Delivering evidence-based care to patients with heart failure: results of a structured programme

The Omada investigators report on a pilot study in nine UK centres looking at improving the management of heart failure.

Abstract

The Omada programme, a nurse-delivered model of care, has achieved improved levels of evidence-based intervention for patients with chronic heart failure in nine secondary care centres in the UK. It may provide an appropriate model for audit and delivery of care, in line with the requirements of the National Service Framework for Coronary Heart Disease.

Key words: National Service Framework, heart failure, guidelines.

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Introduction

The management of heart failure has progressed substantially in recent years, as reflected in evidence-based guidelines.[1-4] Management aims to delay death and maintain or improve the patient's quality of life. Over the past decade, randomised clinical trials have demonstrated that angiotensin-converting enzyme (ACE) inhibitors, beta blockers and spironolactone improve prognosis, but implementation of the evidence into routine clinical practice is widely perceived to be slow and variable across the NHS. Consequently, heart failure has been identified as a target area for service improvement.[5]

One of the aims of the National Service Framework (NSF) for Coronary Heart Disease is that, by April 2002, all NHS hospitals in England will be expected to have audit data no more than 12 months old describing the delivery of key investigations (such as 12-lead ECG, echocardiogram and chest radiograph) and treatments (particularly ACE inhibitors and beta blockers) for patients with heart failure.[5]

As part of the drive to raise standards of care for heart failure, the NSF proposes three service delivery models linking primary and secondary care. These include:

- outreach follow-up by specialist nurses of heart failure patients following discharge from hospital
- multidisciplinary support in the community for those with established heart failure
- heart failure clinics for investigation and/or follow-up, based in either primary care or secondary care.

> ***'The baseline audit revealed poor record-keeping with regard to patient education'***

The Omada programme is a unique, secondary care-based, nurse-delivered patient management programme designed to improve treatment for patients with heart failure, provide appropriate patient education and foster partnership between health professionals in primary and secondary care. It was developed during early 1999 by a steering committee of secondary care physicians with an interest in heart failure from nine hospitals across England, Scotland and Wales, with input and support from Roche Products Ltd.

These nine 'pilot' hospitals included tertiary and teaching centres as well as district general hospitals (see box). Most offered some form of heart failure

Table 1. Baseline characteristics of the audited population (n=2,010)

Age (years)	Mean age 69 (95% range 42–88 years)
Sex and age	Males: 1,368 (68%) mean age 68 (95% range 46–86 years) Females: 642 (32%) mean age 72 (95% range 43–91 years)
NYHA class (most recently recorded)	Class I 9% Class II 59% Class III 28% Class IV 4%
Symptoms recorded	Shortness of breath 68% Cough 5% Fatigue 19% Chest pain 15% Fluid retention 20% Palpitation 5% Orthopnoea 11%
Past history	Myocardial infarction 39% Angina 41% Angina and/or MI 52% Hypertension 33% Alcohol misuse 7% Hyperlipidaemia 27%
Co-morbidities	Stroke 8%, diabetes 16% (27% insulin-treated; 73% oral agents or diet control alone) Obstructive airways disease 13% (of which 44% COPD; 31% asthma; 25% unspecified)
Smoking history	Never smoked 31% Ex-smoker 40% Current smoker 12% Unknown 17%
Ejection fraction (EF)	Unknown 55% Of known: 43% had EF < 35%

service prior to joining the Omada programme, usually a consultant-led out-patient clinic. A specialist heart failure nurse was appointed in each of the nine hospitals. Each nurse underwent a two-week initial education course that included medical training in heart failure pathology and management, the audit process, and the development of information technology and organisational skills necessary to set up a nurse-led out-patient clinic.

Baseline audit

Upon appointment, each nurse conducted a retrospective audit of medical records regarding the diagnosis, investigation, management and education of patients with heart failure at their centre. This provided centre-specific data on local practice and areas for improvement. Data were fed back by the nurses to health care professionals in each hospital and action plans developed to address the issues raised at local level.

