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Treatment of Rheumatoid Arthritis with Marine and Botanical Oils: Influence on Serum Lipids

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BACKGROUND

Over the past 30 years substantial progress has been made in the medical and surgical management of patients with rheumatoid arthritis (RA). Despite this progress, there is an increasing gap in mortality between patients with RA (1.5-3.0 fold risk) and the general population. This disparity is mainly attributable to cardiovascular disease (CVD) as the CVD risk is comparable in RA patients as to patients with diabetes mellitus. Although the reasons for this gap are not entirely clear, the traditional risk of abnormalities in lipid profiles appears to be enhanced by a chronic increase in inflammatory cytokines, resulting in accelerated atherosclerosis.

Study Objective

The object of this study was to determine the effect of marine (fish oil) and botanical oils (borage oil) on lipids (TC, HDL, LDL, TG), a risk factor for cardiovascular disease in patients with RA. The main outcome (to be presented elsewhere) was to determine whether a combination of borage seed oil rich in gamma-linolenic acid (GLA) and fish oil rich in eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) is superior to either oil alone for the treatment of RA.

METHODS

Population and Setting

• The study was an 18 month randomized, double-masked comparison of borage seed oil, fish oil, and the combination of both oils in RA patients with active synovitis.

• The protocol was approved by the Committee for the Protection of Human Subjects in Research at the University of Massachusetts Medical School and by the Food and Drug Administration. Subsequent approvals were obtained from Review Boards at the University of Alabama, Geisenger Clinic, Fallon Health Care, and the New England IRB.

Eligibility /Demographics for the RCT

• Patients were eligible to participate in the study if they had RA according to the 1987 criteria of the American Rheumatism Association, were in functional class I, II, or III according to the revised criteria of the American College of Rheumatology, and were between the ages of 18 and 85.

• The mean age of participants was 59 years, and the sample predominantly female (80%). Most were white (90%), married (69%), and had a mean body mass index (BMI) of 30.5. An equal number were retired (33%) or working full time (34%), and 16% listed themselves as disabled. There were no significant differences between groups.

Analysis

To assess the effect of the intervention on lipids, lipid values were modeled using linear mixed modeling as a function of time (baseline, 9 month and 18 month, or final visit treated as a categorical variable to allow for non-linear trajectories), treatment arm, and their interaction, with adjustment for baseline value. To assess the overall changes over time, outcome measures were modeled using linear mixed modeling as a function of time, treatment arm and with adjustment for baseline value. All analyses were intention to treat. Analyses included all participants with a baseline lipid measure.

Intervention: Patients received 3.5 gm omega-3 fatty acids daily in a 2.1gm EPA/1.4 gm DHA ratio (7 fish oil and 6 sunflower oil capsules daily); or 1.8 gm /d GLA (6 borage oil and 7 sunflower oil capsules /d); or 7 fish oil and 6 borage oil capsules daily (combination therapy).

Measurements

Laboratory Measures:

Lipid profile: Fasting triglycerides, cholesterol, HDL and calculated LDL cholesterol, complete blood cell count (CBC), platelet count, ESR, albumin, creatinine, AST, ALT, total bilirubin.

Anthropometric Measures:

Height and weight; calculated body mass index (BMI) Systolic and diastolic blood pressure (SBP, DBP)

Survey Measures:

Diet: assessed by 24-hour dietary assessment calls (24HR), performed at baseline and 18 months.
Demographics: Age, gender, education, income, medications, and the modified disease activity score (DAS 28); and Clinical Disease Activity Index (CDAI) were also collected.

