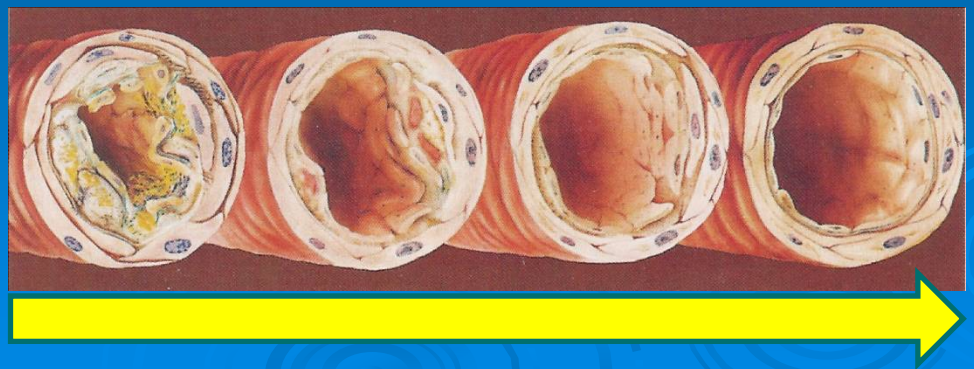
Plaquex® Therapy

Intravenous Phosphatidylcholine Application for the Treatment of Atherosclerosis & much more



Phosphatidylcholine (PC)

- 1. What is it ?
- 2. What does it do ?
- 3. How to use it

What it's not

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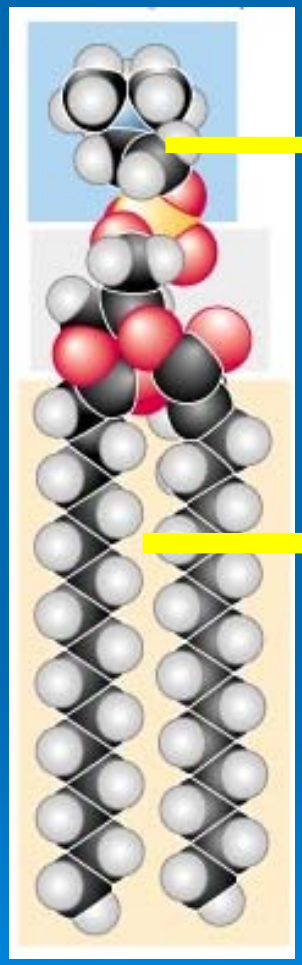
What is Phosphatidylcholine ?



Choline head group: *Hydrophilic part*

Fatty acid tails:

E.g.. Linoleic acid from soy

= both tails unsaturated

1,2 Dilinoleoylphosphatidylcholine, also called Polyenyl PC =

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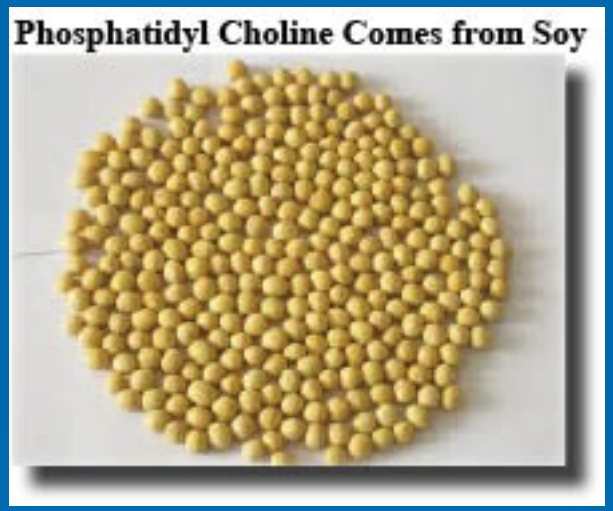
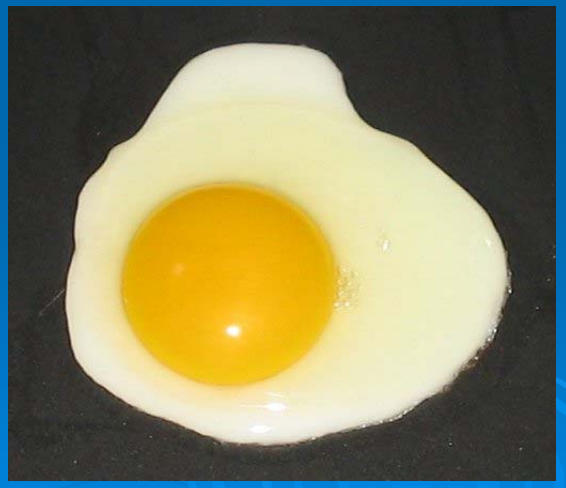
The PC to use is:
1,2 Dilinoleoylphosphatidylcholine
from Soy



PC from egg yolk contains Saturated fatty acids. Origin of the term Lecithin
Lekithos = Greek for egg yolk.



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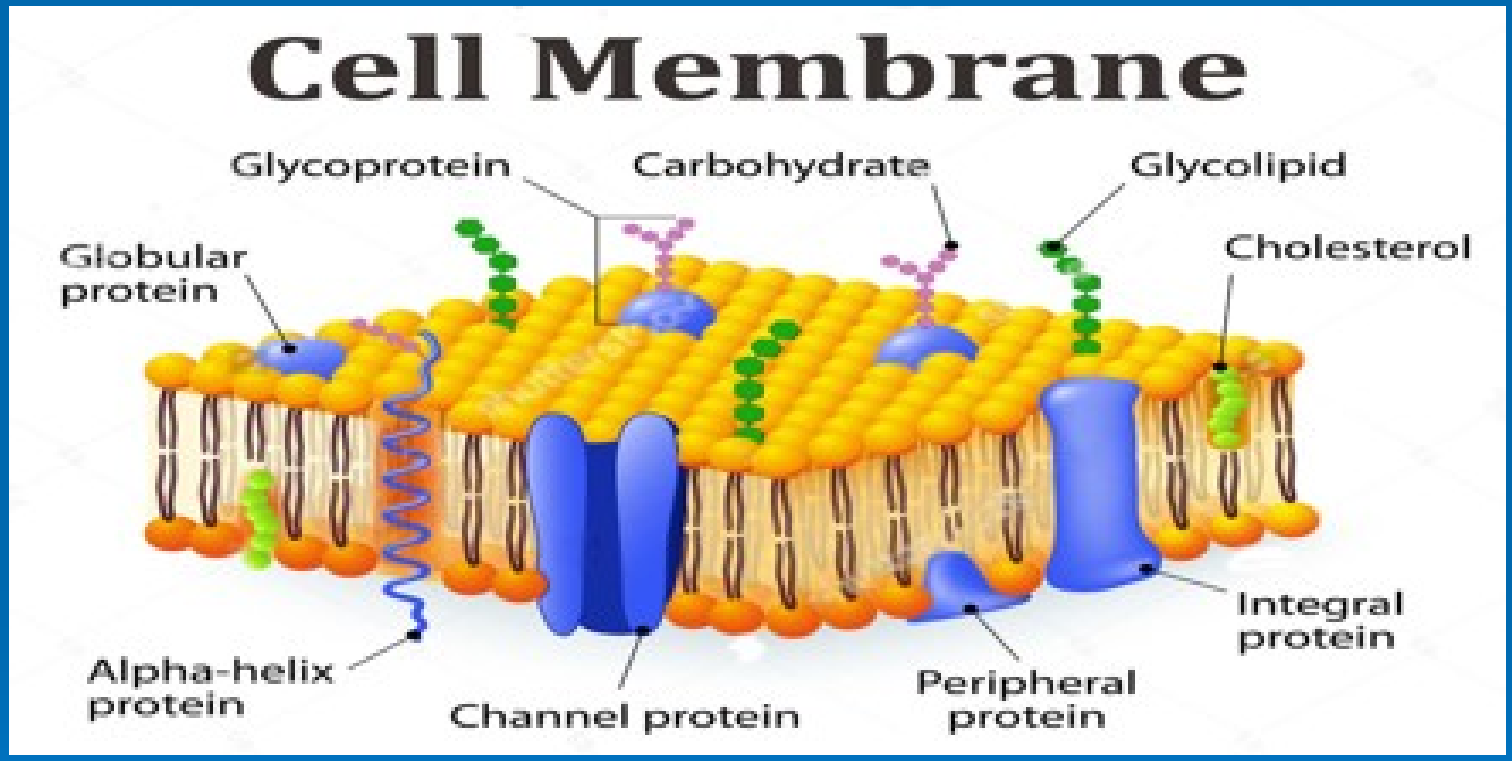
Structural Element for Formation & Regeneration of Biological Membranes



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PC builds cell membranes

Bilayers of polyunsaturated Phosphatidylcholine molecules.

Embedded proteins, receptors, electrolyte channels and Cholesterol.

Membrane synthesis begins in the endoplasmatic reticulum as precursor vesicles who fuse with the already existing plasma membrane.

PC is a membrane therapeutic

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Function of PC in membranes

PC affects a number of cellular functions:

- - Carrier mediated transport
- - Receptor function
- - Phago-, Endo- & Exocytosis
- - Cell – Cell interaction
- - Cell cycle and differentiation

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- Membrane Fluidity:
  - Unsaturated fatty acid chains increase the membrane fluidity.
  - Effects on Immune Cell Activation

- - Determines properties of membrane bound enzymes involved in detoxification and lipid metabolism (1)

  → SOD,Glutathione, LCAT, Lipases ↑

- - Precursor function for Prostaglandins and Acetylcholine, Eicosanoids

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- Surfactant function in GI and Lung tissue (2,3)

  Protection of gastric lining from NSAID damage (4)

  Prevents alveolar collaps, activates alveolar macrophage defense

  Anti Glue function in Peritoneum

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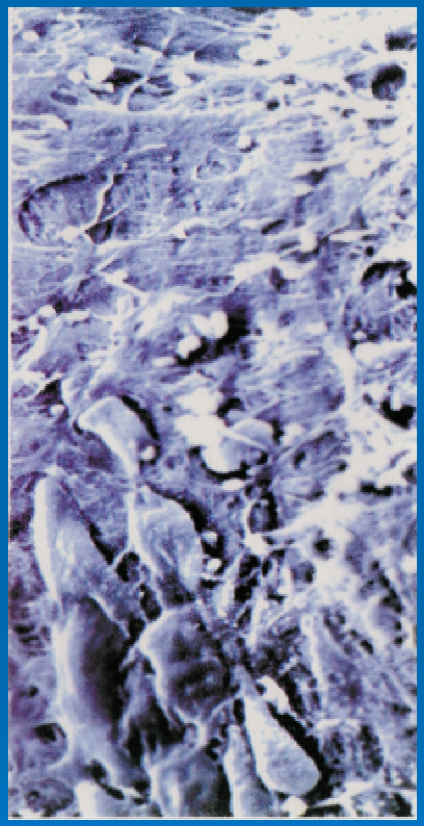
Cell Membrane Damage by:



- Free Radicals
- Toxic Substances
- Heavy Metals
- Detergents
- Mechanical (Heart Catheter!)
- High Blood Pressure
- High levels of Adrenalin, Aldosterone & Cortisol (5)
- High Blood Sugar & Insulin
- Smoking, Cocaine
- Bacterial LPS

INFLAMMATION

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Break Down of Repair Mechanisms

At birth our cell membranes consist of 90 % Polyenyl-Phosphatidylcholine. As we age we lose more and more until there are only 10 % left in old age.