Overall, the patients identified appear to be closer to those identified in population-based studies rather than those entered into clinical trials (table 1).[6] Patients were predominantly male with a mean age of 69 years (95% range 42–88 years). Most were symptomatic on mild to moderate exertion (87% New York Heart Association [NYHA] Class II or III), with shortness of breath being the most common symptom recorded. Most patients had been admitted to hospital with a diagnosis of heart failure at least once; 76% of these admissions had been unplanned. Coronary artery disease was the single most common cause of heart failure, recorded in around half of patients, and around one-third had a history of hypertension.

Table 2. Pharmacological management of patients in the baseline audit

Drug group	Number (percentage) of patients
Diuretics	1,666 (83%)
Digoxin	572 (28%)
ACE inhibitors	1,569 (78%)
Angiotensin receptor blockers	162 (8%)
Beta blockers	469 (23%)
Spironolactone	342 (17%)

There was some variation between centres in the type of patient enrolled, reflecting the interests of the centres – cardiomyopathy, for example, was recorded as the aetiology in 75% of patients from one tertiary referral centre, but was less than 10% at another centre.

Patients had been relatively well-investigated – ECGs were found in the notes of 84% of patients; 55% of patients had a record of the result of a chest radiograph; results of an echocardiogram were available in 79% of cases, although an ejection fraction was not recorded in many. Of those calculated, 43% had an ejection fraction of < 35%.

Overall, 83% of patients were taking diuretics and 28% were on digoxin. Pharmacological management of these patients was generally good (table 2): 78% of patients had a history of ACE inhibitor usage, although closer analysis suggests considerable suboptimal dosing (table 3), as reported previously.[8,9] For instance, among those patients taking captopril where a dosage was recorded, less than one-third of patients were taking the daily dose of the drug recommended for heart failure. Al-though lisinopril was clearly the most favoured ACE inhibitor, there was a great variation in dosages used. The SIGN guidelines recommend a daily dose of 30 mg, presumably on the basis of the results of ATLAS (Assessment of Treatment with Lisinopril and Survival

Table 3. ACE inhibitor usage in patients in the baseline audit

ACE inhibitor	Number of patients	Recommended daily dose in heart failure[3]	Percentage of baseline audit patients taking recommended daily dose of drug
Lisinopril	571	30 mg	2%
Perindopril	284	4 mg[7]	55%
Enalapril	279	20–40 mg	58%
Ramipril	275	10 mg	42%
Captopril	149	150–300 mg	29%
Others	121	-	-

Study).[10] This reported a statistically significant 14% relative risk reduction in the combined end point of death and need for hospital admission with a dosage of 32.5–35 mg daily compared with 'low' dose (2.5–5 mg daily). Only 1% of patients in this audit were taking lisinopril at above 30 mg daily, but 96% were taking a dose of 2.5 mg daily or above. Since ATLAS found no statistically significant reduction in all-cause mortality and cardiovascular mortality with high-dose versus low-dose lisinopril, UK clinicians may have concluded that the lower dose was sufficient.

In the audited population, 55% of patients were identified as being eligible for beta blockade therapy, according to the criteria defined by the Omada investigators based on the license restrictions at that time (early 1999). Over one-fifth of the audit population were already taking these drugs but most of these patients (78%) had a history of ischaemic heart disease or hypertension: heart failure may not have been the primary reason for the prescription. This interpretation is supported by the observation that atenolol, which is not licensed for use in heart failure, was the single most commonly prescribed beta blocker. Carvedilol and bisoprolol, which are licensed for use in heart failure, accounted for less than half of all beta blockers used.

The use of spironolactone represents another recently proven intervention. Overall, the proportion of patients on spironolactone in the baseline audit was 17%, although this varied from 4% in one centre up to 36% in another, perhaps reflecting particular interests.

In summary, the baseline audit clearly showed that in these centres taking an interest in heart failure, patients were investigated to a greater degree than the 'average' suggested by previous published work. There was also a relatively high usage of drugs shown in clinical trials to be associated with significant patient benefit. Nevertheless, there was clearly scope for improvement in drug therapy, as demonstrated by the low dosing of many patients with ACE inhibitors and by the large number of patients identified as being eligible for beta blockade but who had not yet started therapy.

