Impact of omega-3 polyunsaturated fatty acids on the occurrence of new coronary events in patients after first myocardial infarction with or without ST elevation, treated primary coronary angioplasty during one year observation.

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The role of polyunsaturated fatty acids in prevention of complications in the cardiovascular system has been investigated since the nineteen fifties. Sinclair was the first to notice the relationship between the type of diet rich in polyunsaturated fatty acids from sea fish and the low cardiovascular mortality rate in the Eskimo population [1]. For many years the impact of fish oil in primary as well as secondary prophylaxis of cardiovascular diseases has been investigated [2, 3, 4]. The benefits of diet supplementation with omega-3 fatty acids have been indicated in patients with myocardial ischaemia, who suffered myocardial infarction [MI] [5], in prophylaxis of sudden cardiac death [4] as well as in patients with cardiac heart failure [6].

The beneficial effect of omega-3 fatty acids results from their influence on atherosclerotic processes, stabilisation of the atheromatous plaque, as well as electrical stabilisation of the cytomembrane of the myocardium cells [7].

Application of polyunsaturated fatty acids can support the antiatherogenic effect of statins and anti-aggregative effect of antiplatelets drugs [8].

The objective of this study was evaluation of the impact of omega-3 polyunsaturated fatty acids on the occurrence of new coronary events [NCE] in patients after ST elevation MI (STEMI) or non-ST elevation MI (NSTEMI), treated primary coronary angioplasty, during one-year observation.

MATERIALS AND METHODS

The prospective study in total included 140 patients [pts] [age 38-82, average 60.2 years of age] admitted between 01.07.2006 – 31.06.2007 to the Cardiology Clinic of the II-nd Chair of Cardiology [Medical University, Łódź, Poland] who were diagnosed first acute coronary syndrome [ACS] - myocardial infarction with or without elevation of the ST segment. The clinical characteristic of the analysed group of patients are presented in table 1. All patients were treated primary coronary angioplasty of the infarct-related artery. The myocardial infarction was diagnosed on the basis of the applicable benchmark cardiac infarct definition: 1. rise in the level of T or I troponin over 99-th percentile of reference value within 24 hours from the onset of the acute event; 2. typical changes in the ECG; 3. typical clinical course. The coronary angioplasty was performed within 12 hours from the onset of pain. The preferred method of procedure was puncture of the right radial artery, which was performed in 124 patients, in the remaining patients the procedure was performed through the puncture in the right femoral artery. To the study included patients with successful primary coronary angioplasty with TIMI flow grade 3 in the infarct-related artery. All patients who underwent coronary angioplasty received a metal stent. In the acute phase of the MI, all patients received pharmacotherapy in accordance with the current recommendations of the European Society of Cardiology, which cover the administration of anti-platelet and anti-thrombotic drugs, beta blockers, angiotensin-converting enzyme inhibitors and statin administered during first 48 hours after the

onset of ACS. Patients with symptoms of cardiogenic shock, advanced circulatory insufficiency [class III-IV acc. to NYHA] and patients with changes in angiography, qualified for surgical treatment of the myocardial ischaemia were excluded from the study.

During the first 48 hours after admission, signed informed consent, patients were assigned to one of the four study arms. Arm one [group 1] included 31 patients, who received per 24 hours: 1g EPA+DHA [2 x 1 tablet of BioCardine 900] and 480 mg alkylglycerols, 480 mg squalene and 100 mg of omega-3 fatty acids [2 x 1 tablet of BioMarine 1140] and statin; arm 2 [group 2] included 33 patients, who received 480 mg alkylglycerols, 480 mg squalene and 100 mg of omega-3 fatty acids [2 x 1 tablet of BioMarine 1140] and statin; arm 3 [group 3] included 30 patients, who received per 24 hours: 1g EPA+DHA [2 x 1 tablet of BioCardine 900] and arm 4 – 46 patients [group 4] who received statin alone. The statin administered to all patients was simvastatin in the initial dose of 40 mg then modified during subsequent follow-up visits in relation to the levels of LDL-fraction cholesterol do that the LDL cholesterol level did not exceed 100 mg%.

