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HEALTHCARE EXECUTIVE ALLIANCE SPECIAL EDITION ON E-LEARNING

Money Talks

- COSTS, COSTS, COSTS! WHO PAYS IN HEALTHCARE?, *C. MCCAHAN*
- HOSPITAL FINANCE, *M. NOPPEN*
- TRANSFORMING COMMISSIONING TO DO MORE WITH LESS, *C. COTTON*
- MAKING AFFORDABLE HEALTHCARE PROFITABLE, *A. MIR*
- PRESENTING A CASE: FINANCING IT PROJECTS, *M. HASIB ET AL.*
- NATIONAL TELEHEALTH CAN SAVE MONEY AND IMPROVE HEALTH, *H.E. HENRIKSEN*
- FINANCE TECHNOLOGY BLOCKCHAIN IN HEALTHCARE IT SECURITY, *T. LAURENCE*
- FRAUD IN HEALTHCARE, *S. PECK & L. MCKENNA*

American College of Cardiology 2017 Meeting

Cholesterol Lowering (R)evolution, TAVI and More...

The latest cardiology research was presented at the American College of Cardiology meeting: transcatheter valve implants emerge as an alternative in less than high risk severe aortic stenosis patients; can iFR define whether your coronary artery requires a stent? Extremely low LDL-cholesterol levels at a price point – but does it translate into better outcomes? Could implantable sensors revolutionise the way we manage heart failure in the 21st century?

Thomas Kaier
British Heart Foundation Research Fellow
Specialist Registrar in Cardiology
King's College London, UK

Country Correspondent, HealthManagement

tk@tomkaier.com

@tomkaier

Washington hosted this year's annual scientific meeting of the American College of Cardiology (ACC), featuring a broad variety of hot topics. The SURTAVI trial (Reardon et al. 2017) demonstrated that a transcatheter aortic valve implant (TAVI) is noninferior to surgical replacement in patients at intermediate surgical risk (similar rates of death and disabling strokes in both groups). This paves the way for a further push towards using percutaneous valve replacements in patients who could conventionally only undergo a surgical procedure. However, this is not without caveats: TAVI incurred an almost four-fold higher risk of requiring pacemaker implantation, and the need for re-intervention 12 and 24 months later was significantly higher in the TAVI group. The long-term durability of the implants is still in question and hence it is unlikely that TAVI will become the preferred modality for the treatment of severe aortic stenosis in younger patients.

> "TAVI IS CLEARLY DEVELOPING INTO A COMPETITIVE TECHNOLOGY THAT MIGHT GIVE CARDIAC SURGEONS A GOOD RUN FOR THEIR MONEY"

Two trials demonstrated noninferiority of instantaneous wave-free ratio (iFR) compared to fractional flow reserve (FFR) at preventing adverse cardiac events when used in the assessment of coronary artery lesions that appear angiographically of intermediate severity: DEFINE-FLAIR (Davies et al. 2017) and iFR SWEDEHEART (Götberg et al. 2017). Both observed a similar rate of major adverse cardiac events at 1 year regardless of whether the patient was investigated with iFR or FFR. Procedure length was on average 4 minutes (8%) shorter and associated with fewer symptoms in the iFR group, as this does not require the administration of vasodilating medication. Given the relatively widespread use of FFR (3-10% of all coronary angiograms performed in interventional centres, depending on the respective healthcare environment), only time will tell whether a different technology achieving similar outcomes will take hold.

