THE EFFECT OF EDTA CHELATION THERAPY PLUS SUPPORTIVE MULTIVITAMIN – TRACE MINERAL SUPPLEMENTATION UPON RENAL FUNCTION: A STUDY IN BLOOD UREA NITROGEN (BUN)

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ABSTRACT: One of the alleged contraindications to the use of EDTA is possible renal damage. In an earlier report, it was shown, as judged by serum creatinine, that EDTA was not only not nephrotoxic but in fact may well improve kidney function. This report underscores that conclusion through a study of BUN.

INTRODUCTION

In the Fall/Winter 1982 issue of the Journal of Holistic Medicine[1] there appeared an excellent review of the relationship of ethylene-diaminetetra-acetic acid (EDTA) therapy to kidney function. In that same journal issue,[2] we reported our observations with serum creatinine as a measure of renal function. The purpose of this study is to reexamine the influence of EDTA plus supportive multivitamin-trace mineral supplementation upon renal activity in humans as judged through a study of blood urea nitrogen (BUN) changes.

MATERIALS AND METHODS

Eighty patients, suffering with chronic degenerative disorders, primarily occlusive arterial disease, were consecutively chosen from a private practice environment and these individuals constitute the subjects of this study. The age and sex distribution is outlined (Table 1). There are 46 males and 34 females. The subjects ranged from 31 to 86 years of age with a mean and standard deviation of 64 ± 9 years. There is no statistically significant difference in age between the sexes ($t = 0.5156$, $p > 0.500$).

At the initial visit, an extensive history and physical examination were

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performed along with an elaborate biochemical battery of tests including fasting blood urea nitrogen (BUN). Table 2 summarizes the BUN values at the initial visit. Each patient was then given a total of 30 infusions of 3 grams of disodium EDTA intravenously in 1000 cc of various carrier solutions over a three-hour period with a varying average interval of several days between infusions. Additionally, a full spectrum multivitamin-trace mineral supplement was administered. Full particulars regarding the supplement and the infusions may be obtained by communicating with the authors. Immediately following the first ten infusions of EDTA therapy plus supportive multivitamin-trace mineral supplementation, which required on the average 50 days, the biochemical series (including blood urea nitrogen) was repeated. Table 2 also summarized the blood urea nitrogen scores at the second visit (after 10 infusions). This was again repeated after 20 and 30 infusions.

An attempt will be made in this report to resolve the following heretofore unanswered questions: (1) What is the distribution of blood urea nitrogen scores in a group of patients with chronic degenerative disease prior to EDTA chelation therapy in a standard private practice environment? (2) What is the effect of intravenous EDTA and supportive multivitamin-trace minerals upon the blood urea nitrogen levels? (3) What clinical conclusions can one draw from these data?

Table 1

age and sex distribution

age groups	male group	female group	total group
30-39	0 (0.0%)	1 (2.9%)	1 (1.2%)
40-49	2 (4.3%)	1 (2.9%)	3 (3.7%)
50-59	14 (30.4%)	9 (26.5%)	23 (28.9%)
60-69	17 (37.0%)	15 (44.2%)	32 (40.0%)
70-79	10 (21.8%)	7 (20.6%)	17 (21.2%)
80-89	3 (6.5%)	1 (2.9%)	4 (5.0%)
totals	46 (100.0%)	34 (100.0%)	80 (100.0%)
mean	64.2	63.1	63.8
S.D.	9.0	9.6	9.2
t	0.5156		
P	>0.5000		
minimum	43	31	31
maximum	83	86	86
range	40	55	55

RESULTS

Question One: Table 2 outlines blood urea nitrogen levels at the initial visit. It is important to underscore the fact that the range is considerable; from a low of 9 mg/dl to a high of 46 mg/dl with a mean and standard deviation of 18.66 ± 6.58 mg/dl.

The so-called "normal" range for blood urea nitrogen differs among investigators between laboratories in part because of the techniques employed and also partially because of the philosophic considerations as to what constitutes "normality." For the purposes of this study, the so-called normal range set by METPATH, the laboratory which performed the testing, is accepted as 6-25 mg/dl. Hence, on the basis of these arbitrary limits, only 10 of the 80 could be viewed as abnormal at the initial visit, all with elevated levels; none with low scores. *Hence, in answer to the first question, to the extent that blood urea nitrogen is a measure of renal function, we can conclude that approximately 10 percent of the entire group displayed impaired renal function prior to treatment.*

Question Two: It should be recalled that following approximately 50 days and 10 infusions of therapy, blood urea nitrogen was remeasured. Table 2 summarizes both the initial and the scores after 10, 20, and 30 infusions.

