number of options that would allow the committee to make an interim decision that would be revisited based on later evidence. The ability to collect robust patient level data given data capabilities in National Health Service Scotland (NHSScotland) was an important consideration.

Results. To ensure that additional evidence would be available to inform a re-assessment, the new approach applies to medicines with a Conditional Marketing Authorisation (MA) from the European Medicines Agency (EMA). This obligates the company to provide specified clinical data to the regulator within a pre-set timeframe. For these medicines, the SMC decision-making committee can accept or not recommend the medicine as at present but can also accept the medicine on an interim basis, if the regulator's mandated Specific Obligations are likely to address the uncertainties in the clinical evidence. When the regulator converts the MA from conditional to standard, the company is required to make a further SMC submission to allow a reassessment and a final decision. The company can also provide additional supplementary post-licensing patient level evidence at reassessment.

Conclusions. This new decision option allows SMC to test an approach to managing uncertainty targeted at a small number of promising new medicines where there is unmet patient need, with the reassurance that a final decision will be supported by additional clinical data.

PP54 A Cohort Case Study On Implantable Cardioverter Defibrillators

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Introduction. Many patients presenting with arrhythmias are treated with antiarrhythmic drug therapy. However, for some patients, usually survivors of previous serious ventricular arrhythmias, treatment implies the use of implantable cardioverter defibrillators (ICDs) and/or Cardiac Resynchronization Therapy (CRT) devices.

Methods. This retrospective study evaluated a cohort of patients with arrhythmia requiring the use of ICDs, CRT or ICDs + CRT from January 2004 to March 2018. Data from a private healthcare organization in Belo Horizonte, Brazil were used to assess all-cause mortality and the need for replacement of the device. Continuous variables were expressed as mean and standard deviation. Cox proportional regression model and Log-Rank test were used to adjust the survival curve.

Results. Five hundred and ninety-three patients were included in the study (median age 67.6 years, range 23 to 89 years; male 62 percent). According to the type of device used to treat these patients, the distribution was 338 (57.0 percent), 169 (28.5 percent), 86 (14.5 percent), for ICDs, ICDs + CRT, CRT, respectively. After a mean follow-up time of 3.12 years (range 0 to 13.6 years), 283 devices were replaced (ICDs n = 140; ICDs + CRT n = 90; CRT n = 53) and 284 deaths occurred (median survival of 6.9 years). The median survival was 7.3, 5.8, 4.8, 5.5 years for ICDs single-chamber, ICDs dual-chamber, ICDs + CRT, CRT, respectively.

Conclusions. Randomized trials are often criticized for their enrollment of highly selected patients. Studies on real-word data can provide reliable information regarding the use of ICDs and/or CRT devices in the treatment of patients with serious ventricular arrhythmias.

PP55 The Effectiveness Of Viabahn In Peripheral Artery Aneurysms

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Introduction. Open repair was considered for several years the gold standard therapy for the treatment of peripheral artery aneurysms (PAAs). However, with advancements in endovascular technology increasing attention has been directed toward repairing PAAs using an endovascular stent graft.

Methods. This retrospective study evaluated a cohort of patients after the correction of PAAs with Viabahn. Patients treated from January 2011 to January 2018 were assessed for all-cause mortality, amputation and the need for re-intervention. Data were extracted from an administrative database from a healthcare organization in Belo Horizonte, Brazil.

Results. Fifty-two patients were included in the study (median age 69.1 years, range 15 to 90 years; male 63.5 percent), three of whom also received Viabahn for contralateral PAAs. In total, 84 devices were used (average 1.5 per PAA); distribution: popliteal and tibial arteries (n = 30; 57 percent), femoral and iliac arteries (n = 19; 37 percent), axillary artery (n = 1; 2 percent), splenic artery (n = 1; 2 percent), abdominal aorta (n = 1; 2 percent). After a mean follow up time of 1.98 ± 1.68 years, we observed death (n = 3; 5.8 percent), amputation (n = 3; 5.8 percent) and the need for re-intervention (n = 17; 32.6 percent) in 23 patients (44.2 percent). The combined overall survival for the first, second and third year of follow up was 70.2 percent (Confidence Interval [95% CI]: 58.9 - 83.6); 63 percent (95% CI: 51.0 - 78.0) and 57.3 percent (95% CI 44.6 - 73.6).

Conclusions. There are still several unanswered questions regarding the best approach for patients with PAAs. In the absence of well-designed clinical studies, the assessment of databanks on real-world patients may contribute to improve our understanding of treatment alternatives and provide guidance to improve current clinical results.

PP57 Outcomes On Transcatheter Aortic Valve Implantation

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