the diagnosis and as a monitor during both medical and surgical treatment. As far as we can establish, there has never been a study of the effect of EDTA chelation upon vascular dynamics measured by this particular noninvasive technique. Parenthetic mention should be made that only one report has appeared in the literature (5) demonstrating the salutory effect of EDTA chelation utilizing oculocerebrovasculometry.

Method of Investigation

The experiment included 41 males and 36 females in whom 117 limbs (60 male; 57 female) were examined (Table I). Segmental blood pressures in the lower extremities along with brachial pressures were determined at the beginning and the end of the study (Model 806-C Directional Doppler, Parks Electronic Laboratory, Beaverton, Oregon) which lasted, on the average, 60 days. Treatment included a series 26.2±8.1 EDTA, each 3 gm infusions, along with multivitamin/trace mineral supplementation. All subjects demonstrated an initial ankle/brachial score <1.0. This cutoff point was used because it is the consensus that the so-called "normal" ankle/brachial ratio is 1.12 (6) and that values lower than 0.97 should be considered abnormal (7, 8, 9).

All measurements were performed at rest in the supine position because the evidence suggests that, under these conditions, systolic blood pressure provides a sensitive index of the stenotic process (10, 11).

TABLE I
Age and Sex Distribution

age group	male group	female group	total group
30-39	0 (0.0%)	1 (2.8%)	1 (1.3%)
40-49	1 (2.4%)	6 (16.7%)	7 (9.1%)
50-59	8 (19.5%)	7 (19.4%)	15 (19.5%)
60-69	18 (44.0%)	15 (41.7%)	33 (42.8%)
70-79	13 (31.7%)	7 (19.4%)	20 (26.0%)
80-89	1 (2.4%)	0 (0.0%)	1 (1.3%)
total	41(100.0%)	36(100.0%)	77(100.0%)
mean	65.0	61.3	63.4
S.D.	8.8	10.8	9.9
t	-1.6322		
P	P>0.100		
minimum	47	35	35
maximum	84	79	84
range	37	44	49

Results

Line 1 (Table II) summarizes the ankle/brachial systolic blood pressure relationship at the start of the experiment. Because of the selection of patients with a ratio <1.0, it is evident (0.77±0.22) that, in all subjects, there is vascular insufficiency (the range, incidently was from 0.00 to 0.99). Following EDTA chelation therapy, the ratio (line 2) increased to 0.94±0.27 (range from a low of 0.43 to a high of 1.59). Hence, subsequent to approximately 26 EDTA infusions extending over 60 days, the occlusive state decreased 22 per cent and this is shown to be highly significant (t=8.0041, P<0.001). This becomes even more significant when it is realized that studies of the reproducibility of the measurements indicate that changes in ankle pressure expressed as a percentage of the brachial pressure are significant if the change is 15 per cent or more, while differences of 10-15 per cent are of borderline significance (7). Of the 117 limbs studied, 95 (81%) improved; 22 (19%) worsened. Phrased another way, the 95 limbs on the average improved 29 per cent;

In the light of the wide range of initial ratios, suggesting that some patients were suffering with more and others less stenosis, the entire sample of 117 limbs was divided into two subgroups. One subset of 46 showed an initial ratio of <0.80. This is designated as the "poorer" group; the other 71 rated an initial ratio of 0.80+ and is labelled the "better" group.

Line 3 (Table II) summarizes the initial scores (0.55 ± 0.19) of the poorer group; line 4 shows the final values (0.71 ± 0.25). Thus, in those with the greater initial occlusion, the improvement (reduction in insufficiency) was of an order of 29 per cent and statistically significant ($t=3.997$, $P<0.001$). Actually, 33 (71%) improved; 13 (29%) worsened. The 33 improved 46 per cent; the 13 worsened 11 per cent. Parenthetic mention should be made that ankle pressures below 50 mm Hg (and some of these patients were in this range) are limits below which gangrene may be expected (12).

In the relatively healthier group of 71, the initial score (line 5) was 0.91 ± 0.06 and the final values (line 6) 1.08 ± 0.17. This was a 19 per cent improvement which was also significant ($t=8.9790$, $P<0.001$). Actually 62 of the 71 (87%) improved; 9 (13%) worsened. Put another way, 62 improved on the average 23 per cent; 9 worsened 10 per cent.

