Heart Failure

1 SACUBITRIL/VALSARTAN IN CHRONIC SYMPTOMATIC HEART FAILURE WITH REDUCED EJECTION FRACTION: FIRST CLINICAL EXPERIENCE FROM A LARGE UK TERTIARY CENTRE

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Introduction Sacubitril/valsartan (SV) is a new drug that has recently been approved by the National Institute for Health and Care Excellence (NICE) to be used as an alternative to ACE-inhibitors/Angiotensin Receptor Blockers in patients with symptomatic chronic heart failure with reduced ejection fraction (HFrEF). We report an early clinical experience of SV use in HF patients at a large tertiary cardiac centre in the UK.

Methods Patients with HFrEF (NYHA class II-IV and Left Ventricular Ejection Fraction <35%) seen in the heart failure clinic and started on Sacubtril/valsartan (one tablet 49/51 mg twice daily) from April till October 2016, were retrospectively evaluated. Change in NHYA class, eGFR, up-titration to target dose (one tablet 97/103 mg twice daily), deaths, hospitalizations and patients tolerability to SV were assessed. All patients had either their ACE-inhibitor or angiotensin receptor antagonist stopped at least 48 hours prior to starting sacubtril/valsartan and re-attended the HF clinic at 4 weekly intervals until up-titration was completed.

Results A total of 44 patients were commenced on SV and in 25 patients (57%) up-titration to the target dose was achieved. In 12 patients (27%) an improvement of NYHA class was seen. Nine patients (20%) had symptomatic systolic blood pressure drop of >10 mmHg at follow-up with 3 patients having hyperkalaemia (7%), preventing target dose up-titration. A total of 4 hospital admissions occurred: 2 due to decompensated heart failure (5%), 1 for hyperkalaemia and 1 non-cardiovascular (CV) related. Out of those hospital admissions, 2 patients died (see table). Four patients (9%) had a worsening of the eGFR>10 (without progressive renal failure preventing up-titration) and in 2 patients (5%) the drug was stopped to due intolerability (reported postural dizziness and abdominal pain).

Abstract 1 Table 1

Total number of patients commenced on sacubtril/valsartan	n=44
Male	36 (82%)
Average Age (years)	64 years
NYHA class improvement (≥1 class)	12 (27%)
Target dose up-titration achieved (97/103 mg)	25 (57%)
Drop of systolic Blood Pressure at follow-up (>10 mmHg)	9 (20%) 3 (7%)*
Hyperkalaemia (>6.0 mmol/L)	*(1 patient hospital admission due to hyperkalaemia)
Mortality and morbidity	2 (5%) in-hospital deaths* and 1 HF hospital admission *(1 due to progressive HF, 1 non CV-related hospital admission and death)
Sacubtril/valsartan intolerability and stopped	2 (5%) (reported dizziness and abdominal pain)
Deterioration in eGFR>10	4 (9%)

Conclusion The clinical use of SV in our centre has a high rate of tolerability with significant improvement in NYHA class (27%). However, in a large proportion of patients the target dose was not achieved (43%), mainly due to symptomatic hypotension and secondly due to hyperkalaemia (7%). A significant number of patients had a drop in eGFR, but this did not prevent up-titration. Our results confirm that HFrEF patients commencing sacubitril/valsartan require close monitoring of symptoms, renal function and dose titration by a specialist heart failure team.

2 SACUBITRIL/VALSARTAN: REAL WORLD EXPERIENCE OF DELIVERY AND TOLERABILITY

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Background Based on the PARADIGM-HF study trial, sacubitril/valsartan (SV) was approved by NICE in April 2016 (TA388) for patients with symptomatic heart failure. SV is recommended in patients with a left ventricular ejection fraction (LVEF) 35% despite a stable dose of ACE inhibitor (ACEi) or angiotensin receptor blocker (ARB), and large numbers are potentially eligible for this first-in-class drug. However, there is a lack of real world experience of both drug tolerability and systems for initiation and monitoring in overstretched heart failure services.

Methods Suitable patients were identified and started on SV by heart failure specialists. Dedicated, registrar-delivered monitoring and up titration clinics were established. Patients were reviewed 2–4 weekly. Symptoms, vital signs, biochemistry and hospital admissions were recorded at each visit. Once stable on optimal doses, patients were discharged to primary care, as pre-arranged with the District Prescribing Committee. Our initial 6 month experience has been analysed.

Results 69 patients (mean age 63.2±11.6 years) were commenced on SV. Mean LVEF 27.5±6.7%; mean baseline eGFR 66.1±21.9 ml/min/1.73m^2. Prior to initiation of SV, mean baseline ACEi/ARB dose was equivalent to 16.3±6.7 mg enalapril daily. Overall 68/69 (98.6%) prescriptions of SV were NICE TA388 compliant (1 patient ACEi/ARB intolerant).

9 patients (13.0%) stopped the medication due to adverse effects (PARADIGM-HF 17.8%), whilst another 3 patients (4.3%) were down titrated to a tolerable lower dose. 15.9% of all patients experienced symptomatic hypotension (PARADIGM-HF 14.0%). No episodes of angioedema, nor significant deterioration in renal function (50% reduction in eGFR) were observed. Only 1 (1.4%) patient was hospitalised with decompensated heart failure symptoms, but 3 (4.3%) patients were admitted with syncope secondary to orthostatic hypotension.