Observation was conducted during 12 months after myocardial infarction. Follow-up visits were conducted in 4th, 12th and 52nd week after ACS. During the follow-up visits, the occurrence of primary endpoints – new coronary events [NCE] – deaths, non-fatal myocardial infarction and the requirement of repeat revascularisation: repeat coronary angioplasty [PCI] or coronary artery bypass surgery graft [CABG].

Statistical analyses.

Quantitative variables were presented as arithmetical means +/- standard deviations. The significance of differences between the average values obtained for the constant variables of normal distribution was compared in t–Student test. For the distribution other than standard, the non-parametric Mann-Whitney U test was applied. The quality variables were compared in the chi-square test. In the statistical report, in order to compare the differences between the groups, Fisher's exact test was applied while the one-year prognosis was analysed with the help of Kaplan –Meier estimator. Statistically significant calculation results were $p<0.05$. Study results were processed with the SPSS 15.0.0 statistics package.

The Study was conducted after the consent of Bioethics Committee was granted.

RESULTS

The study included 140 patients in total. The clinical characteristic of each group of patients are presented in table 1. No statistically significant differences were found between the analysed patient groups in terms of age, which was as follows: for group 1 – 61.8 lat, group 2 – 56.6, group 3 – 62.0 and group 4 – 60.8 years [$p>0.05$]. Lipid disorders, arterial hypertension, diabetes and smoking occurred with similar frequency in the analysed groups [$p>0.05$]. The medical history of ischemic heart disease

was registered more often in groups 2 and 4 – that is 58.6% and 56.6% of patients respectively in comparison to 84% and 80% in groups 1 and 3. Atrial fibrillation was most frequent in group 3 [25% of patients], and least frequent in group 2. The average value the left ventricular ejection fraction [LVEF] in the analysed groups was as follows: 44.5%, 45.3%, 44.0 and 43.2%. These differences were not statistically significant [$p>0.05$]. Also the average hospitalisation time did not differ between the groups [$p>0.05$] and was as follows: 4.9, 4.7, 4.4 and 4.7 days. The frequencies of the primary coronary angioplasty procedure of the infarct-related artery in the right and left coronary artery did not differ not to be statistically significant between the groups [$p>0.05$].

The applied pharmacotherapies in each of the patient groups are presented in table 1. No statistically significant differences were found between the groups in terms of administration frequency of beta-blockers, angiotensin-converting enzyme inhibitor, statins, anti-platelet drugs – clopidogrel and acetylsalicylic acid.

Analysis of the primary endpoints of the study

The results are presented in table 2. During the one-year observation, 43 new coronary events [NCE] were recorded in total. The number of NCEs was similar in groups 1, 2 and 3 and was 7, 8, and 7 events respectively. In group 4, the number of SCE was 21. The difference in the NCE frequency between groups 1, 2, 3 and group 4 was however not statistically significant [$p>0.05$].

In the analysed patient group, within the one-year observation period, in total, 8 deaths were registered [5.7% mortality]. In groups 1 and 3, one death in each was occured – mortality rate was 3.2% and 3.3%, in group 2 – 2 deaths [6.1% mortality rate]. The highest mortality was observed in group 4 – in patients treated with statin only – 4 deaths [8.7% mortality]. These differences were however not statistically significant, $p>0.05$. The Kaplan-Meier curve of cumulative primary end-points for each patient group were presented in figure 1.

Within the one-year follow-up observation, 6 non-fatal myocardial infarctions occurred in total [4.2%]. In groups 1 and 4, 2 myocardial infarctions occurred, while in group 2 and 3 one myocardial infarction in each one. The differences between the analysed groups were not statistically significant [$p>0.05$].

Recurrent revascularisation of myocardium

The need to perform recurrent myocardium revascularisation procedure: coronary angioplasty or coronary artery bypass surgery occurred in 29 cases in total. Only in three cases was the cardiosurgical procedure required - coronary artery bypass surgery [one procedure in group 2, 2 procedures in group 4]. The majority of procedures – 15 [32.6%] of recurrent percutaneus revascularisation were performed in group 4, in patients receiving statin only. In the remaining groups the number of repeat myocardium revascularisations was lower and was as follows for each group: 1- 4 cases [12.9%], 2 – 5 cases [15.1%] and 3 -5 cases

[16.6%]. The statistical analysis did not indicate any statistically significant differences between the groups [p>0.05].

