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## **Cardiac Transplantation and Artificial Hearts: Highlighting Medical and Ethical Complexities of Spare Parts Surgery**

### **ACS module in history of surgery**

#### Case Reports in the Medical Literature:

C.N. Barnard, "Human cardiac transplantation. An evaluation of the first two operations performed at the Groote Schurr Hospital, Cape Town," *American Journal of Cardiology* 22,4 (Oct 1968): 584-96.

Denton A. Cooley, et. al., "Orthotopic cardiac prosthesis for two-staged cardiac replacement," *American Journal of Cardiology* Vol 24 (November 1969): 723-30.

Dramatic transplant and implant cases seized headlines during the 1960s, forging medical allegiances to one approach or the other and tantalizing the American public about the possibilities that seemed within reach. In Capetown, South Africa, Christiaan Barnard performed the first heart transplantation in 1967 and two years later, Denton Cooley performed the first total artificial heart implant in Houston, Texas. Both patients died within a matter of days.

Neither case immediately ushered in a new era of life-saving surgery, and the field remained divided over the question of human or mechanical placement parts and the overall legitimacy of cardiac replacement therapy. Plus, there emerged a well-publicized feud between Houston cardiac surgeons Michael DeBakey and Denton Cooley over an accusation of device theft. This overlapped with a debate regarding the premature nature of implanting the device in a patient as well as the issue of innovation credit and institutional reputations.

This module explores these two cases towards a discussion of some of the medical and ethical complexities surrounding cardiac replacement therapy such as the experiment-therapy continuum, the decision to shift from the laboratory to the operating room and who best to perform the 'first' clinical case, which patients should receive the precious few donor hearts available, informed consent and other issues surrounding high-risk surgical procedures. Cardiac replacement attempts were taking place alongside other promising innovations in surgery during the 1960s, including kidney and liver transplant work as well as coronary artery bypass grafting (CABG) operations.

#### 1967: The First Heart Transplantation

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In the United States, cardiac surgeons Norman Shumway and Richard Lower led the research pack in heart transplantation. Beginning in 1959 at Stanford University, Shumway and surgical resident Lower started transplanting hearts in dogs, and began publishing academic papers on the surgical technique and immunological aftercare of these experimental animals. In 1960, Shumway and Lower reported the first successful heart transplant in dogs, and established the surgical technique for cardiac transplantation used by surgeons in both animals and humans for

decades thereafter. In addition to the surgical technique, the Stanford team, more than any other research team at the time, contributed greatly to the knowledge regarding the functioning of transplanted hearts and the body's immune response to transplanted organs in hundreds of animals. By the mid-1960s, the Stanford team reported an 85% survival rate in dogs. Shumway and Lower's research gave them credibility and authority within the transplant field, however, neither performed the first human transplant case.

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On December 3, 1967, South African cardiac surgeon Christiaan Barnard performed the world's first human heart transplant operation. He replaced the failing heart of 55-year-old Louis Washkansky, who suffered from coronary occlusive disease, with the healthy heart of Denise Darvall, a 25-year-old white woman with extensive brain damage due to an automobile accident. The donor heart began pumping in Washkansky's chest and initial organ rejection subsided after drug treatment. However, on the 18<sup>th</sup> day after the operation, Washkansky died due to a pulmonary infection, which had earlier been misdiagnosed as a rejection problem and treated incorrectly.

Barnard's next transplant case, performed on January 2, 1968, produced better results. Philip Blaiberg, a 58-year-old white Jewish patient suffering from congestive heart failure due to coronary artery disease, received the heart of Clive Haupt, a 24-year-old coloured South African who died of a cerebral hemorrhage. Blaiberg lived over 19 months with his transplanted heart, setting a long-term survival record that other cases aimed to match.

Barnard's transplant work garnered widespread and sustained media coverage nationally and internationally for months. The first transplant operation was both a medical and media phenomenon – journalists dramatically reported the surgery, made international celebrities of the surgeon and patient, and hooked thousands of readers into following Washkansky's recovery. Both Barnard and Washkansky were willing participants in the sustained media attention, posing for photographs and talking with journalists. For this perceived media-courting, Barnard drew much professional criticism. Barnard remained in the limelight for most of 1968 as he travelled to Europe, England, and the United States, speaking at medical conferences and to the press, seemingly embracing his new-found fame.

