CARDIOLOGY MANAGEMENT

Volume 1 - Issue 1, November-December 2007

Improving Clinical & Economic Effectiveness

Telemonitoring & Heart Failure

- Handheld Echocardiography
- Improved Heart Failure Management
- Cardiology Requirements for PACS
- Managing & Preventing CVD

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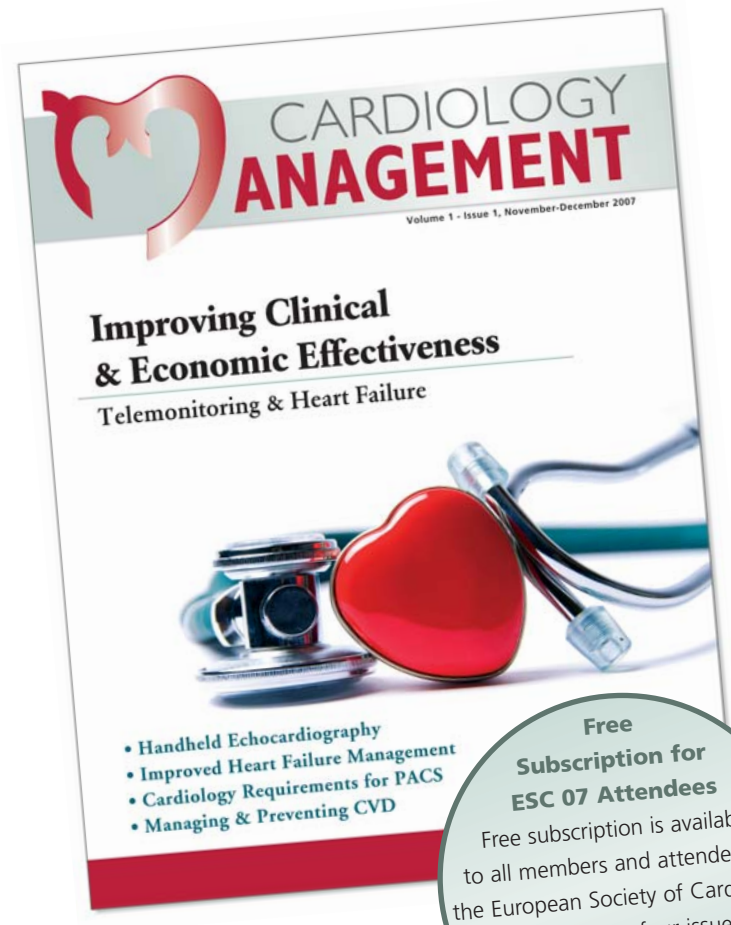
CARDIOLOGY MANAGEMENT

The Management Journal for Cardiologists



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Cardiology Management is the only hard-copy journal focusing on best practice in management in cardiology departments across the world. Distributed four times per year, this journal is tailored to meet your information needs on the latest best practices in management topics, such as staff, financial and IT-related management issues. Sections include:

- **EU News** – Covers developments at an EU level that are relevant to cardiologists
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Please submit all management-related abstracts to Managing Editor Dervla Gleeson at dg@cardiologymanagement.eu before November 16, 2007. A full list of desired topics is available from our website.

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Editorial

Editor-in-Chief
Professor Panos Vardas

Publisher
Christian Marolt

Dear Readers,

Better management practices can have a profoundly positive impact on the efficiency of any medical department. An exchange of management information and experiences will inevitably allow for a more efficient and patient-orientated provision of services, as well as a more informed medical team.

While at a general hospital level, management awareness is more clearly evident, cardiologists have thus far not been provided with a specifically-tailored platform by means of which they can share their experiences and continue to augment their knowledge of management concerns for the benefit of both patients, staff, and budgets!

Given the steady increase of financial pressure on healthcare institutions, it is evident that the existing range of publications in the field of cardiology are not specifically geared towards the more complex management challenges that will arise. For this reason, Cardiology Management will be launched as an independent voice for these concerns, as a portal for department heads and managers to share their experiences in meeting the increasingly complex and demanding challenges on finite resources.

Topics

Cardiology Management will cover topics such as best practice, medical quality & safety, better value-for-money investments, cost-efficiency, personnel development & management, cardiology informatics and optimal patient satisfaction. By covering topics that assist the development of more efficient, cost- and consumer-friendly services, it provides insight into and analysis of the constantly evolving field of cardiology management.

If you would like to raise your personal management concerns with our editorial team or subscribe online to Cardiology Management, please contact our Managing Editor, Dervla Gleeson, at editorial@cardiologymanagement.eu with your feedback or visit our website at www.cardiologymanagement.eu.

Yours faithfully,

Panos E. Vardas, MD, PhD
Professor of Cardiology

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Medical Doctors (respond below)

1. What is your occupation? (check only one)
   - ❑ Chief Cardiologist
   - ❑ Other Physician (please specify)

1a. What is your Cardiology sub-specialty? (check only one)
   - ❑ General Cardiology
   - ❑ Interventional Cardiology
   - ❑ Cardiac Radiology (Cardiac MRI, Echography, Cardiac CT)
   - ❑ Cardiac Surgery/ Cardiovascular Surgery
   - ❑ Paediatric Cardiology
   - ❑ Other (please specify)

1b. I am Chief of my Department
   - ❑ Yes
   - ❑ No

Non-physician professionals (respond below)

1c. What is your occupation? (check only one)

Administrator/Manager:
- ❑ Cardiology Administrator
- ❑ Cardiology Business Manager
- ❑ Cardiology PACS Administrator

Executive
- ❑ Chief Information Officer / IT Manager
- ❑ Chairman / Managing Director
- ❑ Director
- ❑ Chief Financial Officer / other executive titles

Other
- ❑ Medical Physicist
- ❑ Academic
- ❑ Chief Technologist
- ❑ Manufacturer
- ❑ Business Consultant
- ❑ Distributor / Dealer

All respondents reply to the questions below

2. In what type of facility do you work? (check only one)
   - ❑ Private clinic
   - ❑ Hospital (check number of beds)
   - ❑ More than 500 beds
   - ❑ 400-499 beds
   - ❑ 300-399 beds

3. How many beds is your ward equipped with?
   - ❑ More than 30 beds
   - ❑ 15 - 30 beds
   - ❑ Less than 15 beds

4. With what technologies or disciplines do you work? (check all that apply)
   - ❑ Echography
   - ❑ Interventional Cardiology
   - ❑ Angiography
   - ❑ Cardiac CT
   - ❑ Cardiac MRI
   - ❑ Cardiology PACS

5. What is your role in purchasing
   - ❑ Final say
   - ❑ Influence
   - ❑ No role

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Content

CARDIOLOGY MANAGEMENT

Cardiology Management, Vol 1, Iss. 1

INDUSTRY NEWS

Cordis Appoints New Vice-President of Microelectronic Technologies

Cordis Corporation has announced the appointment of Joseph M. Smith, M.D., Ph.D. to Vice President, Microelectronic Technologies. Dr. Smith will lead the company's efforts to develop implantable microelectronic technologies in the management of cardiovascular disease. Dr. Smith brings more than 25 years experience in cardiac rhythm management (CRM) to Cordis Corporation. Most recently, he served as Senior Vice President and Chief Medical Officer of the CRM business at Guidant (later Boston Scientific). Prior to his corporate positions, Dr. Smith founded and served as Director of The Arrhythmia Institute, a private clinical and research organisation in clinical cardiac electrophysiology located in Fairfax, Virginia. He also led a research programme in biomedical signal processing and served as associate director of the clinical and teaching programme in clinical cardiac electrophysiology at Washington University in St. Louis, Missouri.

