

Multicenter Registry for Omarcor[®] in Patients with AMI (MR-OMARCORMI)

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PUFA in AMI-DART

- **2,033 men surviving recent MI**
- **Fatty fish, 2/wk**
- **29% decrease in overall mortality over 2 yrs**

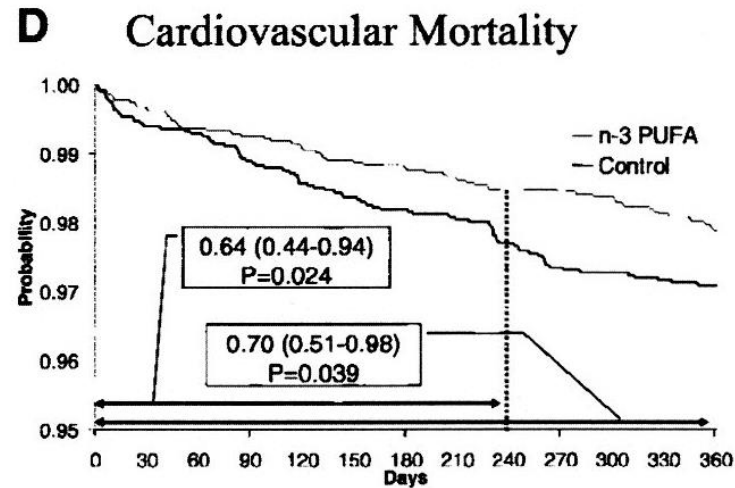
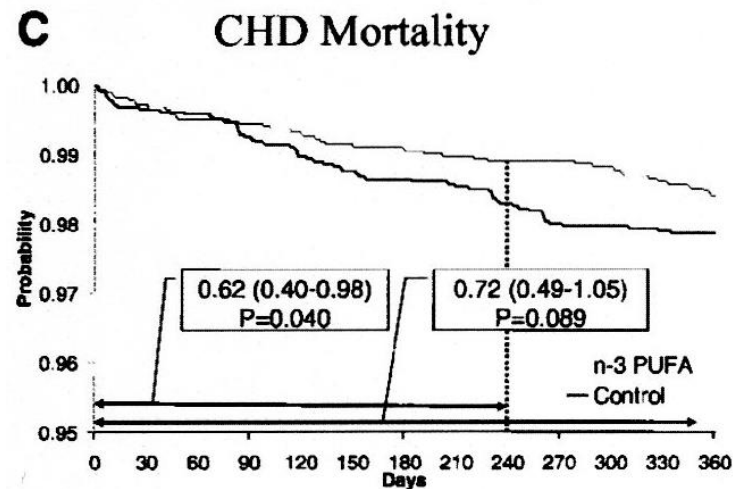
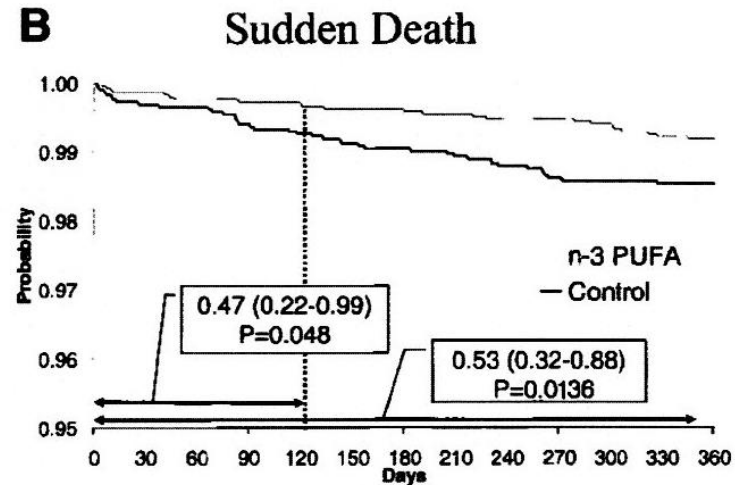
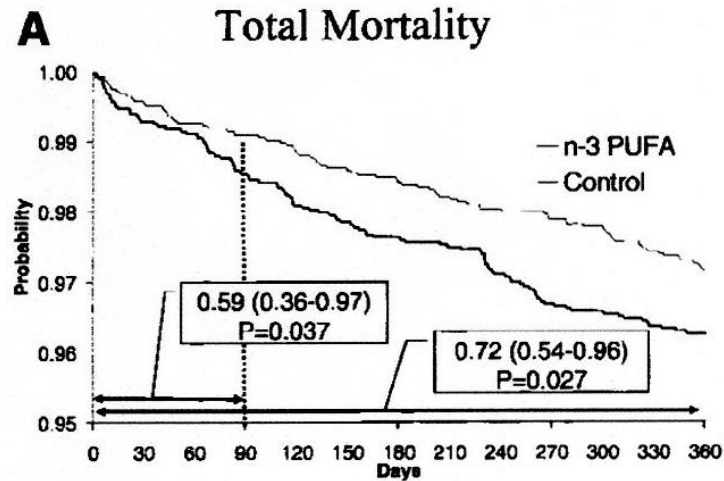
- **no decrease in the rate of non-fatal myocardial infarction**