- Loss of cell membrane fluidity
- Loss of enzyme function within the membranes
- Loss of receptor function
- Loss of waste elimination/nutrient uptake
- Loss of membrane integrated LDL
- Loss of membrane proteins
- Loss of cell integrity, cell death

Result of the damage

- Scar tissue
- Formation of Plaque/Thrombus
- Cell malfunction, Cell death
- ? Cancer formation?

Thought Experiment on Cancer

- *The Body Electric* by Dr. Robert O. Becker, MD.
  minus 10 mV normal cell voltage. +25 mV causes dedifferentiation into stem cell

- *Healing is Voltage* by Dr. Jerry Tennant, MD.
  Positive voltage causes formation of placenta/cancer in human cells

- *Biology of Belief* by Dr. Bruce Lipton, PhD:
  Sodium-Potassium ATPase keeps membrane potential negative

- Zierenberg O. et al: supplemented PC is integrated into cell membranes and ensures optimal enzyme function

- GRAS Report: carcinogen did not induce cancer when given with PC (6)

- Theoretical Conclusion:

PC may help maintain negative cell voltage and thus prevent cancer

1. Effects of Phosphatidylcholine

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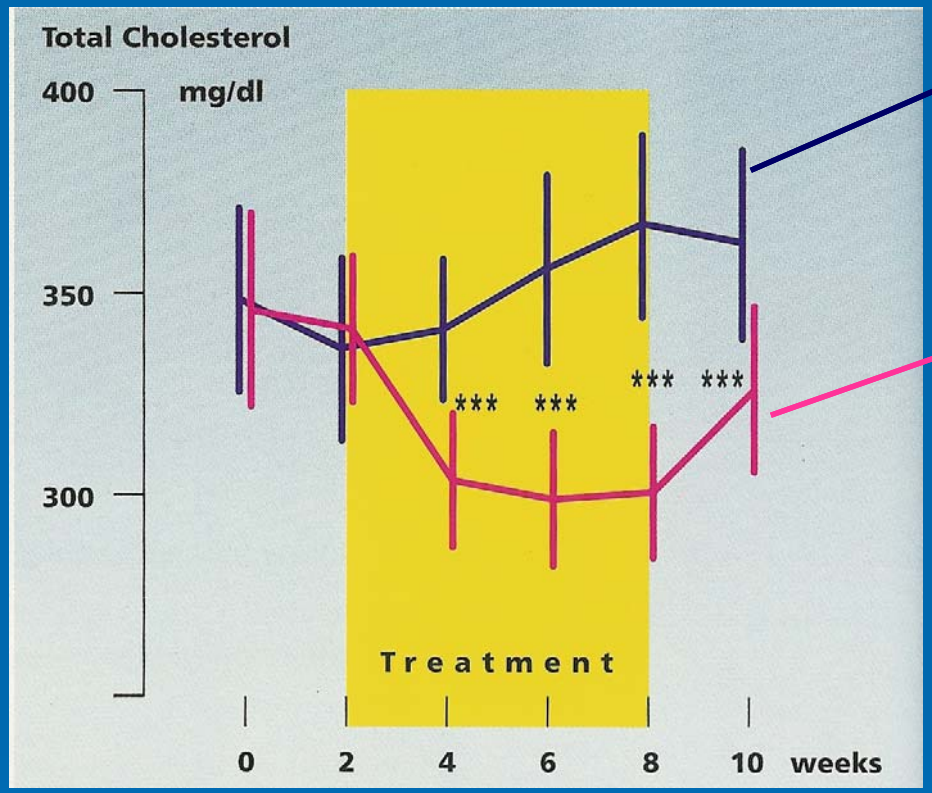
1.1 Effects on total serum cholesterol



Controls

Total Cholesterol Verum group

6 week treatment and
2 week follow up

Levels increase after stopping treatment.(7)

Summary: Give a high enough dosage, treat long enough and do maintenance Therapy

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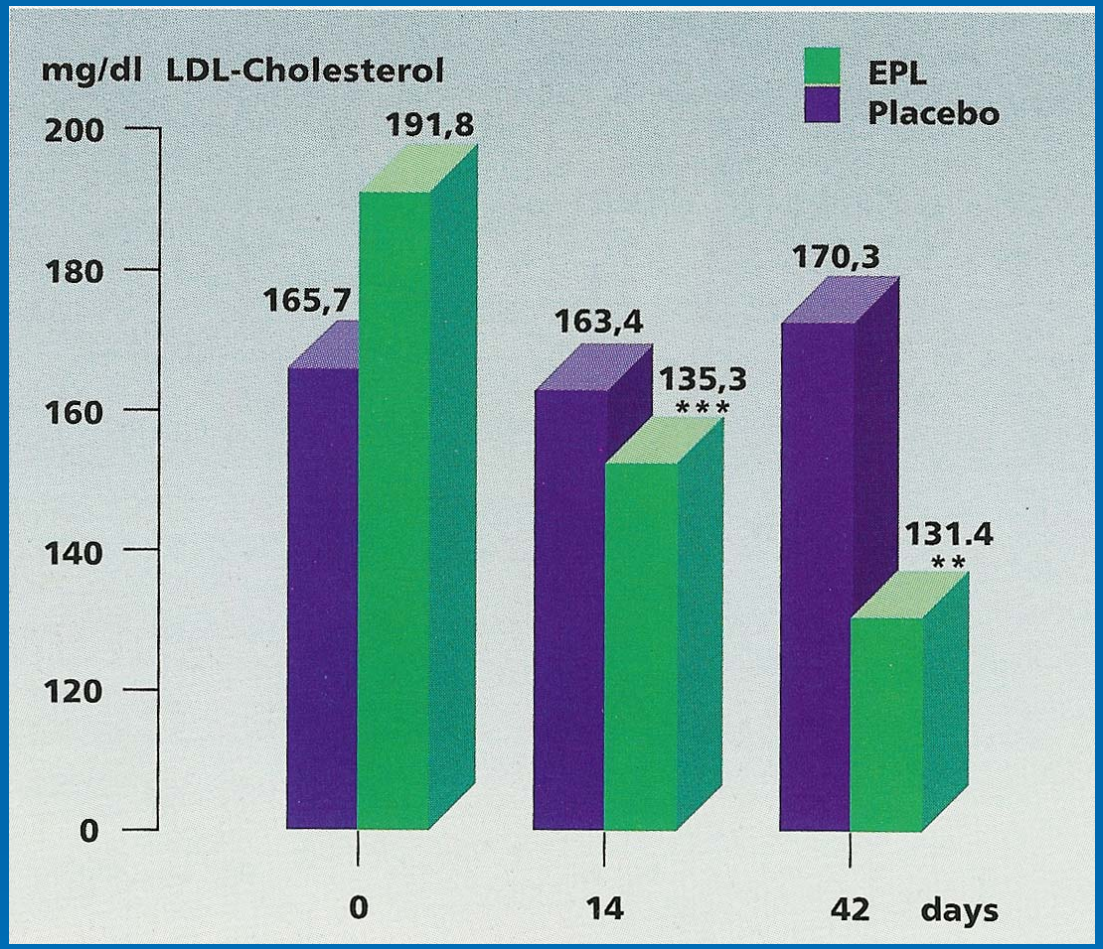
1.2 Effects on LDL cholesterol in Serum

- Reduction of LDL cholesterol in 1160 patients with the reduction ranging from 10 – 31 % of mean values.

- Double blind trials against placebo for 14 days did not show distinct changes in the serum profile of lipoproteins.

→ the treatment time most be long enough



LDL levels after 14 and 42 days with 1.9 g PC/d in comparison to controls (purple)
(75,76)

<u>Summary:</u> Give a high enough dosage, treat long enough and do maintenance Therapy

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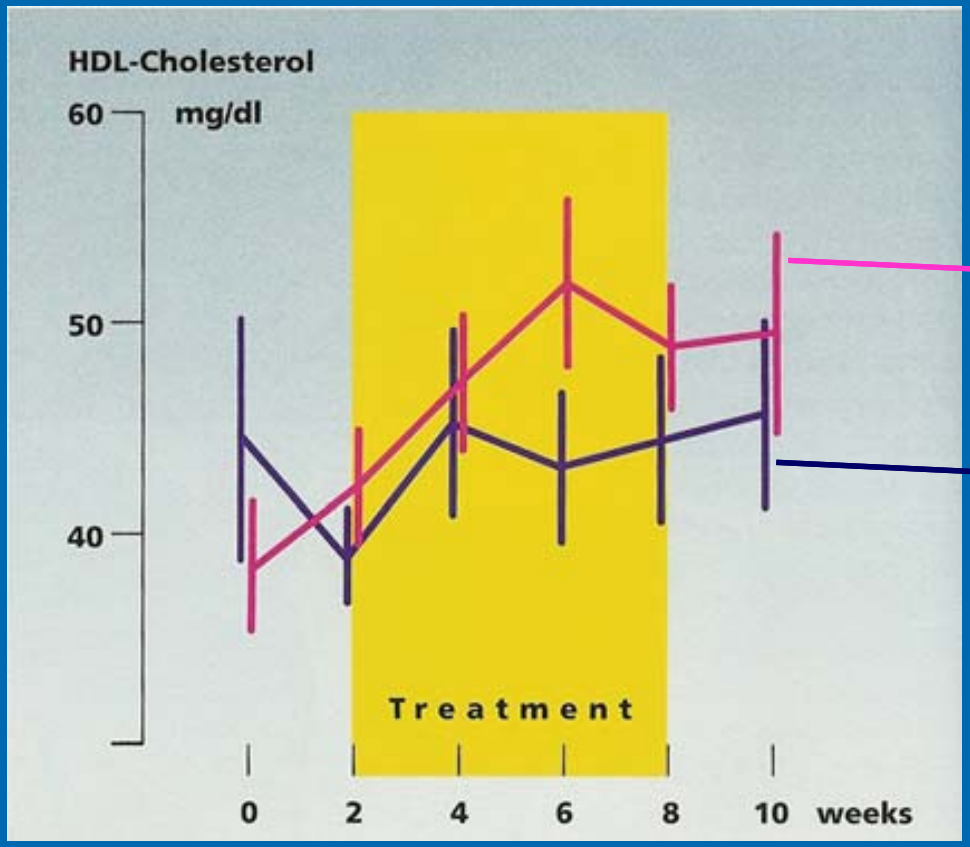
1.3 Effects on HDL Cholesterol in serum

- HDL increase 13.4-20% in diabetics with 12 month oral PC 1.5 g/d (8)
- Other studies show an increase between 10 and 45 % with various initial values. Very low initial values were raised while high initial values were hardly influenced. (9-21)
- The rise of HDL was more pronounced in non-smokers compared to smokers.



