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Editorial Comment

Cardiomyoplasty: Is It Time to Wrap It Up?*

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A letter to *Lancet* in 1985 from Carpentier and Chachques (1) represents the first published report of a successful latissimus dorsi cardiomyoplasty operation in human heart failure. In the current issue of *JACC,* Furnary et al. (2) report their prospective experience with latissimus dorsi cardiomyoplasty in 68 patients with New York Heart Association functional class III heart failure. The intervention, performed between May 1991 and September 1993 at eight American centers (five in the United States, two in Canada, one in Brazil) well experienced with the operation, was assessed at 6 and 12 months postoperatively for changes in clinical status, ventricular and hemodynamic function, exercise capacity and survival. A nonoperated group (n = 58) of patients with functional class III heart failure, selected from seven of the centers was added as a reference group for comparison.

Despite the advances in the pharmacologic and nonpharmacologic approaches to heart failure over the past two decades, the morbidity and mortality of ventricular dysfunction and heart failure remain unacceptably high. Additional advances and interventions are most certainly needed to bring this condition under control. Does latissimus dorsi cardiomyoplasty represent such an intervention? On the basis of the report in this issue of the Journal by Furnary et al. (2), the answer to this question is still "possibly." The results of this nonrandomized, uncontrolled and relatively small (n = 68) study only allow one to conclude that latissimus dorsi cardiomyoplasty is feasible for patients with functional class III heart failure, with acceptable 6- and 12-month survival rates, when performed at centers experienced with the operation. Nevertheless, this report is the first to attempt a meaningful comparison with a matched, nonoperated heart failure group.

The use of nonrandomized reference groups for comparison always raises concern about patient selection and proper case matching. In the present study, the baseline characteristics of the cardiomyoplasty and the reference heart failure groups were comparable with respect to fundamental demographics, historical functional assessment and left ventricular ejection fraction. Hemodynamic and exercise data were not reported and are, thus, presumably unavailable for the reference group. These circumstances perhaps still permit use of the reference group to generally compare survival rates.

What constitutes an adequate control group for the cardiomyoplasty operation in human heart failure? The true placebo for latissimus dorsi cardiomyoplasty is a sham operation, hardly acceptable in humans in any era. However, the absence of any form of placebo treatment (even an oral preparation) in the reference group is a huge shortcoming of the study by Furnary et al. (2). Because placebo therapy itself can evoke significant improvement in clinical status, functional classification and exercise capacity in human heart failure (3–5), this major shortcoming does not allow an interpretable, comparative assessment of functional status, quality of life and hospital admission rates between the two groups. With respect to the survival curve of the reference group, data from recent pharmacotherapeutic trials indicate that more favorable survival curves (rates) are evolving for patients with heart failure. However, as surgical experience and methods continue to improve, the survival rates for cardiomyoplasty undoubtedly will also increase above those available in the present report. The early postoperative (in-hospital) mortality rate of 12% and the additional major morbidity rate of 19% with experienced surgical teams in functional class III patients should not escape attention.

For survivors of the cardiomyoplasty procedure, exercise capacity was not altered, and the degree of improvement in left and right ventricular ejection fraction and central hemodynamic variables reside somewhere between trivial and modest. These results also fall short of those recently noted for several pharmacologic interventions (e.g., angiotensin-converting enzyme inhibitors, digoxin, carvedilol, metoprolol). The observed reduction in heart rate after cardiomyoplasty is important in the setting of cardiac disease and failure; but whether the cardiomyoplasty, concomitant pharmacotherapy or other factors evoked this favorable effect was not addressed by the present report. Basically, the investigation by Furnary et al. (2) still cannot tell us whether latissimus dorsi cardiomyoplasty represents a beneficial approach to heart failure or one that will ultimately be relegated to the "surgical placebo" group of operations, joining the Becks, Vineberg and others in the museum of medicine.

The most frustrating aspect of the cardiomyoplasty story at the present time is that the procedure is not yet applicable to functional class IV patients because of unacceptably high operative–postoperative mortality rates, and functional class III patients can be effectively managed, rehabilitated, kept employed and so forth without the procedure by experienced cardiologists and heart failure specialists. In short, those who need it don't survive it, and those who survive it don't need it. Improvement in surgical methods and cumulative surgical experience with cardiomyoplasty will most likely permit the application of this intervention to an appropriate heart failure subpopulation, namely those who would clearly benefit from the operation and do so at a level beyond its risk and cost.

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Parenthetically, very specific cardiac conditions may eventually be best approached by latissimus dorsi cardiomyoplasty (6,7), although these have not yet been rigorously tested; an example is Chagas disease of the heart, a rapidly progressive, malignant cardiomyopathic process for many of those afflicted.

Despite its limitations in design, the study by Furnary et al. (2) is, nevertheless, noteworthy as a preliminary investigation in that it provides the feasibility component for planned multicenter trials on cardiomyoplasty in human heart failure. It relates the absolute necessity of a randomized, parallel control group and the need to add a form of placebo therapy for control patients. Unless interim analyses of controlled trial or trials suggest otherwise, the results of the present study indicate that treatment failure in nonoperated control patients does not mandate crossover to cardiomyoplasty treatment (i.e., all intention to treat patients will remain in their original treatment group); and in a subtle manner, it addresses the essential role of cardiologists with expertise in the evaluation and management of patients with heart failure in the design and performance of these heart failure trials. Whether latissimus dorsi cardiomyoplasty will earn a role in the treatment of heart failure depends on the outcome of properly designed, randomized, controlled trials and the positioning of cardiomyoplasty among ever-improving pharmacologic therapies, cellular–molecular advances (including "cellular cardiomyoplasty"), mechanical innovations (e.g., self-contained, portable, permanent ventricular assist devices) and xenograft transplantation.

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