The Omada programme

Those patients identified in the audit as being in need of further medical care, together with new referrals as appropriate, were invited to attend the nurse-led heart failure clinic and to join the Omada patient management programme. Patients were asked to give consent to anonymised data being entered into an electronic patient management database devised and maintained by a data management organisation and held under the constraints of the Data Protection Act.

At the first clinic appointment, an assessment was made of the patient's educational needs, severity of symptoms, cardiovascular risk factors and drug therapy. This provided an opportunity for the nurse to optimise standard pharmacological management (diuretics, ACE inhibitors and/or digoxin) and to devise an individualised care plan based on a protocol drawn up by the participating centres and modelled on the guidelines of the European Society of Cardiology[2] and the Scottish Intercollegiate Guidelines Network.[3]

Under this protocol, patients with mild to moderate chronic heart failure (NYHA class II or III) who were clinically stable and maintained on optimal standard therapy and deemed suitable for treatment, had a licensed beta blocker initiated and titrated in the nurse-led heart failure clinic, where they also received education and lifestyle advice.

Impact of the programme

After the programme had been running for 18 months, a total of 1,118 patients had been enrolled into the patient management programme across the nine centres.

Analysis of the electronic patient management database showed that the overall characteristics of these patients, their symptomatology and the use of investigations were broadly similar to those in the earlier audited population. As previously, these patients were predominantly male (73%), of mean age of 67 (95% range 40–85 years) and most (62%) had NYHA class II or III heart failure. Again, shortness of breath was the most common symptom recorded, and around half of the patients had a history of coronary artery disease.

All patients had at least one chest radiograph after admission into the Omada programme, and 92% had an ECG on their first (entry) visit on the programme. Only 616 of the 1,118 patients had the result of an echocardiogram recorded in their notes, and only a minority of these (42%) had an ejection fraction recorded.

Before enrolment on the Omada programme, around 60% of patients had been admitted to hospital at least once, with unplanned visits accounting for 70% of all admissions.

Drug utilisation data show that, during the patient management programme period, 869 of the 1,118 patients (78%) received one or more diuretics. Spironolactone use was rela-

Table 4. ACE inhibitor usage by patients enrolled in patient management programme

ACE inhibitor	Number of patients entering programme	Recommended daily dose in heart failure[3]	Percentage of patients taking recommended daily dose of drug at entry to programme	Percentage of patients taking recommended daily dose of drug at end of programme
Lisinopril	441	30 mg	3%	13%
Perindopril	172	4 mg[7]	64%	76%
Enalapril	181	20–40 mg	65%	72%
Ramipril	273	10 mg	45%	51%
Captopril	78	150–300 mg	38%	47%
Others	62	-	-	-

tively high, with 32% of patients in this group given it (compared with 17% prior to the programme, $p < 0.001$).

Among the 1,118 programme participants, 896 (80%) were taking ACE inhibitors and 91 (8%) patients were taking an angiotensin receptor blocker at entry. There was little change in these numbers during the programme, but more importantly, there was an increase in the proportion of patients taking dosages based on clinical trials (table 4). For example, whereas only 34% of patients at entry to the Omada programme were taking an appropriate daily dose of ACE inhibitor, the last recorded entries from the programme showed that 47% were taking an appropriate dose ($p < 0.001$).

Similarly, the programme appeared to result in an increase of appropriate beta blocker usage. Only 269/1,118 (24%) patients were taking beta blockers when they joined the programme. Subsequently, all who were eligible for beta blocker therapy (an additional 458 patients) benefited from attempted introduction and titration of this therapy. A large number of entries (1,796 records) were recorded in the Omada database on these patients, representing the various dosage changes over time. Patients made an average of four visits during this period.

The most commonly used beta blocker was carvedilol; it accounted for 63% of all beta blocker usage across the centres while bisoprolol accounted for 26%. Of 431 patients taking carvedilol, 23% (99 patients) only tolerated the first level dosage of 3.125 mg bd, but 29% (126) reached the optimal dose of 25 mg bd. A total of 124 patients (29%) stopped taking carvedilol while on the programme, predominantly due to side effects. The remainder are currently in the process of titration.