Prevention rather than treatment is key—at least when correlating the amount of data presented at the ACC meeting investigating both (LDL-) cholesterol-lowering and (HDL-) cholesterol-increasing medication. Two major trials—FOURIER (Sabatine et al. 2017) and EBBINGHAUS (technically a substudy of FOURIER)—investigated safety and efficacy of evolocumab, an injectable proprotein convertase subtilisin/kexin type (PCSK) 9 inhibitor aimed at reducing LDL-cholesterol levels. Participants with established cardiovascular risk on statin therapy and LDL-C ≥ 70 mg/dl (equivalent to 1.8 mmol/l) were eligible for enrolment. EBBINGHAUS focused on whether the drug would cause cognitive impairment (it did not, at 19 months follow-up), while FOURIER demonstrated effective LDL-C reduction by 59%. Further, the primary endpoint (incidence of cardiovascular death, myocardial infarction, stroke hospitalisation for unstable angina or coronary revascularisation) was met, and evolocumab performed statistically significantly better than placebo (9.8% vs 11.3%, respectively). Overall, the drug was well tolerated and showed only a slight increase of injection site reactions (2.1 vs 1.6%). Interestingly, the benefit at three-year follow-up is predominantly derived from a lower rate of myocardial infarction (3.4 vs 4.6%), coronary revascularisation (5.5 vs 7.0%) and stroke (1.5 vs 1.9%). Cardiovascular as well as death from any cause were similar in both groups and did not seem to benefit from

aggressive LDL-cholesterol lowering medication. One might argue that, intuitively, even extremely low LDL-C levels of median 0.78 mmol/l cannot reduce cardiovascular death rates after only three years. However, this is certainly worth considering when assessing the costs of treatment. In the UK, the National Institute for Health and Care Excellence (NICE) has evaluated Evolocumab in a technology appraisal published in June 2016: it is thus recommended as an 'option for treating primary hypercholesterolaemia or mixed dyslipidaemia' (NICE 2016). The guideline endorsement only applies to patients without cardiovascular disease (CVD) in the context of hereditary forms of high LDL-C concentrations (>5.0 mmol/l; 3.5 mmol/l if high CVD risk), or patients with a primary (non-familial) form of hypercholesterolaemia at high CVD risk (starting at LDL-C >3.5 mmol/l, depending on risk factor profile). The annual cost has been quoted between GBP 4,400 and 6,100 (EUR 5,100-7100; excl. VAT). According to NICE, a discount in the context of a patient access scheme has been agreed between the Department of Health and the manufacturer Amgen, but the level of discount has not been publicised. One is thus left in a grey area when it comes to healthcare economic considerations. Would the average patient accept a two-weekly injection, given it does not prevent death but slightly modifies cardiovascular risk?

Quite exciting possibilities were presented with an implantable device (CardioMEMS HF) measuring pulmonary artery pressures (PAP) in patients with heart failure; the CHAMPION trial (Desai et al. 2017) examined whether readmissions to hospital could be averted by ambulatory monitoring of haemodynamic data. More than 1,000 patients had received the device and the percentage of patients admitted for heart failure reduced from 59% to 22% in the 6 months following implant. For the individual, this translates into a markedly reduced frequency of admissions: 0.92 vs 0.37 admissions per 6 months. This was achieved through early adjustment of the medical therapy, with intensified therapy if measured PAP increased (indicating impending clinical deterioration). Medical and quality-of-life implications aside, this makes further economic sense: An average cost of USD 23,000 (EUR 21,500) is quoted by Medicare for device implant in the US, and the average cost reduction equates to USD 13,000 (EUR 12,100) per patient per year (by reducing the number of hospital admissions), hence reaching a break-even point at roughly two years. Maybe the associated savings could then fund the rather costly PCSK9 inhibitors?

Conclusion

The field of cardiology is clearly making progress on all fronts. The field of preventive therapy sees exciting new opportunities through aggressive cholesterol reduction; the physiological assessment of coronary artery disease in the catheter laboratory could become simpler, and TAVI is clearly developing into a competitive technology that might give cardiac surgeons a good run for their money. The validation of the PAP sensor devices exhibits truly disruptive potential: remote-control adjustment of medical therapy could revolutionise the way physicians manage heart failure, leading to better quality of life and fewer hospital admissions for a large patient cohort. ■

KEY POINTS

- ✓ Transcatheter valve implants emerge as an alternative in less than high risk severe aortic stenosis patients
- ✓ Physiological assessment of coronary artery disease in the catheter laboratory simplified: can iFR define whether your coronary artery requires a stent?
- ✓ Extremely low LDL-cholesterol levels at a price point – but does it translate into better outcomes?
- ✓ How implantable sensors could revolutionise the way we manage heart failure in the 21st century

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