
The Literature of EDTA Chelation for Cardiovascular Disease

**“There are three kinds of lies:
lies,
damned lies,
and statistics.”**

Mark Twain

Types of Clinical Data

- **Case reports**
- **Case-series**
- **Longitudinal studies**
- **Randomized, controlled trials**
- **Registries**
- **Population-based prospective studies**

Randomized Controlled Trials

- **Randomization — Rationing care**
- **Adopted by FDA after Kefauver amendment**
- **\$700 billion per year industry**

Randomized Controlled Trial Features

- **Prospective**
- **Test null hypothesis**
- **Randomization**
 - Minimize bias**
 - Comparable study groups**
- **Blinding**
 - Minimize bias**
 - Minimize placebo effect**
- **Control**
 - Active**
 - Placebo**

Randomized Controlled Trial Drawbacks

Even when well-designed and honestly conducted

- **Select patient population**
- **Type I error - outcome due to chance**
- **Type II error - real effect missed**

The Trouble with the Literature

- **Institutional bias**
- **Publication bias**
- **Vested interest**
- **Statistical vs. clinical relevance**
- **Inadequate study design, analysis, and reporting**

EDTA Chelation & Coronary Heart Disease Case-series

- **Clark et al. 1956**
- **20 Pts — 16 unstable angina**
- **Complete relief of angina in 17**
- **16 asymptomatic 1- 21 months**
- **ECG normalized in nearly 33%**

EDTA Chelation & Coronary Heart Disease Case-series

- **Clark et al. 1960**
- **76 patients — 33 S/P MI**
- **66 (87%) 90 - 100% relief of angina**
- **2 year mortality 13%**
(Historical control was 23.6%)
- **20% had recurrent angina Rx
with “boosters”**

EDTA Chelation & Coronary Heart Disease Case-series

- **Kitchell & Meltzer 1960**
- **10 Pts with angina— 6 S/P MI**
- **9 had relief of angina**
- **5/9 Pts abnormal ECG improved**
- **3 with cardiomegaly —> normal heart size**

EDTA Chelation & Coronary Heart Disease Case-series

- **Kitchell & Meltzer 1963**
- **28 new patients — 23 S/P MI**
- **2 “markedly” improved; 16 improved**
- **Exercise capacity mirrored
clinical improvement**

EDTA Chelation & Coronary Heart Disease Case-series

- **Kitchell & Meltzer 4 yr experience**
- **38 total Pts — 29 S/P MI**
- **71% improvement in disabling angina**
- **45% sustained improvement 18 - 46 mos**
- **No follow-up treatments given**

EDTA Chelation & Coronary Heart Disease Case-series

- **Olszewer & Carter 844 patients**
77% “marked improvement”
3% no improvement
- **Deucher 215 patients; few details**
70% symptomatic improvement
- **Hancke & Flytie 265 patients**
91% symptomatic improvement
8% unchanged; 1% worse

EDTA Chelation & Peripheral Vascular Disease Case-series

- **Clarke et al. 1960**
- **31 Pts — 22 rest pain, 1 dry gangrene**
- **74% relief of rest pain & claudication**
- **1 Pt no change, 2 Pts worse**
- **2 Pts amputated, 3 Pts died**
- **3/4 Pts recurrent Sx responded to Rx**

EDTA Chelation & Peripheral Vascular Disease Case-series

- **Lamar 1964, 1966**
- **18 Pts — DM in all, severe Sx**
- **100% improvement in Sx**
- **Healed ulcerations, improved oscillography**
- **Detailed reports of 6 Pts**
- **Large number of EDTA infusions (up to 99)**

EDTA Chelation & Peripheral Vascular Disease Case-series

- **Olszewer & Carter 1989**
- **1130 Pts; heterogeneous group**
- **91% “complete recovery”**
- **8% “good recovery”**
- **7/10 Pts dry gangrene “satisfactory recovery”**

EDTA Chelation & Peripheral Vascular Disease Case-series

- **Hancke & Flytlie 1993**
- **262 Pts — claudication; 103 with rest pain**
- **27 Pts for amputation**
- **82% improved Sx (85% Pts with rest pain)**
- **24/27 Pts amputation averted**
- **Improved skin temperature in 80%, skin color in 76%, ABI in 83%**

EDTA Chelation & Peripheral Vascular Disease Controlled Trials

- **Danish Trial 1992**
- **159 Pts — intermittent claudication**
- **1^o end pt Absolute claudication distance (ACD)**
- **2^o end pts Initial claudication distance (ICD),
ankle brachial indices (ABI)**

EDTA Chelation & Peripheral Vascular Disease Danish Trial Results

	ICD		ACD	
	EDTA	Placebo	EDTA	Placebo
Pre Rx Study EDTA n=75; Placebo n=78	74±25	82±36	119±38	157±226
Post 20 Infusion Study EDTA n=68; Placebo n=67	93±40	109±56	159±99	206±239
3 Month Study EDTA n=68; Placebo n=67	95±48	102±42	162±101	204±248
6 Month Study EDTA n=68; Placebo n=67	97±47	119±93	180±150	194±127

EDTA Chelation & Peripheral Vascular Disease Danish Trial Defects

- **Inadequate sample sizes - 462 needed for Δ 25 m**
- **Violation of blind by investigators**
- **High drop out rate - 36.8% EDTA, 29.1% control**
- **Lack of concordant baseline exercise tests**
- **Inappropriate statistical analysis**

EDTA Chelation & Peripheral Vascular Disease Controlled Trials

- **New Zealand Trial 1992**
- **32 Pts — claudication, not surgical/PVI candidates**
- **1° end pt Absolute claudication distance (ACD)**
- **2° end pts Initial claudication distance (ICD), ankle brachial indices (ABI), pulsatility index, exercise capacity and lifestyle questionnaires**

EDTA Chelation & Peripheral Vascular Disease New Zealand Trial Results

- **↑ACD 25.9% EDTA; ↑ACD 14.8% control**
- **No Δ in post exercise ABIs**
- **EDTA improved resting ABI at 3 mos**
- **EDTA improved worse leg FA pulsatility index**
- **EDTA improved physical activity ability**
- **Other positive trends; not statistically significant**

EDTA Chelation & Coronary Artery Disease Controlled Trials

- **PATCH Trial 2002**
- **84 Pts — CAD; 30% no angina; mild angina in 54% EDTA grp & 40% control grp**
- **1° end pt Δ in mean “exercise time”**
- **2° end pts time to ST depression, total exercise time, VO_2 max, anaerobic threshold, lifestyle questionnaires**

EDTA Chelation & Coronary Artery Disease PATCH Results

- **↑↑ time to ST Δ 63 sec EDTA; ↑↑ 54 sec controls**
- **Significant ↑↑ VO₂ max EDTA grp**
- **0 PCIs in EDTA grp; 4 PCIs in controls**
- **No significant Δ in other end points**

EDTA Chelation & Peripheral Vascular Disease PATCH Defects

- **Highly select population (2.7% of 3140 Pts)**
- **Null hypothesis unclear**
- **Inadequate sample sizes - 169 needed for Δ 60 sec**
- **Bizarre exercise protocol**
- **Lack of concordant baseline exercise tests**
- **Inappropriate statistical analysis**

“In God we trust.

All others must show data.”

National Institutes of Health

“Look at that data carefully.”

Dr. Olmstead