ISHR/Servier Research Fellowship Winner Announced

The ISHR-ES SERVIER Research Fellowship has been presented to Dr Marta Roccio, a postdoctoral research fellow at the Department of Cardiology and Laboratory of Experimental Cardiology University of Utrecht, Utrecht, The Netherlands.

Dr Roccio's project is titled: "Molecular mechanisms of cardiac progenitor cells differentiation". This 20,000 Euro grant is offered for the sixth time by SERVIER in partnership with the European section of the ISHR to support a cardiovascular research project within a European research group for a period of one year.

First Patient Enrolled in Clinical Trial to Study Drug Eluting Stent Treatment in Women

Abbott has announced that the first patient was enrolled in its Xience V Spirit Women clinical trial, the world's first clinical trial designed to study the safety and effectiveness of drug eluting stent treatment in women. Liliana Grinfeld, M.D., of the Hospital Italiano in Buenos Aires, Argentina, performed the first procedure.

The goal of the trial is to increase understanding of how heart disease affects women and to assess the performance of the Xience™ V Everolimus Eluting Coronary Stent System in women with previously untreated coronary artery lesions from Europe, Asia-Pacific, Canada and Latin America. The trial will focus on specific aspects of women's health in relation to coronary artery disease such as general awareness about the disease, symptoms at time of presentation, referral patterns, and hormonal menopausal status.

CardioDynamics Gains Support for Vermed Sale

CardioDynamics International has reported that it is progressing with its shareholders' approval for the sale of its Vermed business unit. The company reached an agreement to sell the Vermed unit to the subsidiary's management team for a cash purchase price of $8 million in late June this year.

Vermed is a supplier of disposable electrodes and related supplies utilised in electrocardiograph (ECG) and other diagnostic procedures. CardioDynamics said the decision to sell Vermed will allow it to focus its resources on its proprietary ICG business, which it believes continues to hold the highest growth potential, while maintaining a long-term preferential relationship with Vermed for ICG sensors.

Medtronic Announces European Introduction of Cardiac Monitor

Medtronic has announced the European introduction of Reveal® XT, the first Insertable Cardiac Monitor that offers long-term and continuous monitoring of Atrial Fibrillation (AF). All other current monitoring tools are either for a limited period or on an intermittent basis. Long-term, continuous monitoring means that a clinician no longer needs to rely only on incomplete data to evaluate how AF may be progressing or treatment effectiveness. The device recently received the CE (Conformité Européenne) Mark, and the first implant of Reveal XT took place at Asklepios Klinik St. Georg in Hamburg, Germany by Prof. Karl-Heinz Kuck, M.D. The Reveal XT insertable cardiac monitor is not currently available for sale in the United States.

Millar Launches World's Smallest Sensor Tip Pressure-Volume Catheter

Millar Instruments, developer and manufacturer of Mikro-Tip® pressure transducer catheters and pressure-volume (P-V) systems, today announced the expansion of its French catheter line with the introduction of the PVR-1045 pressure-volume catheter.

With a catheter tip size of 1F (1/3 mm), the PVR-1045 is the smallest and least invasive sensor tip pressure-volume catheter available on the market. The smaller diameter gives researchers using Millar's pressure-volume systems (MPVS) a new tool in the characterisation of cardiovascular function by allowing access to smaller animals than previously possible.

Boston Scientific to Explore Sale of Cardiac & Vascular Surgery Businesses

Boston Scientific announced it intends to explore the sale of its cardiac surgery and vascular surgery businesses as part of its plan to review its portfolio of assets and divest those considered non-strategic, and to strengthen its operating and financial performance. Paul LaViolette, chief operating officer of Boston Scientific noted that if finalised, the sale will support the company's efforts to focus resources on its core businesses and improve its operating and financial performance. He said that Boston Scientific is in discussions with several potential buyers, and that it expects the process to take a number of months.

In recent months the firm has retained its endosurgery group, entered into an agreement to assume sole management and control of the pain management business from Advanced Bionics and sell the Advanced Bionics auditory business, monetised parts of its portfolio, and begun developing an expense and head count reduction plan, which it said it plans to announce next quarter.

Boston Scientific continues to focus on the recovery of the drug-eluting stent and cardiac rhythm management markets.

Sanofi-Aventis Announces Approval of Labelling Update of Acomplia® in Europe

Sanofi-Aventis announced that the Committee for Medicinal Products for Human Use (CHMP), after re-evaluation, confirms the positive benefit-risk profile of rimonabant in the indicated patient population and has issued a positive opinion on the labelling update.

Acomplia® labelling has been updated based on data reflecting one year of post-marketing experience mainly from Germany, France and the UK, as well as results of five additional clinical trials completed since the original dossier was approved.

With this updated labelling, Acomplia® is now contraindicated in patients with ongoing major depressive illness and/or ongoing anti-depressive treatment. "Special Warnings and Precautions" of the Summary of Product Characteristics (SmPC) have been updated as well to include information on depressive disorders.

Schering-Plough Corporation Prices Public Offering

Schering-Plough Corporation has announced that it priced its registered public offering of 50,000,000 common shares at $27.50 per share. The underwriters have an option to purchase up to an additional 7,500,000 common shares from Schering-Plough.

Schering-Plough also announced that it has concurrently priced its registered public offering of 10,000,000 shares of its 6.00% mandatory convertible preferred stock at $250 per share. The shares of 6.00% mandatory convertible preferred stock have a liquidation preference of $250 per share, for an aggregate liquidation value of $2.5 billion. The preferred stock will pay dividends at a rate of 6.00 percent per annum, payable quarterly. The first dividend payment date will be November 15, 2007. Unless earlier converted, the 6.00% mandatory convertible preferred stock will automatically convert on August 13, 2010, into between approximately 74,206,000 and 90,909,000 common shares, assuming no exercise of the underwriters' option to purchase additional shares. The conversion rate will be subject to anti-dilution adjustments in certain circumstances. The underwriters have an option to purchase up to an additional 1,500,000 shares of 6.00% mandatory convertible preferred stock from Schering-Plough with an aggregate liquidation value of $375 million. The 6.00% mandatory convertible preferred stock has been approved for listing on the New York Stock Exchange under the ticker symbol "SGP PrB", subject to issuance.

