

TRANSPLANTATION AND ARTIFICIAL ORGANS

Edited by

John P. Bunker

Stanford University

Bryan Jennett

University of Glasgow

IMPLANTS, TRANSPLANTS AND ARTIFICIAL ORGANS

Technical Feasibility versus Social Desirability

Bryan Jennett

University of Glasgow

Substitution of lost anatomical structure or physiological function by various devices was one of the earliest technologies in medicine. The wooden leg, the spectacle lens, and the ear trumpet were antecedents of today's powered limb prostheses, pacemakers, valves, vessels, and hearts. Transplantation of tissues or organs from humans and animals represents a further step along the same path. The replacement of deficient organic chemicals such as insulin and coagulation factors might be considered as part of the same continuum. Such substitutes may be wholly external. These include the extension of extremities foreshortened by congenital or acquired abnormality and various communication aids that allow the transmission or reception of information. Replacing the chemical activity of the kidney by dialysis is another external device.

Implanted substitutes vary in complexity. Replacing a purely mechanical structure is the simplest—lens, bone, joint, large vessel, or heart valve. Replacing lost electrical conduction by various activators that cause healthy distal tissue to react is another class of substitution. Success of these depends largely on how simply the activity is generated. When it is the beat of the heart in response to a pacemaker, then simulation of normal function can be almost perfect because continuous activity is required. The problem of initiating an implant in response to will or to changing physiological demand is more difficult. Examples are artificial simulation of the bladder wall and sphincter to reproduce natural micturition or of the muscles below spinal transection to simulate walking. The artificial heart is between these two extremes—complex moving parts require a supply of power, yet this is needed to activate only a relatively simple mechanical pump that works continuously. Artificial implants pose problems in finding materials

that will function for long periods in the body, and in some cases, artificial implants pose problems in devising reliable power sources.

Organ transplants provide a regenerating replacement but there are the difficulties of tissue rejection and of finding donors. These pose fewer problems when it is tissue that is transplanted (skin, cornea, bone, bonemarrow). Transplantation of organs such as kidney, liver, heart, and lungs may well be a passing phase in medical technology until alternative means of substituting lost function are found. By the same token the main use of the artificial heart may be to support a patient for weeks or months until a biological transplant is possible for that particular patient. Meanwhile organ transplantation inevitably attracts attention because it is life-saving or life-enhancing and because it is costly. And also because it raises ethical issues about the procurement of organs and about the balance between burdens and benefits for the patient who receives a donor organ. Thanks to television, there is now keen public interest in the technicalities, the financing, and the personal dramas associated with transplantation—as well as with its effect on other types of health care that compete for limited resources.

In this debate the artificial heart has won a special place for itself as reflected in its prominence in this issue of the *Journal*. This technology is still, however, a matter of major concern only in the U.S. where its development has been influenced by aspects of the politics of health care and of research that are peculiar to the U.S. In other countries the concern is not about how soon the artificial heart will become feasible but about how to cope with the present success of kidney, heart, and liver transplants in extending life and improving its quality in selected patients. The arguments are mainly about how to select patients—because these criteria determine how many transplants doctors claim to be required and what response is made to that estimate by those who finance health care in various countries. Usually governments attempt to set a limit on the number of procedures per year and on the number of centres, as de Charro and Banta describe for the Netherlands (p. 533).

Selection depends on balancing trade-offs between benefits and burdens for individual patients and for the health care system as a whole (1). Account has to be taken of the probability that transplantation will succeed and if it does of the expected duration of survival and the likely improvement in health in medical terms. Also important is the quality of life expected after transplantation as described by Christopherson (p. 553). Variations in selection criteria are mainly in the extent to which patients are excluded because they are more severely affected, have complicating conditions, or are older. Such exclusions can crucially affect estimates of need, e.g., the number of heart transplants projected in the Netherlands is twice as great if the upper age limit is raised from 50 to 55 years. They also contribute to the wide variations in the use of certain technologies in different places (Table 1). Selection criteria also influence results and it is therefore a mistake to expect a linear increase in overall benefit as more patients per million population (PMP) are treated. One reason is that the additional cases will likely be those previously excluded because of a less favourable prognosis. Another factor that can reduce success rates is the spread to a larger number of centres which often have a low volume throughput and therefore less expertise.