PUFA in AMI-GISSI

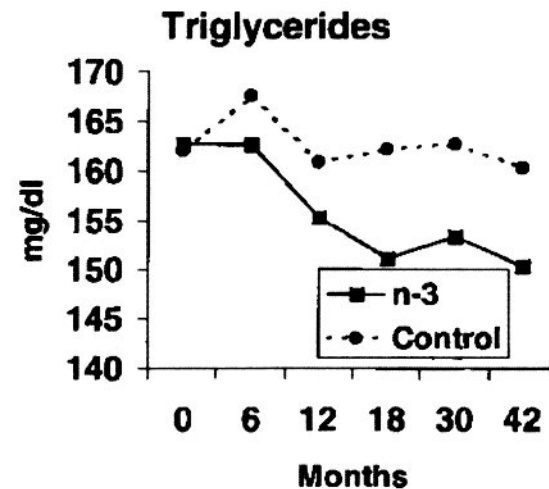
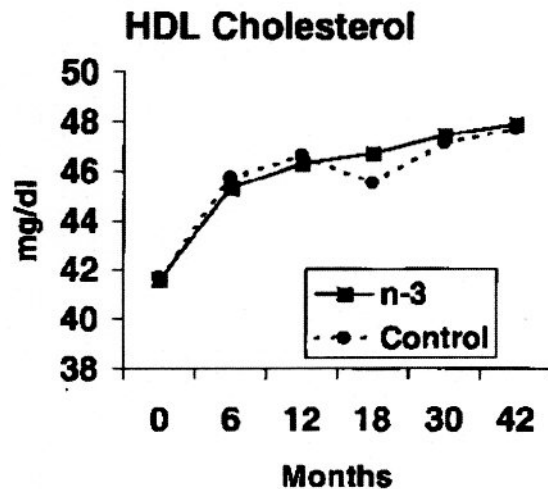
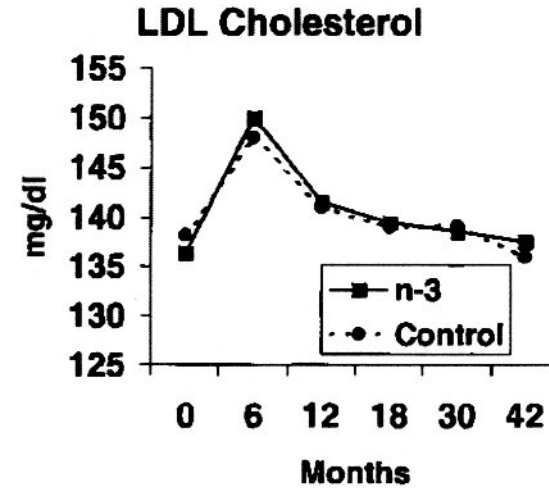
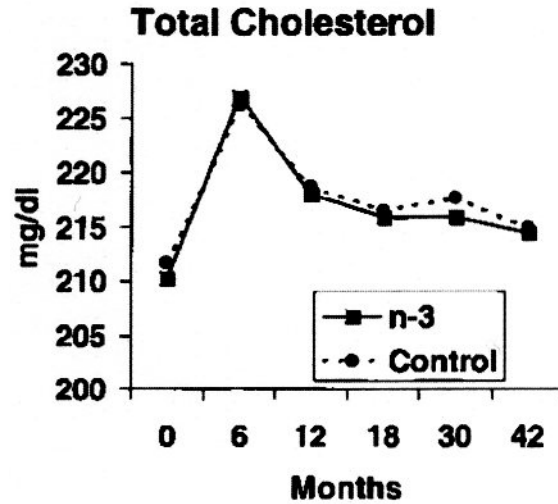
- **11,234 pts surviving recent MI**
- **1 capsule/day of PUFA (850-882mg EPA and DHA)**
- **PUFA decreased the risk of death over 3.5yrs (14%~20%)**