Cardiatis completes stent trial recruitment

Cardiatis of Brussels, Belgium, has completed recruitment of patients into its first-in-man European clinical trial of its FluidSmart 3D multilayer braided stent for repairing aneurysms. Patient recruitment, which began in December last year, culminates four years of extensive concept testing that demonstrated the ability of the 3D multilayer stent to repair aneurysms endovascularly without the need for coils or stent grafts, Cardiatis said. The company said it anticipates filing for a CE Mark on the device by the end of this year.

USE OF TELEMONITORING IN CHRONIC HEART FAILURE

Improving Clinical and Economical Effectiveness

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Multiple hospital admissions for acute decompensation are characteristic for congestive heart failure (CHF) patients, deleteriously affecting their quality of life and imposing a major burden on national healthcare costs. The direct costs of CHF-related hospitalisations amount to 2.7 billion Euro per year. Due to the demographic evolution of European societies, the number of hospitalisations is likely to further increase (see fig. 1).

Adherence to guidelines will improve survival and reduce hospitalisation rates, thus lowering the socio-economic burden. However, disease management strategies should not only focus on drugs but comprise means to react to changes of health status and to coordinate adaptation of the individual patient to both their disease and environment. Telemedicine could be the key to integrate these prerequisites, to facilitate communication with the patient and between caregivers to reduce overall hospitalisation rates and costs. Furthermore, a recent meta-analysis concluded that telemonitoring may be even more effective at shortening hospital stays than reducing admissions, which would in turn have a considerable effect on hospital capacity needed, patient turnover and patient costs to the hospital.

The Concept of Telemedical Care

Predefined vital parameters (e.g. weight, blood-pressure, heart-rate) are transmitted automatically via modem to the telemedical centre, which can be contacted daily at any time during the day. In case individual limits for vital parameters are exceeded an alarm is triggered, allowing for immediate therapeutic action. Furthermore, to enhance medical compliance and to detect changes in individual health status, all patients could be proactively contacted alongside counseling on nutrition, exercise and drug therapy in adjustment with the primary care physician.

Clinical and Economical Effectiveness of Telemonitoring

Prospectively, 478 patients were included in the protocol, 270 (men: 85,5%; mean age 62,5 + 10 years; NYHA II, III, IV: 80 vs. 17 vs. 3%; main diagnosis: coronary heart disease, hypertension, cardiomyopathy) of whom were monitored via

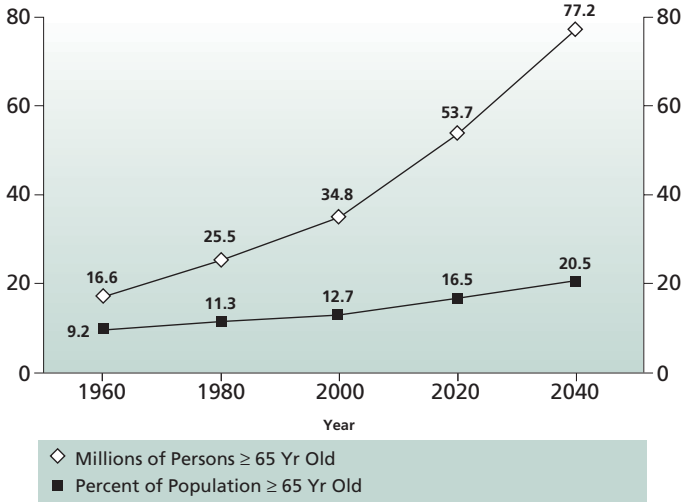

Figure 1: Projected Increases in the U.S. Population 65 Years of Age or Older; Data from the U.S. Census Bureau accessed on http://www.census.gov.

telemedical care and analysed in comparison to a matched control collective.

During an observation period of 3 months, hospitalisation (NYHA II, III, IV: 5,2 vs. 2,4; 8,1 vs. 3,0 und 2,4 vs. 1,2), length of stay (NYHA II, III, IV: 50,7 vs. 21,9; 78,4 vs. 27,5 und 23,0 vs. 10,9 days) and number of contacts to the GP (303,7 vs. 83,2) as well as to the cardiologist (105,3 vs. 30,4) were significantly reduced in the group of patients with telemedical care. Furthermore, increased compliance with a more appropriate adaptation of medication could be clearly demonstrated by standardised questionnaires.

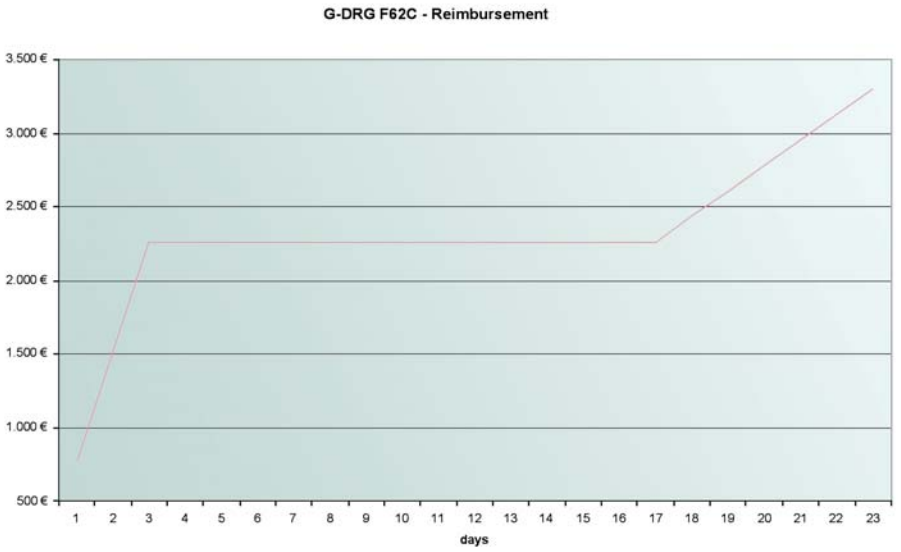

Figure 2: The average length-of-stay for the DRG: F62C (heart insufficiency) is nine days in Germany. Since the reimbursement per case depends on casemix points and not on hospital days, reduction in length-of-stay by telemedical care could improve the net yield in patients. (Reimbursement for the G-DRG calculated with a rate of 2,800 Euro).

	cohort with standard care	cohort with telemedical care
Number	111	111
Mean days of inability to work	6,46	2,91
Number of referrals	63	37
Hospitalisations per patient	0,5676	0,3333
Hospitalised patients	46	28
Number of days in hospital	754	196
Mean number of days in hospital per case	11,97	5,3
Inhospital rehabilitations	28	3
Days of inhospital rehabilitation	660	65
Mean duration of inhospital rehabilitation	5,95	0,59
Costs of hospitalisation (DRG)	304.897 €	94.725 €
Costs of hospitalisation incl. rehabilitation	370.031 €	101.329 €
Costs of rehabilitation	65.134 €	6.604 €
Costs of rehabilitation per case	2.326 €	2.201 €
Costs of rehabilitation per patient	587 €	59 €
Mean total costs	**5.873,50 €**	**2.739 €**

Table 1: Economic analysis of hospitalisation related costs after 180 days

Furthermore, an independent economical analysis demonstrated a significant decrease of CHF-related costs (about 3000 € per patient per year) in patients monitored via telemedical care, predominantly due to a reduction of hospital days. The according results can be seen in table 1.