Table 2

distribution of BUN scores
number and percentage of subjects

BUN groups (mg/dl)	initial scores	after 10 infusions	after 20 infusions	after 30 infusions
<10	1 (1.3%)	5 (6.2%)	2 (2.5%)	1 (1.3%)
10-12	11 (13.7%)	13 (16.3%)	14 (17.5%)	11 (13.7%)
13-15	16 (20.0%)	18 (22.5%)	17 (21.2%)	25 (31.2%)
16-18	15 (18.7%)	18 (22.5%)	24 (30.0%)	15 (18.7%)
19-21	12 (15.0%)	11 (13.7%)	6 (7.5%)	12 (15.0%)
22-24	15 (18.7%)	8 (10.0%)	8 (10.0%)	9 (11.3%)
25-27	7 (8.8%)	3 (3.8%)	3 (3.8%)	4 (5.0%)
28+	3 (3.8%)	4 (5.0%)	6 (7.5%)	3 (3.8%)
totals	80 (100.0%)	80 (100.0%)	80 (100.0%)	80 (100.0%)
mean	18.66	17.64	17.41	17.59
S.D.	6.58	8.41	6.37	6.37
minimum	9	4	7	9

Table 3 outlines the statistical significance of the difference of the means at the various temporal points and the percentage differences. It is obvious that there is no change in blood urea nitrogen after the initial 10 infusions (– 5 percent). However, there are statistically significant reductions after both the 20 and 30 infusions, – 7 percent and – 6 percent respectively. None of the other relationships is statistically significant. *Hence, in answer to the second question, to the degree that one can measure by this approach, the blood urea nitrogen seems to be significantly reduced for the entire group after 20 and 30 infusions.*

There is a second way of examining the changes in serum blood urea nitrogen (Table 4). It will be observed that, for the entire group, 22 patients (27.4 percent) showed an increase in the BUN, 7 patients (8.8 percent) were unchanged, and 51 patients (63.8 percent) declined from the initial values compared to those after 10 infusions. Hence, while the overall picture suggests a statistically insignificant decline of an order of 5 percent between the initial state and measurements after 10 infusions, a considerable number remained

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Table 3

percentage of change and
significance of the difference of the means

infusions	10	20	30
0	t=1.21 (-5%)	t=2.32 (-7%)*	t=2.00 (-6%)*
10	--	t=0.28 (-1%)	t=0.60 (<1%)
20	--	--	t=0.35 (+1%)

*statistically significant difference of the means

unchanged and a sizable number actually increased. This is also true with regard to the relationship of 0 versus 20 infusions and 0 versus 30 infusions.

Finally, there is a third approach to these data (Table 5). The subjects are arranged in four near-equal subgroups according to initial blood urea nitrogen. Of the 22 subjects with an initial BUN of 9 to 14 mg/dl (line 1), there was an overall actual increase of 2.4 mg/dl (12.0 to 14.4) which amounted to a statistically nonsignificant 20 percent rise ($P > 0.100$). On the other hand, the initial BUN group (line 2) of 15 to 17 mg/dl ($n = 18$) showed a 7 percent statistically significant decline ($P < 0.025$) in BUN. There was an even greater decrease of 13 percent (line 3) in those with initial BUN of 18-22 ($P < 0.005$). A 10 percent (and not significant $P > 0.200$) decrease, in the

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Table 4

distribution of change in blood urea nitrogen

	initial versus 10 infusions	initial versus 20 infusions	initial versus 30 infusions
increase in BUN	22 (27.4%)	25 (31.3%)	29 (36.2%)
no change	7 (8.8%)	6 (7.5%)	9 (11.3%)
decrease in BUN	51 (63.8%)	49 (61.2%)	42 (52.5%)
total	80 (100.0%)	80 (100.0%)	80 (100.0%)
maximum increase	32	27	11
maximum decrease	28	29	11