- **no decrease in the rate of non-fatal myocardial infarction**

Death & PUFA in AMI



Lipid & PUFA in AMI



Pathophysiological Basis of PUFA

- Arrhythmogenesis
- Dietary fish oil can reduce VPC in CHF pts¹
- PUFA can prevent ischemia-induced VF in dog model of SCD²

¹Sellmayer A, et al. AJC 1995;76:974-7

²Billman GE et al. Circulation 1999;99:2452-7

Objectives

- 1. To see the effect of Omega-3-fatty acids on mortality in Korean AMI patients**
- 2. On other MACE**
- 3. On lipid profile**

Study Design

1. Prospective registry
2. Dose : Omarcor 1~2g/day

Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
D0	12 M \pm 12w	24 M \pm 12w	36 M \pm 12w	48 M \pm 12w
Consent	Medication			Closeout visit

Inclusion Criteria

- 1. Aged 18~80**
- 2. AMI patients within 3 months**
- 3. Patients underwent PCI**
- 4. Gave consent to the study**

Exclusion Criteria

1. 방문 1에서 신증후군(nephrotic syndrome)이 관찰된 경우
2. 황달성 간질환을 동반한 환자
3. 조절되지 않는 갑상선 기능저하증 또는 항진증 환자
4. 1주일 동안의 알코올 소비가 14 잔(drinks)을 초과하는 환자
5. 임신부 또는 수유부
6. HIV 항체 양성인 환자
7. 과거 5년 이내에 암이 발현된 경우
8. 경구용 코르티코스테로이드 약물의 경구 복용을 방문 1기준 6주 이내에 새로이 시작하여 단기간 치료 예정인 경우
(단, 뇌하수체/부신 질환에 대한 대체요법으로 처방받고 방문1이전 최소 6주 동안 안정적인 치료 요법을 유지하고 있는 경우는 예외)
9. 연구자 판단에 의해 예상수명이 연구기간보다 짧을 것으로 예상되는 경우
10. 환자가 본 등록관찰연구 참여에 성실히 참여할 수 없는 상황이나 조건이 있다고 연구자가 판단한 환자

Primary Efficacy Parameter

Long-term MACE (CV mortality, MI, Stroke)

Secondary Efficacy Parameter

- 1. Lipid Profile & hs-CRP**
- 2. Revascularization (PCI & CABG)**
- 3. Arrhythmic event**
- 4. Admission due to cardiovascular event**

Enrollment Status (Jul 2010~Dec 2013)

No.	병원명	연구자	등록 수	No.	병원명	연구자	등록 수
1	서울대학교병원	김효수	159	14	계명대학교 동산병원	허승호	61
2	가천대학교 길병원	강웅철	145	15	충북대학교병원	김동운	58
3	분당서울대학교병원	최동주	137	16	고려대학교 구로병원	나승운	47
4	건양대학교병원	배장호	121	17	충남대학교병원	최시완	43
5	서울특별시보라매병원	김상현	110	18	한림대학교 성심병원	조상호	42
6	영남대학교병원	김영조	109	19	원주기독병원	윤정한	34
7	해운대백병원	김두일	100	19	양산부산대학교병원	김정수	34
8	전남대학교병원	정명호	96	21	대구가톨릭대학교병원	김기식	32
9	한양대학교 구리병원	최성일	95	22	강동성심병원	한규록	31
10	의정부성모병원	전희경	92	23	강동경희대학교병원	김종진	27
11	인제대학교 상계백병원	고충원	86	24	부산대학교병원	홍택중	15
12	제주대학교병원	주승재	80	25	경북대학교병원	양동헌	14
13	삼성서울병원	권현철	67	26	안동병원	김건영	12
계						1847	

Study Subjects

Before Omnicor
Launch in Korea
From KAMIR

OMARCOR group
(Jul 2010~Dec 2013)

Total n=1847

Incomplete data (n=36)

Total n=1811

FU duration < 12 months (n=435)

CONTROL group
(Oct 2005~Dec 2006)

Total n=7973

Incomplete data (n=52)