Impact of Telemedicine on Hospital Management

Since 2004, the German Diagnosis Related Groups system (G-DRG) has made compulsory, a prospective payment system for the purposes of budget determination and thus hospital financing in Germany. Based on the Australian Refined DRGs (AR-DRG), more than 1,000 different DRGs allow the categorisation of medical cases in homogeneous groups of equal economic expenditure. The sum of all casemix values per year corresponds to the budget of a hospital granted by the German health insurance companies. Therefore a clinic, specialised in heart failure treatment, might worry about losses by the decrease of the gained casemix points, as in-hospital days could be reduced by application of telemonitoring systems.

However, two aspects ensure that telemonitoring leads not only to improved patient care, but also to an improvement of the economic situation of a hospital. If a patient is hospitalised with the same DRG (due to repeated cardial decompensations) within a defined time interval to the same hospital, the hospital must connect both hospital stays to one case. Thus, the high costs of individual cases are no longer covered by the DRG-reimbursement system. Therefore reduction of hospital readmission in patients monitored via telemedical care reduces the danger of noneconomical unification of individual heart failure cases.

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EMERGING TECHNOLOGY FOR PERSONALISED CARDIOVASCULAR RISK PREDICTION

Preventing & Managing CVD

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Cardiovascular disease (CVD) is responsible for half of all deaths in Europe every year and 25% of chronic disease burden. Aside from the direct effects on human health and welfare CVD costs the European economy over €169 billion per year. The scale of the problem in human and fiscal terms means that urgent action is required to reduce the CVD burden in the population.

Who is at Risk?

At one end of the spectrum are those young individuals who need healthy lifestyle advice to shift their CVD risk downwards. In this group relatively modest intervention is necessary to have a major effect in decades to come. At the other end of the spectrum, for those people with established CVD, current therapies are in place to attempt to reduce and delay the likelihood of recurrent events, although their residual risk still remains very high.

In the middle are the largest group, who are at moderate risk but have not yet manifest CVD. Assessing risk in these individuals is complex. Since the risk factors for CVD are highly prevalent in the population they are poor discriminators of whether an individual will develop CVD (see fig. 1). Also, there is considerable variability in an individual's susceptibility to risk factors.

Need for Improved Risk Assessment Factors

Risk assessment tools (e.g. Framingham score) are widely available and are excellent at predicting risk in populations but far less useful for the individual where risk factor susceptibility is also important. There is need for improved and personalised risk assessment. Recently, two non-invasive techniques, carotid intima-media thickness (IMT) measurement and pulse wave velocity (PWV), have emerged as potential tools to refine risk assessment for CVD in individuals.

Carotid IMT measures the thickness of the intima media layer in the carotid artery using high resolution ultrasound; PWV uses Doppler ultrasound or photoplethysmography to determine the speed of transit of the pulse wave through large conduit arteries. Rather than simply measuring the presence or severity of classical risk factors these techniques determine the consequences of the risk factors directly in the blood vessels where atherosclerosis occurs.

Carotid IMT and PWV increase with age in normal individuals and by relating the results of these tests to large population databases, it is possible to simplify the results as a measure of the vascular age in years. A simple comparison of the chronological and vascular age immediately allows the individual an assessment of the state of their arteries. Our experience has suggested that patients find the interpretation of risk difficult, whereas they readily understand if their arteries are ten years older than their chronological age. These techniques measure the consequences of the risk factors, therefore they may provide information on individual susceptibility.

Carotid IMT Technology

Carotid ultrasound is usually used to determine the presence of carotid stenosis in people who have had a cerebrovascular event or in asymptomatic people found to have a carotid bruit. Using high frequency B-mode ultrasound systems resolution is high enough to see the individual layers of the carotid artery wall and to measure the intima-media thickness. The key advance in this assessment has come from the development of accurate image analysis that allows measurement using automatic computer software.

IMT can be easily and reliably used to determine vascular age. Some investigators are now using the IMT estimated vascular age as a substitute for chronological age to recalculate Framingham risk. In one study 50% of people at moderately high risk (10-20%) had a significant

change in risk classification with 28% increasing and 22% decreasing. These changes are important because they can be translated into alteration in the intensity of drug therapy.

Integrating Carotid IMT into Risk Assessment

Carotid IMT can be integrated with standard cardiovascular risk assessment in a one-stop vascular clinic run by a cardiologist or physician and supported by a vascular technologist. In our clinic, using a portable ultrasound system measurements take about twenty minutes to perform and the analysis is completed immediately using on board computer software.

The only potential disadvantage to performing carotid IMT measurement routinely is the requirement for relatively expensive equipment (~30,000 Euro), a trained individual to perform data acquisition and analysis and the addition of time to the clinical assessment. For these reasons other technologies which are cheaper and operator independent deserve further consideration. One such technology is the measurement of vascular stiffness.

Pulse Wave Analysis Technology

Identifying premature vascular stiffening is of value in the detection of cardiovascular disease. Arterial stiffness can be determined indirectly by velocity of the pressure pulse as it travels through the arterial system. Pulse wave velocity is measured using Doppler ultrasound to detect the arrival of the pulse at the carotid and femoral arteries and timing this against the onset of ventricular systole on the electrocardiogram.

Pulse wave velocity is a strong independent predictor of CVD risk in patients with end stage renal disease, hypertension, the elderly and diabetics and has been shown to predict CVD events better than Framingham risk equations. An increase in pulse wave velocity of one standard deviation above the mean is associated with a 39% increase in risk independent of classical CVD risk factors.

Pulse wave analysis can be time consuming, though newer technology analyses the shape of the digital volume pulse (DVP) obtained from an infra-red sensor using a technique called photo-plethysmography. The stiffer the arteries the quicker the pulse waves travel and therefore the smaller is this delay. By dividing the subject's height in metres by the time delay between the direct and reflected waves it is possible to determine a stiffness index. Stiffness index and pulse wave velocity are closely correlated with <4% difference when compared directly.

In the age of personalised medicine, both Carotid IMT and Pulse Wave analysis are likely to have increased uptake and become established as a routine part of cardiovascular screening and risk assessment.