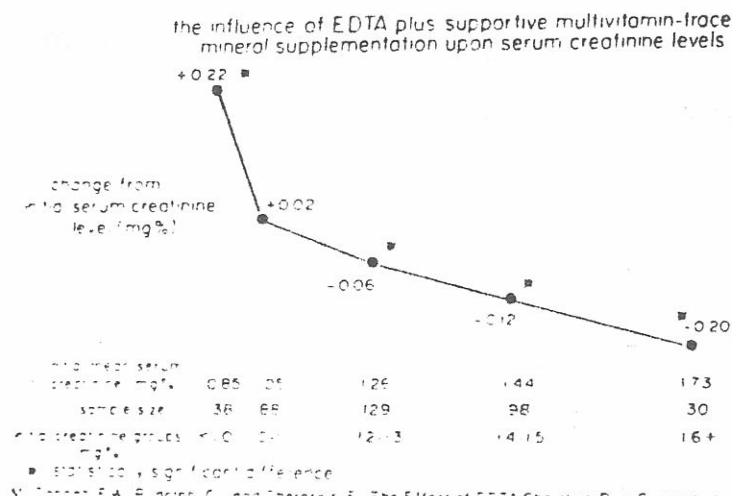
initial BUN occurred in the highest initial BUN group of 23-46 mg/dl (line 4). *It therefore appears that the changes in blood urea nitrogen following chelation therapy varies with the initial BUN score.. Those with the lowest blood urea nitrogen values seem to increase while those with the highest levels appear to decrease. Thus, no evidence was found for nephrotoxicity.*

A similar analysis of the initial BUN versus the measurements after 20 infusions is also summarized (Table 6). Those with the lowest initial BUN scores (line 1) seem to rise though not significantly, $P > 0.100$; those with the highest values (line 4) seem to significantly decline ($P < 0.0100$). *Hence, overall, the pattern for a comparison of initial BUN versus after 20 infusions is very similar to that for after 10 infusions except that the values seem to be more sharply defined and more significant.*

Finally, we have included a summary of the relationship of initial BUN to the values after 30 infusions (Table 7). *Once again, the pattern is essentially that described earlier for analysis after 10 and 20 infusions, especially 20 infusions.*

DISCUSSION

Question Three: It is generally agreed that there are a number of methods available for measuring renal function.[3] At the clinical and practical level, serum creatinine appears to be the most sophisticated and this was the parameter discussed in an earlier report.[2] It was shown at that time that, following EDTA therapy plus vitamin-mineral supplementation, the relatively low serum creatinine levels rose; the high ones declined. It would appear, from previously published data (Figure 1) that not only is EDTA therapy, under these conditions, not toxic, but, in fact, homeostatic. Blood urea nitrogen is generally regarded as a much cruder test than serum creatinine function. An examination of Figures 2, 3, and 4 shows patterns with BUN similar but



