The main paradigm of evidence-based medicine stresses the need for interventional randomized controlled studies with the purpose of testing hypotheses on the efficacy of medical approaches. In the past decades, such studies have changed our knowledge of the treatment of heart failure (HF), and our beliefs regarding the efficacy of these therapies is comfortably based on the fact that this information was obtained from clinical trials using proper methodology. On the other hand, evidence-based medicine brings us a second important paradigm: efficacy is not synonymous to effectiveness. Usually, there is a considerable gap between the knowledge provided by clinical trials (efficacy) and the real benefit enjoyed by the target patients using the therapy (effectiveness). There is no comfort zone as regards the guarantee of effectiveness. Given the complexity of the management of patients with HF, the mere prescription of efficient medications may not be sufficient to ensure all the potential benefit of the treatment proposed. For this reason, disease management programs have been tested with the purpose of improving patient compliance to treatment, in addition to identifying and readily treating decompensated patients.

The study of strategies of treatment implantation is part of a branch of the medical science recently named outcomes research. This line of investigation uses two types of methodologies: i) observational studies, when the purpose is to describe the effectiveness of a treatment or to identify determinants of this effectiveness; or ii) interventional studies (clinical trials) used to test strategies for the implementation of medical treatments. Domingues et al’s article published in the current edition of Arquivos represents a randomized clinical trial testing the benefit of an outpatient management program in patients hospitalized for HF.

The intervention performed was an education program during hospitalization applied to all the study patients. It was followed by randomization for either systematic phone calls (made by a nurse for three months after hospital discharge of patients with HF) or no phone calls. The authors show two conclusions: i) no benefit from the phone calls strategy; and ii) benefit from the education strategy applied during patient hospitalization. Like all scientific evidence, this study has to be scrutinized by a methodological analysis. For the critical analysis of studies on management programs, four criteria that can be summarized under the acronym PICO must be used: population, intervention, comparison and outcome.

As regards the analysis of the first item (population), we can state that the criteria for population sample selection adequately represent the target population, i.e., individuals hospitalized for HF. On the other hand, the other three criteria are debatable as regards the authors’ conclusions. As previously mentioned, the authors suggest that there is no benefit from the strategy of outpatient phone calls. However, the type of intervention (I) should be more thoroughly described. In other words, what was the nurse’s approach during the phone calls made to the patients? Was the patient questioned about weight gain or loss? Were symptoms indicative of early decompensation systematically sought? The lack of description of the methodology of the phone calls raises doubts as to whether an adequate protocol was used in the study. Second, the outcome (O) assessed does not permit a conclusion regarding the phone call strategy. The primary outcome to evaluate the phone call strategy should not be the patients’ level of knowledge, since this outcome is more influenced by the hospital education program, which was equally applied to both groups. In fact, it would be odd if this outcome were different. The outcome used to compare the two strategies should consider the incidence of clinical events, given that through telephone monitoring a potential decompensation could be early identified, and this would lead to early treatment strategies. Nonetheless, the present study is not adequately sized for clinical outcomes, and this is why the authors did not define this type of outcome as primary. In absolute numbers, there was a smaller proportion of visits to emergency units, as well as a lower frequency of death in the group randomized for phone calls; however, the differences were not statistically significant. Considering the number of patients in our study (N = 108), the probability of a type II-error (resulting from a low statistical power) is considerable. Thus, based on the present study, we cannot conclude that there was no benefit from the phone call strategy. In fact, in a systematic review, Holland R. et al suggested that there was a reduced incidence of hospitalization and death when this strategy was applied to patients with HF.

As regards the conclusion that the patients benefited from the education program, the analysis of the comparison (C) group raises doubts regarding this statement. Considering that both groups underwent the same education program during hospitalization, there is no control group for this intervention, which indicates that the hypothesis that this strategy is
beneficial was not methodologically tested. It is known that intragroup comparisons are not sufficient to test hypotheses, since the regression to the mean phenomenon may simulate nonexistent benefits.

Finally, we should point out that the type of methodological discussion generated by Domingues et al’s study is useful to stress the importance of outcomes research studies. Domingues et al’s example should be followed, so that further studies evaluate the benefit of management programs in samples of patients with HF, with the purpose of identifying means of increasing the effectiveness, in our midst, of strategies proven efficient.

References


