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A Nonsurgical Approach to Obstructive Carotid Stenosis Using EDTA Chelation

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ABSTRACT: Thirty subjects with atherosclerotic vascular disease were treated with 3 gram intravenous infusions of disodium ethylene diamine tetraacetic acid (EDTA). These patients were evaluated objectively for both right and left internal carotid atheromatous stenosis at the bifurcation, before and after EDTA chelation. Each subject had treatments over a period of approximately 10 months. Overall intra-arterial obstruction decreased 20.9± 2.3 % ($t = 8.921$, $p < 0.001$*). Subjects with greater than 33% (i.e. statistically $+1\ \sigma$) above initial mean obstruction, experienced a reduction in stenosis of 35.00 ± 4.3% after treatment ($t = 8.178$, $p < 0.001$*, $n = 16$). [*Statistically significant change comparing the difference of the means.]

Introduction

This continues a series of papers analyzing the effects of intravenous ethylene diamine tetraacetic acid (EDTA) therapy (1-13). Many physicians have successfully used EDTA to treat atherosclerotic vascular disease (14-16). In particular, this research studied stenosis at the bifurcation of the common carotid and in the internal carotid arteries before and after EDTA infusions.

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Materials and Methods

The thirty patients that participated in this study, conducted in a private practice environment, were selected because of vascular occlusive disease present in the internal carotid arteries. Many of these patients presented with a primary problem of their carotid arteries such as stroke, episodes of transient ischemic attacks or audible neck bruit. Other patients suffered from degenerative diseases localized to other areas of the vascular system including coronary artery disease and intermittent claudication. Reasonable medical suspicion dictated carotid doppler studies. A third category of patient was one with a non-vascular complaint such as osteoarthritis, in whom x-ray studies of the cervical spine revealed calcification in the area of the carotid bifurcation. Several patients were symptomatic but as it usually takes occlusions of 70 to 80 percent to produce symptoms, many were asymptomatic.

There were fifteen males ranging in age from 51 to 80 years of age (mean 65.5 ± 8.6 years) and fifteen females, ranging in age from 49-81 years (mean 69.4 ± 9.2 years). Each subject was evaluated for right and left internal carotid artery stenosis at the bifurcation.

A certified Horizons Research Laboratory (HRL)* technician performed the ultrasound with a Scannex SV HRL advanced imaging unit. Echoes returning from tissue and interfaces provided an instantaneous image on a calibrated television screen. In the freeze frame mode, the technician accurately measured wall lumen, arterial wall thickness and excursion, and plaque size, by computing microprocessor controlled distances between specific anatomical points (17). The scannex SV has the capability of resolving a piece of arteriosclerotic plaque as small as 0.5mm (17). The degree of obstruction was observed in two of three views, anterior, posterior, or lateral to rule out chance of shadow and artifact. For reference a calibrated photograph and videotape were included in the record.

After the initial examination, patients received a course of thirty infusions with intravenous EDTA and supplemented their diets with multivitamins and trace minerals according to the protocol of the American Academy of Advancement in Medicine (18). After completion of treatment, carotid artery studies were repeated using the identical method by which they were evaluated approximately ten months earlier.

Results

Data were analyzed from five perspectives. Initially, the entire group was assessed for net mean percentage change in stenosis of both internal carotid arteries. Then the right and left arteries were evaluated individually. Subjects with initial stenosis in the range of 70% or more (actually those patients with >33% or statistically 1 sigma be-

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TABLE 1

Percentage of Internal Carotid Artery Blockage Before and After EDTA Chelation Therapy

	Initial	Final	Decrease	t-score	p-value	Age (Years)
total group n=60	48.53%	27.65%	−20.88 ± 2.34	8.921	<0.001*	67.4 ± 8.91
men n=30	51.23%	28.43%	−22.80 + 3.31	6.878	<0.001*	65.5 ± 8.62
women n=30	45.83%	26.86%	−18.97 ± 3.33	5.696	<0.001*	69.3 + 9.19

*statistically significant difference of the means

yond initial mean blockage) were considered also as a separate group. Finally, the data were analyzed mathematically so the degree of improvement in cerebral perfusion could be calculated.

When the data from the entire group were analyzed before and after treatment, the decrease in atheromatous stenosis was statistically

TABLE 2

Percentage of Left Internal Carotid Artery Blockage Before and After EDTA Chelation Therapy

	Initial	Final	Decrease	t-score	p-value	Age (Years)
total group n=30	47.93%	28.96%	−18.97 ± 3.32	5.713	<0.001*	67.4 ± 8.91
men n=15	42.73%	28.73%	−14.0 + 4.20	3.336	<0.010*	65.5 ± 8.62
women n=15	53.13%	30.13%	−23.0 ± 5.30	4.340	<0.001*	69.3 + 9.19

*statistically significant difference of the means

TABLE 3

Percentage of Right Internal Carotid Artery Blockage Before and After EDTA Chelation Therapy

