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Sacubitril/Valsartan versus Enalapril in Nonischemic Heart Failure in Paradigm-Hf Trial

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Introduction

In PRADIGM-HF trial, A 8442 patients (mean age 63.8 ± 11.4 years) with class II, III, or IV heart failure and an ejection fraction of 40% or less to receive either LCZ696 (at a dose of 200 mg twice daily) or enalapril (at a dose of 10 mg twice daily), in addition to recommended therapy.

Both groups received optimal medical therapy (93% on a beta blocker, 56.6 % on a mineralocorticoid antagonist) and 21.6 % of both groups receiving CRT or ICD. Over a median follow up of 27 months. The primary outcome was a composite of death from cardiovascular causes or hospitalization for heart failure. The trial was stopped early, according to prespecified rules, after a median follow up of 27 months, because the boundary for an overwhelming benefit with LCZ696 had been crossed. At the time of study closure, the primary outcome had occurred in 914 patients (21.8%) in the LCZ696 group and 1117 patients (26.5%) in the enalapril group (P<0.001). A total of 711 patients (17.0%) receiving LCZ696 and 835 patients (19.8%) receiving enalapril died (P<0.001); of these patients, 558 (13.3%) and 693 (16.5%), respectively, died from cardiovascular causes (P<0.001). As compared with enalapril, LCZ696 also reduced the risk of hospitalizationfor heart failure by 21% (P<0.001) and decreased the symptoms andphysical limitations of heart failure (P = 0.001). The causes of heart failure in this trial were 60% ischemic and 40% non- ischemic[1].

The non-ischemic causes were idiopathic (N:1595), hypertension (N:968), invective/viral (N:185) , alcoholic (N:158), valvular (N:110), Diabetic (N:66), drug related (N:30), Peripartum -related (N:14) and others (N:237)[2].

In this article we analysis the primary end point and CV death between ischemic and idiopathic non-ischemic patients in PARADIGM Trial. The ischemic patients were 5036 (60%) patients and non-ischemic patients were 3363 (40%) patients. In ischemic and in non ischemic group the sacubitril/valsartan was superior to enalapril for reduce primary outcome and CV death (Table 1).

Table 1:

	Ischemic (5036)			Non-Ischemic(3363)		
	Enalapril (2530)	Sac/Val. (2506)	p	Enalapril (1682)	Sac/Val. (1681)	P
Primary end Point	697 (27.55%)	575 (22.94%)	0.0002	420 (24.97%)	339 (20.16%)	0.0008
CV Death	430 (16.99%)	359 (14.32%)	0.008	263(15.64%)	199 (11.84%)	0.001

In a follow-up of 27 monthsthe number needed to treat to prevent primary end points was 22 patients and to prevent one CV death was 37 patientsin ischemic group
In non-ischemic groupthe number needed to treat to prevent primary end points was 21 patients and to prevent one CV death was 26 patients.

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In sacubitril/valsartan group: the primary outcome had occurred in 339 patients (20.16 %) in the non-ischemic group and 575 patients (22.9 %) in the ischemicgroup (P: 0.03). A total of 199 patients (11.8%) in non-ischemic group and 359 patients in ischemic group (14.3%) died from cardiovascular causes(P: 0.01).and no significant difference between in CV death and primary outcome in enalapril group in the ischemic and nonischemic patients (Table 2).

Table 2:

	Sac/Vals. Group			Enalapril Group		
	ischemic	nonischemic	P value	Ischemic	Nonischemic	P Value
Primary end point	575 (22.94%)	339 (20.16%)	0.03	697 (27.55%)	420 (24.97%)	0.07
CV death	359 (14.32%)	199 (11.84%)	0.01	430 (16.99%)	263 (15.64%)	0.2

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