Results Patients were enrolled at 44 centres in 9 countries. A total of 331 patients were randomised to RDN (N=166) and sham control (N=165). The primary and secondary efficacy endpoints were met, with Bayesian posterior probability of superiority >0.999. The treatment differences were -3.9 mmHg for 24-hour SBP and -6.5 mmHg for office SBP between RDN and sham control groups. Treatment differences in 24-hour and office diastolic pressure at 3 months were -3.1 mmHg and -4.4 mmHg, respectively. Reductions in BP after RDN were consistent throughout 24 hours. There were no major procedural safety events to 3 months.

Conclusions Results from the SPYRAL HTN-OFF MED Pivotal trial, first reported at ACC2020, demonstrate the efficacy of catheter-based RDN compared to sham control to safely lower BP in the absence of anti-hypertensive medications.

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## CORRELATION OF INCIDENTAL LEFT ATRIAL APPENDAGE THROMBUS ON NON-CARDIAC GATED CT WITH TRANSOESOPHAGEAL ECHOCARDIOGRAPHY

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10.1136/heartjnl-2020-ICS.17

Background Transoesophageal echocardiography is recognized as the gold standard for detection of a left atrial appendage (LAA) thrombus. LAA thrombus is visualized as filling defect on computed tomography (CT), however it can be difficult to differentiate between slow flow and thrombus. This poses challenges in both the reporting and interpretation of left atrial filling defects on non-cardiac gated CTs, and whether to classify this as thrombus or an issue with imaging technique when reporting. Due to the risk of stroke with a LAA thrombus, the reporting of a LAA thrombus on CT makes it difficult for physicians to ignore and usually leads to anticoagulation, thereby exposing the patient to the risk of bleeding. In this study we assessed the correlation between left atrial appendage thrombus or filling defects on a non-cardiac gated CT, with confirmation on TOE.

Methods We retrospectively analyzed TOE cases performed at our center between March 2016 and March 2020. Patients were included if they had been referred for LAA assessment following identification of a suspected LAA thrombus on CT thorax.

Results 757 TOEs were conducted at our center during the study period. This study includes 19 patients who were referred for TOE following incidental left atrial appendage thrombus on CT. Baseline characteristics include; mean age 69.5 years, male 68.4%, hypertensive 79%, history of atrial fibrillation 63.2%, on long-term anticoagulation 63.2%, on anti-coagulation following CT prior to TOE 89.5%, previous stroke 21%, median CHA2DS2-VASC 3. The mean time from CT to TOE was 16 days.

15.8% (n = 3/19) of the patients referred had evidence of a LAA thrombus on TOE. 66% (n = 2) of these patients had a history of prior stroke, the median CHA2DS2-VASC score was 5 and overall 50% of the patients in our cohort who had a history of stroke had a LAA thrombus at TOE. The mean peak LAA filling velocity was only mildly reduced at 37 cm/s, and 63% (n = 12) of LAA were windsock morphology. In the follow-up period from TOE to data collection, there was no reported subsequent strokes in the 19 patients analyzed, mean follow-up time 14 months.

Discussion In patients who have an incidental left atrial thrombus or filling defect reported on non-gated CT thorax, only a minority have a thrombus at TOE and it was no associated with subsequent stroke risk. A history of stroke or CHA2DS2-VASC of >5 conferred a higher probability of thrombus being present and we recommend that physicians take this into consideration when deciding on anti-coagulation. The LAA filling velocities were only mildly reduced and the radiographic findings are likely related to CT gating rather than an physiological process in the left atrium. Incidental LAA thrombus on CT correlates poorly with presence of thrombus on TOE, and if there is concern a TOE should be performed to assess for a thrombus.

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## HEART FAILURE PATIENT AND CAREGIVER NEEDS AND EXPECTATIONS REGARDING SELF-MANAGEMENT VIA DIGITAL HEALTH – THE PASSION-HF PROJECT

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10.1136/heartinl-2020-ICS.18

Background Current heart failure (HF) healthcare services are not sufficient to meet the needs of an aging population with increasing comorbidities and disease complexity together with the unequal distribution of medical care in rural and urban regions. These factors have created an imminent need to identify alternative healthcare approaches. eHealth applications have potential to alleviate much of the burden on healthcare services and improve patient treatment. The 'PASSION-HF' project aims to develop a digital decision support system – a virtual doctor – that provides solutions based on current clinical guidelines. Patient independence is maximized through 24/7 access to personalized HF management. Furthermore, the application (named DoctorMe) defines processes and decision points where medical professionals need to be included in the process.

Purpose To understand the needs and requirements of HF patients and their informal caregivers in regard to a virtual doctor

Methods We conducted an exploratory mixed-method study within the Netherlands, United Kingdom, Ireland and Germany. Qualitative, guided interviews were supplemented by a standardized questionnaire. The interviews focused on acceptance factors, motivation to use a decision support system and satisfaction with their current health care situation. Interviews were analysed using the content analysis according to Mayring (2010) with the help of 'Atlas.TI' software. Supplementary questionnaires on self-management of HF-patients, the role of the informal caregivers, technology acceptance, and decision making.

Results A total of 49 patients and 33 informal caregivers were interviewed. Patients were male (76%) aged between 60 and 69 years (43%). Three key themes were identified in regard to digital health: 1) Reassurance: patients often feel uncertain about their condition and their symptoms and a need for

A12 Heart 2020;**106**(Suppl 4):A1-A43

instant feedback about their current health status; 2) Personalized advice: patients want a system that can adapt medication, sport activities and food recommendations to their current health status; 3) Transparency: patients want to know the source, reasons, and individualized interpretation of any recommended changes to the management of their condition. Additionally, patients have a desire to adapt their lifestyle to the needs of HF, but they require help to remain motivated to achieve this goal.