Total n=7921

Patient Demographics

	OMARCOR (n = 1811)	CONTROL (n = 7921)	P value
Age (yrs)	60.1±12.0	62.9±12.8	0.000
Male	1475 (81.4%)	5532 (69.8%)	0.000
Smoking	920 (51.6%)	3328 (42.4%)	0.000
Hypertension	384 (21.2%)	3825 (48.9%)	0.000
Diabetes	402 (22.2%)	2165 (27.8%)	0.000
Dyslipidemia	200 (11.0%)	668 (8.5%)	0.000
LVEF (%)	54.9±22.8	51.7±20.6	0.000
History of IHD	87 (4.8%)	1377 (17.5%)	0.000
STEMI	1016 (57.1%)	4625 (58.8%)	0.194
Clinical FU	1722 (95.1%)	4916 (61.9%)	0.000
FU loss	89 (4.9%)	3014 (38.1%)	

Patient Demographics (Propensity Matching)

	OMARCOR (n = 1718)	CONTROL (n = 1718)	P value
Age (yrs)	60.1±12.0	60.6±12.7	0.304
Male	1400 (81.5%)	1395 (81.2%)	0.827
Smoking	891 (51.9%)	858 (49.9%)	0.241
Hypertension	361 (21.0%)	319 (18.6%)	0.072
Diabetes	385 (22.4%)	381 (22.2%)	0.870
Dyslipidemia	188 (10.9%)	167 (9.7%)	0.000
LVEF (%)	54.9±23.0	55.4±29.5	0.625
History of IHD	77 (4.5%)	60 (3.5%)	0.138
STEMI	976 (57.7%)	1078 (62.9%)	0.002
Clinical FU	1636 (95.2%)	1636 (95.2%)	1.000
FU loss	82 (4.8%)	82 (4.8%)	
FU duration<1yr	394 (22.9%)		

Patient Demographics (Propensity Matching)

	OMARCOR (n = 1718)	CONTROL (n = 1718)	P-value
Creatinine (mg/dl)	1.1±1.2	1.0±0.5	0.170
Glucose (mg/dl)	162±74	161±72	0.474
Total cholesterol (mg/dl)	189±44	184±43	0.002
Triglyceride (mg/dl)	164±131	129±112	0.000
HDL-C (mg/dl)	42.8±21.8	45.1±12.1	0.000
LDL-C (mg/dl)	120±39	119±41	0.495
hs-CRP (mg/dl)	2.1±10.4	15.0±67.2	0.000

Patient Demographics (Propensity Matching)

	OMARCOR (n = 1718)	CONTROL (n = 1718)	P-value
Involved vs no.			0.008
1 vessel	751 (44.1)	756 (48.7)	
2 vessels	536 (31.5)	434 (27.9)	
3 vessels	388 (22.8)	319 (20.5)	
Involved vessel			0.439
LAD	821 (48.3)	775 (49.9)	
LCX	290 (17.1)	241 (15.5)	
RCA	565 (33.3)	509 (32.8)	
LMT	23 (1.4)	28 (1.8)	
Lesion type, B2/C	1063 (77.4)	1141 (76.4)	0.506
Pre-PCI TIMI flow 0/1	1056 (72.2)	790 (51.6)	0.000

PCI Findings (Propensity Matching)

	OMARCOR (n = 1695)	CONTROL (n = 1716)	P-value
PCI performed	1688 (99.6%)	1490 (86.8)	0.000
PCI success	1672 (98.8)	1422 (92.4)	0.000
Stenting	1615 (95.8)	1418 (91.7)	0.000
Type of stent			0.000
BMS	25 (1.6)	112 (8.0)	
Cypher	21 (1.4)	686 (48.8)	
Taxus	1 (0.1)	499 (35.5)	
Endeavor	425 (28.0)	5 (0.4)	
Other DES	1044 (68.9)	104 (7.4)	
Stent diameter, mm	3.13±0.49	3.19±0.38	0.003
Stent length, mm	24.1±7.7	25.3±6.2	0.000
Stent number	1.43±0.80	1.49±0.80	0.026
Post-PCI TIMI flow 2/3	1407 (96.8)	1459 (98.0)	0.039

