EDITORIALS

One More Reason to Disseminate Disease Management Programs for Heart Failure in Spain

Fernando Rodríguez-Artalejo and Pilar Guallar-Castillón

Departamento de Medicina Preventiva y Salud Pública, Facultad de Medicina, Universidad Autónoma de Madrid, Madrid, Spain.

Morcillo et al[1] have published a very important paper in this issue of REVISTA ESPAÑOLA DE CARDIOLOGIA, showing that a simple home-based educational intervention carried out by nursing staff in patients with heart failure (HF) substantially reduces hospital readmissions and emergency department visits at 6-month follow-up. Furthermore, they show that this intervention improves the quality of life of patients and is probably justified in economic terms since it reduces net costs by almost €1200 per patient.

The results of this work agree in general with the other 5 studies that systematically reviewed the subject and which were published in 2004.[2-6] All of these showed that such interventions, known as disease management programs (DMP), yield benefits similar to those obtained by the most effective drugs for HF, i.e., ACE inhibitors, beta-blockers, and diuretics. The main contribution of Morcillo et al's[1] work is that it shows that these interventions can also be useful in Spain, even though the Spanish health system and the psychosocial characteristics of the patients (educational status, social network, family support, frequency of depression, etc) are different to those found in Nordic countries, the United Kingdom, the United States, and Australia, where most previous works have been carried out.

Some specific aspects of this work deserve comment. First, a very important reduction in mortality associated with the educational intervention was found

SEE ARTICLE ON PAGES 618-25

Correspondence: Dr. F. Rodríguez-Artalejo.
Departamento de Medicina Preventiva y Salud Pública.
Facultad de Medicina. Universidad Autónoma de Madrid.
Avda. Arzobispo Morcillo, s/n. 28029 Madrid. España.
E-mail: fernando.artalejo@uam.es

(2/34 in the intervention group versus 11/36 in the control group; $P<.01$). This is very striking because, up to now, this type of intervention has not conclusively demonstrated reductions in total mortality, partly due to short follow-up (generally no longer than 6 months) and the fact that the sample size was selected to evaluate the impact of the intervention on other more frequent events, such as readmissions.

The high mortality in the control group may also have had an effect on the other results of the study. It would have been interesting to know when the deaths took place because, if they occurred at the beginning of follow-up, the comparability of the 2 groups to measure the intervention's impact on readmission might have been lost. The relatively high number of deaths in the control group could have also "competed" with hospital readmissions, preventing the correct characterization of their frequency. However, if these readmissions had taken place in the control group, the comparative efficacy of the educational intervention to reduce readmission would have been still greater than that observed. This is very striking, because the efficacy found is already very high.

Very few health interventions have as strong a benefit as the one reported by Morcillo et al.[1] The educational intervention yielded a 90% reduction in hospital readmissions, whereas the average reduction in the studies reviewed did not exceed 40% in readmissions for cardiovascular reasons and 20% for any reason.[3] The interventions in these studies were heterogeneous, which means that in some cases the benefits may have been high due to the specific characteristics of the intervention and the patients. Despite this, Morcillo et al's[1] study yielded surprisingly strong benefits for the following reasons: first, as in Morcillo et al's[1] study, a large number of the studies reviewed included home interventions carried out a few days after hospital discharge in patients with NYHA grade II to IV. Second, the specific content of the intervention is relatively "standard" with clear precedents in the medical literature.[7] Third, in the first studies carried out, the quality

of treatment was lower than in the current one, and so it is possible that the intervention worked via two mechanisms. On the one hand, it might have improved patient education regarding managing their disease and, on the other, it might have optimized the quality of both lifestyle and drug prescription. As a consequence, it is reasonable to assume that, as the care of HF patients increasingly improved, the second mechanism would lose relevance and the efficacy of the intervention would be lower in more recent studies, such as Morcillo et al's.[1]

Therefore, the main reasons for such spectacular results should be sought in other aspects of the study, such as its small size. When samples are small they can yield extreme results because of the instability of the data. Three or four readmissions "up or down" in each group could translate into very different results. The instability of the data is revealed by the wide confidence intervals regarding the results. In the case of readmissions, the mean reduction in hospitalization is around 0.84 readmissions per patient over 6 months with a 95% confidence interval of approximately 0.69-0.96 (based on Table 4 in the article). Therefore, the results of the study are compatible with an intervention benefit which is considerably lower than the central value of the confidence interval.