HDL (pink) during 6 weeks double blind treatment with 2.7g PC/day and 2 week follow up

Summary: Give a high enough dosage, treat long enough and do maintenance Therapy

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1.4 Effects on Serum Triglycerides

Authors	Reduction in TG in %	Treatment with EPL
KUKES et al. (130)	33.4	oral / 2 months
FAKHRI et al. (106)	34	oral / 2 months
UCHIDA (174)	34–37	oral / 2 months
UNGER et al. (176)	58	i.v. / 3 months
SABA et al. (151)	58	oral / 4 months

Most effective reduction: intravenous for 3 months

Influence of nutrition on PC effectiveness

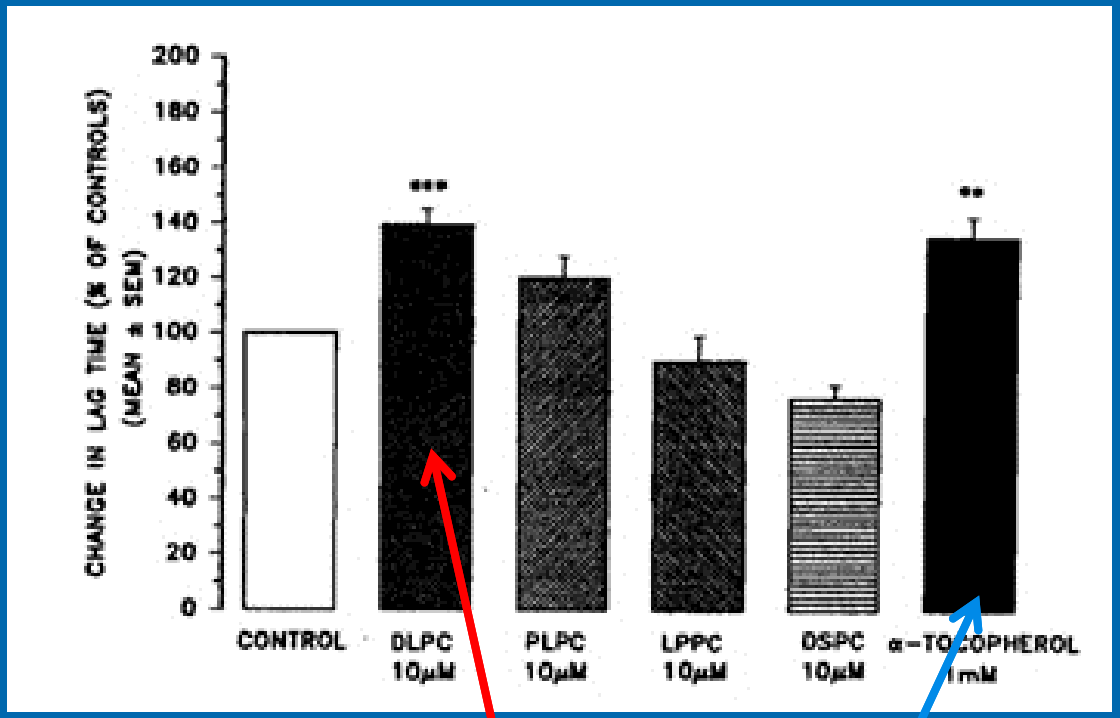
Higher caloric intake reduces the effect of PC on triglycerides (22)

Winter: TG – 22.7 % Summer: TG – 58.6 %

1.5 Influence on Lipid Peroxidation

- In vitro LDL from humans show increase in lipid peroxidation under oxidative stress. Simultaneous incubation with PC significantly inhibits this increase. (23)
- Excessive lipid peroxidation in rats with liver damage induced with tetracycline was suppressed by concurrent or subsequent PC administration. (24,25)

PC reduces LDL oxidation (26)



Oxidizing agents were added to LDL with various PC's and alpha Tocopherol

Lag time for **Dilinoleoyl PC**: **140 %** compared to control (both chains unsaturate
Lag time for **alpha tocopherol: 135 %**
Lag time for Distearoyl PC: 76 % (both chains saturated)
Lag time for Linoleoyl-palmitoyl PC: 90 % (one chain saturated, one unsaturated)

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PC increases Glutathione levels

- Increase of Glutathione levels in the liver, plasma and aortic tissue. The glutathione dependent antioxidative capacity in the aortic walls was increased significantly.(27)

→ PC produces distinct antioxidative effects.

1.6 Effects on enzyme activity

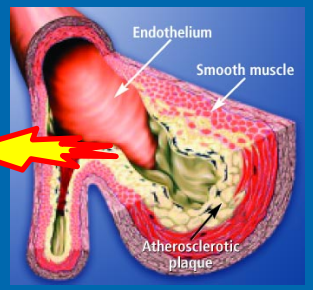
LCAT

- Lecithin-Cholesterol-Acyl-Transferase catalyzes the esterification of free cholesterol so it can be taken up by HDL and eventually eliminated from plasma. (28)
- Unsaturated PC activates LCAT activity while saturated PC diminishes its activity. (8,12,13,15,29,30,31,32)
- Other enzyme systems activated by PC: Lipoprotein Lipase, Triglyceride Lipase (33)

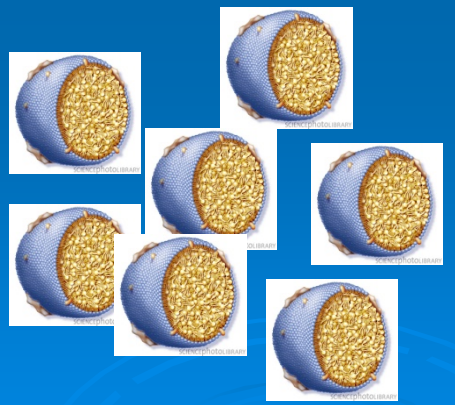
Summary of what LCAT does

El Cat

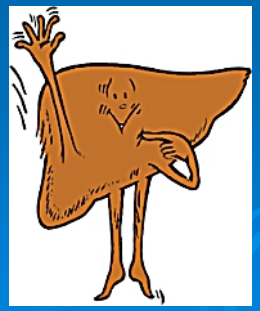
Esterification



HDL with esterified cholesterol



Good bye



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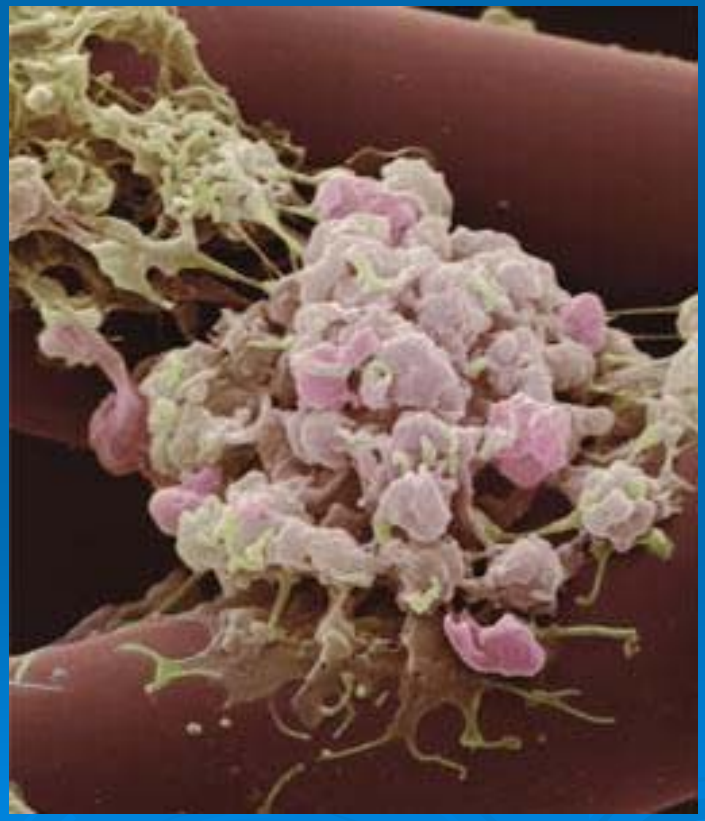
1.7 Influence on Platelets and Red Blood Cells:

a) Influence on Platelet Aggregation



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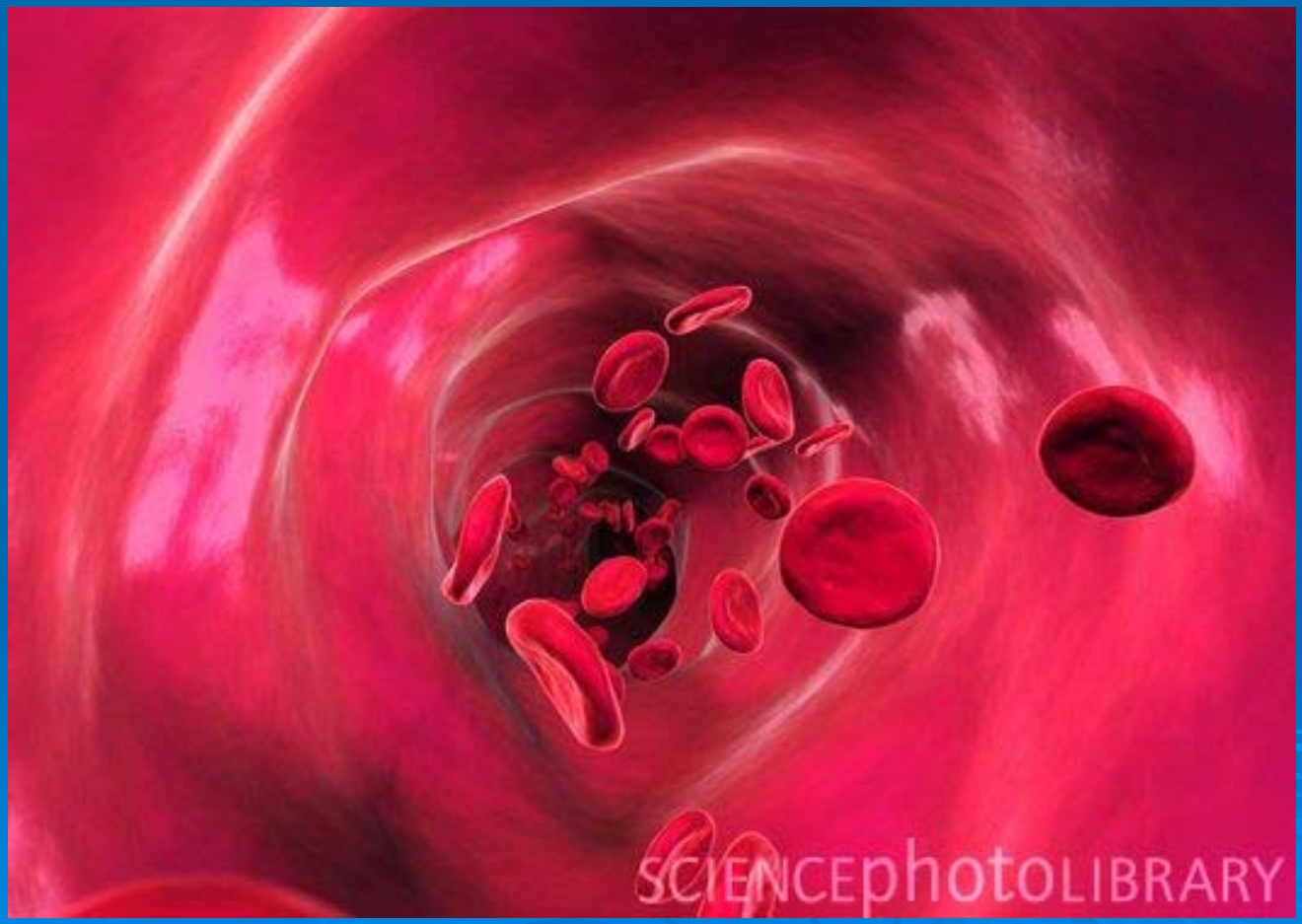
- Infusions of 500 mg PC/d reduces platelet aggregation by 60 % (34).

- „ Lipid Exchange Therapy“
- 6-keto Prostaglandin2 levels increase
- Thromboxane decreases

- IV Push Therapy only works on platelet aggregation, NOT ON PLAQUE !

b) Influence on red blood cell fluidity



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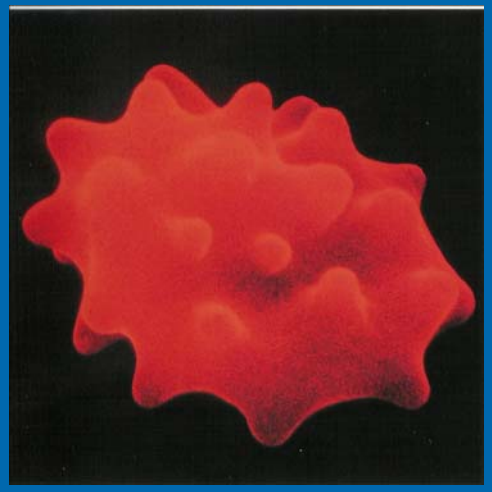
- Cholesterol accumulation in the RBC membrane decreases fluidity and deformability

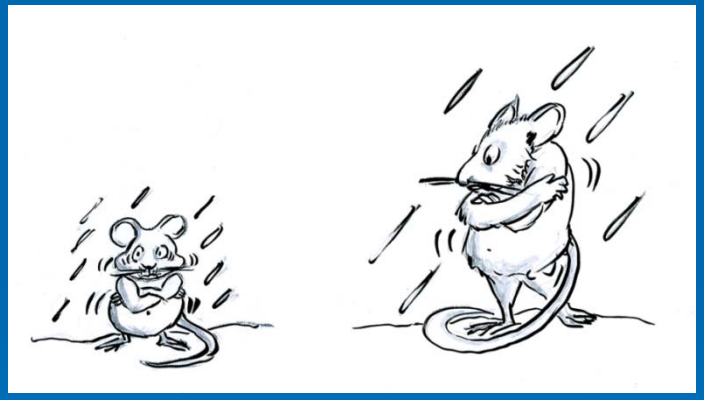


- PC activates LCAT to esterify and eliminate cholesterol from RBC membranes
- Increase in membrane fluidity and deformability
- Pass through tight capillaries easily

1.8 Effects on Inflammation & Oxidation

PC increases SOD, Glutathione, Prostaglandin2 (35)

PC decreases TNFa, IL6 and IL10 (35), Inactivates NFKB and inflammatory Pathways (77)



(36)

Conclusion:

Treatment with Polyenylphosphatidylcholine has antinflammatory and antioxidative effects.

(37,38-41)

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1.9 Effects on Immune Cells

Increased membrane fluidity activates lymphocytes, monocytes and macrophages

Take down of biofilm forming plaque (?)

Biofilm found in plaque Surrounding cholesterol Deposits (42)

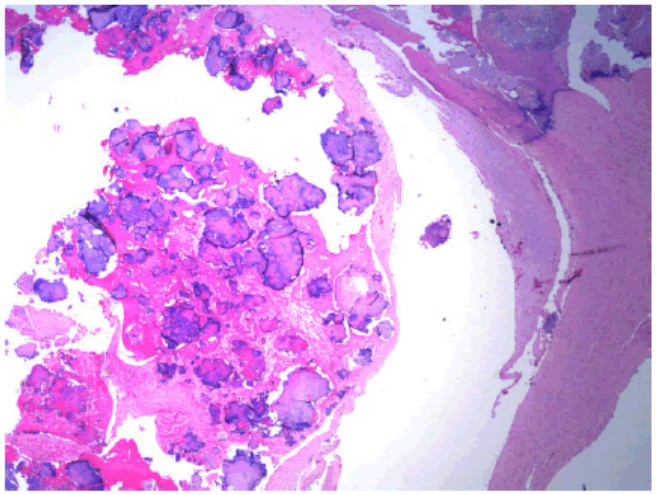

Figure 1: In the lumen of this artery, there is a plaque which shows cholesterol clefts and calcium deposits. PAS positive material (biofilm), surrounding the calcium deposits, is present (PAS 2.5X).

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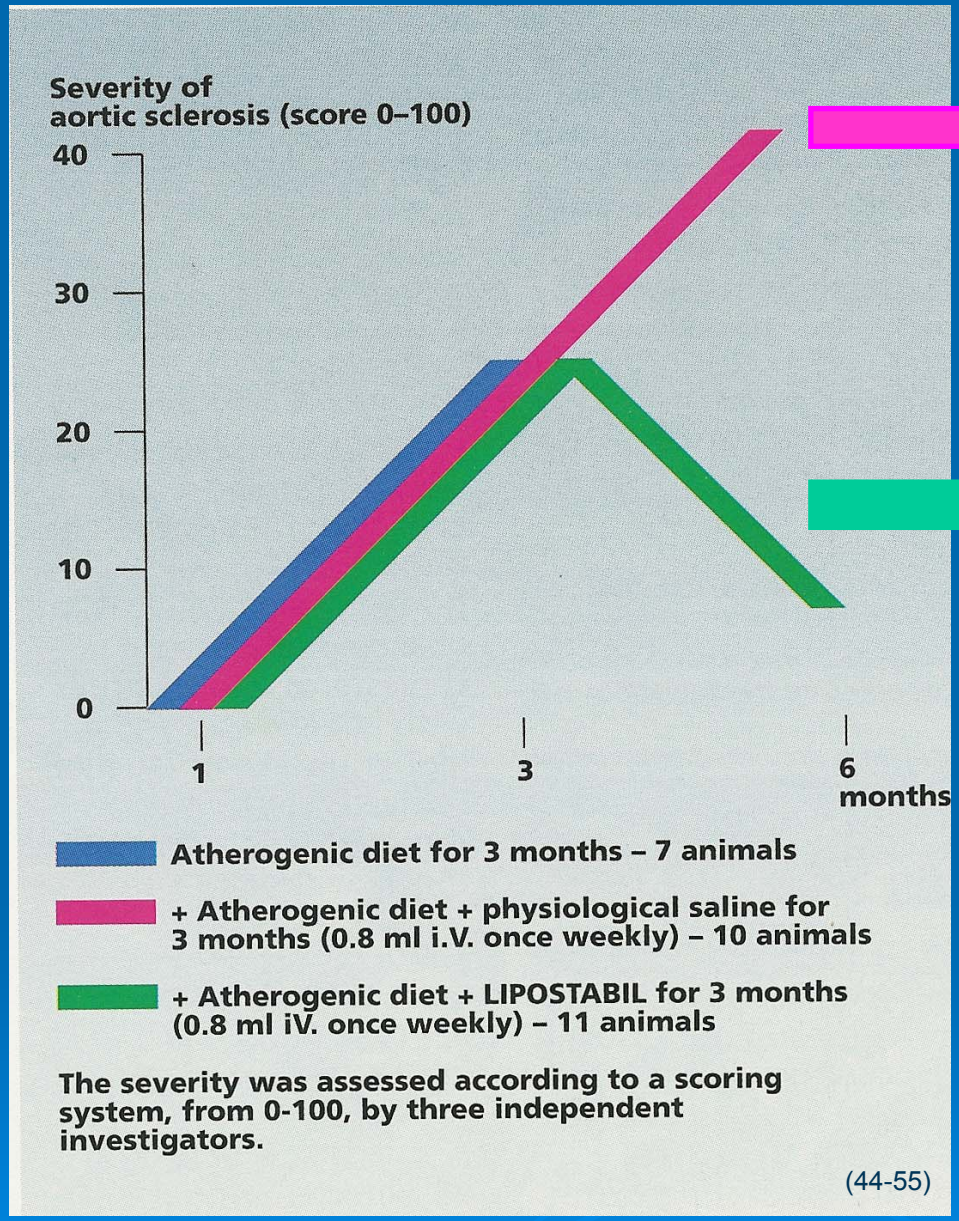
1.10 Effects on Atherosclerotic Changes

Cellular cholesterol content was lowered in comparison to that of untreated endothelial cell cultures by 40 %.

In Animal studies:

→ concurrent PC treatment prevented formation of atherosclerotic changes

→ PC treatment after discontinuation of the 6 month diet showed marked or complete regression of atherosclerotic changes.