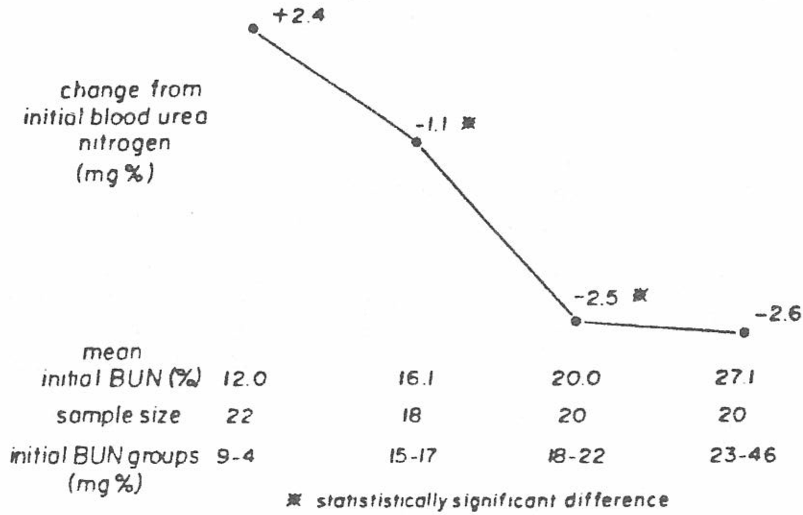


Figure 2

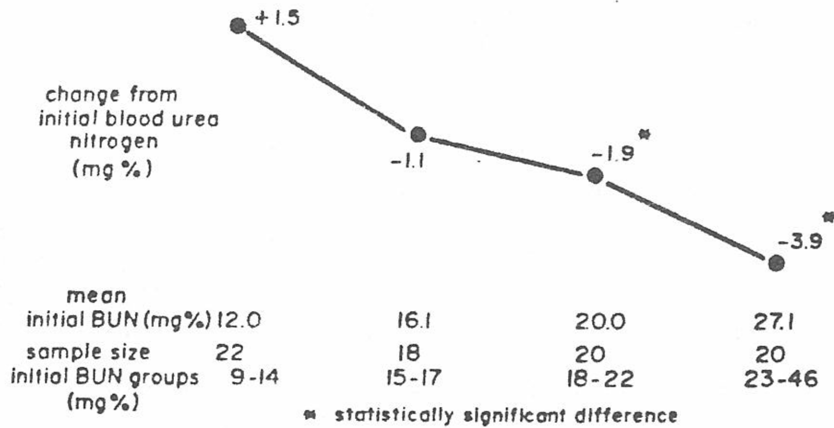


Figure 3

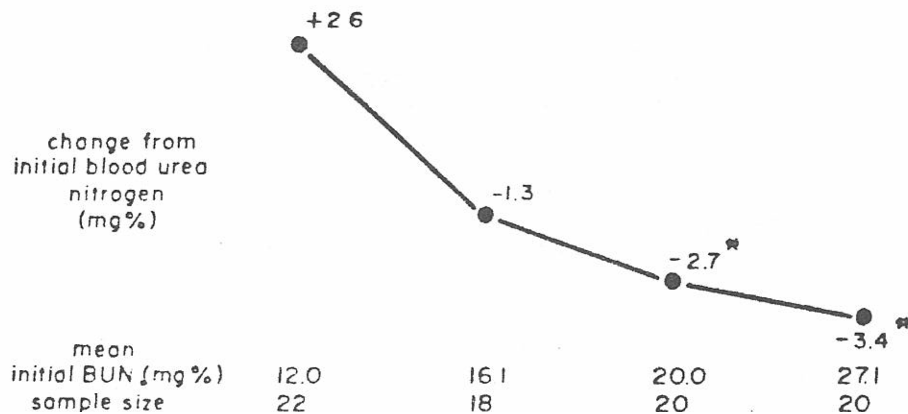


Table 5

effect of EDTA plus multivitamin-trace mineral supplementation upon blood urea nitrogen after ten infusions

line	initial BUN groups (mg/dl)	sample size	mean initial BUN	mean after 10 infusions	actual change	% change	t	P
1	9-14	22	12.0	14.4	+2.4	+20%	1.4831	>0.100
2	15-17	18	16.1	15.0	-1.1	- 7%	2.5970	<0.025*
3	18-22	20	20.0	17.5	-2.5	-13%	3.4554	<0.005*
4	23-46	20	27.1	24.5	-2.6	-10%	1.0016	>0.200
5	totals	80	18.7	17.6	-1.1	- 6%	1.2100	>0.200

*statistically significant difference of the mean

Table 6

effect of EDTA plus multivitamin-trace mineral supplementation upon blood urea nitrogen after twenty infusions

line	initial BUN groups (mg/dl)	sample size	mean initial BUN	mean after 20 infusions	actual change	% change	t	P
1	9-14	22	12.0	13.5	+1.5	+13%	1.6662	>0.100
2	15-17	18	16.1	15.0	-1.1	- 7%	1.0106	>0.200
3	18-22	20	20.0	18.1	-1.9	-10%	2.1111	<0 050*
4	23-46	20	27.1	23.2	-3.9	-14%	3.0225	<0.010*
5	totals	80	18.7	17.4	-1.3	- 7%	2.3200	<0.025*

*statistically significant difference of the means

Table 7

effect of EDTA plus multivitamin-trace mineral supplementation upon blood urea nitrogen after thirty infusions

line	initial BUN groups (mg/dl)	sample size	mean initial BUN	mean after 30 infusions	actual change	% change	t	P
1	9-14	22	12.0	14.6	+2.6	+22%	0.4012	>0.500
2	15-17	18	16.1	14.8	-1.3	- 8%	1.7627	>0.050
3	18-22	20	20.0	17.3	-2.7	-14%	2.9979	<0.010*
4	23-46	20	27.1	23.7	-3.4	-13%	2.7314	<0.025*

less significant than with serum creatinine. Hence, the less-sensitive measure (BUN) shows similar but less significant relationships following 10, 20, and 30 infusions of EDTA.

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