> "In general cardiology, portable echocardiography reduced the price of an echo from 132 to 75 Euros"

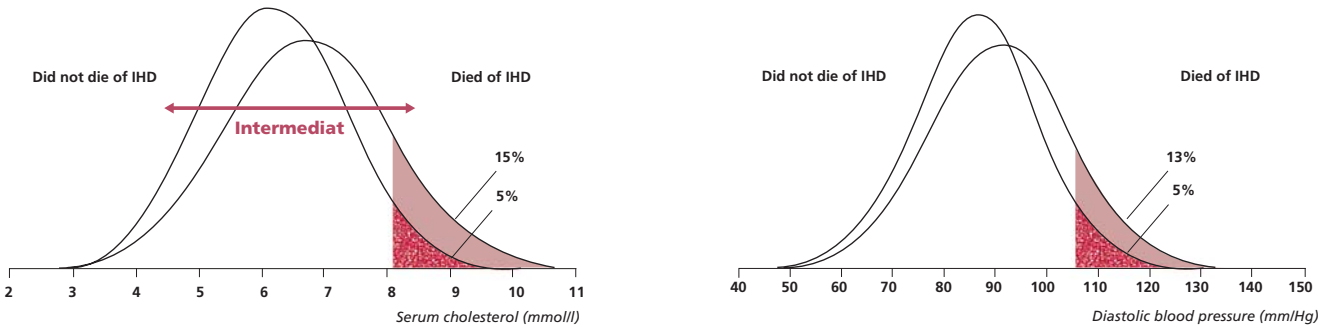

Figure 1: Classical risk factors are poor screening tools for identification of individuals who will develop CVD

HANDHELD ECHOCARDIOGRAPHY

Easy as Childs Play?

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Portable echocardiography has the capacity to identify defects with comparable accuracy to standard machines, to change diagnoses and treatment and has facilitated early discharge in up to 50% of patients. While these figures may depend on the nature and profile of the patients screened and the skills available, in principal it validates the increased potential for patient care. This article discusses the potential applications of echocardiography to improving the efficiency and delivery of healthcare and the potential pitfalls that may be encountered.

Echocardiography in a Critical Care Setting

Starting with a patient's journey before arrival during and after the emergency room, portable echocardiography has proven successful. In the Coronary Care Unit (CCU) in particular, it is not surprising that in the hands of cardiologists, portable devices could be used to assess areas such as left ventricular ejection fraction and pericardial effusions. This helps to prognosticate and triage patients to the most appropriate therapy immediately and reduce the immediate burden on departmental echocardiography.

Most studies in this area have confirmed that portable echo almost inevitably changes or at least consolidates clinical decisions made at the bedside. Portable machines have also been used effectively in environments such as the catheter lab where assessment of cardiac tamponade is often challenging and similar devices have been shown to correctly address 90% of clinical questions in the ICU. This is particularly surprising since the investigations were performed by ICU physicians in patients that are traditionally regarded as challenging for standard echocardiography.

Echocardiography & Screening

An increasing role for echocardiography pertains to the screening of patients for occult or mildly symptomatic conditions for the prevention of disease. These investigations can be performed either in the community, at designated health screening centres or in hospitals. Moreover, the echocardiography can be combined with electrocardiography and biomarkers (e.g. BNP).

However, a characteristic feature of these screening programmes is the general trend to less direct involvement by doctors and a greater responsibility placed on sonographers.
A number of studies have shown the potential for such screening activities. One study showed that portable echocardiography was far superior to the clinical examination alone, almost doubling the number of cardiac anomalies detected (detecting ~70% of all such abnormalities and ~80% of all major abnormalities).

Similar studies have confirmed that in community screening, portable echocardiography is as accurate as standard departmental echocardiography in detecting cases of ventricular dysfunction and left ventricular hypertrophy. These programmes have therefore been demonstrated to be of significant clinical value, and are being rolled out in a number of clinical centres.

Effectiveness

Applications for portable echocardiography are diverse and immediate. However enduring question are; whether these scans approximate to those from standard departmental studies, whether they have a significant impact on patient treatment by more accurate prognostication, whether they lead to substantial changes in treatment and in outcome and finally whether they are cost-effective.

With respect to the first question, scans approximate to departmental scans under optimal conditions. The latter proviso is not insignificant as there is often a tendency to perform portable echos in suboptimal settings or in a more focused manner which will inevitably increase the rate of errors or omissions. Portable machines are now so advanced that the GE Vivid I and the Sonosite Micromax have tissue Doppler imaging and almost identical capacities to large departmental machines.

With respect to the second question, portable echocardiography does have the capacity to prognosticate, change treatment and potentially outcome. Finally, with respect to cost-effectiveness, studies have confirmed that portable echo can confer major time and cost savings. For limited or focused studies, portable machines have been shown to confer substantial time, cost and hospital clinic and bed-occupancy savings. Although precise cost calculations are heavily context dependant, at least in general cardiology, portable echocardiography approximately halved the price of an echo from 132 to 75 Euros.

Training Still a Contentious Issue

While there is excitement that increasingly portable machines which will become ever more available to practitioners, will mean major advances in patient care, there is genuine concern that harm may be inflicted upon patients by untrained or inadequate physicians/sonographers.

The question remains – what is adequate training? This question is complicated by the fact that different practitioners require different levels of proficiency and support for their different applications. At present, the American Society of Echocardiography (ASE) require an exacting 150 portable exams, in line with the exacting requirements of standard echo accreditation. The rationale behind this approach is that portable echo may be even harder than standard echo to interpret and that the practitioner may often be unsupported or have to make decisions in real time.

The British Society of Echocardiography (BSE) has also recently developed a structured approach to accreditation. Detractors from such accreditation procedures have suggested that non-cardiologists may not be able to achieve such numbers in a practical time period and that many of the skills can be "learnt on the job" so long as adequate support and attention to the limitations of the technique are noted. Support for the latter position has come from studies with medical students showing that a carefully designed short training programme can permit students to make assessments of specific echo parameters rapidly and efficiently. Ultimately, the easy availability and power of this technology suggests that there will be rapid dissemination irrespective of these two polarised positions.

To ensure patient care is not compromised, ideally, the accreditation programmes of the ASE and BSE should be heeded. It is at least essential to have attended some form of formal training programme with a handheld component. The operator should make diligent attempts to spend time with an experienced sonographer and to operate in a department with support, with respect to imaging and reporting. Ultimately, it is essential that the operator document the report of the imaging clearly and emphasise the fact the study was a portable study with the implicit limitations. This will be particularly robust if the study is recorded for later retrieval if necessary.

Conclusion

While the future is bright for these machines, in order for them to entirely fulfill their potential a concerted effort of cooperation will be needed from cardiologists, sonographers, and other physicians such as ancillary medical staff to ensure that patient care is not compromised. In this way, real-time cost-effective studies will improve immediate patient care, reduce waiting times and ultimately reduce costs.

