Such problems include permeability to moisture (undesirable) and to gases (desirable), and the need for volume and pressure compensation behind the moving pistons in a mechanically activated pump. It can be assumed that problems that cannot be identified at present will also present themselves.

QUALITY OF LIFE

The stated goal of every transplantation program is to return patients to active, productive lives. The experience of heart transplants, kidney transplants and. dialysis suggests that, while for many patients the quality of life is considered good, the replacement of a vital organ often produces unforeseen complications in other parts of the body. It is impossible to predict the spectrum of adverse outcomes that will be encountered with the artificial heart. Nevertheless, it may be possible to draw inferences concerning the chances for partial or total rehabilitation after implantation of an artificial heart by examining related experience with these other major surgical and medical interventions. Therefore, we examine that experience below. We also discuss the problems that might be associated with a nuclear-powered device.

Hemodialysis and Kidney Transplants

In general, short-term complications were expected very early in the use of dialysis. These included hemolysis, bleeding from heparinization, calcium disturbances, and electrolyte disturbances, It was only after a few years that renal bone disease, neuropathies, and hepatitis were seen (9). Some progress has been made with these problems, but accelerated atherosclerosis, dialysis ascites, and dialysis dementia (an acute deterioration of cerebral function) remain. In the United States, 55 percent of dialysis patients and 34 percent of staff are carriers of hepatitis virus B. Of those infected, 70 percent of patients and 15 percent of staff develop an anicteric hepatitis (9). Depression and rapid mood swings are recurring or chronic problems and may be related in part to electrolyte changes and other physiologic changes and in part to the psychic stress of ESRD. Barnes (9) quotes studies indicating that as many as 11 to 18 percent of deaths on dialysis may result from progressive dialysis encephalopathy. This may be caused by excessive aluminum in the central nervous system, which can result from aluminum hydroxide used to bind phosphates in the intestine or even from aluminum in the water supply.

Family-related problems occur frequently. Sometimes there is a reversal of dependency relations between spouses. Patients must restrict their diet and fluid intake. Females are frequently anovulatory and develop amenorrhea. Many males are impotent (59 percent at Mt. Zion Hospital). Women, especially, have self-image problems due to surgical scars from parathyroidectomies, splenectomies, sometimes nephrectomies, and transplant surgery (64). Levy reported on a study of 15 children in six families in which psychological assessment revealed that all 15 were clinically depressed and showed decreased academic achievement and some psychomotor disorders (43). He also reported that children whose parents were dialysed in centers rather than at home did better and were able to see the parent as more normal.

Serious dependence-independence conflicts are reported by several authors (4,25,43). Patients who had been very independent initially were forced to depend on other people and machines. Those who had always been dependent tended to regress and become extremely passive, refusing to participate in their care, attempt to work, etc. Levy reports that staff, who are also under constant strain of working with very ill, irritable, depressed patients, often use the power differential to meet their own emotional needs and may contribute to forcing people to be even more dependent (43). It is a rare patient and family who are knowledgeable enough to overcome this.

A study on suicide by Abram, Moore, and Westerfield (1971) is reported in Levy (43). That study indicates that the rate of suicide by direct action is similar among patients with ESRD to the rate among persons with other chronic diseases—seven times greater than the rate for the general population. If one includes "indirect" suicide (e. g., that caused by ignoring dietary limits, fluid overload, etc.), the rate is considerably greater.

Finally, cadaver transplants present another problem. Patients often anticipate holiday weekends with joy, since the highway death toll presents them with a chance for a better life. Then they feel guilty for wishing for another person's death. For the patients who do not obtain a kidney, there is a "Christmas eve, no Christmas morning" syndrome of disappointment and depression. Kidney transplantation is still high-risk surgery. It also requires immunosuppression, with many complications, for the rest of the person's life. Physicians, themselves, when suffering from ESRD almost never opt for kidney transplants (43), and one physician has described the agonies associated with treatment (15).

Rettig reports that one of the major disappointments and cost contributing factors of the ESRD program is that quality of life has remained poor (64). At this time, there are few solutions to this. As older and sicker patients (e.g., diabetics) are put on dialysis, this problem is apt to worsen. Yet, in most centers, potential and current patients are not routinely given an option of not starting or of terminating treatment.

Heart Transplants

There are a number of problems that all cardiac transplant patients must deal with after surgery. After discharge from the hospital, each patient must make frequent clinic visits, stay on a special diet, maintain a good weight, and get regular but moderate exercise. Most important, patients must accustom themselves to a life-long dose of immunosuppressant drugs to prevent rejection of the transplant. Artificial heart recipients would not encounter all of these problems, but their quality of life maybe severely impaired by sequelae (aftereffects) of surgery, many of which may be unforeseen.