DISCUSSION

In recent years, many researchers have pointed towards the therapeutic properties of polyunsaturated fatty acids [PUFA]. The sources of PUFA are mainly fatty sea fish, seafood and seaweed. First reports concerning the relationship between a diet rich in PUFA and a lower rate of cardiovascular disease and mortality come from the nineteen-fifties. It was observed that the Eskimo, whose diet was rich in PUFA, were at a lower risk of cardiovascular events [1]. The cardioprotective effect of PUFA is the subject of many studies. PUFA's role is evaluated in both primary and secondary prevention of ischemic heart disease [3, 9, 10, 11] as well as in congestive heart failure [12,13].

The mechanisms of cardioprotective effect exerted by PUFA omega-3 are multi-directional – they stabilise the atheromatous plaque by lowering the level of metalloproteinase MMP-7,9,12, reduces the expression of VCAM1 and ICAM adhesive molecules, reduce the synthesis of prostaglandins, thromboxane, influence the synthesis of nitrogen oxide [14,15], and also indicate anti-inflammatory properties – they lover the level of C-reactive protein [9]. Theoretically the above mechanisms of PUFA effects should translate to improvement of clinical course of

cardiovascular disease, including improvement of prognosis in patients after myocardial infarction.

In this study, we attempted to evaluate the influence of PUFA, added to the currently applied standard pharmacotherapy, on remote prognosis in patients after ACS treated in the acute phase with primary coronary angioplasty method with metal stent insertion in the infarct-related artery. The analysed group initially included 140 patients after first myocardial infarction treated with primary coronary angioplasty. From the study excluded patients with multivascular disease, with indications to multi-stage percuteneus revascularisation or surgical. The analysed patient groups were compared in terms of basic, initial clinical parameters: sex, MI location, existence of myocardial ischaemia risk factors, left ventricular function. Significant differences between the groups concerned the frequency of atrial fibrillation and a history of myocardial ischaemia prior to the ACS. During the one-year observation, in total 43 NCE were reported. A trend was observed towards more frequent occurrence of NCE including deaths, non-fatal reinfarction and the necessity for repeat revascularisation in group 4 – patients not receiving polyunsaturated fatty acids. These differences were not statistically significant [$p>0.05$]. It seems that this stems from on the one hand, a small size of the analysed patient groups, on the other hand such study result may be influenced by administration of currently recommended pharmacotherapy in all patients in the post-MI period.

The results obtained in this study suggest a positive effect of polyunsaturated fatty acids in secondary prevention of myocardial ischaemia. It seems that the patient group after myocardial infarction treated with primary coronary angioplasty can reap special benefits from PUFA omega-3 supplementation. An increase supply of PUFA leads to reduced aggregation of platelets and demonstrates anti-inflammatory effects [8,16]. This can intensify the anti-aggregation effect of anti-platelet medication, normally used in patients with stent insertions in coronary vessel - clopidogrel and acetylsalicylic acid and decrease the risk of restenosis or thrombosis in the stent. At the same time, the GISSI-Prevenzione study proved that the combination of protracted use of acetylsalicylic acid in combination with PUFA omega-3 does not increase the risk of bleeding [17]. The postulated mechanism which reduces the mortality in myocardial infarction patients in case of medication with PUFA omega-3 is its anti-arrhythmic effect. It was proven that PUFA omega-3 hinder the excitability and automatism of myocardium cells and decrease their sensitivity to catecholamines [6,11]. In their study Christensen et al. indicated that the application of polyunsaturated fatty acids decreases the frequency of complex ventricular arrhythmia in patients with myocardial ischaemia [10]. Similar results, confirming the anti-arrhythmic effect of PUFA omega-3 supplementation, were presented by Marchioli et al. [18]. It was also shown that use of PUFA in patients after myocardial infarction decreased the frequency of atrial fibrillation episodes [19]. In some studies, where ALA was used – polyunsaturated alpha-linoleic acid,

occurring naturally in rapeseed, soy, linseed and walnut oils – no significant influence was found of ALA supplementation on the reduction of myocardial ischaemia risk [20]. The beneficial effects of PUFA omega-3 administration in patients in secondary prevention of myocardial ischaemia was also reflected in the currently applicable guidelines of the European Society of Cardiology, which recommends supplementation of 1 gram of PUFA omega-3 from fish oils [recommendation class I, evidence level B][21].