CARDIOLOGY REQUIREMENTS FOR PACS

Defining Future Needs

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The Robert Bosch Krankenhaus was opened in 1973 and has created a worldwide reputation in medical and surgical care, for pioneering the practical application of innovative IT solutions to improve healthcare delivery. In my position as "Oberarzt", a function that is somewhere between consultant and registrar, I am responsible for our ten-bed intensive care unit, in particular our Cardiac Magnetic Resonance (CMR) unit, which performs 1,500 CMR procedures each year. CMR imaging has emerged as a new non-invasive imaging modality providing high-resolution images of the heart in any desired plane.

In our department we have 80 beds, operate three echography machines, one magnetic resonance and two angiography units. We perform 3,500 coronary angiographies, 1,500 percutaneous transluminal coronary angioplasty (PTCA) interventions, and over 6,500 echocardiographies on an annual basis.

Current PACS in our Department

The leading system, as in most medical facilities, is the Hospital Information System (HIS). Our current HIS is made by ISOFT. This enables us to have one

convenient front-end for patient history, images and all other patient data, avoiding time loss in searching for one patient through different systems. While it is of core importance that cardiology PACS should be enterprise-wide and integrated, presently we have a separate PAC system in our department for echography, angiography and CMR and use a blend of service providers to meet our needs.

We also have a local echography PACS with three echography machines and a workstation. Using this set-up, images can only be reviewed at the workstation. Our web-based CMR PACS, in use since four years ago, is made by HeartIT. Images can be reviewed on all PCs in the hospital. For echography we use GE Vingmed solutions with a workstation using a system called ECHO-PAC. For angiography, we have local workstations but not a real PACS, using two Siemens cath-labs with local workstations from Siemens. For radiology our hospital has been using a PACS for the last two years made by Image Devices.

Benefits of Integrated Cardiology PACS

The benefits of integrated PACS in cardiology departments, surprisingly, has little to do with gains in time, which are only marginal. Recently, as part of our drive to re-evaluate our current system, a consultant assessed possible improvements in real terms. What he found was that while gains of time are only marginal, the improvement in image quality may be considerable and is certainly enough to make an integrated system an essential addition. The main vendors of cardiology PACS on the European scene for stand-alone solutions presently, are GE, Philips and Siemens. For integrated solutions Agfa and Medcon (McKesson) are proving to be leading providers, while in the future HeartIT, Witt working in partnership with Philips, and of course Agfa are shaping up to take the pole positions.

The presence of a comprehensive support solution is a vital part of our decision. In our own case, final decisions on which vendor to purchase new IT solutions from are made by both management and staff, and our chosen vendor must provide back-up consultation services. Future IT upgrades for our department's cardiology PACS, will be based on the need for a web-based system, which can be used on every PC in the hospital to view all cardio exams. The other main criteria is speed as well as image quality.

An Integrated Approach

With systems of the future, the electronic health record will enable referring physicians to view their patient's cardiology studies in an integrated and accessible way. Currently with CMR, we are able to give every outpatient a CD with exam results stored on it. In the future we hope to develop a more comprehensive IT solution for the department that sees it integrated with the HIS rather than as a stand-alone system. Deploying this kind of holistic approach is tricky, not least because although DICOM is an invaluable protocol for the transmission of image data, the proprietary formats such as for echography are an obstacle to a wholly integrated solution. That is why most vendors of cardiology PACS enable sending of images not in DICOM but as mpg4 or animated .gif files. No vendor with pure DICOM viewers can be fast enough.

Challenges Particular to Cardiology PACS

Cardiology departments in hospitals have been far slower to adopt PACS than radiology, purely because there are by necessity far more images and data produced per case. Also, the multimodality nature of cardiology brings specific challenges in synchronising information on a PACS. For example, until two years ago it was not possible to convert our echo loops into DICOM. ECG has yet another format and is difficult to store. Of course there are technical differences in requirements between radiology and cardiology PACS, particularly in the different front-end systems needed in each case. The absolute basic IT infrastructure I consider essential for a department considering purchasing a cardiology PACS, is a deep archive with a long- and short-term storage, PCs and a 100MB net.

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The second aspect is the clear decrease of length-of-stay (LOS) in hospitals due to telemedical care. Since LOS is has little impact on the hospital's reimbursement, a shortened stay only leads to reduced costs for the individual case. Thus, the use of telemonitoring by reduction of readmissions and LOS in heart failure patients could improve the net yield in patients, as reimbursement per case depends on casemix points and not on hospital days.

Implications

Following this analysis, telemedicine appears feasible both on economic and medical grounds. Intelligent algorithms for vital parameters allow efficient monitoring of multiple patients. More importantly, doctors can contact their patients earlier to prevent hospitalisations or to individually adjust medication. After a given hospitalisation and during titration of medication, a concept of technical de-escalation on a modular basis along with counselling measures appears highly likely to improve both patient awareness and CHF management. Finally, this implementation of telemedical care can work cost efficiently.

LIVE 3D ULTRASOUND SOLUTIONS

Defining Future Needs

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Heart failure, the inability of the heart to pump sufficient blood to meet the metabolic demand of the body, impacts millions worldwide every year. Implications of heart failure are broad and have become a tremendous economic burden. Worldwide, heart failure affects nearly 23 million patients. In Europe, nearly 14 million people suffer from heart failure, a number that is expected to reach 30 million by 2020, according to the European Society of Cardiology.

Addressing the increased scope and severity of heart failure, the American College of Cardiology (ACC) and the American Heart Association (AHA) issued updated heart failure management guidelines in 2005. The defacto paper helps physicians diagnose and treat patients, as recommended by ACC and AHA's panel of experts. Guidelines recommend use of the term heart failure instead of congestive heart failure, and recognise the value that cardiac resynchronisation therapy (CRT) brings in improving quality of life and exercise capacity in patients who respond to CRT. Revised guidelines recognise diastolic heart failure as clinical heart failure, even with normal ejection fraction (EF). Guidelines also expand the number of patients eligible for implantable cardioverter defribrilators (ICD) based on low ejection fraction (EF) of 30%.

However, worthy to note in the revised guidelines is use of Live 3D Echocardiography in diagnosing the variety of conditions that contribute to heart failure, with recommendations on use of Live 3D Echo in diagnoses.

The primary role of Live 3D Echo in clinical practice is to provide minimally invasive, cost-effective answers to the clinical questions of structure, function and risk. Measurement of cardiac function anatomy can be a time-consuming, costly task often relegated to the research department, which typically uses expensive offline systems to evaluate cardiac function. Live 3D Echo, a faster, less expensive method, has the capability to accurately measure cardiac anatomy and function to improve quality of care and diagnostic confidence.