The family of the cardiac transplant patient must also make adjustments. It is sometimes difficult for patients and their families to adjust to the new roles in which they find themselves. The sick role of the patient is no longer appropriate or desirable after transplantation, but some patients find it difficult to give up. Other potential problems include insecurities regarding self-image, guilt feelings over the burden placed on family or society, and severe depression triggered by their new status as a heart transplant patient. Of those patients who survive more than a year, 90 percent have been rehabilitated. For some, this implies a return to previous employment; for others, it means an active life as students, homemakers, or retirees (19).

It has been possible to rehabilitate the majority of Stanford's surviving cardiac transplant patients, in part because of the stringent patient selection criteria which Stanford applies, and in part because Stanford works intensively with a small number of patients. * Medical criteria include the presence of end-stage heart disease, absence of systemic disease, and minimal secondary organ damage. The psychosocial criteria include a stable work history, a history of good medical compliance, a supportive family, and a reasonable expectation that additional life will be gained by transplantation. Patients undergo extensive evaluation for psychological problems that would preclude good rehabilitation. The fact that recipients are very carefully selected and are attended closely by Stanford staff before, during, and after surgery appears crucial for the success of the Stanford program.

Problems of a Nuclear= Powered Heart

As mentioned earlier, Federal funding for research on a nuclear device has been ended—but many researchers still believe that it is preferable to other potential sources of power and continue

*Rehabilitation following heart transplantation is defined as "restoration of physical and psychosocial capacity to a level at which the patient has the options to return to employment or to an activity of choice" **(73).**

to cite it as an alternative. One drawback to the pneumatic systems that are currently being used in clinical assist devices and experimental replacement devices is that the patient or experimental animal is literally tethered to a source of compressed air. The associated noise and lack of mobility would surely have profound psychological effects on the patient were such a device to be used over a prolonged period. An additional major drawback is the risk of infection along the track of the tubing passing through the patient's chest wall.

The risk of infection is also a serious drawback to electrically powered systems that depend on percutaneous electrical leads, but is avoided by chemical batteries that can be recharged transcutaneously. Reliability, bulk, and other physical limitations are other problems with electrical and battery systems that remain to be satisfactorily resolved.

The most advanced nuclear system depends on the principle of heat generation by radioactive decay. The heat powers a miniature gas/vapor engine, which in turn drives a blood pump. Of several isotopes that might have been selected, the isotope Pu-238 with a half-life of 87 years has been used most extensively. The design requires the system to respond to physiological demands; the waste heat of the energy source must be dissipated from and by the body, and the radiation exposure must be "tolerable."

The normal heart produces some 1.5 to 4 watts of mechanical pumping power. (These power levels are over 10,000 times higher than those required for cardiac pacemaking.) Given a system of 10-percent efficiency, approximately 50 watts of energy must be produced, and 45 watts of waste heat must be continuously rejected to minimize a resultant rise of body temperature.* The proposal for the use of radioisotopes in such devices arose when the concept of "maximal permissible dose" was prevalent. This theory, postulating that there was a dose of radiation below which there was no detectable adverse biological effect, is now discredited (49).

*Current thermal engines use 25 watts of heat and have efficiencies of 13 percent or more **(30).**

Pu-238 was chosen as a power source on the basis of its short half-life, relatively low radiation, containment technology, and costs. It is an alpha-particle emitter that also has a spontaneous fission half-life of 4.9×10^{10} years, which is a source of neutron and gamma radiation. Its decay scheme is complex and results in the buildup of plutonium-236 (Pu-236), which in turn decays to emit energetic gamma. All this makes shielding the most serious problem; shielding requirements need to be determined experimentally.

A Pu-238 heat source and shielded capsule sufficient to produce 52 watts, as reported by NHLBI in 1972, was found to produce 2.7 rads per hour measured at the capsule surface and 0.6 millirem per hour measured 1 meter from the surface. Simple calculations indicate that the patient would be exposed to 23,652 rads in 1 year. The radiation dose for a spouse sharing the same bed for 8 hours per night 1 meter distant would be 1.752 rads in 1 year. To indicate the magnitude of these exposures, it should be noted that natural background radiation is about 100 millirem per year—the doubling dose of genetic mutation is estimated to fall in the range of 70 to 200 rem, and exposure of the U.S. population to 5 additional rem per 30 years could cause 3,000 to 15,000 cancer deaths annually (depending on the assumptions made in the calculation).

Discussion

From the information presented above, it can be seen that in the case of kidney and cardiac transplant patients, there exist definite barriers to posttransplant rehabilitation. Although the greatest medical problem for these patients—the host immune response to the implanted organ—would not occur in artificial heart recipients because the implanted organ would be completely artificial, the psychosocial barriers to posttransplant rehabilitation are numerous. While many dialysis and cardiac transplant patients have been able to return to work and lead active lives, many more have had substantial difficulty in doing so. If recipients of the artificial heart fare no better than recipients of heart or kidney transplants, then the claims regarding their