CONCLUSIONS

This study is part of the wide range of research in the influence of PUFA omega-3 supplementation in secondary prevention of myocardial ischaemia. On the basis of the study results it seems that the PUFA omega-3 supplementation, applied for one year in myocardial infarction patients treated with primary coronary angioplasty with stent implantation, was clinically beneficial. A tendency was found towards the decrease in frequency of cardiac events, including cardiac death, recurrent non-fatal myocardial infarctions and the necessity of repeat revascularisation of myocardium in patients receiving supplementary medication containing PUFA omega-3 as part of the pharmacotherapy. Is a very significant that our results were obtained by supplementation only prophylactic dose of PUFA [1 gram]. It seems appropriate to continue

these studies in the application of polyunsaturated fatty acids omega-3 in secondary prevention in patients after acute cardiac events, treated with primary coronary angioplasty with vascular stent implantation.

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Table 1: Basic clinical characteristic of ACS patients analyzed in the study

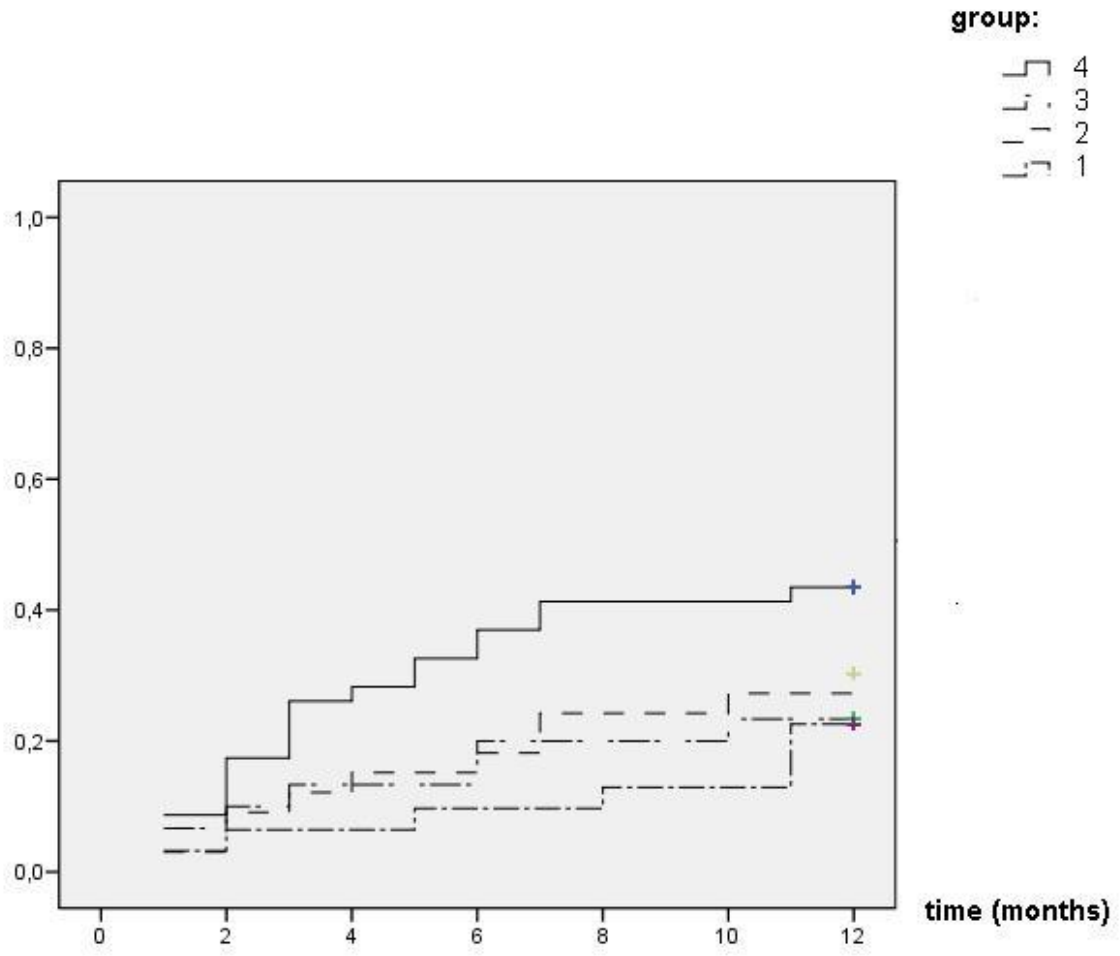
Characteristics	Group 1 Biocardine, Biomarine and statin N = 31 pts	Group 2 Biomarine and statin N = 33 pts	Group 3 Biocardine and statin N = 30 pts	Group 4 Statine alone N= 46 pts	P value
Age, y, mean [SD]	61,81 ± 12,58	56,59 ± 11,11	62,0±8,49	60,85 ± 12,19	>0,05
Sex: male Female	27 (87,1%) 4(12,9%)	26(78,8% 21,2%	50% 50%	60,8% 39,2%	<0,05 <0,05
Anterior myocardial infarction	21 (67,8%)	20 (60,6%)	20 (66,6%)	28 (60,9%)	<0,05
Hiperlipidemia	41,9% (13)	45,5% (15)	53,3% (16)	56,5% (26)	>0,05
Prior ischemic heart disease	26(84%)	19 (58,6%)	26 (80%)	25 (56,5%)	<0,05
