

# Integrated management of cardiac failure: the cardiac failure clinic

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**Abstract** The prevalence of the risk factors and the risk of cardiac failure are both increasing in China. This might be the consequence of the changes of the life conditions (emigration to the urban areas, changes in the diet and life style, lack of physical exercise, *etc.*). The wide range of clinical presentations of cardiac failure (acute or chronic) and of therapeutic approaches (medical or surgical) makes necessary the integration within the same structure of the various experts involved in the diagnosis and the treatment of cardiac diseases. Technologic and human resources required to offer all the options represent a multifaceted commitment which should be focused optimally in dedicated centers. In these centers, collaboration should replace competition between the medical and the surgical cardiac specialists. Development of team work should permit to optimize the cost efficacy of the treatments. Most of all, such a structure will facilitate the translation of innovative therapies between the research centers and clinical facilities.

**Keywords** cardiac failure; cardiac transplantation; mechanical circulatory support

## 1 Introduction

Cardiovascular pathology is a serious problem in the western world and in the developing countries. It is the leading cause of death and accounts for a huge cost. In the mean time, the medical and surgical management of cardiac structural diseases has been dramatically improved over the past 30 years, leading to improved life expectancy of the general population, improved survival of the cardiac patients after acute complications and consequently increase the number of patients reaching the stage of

chronic cardiac failure.

Cardiac failure is then becoming a major concern in health care throughout the world. The prevalence in Europe is about 0.4% to 2% of the population. Ten million patients will require medical treatment in the coming years. The figure in China is also quite impressive: cardiac problems are the third cause of death in China, after cancer and cerebro-vascular diseases. Two hundred and thirty million patients are facing a problem related to cardiac diseases. There are 2930 million new cases of acute myocardial infarction every year [1] (~217/100000 habitants to be compared to 220/100000 in France). There are 2275 million cases of rheumatic heart diseases, and 1.8 million of congenital cardiac abnormalities [1]. There are 500 000 new cases of cardiac failure every year, 46% of them being related to ischemia, 18% to rheumatism [1]. This high figure is related to the prevalence of the risk factors in the population: hypertension, obesity, smoking habits, and hypercholesterolemia [1]. Both the prevalence of the risk factors and the risk of cardiac failure are increasing, this being the consequence of the changes of the life conditions (emigration to the urban areas, changes in the diet and life style, smoking habit at the young age, lack of physical exercise, *etc.*).

The huge variety of clinical presentations (acute or chronic) and therapeutic approaches (medical and surgical) makes necessary the integration within the same structure of the various experts involved in the diagnosis and the treatment of cardiac diseases. Technologic and human resources required to offer all the options represent a multifaceted commitment which should be focused optimally in dedicated centers. In addition, the increasing cost of the technologies can be minimized by a real mutualisation of the resources. In these centers, collaboration should replace competition between the medical and the surgical cardiac specialists. Development of team work will then permit to optimize the cost-efficacy of the treatments.

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## 2 The medical approaches

The progress in pharmacology has made available numerous classes of agents that can impact the physiopathology of cardiac diseases and consequently the evolution. The time when digitalis was the only treatment available is totally over. Drugs permit to interact with the various physio-pathological disorders induced by the cardiac disease: control of the pre-load and the after-load, adjustments in the energy requirements of the myocardium, in the coronary blood flow control and the myocardial perfusion, action in the neuro-endocrine control of the arterial pressure, management of the coagulation cascade and the platelet function, management of the cardiac rhythm and rate. These agents finally create a new equilibrium, permitting a good quality of life and an improved survival at the different steps of the evolution of the cardiac disease.

The medical therapy has to be adjusted to the real needs of the patients and to the individual characteristics [2]. Side effects and complications of the cardio-vascular agents have to be considered. The daily regimen has also to be tailored to the patients needs. Finally, one of the most difficult problems when the adequate therapy has been started in a patient is the observance of the treatment: less than 30% are following seriously the prescriptions and frequently the optimal effect of the medical therapy cannot be reached.

Besides pharmacology, there are many specialties which can help the cardiac patients. Physical therapy and muscular training, sleep apnea control, retraining in the living habits (diet, smoking habits, stress control), psychological support may play a significant role in the improvement of the quality of life of the cardiac patients and in the chances for survival.

