

Evaluation of real-world treatment outcomes among women 50 years of age and older who were treated with statin + ezetimibe or statin monotherapy in Italy and Belgium

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■ BACKGROUND

- Statin have demonstrated efficacy in reducing major cardiovascular events¹
- However, individuals undergoing statin therapy alone may not consistently achieve the desired reduction in low-density lipoprotein-cholesterol (LDL-C), which could leave them at continued risk²
- In such scenarios, increasing the statin dosage or introducing adjunctive nonstatin lipid-lowering agents such as ezetimibe is often prescribed in clinical practice²
- Despite this, empirical real-world evidence (RWE) on the clinical advantages of including an add-on therapy remains scarce, especially among older women

■ STUDY AIM, DESIGN AND OUTCOMES

- This retrospective study (2017–2020) assessed LDL-C goal attainment and % LDL-C reduction in women ≥50 years of age receiving combination therapy vs those receiving statin monotherapy in Italy and Belgium
 - The LDL-C goals evaluated were the intensified/additional goals in the 2021 European Society for Cardiology (ESC) guidelines on cardiovascular disease (CVD) prevention in clinical practice²
- Data were obtained from primary care electronic medical records in Italy and Belgium through The Health Intervention Network (THIN) database
- Patients had a 12-month baseline period before the initial treatment date with a follow-up period of at least 12 months, a minimum of 4 weeks of continuous treatment with the prescribed lipid-lowering therapy, and LDL-C tests within prespecified windows
- To mitigate potential confounding effects, propensity score matching was performed; the treatment groups were matched by age group (categorized as 50–69 and ≥70 years), CVD risk (high or very high risk per 2021 ESC guidelines), and statin intensity (low, moderate, high)
- Multiple regression analyses for goal attainment and % change in LDL-C included treatment group, age group, CVD risk, statin intensity, and baseline LDL-C value as covariates
- Analyses were performed separately for Italy and Belgium

■ REFERENCES

- Cholesterol Treatment Trialists' Collaboration. Lancet. 2019;393:407-415.
- Visseren et al. Eur Heart J. 2021;42:3227-3337.