Accuracy Critical in Improving Patient Management

Obtaining accurate images of a patient's ventricular size and measuring a patient's EF is critical in improving management of patients with heart failure and reduced liability since the greater the accuracy, the greater the chance for a physician to make an educated diagnosis. Besides EF, understanding LV remodelling as with LV size of diastolic and systolic volume and wall thickness is important. Many patients with heart failure have coexisting valvular disease. In fact, some patients who have a dilated heart can actually have leaking through the mitral valve, known as mitral regurgitation, which can adversely affect valvular function. Additionally, the use of CRT, or use of a pacemaker to improve synchronous timing of LV contraction, is an emerging medical therapy being used to treat heart failure patients.

The role of Live 3D Echo in treating heart failure patients is critical in enabling physicians to obtain accurate images. In the past, the role of ultrasound in obtaining an accurate EF was a challenge using 2D ultrasound, which previously provided only single dimensional views. 2D views cause foreshortening of the image, meaning the true view through the apex is not possible. As a result, even the most seasoned physician or sonographer can never be completely sure they are obtaining a true view. Technological advancements in ultrasound technology enables accuracy by reducing apical foreshortening errors, and helps avoid geometric assumptions because it uses all the voxels in the data set. This is critical in providing accurate quantification in a semi-automated fashion by providing an EF in

a matter of seconds leading to potentially greater accuracy in diagnosing a condition, faster exam times, and improved patient care.

Live 3D Echo in Cardiac Resynchronisation Therapy

While obtaining EF volumes for ventricular modelling is important, Live 3D Echo for use in CRT is gaining more attention in certain heart failure patients. As a result, a variety of echo solutions are under development for more advanced CRT assessment. One such advancement is Live 3D Echo's role in assessing the regional LV wall motion in CRT patients. CRT is a treatment option for certain patients with heart failure, specifically patients who exhibit conduction abnormalities and have a reduced ejection fraction as well as symptoms of HF.

Cardiomyopathy and heart failure in moderate to severe patients are caused by an abnormality of the heart's electrical system, resulting in an uncoordinated contraction of the heart muscle. The most common abnormality is a delay in electrical conduction through the left bundle branch. Since this delays the electrical signal in traversing the LV, the right ventricle may contract before the left instead of simultaneously as it should in a normal cardiac rhythm. Another relevant aspect is the LV needs to contract simultaneously. It may have delayed contractile segments and this may lead to pumping inefficiency and adverse remodelling and dilatation of the left ventricle. The result is an uncoordinated contraction of the heart muscle, reducing the pumping ability of the weakened heart muscle.

CRT based on biventricular pacing may improve the LV function in patients with heart failure and left bundle branch block (LBBB) and may restore normal coordinated pumping action by overcoming the delay in electrical conduction caused by LBBB. This occurs with a unique type of cardiac pacemaker that continuously monitors the patient's heartbeat and delivers a tiny electrical charge to stimulate the heartbeat when necessary. While the response to CRT may vary, studies have demonstrated modest improvements in exercise tolerance, heart failure class, and quality of life. It is still a significant goal in cardiac imaging to identify definitively the best patient candidates who will be responders to CRT.

2D echo provides images of the LV. Its advantages are ease of use during a conventional 2D examination, high frame rate and availability of quantitative tools for analysis of wall motion patterns. However, it does not assess the LV in its entirety.

2D Doppler techniques allow wall motion analysis at high frame rates. This is useful in assessing for example, transmural patterns of thickening. Nonetheless, only motion in the direction of the Doppler ultrasound interrogation is part of the analysis. The spectrum of cardiac mechanical function is more complex. While 2D and Doppler echocardiography allow the direct evaluation of the mechanical dysynchrony, it is nearly impossible for either of these devices to examine all 17 segments of the LV. MRI, long considered the gold standard for assessing LV, cannot be used due to the metal found in the special pacing device and issues regarding potential magnetic inductance of leads. In this case, the use of Live 3D Echo in combination with semi-automated contour tracing algorithms can be an ideal tool for analysing regional LV wall motion in CRT patients.

Live 3D Echo allows a comprehensive analysis of LV wall motion before and during CRT and, in contrast to conventional 2D echo, the comparison of all LV segments. Live 3D Echo also helps obtain quantifiable data and acquire images more rapidly.

Conclusion

In summary, advances in ultrasound technology are making it possible for physicians to obtain more accurate images of the heart than ever before, a critical factor in accurate diagnosis, and provide appropriate treatment for heart failure patients. From a business perspective, Live 3D Echo is enabling hospitals and clinics to improve workflow through faster exam times and improved patient management by being able to provide a timely, more accurate diagnosis. New ultrasound capabilities are providing many healthcare facilities the opportunity to expand services without major capital expenditures.

AN INNOVATIVE WIRELESS TELECARDIOLOGIAL MONITORING SYSTEM

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Heart-related diseases and disorders are abundant in the western world. Around 500,000 cases of sudden cardiac death, over three million patients with atrial fibrillation and about 600,000 heart attacks are a significant factor in the cost structure of the European healthcare system every year.

The need for a cardiological home monitoring system

Effective therapy in this area is usually no longer the problem. Defibrillators and sufficient medication have had revolutionary success in saving the lives of patients with heart disorders. Crucially, the biggest issue is the lack of diagnosis. So far, the standard is that even high-risk patients only visit their physician every six months for a check-up. If the health situation worsens between visits, problems will not be identified until the symptoms become acute. Due to a prevalent fear of hospitals, many patients wait until their health condition develops into an unbearable situation. It is at this point that they would call the emergency service and be brought to the hospital, normally needing to remain there for days before becoming healthy enough to return home, thus costing the healthcare system a great deal.

Different programmes to circumvent these problems have been carried out with patients for the first symptoms of heart-related diseases. These programmes have proved to be successful. However, for more effective prevention, the best solution would be a continuous monitoring of the relevant vital parameters, especially the electrocardiogram (ECG). The monitoring in hospitals is very effective but also very expensive. Furthermore, most patients prefer to remain at home in their place of comfort, where they have the support of their family and friends. In contrast to the often very sterile atmosphere in hospitals, from a psychological point of view, the home is a much better surrounding for treating patients. Obviously, it is also much more cost effective if patients do not have to stay in a hospital or can leave the hospital as early as possible. To give the necessary medical security at home, a monitoring system for the homecare area must be the goal.

There have been many attempts to find a practical and efficient way to monitor patients with heart-related problems at home. Recent approaches rely on the interaction of the patient. In the event that symptoms arise, the patient has to apply an ECG recorder or, as a minimum precaution, has to activate a recorder that he is wearing. Afterwards, the ECG is transmitted via the telephone line or a mobile phone. Some downsides are that often this procedure is not possible because the patient either does not feel any symptoms or it is an acute situation where he is unconscious within seconds and therefore unable to activate the device.