RESULTS

Serum Lipids Results

| | Baseline Mean (SD) (N=145) | Change from Baseline to 9 months (N=83) | Change from Baseline to 18 months (N=69) |
|-----------------------------|-------------------------------|--|---|
| Total cholesterol | 195.77 (37.48) | -3.45 (-7.88 to 0.98) | -8.43* (-12.99 to -3.86) |
| LDL | 114.63 (32.20) | -4.39** (-8.03 to -0.74) | -9.43* (-13.75 to -5.11) |
| HDL | 54.14 (16.21) | 3.96* (2.44 to 5.49) | 5.02* (3.24 to 6.81) |
| TC/HDL ratio† | 3.83 (1.03) | -0.26* (-0.41 to -0.12) | -0.43* (-0.58 to -0.28) |
| Triglyceride † | 138.05 (79.65) | -21.96* (-30.52 to -13.40) | -24.42* (-33.22 to -15.61) |
| Atherogenic Index of Plasma | 0.84 (0.67) | -0.22* (-0.29 to -0.16) | -0.26* (-0.33 to -0.19) |

Change from Baseline for Other Measurements

| | Change at 9 months: β (95% CI) | Change at 18months: β (95% CI) |
|--------------------------|-----------------------------------|-----------------------------------|
| Weight | 0.52 (-1.41 to 2.46) | 0.35 (-2.43 to 3.14) |
| Systolic blood pressure | 1.77 (-0.66 to 4.20) | -0.24 (-3.37 to 2.90) |
| Diastolic blood pressure | 2.32* (0.56 to 4.09) | 1.88** (-0.003 to 3.79) |
| ESR† | -5.39* (-9.71 to -1.07) | -4.42** (-9.22 to 0.38) |
| CRP† | -0.65* (-1.20 to -0.10) | -0.09 (-0.77 to 0.60) |

Values are presented as regression coefficient (95% CI) unless stated otherwise and control for baseline values. * p <0.001 ** p<=0.05 † P-values are from log-transformed data.

Triglycerides and Atherogenic Index of Plasma (AIP) by Group

| | Combination Group β (95% CI) | Fish Oil Group β (95% CI) | Borage Oil Group β (95% CI) | p- value |
|------------------------|------------------------------------|---------------------------------|-----------------------------------|-------------|
| Triglyceride ** | | | | 0.031 |
| 9 months | -30.81 (-46.58 to -15.03) | -20.50 (-35.16 to -5.85) | -16.57 (-30.86 to -2.27) | |
| 18 months | -38.24 (-54.28 to -22.19) | -15.27 (-29.81 to -0.74) | -22.10 (-37.32 to -6.89) | |
| AIP | | | | 0.011 |
| 9 months | -0.33 (-0.45 to -0.20) | -0.20 (-0.32 to -0.08) | -0.17 (-0.33 to 0.002) | |
| 18 months | -0.45 (-0.57 to -0.32) | -0.16 (-0.28 to -0.05) | -0.21 (-0.33 to -0.09) | |

** P-value is from log transformation. Changes shown are from the original scale for the group x time interaction and control for baseline values. Values are presented as regression coefficient (95% CI).

DISCUSSION

Rheumatoid Arthritis (RA) is a chronic systemic inflammatory disease. Mediators of inflammation and prothrombotic factors contribute to endothelial dysfunction and development of cardiovascular disease in RA patients. Marine and botanical oils represent an excellent primary or secondary therapy for improvement of the cardiovascular risk management in RA.

Patients taking these oils exhibit significant additional reductions in total and LDL-cholesterol, triglycerides, the TC/HDL ratio, and in the atherogenic index, and experience a significant increase in HDL-cholesterol. All of these improvements in the lipid profile were seen after 9 months of therapy, and increased after 18 months of oils administration.

The overall dropout rate was 51%, and was similar across groups: 25 in the borage oil group, 28 in the fish oil group, and 22 in the combination group. Reasons for dropout were mainly gastrointestinal distress (belching, bloating, diarrhea, nausea, cramping), or an inability to swallow the large number of rather sizable capsules. This can be ameliorated by freezing the capsules and reducing their size. Among those evaluated for this study, compliance was 100%, assessed by pill counts.

Learning Outcome:

All treatments were safe, thus treatment of RA patients with one or a combination of these or similar oils should prove useful for reduction of cardiovascular risk in RA patients.

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