Medical technology has been dramatically improved. Cardiac rhythm and cardiac rate may be controlled by electronic implantable devices: pace makers, defibrillators, ventricular re-synchronisation devices are now widely used, both in the treatment of cardiac rhythm disorders and in the management of cardiac failure. The selection of these therapies has to be adjusted to the characteristics of each individual patient, which leads to sophisticated and expensive testing in the pre-implantation period.

These medical therapies contribute to prolong life and consequently to increase the pool of patients with advanced cardiac failure. The daily condition of the patients is becoming sooner or later less than acceptable. Consequently, there is a growing and huge demand for a more active treatment. In this group of very sick patients, an increasing preference has been expressed by the patients themselves for an improvement in the quality of life, even at the risk of an increased early mortality [3]. Quality of life is actually becoming more important than the prolongation of life at any cost.

## 3 The surgical approaches

There is clearly a time in the evolution of cardiac failure when surgery becomes the best therapeutic option. Indeed, surgery permits to correct the structural abnormalities of the heart (the valves, the ventricular walls), the dysfunction in the perfusion of the ischemic myocardium. Morphology of the left ventricle itself plays a major role in the evolution of the cardiac failure: a spherical shape itself permits a better left ventricular contraction. With a surgical treatment, the patients can expect a new situation where myocardial function is improved. In addition, surgery plays an increasing role in the treatment of the end of life of the cardiac patients, making possible either cardiac support or cardiac replacement.

The development of myocardial revascularization by percutaneous techniques and coronary bypass surgery has permitted to improve life expectancy and quality of life of the coronary patients in profound cardiac failure. Valve repair is a quite effective technique to bring the patients with a profound left ventricular dysfunction back to an almost normal life. Finally, surgical ventriculoplasty and left ventricular remodeling have been shown to improve rapidly left ventricular ejection fraction: they permit to improve the metabolism in the adjacent areas and consequently enhance the mechanical performance [4]. These observations have led to a dramatic change in the indications for surgery: thirty years ago, cardiac failure was a contra-indication for surgical repair. Today cardiac failure is an indication for surgery!

Cardiac transplantation offers the chances for a prolonged survival and a good quality of life in the end stage patients who can get the chance to be transplanted. However, very few patients can actually receive a cardiac transplant. This treatment is totally dependent on organ donation. Organ donation is, in every country of the world, a real societal issue. Active and precise information of the public about brain death has not dramatically changed the acceptance of organ donation. Logistical problems make availability of a suitable graft almost unlikely in every urgent situation. Finally, cardiac transplantation imposes a life long immunotherapy, which carries its own risk and does not totally prevent the development of coronary diseases.

The alternative remains then mechanical devices which will support or replace the ventricular function. Different devices are now proposed for the various clinical presentations of cardiac failure. After 30 years of technological and clinical developments, the techniques of mechanical circulatory support (the implantable ventricular assist devices) and techniques of cardiac replacement (artificial heart) may offer to the patients the best chances for an improved quality of life. There is a wide range of systems which are suitable for each individual situation and each individual patient. In the acute

situations, ECMO (extracorporeal circulation with membrane oxygenation) permits to gain time, from a few hours to many days. ECMO permits to re-establish immediately an adequate perfusion of the brain, saving then the patient's future. These gained hours will allow triage of the patients and selection of the optimal therapeutic protocol to correct the cardiac problem. These two techniques are easily available in every cardiac surgery department and do not require any major investment. ECMO can be installed on any patient within a few minutes. It will achieve immediately a stabilization of the patient's condition. In addition, ECMO can be installed in a non-specialized center, permitting eventually the transfer of patients from a remote hospital to a specialized center.