A total of 36 patients were discharged, with a median follow up time of 39 days (IQR 23) from commencement to stable discharge dose each requiring 1 initiation consultation and a mean of 2.4±1.0 follow up consultations. The majority of patients 25 (69.4%) were discharged at the highest dose – 97/103 mg BD. 23 (63.9%) of those discharged

reported a subjective improvement in symptoms and quality of life.

Conclusions Initiation of SV and dose optimisation in clinical practice represents a significant burden of additional work for heart failure teams. Dedicated, registrar-led outpatient clinics to monitor patients commenced on SV by heart failure specialists can successfully address this.

Prescribing within NICE TA388 guidelines in real world patients, there were similar drug tolerance and adverse event rates to those reported in PARADIGM-HF. However, the lower mean age within this particular population, who were carefully selected, may indicate that such findings are not representative of the entire heart failure population.

3 A RETROSPECTIVE AUDIT OF MINERALOCORTICOID RECEPTOR ANTAGONIST (MRA) AND DEVICE THERAPY FOLLOWING MYOCARDIAL INFARCTION (MI) COMPLICATED BY LEFT VENTRICULAR (LV) SYSTOLIC DYSFUNCTION

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Introduction The EPHESUS trial demonstrated that eplerenone reduces mortality and hospitalisation from cardiac events in patients with symptomatic LV systolic dysfunction (LVSD) or diabetes following MI with LVEF 40%. The SCD-HeFT and MADIT-II trials demonstrated a reduction in mortality with the use of primary preventative ICDs in heart failure with reduced ejection fraction (HF-rEF).

We conducted a retrospective audit of patients presenting with HF-rEF secondary to MI between 1/4/15 and 31/3/16. Our focus was on the initiation of MRA therapy, repeat assessment of LV function post MI and the use of device therapy if indicated.

Aims **1.** Establish the proportion of eligible patients with a post MI LVEF 40% prescribed an MRA.

2. Identify whether patients with LVEF 35% are having LV imaging at 6–12 weeks and if severe LVSD persists whether device therapy is considered.

Methods Patients presenting with either NSTEMI or STEMI to The Ulster Hospital, Northern Ireland were identified using the hospitals MINAP database. Data regarding these patients was collected using electronic patient records and echo database. Each patient with an ejection fraction 40% with clinical heart failure or diabetes was considered eligible for MRA therapy provided not contraindicated by renal function or potassium.

In patients with LVEF 35% we examined whether a repeat assessment of LV function with either echo or cardiac MRI was undertaken, when it was performed, and if appropriate whether ICD/CRT had been implanted. Patients were not considered eligible for a device if they had a pre-existing device, precluding co-morbidities, failed to attend echo or if they had died as an in-patient.

Results 350 patients presented to our institution with MI. 326 of these patients underwent IP assessment of LV function. 24% of the patients had LVEF 40% and 17% had LVEF 35%. 14% of patients were considered appropriate candidates for MRA therapy, but only 47% of this cohort had been prescribed an MRA.

54 patients had LVEF 35%, however only 27 were appropriate candidates for device consideration. 85% of appropriate candidates had a repeat assessment of LV function with a mean time to repeat imaging of 107 days. 17% of these patients had ongoing severe LVSD with the remainder having improved to >35%. Only 25% of those with ongoing severe LVSD had an ICD inserted, 25% died prior to review and in 50% there was no documentation why device therapy had not been considered.

Abstract 3 Table 1

Variable	n (%)
Patients with MI	350 (100%)
IP assessment LV function	326 (93%)
LVEF 40%	77 (24%)
• Eligible for MRA	47 (14%)
MRA prescribed at discharge	22 (47%)*
LVEF 35%	54 (17%)
Eligible for device therapy	27 (50%)**
Not eligible for device:	8 (15%)**
• Died as IP	3 (6%)**
• Did not attend follow-up	5 (9%)**
• Device already *in-situ*	11 (20%)**
• Extensive co-morbidities	23 (85%)***
• Repeat LV assessment	4 (15%)***
• LVEF 35% on repeat LV assessment	1 (25%)****
• ICD implanted	

* = percentage of patients meeting eligibility criteria for MRA
**= percentage of patients with LVEF 35%
***= percentage of patients with LVEF 35% and appropriate for device therapy
****= percentage of patients eligible for primary preventative ICD after post discharge LV assessment

Conclusions This audit demonstrated that there is scope to improve our practice in the management of post MI patients with severe LVSD. Explanations for this may include staff education and resource pressures. The appropriate prescription of MRA therapy and implantation of ICDs have a big impact on mortality in this cohort. It is therefore of the upmost importance to address any potential barriers to compliance with guidelines in order to improve the quality of care that is delivered.

4 IRON DEFICIENCY IN HEART FAILURE PATIENTS IN ENGLAND: INSIGHTS FROM ANALYSIS OF HOSPITAL EPISODE STATISTICS

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Introduction Iron deficiency (ID) has been shown to be present in about 50% of patients with heart failure (HF). Associated with a poor quality of life, impaired effort tolerance, and increased mortality, ID responds to appropriately provided iron therapy. In those admitted with HF, screening for ID is inconsistent, and the impact of this condition is uncertain.