

# THE EFFECT OF EDTA CHELATION THERAPY PLUS SUPPORTIVE MULTIVITAMIN-TRACE MINERAL SUPPLEMENTATION UPON RENAL FUNCTION: A STUDY IN SERUM CREATININE

EW McDonagh, DO,  
CJ Rudolph, PhD, DO  
E Cheraskin, MD, DMD

**ABSTRACT:** One of the alleged contraindications to the use of EDTA is possible renal damage. Three hundred and eighty-three subjects with chronic degenerative disorders were treated with EDTA and supportive multivitamin-trace mineral supplements for approximately 50 days. Overall, the fasting serum creatinine levels declined ( $P < 0.05$ ). Specifically, those with relatively low initial serum creatinine levels increased; those with relatively high, but generally felt to be within the physiologic range, levels declined; those in the area of approximately 1.0 mg/dl (the supposed ideal in terms of renal clearance) remained unchanged. Hence, it would appear, within the limits of this study, that this therapeutic regimen is not nephrotoxic. There is even a suggestion that this treatment procedure may improve kidney function.

## *INTRODUCTION*

The use of chelating agents, and particularly EDTA, has been available for a number of years. One of the major objections to its use has been the possible deleterious effect upon the kidney. The purpose of this study is to examine the influence of EDTA plus supportive multivitamin-trace mineral supplementation upon renal function in humans as judged through a study of serum creatinine changes.

## *MATERIALS AND METHODS*

Three hundred and eighty-three patients consecutively chosen from a private practice environment suffering with chronic degenerative disorders of aging, primarily occlusive arterial disease, were the subjects of this study. The age and sex distribution is outlined (Table 1). There are 193 males and 189 females (in one patient the age and sex were not available). The subjects ranged from 14 to 86 years with a mean and standard deviation of  $60 \pm 12$  years. There is no statistically significant difference in age between the sexes ( $t = 0.3923$ ,  $p < 0.500$ ).

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Dr. E.W. McDonagh, a member of the Board of Directors of the American Academy of Medical Preventics, founded the McDonagh Medical Center in Gladstone, Missouri, where he practices with Dr. C.J. Rudolph. Dr. E. Cheraskin is Professor Emeritus and former Chairman of the Department of Oral Medicine at the University of Alabama.

an elaborate biochemical battery of tests including fasting serum creatinine. Table 2 summarizes the serum creatinine values at this initial visit. Each patient was then given ten infusions consisting of three grams of disodium EDTA intravenously in 1000 cc of normal saline over a three-hour period with an average interval of five days between infusions. Immediately following ten infusions of EDTA therapy plus supportive multivitamin/trace mineral supplementation, which required on the average 50 days, the biochemical series (including serum creatinine) was repeated. Table 2 also summarizes the serum creatinine scores at the second visit.

Table 1

AGE AND SEX DISTRIBUTION

age groups	male group	female group	total group
10-19	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.3%)
20-29	2 ( 1.0%)	3 ( 1.6%)	5 ( 1.3%)
30-39	7 ( 3.6%)	5 ( 2.6%)	12 ( 3.1%)
40-49	20 ( 10.4%)	22 ( 11.6%)	42 ( 11.0%)
50-59	65 ( 33.7%)	59 ( 31.2%)	124 ( 32.3%)
60-69	68 ( 35.2%)	51 ( 27.0%)	119 ( 31.1%)
70-79	24 ( 12.4%)	42 ( 22.2%)	66 ( 17.2%)
80-89	7 ( 3.6%)	6 ( 3.2%)	13 ( 3.4%)
not determined	-	-	1 ( 0.3%)
<b>totals</b>	<b>193 (100.0%*)</b>	<b>189 (100.0%*)</b>	<b>383 (100.0%)</b>
mean	59.4	59.9	59.5
S.D.	11.0	12.5	11.7
t		=0.3923	
P		>0.5000	
minimum	21	14	14
maximum	84	86	86
range	63	72	72