Furthermore, when the sample is small, the efficacy of randomizing tends to decrease. The authors point out that Tables 2 and 3 demonstrate no statistically significant differences between the 2 groups of patients. But this has little relevance.[8] The important issue is the substantial differences in the frequency of some predictors of readmission or death between groups. For example, there were 5 times more patients living on their own (15%) in the control group than in the intervention group (3%). This is important because the level of social integration is a key prognostic factor in patients with HF.[9] The problem could even be more serious. In the same way that randomization did not control some of the prognostic factors in the study (NYHA functional class and diabetes are good examples), it might not have controlled other known factors which were not studied (e.g., depression) and the same might apply to many other factors we are not even aware of. This is a problem inherent in every small study. Therefore, the comparability of the 2 groups in the trial is not fully reliable. We can even consider its results to be closer to those of non-random trials which, according to empirical evidence, favor educational interventions more than random trials.[3] A recent review has shown that readmissions were reduced by 60% for cardiovascular causes and 50% for all other causes in non-random trials.[3]

Finally, the efficacy of a given intervention depends both on its own merits and on the frequency of readmissions in the control group. Out of the 36 patients in the control group there were 33 readmissions over 6 months, which is more than reported in most previous studies.[2-6] This also contributes to the study's exceptional results.

However, these arguments are unlikely to account for all the beneficial effects of the intervention carried out by Morcillo et al.[1] What are the potential mechanisms of the intervention? The most important seems to be a double mechanism. First, it reinforces therapeutic compliance in the home; second, it enables the patient to take suitable action during the initial phases of decompensated HF. At a time when new and sophisticated technologies are appearing in medicine on an almost daily basis, it is striking that simply examining how patients live at home and offering educational advice just once is so effective. In fact, HF is one of the chronic processes that, a priori, can most benefit from this type of intervention. First, as the work of Morcillo et al[1] shows, the patients received an average of 6 cardiovascular drugs. Second, patients need very close follow-up, since some of the most effective medications, such as beta-blockers, tend to be poorly tolerated at the beginning of treatment and the dose has to be increased a little at a time over several weeks. Both factors suggest that optimal therapeutic compliance could be very difficult to achieve. Third, although HF decompensation is very frequent it can be treated very effectively via prevention and control. Finally, evidence is beginning to accumulate that patients' knowledge of the nature and management of their disease is relatively low as well as their compliance with therapy. In a study conducted in 4 Spanish hospitals with nearly 400 patients, only 33% knew that "if their ankles or legs were swollen, they should not drink too much liquid;" 64%, that "the flu vaccine does not aggravate heart problems," and 54%, "that they could not take just any analgesic or antiinflammatory drug for pain." Furthermore, therapeutic compliance assessed with the Morisky and Green test was 34%, and it is known that this test tends to overestimate patient compliance.[10]

Before this type of intervention is implemented more generally, several questions remain to be answered. As Morcillo et al[1] rightly point out, many of the previous clinical trials were carried out with patients who had been hospitalized for HF at least once. This involves a certain degree of severity and high risk of readmission. Furthermore, in almost all cases, the intervention was administered at a time close to the admission index. It is still unknown whether less seriously ill patients would also benefit from these programs or not,[11] or whether the intervention could begin later. In fact, the clinical characteristics of the patients who could most benefit from these types of intervention are unknown. In most previous studies less than 50% of the individuals screened were finally included,[3] and in the work of Morcillo et al,[1] their selection criteria forced them to rule out 174 of the 224

patients admitted to hospital for HF during the recruitment period. Future studies should include most of the patients with HF (i.e., more pragmatic studies) or clarify in which patients DMPs are efficient and in which they are not.

Similarly, data are very limited regarding the effects of DMP on general long-term mortality and whether their benefits last longer than 1 year.[12] Furthermore, DMPs should include and evaluate interventions on frequent comorbidities in HF patients such as diabetes and chronic obstructive pulmonary disease, among others. Furthermore, the economic analyses carried out up to now in the clinical trials is not enough to conclusively show the cost-effectiveness of DMP; this is particularly important when they are implemented outside the research context.[3]

Finally, the question regarding which body should carry out DMPs is unclear. In the United States there are two typical models for providing DMP.[3] In the first model the intervention is provided by a company different from the patient's normal health-care provider. This company contacts patients (normally without seeking the consent of their physician) to invite them to participate in a DMP. If the patients accept, they will receive telephone calls, mobile phone messages, educational material packs, e-mail messages, and, from time to time, visits to their home. The second model is based on the chronic care model developed by Bodenheimer et al.[14] As in business models, there is an attempt to educate or train patients to manage their own disease; however, clinical practice is modified in the center normally in charge of the patient's healthcare. Specifically, there is an attempt to transform the center from being focused on the management of acute symptoms to one specializing in following up chronic patients. The strength of the first model lies in its specialization (the companies only provide DMP) and in its large economies of scale. For example, once the company develops an Internet portal to communicate with patients, the cost of extending it to thousands of patients is very low. Only 10 companies cover the North American market and each one provides services to tens or hundreds of thousands of patients. Furthermore, these companies are financially strong and therefore they can afford to invest heavily in the information technology systems (which include administrative and clinical data, drug costs, claims from patients, etc) needed to monitor the people participating in DMPs. Finally, the DMP fund provider can make agreements with the business supplier to obtain partial refunds if the program does not achieve certain clinical objectives (e.g., reduced readmissions) and reductions in previously established costs. On the other hand, the main strength of local health organizations adopting the chronic care model is that they specifically have personal and direct knowledge of the patients and this can be used to achieve better health outcomes through effective patient education and training. Thus, direct knowledge of the patient's environment, gained especially via home visits, can be very useful to identify problems regarding patient care which otherwise would have been missed, and to guide self-care training. Furthermore, the reorganization of clinical practice advocated by the model can have favorable effects on several chronic diseases rather than just one.