Hypertension	20 (64,5%)	16 (55,2%)	15 (50%)	24 (52,2%)	>0,05
Diabetes	7 (22,6%)	11 (34,5%)	2 (8,3%)	11 (23,9%)	<0,05
Atrial fidrillation	5 (16,1%)	0 (0%)	8 (25%)	3 (6,5%)	<0.05
Current smoker	48,4%	48,2%	37,5%	43,5%	>0,05
Left ventricular ejection fraction – EF - (%)	44,58±8,40	45,33±8,42	44,07±8,51	43,22±9,29	>0,05
Hospitalization time [days]	4,90±0,98	4,70±1,18	4,40±0,77	4,72±1,17	>0,05
Beta- blockers	31 (100%)	31 (93,9%)	29 (96,6%)	43 (93,4%)	>0,05
ACE Inhibitors	31 (100%)	33 (100%)	28 (93,3%)	44 (95,7%)	>0,05
Calcium Channel blockers	4 (12,9%)	4 (12,1%)	6 (20%)	7 (15,2%)	>0,05
Statins	31 (100%)	32 (96,7%)	30 (100%)	45 (97,8%)	>0,05
Clopidogrel	31 (100%)	32 (96,7%)	28 (93,3%)	44 (95,7%)	>0,05
Ticlopidine	0 (0%)	1 (3,03%)	2 (6,7%)	2 (4,3%)	>0,05
Aspirin	31 (100%)	33 (100%)	30 (100%)	46 (100%)	>0,05

P values in the table compared characterisctics between analyzed groups.

Table 2. New coronary events: deaths, non-fatal myocardial infarction and revascularization procedures in patients after ACS during 12 month follow-up

New coronary events during observation	Total N=140	Group 1 BioCardine, BioMarine and statin N = 31 pts	Group 2 BioMarine and statin N = 33 pts	Group 3 BioCardine and statin N = 30 pts	Group 4 Statine alone N= 46 pts	P value
Death	8 (5,7%)	1 (3,1%)	2 (6,1%)	1 (3%)	4 (8,7%)	>0,05
Non fatal Myocardial infarction	6 (4,3%)	2 (6,2%)	1 (3,0%)	1 (3%)	2 (4,4%)	>0,05
PCI/CABG	29 (20,7%)	4 (12,4%)	5 (15,5%)	5 (15%)	15 (32,6%)	>0,05
Total	43 (30,7%)	7 (22,5%)	8 (24,2%)	7 (23,3%)	21 (45,6%)	>0,05

Figure 1. : Kaplan-Meier curves of cumulative end-points: death, non-fatal myocardial infarction and recurrent revascularization procedures during 12 month follow-up.



p>0.05

Summary

Introduction: Patients who survived an acute coronary syndrome (ACS) have an increased risk of new coronary events during follow-up.