Conclusion These findings provide valuable information for the development and implementation of eHealth solutions. Patients want reassurance 24/7, independently of the availability of healthcare services, combined with personalized medical advice regarding day-to-day management of their HF. In a next step, we are planning a multicentre clinical trial to test the first prototype of the eHealth product (DoctorMe).

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## DYSTROPHIN DEFICIENT CARDIOMYOPATHY – PREDICTORS ASSOCIATED WITH THE CARDIAC PHENOTYPE IN A DUCHENNE'S REGISTRY POPULATION – A GUIDE FOR DEVICE THERAPY

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10.1136/heartinl-2020-ICS.19

Background Patients with Duchenne muscular dystrophy (DMD) typically exhibit cardiac dysfunction and arrhythmia. With increasing life expectancy due to advances in respiratory support, cardiomyopathy and associated dysrhythmia are fast becoming the primary cause of morbidity and mortality in this patient group. Despite advances, the correlation between genotype and cardiac phenotype remains poorly understood and individual registries small, with implementation of device therapy often delayed due to poor diagnostic image quality.

Methods A single-center registry for DMD patients was established and data including genotyping, medical therapy and investigations such as cardiac MRI, nt-Pro BNP levels, echocardiogram and holter monitor was analysed. The aim was to potentially identify predictors associated with a more severe cardiac phenotype.

Results A total of 22 patients (age 17 -31) with DMD were reviewed (demographics summarised in table 1). All patients were evaluated with echocardiography on at least one occasion (mean EF 44.3%). Cardiac MRI was attempted in six patients, however due to contractures preventing access to the scanner only three were completed. 14 of 22 patients (64%) demonstrated an impaired left ventricular ejection fraction (EF) < 50% (mean EF 41%). Proximal 'hot spot' deletions/mutations (exon 2-19) appeared to be associated with a more pronounced reduction in EF - all those patients with proximal mutations demonstrated an EF < 45% (mean 41%). Seven of the eight patients (87.5%) with mutations involving >1 exon deletion demonstrated more severely impaired EF (mean EF 37.5%) compared to those with single exon deletions (mean EF 52%). Interestingly, one patient with a proximal mutation (exon 3-6 deletion) remains mobilising to distances up to 70 m, however CMRI performed has shown a moderate degree of fibrosis with an EF of 42%. Correlation between nt-Pro BNP levels and reduced EF (rEF) was not uniform, however a level < 100

Abstract	19	Table	1	Demographics	
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	Age	Mutation	EF	nt-Pro BNP	No. of HF Medications
ī	17	Exon 3–6 Del	42%	Not Available	2
II	17	Nonsense Exon 19	45%	Not Available	2
Ш	18	Nonsense Exon 19	45%	Not Available	2
IV	19	Exon 47-52 Del	40%	251	3
V	20	Exon 37-43 Del	50%	300	1
VI	20	Exon 45-53 Del	30%	37	3
VII	17	Exon 44-47 Del	50%	Not Available	3
VIII	22	Exon 45-50 + 52 Del	30%	231	2
IX	21	Exon 43-53 Del	25%	37	3
Χ	21	Exon 45 Del	45%	290	3
XI	28	Absent on IHC	50%	35	2
XII	20	Absent on IHC	40%	164	2
XIII	31	Uncertain	20%	108	2
XIV	18	Exon 68 Del	45%	140	3
XV	20	Exon 68 Del	70%	36	1
XVI	20	Exon 45 Del	35%	290	3
XVII	19	Exon 44 Del	55%	12	2
XVIII	26	Uncertain	55%	24	1
XIX	31	Uncertain	60%	47	3
XX	17	Uncertain	55%	113	3
XXI	26	Uncertain	55%	Not Available	1
XXII	31	Exon 50 Del	60%	63	2

Nt-Pro BNP – N-terminal pro-B-type natriuretic peptide, HF – Heart Failure, IHC – immuno-histochemistry, EF – ejection fraction.

was associated with EF >55% in 89% of cases. Of those on steroid regimes, 6 (54%) had impaired LVEF compared to 5 (83%) of those not on steroid therapy. All patients are taking at least one class of heart failure modification, with 79% on two and 37% on three. Only one patient in the registry has had an ICD implanted. This patient has had a device for 10 years and in this time there have been no therapies delivered.

Conclusion Correlation between predictors and cardiac phenotype in a Duchenne population remains unreliable. Location and size of exon alteration appears to be indicative of more markedly impaired LV function, however larger studies are required to characterise this further and challenges remain with regard to accurate assessment of EF. The use of predictors in future may help to guide appropriate provision of device therapy.



## HOW DOES BMI INFLUENCE HEART FAILURE PROGRAMME OUTCOMES?-TESTING THE OBESITY PARADOX

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10.1136/heartjnl-2020-ICS.20

Introduction A complex physiological relationship exists between obesity and heart failure (HF) with many large-scale studies reporting a paradoxical improvement in cardiovascular (CV) mortality in obese patients. Many of these studies retrospectively analyzed RCT trials not designed to investigate the role of obesity in HF outcomes. We aim to establish if

Heart 2020;**106**(Suppl 4):A1–A43