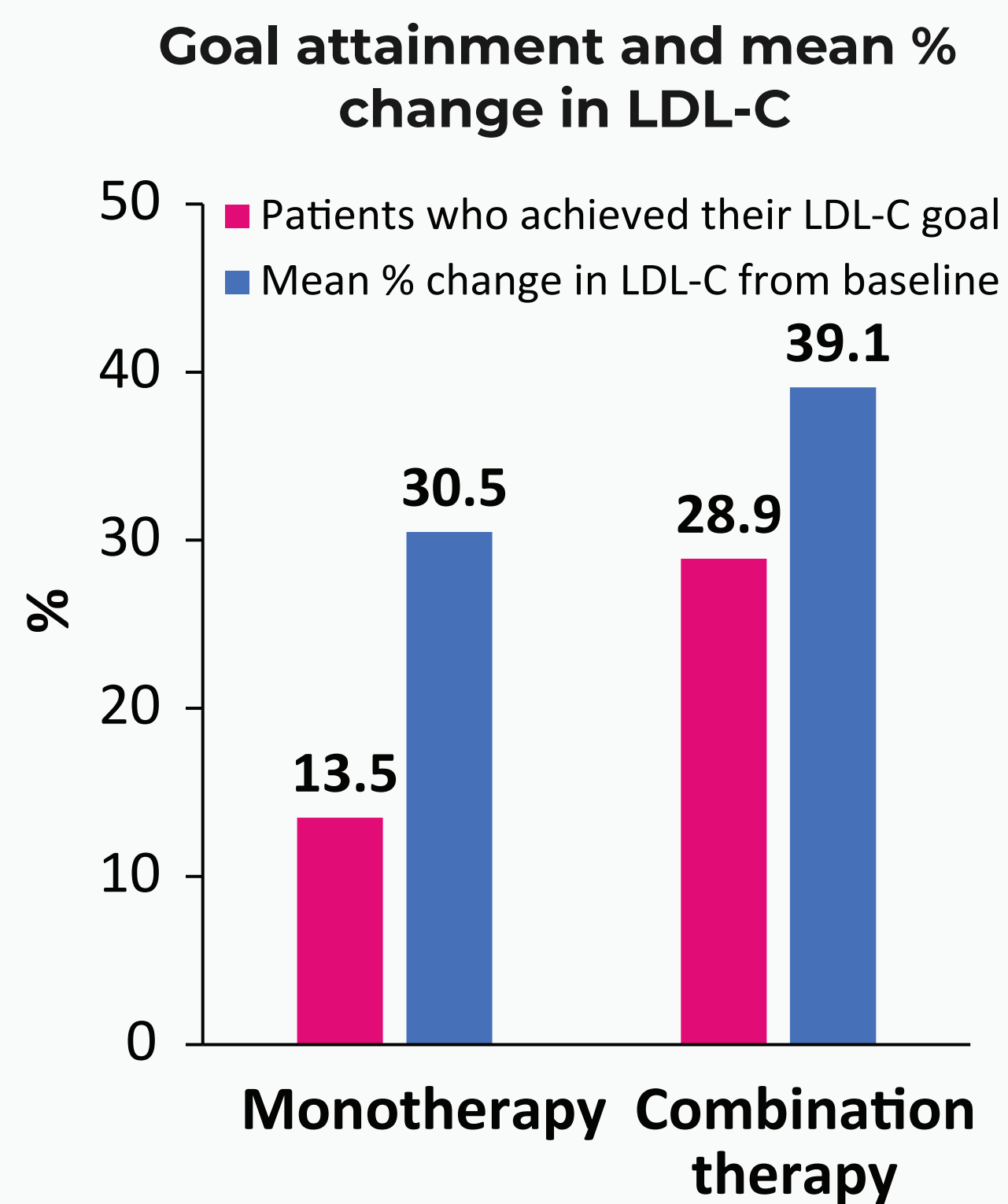
■ DISCLOSURES & FUNDING STATEMENT

- P Chu, J Li, G Goodall: Organon employees and stock/shareholders
- A Zhao: Employee of Net2Source Inc (under contract with Organon)
- This study was funded by Organon & Co.
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■ RESULTS – LDL-C goal attainment and % reduction