Placebo

3 weeks treatment with PC

The effect of PC on atherosclerosis was studied in 22 studies in 7 animal models and all show prevention and/or elimination of plaque

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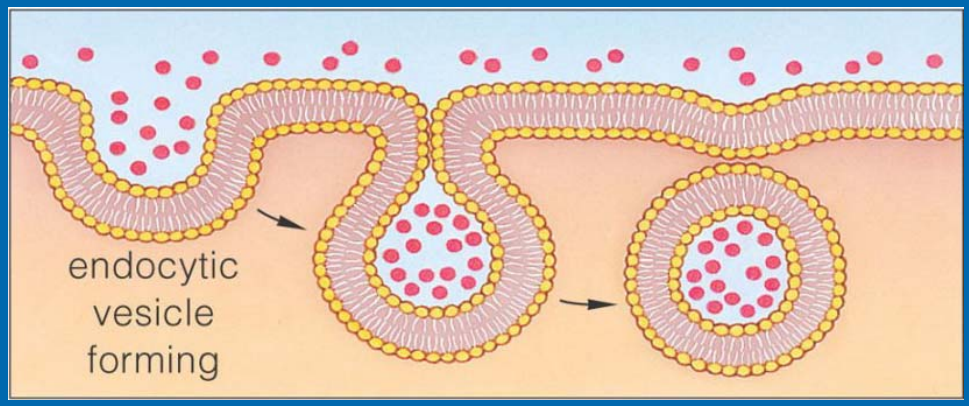
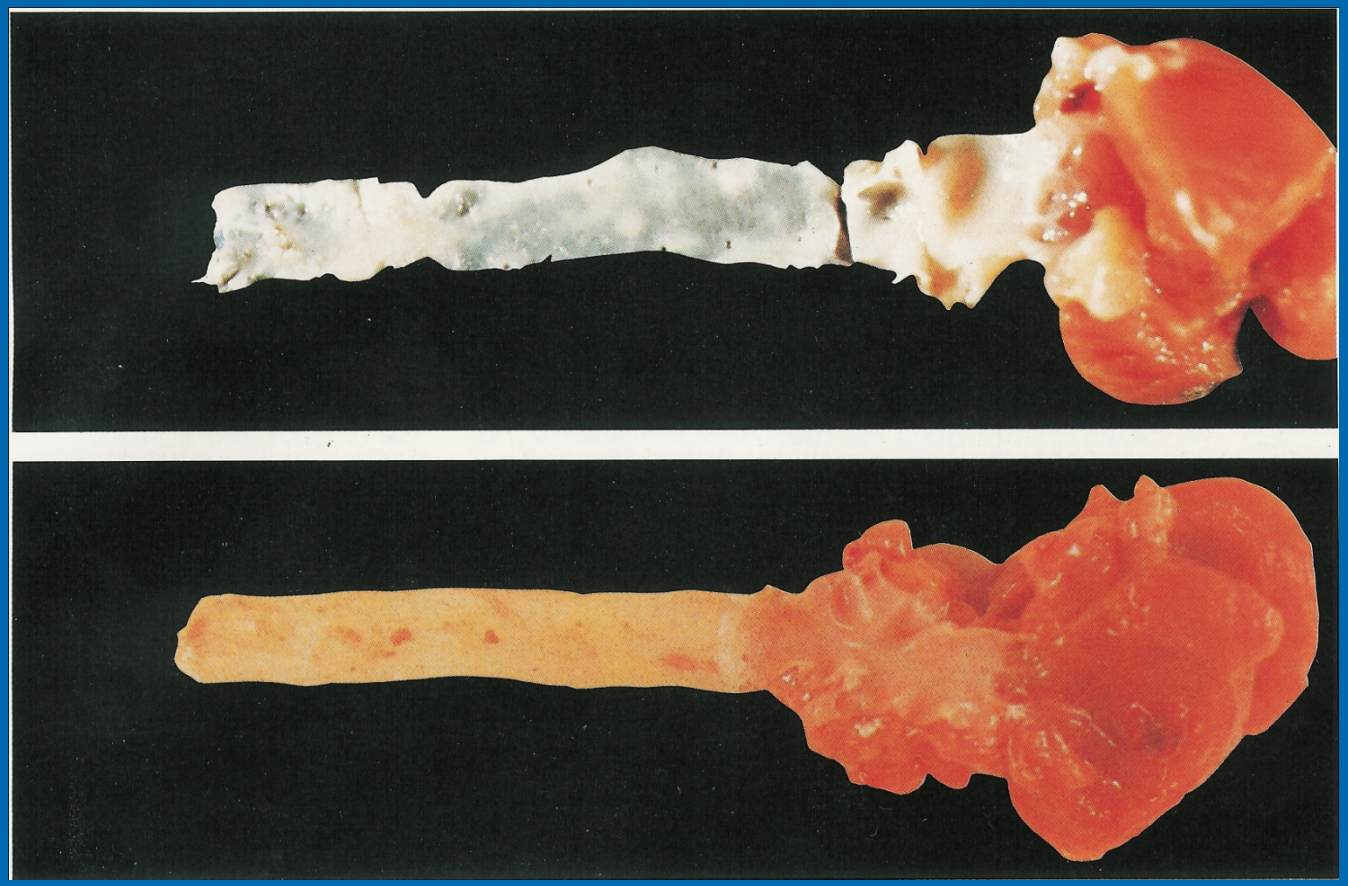
PC inhibits endocytosis in smooth muscle cells

PC has an inhibitory effect on atherogenic processes by reducing the endocytosis of plasma contituents.(43)



PC Prevents foam cell formation by reducing cholesterol content in Macrophages

Macrophages with labelled cholesterol incubated in PC medium led to release of 15-20% of cholesterol.



After 2 months of high cholesterol diet.

After 2 months of high cholesterol diet and subsequent 2-month PC administration together with normal diet.

Semilunar valves, ascending & descending branches and aortic arch of a rat. (44)

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1.11 Effects of PC in Hepatology

126 clinical studies with a total of 8'334 patients including a phase-IV multi-center study with 2'862 patients:

PC prevents lipid peroxidation

PC prevents suppression of cell respiration caused by snake venom. (45)

PC prevents loss of glucose-6-phosphatase activity due to intoxication with CCL4 (46).

PC leads to dose related inhibition of collagen synthesis in human fibroblasts, thereby preventing and postponing liver cirrhosis. (47)

PC Effects in Liver Patients:

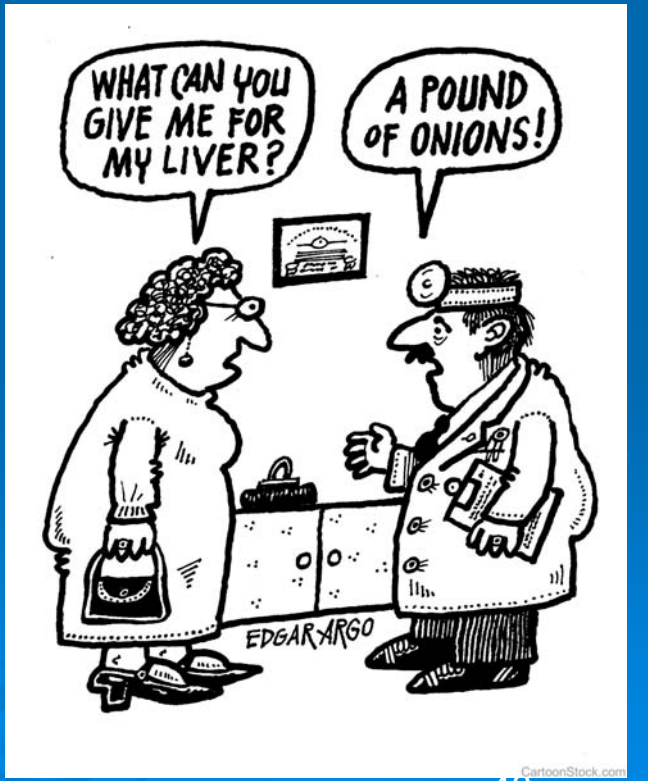
1) Accelerated improvement or normalisation of subjective complaints,clinical findings and numerous biochemical parameters

2) Better histological or electron-microscopic findings as compared with control groups

3) Shortened time of hospitalisation,

4) less post-hepatic residues.

5) PC reverses fatty liver



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1.12 PC improves kidney function

23 clinical studies:

- Chronic glomerulonephritis patients showed a reduction in edema and increased serum albumin (51)

- 3-15 year old children with chronic nephritis showed reduced symptoms of intoxication, normal BP. Proteinuria, hypoalbuminemia and leucocytosis disappeared. (52)

- In renal insufficiency creatinine, urea and sodium clearance increased, BP normalized (53, 54)

- Anectdotal reports were made that PC treatment is able to reduce the frequency of dialysis.

1.13 PC for Psoriasis

Various studies in patients with psoriasis, neurodermitis and seborrhoic eczema showed:

- Early onset and more complete remission of skin manifestations

- Reduced recidivations, sustained improvement

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Animal Studies

In 22 studies on 7 different animal species diet induced Atherosclerotic changes were prevented or reduced by simultaneous or curative PC administration.

- Atherosclerosis induced in hypercholesterolaemic baboons by immunological injury and the effects of i.v. polyunsaturated phosphatidylcholine (55)

Only those animals with the cholesterol rich diet and BSA injections developed aortic and coronary sclerosis.

An i.v. injection of polyunsaturated soy phosphatidylcholine 3x/week

reduced the incidence and severity of aortic atherosclerosis.

Baboon Groups: 1. Atherogenic Diet, BSA
2. Atherogenic Diet, BSA, Phosphatidylcholine
3. Atherogenic Diet, Saline
4. Control Diet, BSA
5. Control Diet, no injections

Group	Number	Diet	BSA	PC	Aortic athero-sclerosis % area
1	8	A	+	-	46.4 ± 12.5
2	8	A	+	+	9.5 ± 4.4
3	5	A	-	-	0
4	5	C	+	-	0
5	5	C	-	-	0

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Modification of aortic atheroma and fatty liver in cholesterol fed rabbits by iv. injection of saturated and polyunsaturated PC (56,57)

- New Zealand rabbits were divided into 3 groups. All groups were fed a cholesterol rich diet.
- One group received ovolecithin injections (saturated) twice weekly and another group received unsaturated PC injections 4 times weekly.

Results

The control rabbits fed a cholesterol rich diet showed fatty streaks and plaque formation.

Cholesterol fed rabbits given ovo-lecithin injections showed more aortic atheroma than the control group.

Cholesterol fed rabbits given unsaturated PC showed no macroscopic evidence of either aortic atheroma or fatty liver.