Morcillo et al,[1] together with other Spanish authors,[15] have given us a new reason to disseminate this type of intervention in Spain. A good way to achieve this is by designing several simple clinical trials enabling us to evaluate DMP in different health contexts and in HF patients who have not been highly selected. It could be that policies and practices effective in a given health center, whose patients have a high socioeconomic level, are less effective in another center located in a more socially depressed area. Similarly, DMP might work only in areas where the health care quality is lower in the comparison group, etc. These kinds of initiatives, aimed at disseminating DMP-like services, but only within the context of clinical trials, are being carried out by Medicare in the United States.[13] Conceptually, this can be compared to the so-called "tutelary use" of other healthcare technologies recently implemented in Spain.[16]

REFERENCES

1. Morcillo C, Valderas JM, Aguado O, Delás J, Sort D, Pujadas R, et al. Evaluación de una intervención domiciliaria en pacientes con insuficiencia cardíaca. Resultados de un estudio aleatorizado. Rev Esp Cardiol. 2005;58:618-25.
2. Phillips CO, Wright CM, Kern DE, Singa RM, Shepperd S, Rubin HR. Comprehensive discharge planning with postdischarge support for older patients with congestive heart failure: a meta-analysis. JAMA. 2004;291:1358-67.
3. Gonseth J, Guallar-Castillón P, Banegas JR, Rodríguez Artalejo F. Effectiveness of disease management programs reducing hospital readmission in older patients with heart failure: a systematic review and meta-analysis of published reports. Eur Heart J. 2004;25:1570-95.
4. Gustafsson F, Arnold JMO. Heart failure clinics and outpatient management: review of the evidence and call for quality assurance. Eur Heart J. 2004;25:1596-604.
5. McAlister FA, Stewart S, Ferrua S, McMurray JJV. Multidisciplinary strategies for the management of heart failure patients at high risk for admission. A systematic review of randomized trials. J Am Coll Cardiol. 2004;44:810-9.
6. Shepperd S, Parkes J, McClaran J, Phillips C. Discharge planning from hospital to home (Cochrane Review). In: The Cochrane Library. Chichester: John Wiley & Sons Issue 4; 2004.
7. Stewart S, Marley JE, Horowitz JD. Effects of a multidisciplinary, home-based intervention on unplanned readmission and survival among patients with chronic heart failure: a randomised controlled study. Lancet. 1999;354:1077-83.
8. Rothman KJ. The assessment and control of confounding. En: Rothman KJ, editor. Modern Epidemiology. Boston: Little Brown; 1986. p. 125-8.

9. Krumholz HM, Butler J, Miller J, Vaccarino V, Williams CS, Mendes de Leon CF, et al. Prognostic importance of emotional support for elderly patients hospitalized with heart failure. Circulation. 1998;97:958-64.
10. Rodríguez Artalejo F. Los programas de gestión de enfermedades. El caso de la insuficiencia cardíaca. In: Menéu R, Ortún V, Rodríguez-Artalejo F, editores. Innovaciones en gestión sanitaria. Barcelona: Masson; 2005. In press.
11. deBusk RF, Miller NH, Parker KM, Bandura A, Kraemer HC, Cher DJ, et al. Care management for low-risk patients with heart failure: a randomized, controlled trial. Ann Intern Med. 2004;141:606-13.
12. Stewart S, Horowitz JD. Home-based intervention in congestive heart failure: long-term implications on readmission and survival. Circulation. 2002;105:2861-6.
13. Casalino LP. Disease management and the organization of physician practice. JAMA. 2005;293:485-8.
14. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. The chronic care model, part 2. JAMA. 2002;288:1909-14.
15. Atienza F, Anguita M, Martínez-Alzamora N, Osca J, Ojeda S, Almenar, et al, PRICE Study Group. Multicenter randomized trial of a comprehensive hospital discharge and outpatient heart failure management program. Eur J Heart Fail. 2004;6: 643-52.
16. Martín Moreno JM, González Enríquez J. La evaluación de tecnologías sanitarias. In: Cabasés JM, Villalba JR, Aibar C, editors. Invertir para la salud. Prioridades en salud pública. Informe SESPAS 2002. Madrid: SESPAS; 2002. p. 377-91.