\*approximate

Table 2

DISTRIBUTION OF INITIAL AND FINAL

SERUM CREATININE SCORES

serum creatinine groups (mg/dl)	initial values	final values
0.7	7 ( 1.8%)	8 ( 2.1%)
0.8	6 ( 1.6%)	13 ( 3.4%)
0.9	25 ( 6.5%)	38 ( 9.9%)
1.0	41 ( 10.7%)	48 ( 12.5%)
1.1	47 ( 12.3%)	53 ( 13.8%)
1.2	58 ( 15.1%)	68 ( 17.8%)
1.3	71 ( 18.5%)	50 ( 13.1%)
1.4	61 ( 15.9%)	36 ( 9.4%)
1.5	37 ( 9.6%)	33 ( 8.6%)
1.6	16 ( 4.2%)	15 ( 3.9%)
1.7	8 ( 2.1%)	15 ( 3.9%)
1.8	0 ( 0.0%)	2 ( 0.5%)
1.9	3 ( 0.8%)	2 ( 0.5%)
2.2	1 ( 0.3%)	0 ( 0.0%)
2.3	1 ( 0.3%)	0 ( 0.0%)
2.7	1 ( 0.3%)	1 ( 0.3%)
3.6	0 ( 0.0%)	1 ( 0.3%)
<b>totals</b>	<b>383 (100.0%)</b>	<b>383 (100.0%)</b>
mean	1.25	1.22
S.D.	0.25	0.28

t=2.0520

An attempt will be made in this report to resolve the following heretofore unanswered questions: (1) What is the distribution of serum creatinine measurements in a group of patients with chronic degenerative diseases of aging prior to EDTA chelation therapy in a private practice setting? (2) What is the effect of EDTA and supportive multivitamin-trace minerals upon serum creatinine levels? (3) What clinical conclusions can one draw from these data?

## RESULTS

*Question One.* Table 2 outlines distribution serum creatinine levels at the initial visit. It is important to underscore the fact that the range is considerable; from a low of 0.7 mg/dl to a high of 2.7 mg/dl with a mean and standard deviation of  $1.25 \pm 0.25$  mg/dl.

The so-called "normal" range for serum creatinine differs among investigators and laboratories in part because of the techniques employed and also partially because of philosophic considerations as to what constitutes "normality." For the purposes of this study, the so-called normal range set by METPATH, the fully licensed and HEW approved laboratory which performed the testing, is accepted as 0.5 to 1.7 mg/dl. Hence, on the basis of these arbitrary limits, only 6 of the 383 could be viewed as abnormal at the initial visit; all with hypercreatininemia; none with hypocreatininemia. Hence, in answer to the first question, to the extent that serum creatinine is a measure of renal function, we can conclude that only 6/383 or 1.6% of the entire group display impaired renal function.

*Question Two.* It should be recalled that, following approximately 50 days of therapy, serum creatinine was remeasured. Table 2 summarizes the effects of therapy including both the initial and final measurements. Several points deserve particular mention. First, it is evident that mean serum creatinine declined for the entire sample. The initial mean and standard deviation of  $1.25 \pm 0.25$  mg/dl decreased to  $1.22 \pm 0.28$  mg/dl. This reduction of about 2% is statistically significant ( $t = 2.0520$ ,  $P < 0.050$ ).

Parenthetical mention should be made of the one patient who responded quite differently than any of the others. She was an 86-year-old female with an initial serum creatinine of 1.9 mg/dl (definitely abnormal by traditional standards) which, in 25 days, rose to 3.6 mg/dl. It is noteworthy that subsequent serum creatinine determinations decreased to 2.8 mg/dl (in 60 days) and to 1.8 mg/dl (in 100 days). This isolated case emphasizes the need to closely follow renal function during EDTA therapy.

There is a second way of examining the changes in serum creatinine (Table 3). It will be observed that, for the entire group, 131 of the 383 subjects (34%) showed an increase in serum creatinine, 62 (16%) were unchanged, and 190 (50%) declined. Hence, while the overall picture (Table 4) suggests a statistically significant decline of an order of 2% (line 6), a considerable number remained unchanged and a greater number actually increased.