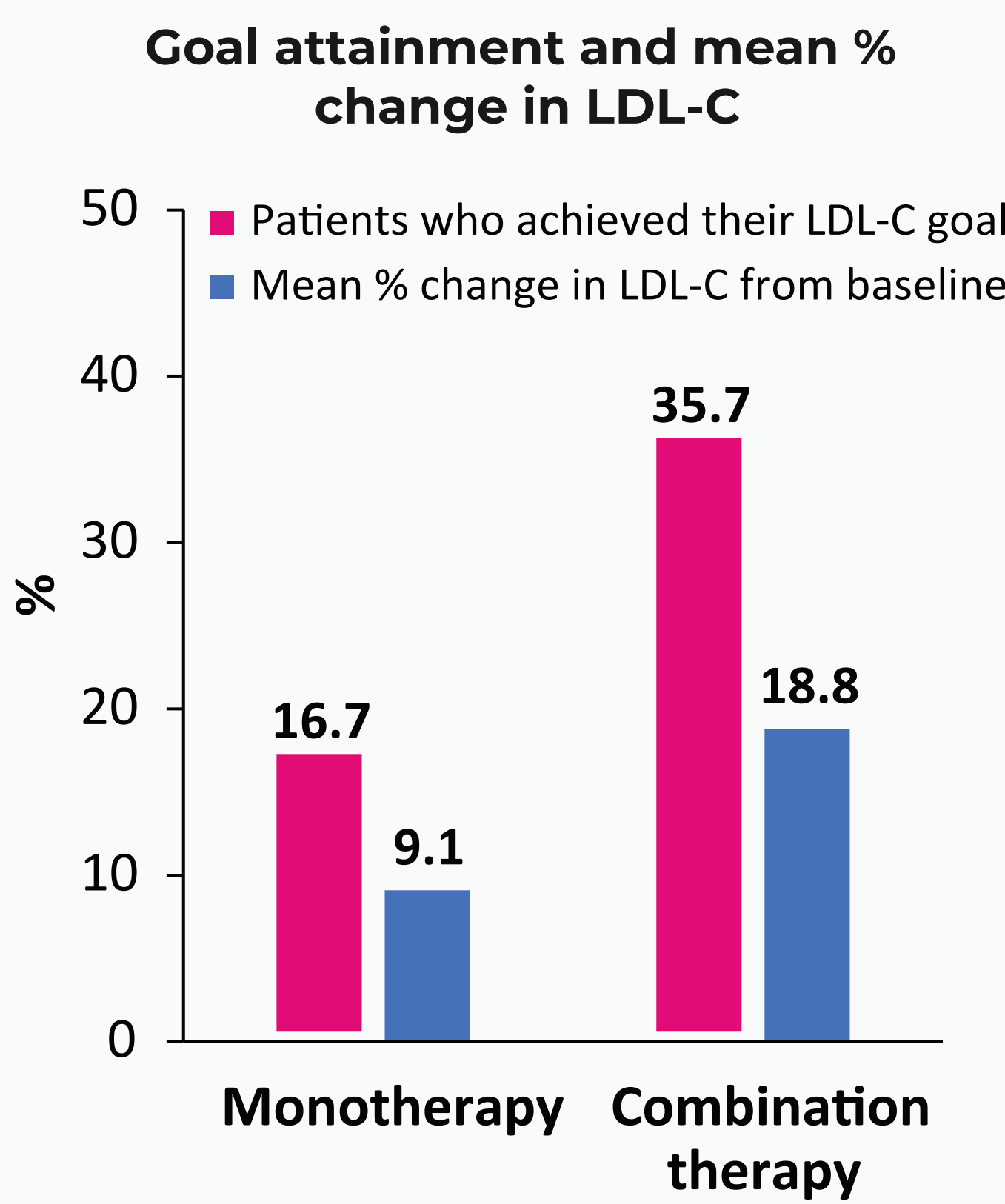
Italy

- 104 patients were included in the analyses after propensity score matching (n=52 each in mono- and combination therapy)
- 50% of patients were ≥70 years old, 80.8% had high CVD risk, and 73.1% received moderate intensity statin therapy in both the groups
- 13.5% in monotherapy and 28.9% in the combination therapy achieved their treatment goal
- LDL-C goal attainment was more likely with combination- vs monotherapy (odds ratio [OR]: 2.97, 95% confidence interval [CI]: 1.05–8.41)
- Although not significant, combination therapy had higher mean % LDL-C change from baseline vs monotherapy (39.1% vs 30.5%, p=0.12)