Dose dependence of anti-atherosclerotic effect of PC. The higher the dose, the more significant the reduction of atherosclerosis (58)

Human Studies

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Effects on impaired coronary circulation

- Angina and post MI patients were assessed with objective and subjective evaluations.
- **EKG:** (59,34,60,61,62,63,43,63,64,65,66,67,68,71)
- S-T depressions were found to disappear; previously negative T-waves were reversed to positive.
- Concomitant relief of angina pain
- Exercise tolerance improved

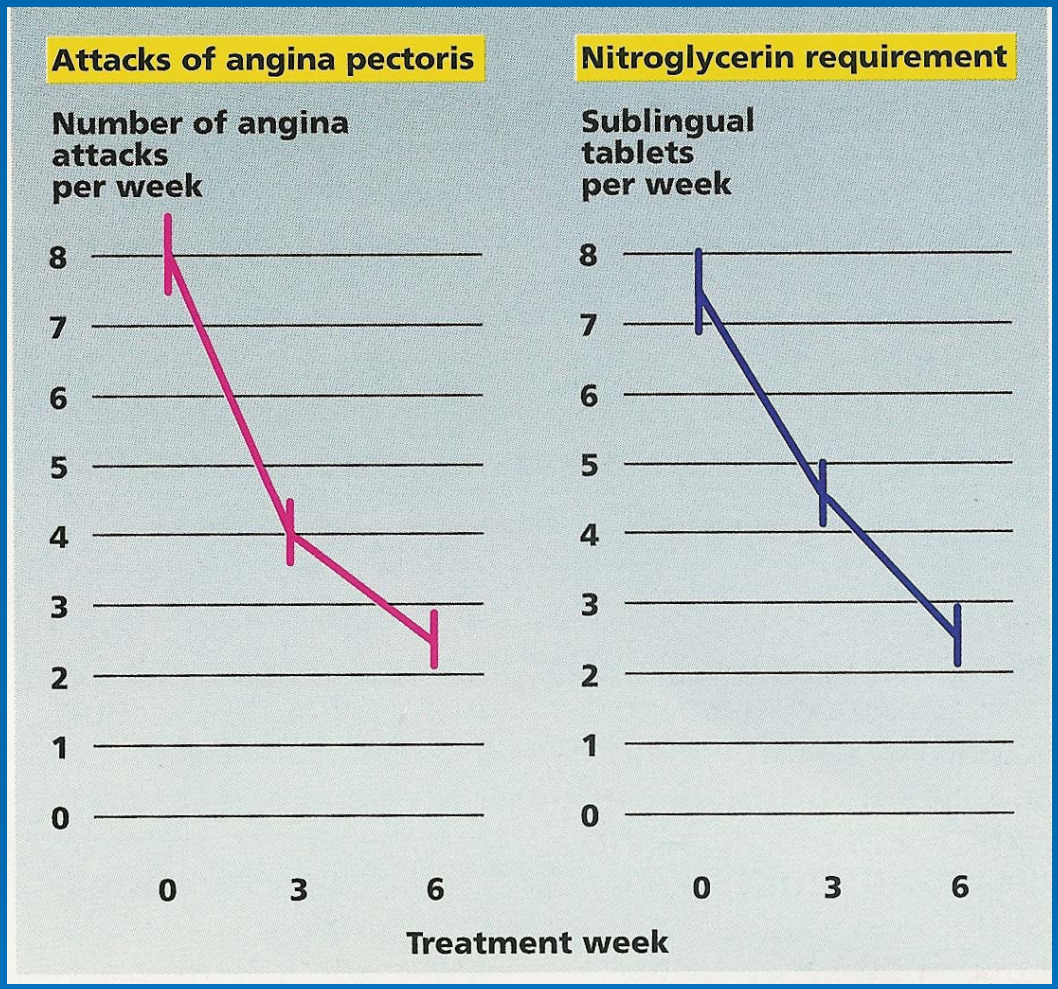
- **Incidence of Anginal Attacks, Nitro-Consumption:**

- 34 male patients suffering from ischaemic heart disease and angina pectoris (stages III-IV):

- Dosage 500 mg/d of intravenous PC for of 14 days.

- 20 of the 34 patients with cessation of angina after 1-2 weeks

- 14 patients with reduction of attacks from 8 to 10 per 24 h to 1 to 3 per24 h, less severity and daily nitro-consumption was reduced to 2 to 5 doses from prior 8-10 doses/day (72)



Mean incidence of anginal attacks per week and consumption of nitro-glycerine per week for patients with diminished coronary blood flow rates before and during a 6-week treatment with PC.(n=507)

(73)

Symptoms decline fast → Motivation to continue Tx

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Effects on exercise tolerance in CAD

In the trial group of V.A. Almazov et al. the walking distance without Stopping or requiring Nitro-glycerine was extended from 30-50 m to 3000 m. (34)

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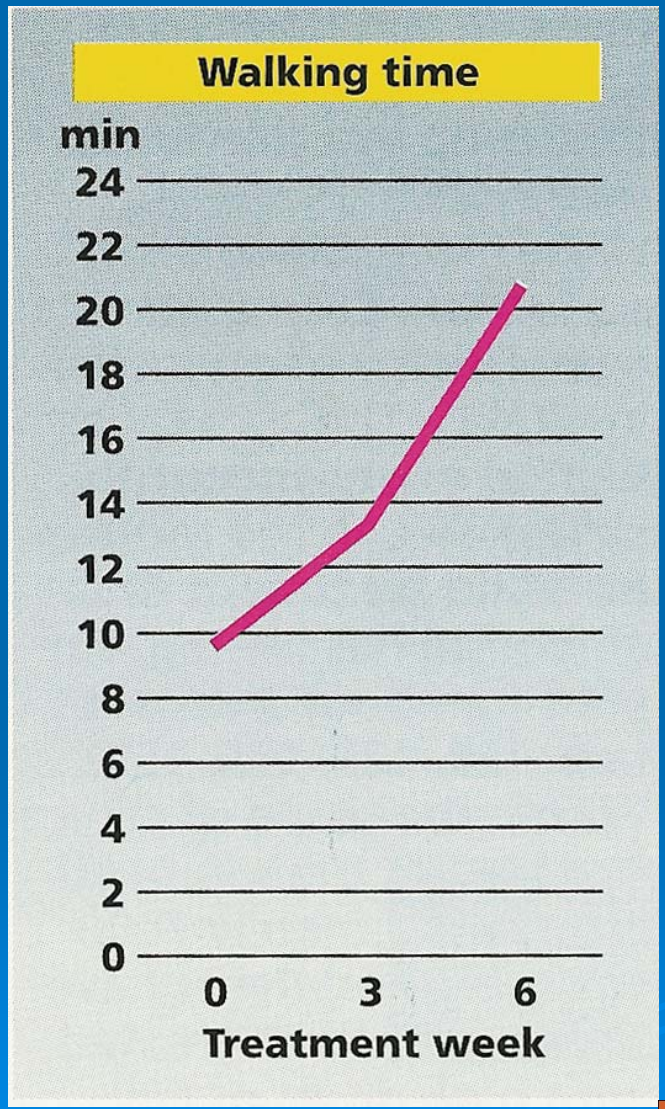
Increased walking distance as well as improved oscillometric index with IV and Oral PC.



Mean walking time in minutes of patients (n=282) before and during treatment with PC of 6 weeks.(73)

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- **Improved well being & mental activity**

- Improvement of :
- Fatigue, low Vitality, disturbed Sleep, retrosternal Pain, Palpitations in 88 out of 94 geriatric patients

- An increase in the physical and mental activity of the patients after PC treatment was also observed (62,63)

Case Histories

Patient 1

- **Calcium Score:**

  Before: 271.88 After:138.4

  Calcium Volume:

  Before: 220.16 After:140.4

Tx time: 3.5 months with 2 PC + 1 Chelation /week

Reduction of 49 % in Ca score and 36 % in volume

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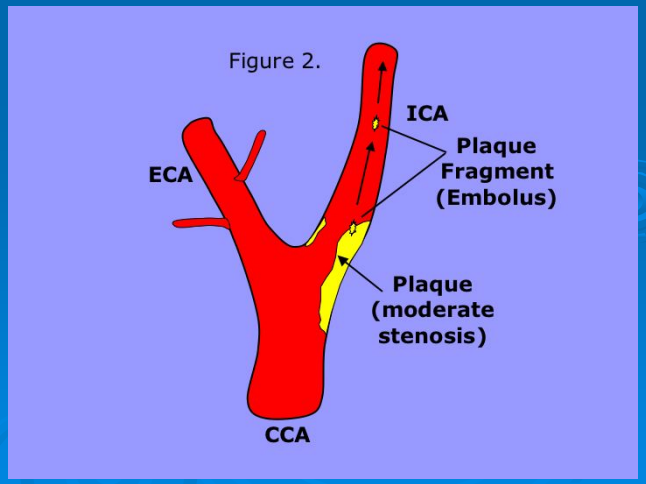
Patient 2