Finally, there is a third approach to these data (Table 5). The subjects are

Table 3

DISTRIBUTION OF CHANGE FROM INITIAL SERUM CREATININE  
FOLLOWING INTRAVENOUS EDTA PLUS MULTIVITAMIN-TRACE  
MINERAL SUPPLEMENTATION

change in serum creatinine scores	number and percentage of subjects
+1.7	1 ( 0.3%)
+0.8	2 ( 0.5%)
+0.7	3 ( 0.8%)
+0.6	2 ( 0.5%)
+0.5	6 ( 1.6%)
+0.4	14 ( 3.6%)
+0.3	21 ( 5.5%)
+0.2	33 ( 8.6%)
+0.1	49 ( 12.8%)
0	62 ( 16.2%)
-0.1	59 ( 15.4%)
-0.2	66 ( 17.2%)
-0.3	33 ( 8.6%)
-0.4	15 ( 3.9%)
-0.5	8 ( 2.1%)
-0.6	5 ( 1.3%)
-0.7	2 ( 0.5%)
-0.9	1 ( 0.3%)
-1.1	1 ( 0.3%)
totals	383 (100.0%)

Table 4

EFFECT OF EDTA PLUS MULTIVITAMIN-TRACE MINERAL  
SUPPLEMENTATION UPON SERUM CREATININE

line	initial creatinine	sample size	mean age	interval in days	initial	final	change	statistical evaluation
1	<1.0	38	57	82	0.85	1.07	+0.22	t=6.6399 P<0.0010*
2	1.0-1.1	88	60	62	1.05	1.07	+0.02	t=1.0903 P>0.2000
3	1.2-1.3	129	60	45	1.26	1.20	-0.06	t=2.6469 P<0.0100*
4	1.4-1.5	98	58	46	1.44	1.32	-0.12	t=5.3922 P<0.0010*
5	1.6+	30	65	30	1.73	1.53	-0.20	t=2.2305 P<0.0500*
6	totals	383	60	52	1.25	1.22	-0.03	t=2.0520 P<0.0500*

\*statistically significant difference of the means

with an initial serum creatinine <1.0 mg/dl (line 1), 30 (79%) increased with EDTA therapy, 7 (18%) showed no change, and 1 (3%) declined. It is noteworthy that, as the initial serum creatinine level increased (moving downward from line 1 to 5), the percentage of subjects showing an increase in serum creatinine declined progressively (in perfect order) from 79% to 44% to 28% to 22% and to 17%, respectively. Conversely, as the initial serum creatinine increased, moving down on Table 5, from lines 1 to 5, the percentage of subjects showing a decrease in serum creatinine actually increased from 3% to 44% to 53% to 59% and finally to 80%.

As shown in Table 4, there is a statistically significant increase in serum creatinine of 0.22 mg/dl (26%) in those with the lowest (<1.0 mg/dl) initial serum creatinine (line 1). There is a statistically significant decrease in serum creatinine in those with the highest initial scores (lines 3, 4 and 5) of 5%, 8%, and 12%, respectively. What is of particular interest is that there is no change with therapy only in the group with an initial serum creatinine of 1.0-1.1 mg/dl

Table 5  
 NUMBER AND PERCENTAGE OF SUBJECTS WITH AN INCREASE,  
 NO CHANGE, OR DECREASE IN SERUM CREATININE  
 FOLLOWING EDTA PLUS SUPPORTIVE  
 MULTIVITAMIN-TRACE MINERAL SUPPLEMENTATION

line	initial creatinine (mg/dl)	increase	no change	decrease	total group
1	<1.0	30 (79%)	7 (18%)	1 (3%)	38 (100%)
2	1.0-1.1	39 (44%)	10 (12%)	39 (44%)	88 (100%)
3	1.2-1.3	36 (28%)	25 (19%)	68 (53%)	129 (100%)
4	1.4-1.5	21 (22%)	19 (19%)	58 (59%)	98 (100%)
5	1.6+	5 (17%)	1 (3%)	24 (80%)	30 (100%)
6	totals	131 (34%)	62 (16%)	190 (50%)	383 (100%)