	Initial	Final	Decrease	t-score	p-value	Age (Years)
total group n=30	49.13%	26.33%	−22.80 ± 3.31	6.888	<0.001*	67.4 ± 8.91
men n=15	59.73%	28.13%	−31.60 + 4.06	7.785	<0.001*	65.5 ± 8.62
women n=15	38.53%	23.60%	−14.93 ± 3.84	3.888	<0.001*	69.3 + 9.19

*statistically significant difference of the means

TABLE 4

Percentage of Carotid Artery Blockage Before and After EDTA Chelation Therapy (Comparing Individuals with Initial Blockage Higher Than 33% Above Mean)

	Initial	Final	decrease	t-score	p-value	Age (Years)
total group n=16 >64.6%	76.63%	41.63%	−35.0 ± 4.28	8.178	<0.001*	67.1 ± 10.23 10 men 6 women
men n=7 >68.3%	78.71%	47.28%	−31.43 + 6.70	4.691	<0.010*	67.4 ± 9.24
women n=7 >61.1%	77.00%	37.57%	−39.43 ± 13.92	2.832	<0.050*	65.1 + 11.23

*statistically significant difference of the means

significant in both males and females. As seen in table 1, carotid obstruction averaged 20.88% less for all patients ($t=8.921$, $p<0.001$), 22.80% less for the men ($t=6.878$, $p<0.001$), and 18.97% less for the women ($t=5.696$, $p<0.001$).

Tables 2 and 3 present data from the right and left common carotids respectively, before and after treatment. Mean reduction in obstruction of lumen for the whole group was statistically significant. However, the women experienced 23% greater mean improvement in the left carotid (Table 2), while the men had 32% greater improvement on the right (Table 3). No obvious reason exists for this difference, which may be by chance in view of the relatively small numbers involved. However, it may be an observation worth examining in future studies.

Table 4 illustrates one of the more significant findings of this study. With an average of more than 70% initial obstruction before chelation, the individuals in this grouping were prime candidates for cerebral vascular accidental and/or subsequent infarction. Even

TABLE 5

Percentage of Carotid Artery Blockage Before and After EDTA Chelation Therapy (Comparing Individuals with Initial Blockage Higher Than 33% Above Mean)

	% OBSTRUCTED		% OPEN		IMPROVEMENT RATIO	BLOOD FLOW INCREASE
	Initial	Final	Initial	Final		%
total group n=16 >64.6%	76.63	41.63	23.37	58.37	2.49	620.00
men n=7 >68.3%	78.71	47.28	21.29	57.72	2.47	610.00
women n=7 >61.1%	77.00	37.57	23.00	62.43	2.71	734.00

though the number of men (n = 7) and women (n = 7) in this group was small, the mean decrease in obstruction was statistically significant for both sexes. The mean decrease for the whole group was 35% (men 31.4%, women 39.4%).

The data summarized in Table 4 were used to calculate the increase in blood-flow. After completion of therapy the mean percentage increase was 610% for men, 734% for the women and 620% for the two sexes combined (Table 5). These figures were calculated by subtracting the percentage obstruction from 100%, thus providing the percentage of arterial caliber.

The post-treatment arterial radius was divided by that observed before treatment to yield an improvement ratio. This ratio is directly proportional to the increase in radius of the blood vessel lumen. Improvement in blood flow was measured by calculating the imaginary surface area of a cross section of the partially obstructed artery and using the equation:

$$Q = v\pi r^2$$

where Q = blood flow, v = velocity of flow and r = radius of the artery lumen. If blood flows at a constant velocity, then the volume of blood flow is directly proportional to the square of the ratio of the radii of the post vs pre treatment arteries. This is the "improvement ratio", which, when squared, indicates the percentage improvement in blood flow.

Blood, however, does not flow at a constant velocity in a tube. Blood flows slower near the wall of the vessel so the arterial radius becomes a factor a second time in our blood flow calculations. Hence our original increase in blood flow may be underestimated when considering factors affecting velocity in a tube such as in the following equation:

$$v = \frac{\Delta P \cdot r^2}{8\,\eta\,1}$$

where P is the pressure gradient in a vessel, η is the viscosity of the fluid and 1 is the length of the vessel. The combination of these two equations formulates Poiseuille's law (19):

$$Q = \frac{\pi\,\Delta P \cdot r^4}{8\,\eta\,1}$$

TABLE 6

Percentage of Carotid Artery Blockage Before and After EDTA Chelation Therapy (at the Bifurcation)