TABLE II

Effect of EDTA Chelation Therapy with Vitamin/Mineral Supplementation upon Ankle/Brachial Systolic Pressure

line		sample size	ankle/brachial pressure	mean percentage change	significance of the difference of the means	
1	initial	117	0.77 ± 0.22			
				+22	$t=8.0041$	$P<0.001$*
2	final	117	0.94 ± 0.27			
3	initial lower (poorer) ratio <0.80	46	0.55 ± 0.19			
				+29	$t=3.9771$	$P<0.001$*
4	final lower (poorer)	46	0.71 ± 0.25			
5	initial higher (better) ratio 0.80+	71	0.91 ± 0.06			
				+19	$t=8.9790$	$P<0.001$*
6	final higher (better) ratio 0.80+	71	1.08 ± 0.17			

*statistically significant difference of the means

Discussion

There are a number of points deserving of special mention. First, the changes in stenosis summarized in this experiment are highly statistically significant (Table II). This becomes even more important when it is realized that single replicate determinations of systolic pressures could differ from

the mean of three or more readings by up to 11 mm Hg for the ankle pressure (7). Expressed as a ratio, this corresponds to 0.09 for the ankle/brachial value. Hence, the changes observed with EDTA cannot be viewed as a purely technical finding.

Secondly, while the principal diagnostic thrust for occlusive problems has led to surgical solutions, there are isolated mentions in the published literature to suggest that vascular insufficiency can be favorably altered by medical means such as clofibrate (13). Ar far as we can ascertain, this report is the very first to suggest the utility of EDTA chelation plus supportive multivitamin/trace mineral supplementation.

Thirdly, because of the leaching effect of EDTA chelation, it is essential that there be a multivitamin and trace mineral supplementation program. This then raises the obvious question as to the relative contributions of the EDTA versus the vitamins and minerals. This experiment does not address itself to that question. It would indeed be interesting to study the effect of a multivitamin/trace mineral supplement versus placebo upon arterial insufficiency. We trust that this report will catalyze others to look at this corollary issue.

Fourthly, it should be underlined that those in the groups that worsened did so approximately 10 per cent. It should be recalled that a change of 10 per cent is of questional significance.

Finally, we note in this experiment that, while there is an overall reduction in vascular insufficiency, there are considerable individual differences (Table III). One might well explain the difference between Case #1 (HaGa) and Case #2 (StVa) by the number of EDTA infusions. Specifically, with 9 infusions (Case #1) the ankle/brachial score rose 0.30. In contrast, with 30 infusions there was a rise of 1.13 in Case #2. However, this explanation, the number of infusions, is not adequate to explain for the difference in Case #3 (CeHa) where there is considerable improvement (#0.30) with fewer infusions (19) than in Case #4 (ToLy) with an improvement of +0.12 with more treatments (29).

TABLE III

Individual Case Differences

case number	ankle/brachial score initial	final	difference	number of infusions
1 (HaGa)	0.00	0.30	+0.30	9
2 (StVa)	0.00	1.13	+1.13	30
3 (CeHa)	0.55	0.85	+0.30	19
4 (ToLy)	0.55	0.62	+0.12	29

We had earlier noted the same seeming paradox with regard to biochemical changes following EDTA chelation. These were reported with serum cholesterol (14, 15), high density lipoprotein cholesterol (16), total serum cholesterol/high density lipoprotein (17), serum creatinine (18), serum calcium (19), and blood urea nitrogen (20). We plan to reexamine the biochemical and vascular data to ascertain whether those who fared best biochemically were those who also showed the greatest reduction in vascular stenosis.

Although there is evidence to suggest that the ankle/brachial determination is an excellent index of peripheral arterial disease, it is not perfect. This is so in part because of artifactually elevated ankle blood pressures observed in patients with rigid arteries in that region (especially in diabetes mellitus). Therefore, it is suggested that a more complete peripheral arte-

rial examination should include measurements of the blood pressure at the thigh, calf, ankle, foot and toe.

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