The "Clinical Change" in Patients Treated with EDTA Chelation Plus Multivitamin/Trace Mineral Supplementation

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Abstract

As far as we can ascertain, this is the first attempt to quantify the "clinical state" of the chelation treated patient within the limits of a time-tested and respected measuring instrument, the Cornell Medical Index Health Questionnaire. It can be safely concluded that the average patient is significantly ill and that, after approximately 26 infusions extending over about 60 days of therapy, the overall clinical symptomatology is reduced about 15 per cent and the system analysis shows an improvement from a low of 11 (in the gastrointestinal and urinary systems) to a high of 31 per cent (in the musculoskeletal system). It is hoped that this report will catalyze more interest in pursuing the "clinical state" of the chelation-treated patient.

Introduction

There is a burgeoning interest in measuring the medical effects of EDTA chelation therapy. Almost without exception, the emphasis has been on physiologic[14] and biochemical[5-11] parameters. As far as we can determine, there has not been a single quantitative clinical appraisal.

Review of the Literature

The need for readily obtainable accurate clinical data from patients and other experimental human subjects is universally appreciated. Also generally recognized is the absence of a single totally satisfactory interrogatory tool. For, the simple fact of the matter is that all of the existing instruments and practices, from structured questionnaires to casual interviews, possess serious strengths and woeful weaknesses.

The now almost thirty five year old Cornell Medical Index Health Questionnaire (CMI) was originally created[1213] to satisfy the need for a device to collect a large body of relevant medical and psychiatric information with a modicum of physician-time output. Over the three or so last decades, this form has been more time-tested than any other history taking technique. The instrument has been utilized to study emotional problems in and out of hospitals[1415], outpatient admitting departments[16], the relationship of patients' complaints to age, sex,

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race and education[17], in the military[1819], industry[20] and sports medicine[21]. What is particularly noteworthy and relevant here is that the CMI (or for that matter any other similar measuring stick) has not been utilized to study the "clinical state" of patients before and after EDTA chelation therapy.

Method of Investigation

By utilizing the questionnaire according to the instructions set forth by the initiators[12], it is possible to derive three major groups of clinical information as well as a score of subset data. First, the entire form may be scrutinized to ascertain the total number of affirmative replies. Parenthetic mention should be made that a significant "health" problem should be suspected when more than 25 questions are answered in the affirmative. The importance of this particular marker will become apparent later in this report.

An examination of the Cornell Medical Health Questionnaire reveals that it contains 195 questions arranged in sections (from A to R). For example, Section A deals with questions relating to the eyes and ears; Section B to the respiratory system; Sections M-R to mood and feeling patterns. Hence, secondly, it is possible to identify clinical problems in terms of sites and/or systems. Thirdly, and lastly, some of the questions are so phrased as to identify
specific clinical problems (e.g. hay fever, high blood pressure, hemorrhoids).

One hundred and thirty-nine routine private practice patients (aged 63.0 ± 10.3 years) including 83 males (62.5 ± 10.6 years) and 56 females (63.6 ±9.7 years) participated in this study (Table 1). At the initial visit, all patients completed the Cornell Medical Index Health Questionnaire. After a series of EDTA chelation (each 3 gm.) infusions (mean 26.2) plus supportive multi-vitamin/trace mineral supplementation over an average of 61.4 days, all participants once again completed the questionnaire.

Results

Table 1 is an overall summary of the affirmative responses for the entire CMI. Three points warrant special consideration. First, the average patient reported 31.7 "complaints." Mention was made earlier that 25 or more positive replies suggests "significant" disease. Hence, on a mean basis, this group must be viewed as being in very poor "health." Secondly, it is also quite evident that the range of responses is considerable; from a low of 3 to a high of 95. Thus, some of the group must be in extreme poor "health." Finally, and not shown in the table, approximately 58 per cent of this group have significant (greater than 25 yesses) problems.

Table 1
Change in CMI scores with EDTA chelation therapy

sample size	139	
total age	63.0 + 10.3 years	
age (male group)	62.5 ± 10.6 years	
age (female group)	63.6 ± 9.7 years	
initial CMI	31.7 ± 16.0	
initial range	3 - 95	
		t=6.5962 P<0.001*
final CMI	25.9 ± 15.2	
final range	4 - 86	
percentage change	-15	
number of treatment days	61.4 days	

*statistically significant difference of the means.

Earlier mention was made that the clinical scores were reexamined following EDTA chelation therapy with supportive multivitamin and trace mineral supplementation. Table 1 shows that, overall, there was a 15 percent improvement in clinical state (from 31.7 to 25.9 affirmative answers). The range, secondly, declined from 3 to 95 to 4 to 86. Finally, 46 per cent (a drop of 12 per cent) displayed significant problems.

