## 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.[1] 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 pretreated 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 proproteinconvertasesubtilisin/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 (CVRF) (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[1] during the pharmaceutical visit.

Statistics:

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

Quantitative variables: mean ±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±8.6 | 55.8±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%) | |
| ≥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%) | |
| **LDL** | | | |
| 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 |
| **Treatment acceptance** | | | |
| 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.

After the survey, all patients desired to continue with iPCSK9.

**Conclusion** After 6–12 weeks of iPCSK9 treatment, all patients reduced LDL level except 1 who was non-adherent. The LDL reduction ranged between 54%–71% and all patients on evolocumab achieved a LDL <70 mg/dL.

The tolerability was excellent and only mild adverse events in about 8% of patients were experienced.

A high acceptance of both alirocumab and evolocumab was reported by all patients who would continue with iPCSK9 treatment.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.

## 4CPS-025 LIPID MODIFICATION THERAPY FOR PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE

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**Background** Cardiovascular disease (CVD) is the leading cause of mortality worldwide, totalling almost one-third of all deaths. Lipid optimisation is a key public health priority to decrease CVD morbidity, mortality and consequential economic burden on healthcare systems. A reduction in cholesterol by 1 mmol with statin therapy reduces the risk of CVD events by 20%–24%, in people with an estimated 10 year CVD risk greater than 10%. In the UK, the National Institute of Clinical Excellence (NICE) recommends atorvastatin 20 mg for primary prevention of CVD in these people, using QRISK2 to estimate their level of risk.

**Purpose** To assess adherence to NICE lipid modification guidance in patients presenting with acute coronary syndrome (ACS).

**Material and methods** Data on lipid-lowering therapy was collected prospectively, over an 8 week period in August 2018, for all patients presenting with ACS. QRISK2 scores were calculated for patients admitted with ACS naïve to statin therapy. Ethics approval was not required.

**Results** Two-hundred and fifty-two patients presented with ACS: mean total cholesterol and low-density lipoprotein (LDL) levels on admission were 4.7 and 2.8 mmol/L respectively. One-hundred and thirty-six (54%) patients were naïve to statin therapy prior to admission, of these 91 (67%) had a QRISK2 score greater than 10% (mean 18.45%). All patients were subsequently discharged on high-intensity statins, 124 (91%) on atorvastatin 80 mg.

**Conclusion** Two-thirds of patients naïve to statin therapy prior to admission had a 10 year CVD risk of 10% or greater, as estimated using QRISK2, and would have been eligible for atorvastatin 20 mg for primary prevention of CVD as per NICE guidance. Identifying patients in primary care at risk of CVD events is key to ensuring appropriate lifestyle modifications are undertaken and statin therapy initiated, both of which have been shown to reduce CVD event rates. Community services, such as NHS health checks at community pharmacies, and development of GP practice-based pharmacists should be targeted and supported by secondary care to ensure high-risk patients are prescribed optimum lipid modification therapy for primary prevention of CVD, thereby reducing the risk of CVD morbidity, mortality and associated financial implications to the health system.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

https://www.nice.org.uk/guidance/cg181/chapter/1-Recommendations#lipid-modification-therapy-for-the-primary-and-secondary-prevention-of-cvd-2

No conflict of interest.

## 4CPS-026 ADHERENCE AND EFFECTIVENESS OF PCSK9 INHIBITORS IN ROUTINE CLINICAL PRACTICE

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**Background** Alirocumab and evolocumab are monoclonal antibodies that belong to a new class of cholesterol-lowering drugs by inhibiting the proprotein convertase subtilisin/kexin type-9 (PCSK9) enzyme.

**Purpose** The main objective of this study was to evaluate the adherence to alirocumab and evolocumab therapies and its relation to drug effectiveness.

**Material and methods** Observational, descriptive and retrospective study conducted in a tertiary hospital. All patients that initiated treatment with alirocumab and evolocumab from October 2016 to February 2018 were included.

Data sources were patients' electronic medical records and outpatients' electronic prescription and dispensation programme. Main variables collected were: gender, age, indication, prescriber's medical departments and low-density lipoprotein (LDL-C).

Adherence was calculated indirectly by consulting dispensing data in the outpatient prescription tool.

Effectiveness was defined as the percentage decrease in LDL-C from baseline to week 24.

**Results** Forty patients were included: 22 men (55%) and 18 women (45%), with median age 57 years (19–85). Nine patients (22.5%) had heterozygous primary hypercholesterolaemia, seven (17.5%) heterozygous primary hypercholesterolaemia and severe cardiovascular disease, 11 (27.5%) severe cardiovascular disease, 10 (25%) severe cardiovascular disease and statin intolerance, and three (7.5%) statin intolerance. Alirocumab was prescribed in 19 patients (47.5%) and evolocumab in 21 (52.5%).

Mean adherence index was 1.03 (SD 0.13). Mean basal LDL-C and LDL-C after 24 weeks were 125, 42 mg/dl (SD 43.34) and 61, 22 mg/dl (SD 44.17), respectively. The percentage decrease in LDL-C from baseline to week 24 was 43%, 31% in the alirocumab group and 54% in the evolocumab group. The adherence index in both groups was similar.

Twenty-eight patients (70%) had a percentage decrease in LDL-C >40% with an adherence index of 1.04 (SD 0.12), while 12 patients (30%) had a percentage decrease in LDL-C <40% with an adherence index of 1.01 (SD 0.15).

**Conclusion**

- Patients under PCSK9-inhibitors treatment are strong adherents to these therapies
- Effectiveness of PCSK9-inhibitors in routine clinical practice has been proven with data comparable to randomised clinical trials. Apparently, evolocumab shows better effectiveness than alirocumab.