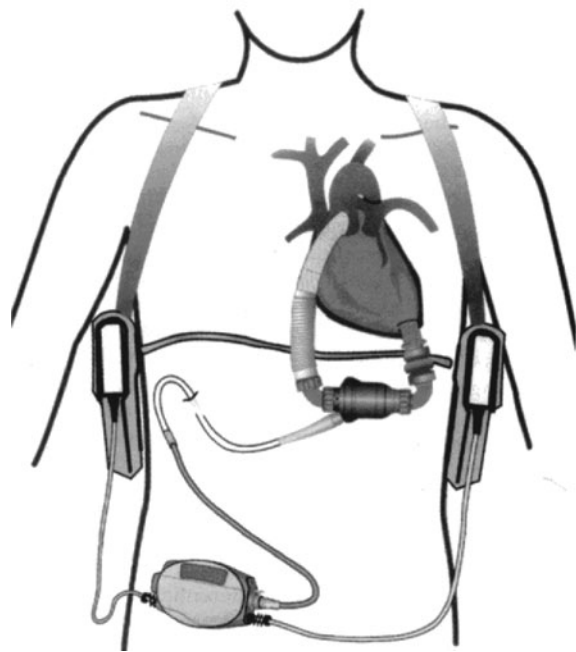
A step further, is the techniques of extra-corporeal ventricular assistance, either mono-ventricular or bi-ventricular. The most commonly used is the Thoratec pVAD (paracorporeal ventricular assist device), a pulsatile device. The pVADs allow a very prolonged circulatory assistance, up to many months, even years. They permit to stabilize immediately the circulatory condition, create a new balance between venous drainage and arterial perfusion permitting end organ recovery. It then permits to rehabilitate physically the patient: the patient can move freely and restore the muscular mass. In the mean time, it also can improve the myocardial function and native ventricular performance, making eventually possible the weaning off the device and a prolonged period of survival on medical therapy. In the mean time, it has been observed in the patients supported long-term that a restoration of the myocardial function is a real possibility, permitting the weaning of the system and the return to a normal autonomous life. Finally, in case of unsatisfactory and incomplete recovery, cardiac transplantation can be performed with the maximum chances of success, in a patient actively rehabilitated [5]. This strategy of two stages cardiac replacement is nevertheless not an option to solve the issue of donor graft scarcity.

In the chronic stable patients, the situation is totally different. The issue is not anymore to save the brain but to allow a prolonged survival with a high quality of life. The implantable devices which permit either bi-ventricular support (iVAD) or mono-left ventricular assistance can achieve this objective. The implantable devices, used in the 80s and 90s have permitted a validation of this therapeutic approach, even in the most severe patients, actually too old to be transplanted. The REMATCH (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) trial [6] has shown the feasibility of this therapeutic option and two important facts: the patients treated aggressively with the VADs are living twice longer than the patients receiving an optimal medical treatment; the patients receiving a VAD have a much better quality of life than the others. Unfortunately the study has also pointed out a high rate of infectious and thromboembolic complications, an unacceptable rate of mechanical

failure of the pumps [7].

More recently, new pumps have been introduced, which are minimizing the risk of device dysfunction: they are more compact, more silent, and more reliable. These new pumps (Heartmate II, Jarvick 2000, DuraHeart, *etc.*) (Fig. 1) are actually giving to the patient the possibility of a long life (up to 6 years), at home. The real issue with these devices is the cost (~80 000 Euros for each device) and consequently the necessity of a drastic selection of the best candidates. The selection procedures make then quite necessary a concerted approach, by the cardiologists and the cardiac surgeons to identify the most suitable patients.

This rapid overview of the therapeutic armamentarium which is now available, together with the immense variety of clinical situations and the very individual response to the medical therapy are summarized in the diagram (Fig. 2). The changes in the patient condition can be extremely rapid, making necessary a permanent monitoring of his condition.



**Fig. 1** The left ventricular assist system “Heartmate II” is the most frequently used device which permits long period of survival.

#### 4 The integration of medical and surgical therapies

The huge variety of the clinical presentations of cardiac failure and the extreme diversity of the treatments accounts for the difficulty to organize the management of the patients in cardiac failure and offer the patients the best chances for survival in the acute and chronic situations.

The optimal approach is probably to organize on the

same unique place the availability of every technique and every medical expertise potentially necessary for a given patient in a given situation. This requires specially designed technical platforms, serviced by every expertise.

