

#### 4CPS-023 SACUBITRIL/VALSARTAN (ENTRESTO) IN REAL LIFE: AN OBSERVATIONAL STUDY IN A HOSPITAL CENTRE

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**Background** Heart failure (HF) is a major public health concern, affecting 26 million people worldwide. The association sacubitril/valsartan was marketed for the treatment of chronic HF. In the PARADIGM-HF trial, Entresto has shown a reduction of HF admissions and cardiovascular mortality significantly higher than standard recommended treatment.<sup>1</sup> The most significant shortcoming of this study was the population included (younger and less severe).

**Purpose** The aim of our study was to compare characteristics of a patient cohort followed-up in a hospital centre with patients in the PARADIGM-HF trial. Other objectives were to estimate the incidence of HF hospitalisation of patients treated by Entresto and identify adverse events.

**Material and methods** A prospective study was conducted from January to December 2017. An extraction of Entresto ambulatory dispensations during this period was carried out. A selection of patients followed-up in our hospital was made. Data were collected in patient medical files. A statistical comparison between collected data and data from the PARADIGM-HF trial was done. Adverse events and the incidence of unexpected hospitalisations were listed.

**Results** Forty HF patients were retrospectively studied. Our patients were older and had a higher NYHA class than in the PARADIGM-HF trial ( $p < 0.05$ ), however fewer comorbidities have been identified ( $p < 0.05$ ) and fewer patients were pre-treated by ACEI and beta-blockers ( $p < 0.05$  for both). Similar adverse events have been reported: arterial hypotension (17.5%), hyperkalaemia (22%), kidney failure (7.5%) and cough (2.5%). Other adverse events have been reported such as hypokalaemia (5.5%) and cardiac decompensation (35%). Thirteen patients were hospitalised in the cardiology care unit for at least one HF decompensation.

**Conclusion** Despite the low total headcount of patients in this study, the difference between baseline characteristics have been shown. Patients were older and had a higher NYHA class which may explain that 13 of 40 patients were hospitalised for at least one HF episodes. The occurrence of adverse effects can explain that patients were treated with a lower dosage of Entresto, only 22% reached maximal dosage (97/103 mg). An investigation needs to be done to compare hospitalisations of patients before and after the introduction of Entresto, to show its the real impact.

#### REFERENCE AND/OR ACKNOWLEDGEMENTS

1. McMurray, et al. *NEJM* 2014.

No conflict of interest.

#### 4CPS-024 EFFICACY, SAFETY AND ACCEPTANCE OF TREATMENT WITH ALIROCUMAB OR EVOLOCUMAB IN PATIENTS WITH DYSLIPIDAEMIA

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**Background** Alirocumab and evolocumab are two monoclonal antibodies proproteinconvertasubtilisin/kexin type 9 inhibitors (iPCSK9) approved for the treatment of hypercholesterolaemia.

**Purpose** Evaluation of the efficacy, safety and patient acceptance of treatment with iPCSK9 in a cohort of patients with dyslipidaemia.

**Material and methods** Retrospective observational study performed in a university hospital. Included patients started with iPCSK9 therapy from September 2016 to June 2018.

Data collected: demographic; iPCSK9 dose; prevention; indication; cardiovascular risk factors (CVR) (excluding dyslipidaemia), cardiovascular risk (CVR) (by ESC 2016 guidelines); and statin intolerance.

At baseline (pre) and 6–12 weeks after starting treatment (post), LDL value and concomitant lipid lowering agents (LLA) were collected.

Additionally, reported adverse events and patient treatment were evaluated through a validated survey<sup>1</sup> during the pharmaceutical visit.

Statistics:

Categorical variables: n (%), Fisher's exact test.

Quantitative variables: mean  $\pm$ SD/median(rank), Mann-Whitney *U* test.

**Results**

Abstract 4CPS-024 Table 1

Baseline	Alirocumab (n=48)	Evolocumab (n=10)	P-value
Male	29 (60.4%)	9 (90.0%)	
Age	62.6 $\pm$ 8.6	55.8 $\pm$ 8.8	
Initial dose:75 mg/2 weeks	40 (83.3%)	-	
Secondary prevention	38 (79.2%)	10 (100.0%)	
Indication			
Polygenic-hypercholesterolaemia	31 (64.6%)	8 (80.0%)	
Familial-hypercholesterolaemia	14 (29.2%)	1 (10.0%)	
Other	3 (6.3%)	1 (10.0%)	
CVRF			
None	13 (27.1%)	1 (10.0%)	
1	17 (35.4%)	2 (20.0%)	
$\geq 2$	18 (37.5%)	7 (70.0%)	
High-risk CVR	38 (79.2%)	10 (100.0%)	
Statin intolerance	25 (52.1%)	4 (40.0%)	
Pre LLA	45 (93.7%)	9 (90.0%)	
<b>LDL</b>			
LDL (mg/dL)			
Pre	138.5 (92–308)	111.5 (92–216)	0.067
Post	59 (17–223)	28.5 (4–59)	0.002
% LDL reduction	57.7 (13.2–87.5)	75.2 (47.3–97.3)	0.015
LDL post<70 mg/dL	29 (60.4%)	10 (100%)	0.022
Adverse events	4 (8.3%)*	0 (0%)	1.000
<b>Treatment acceptance</b>			
Very acceptable	40 (83.3%)	9 (90.0%)	
Quite acceptable	6 (12.5%)	0 (0%)	
Acceptable	2 (4.2%)	1 (10.0%)	

\*Pseudogrippal syndrome (3) and constipation (1).

All patients decreased LDL except 1 patient on alirocumab who was non-adherent.

Post: 15 treatment changes in 13 (27.1%) patients with alirocumab (five (33.3%) alirocumab dose increase, seven (46.7%) other LLA introduction/dose increase, three (20.0%) other LLA suspension/dose decrease). With evolocumab patients, only 1 stopped ezetimibe.