In assessing results a distinction should be drawn between different organs. For patients considered for heart or liver transplants there is no satisfactory al-

Table 1. Regional Variations in U.K. (PMP^a)

| | |
|-------------------|--------|
| Cardiac surgery | 83–249 |
| Valve replacement | 31–129 |
| Renal replacement | 95–226 |
| Hospital dialysis | 8–44 |
| Renal transplant | 39–107 |

^a PMP = per million population.

ternative treatment; but these patients often have progressive disease beyond the organ that has failed (atheroma or cancer). This contrasts with kidney and pancreas where the disease is often localised but where other methods of extending life are possible. When assessing expenditure on transplantation it is essential to consider not only direct but also indirect costs, as well as those incurred not immediately but over the next few years—as the Swedish paper shows (p. 545). Transplantation may be costly but it is often less expensive than not doing it—unless the patient then dies which is usually the least costly alternative. The rate of success determines cost as a failed transplant may mean a return to expensive medical therapy and later another transplant operation. But success also commits resources and is one reason why aggregate costs for dialysis increase as improved techniques mean longer survival. The proportion of patients alive at yearly intervals after transplantation of kidney and heart (and liver also in the best centres), now compare favourably with those after treatment for most common cancers. To compare the relative values of different technologies in medicine calls for a better measure of benefit than simple survival however. Health economists have devised the quality adjusted life year (QALY) as a means of combining the duration and quality of additional life conferred by treatment by ascribing monetary values to various aspects of quality of life. This provides a much more sensitive comparator of “value for money” than either the unit costs of various procedures or the cost per survivor. The cost of gaining an additional QALY by a variety of technological interventions has been estimated by health economists in Britain (2,3). This makes it possible to draw up a league table that shows the relative cost-benefit of different technologies (Table 2). Not only is renal transplantation a much better value than dialysis but it is also better than coronary bypass surgery for patients with limited disease.

As rationing becomes accepted as the rule for expensive technologies, there should be demand for more comparisons of this kind—for only then can rationing be rational. Britain is commonly regarded as the country that has the tightest control on the use of technologies because of its cost-limited health service. Per capita comparisons with the U.S. some years ago revealed 10 times fewer critical care beds, six times fewer CT scanners, and five or six times less use of chemotherapy for unresponsive tumors (4). These are all technologies of dubious benefit for many patients. Yet Britain does renal transplantation at the same rate as the U.S. (28 PMP), has the second largest liver transplant series in the world, and a successful and expanding program of heart transplantation. Of patients on renal replacement therapy, 46% in Britain have a transplant compared with 20% in U.S. and even less in France, Germany, and Italy as the MacPherson article

Table 2. Costs and Benefits of Various Technologies (U.K.)

| | <i>£000 per extra QALY gained</i> |
|--------------------------|-----------------------------------|
| Hospital dialysis | 14 |
| Home dialysis | 11 |
| Heart transplant | 8 ^a |
| CABG—one vessel disease | 6 |
| CABG—two vessel disease | 3 |
| Renal transplant | 3 |
| CABG—left main disease | 1 |
| Aortic valve replacement | 0.9 |
| Hip replacement | 0.75 |
| Cardiac pacemaker | 0.50 |

^a Cost now falling.

Source: Jennett: *High technology medicine, benefits and burdens* (2nd edition). Oxford: Oxford University Press, 1986; derived from Williams (2) and Buxton (3).

shows (p. 497). Of those on dialysis, a larger proportion in U.K. are treated at home than in other countries. All studies show transplant and home dialysis as the least expensive means of treating renal failure and those that are best for quality of life, so Britain seems to be responding rationally to the need for cost-effective and cost-benefit care. The assumption of the U.S./U.K. study (4) that the level and type of provision of technology in the U.S. is a benchmark of optimal conditions must be questioned. The request by some patients or families in the U.S. that dialysis be withdrawn (5) is a clear indication that over-provision is not only costly to society but can bring misery to some of those who are supposed to benefit. There are compelling humanitarian as well as economic grounds for assessing technologies thoroughly and for making wise choices when deciding which patients to treat and when to stop.

REFERENCES

1. Jennett, B. *High technology medicine, benefits and burdens*. (2nd edition). Oxford: Oxford University Press, 1986.
2. Williams, A. Economics of coronary artery bypass grafting. *British Medical Journal*, 1985, 291, 326–29.
3. Buxton, M., Acheson, R., Caine, N., et al. Costs and benefits of the heart transplant programmes at Harefield and Papworth Hospitals. DHSS Research Report No 12. London: HMSO, 1985.
4. Aaron, H. J. & Schwartz, W. B. *The painful prescription: Rationing hospital care*. Washington DC: The Brookings Institutions, 1984.
5. Neu, S. & Kjellstrand, C. M. Stopping long-term dialysis. *New England Journal of Medicine*, 1986, 314, 14–20.