		LEFT			RIGHT			
SUBJECT	SEX	initial %	final %	DECREASE	initial %	final %	DECREASE	AGE
1.	F	*75.00	45.00	−30.00%	60.00	44.00	−16.00%	78
2.	F	*86.00	53.00	−33.00%	60.00	57.00	−03.00%	81
3.	F	*67.00	00.00	−67.00%	00.00	00.00	−00.00%	57
4.	F	00.00	00.00	−00.00%	*75.00	50.00	−25.00%	58
5.	F	*98.00	33.00	−65.00%	25.00	00.00	−25.00%	60
6.	F	*75.00	45.00	−30.00%	50.00	49.00	−01.00%	49
7.	M	*75.00	40.00	−35.00%	52.00	35.00	−17.00%	73
8.	M	*65.00	50.00	−15.00%	60.00	55.00	−15.00%	73
9.	M	34.00	34.00	−00.00%	*83.00	34.00	−49.00%	77
10.	M	*80.00	69.00	−11.00%	33.00	00.00	−33.00%	64
11.	M	48.00	44.00	−04.00%	*86.00	63.00	−23.00%	51
12.	M	00.00	00.00	−00.00%	*84.00	25.00	−59.00%	65
13.	M	*70.00	40.00	−30.00%	*67.00	33.00	−34.00%	80
14.	M	00.00	00.00	−00.00%	*73.00	60.00	−13.00%	62
15.	M	40.00	00.00	−40.00%	*67.00	22.00	−45.00%	66
16.	M	25.00	22.00	−03.00%	50.00	22.00	−28.00%	75
17.	M	00.00	00.00	−00.00%	54.00	00.00	−54.00%	57
18.	M	58.00	45.00	−13.00%	33.00	20.00	−13.00%	60
19.	M	63.00	43.00	−20.00%	48.00	00.00	−48.00%	68
20.	M	33.00	00.00	−33.00%	50.00	25.00	−25.00%	52
21.	M	50.00	44.00	−06.00%	56.00	38.00	−18.00%	59
22.	F	42.00	34.00	−08.00%	56.00	47.00	−09.00%	64
23.	F	50.00	40.00	−10.00%	00.00	00.00	−00.00%	67
24.	F	40.00	20.00	−20.00%	25.00	00.00	−25.00%	77
25.	F	57.00	25.00	−32.00%	44.00	00.00	−44.00%	78
26.	F	21.00	20.00	−01.00%	63.00	37.00	−26.00%	73
27.	F	44.00	35.00	−09.00%	30.00	26.00	−04.00%	70
28.	F	44.00	22.00	−22.00%	40.00	00.00	−40.00%	83
29.	F	50.00	40.00	−10.00%	00.00	00.00	−00.00%	67
30.	F	48.00	40.00	−08.00%	50.00	44.00	−06.00%	78

*initial blockage >64.60% (10 beyond mean% blockage comparing total group), included in Table 5.

Taking Poiseuille's law into consideration, if an improvement is based upon the 4th power of the radius, the 600 to 800% improvement shown in Table 5 may actually be in the range of 3700 to 5400%. In other words, blood flow is increased dramatically with a very small increase in radius of the vessel lumen.

Table 6 provides information on the pre and post treatment evaluation of each of the 30 patients. None became worse over the 10 or more months covered by the study. Only one patient (case 9) showed no reduction at all in the left carotid artery, although there was highly significant improvement on the right. In a few patients (cases 23,27,29,30) the reduction was minimal but, for statistical significance for the group as a whole, these cases are offset by the very marked improvement of the majority.

Discussion

In developed countries vascular stroke kills one in every thousand people each year. Only heart disease and cancer exceed it as America's leading cause of death and the bifurcation of the common carotid artery is the most common site for occlusion (20). Approximately 5 million strokes occur each year and 75% occur in the distribution of the carotid arteries (21).

Drug therapy or endarterectomy are the commonly recommended treatments for carotid artery occlusion. The results of this study suggest that EDTA chelation may also be recommended as an alternative treatment. We have shown that there is a statistically significant decrease in obstructive blockage of carotid arteries after chelation, in contrast to as much as a 40% increase expected in less than a year in untreated patients (21).

Of 30 subjects tested, 16 had an average of more than 70% stenosis, which is an indication for carotid artery endarterectomy according to the Health and Public Policy Committee of the American College of Physicians (22). After EDTA chelation, this group of patients in our study were shown to have experienced a mean decrease in obstruction to 41.6% of arterial lumen (Table 4), thus obviating surgery. All our patients experienced some decrease in atheromatous stenosis. None developed complications while under treatment and no cerebrovascular accident occurred within thirty days of the last treatment. In a Rand community-based study the rate of major complications associated with endarterectomy (stroke or death within 30 days of surgery)

was 9.8% (23). Restenosis within 2 years of surgery is also a significant problem which develops in as much as 25% of cases (21).

Conclusion

Significant improvement in the treatment of carotid occlusive diseases should be at least as effective as surgery. The results from this study demonstrate that EDTA chelation, together with appropriate nutritional supplements and diet management, can significantly decrease atheromatous plaque and the chance of cerebral infarction, thus satisfying this requirement.

Moreover, it should be emphasized that the safety of treatment, repeatedly demonstrated in our own studies (1-13), far outweighs the published risks of endarterectomy (23). If the end result is equal to, or better than, surgery, chelation should be offered as the preferred treatment.

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