for the Ross operation can be met by establishing tissue banks and, importantly, by developing biological substitutes with tissue engineering technology.

This lost opportunity needs to be addressed by individual physicians and patients, and by professional bodies responsible for patient care, to better manage the heart valve disease epidemic that we are facing.

Magdi Yacoub Institute, Imperial College, London UB9 6JH, UK (MYH); Montreal Heart Institute, Montreal, Canada (IE-H); University Hospital Lubeck, Lubeck, Germany (H-HS, EIC); Northwestern University Feinberg School of Medicine, Chicago, IL, USA (ROB); Mount Sinai Hospital, New York, NY, USA (BAC, PST); Department of Cardiovascular Surgery, Santa Casa de Curitiba, Brazil (FDAdC); Saarland University Medical Center, Homburg, Germany (HJS); The Royal Melbourne Hospital, Melbourne, Australia (PSk); University of Verona, Verona, Italy (GBL); and Department of Cardio-Thoracic Surgery, Erasmus MC, Rotterdam, Netherlands (JJMT)

m.yacoub@imperial.ac.uk

We declare no competing interests.

Telemonitoring implants for patients with heart failure

Many individuals with heart failure have an implanta ble cardioverter-defibrillator (ICD) or a cardiac resynchronisation therapy defibrillator (CRT-D). These devices are implanted for therapeutic reasons but can collect and transmit information about the individual’s physiology and device function. Does monitoring such information improve clinical outcomes? Observational data suggest that remotely monitored patients have a better outcome than do those who are not, but these studies are likely to have patient and physician selection bias.¹

In The Lancet, Gerhard Hindricks and colleagues report the results of the IN-TIME trial.¹ 664 patients with mild-to-moderately symptomatic chronic heart failure and a recent dual-chamber ICD or CRT-D implant were randomly assigned to either automatic daily implant-based monitoring in addition to usual care, or usual care alone. The primary endpoint was a composite clinical score combining all-cause death, heart failure hospital admission, functional class, and patient global assessment. At 12 months, 63 (18·9%) of 333 patients in the telemonitoring group had a worsened composite score compared with 90 (27·2%) of 331 in the control group (odds ratio 0·63, 95% CI 0·43–0·90). This difference was largely driven by significantly lower mortality in the telemonitoring group (ten vs 27 deaths, 1-year hazard ratio 0·36, 95% CI 0·17–0·74).

Ventricular tachyarrhythmia, defibrillation shocks, onset of atrial fibrillation, low percentage of biventricular pacing, change in patients’ activity, abnormal sensing, and other technical issues were monitored remotely. On average, only four observations per patient-year were flagged up by the central monitoring unit to the sites, and, in response to the data, investigators made only 641 contacts with 238 patients. Most of the notifications related to gaps in data transmission (although transmission occurred on 85% of days), and

See Articles page 583

References

thereafter the most common observations were of new-
onset atrial tachyarrhythmia, cardiac resynchronisation
therapy of less than 80% over 48 h (suboptimal pacing),
frequent ventricular ectopics, and sensing problems. 
Most of these notifications triggered a telephone call to 
the patient. After such contact, around 50% of patients 
had earlier follow-up scheduled.

Most of the deaths in both groups were cardiovascular,
with fewer deaths from worsening heart failure (six vs 
15) and sudden death (one vs two) in the telemonitoring 
group. Although there were fewer deaths from 
worsening heart failure in the telemonitoring group,
neither the total number of hospital admissions for 
worsening heart failure nor the proportion of affected 
patients was significantly different.

What might be the mechanism of the mortality 
benefit? We do not know whether there was better use 
of disease-modifying drugs in the telemonitoring group 
(or better compliance) as time went on—although 
both groups seemed to be well treated at baseline, 
reflected in the low number of admissions to hospital 
throughout the study. The authors speculate that the 
earlier detection of ventricular and atrial arrhythmia 
might enable changes to treatment that reduce the 
risk of worsening heart failure, stroke, and sudden 
death. Indeed, new onset atrial arrhythmia was the 
commonest medical telemonitoring observation 
leading to patient contact, and patients with a history 
of paroxysmal atrial fibrillation had greater benefit 
telemonitoring than did other patients. Other 
possibilities include earlier detection of inappropriate 
shocks or sensing problems that might lead to inappropriate shocks. 