The proposed system

An innovative system has been developed which overcomes these disadvantages. The central part of this monitoring system is a mobile sensor, an ECG chest strap, which is worn by the patient and analyses the patient's ECG. When an event is detected, an automatic wireless connection is activated to a relay station, which receives the message from the ECG chest strap and sends it via the mobile telephone network to a central internet-based Electronic Health Record (EHR). This EHR automatically informs a care giver via fax. The care giver logs in the EHR, checks what happened and initiates the appropriate help.

In this scenario, the patient is monitored with a small and light ECG chest strap, which is worn in a way similar to the pulse watches familiar from the field of sports. The chest strap contains an integrated ECG sensor, which continuously analyses the patient's ECG readings. A one-lead ECG is picked up with dry stainless steel electrodes, further adding to the comfort. The ECG is

filtered to a bandwidth of 0.5 to 60 Hz and sampled with a rate of 200 Hz. If the analysis identifies a tachycardia including ventricular fibrillation, a bradycardia including an asystole, or an arrhythmia absoluta, a message is automatically sent to the relay station via a wireless data transmission. The message, includes an indicator for the detected event and two minutes of ECG. The transmitted ECG starts one minute before the detected event and ends one minute afterwards. To enable this, the ECG chest strap always has the last minute of ECG stored in its memory. Testing has shown that the settings for the detection need to be adapted to the individual patient, and is now possible via the EHR.

Once the ECG reading has been transmitted, the relay station switches the wireless near-field communication from the ECG chest strap to the wireless far-field communication and then to the EHR. For near and far-field communications, bluetooth and General Packet Radio Service (GPRS), respectively, are applied. The relay station is a mobile phone with an integrated application for data handling. Once the data is in the EHR, it is stored in a database and, depending on the prior setting, a message is sent to a care provider. This can be via fax, SMS, email or voice call. The EHR is especially adapted to the needs of a telemonitoring system. To ensure data security, the EHR complies with high security standards for EHRs such as tripple DES incryption and XPath compatible access rights managed. The care provider has to log in via a secure internet connection and can then access the ECG and any additional data from the medical history of the patient. On this basis, he can make a qualified decision as to what actions should be taken. In less acute cases, it is sufficient to make an appointment with the family physician. In acute cases the emergency medical service is sent to the patient to guarantee prompt assistance.

Results of the system implementation

The described system and its parts were tested in detail and proved to be reliable. Although dry electrodes were used, the ECG signal in this long-term application showed no significant differences to standard Holter ECGs. The system was tested with a dozen patients suffering from persistent atrial fibrillation, tachycardia and bradycardia. All the pathologies were identified correctly. The patients were questioned about the application and the benefit of the system and the overall impression was a remarkable 1.6 average score (1 best; 6 worst), with comfort, simple application and handling especially being mentioned. The algorithm tests with different databases showed both a sensitivity and a specificity of over 88%. Further extensive tests are currently being conducted.

sensor	parameter
scales	body weight
blood pressure meter	blood pressure
pulse oxymeter	oxygen saturation of blood
peakflow meter	lung function (PEF, FEV1)

Table 1: sensors for a modular system extension

Scenarios of application

There are different circumstances in which the system can be applied. The most important may be for hospitals to save costs in diagnostic related group (DRG) surroundings. With such a system, patients can leave the hospital much earlier without the risk of unnoticed medical complications. At home they profit from a more comfortable atmosphere. Furthermore, patients hooked up to an expensive monitoring unit can be moved to a normal ward when they are equipped with this system.

Other scenarios would be the temporary monitoring of pre-operative patients who could stay at home instead of waiting for the operation in the hospital.

Another interesting area is the preventative monitoring of high-risk patients, e.g. in disease management programmes, where the option to extend the ECG system by other relevant sensors (see Table 1) is an advantage. This allows an adaptation of the system to the specific needs of the patient.

Final analysis

This monitoring system meets current and future demands of the healthcare sector, which is more and more aiming at the ambulatory area. This system provides the necessary security for patients and their relatives to live without the threat of an unnoticed cardiac event. The ECG chest strap is the first device that can summon help to the patient's home automatically without the necessity that the patient himself has to be active, and is an available CE certified medical product. This system, which can be combined with other vital sensors, provides an ideal platform for hospitals, disease management programs and many other homecare applications.

Key Upcoming Events & Congresses

SEPTEMBER 2007

27 - 30 19th Annual Meeting of the Mediterranean Association of Cardiology and Cardiac Surgery
Opatija, Croatia
www.alphastudio.it

OCTOBER 2007

3 - 5 Bleeding Complications in the Treatment of Acute Coronary Syndrome
Lund, Sweden
www.malmokongressbyra.se

4 - 7 XVI International Symposium on Drugs Affecting Lipid Metabolism
New York, USA
www.lorenzinifoundation.org/dalm2007.html

7 – 10 7th International Congress on Coronary Artery Disease - from Prevention to Intervention
Venice, Italy
www.kenes.com/cad7

7 – 10 10th International Congress on Cardiac Arrhythmias
Venice, Italy
www.venicearrhythmias.org

12 – 14 12th Annual Meeting of the European Council for Cardiovascular Research
La Colle sur Loup, Nice, France
www.eccr.org

14 – 16 5th International Meeting on Intensive Cardiac Care
Tel Aviv, Israel
www.isas.co.il/cardiac-care2007

NOVEMBER 2007

04 – 07 American Heart Association Scientific Sessions
Orlando, Florida, US
www.americanheart.org

28 – 02 14th International Congress for Cardiovascular Pharmacotherapy
Antalya, Turkey
www.iscp2007.org

30 Annual Symposium of the Belgian Working Group on Non-Invasive Cardiac Imaging
Antwerp, Belgium
www.bscardio.be

DECEMBER 2007

5 – 8 Annual EUROECHO Conference
Lisbon, Portugal
www.euroecho.org

JANUARY 2008

31 – 02 27th Annual Scientific Meeting of the Belgian Society of Cardiology
Brussels, Belgium
www.bscardio.be

FEBRUARY 2008

7 – 10 International Conference on Fixed Combination in the Treatment of Hypertension and Dyslipidemia
Budapest, Hungary
www.paragon-conventions.com/fixed

17 – 21 14th International Postgraduate Course on Advances in Cardiac Ultrasound
Davos, Switzerland

APRIL 2008

26 – 29 European Atherosclerosis Society Congress 2008
Istanbul, Turkey
www.kenes.com/eas/call.asp

SEPTEMBER 2008

26 – 27 6th Advanced Symposium on Congenital Heart Disease in the Adult
Thessaloniki, Greece
www.achd2008.com

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- Selecting & Purchasing Equipment
- Personnel Management Strategies
- Best Practice in Patient Care
- Cardiology Research Management Issues
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For further details or to request a copy of the 2008 editorial planner, with topics and focus areas included, please email editorial@cardiologymanagement.eu.

Thank you,

The Cardiology Management Editorial Team