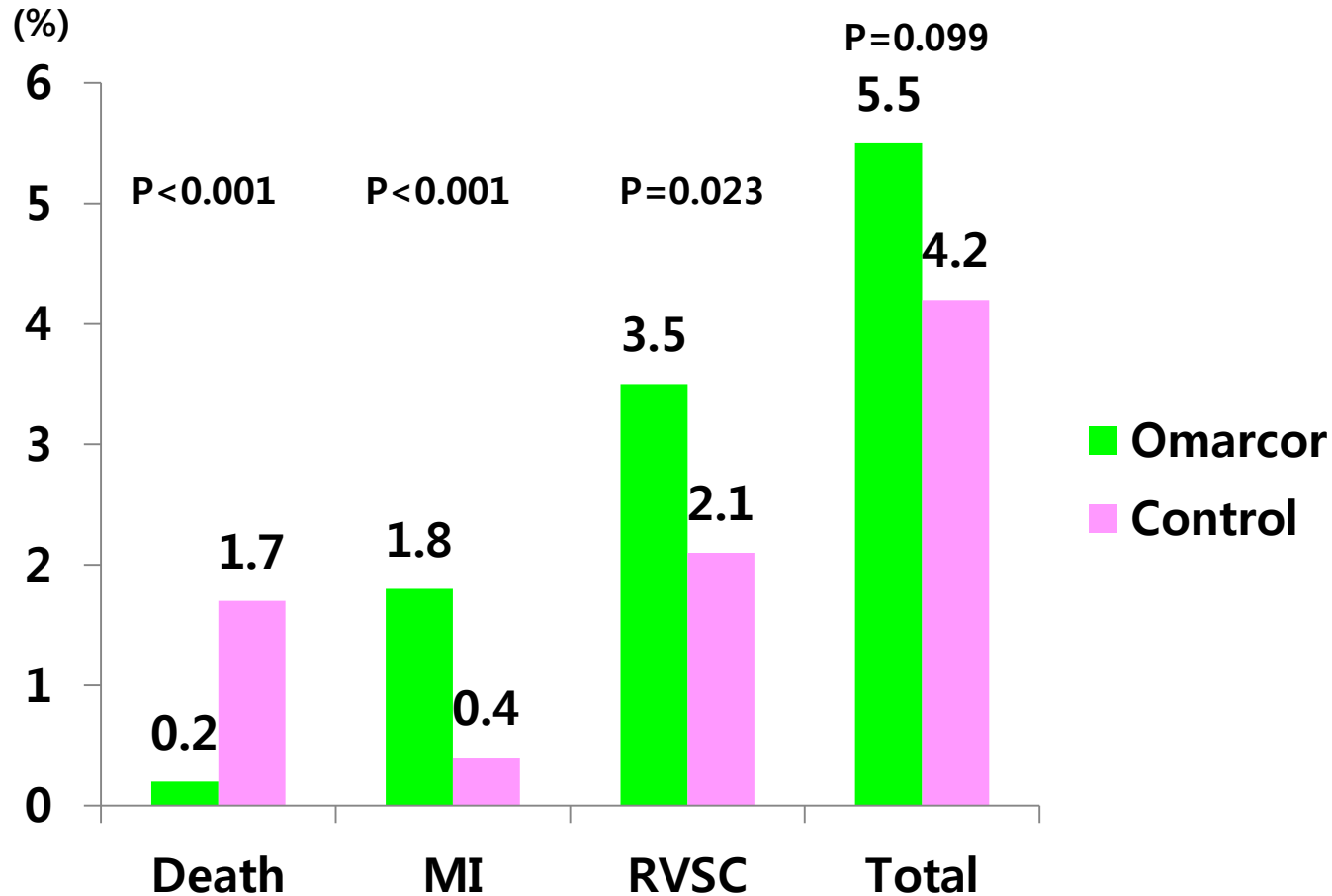
Twelve-Month Outcome

(Propensity Matching)

	OMARCOR (n = 1242)	CONTROL (n = 1636)	P-value
Clinical FU	1636 (95.2%)	1636 (95.2%)	1.000
FU loss	82 (4.8%)	82 (4.8%)	
N/A (FU duration<1yr)	394 (22.9%)		
Death	3 (0.2%)	27 (1.7%)	0.000
MI	22/1239 (1.8%)	7/1609 (0.4%)	0.000
Revascularization	43/1217 (3.5%)	34/1602 (2.1%)	0.023
Re-PCI (TVR/non-TVR)	42	32	
CABG	1	2	
Total	68/1242 (5.5%)	68/1636 (4.2%)	0.099

Twelve-Month Outcome

(Propensity Matching)