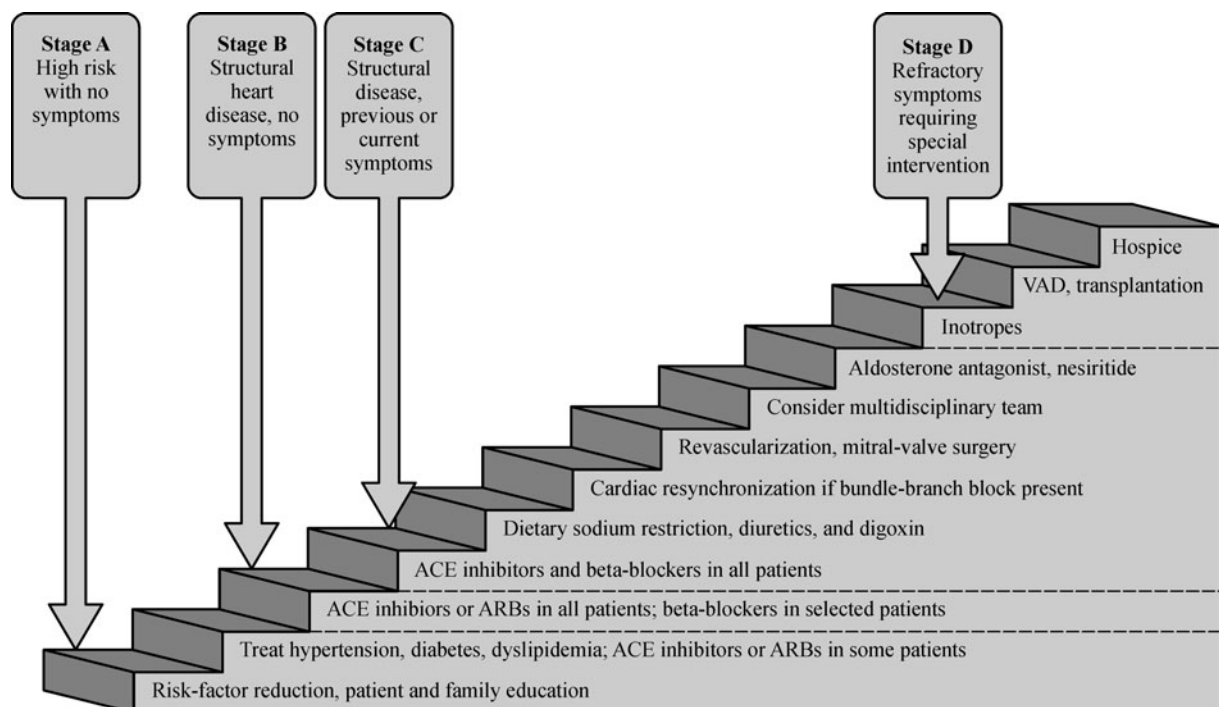
(1) The technical platform has to be adjusted to the needs of non-invasive and invasive methods for evaluation of the cardiac function. Echocardiographic (2D and 3D) evaluation is on the first line. MRI (magnetic resonance imaging) and CT (computed tomography) scans are very efficient non-invasive tools in the most precise evaluation of the patients. The progress in these non-invasive techniques reduces the need for invasive techniques such as the cardiac catheterization and the angiography. The evaluation can be performed in the resting conditions and during stress (exercise or pharmacologically induced). The platform has to include in the very near vicinity the surgical theater and the facilities to implant devices (cardiac rhythm devices, ventricular assist devices from the devices for extracorporeal circulation to the implantable long-term assist devices). The possibility of a rapid electronic transmission of data is opening a new era in the management of the patients living away from a specialized center: telemedicine can help a lot in the selection of the optimal therapy and in its management.

(2) The medical expertise should include every medical and surgical specialist. Many sub-specialities have been developed in cardiology to optimize the clinical applications of the new techniques. The progress in the non-invasive techniques has created a new group of specialists used to the hybrid techniques combining the percutaneous

techniques and the surgical techniques. All of these new specialists have to function within the frame of the same unit, with a shared commitment to work together. Clinical technicians and nurses should be trained to techniques easily reproducible, such as ECG (Electrocardiography), stress ECG, and routine and stress echo. Most of all, the medical doctors should be trained to a combined approach of the patient and the combined application of hybrid techniques.