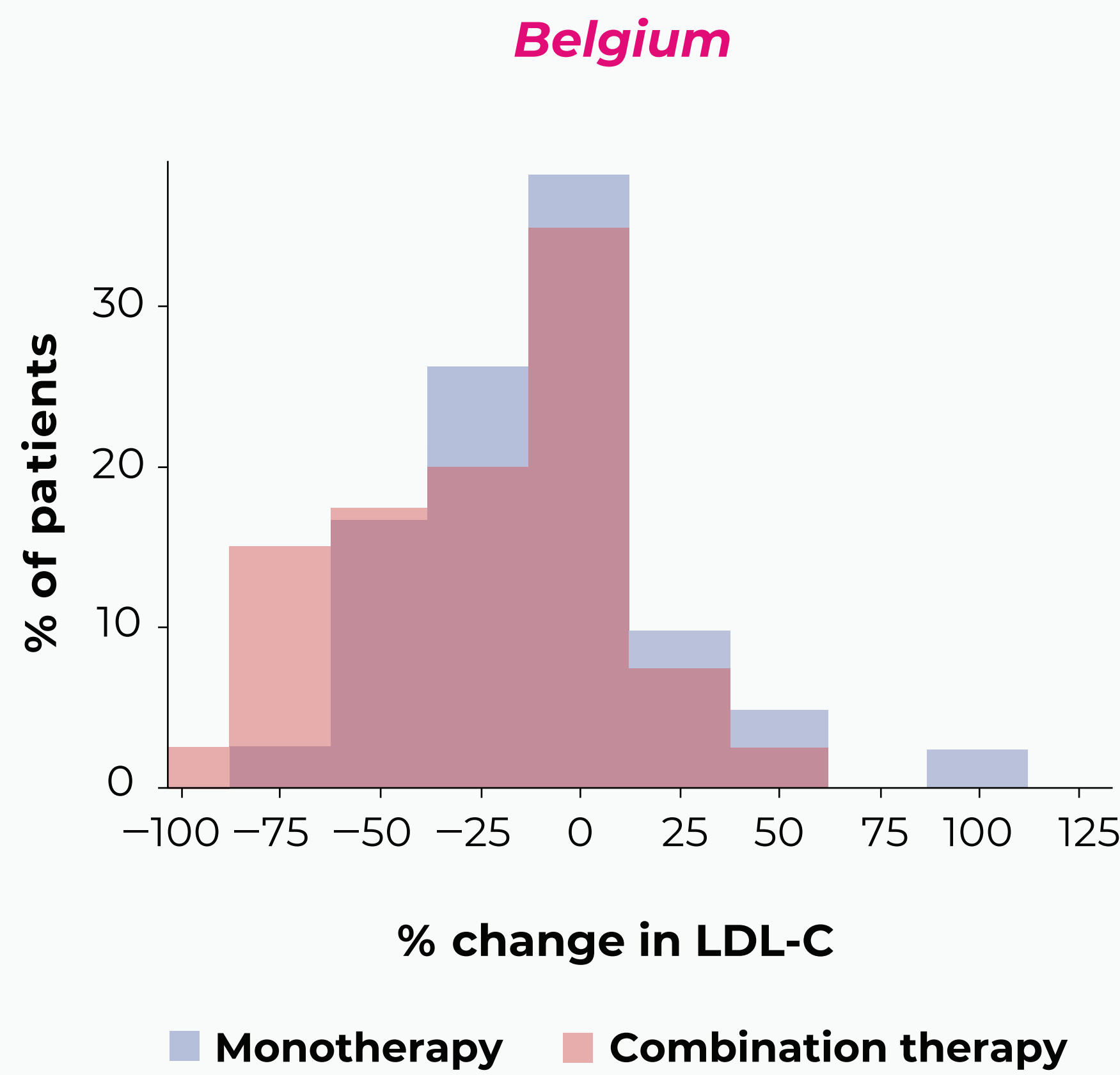
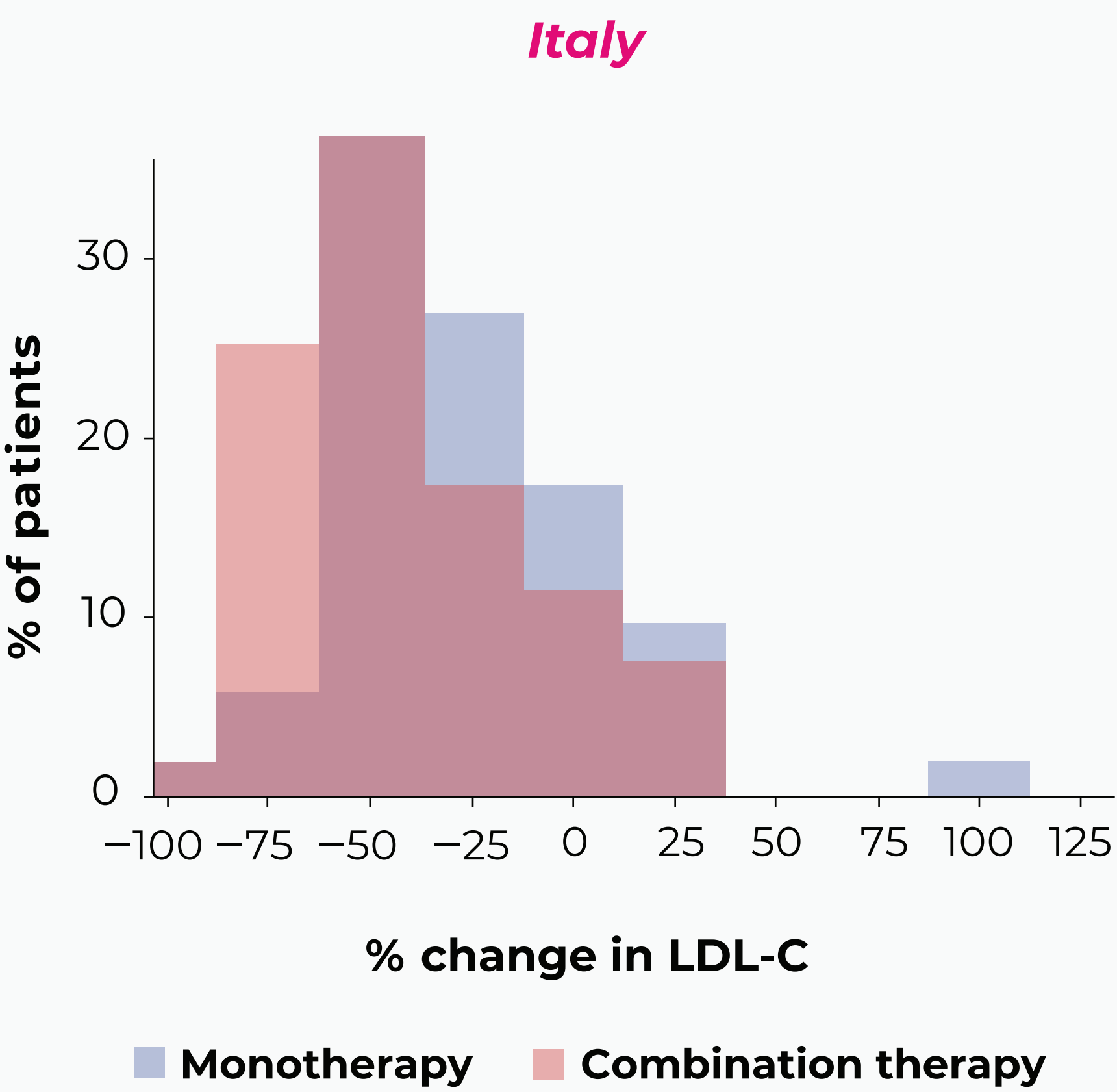