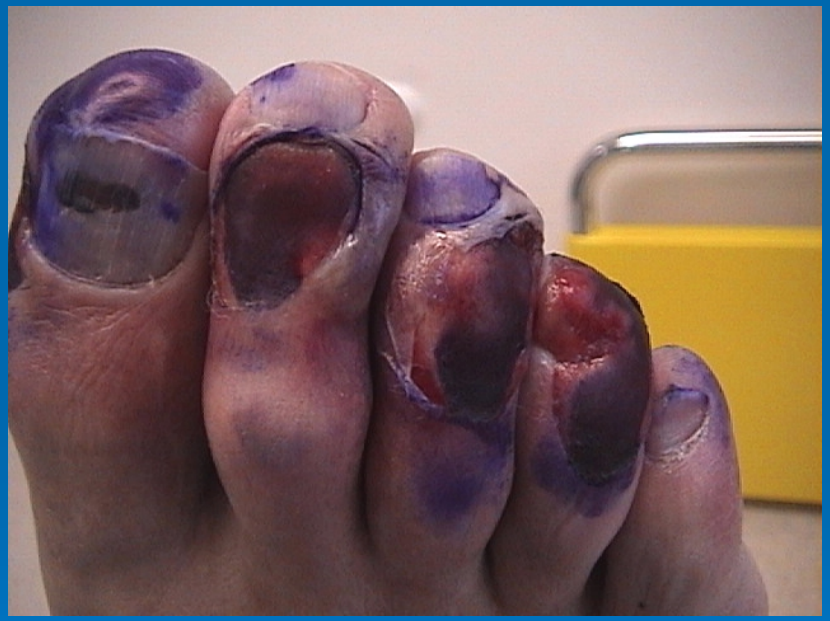
Carotid Stenosis

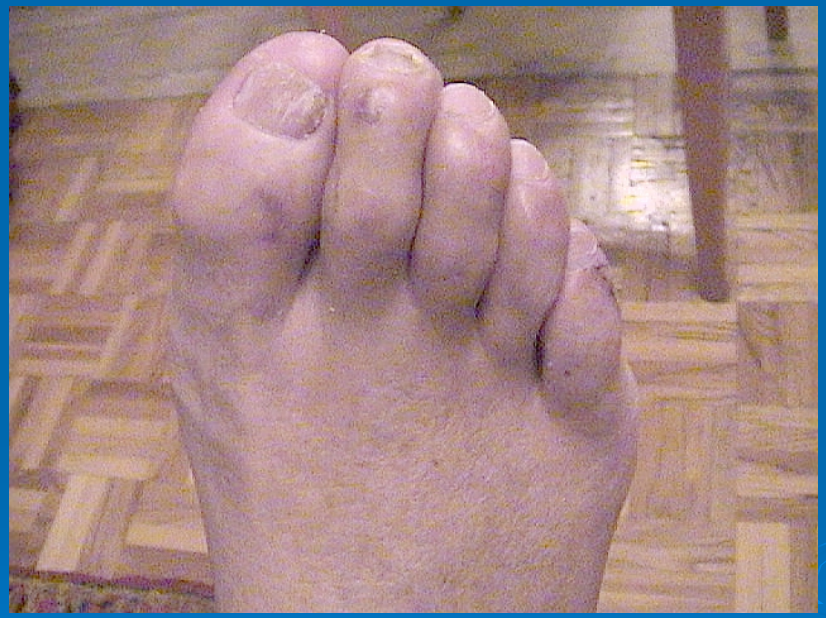
- Initial Carotid stenosis of 75%. After 30 PC treatments it was reduced to 40%. 1.5 years later the stenosis increased to 95% due to the lack of maintenance therapy. After another 40 treatments the stenosis is down to 60%.



Patient 3

54 year old male Diabetic with Hepatitis C and Vasculitis of the toes and peripheral circulatory disease, causing difficulty with wound healing





After 6 Months with 20 Plaquex Infusions as well as 10 Vitamin C Infusions, Low Level Laser Tx and iv Ozone Tx.

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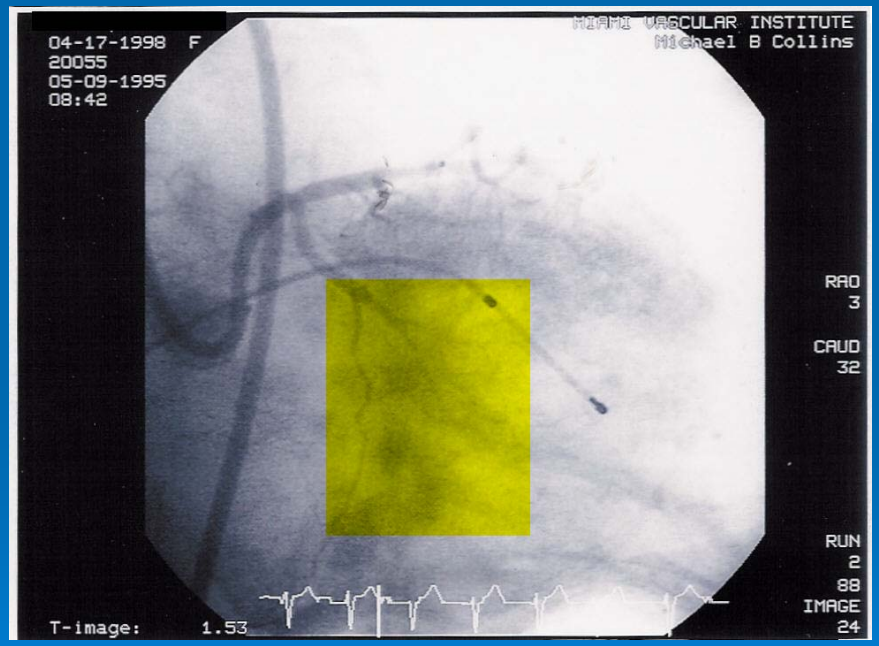
Patient 4

- 65 year old female patient with 90 % stenosis of the right coronary artery.



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Score Summary:

Coronary Artery Name	Score
Left Anterior Decending	23.8
Left Circumflex	4.3
Right Coronary Artery	176.7
Left Main Artery	0
Total Score	204.8

Physicians' Report

___ Score of zero. Normal. No identifiable atherosclerotic placque.

___ 1 - 149. Mild identifiable placque. Possible mild or minimal coronary artery stenosis.

_X_ 150 - 499. Moderate identifiable placque. Possible mild or minimal coronary artery stenosis.

___ **500 - 999. Moderate to Severe identifiable placque. Likelihood of significant stenosis of at least one coronary vessel.**

___ **1,000 - to 10,000 or above. Severe identifiable placque. High likelihood of significant stenosis of more than one coronary vessel.**

Patient 5

Fast CT Score	Before	After
Total Score	1362.6	563.2
Number of Lesions	13	4

Treatment: 30 Plaquex infusions over 4-5 months.

58% Reduction in Calcium Score

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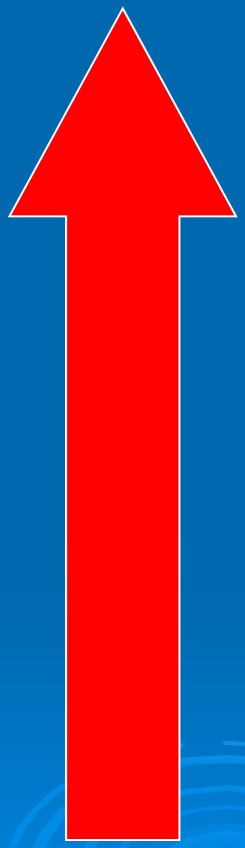
Patient 6

- 67 year old patient with claudication since several years. Pain in the right calf > left calf and a walking distance under 300 m, often even resting pain.
- Diagnosis: PAD Stage IIb.

- Doppler Diagnosis: 90 % stenosis of the right A.poplitea and
- 70 % stenosis of the left A.femoralis sup.

	Before Plaquex		After Plaquex	
	mmHg		mmHg	
A.tib.p. R	140		178	
A.tib.p. L	60		167	
A.dors.p R	170		180	
A.dors.p L	140		180	

Summary of Effects



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Reduction of lipid peroxidation

Mountain of rancid fat
and wet wipes
In UK sewers

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LCAT hard at work

Activation of Lecithin Acyl Transferase, Lipoprotein Lipase and Triglyceride Lipase

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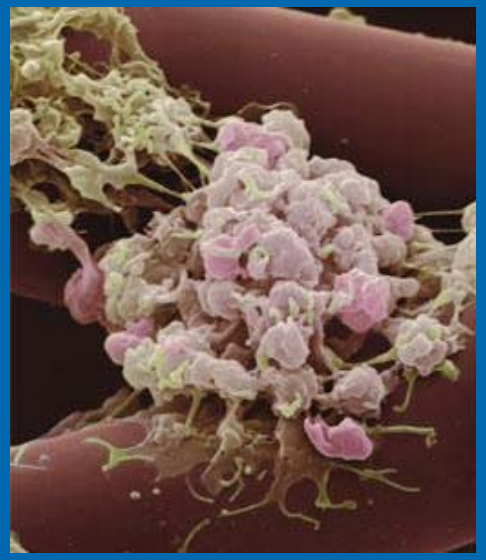
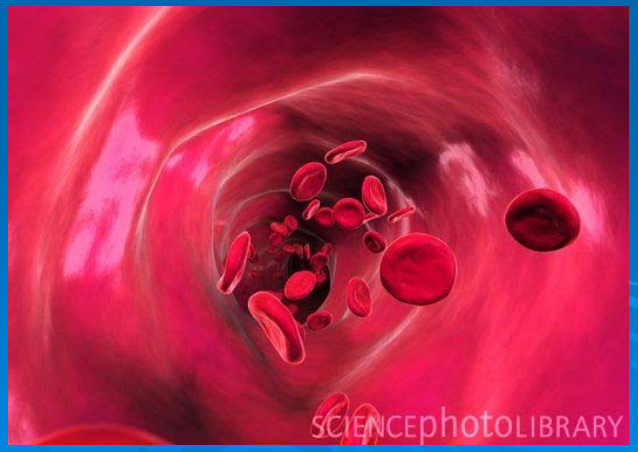
Effects on Hemorrheology

- Reduced Platelet Aggregation



- Increased RBC fluidity



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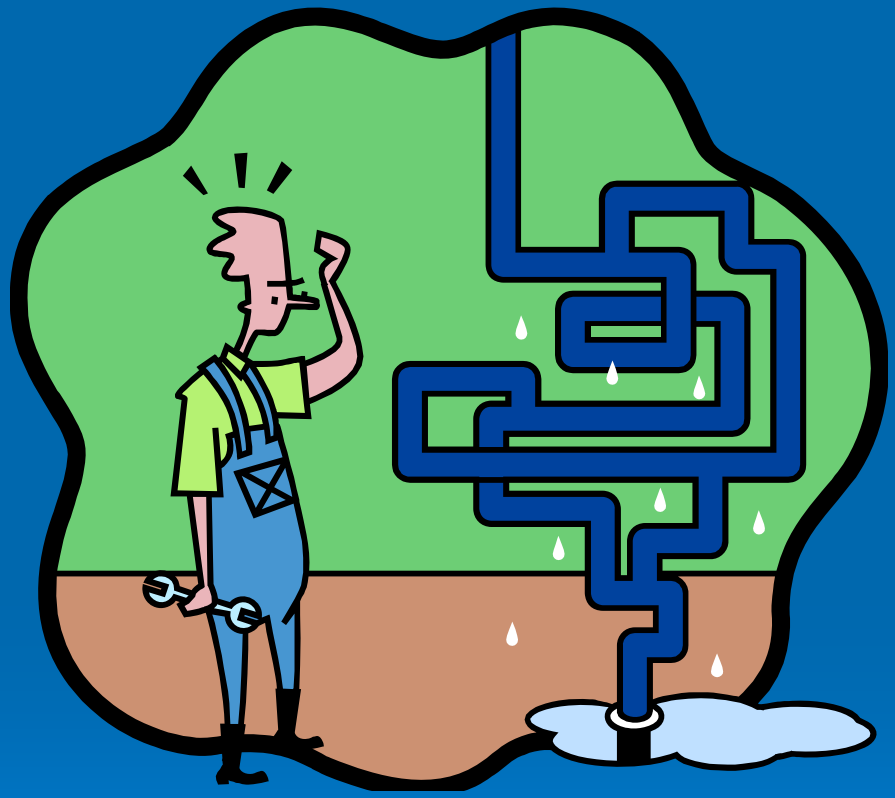
Other Effects

- GI Lining Protective Effect
- Integrity of Alveoli
- Activates Immune Cells
- Antioxidant
- Anti-Inflammatory
- Choline Donor
- Improves liver & kidney function
- Reduces Psoriasis and Neurodermitis
- General Rejuvenation

2.Practical Application

How do I clean these pipes ?