Integration of a daily review of remotely collected 
data from an implanted device into clinical practice is 
challenging.1 IN-TIME had a central monitoring unit in 
addition to the sites accessing the data. Those reviewing 
data need the appropriate competencies and support, 
and the ability to react appropriately to the data. Delay in 
response, often introduced by multiple layers of review, 
defeats the purpose of early identification of problems.4 
Avoidance of data overload is also important: in IN-
TIME, the additional workload related to telemonitoring 
was small.

Many studies have been done of remote monitoring 
of heart failure. They included three types of 
technology: stand-alone systems that transmit 
information for blood pressure, heart rate, weight, and 
symptoms; remote monitoring of therapeutic devices 
(such as in IN-TIME); and remote monitoring of devices 
implanted for purely monitoring purposes. Meta-
analyses of remote monitoring of stand-alone systems 
suggest that they improve mortality and hospital 
admissions for heart failure;5,6 but results of two large 
randomised controlled trials of stand-alone remote 
monitoring (TELE-HF7 and TIM-HF8) have been neutral.

The only other large randomised trial of remote 
monitoring of patients with ICDs and mild heart 
failure showed no significant difference in mortality.9 
A previous study10 of daily monitoring and alerting 
to changes in lung fluid reported a 79% increase 
in hospital admissions for worsening heart failure, 
perhaps because of patient and physician anxiety when 
the alarm was triggered.

Another large randomised controlled trial of 
1650 patients (REM-HF) has completed enrolment 
in England, and it will be helpful in corroborating the 
mortality benefit shown in IN-TIME. It will examine the 
likely mechanisms of benefit, and the cost-effectiveness 
of such an approach, over a longer time period.11

Monitoring data from an implanted pulmonary 
artery pressure monitor has been reported in one trial 
to reduce hospital admissions for worsening heart 
failure by 30% at 6 months (p<0.0001), but with no 
mortality benefit.12 

Remote monitoring is technically feasible but 
requires services to be redesigned at a time when
Risk and decision making in patients with hypertension

In The Lancet, the Blood Pressure Lowering Treatment Trialists’ Collaboration (BPLTTC) report an individual patient data meta-analysis of trials that randomly assigned patients to blood pressure-lowering drugs or placebo, or more intensive or less intensive blood pressure-lowering strategies.¹ The expected, albeit important, conclusion of the study is that blood pressure-lowering drugs provide a similar relative benefit across different strata of predicted cardiovascular risk: in an analysis of 51,917 participants in 11 trials, blood pressure-lowering treatment reduced the relative risk of events in patients in four groups of increasing estimated baseline cardiovascular risk by 18% (95% CI 7–27), 15% (4–25), 13% (2–22), and 15% (5–24), respectively. Hence, by definition, the absolute benefit of treatment would increase with the baseline risk, and treatment of 1000 patients in each group for 5 years should prevent 14 (95% CI 8–21), 20 (8–31), 24 (8–40), and 38 (16–61) cardiovascular events, respectively. The number-needed-to-treat to prevent an event would decrease accordingly.

This study is reminiscent of a landmark analysis undertaken by the Cholesterol Treatment Trialists that showed the absolute benefit of cholesterol reduction with statin treatment to be proportional to the baseline absolute cardiovascular risk.² The BPLTTC analysis is timely and important because its findings could affect future revisions of hypertension guidelines that seem to be reluctant to consider total cardiovascular risk, instead of blood pressure alone, as the main driving force to guide initiation of treatment.³⁻⁵

Understanding the methods of the BPLTTC study is not purely academic, but pivotal to realise the extent to which the findings are generalisable.⁶ The authors used the placebo groups of ten trials with available time-to-event data to develop risk prediction models for six prespecified outcomes. A parsimonious set of covariables, with the notable exception of blood lipids, was used to balance model fit with the availability of risk factor data. Subsequently, they applied the equations to all trial participants and ranked them by estimated absolute 5-year risk of outcome events. 5-year risks, rather than more conventional 10-year risks, were estimated because 5 years was closer to the actual median follow-up of 4 years. Thereafter, considering