(3) The real progress will come from the concerted action of each specialist. Consensus has to be obtained in the selection of the optimal therapeutic program for each individual patient. Every decision has to be shared by the clinical cardiologist, the interventional cardiologist and the surgeon. The decisions have to be made according to the recommendations of the scientific societies, and when they are not available, according to a protocol designed by the community working as a group.

(4) The structure can be either a unique building with clearly identified units for stable patients, both medical and surgical, or an intensive care unit, closely related to the facilities for interventional cardiology and surgery. This central structure has to be connected to peripheral remote structure to expand the pool of potential referrals: internet connections can be used to minimize the transfers of the patients at the time of the selection procedure of the optimized therapeutic protocol. If such a centralized structure is not available, every effort has to be made to allow the development of a real team action: frequent meetings of the various members of the team. Each



**Fig. 2** Cardiac failure is an evolving problem. A specific treatment is required at the different stages of the evolution.

segment of this team can get a specialty, leading to a sufficient case load which permits to increase the cost efficacy of the treatment.

## 5 The benefit offered by a cardiac failure clinic

The patient is the first to take advantage of a concerted action of the specialists, following strict protocols. One of the main difficulties in the management of the cardiac failure patient is the optimization of the medical treatment to the individual characteristics of the patient. This requires frequent outpatient visits and a precise evaluation of the effect of the therapy. There is nothing more unacceptable for the patient than missing the time when left ventricular dysfunction becomes responsible for a pulmonary hypertension and/or a right ventricular failure: the opportunity to offer a more active treatment such as a left ventricular assist device is missed. Management of a patient at the stage of isolated left ventricular failure offers more chances to improve the patient than considering the same patient later, at the stage of bi-ventricular failure: the early implantation of an implantable left ventricular assist device will permit a comfortable survival at home, as long the native right ventricular function is preserved. Later on, at the time of bi-ventricular failure, the technology of bi-ventricular mechanical assist system is still cumbersome and does not permit yet a comfortable life. The worst situation is actually to decide too late the changes in the therapeutic strategy and the discussion of an aggressive treatment.

One of the main advantages of the concerted approach of the cardiac failure patient is the possibility to select the optimal therapy at a given time in a given clinical situation. The proper timing of the initiation of an invasive therapy depends largely on the possibility of a concerted action of the various specialists potentially involved in the treatment to be selected: the good results of aggressive treatment such as transplantation or implantation of a mechanical assist device are obtained in the early applications [8]. Most of the complications observed after these aggressive treatments are occurring in the patients referred late. This issue is critical in the stable chronic patients. It is even more critical in the unstable acute patients where a minimum loss of time at the time of the decision will impact dramatically the final result.

Another benefit offered by this approach is the optimization of rare or expensive resources as transplant grafts or ventricular assist devices. A concerted decision permits to rule out these techniques in the less than optimal cases and propose efficient alternatives. This permits a dramatic improvement in the cost efficacy of the treatment.

Importantly, it must be emphasized that the best results are obtained in the most experienced centers. Experience permits to improve both the patient selection and the

patient management when aggressive therapeutic options are selected. Optimal timing before the transplantation of the implantation of a device for mechanical circulatory support, and optimal control of the infection, and the anti-coagulation, expertise in the rehabilitation procedures are key factors for the success. This requires a long and tedious learning curve. The optimal platform to pass rapidly and successfully this learning curve is a cardiac failure clinic.

Finally, it must be emphasized that management of cardiac failure is a very evolving issue. This observation points out the necessity of developing clinical and basic research in the close vicinity of the cardiac failure clinic. Major improvements can be expected from basic sciences. Cell and gene therapy are developing rapidly but there is still a long time to go to optimize these innovative therapies. In addition, it is very likely that combination of these therapies to more conventional treatments will be necessary. The impact of the environment on the outcome of cell grafting into the myocardium of cell injection into the coronary circulation has been recognized. Adjusting this environment by mechanical circulatory assistance is, theoretically, a new route for development which deserves specific study protocols: we may expect that the chances for a rapid recovery of the native myocardial function will be enhanced by a combined therapy including left ventricular unloading, support to the peripheral circulation by mechanical assist systems and specific cell/gene therapy [9]. This comment supports strongly the concerted action of a variety of different experts within an identified structure.

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