Belgium

- 84 patients were included in the analyses after propensity score matching (n=42 each in mono- and combination therapy)
- 45.2% of patients were ≥70 years old, 73.8% had high CVD risk, and 88.1% received moderate intensity statin therapy in both the groups
- 16.7% in monotherapy and 35.7% in combination therapy achieved their treatment goal
- LDL-C goal attainment was more likely with combination- vs monotherapy (OR: 2.92, 95% CI: 1.02–8.34)
- Although not significant, combination therapy had higher mean % LDL-C change from baseline vs monotherapy (18.8% vs 9.1%, p=0.08)



% change of LDL-C from baseline to follow-up: monotherapy vs combination therapy



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■ CONCLUSIONS

- This RWE study revealed that women aged ≥50 years who received combination therapy were more likely to attain LDL-C goal targets compared with statin monotherapy
- Furthermore, this cohort experienced a substantial reduction in LDL-C levels during the follow-up period when compared with matched cohorts receiving statin monotherapy
- While combination therapy improved LDL-C levels, this study highlights the need for proactive lipid management to achieve the known cardiovascular benefits and ensure compliance, given the low overall goal attainment

■ ADDITIONAL RESULTS – Propensity score matching

Italy

Baseline characteristics	Before matching		p value	After matching	
	Monotherapy (n=554)	Combination therapy (n=52)		Monotherapy (n=52)	Combination therapy (n=52)
Age at index date			0.636		
50-69 years	296 (53.4)	26 (50.0)		26 (50.0)	26 (50.0)
70+ years	258 (46.6)	26 (50.0)		26 (50.0)	26 (50.0)
Cardiovascular disease risk			0.391		
Very high risk	136 (24.6)	10 (19.2)		10 (19.2)	10 (19.2)
High risk	418 (75.5)	42 (80.8)		42 (80.8)	42 (80.8)
Statin intensity			0.005		
Moderate	451 (81.4)	38 (73.1)		38 (73.1)	38 (73.1)
High	59 (10.7)	3 (5.8)		3 (5.8)	3 (5.8)

All values are n (%) unless stated. The percentages do not add up to 100 since some patients were on low intensity statins

Belgium

Baseline characteristics	Before matching		p value	After matching	
	Monotherapy (n=1,114)	Combination therapy (n=42)		Monotherapy (n=42)	Combination therapy (n=42)
Age at index date			0.863		
50-69 years	595 (53.4)	23 (54.8)		23 (54.8)	23 (54.8)
70+ years	519 (46.6)	19 (45.2)		19 (45.2)	19 (45.2)
Cardiovascular disease risk			0.011		
Very high risk	141 (12.7)	11 (26.2)		11 (26.2)	11 (26.2)
High risk	973 (87.3)	31 (73.8)		31 (73.8)	31 (73.8)
Statin intensity			0.489		
Moderate	921 (82.7)	37 (88.1)		37 (88.1)	37 (88.1)
High	165 (14.8)	5 (11.9)		5 (11.9)	5 (11.9)

All values are n (%) unless stated. The percentages do not add up to 100 since some patients were on low intensity statins