Predictors for Death

	Odd Ratio	P value	95% CI
No Omarcor	4.759	0.043	1.053~21.521
PCI success	1.189	0.870	0.150~9.437
MVD	1.559	0.446	0.498~4.878
STEMI	1.412	0.570	0.429~4.653
CRP	1.295	0.654	0.418~4.012
Dyslipidemia	0.448	0.389	0.072~2.777

Binary Logistic Linear Regression Analysis

Predictors for MI

	Odd Ratio	P value	95% CI
No Omarcor	0.279	0.015	0.100~0.778
MVD	1.165	0.717	0.511~2.657
STEMI	1.043	0.920	0.457~2.379
CRP	0.471	0.237	0.135~1.639
Dyslipidemia	0.508	0.404	0.104~2.492

Binary Logistic Linear Regression Analysis

Predictors for Revascularization

	Odd Ratio	P value	95% CI
No Omarcor	0.731	0.254	0.427~1.253
PCI success	1.178	0.789	0.354~3.919
MVD	2.087	0.008	1.213~3.591
STEMI	1.351	0.261	0.799~2.284
CRP	0.700	0.256	0.379~1.296
Dyslipidemia	1.012	0.976	0.471~2.176

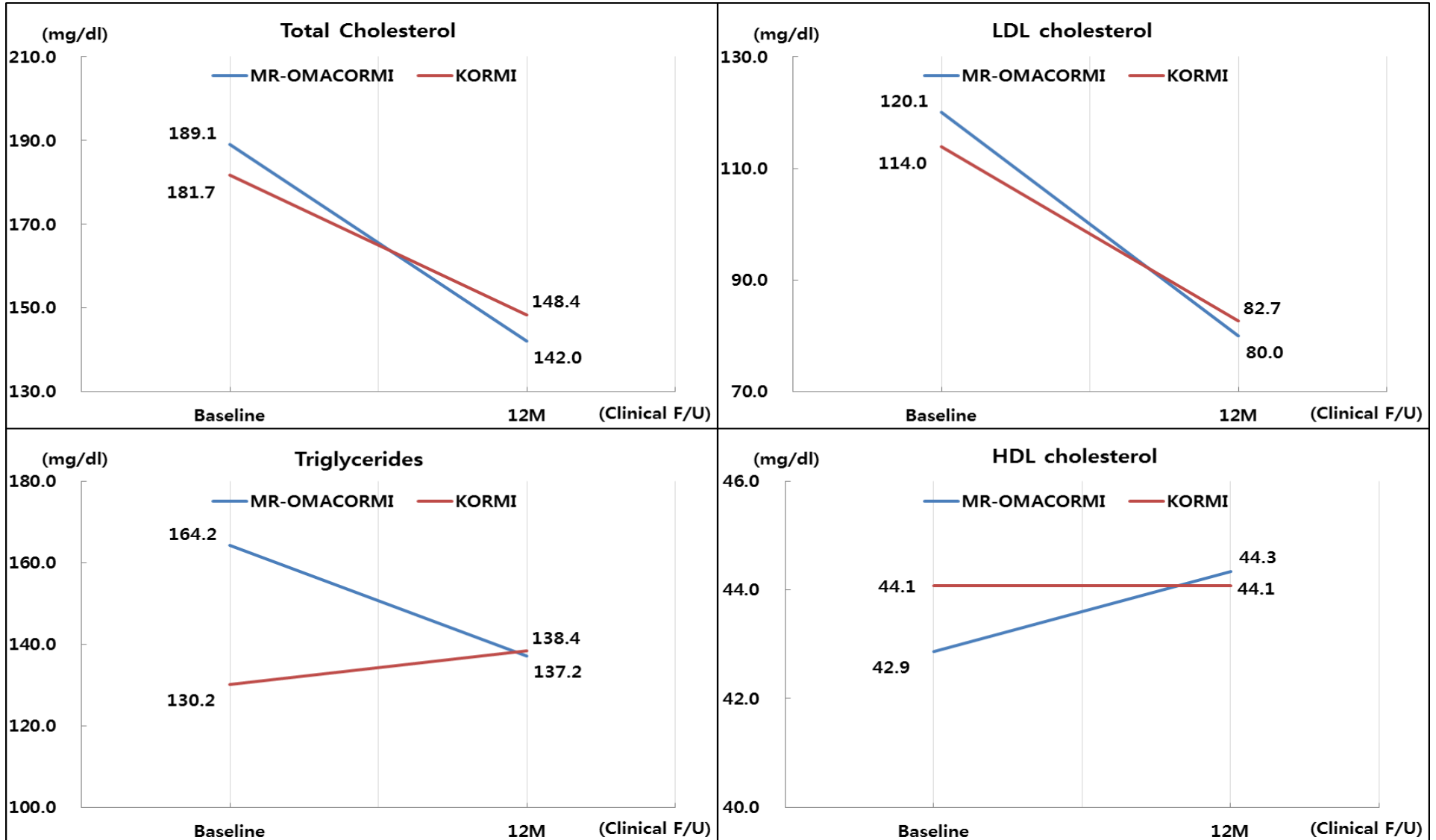
Binary Logistic Linear Regression Analysis