The aim of our study was to assess efficacy of polyunsaturated fatty acids (PUFA) used as adjunct therapy in secondary prevention after ACS.

Materials and methods: 140 consecutive patients with diagnosed the first ACS treated with primary angioplasty of infarct related artery were included into study. Patients were divided into 4 groups (I - BioCardine, BioMarine and statin N = 31 pts, II - BioMarine and statin N = 33 pts, III - BioCardine and statin N = 30 pts, IV - statine alone N= 46). During 12 month follow-up frequency of new coronary events: deaths, non-fatal myocardial infarction and revascularization procedures were assessed.

Results: there were no statistical differences in basic clinical characteristic. In observation period total of 49 episodes of new coronary events were noted. More frequent 21 new coronary events was in group IV, but there were no significant differences between studied groups.

Conclusion: We observed tendency to less frequency of new coronary events in patients after first acute coronary syndrome with supplementation PUFA, according to patients who received only statin therapy.

Streszczenie

Wprowadzenie: Wpływ wielonienasyconych kwasów tłuszczowych na występowanie powikłań ze strony układu sercowo- naczyniowego jest od wielu lat przedmiotem analiz. Chorzy po przebytym ostrym zespole wieńcowym mają podwyższone ryzyko wystąpienia ponownego ostrego epizodu wieńcowego w obserwacji odległej. Celem redukcji tego ryzyka, w prewencji wtórnej stosowana jest uznana farmakoterapia. Stosowanie preparatów suplementów diety może być jej cennym uzupełnieniem.

Cel pracy: Ocena przydatności dodania do rutynowej farmakoterapii wielonienasyconych kwasów tłuszczowych [PUFA] w prewencji ponownych incydentów wieńcowych u chorych po przebytym ostrym zespole wieńcowym [OZW] leczonym pierwotną angioplastyką wieńcową.

Materiał i metodyka: Do badania włączono 140 kolejnych chorych z rozpoznanym pierwszym w życiu OZW. Wszyscy chorzy leczeni byli pierwotną angioplastyką dozawałowej tętnicy. Chorzy, po wyrażeniu pisemnej zgody, włączani byli w ciągu 48 godzin po leczeniu interwencyjnym do jednej z czterech analizowanych grup. Grupa 1 obejmowała 31 chorych otrzymujących BioCardine, CioMarinę oraz statynę, grupa 2 – 33 chorych otrzymujących BioMarinę i statynę, grupa 3 – 30 chorych otrzymywała BioCardine i statynę, grupa 4 – 46 chorych otrzymywała wyłącznie satynę. Okres obserwacji odległej wynosił 12 miesięcy. Oceniano częstość występowania ponownych incydentów wieńcowych: zgonów, ponownych zawałów oraz ponownych zabiegów rewaskularyzacji mięśnia sercowego.

Wyniki: Nie stwierdzono istotnych różnic pod kątem wyjściowej charakterystyki klinicznej analizowanych grup. W okresie obserwacji odległej wystąpiło ogółem 49 ponownych incydentów wieńcowych, najwięcej w grupie 4. Obserwowano tendencję do mniejszej liczby ponownych incydentów wieńcowych u chorych dodatkowo otrzymujących suplementację nienasyconych kwasów tłuszczowych.

Wnioski: Suplementacja wielonienasyconych kwasów tłuszcowych u chorych po ACS leczonym pierwotną angioplastyką wieńcową wydaje się być korzystnym uzupełnienie rutynowej farmakoterapii w ramach prewencji wtórnej ponownych incydentów wieńcowych.