### DISCUSSION

*Question Three.* Possible conclusions from the preceding data are as follows: It is well known that a gross estimate of renal function may be obtained from routine urinalysis.<sup>1</sup> However, a more accurate quantitative test of kidney activity should include a measure of clearance. One precise measurement of clearance utilizes insulin, but endogenous creatinine is more practical.

Creatinine is an endogenous end product of muscle metabolism. It is generated at a fairly constant rate and is cleared primarily by glomerular filtration. Creatinine clearance is a practical measure of glomerular filtration readily available to the practicing clinician. Under presumably normal conditions, creatinine clearance is approximately 140 liters/24 hours or approximately 100 ml/minute.

Especially relevant to this report is the fact that serum creatinine correlates reasonably well with creatinine clearance. A serum creatinine of 1.0 mg/dl is correlated with a so-called normal (100%) creatinine clearance. When the creatinine clearance falls to 25% of normal, the serum creatinine approaches 2 mg/dl. Hence, a 7.5% decline in renal function approximates a rise of 0.1 mg/dl of serum creatinine between 1 and 2 mg/dl.<sup>2</sup>

Overall, serum creatinine declined under EDTA and supportive therapy. However, in the light of the relationship between serum creatinine and renal clearance, it is significant, and previously not reported, that with this form of therapy under the conditions spelled out in this study, the high serum creatinine levels decline and the very low ones rise and all tend to settle in the neighborhood of 1 mg/dl, postulated by the authors to represent the "ideal." This is graphically portrayed in Figure 1.

Casdorph made the statement, "In fact, two patients have shown improvement in creatinine clearance during the course of chelation therapy, raising the possibility that this form of treatment may even improve renal function in some patients."<sup>3</sup>

The observations derived from this study of 383 subjects seems to corroborate the previous observations by Casdorph.

E.W. McDONAGH, C.J. RUDOLPH, E. CHERASKIN

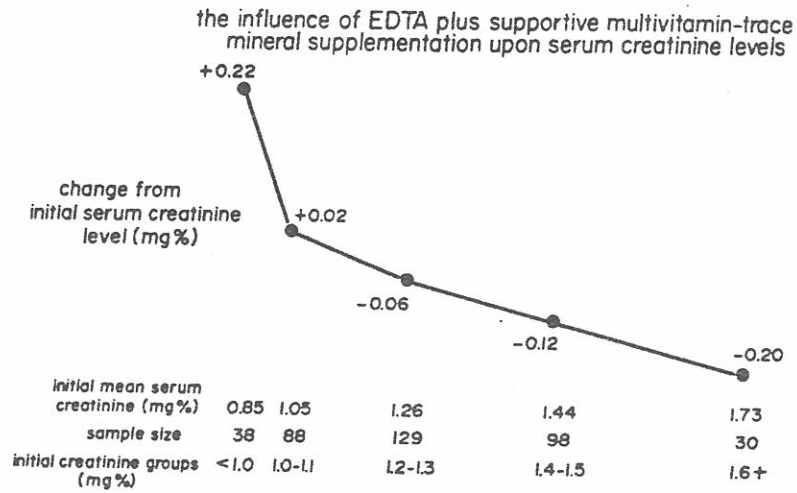


FIGURE 1. The relationship of initial serum creatinine (shown on the horizontal axis) versus the change (displayed on the vertical dimension) following therapy. It is especially noteworthy that initial serum creatinine scores below 1.0 mg% increased, those above 1.0 mg% declined, and those at or about 1.0 mg% remained unchanged.

### REFERENCES

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*McDonagh Medical Center, Inc.*  
 2800-A Kendallwood Parkway  
 Gladstone, MO 64119