Predictors for Total MACE

	Odd Ratio	P value	95% CI
No Omarcor	0.717	0.130	0.466~1.103
PCI success	1.003	0.996	0.355~2.835
MVD	1.778	0.008	1.160~2.724
STEMI	1.272	0.260	0.836~1.935
CRP	0.727	0.203	0.445~1.188
Dyslipidemia	0.801	0.510	0.415~1.549

Binary Logistic Linear Regression Analysis

Lipoprotein Profile



Conclusions

1. Mortality benefit in OMARCOR group
2. Higher MI in OMARCOR group (?)
3. No different in total MACE
4. Favorable in TG & HDL-C

Thank You
Very Much

Discharge Medications (Propensity Matching)

	OMARCOR (n = 1310)	CONTROL (n = 1707)	P-value
Aspirin	1239 (94.6%)	1707 (99.4%)	0.000
Clopidogrel	1068 (97.0%)	1667 (97.0%)	0.000
Cilostazol	0 (0%)	614 (35.7%)	0.000
Beta blocker	1055 (80.5%)	1292 (75.2%)	0.001
ACEI	416 (31.8%)	1279 (74.4%)	0.000
ARB	523 (39.9%)	218 (12.7%)	0.000
Statin	1130 (86.3%)	1311 (76.3%)	0.000
Diuretics	156 (11.9%)	401 (23.3%)	0.000
OHA	188 (14.3%)	212 (12.3%)	0.107
Fibrates	6 (0.5%)	8 (0.5%)	0.978

