

in this trial was not sufficient to overcome the unfavourable impact of non-sudden deaths in the ICD arm, resulting in an overall neutral outcome. The experience of the DINAMIT trial⁴ clearly pointed out the importance, especially in a heart failure population, of considering total mortality as primary outcome, avoiding the pitfalls of considering only sudden death reduction.

On the basis of the abovementioned considerations, it becomes clear that the third recommendation should be corrected by deleting the phrase 'sudden death' and replacing it by 'total mortality'.

We feel strongly about correcting this error, not only because it is a misinterpretation of the pertinent trial outcomes, but more importantly, because it implicitly underestimates the importance of ICD therapy in the heart failure population, as demonstrated by these landmark studies.

Thank you for your consideration.

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doi:10.1093/eurheartj/ehi551

Online publish-ahead-of-print 4 October 2005

The Task Force for the Diagnosis and Treatment of Chronic Heart Failure of the European Society of Cardiology: Guidelines for the Diagnosis and Treatment of Chronic Heart Failure: reply

Dr Krum suggests changes to the ESC Guidelines on the diagnosis and treatment of chronic heart failure and of *Figure 4* in particular. We appreciate the opportunity to clarify the role of the figure. As stated in the legend, the figure should be viewed as an example for decision-making. The figure is designed to complement the explanatory text, but is no substitute for it. In the text and in *Table 18*, it is stated (as pointed out by Krum) that the addition of an angiotensin receptor blocker (ARB) should be considered in symptomatic patients regardless of background angiotensin-converting enzyme (ACE)-inhibitor therapy. The reason for not stating that ACE-inhibitor/ARB should be used in combination in the figure is that these patients require re-evaluation after the institution of basic therapy and only those with persisting NYHA class-II symptoms should, in the absence of an indication for an ARA, then receive an ARB.

Similarly, *Figure 4* uses the term 'post MI' and this is clarified as meaning 'recent MI' in both tables and text.

Dr Gasparini and co-workers propose that the recommendations for the benefits of ICDs should be extended to include 'all-cause' mortality and not only applied to sudden death. In the full text document (www.escardio.org/knowledge/guidelines), the background documentation on all-cause mortality is expanded. The statistical evidence for a reduction in sudden death and all-cause mortality in patients with heart failure and reduced left ventricular function cannot refute the size of the benefit, the fact that most patients who receive such a device will not benefit and because all patients will be exposed to the considerable morbidity associated with defibrillators.

Much of these data are new, including the DINAMIT study which was included through a meta-analysis, and have yet to be placed in the context of other treatments that can reduce mortality in patients with heart failure, including pharmacological therapy and cardiac resynchronization devices. These constitute important gaps in knowledge about an intervention, which has a modest effect on mortality and considerable morbidity. Accordingly, the Task Force felt strongly that the selection of patients in whom the benefits of a defibrillator outweighed the adverse effects required considerable expertise and fine judgement on the part of the clinician and that no general mandate could be given at present.

Every clinician and medical system has to interpret this new and innovative technology in the light of their competence, resources, and priorities. The difficulties have been recognized in a recent review.¹ Guidelines can guide on such matters, but not decide for individual patient care.

More information exists on the diagnosis and treatment of heart failure than most other areas of medicine. This abundance of evidence is complex to interpret, may be conflicting at times, but does provide a basis for making some strong recommendations. However, the information is still imperfect, reflecting the need for further research.² Clinical judgement is always important for the final decision. Guidelines provide a framework for clinical practice and training, but are no substitute for personal expertise.

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doi:10.1093/eurheartj/ehi560

Online publish-ahead-of-print 5 October 2005

Evidence-based vs. 'impressionist' medicine: how best to implement guidelines

Bassand *et al.*¹ make a good case for increased use of guidelines. However, they underestimate the role for clinical judgement, patient choice, and physician concerns about cost effectiveness and polypharmacy. Randomized clinical trials and meta-analyses have enormously improved the data base to allow guidelines to be formulated and improve knowledge in pathophysiology and therapeutics in so many countless areas. For this, all clinicians are grateful. However, on a daily basis, the clinician has to make decisions for the individual patient and does not always have the same confidence as the guideline makers that the patient fits the criteria for a specific pathway. Even more importantly, because the morbidity/mortality benefit is likely to be so small, the odds are very strong and the individual patient is most unlikely to benefit. When one presents the numbers needed to treat (NNT) for a benefit to the patient, they are frequently unimpressed and opt not to proceed. Clinicians will regularly opt to compromise, sensibly in our view, with the patient and choose a more user friendly regime to facilitate compliance.

All will agree that the health authorities and the professionals should collaborate to facilitate guideline development and rationalization to guard against guideline overload. We have reservations about industry being involved in guideline development and promotion, as historically their promotions have emphasized relative risk reduction with little reference to absolute reduction and NNT. We would suggest that information on numbers treated effectively and ineffectively should also stand side by side. For a counter opinion, we would recommend the work of James Penston.²

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doi:10.1093/eurheartj/ehi561

Online publish-ahead-of-print 5 October 2005

Evidence-based vs. 'impressionist' medicine: how best to implement guidelines: reply

Drs Fennell and Worrall make interesting and valuable comments on our recent paper,¹ which was intended only as an editorial, stressing the wide discrepancy between the recommendations to treat and the actual implementation of guidelines. This lack of implementation can result in loss of benefit for patients who are under treated. The impact of under use of medical therapies or strategies with proven efficacy on immediate and long-term outcome has been amply documented. We based our assumptions on some of the critical areas of our discipline, particularly acute coronary syndromes, where the life of the patient is at stake, and also heart failure. Registries have proven that in the field of acute coronary syndromes, poor compliance with guidelines can result in a two-fold increase in mortality at 1 month and 1 year. It is, therefore, the duty of every physician to implement guidelines, when one is absolutely certain that they will have a positive impact on the life expectancy of the patient.

This said, we understand the concerns of Drs Fennell and Worrall about the involvement of the industry in the development of implementation programmes. From a purely pragmatic point of view, it can be acknowledged that little or no funds are provided by health authorities to promote best practice through implementation programmes for guidelines, although some initiatives supported by health authorities are beginning in Europe.

The most important remark by our colleagues Fennell and Worrall is about the strength of evidence of recommended therapies included in guidelines. They propose that it could be based more on the number needed to treat (NNT), which may reflect the cost effectiveness of a given treatment. This comment is certainly valid, and indeed, NNT and also number needed to harm will be incorporated in a future set of guidelines to be