Discussion

Promoting evidence-based interventions has educational, organisational and financial implications for providers of patient care. Traditionally, health services have been slow to implement even the best research findings into practice. Evidence for the use of ACE inhibitors in heart failure has been accumulating since publication of the Co-operative North Scandinavian Enalapril Survival Study (CONSENSUS) in patients with severe heart failure in 1986[11] and the Study of Left Ventricular Dysfunction (SOLVD) in patients with less severe symptoms in 1991.[12] Yet the uptake of this evidence into practice has been slow.[8,9]

The Randomized Aldactone Evaluation Study (RALES), showing the benefit of spironolactone in patients with severe heart failure, was published only in 1999.[13] Most of the evidence for the use of beta blockers has accumulated within the past five years[14-16] and is still emerging.[17] Since beta blockers were generally considered contraindicated in patients with heart failure until recently, it may be unreasonable to expect a rapid uptake in their use. Furthermore, the process of introducing beta blockers in patients is time consuming and requires considerable resource and organisation.

However, these data suggest that clinics led by trained nurses can increase the use of beta blockers and other therapies of prognostic benefit. Upon entry to the Omada programme, only around one in four eligible patients were receiving a beta blocker. As a result of joining the programme, beta blockade therapy was introduced in all eligible patients and almost three quarters were able to tolerate this at some dose level. Since the Omada nurses take on responsibility for titrating the dosage and for monitoring the patients, medical staff were spared the additional workload that this entailed. However, the nurses also provide other benefits to patients.

A number of studies have shown that patients with heart failure benefit from relevant information about self-management of their disease. Experience in other chronic diseases, such as diabetes and hypertension, suggests that advice of this nature is perhaps better delivered by nurses than by doctors. Indeed, care by trained nurses has been shown to improve outcomes for patients with chronic heart failure, significantly reducing the number of unplanned readmissions, length of hospital stay, hospital costs, and perhaps mortality.[18,19]

The baseline audit revealed poor record-keeping with regard to patient education even in these highly motivated centres. Although the Omada programme included no formal means of assessing the education delivered to patients through the programme, the nurses were trained to view education regarding lifestyle, symptom management and drug side effects as core components of the care delivered to patients and their carers. Patients were given educational leaflets, such as those from the British Heart Foundation, together with information sheets on diet and weight management. Patients were also given an Omada

Key messages

- A nurse-led programme of structured out-patient care for patients with chronic heart failure can improve the uptake of evidence-based drug therapies such as ACE inhibitors and beta blockers
- Such a programme can facilitate collection of key audit data, including those required by the National Service Framework for Coronary Heart Disease

booklet on heart failure entitled *Taking care of your heart*. This includes charts on which patients are encouraged to monitor their weight, together with details of their drug regimens. It also provides emergency contact details for the nurse, their general practitioner, and the local accident and emergency service.

'Trained nurses can increase the use of beta blockers and other therapies'

Patients appear to value the more 'holistic' form of care provided by the nurse, who is able to develop a relationship with the patient and their family, and is able to provide continuity of care. This, together with the education provided by the nurse, empowers patients to ask more questions and gain greater understanding of their disease and how to manage it. It is hoped that this approach will facilitate compliance with both the lifestyle and drug-related aspects of management. Frequent contact with the specialist nurse also offers greater opportunity for detection of underlying problems, such as anxiety, depression and diabetes. In such cases, the Omada nurse can arrange onward referral to other health care professionals as necessary, either through medical staff or direct to dietitians, social workers and counsellors.

This nurse-led approach does represent a significant resource requirement in terms of nurses' time in seeing a relatively small number of patients, titrating drugs and counselling patients. For the pilot sites, partnership with a pharmaceutical company provided funding for the nurse and IT requirements. In the longer term, achieving the heart failure goals of the National Service Framework for Coronary Heart Disease will require investment by NHS organisations in this or similar service models. The lessons of the Omada programme, together with the audit software, are now available to any hospital or primary care organisation that has a specialist heart failure nurse (see 'Further information' below).