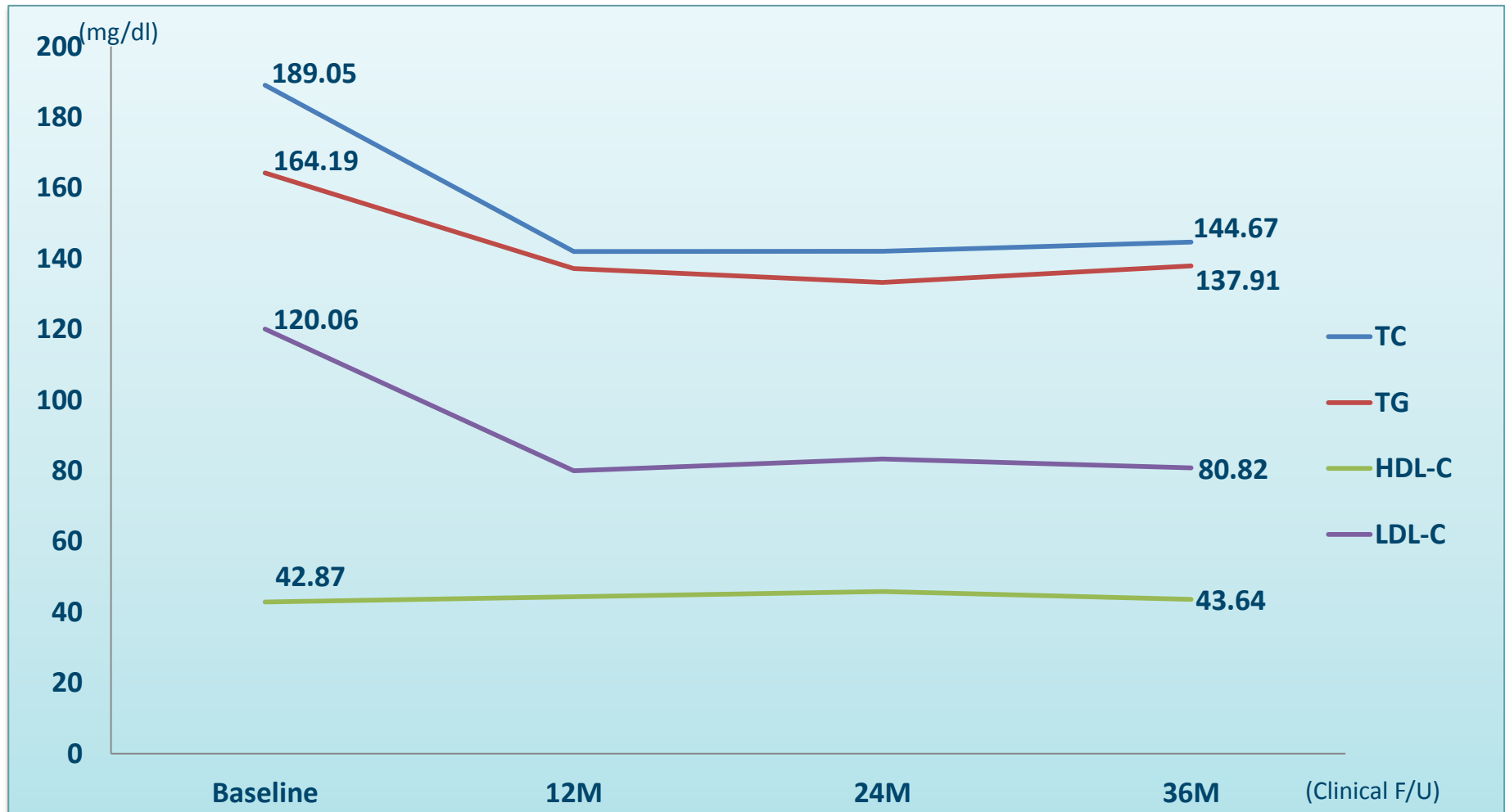
Lipoprotein Profile

항목	Baseline (0 month)		F/U (12 month)		F/U (24 month)		F/U (36 month)	
	n	Mean±SD	n	Mean±SD	n	Mean±SD	n	Mean±SD
Total Cholesterol (mg/dl)	1,707	189.05±44.50	855	142.00±32.59	376	142.07±32.45	48	144.67±31.87
Triglycerides (mg/dl)	1,698	164.19±131.4	820	137.16±82.56	358	133.24±80.85	46	137.91±70.13
HDL-C (mg/dl)	1,699	42.87±21.71	813	44.34±18.06	358	45.86±25.88	45	43.64±11.43
LDL-C (mg/dl)	1,531	120.06±38.64	738	79.96±38.15	334	83.31±55.81	39	80.82±27.49
hs-CRP (mg/l)	1,453	2.07±9.52	584	0.58±5.61	219	0.31±0.97	-	-

Lipoprotein Profile

항목	치료군	Baseline (0 month)		Clinical F/U (12 month)		Mean Change	
		n	Mean±SD	n	Mean±SD	n	Mean±SD
Total Cholesterol (mg/dl)	MR-OMACORMI	1,707	189.05±44.50	855	142.00±32.59	1,707	47.05±38.55
	KORMI	20,258	181.65±46.45	5,785	148.35±36.54	20,258	33.30±41.50
Triglycerides (mg/dl)	MR-OMACORMI	1,698	164.19±131.4	820	137.16±82.56	1,698	27.03±106.9
	KORMI	19,729	130.21±101.4	5,248	138.40±88.76	19,729	-8.19±95.08
HDL-C (mg/dl)	MR-OMACORMI	1,699	42.87±21.71	813	44.34±18.06	1,699	-1.47±19.89
	KORMI	19,730	44.08±18.2	5,147	44.07±18.89	19,730	0.01±18.55
LDL-C (mg/dl)	MR-OMACORMI	1,531	120.06±38.64	738	79.96±38.15	1,531	40.10±38.40
	KORMI	19,334	113.95±40.72	4,902	82.66±36.86	19,334	31.29±38.79
hs-CRP (mg/dl)	MR-OMACORMI	1,453	2.07±9.52	584	0.58±5.61	1,453	1.49±7.57
	KORMI	17,008	9.28±42.13	4,046	2.58±15.13	17,008	6.70±28.63

Lipoprotein Profile



Treatment Strategy in STEMI

(Propensity Matching)

	OMARCOR (n = 987)	CONTROL (n = 1073)	P-value
Primary PCI	985 (99.8)	781 (72.8)	0.000
Thrombolysis	2 (0.2)	101 (9.4)	
Facilitated PCI	0 (0)	32 (3.0)	
Conservative	0 (0)	159 (14.8)	