It should be recalled that the questionnaire is so structured as to allow analysis of data subsets (Table 2) as shown by a study of the findings according to systems for the total sample of 139 patients. Five summary points should be made. First, on a mean percentage basis, all systems improved ranging from a reduction of 25 in the musculoskeletal system (line 1) to 11 per cent in the gastrointestinal and urinary systems (lines 7 and 8). Second, all but two of the systems (integumentary and genital) appear to be statistically significant. In the two that are not significant (lines 4 and 6), the lack of statistical significance may be simply the result of the large standard deviations. This suggests that there may be an exceptionally large number of subjects, especially in these two systems, who were asymptomatic (showing zero scores). Accordingly and thirdly, the data was recalculated only for those who were symptomatic (Table 3). For example, of the entire sample of 139 subjects studied in terms of the musculoskeletal system (Table 2, line 1) only 101 reported musculoskeletal findings (Table 3, line 1). Fourth, now we find that the percentage of improvement is greater in all groups. Lastly, the reduction of problems is now statistically significant in all categories.

Discussion

All of the information provided here is new in the sense that, as far as we can determine, it has never been developed in this kind of patient population undergoing this special type of therapy. And so, it cannot be compared to similar observations for confirmation or rejection. Notwithstanding, the data do suggest that it is possible to get some kind of fix on the clinical "health" of a chelation-treated patient. More importantly, it is clear that there is an overall improvement as well as specific reduction in

Table 2
effect of EDTA chelation upon systems in the entire sample

line	system	sample size	initial clinical scores	final scores	mean percentage reduction	significance of the difference of the means
1	musculoskeletal	139	1.77 ±1.76	1.33 ±1.68	25	t = 4.1900 P<0.001*
2	neurologic	139	1.99 ±1.79	1.60 ± 1.64	19	t = 3.5220 P<0.001*
3	cardiovascular	139	3.76 ±2.54	3.05 ±2.30	19	t = 4.9415 P<0.001*
4	integumentary	139	0.88 ±1.21	0.73 ±1.03	18	t = 1.8490 P>0.050
5	respiratory	139	2.23 ±2.14	1.86 ±2.01	17	t = 2.6806 P<0.010*
6	genital	139	1.13 ±1.67	0.99 ±1.54	13	t= 1.5898 P>0.100
7	gastrointestinal	139	3.23 ±2.54	2.88 ± 2.56	11	t = 2.0669 P<0.050*
8	urinary	139	1.74 ± 1.39	1.55 ± 1.25	11	t = 2.5679 P<0.025*

*statistically significant difference of the means

Table 3
effect of EDTA chelation upon systems in symptomatic subjects

line	system	sample size	initial clinical scores	final clinical scores	mean percentage reduction	significance of the difference of the means
1	musculoskeletal	101	2.44 ±1.62	1.69 ±1.74	31	t = 5.6688 P<0.001*
2	integumentary	64	1.92+1.09	1.39 ±1.11	28	t = 3.2469 P<0.005*
3	neurologic	108	2.56 ±1.63	1.97 ± 1.67	23	t= 4.4536 P<0.001*
4	genital	58	2.71 ± 1.56	2.10 ±1.70	23	t = 3.4717 P<0.005*
5	cardiovascular	130	4.02 ±2.43	3.13 ±2.20	22	t = 5.6488 P<0.001*
6	respiratory	106	2.90 ±1.99	2.32 ±2.04	20	t = 3.5657 P<0.001*
7	urinary	106	2.28 ±1.14	1.94 ±1.15	15	t = 3.7401 P<0.001*
8	gastrointestinal	124	3.62 ± 2.41	3.16 ±2.54	13	t = 2.5317 P<0.025*

*statistically significant difference of the means

clinical findings in all categories.

An examination of the Cornell Medical Index Health Questionnaire discloses that different systems are assigned different numbers of questions (Table 4). Thus, for example, the gastrointestinal system (line 5) is investigated with 23 questions; the urinary (line 1) with only 5. Hence, while the absolute scores in Tables 2 and 3 are interesting, they do not address one remaining question, namely, the relative frequency of systemic problems after weighting. Table 4 shows, for example, with such factoring, that while the urinary system was accorded the fewest number of questions (line 1), it proves to be the system responding with the greatest number of problems. In contrast, the neurologic system (line 8), with the second greatest numbers of questions, proves to be the area with the least number of reported problems. It is fascinating to note the ubiquitous salutory effect of EDTA chelation therapy plus multivitamin/trace mineral support. It is of interest to speculate on the common

Table 4
distribution of questions

line	systems	number of questions	weighted initial score
1	urinary	5	0.35
2	cardiovascular	13	0.29
3	musculoskeletal	8	0.22
4	genital	6	0.19
5	gastrointestinal	23	0.14
6	integumentary	7	0.13
7	respiratory	18	0.12
8	neurologic	18	0.11

denominator which may well be the fact that this form of treatment invites a generalized improvement in cellular nutrition. A report to follow will examine the role of this same therapeutic regimen for emotional problems[22].

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