Conclusion

The Omada programme has achieved improved levels of care for patients with heart failure in a range of secondary care settings. As such, it may provide an appropriate model for audit and delivery of evidence-based patient care in line with the requirements of the National Service Framework for Coronary Heart Disease.

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Further information

The Omada programme toolkit is designed to help NHS organisations meet the heart failure audit requirements of the National Service Framework for Coronary Heart Disease. The toolkit includes written materials and audit software designed to assist in setting up a nurse-led clinic, including referral protocols, process audit, job descriptions for nurse specialists and introduction letters for the patient's general practitioner. For further details, please telephone Jacqui Groom, National Nurse Manager for Omada on 07736 167980 or enquires@omada.org.uk

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Delivering evidence-based care to patients with heart failure: a comment from primary care

Standard 11 of the National Service Framework for Coronary Heart Disease states that doctors should arrange for people with suspected heart failure to be offered appropriate investigations, eg. electrocardiography and echocardiography, that will confirm or refute the diagnosis. For those in whom heart failure is confirmed, its cause should be identified; treatments most likely to both relieve their symptoms and reduce the risk of death should be offered.

Martin Cowie and his co-investigators in the Omada programme have demonstrated in the article above (pages 171–80) how it is possible to achieve improved levels of evidence-based intervention for patients with chronic heart failure in nine secondary care centres in the UK.

There have been other studies of nurse-led committee management programmes, which have been shown to lead to both improved compliance and a reduction in hospitalisations.[1,2] The first landmark trial in this area was published in 1995.[3] This was a prospective, randomised trial of the effect of nurse-based, multidisciplinary intervention on the rates of hospital admission, quality of life and costs of care within 90 days of discharge among elderly patients hospitalised with congestive heart failure (CHF). At follow-up, the patients were given education and advice regarding concordance with diet, lifestyle and drug therapy, and symptoms were reviewed. The number of re-admissions for CHF were reduced by 56% in the treatment group. Heart failure clinics in primary care have also been shown to be effective.[4] Patients registered at a practice in Scotland were identified by case record review and invited to attend a general practice heart failure clinic. Initially, only 58.3% of the patients were receiving either an ACE inhibitor

'It is clear structured care can make a difference.... but who is going to pay for it?'
Michael Kirby

or an ARB (angiotensin receptor blocker). At follow-up, one year later, this figure had risen to 90.5%.

It is clear, therefore, that structured care can make a difference. Practice nurses have already demonstrated their skills in protocol-driven care in clinics such as diabetes and asthma. In my own practice, we are currently running a nurse-led CHD clinic in an attempt to tighten up on secondary prevention; a protocol to include the management of heart failure based on the Omada study would be perfectly feasible. The question that arises is who is going to pay for it – this is a matter that will have to be debated at PCT level. The evidence to support the possibility that nurse-led intervention may be cost effective was demonstrated by Rich *et al*;[3] nurse-led intervention reduced the hospitalisations compared with the usual care group and this was associated with a reduction in the overall cost of US $460 per patient.

The National Institute for Clinical Excellence (NICE) guidelines published in April 2001 underscored the importance of patients with myocardial infarction (MI) who develop heart failure needing special attention with regard to ACE inhibitors, aspirin and beta blockade. The advice is that beta blocker therapy should start with a low dose and slowly increase over a period of up to 12 weeks. The new guidelines have not been greeted with enthusiasm by GPs for two reasons: one is that supervision of the patient requires a lot of extra work and, secondly, using beta blockers for patients with heart failure is something GPs have been warned against in the past.

'Clearly local guidelines are required'

The British National Formulary recommends hospital supervision for initiation of beta blockers whereas the NICE guidance suggests that there may be a group of patients with heart failure for whom GPs (based on their knowledge of the patient's clinical condition) may feel able to initiate. Clearly, local guidelines are required because the willingness of primary care to take on this work would depend on access to echocardiography, expert cardiological advice and support, combined with trained nurses.

The big question that will remain is who is going to pay for it and where do we find the trained nurses?

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