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Indications

- Hyperlipoproteinaemia, elevated TG
- Atherosclerosis
  → Angina Pectoris, peripheral vascular disease, impaired cerebral and carotid circulation
- Nephrotic Syndrome, Glomerulonephritis
- Liver disease including fatty liver
- Fatty embolism
- Cognitive Dysfunction
- Heart burn, NSAID side effects
- Psoriasis, Neurodermitis

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- **Contraindications:**
  due to the alcohol it should not be used in new-borns or premature babies
- **Side-effects:**
  Diarrhea, phlebitis* , drop in blood pressure when given too fast,very rare cases of hyper sensitivity, fatigue in Asians
- **Precautions:**
  To prevent thrombophlebitis the treatment protocol must be followed exactly.
- * If using a bad product or not following instructions

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Recommended Exams

- Lipid profile
- Homocysteine levels, hsCRP, Fibrinogen
- Liver profile
- Kidney profile
- Hormones

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Prior tests: for ex. EKG, Angiogram, Fast-CT, Perfusion- PET, Carotid US, Doppler Ultrasound depending on diagnosis

Medication history (earlier and actual Medications, Supplements)

Hair mineral analysis (toxic elements, such as heavy metals [lead, mercury], mineral deficiencies or excesses)

Urine status (Sediment, Microalbuminuria)

- **Important factor when choosing a PC product**
- **Raw PC must have 90% PC.**
- **PC with only 30-60% PC can lead to the dissociation of deoxycholic acid from PC.**
- **This can lead to phlebitis and haemolysis that can even lead to kidney failure..**

Application & Dosage

- Oral Application

-Reduces LDL, Triglycerides

-Increases HDL

-Improves kidney and liver function

DOSAGE: start slowly with 1 x 900 mg/d and increase over a period of 2 weeks to 2 x 900 mg/d and then 3 x 900 mg.

Use after completion of the infusion series.

It takes about 15 kg/33 lbs of Soy to make 1.8 g of PC.

Plaquex® Therapy

IV Treatment Schedule

- The half time time in Serum is 32 hours, therefore 2-3 treatments per week are recommended. If possible there should a 48 hour interval between treatments.The basic treatment consists of 30 infusions.

Maintenance Therapy

- In order to keep the patients condition stabilized it is recommended that they receive 1-2 treatments every month plus oral PC.

Dosage & Administration

PC should be mixed solely with

250 ml – 500 ml 5 % Glucose

or **Dextrose (D5W)!**

DO NOT MIX WITH ANYTHING ELSE !!

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- Length of the infusion

90 – 120 minutes !!!

If applied faster than the above time Phosphatidylcholine can very rarely cause thrombophlebitis. It can also cause a drop in BP.

Dosage schedule

1. Treatment: 20 ml PC (1000 mg)

2. Treatment: 30 ml PC (1500 mg)

From the 3rd treatment: 50 ml PC (2500mg)

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Caveat Dosage Changes

If the patient weighs less than **120 lbs.**, it is recommended to lower the dosage to **40 ml** for **treatments #3 – 30**.

Asian patients should not be dosed higher than 25- 30 ml as they tend to react with extreme fatigue. Split a vial into 2 Tx.

Concomittant Treatments

- Dietary changes
- Pomegranate
- Curcumin
- Vitamins D3 and K1 and K2
- Vitamin C
- Tocotrienols
- Bio-identical HRT, optimize Thyroid
- Stress Reduction

Make your patients comfortable

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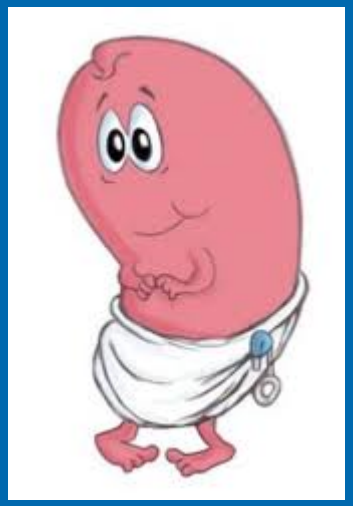
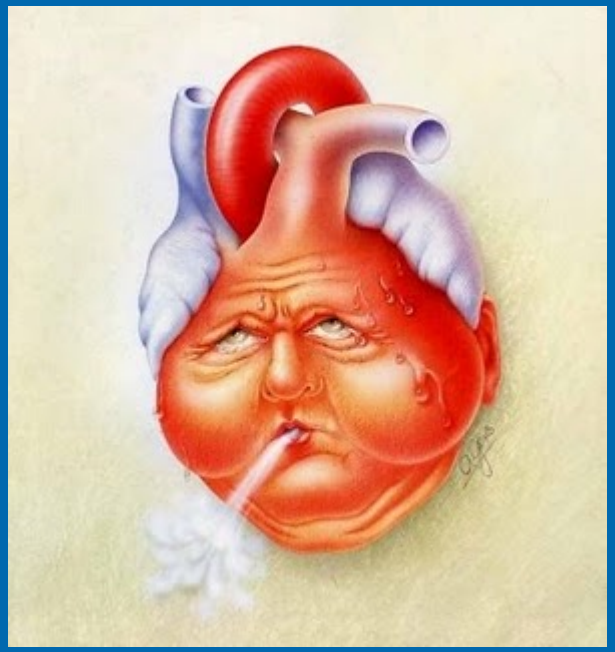
Kidney Disease



- Dose depends on fluid tolerance

Congestive Heart Disease



- Fluid tolerance is limiting factor

When PC doesn't work well

- 1. Patients on Coumadin

Patient JK with Ca Score in March 2018: 1787

after 31 PC treatments in Nov 2018: 1475.

- 2. Patients with restenosis inside stents

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FAQ

- Q: Can I mix the PC Formula with the chelation solution?
- A: NO

Chelation is a sodium chloride solution and the PC Formula can only be mixed with D5W (Dextrose 5% in water) or Glucose 5%.

- One after the other is OK

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- Q: What side effects can PC have?
- A: Diarrhea in severely atherosclerotic patients, patients receiving treatments 3 times weekly

- Transient elevation of lipids and liver enzymes in the beginning, which will normalize with continuing treatment
- Fatigue (Asian)
- Drop in BP (low body weight, Asian)

- Thrombophlebitis at the infusion site which can be avoided by observing the following rules of application:

- How to avoid thrombophlebitis:
- Use the correct PC product !
- Use BD (Becton, Dickinson) or Braun Teflon catheters or Butterfly.
- **Do not use** Terumo catheters because they interact with the PC Formula and may cause thrombophlebitis.

If burning occurs at infusion site:

- Mix 500 cc D5W or Glucose 5% instead of 250 cc
- Increase the infusion time to 120 minutes.

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- Q:How should I store the PC Formula ?
- A:Store PC in the refrigerator until about 1 hour before it is ready to be mixed into D5W or Glucose for infusion. Do not store in the freezer.

- Q: Can I alternate PC and Chelation treatments?
- A: Yes, a recommended ratio of 2 PC to 1 Chelation, unless the patient has a severe heavy metal load, in which the treatment regimen should be 1 to 1.

- Q: Can dialysis patients be treated with PC ?
- A: Absolutely. The limiting factor is the amount of fluids that can be tolerated.

- Q: How many treatments are recommended?
- A: This depends on the severity of the problem. Some patients only need 20-30 treatments; others may need up to 60 treatments.

- Q: Is maintenance therapy necessary?
- A: The underlying cause of plaque deposits will continue to cause a build-up of plaque in the blood vessels after PC treatments. For this reason, it is important to continue maintenance therapy after the initial treatment series. Severely ill patients should have maintenance treatments twice a month and all other patients should have maintenance treatments once a month.

IV Push ?

- Only low dose (5 – 10 cc/ 250 -500 mg PC)

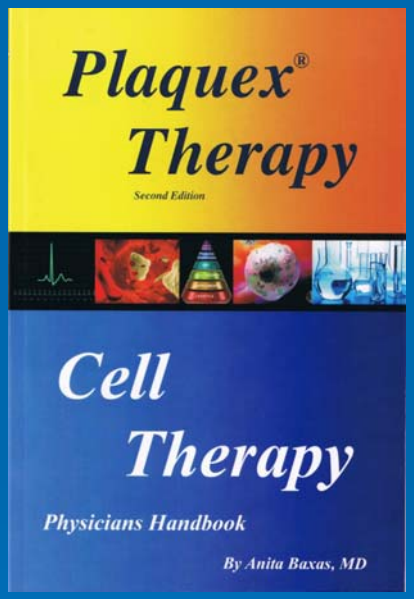
  ⟶ ineffective for plaque removal
- Given slowly over 5 – 10 minutes
- Serves only as PC supplementation
- Little effect on atherosclerosis and lipid profile

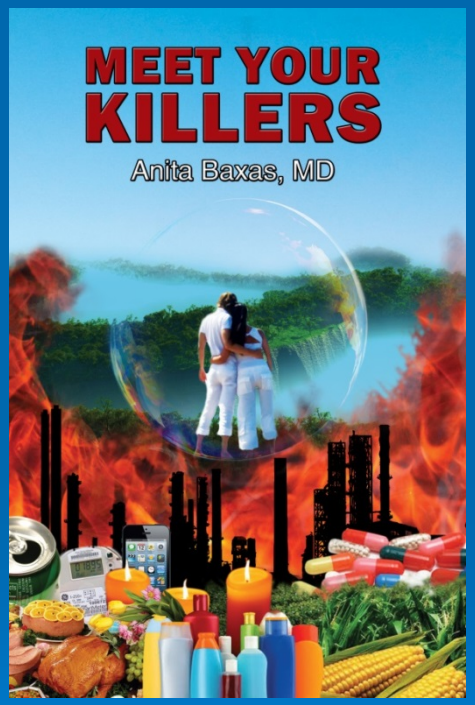
Protocol Summary

- 1st Tx: 20 ml in 250 ml D5W/Gluc.5%
- 2nd Tx: 30 ml " " " " "
- 3rd Tx: 50 ml " " " " "
- Catheters: B&D, Braun, Butterfly
- 2-3x/week x 90 minutes
- 20-30 Tx + maintenance 1/mt + oral
- Caveat Asian and low body weight

MORE INFORMATION

- Contact Info: abaxas@baxamed.com
- www.plaquex.com





Books available on www.biorica.biz or Amazon

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