Possible discussion re: state of knowledge surrounding organ transplantation –

- Are some organs not more difficult to transplant than others?
- How was the surgical technique perfected by Shumway and Lower acknowledged as a surgical contribution?
- What was known about organ viability and organ rejection at this time? How are these still issues today?
- How is the heart a culturally-loaded organ which challenges cardiac transplantation among some communities?

Possible discussion re: American scientific research culture –

- How is the value of basic research, animal and bench testing, reflected in these early cases of cardiac replacement?
- How do socio-cultural values shape innovation and early clinical experiences?
- In his second transplant operation, Barnard 'crossed the cardiac color line' when he transplanted a colored heart into a white body in apartheid South Africa. What, if any, issues does this raise regarding racial politics, perceptions of black donor bodies, and national contexts (for both South Africa and the United States)?

- How best to navigate professional and public reporting of innovative new medical procedures?

### 1969: The First Artificial Heart Implant

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On April 4, 1969, Texas Heart Institute cardiac surgeon Denton Cooley replaced the failing heart of 47-year-old Haskell Karp with a total artificial heart. Karp's heart was greatly enlarged due to advanced coronary arterial occlusive disease and myocardial fibrosis, and there was complete heart block. Before going into surgery, Karp agreed to a heart transplantation, consenting to the use of the mechanical heart as a bridge device if necessary, should the planned ventriculoplasty operation fail. With the implanted artificial heart, Karp was disconnected successfully from cardiopulmonary bypass support, but he still required intensive monitoring, respiratory support and isolation. Two days later, a donor heart was found. A medical team flew Mrs. Barbara Evans, who was suffering irreparable brain damage, from Lawrence, Massachusetts to Houston, Texas where she was pronounced dead and her heart removed for transplantation. After living for 64 hours with a mechanical heart, Karp returned to the operating room for removal of the device and transplantation of the newly-acquired donor heart. In the end, neither the device implant nor the heart transplant worked well enough to reverse Karp's multiple problems. On April 8, 1969, Karp died due to pneumonia and kidney failure, 32 hours after his transplant operation.

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The more well-known Houston surgeon at this time was Michael DeBakey, who led a large, NIH-support artificial heart program at Baylor College of Medicine in collaboration with Rice University. DeBakey openly charged Cooley with 'covertly taking' the Baylor-Rice artificial heart, without permission, from the Baylor Surgical Laboratory to St. Luke's Hospital for implantation in Karp. DeBakey was also furious that Cooley, as a Baylor College faculty member, had not followed institutional guidelines for introducing new clinical procedures. Cooley had not gained permission to use the device from the Baylor Committee on Research Involving Human Beings, a group of doctors who could have easily assembled for this emergency decision.

Cooley defended himself by stating that he had secured informed consent from Karp's family, and needed to act quickly to save the life of his patient. Cooley acknowledged that the surgery was a desperate act, but his actions reflected his surgeon's obligation to save the patient and to do everything possible. He had not been motivated to perform the operation for the sake of testing the artificial heart to see if it worked in humans.

Accusations of wrongdoing also came from Shirley Karp, the wife of Haskell Karp, who filed an unsuccessful medical malpractice suit against Cooley and Liotta for wrongful death in 1971. At the centre of the lawsuit were accusations of lack of informed consent and brazen human experimentation.

This artificial heart model was never implanted in another human case. It would be another 12 years before the next artificial heart case, in which the surgeon implanted a different device. Upon closer examination, the Karp case confirmed the mechanical and biological problems already identified in animals. It did not immediately set off more human implant cases with other devices, but reinforced the imperative role of careful laboratory research.

### Possible discussion re: the experiment-therapy continuum –

- To what extent is this a cautionary tale about transitioning experimental procedures from animals to humans?
- How does the surgeon's desire to do everything possible challenge human experimentation protocol?
- Are Institutional Review Boards (IRBs) more of a safeguard or problem when it comes to innovation and saving patient lives?

### Possible discussion re: Ethical issues

- How were celebrity-surgeons and celebrity-patients created, and what role does the media play in this?
- Is there an opportunity (or hindrance) for the media to serve a role in educating the public?
- To what extent is public media coverage detrimental or helpful to surgical innovation?
- What are the ethical issues surrounding interracial transplants, harvesting organs, the definition of death, organ donor shortages, mechanical device implants, and treatment alternatives?

### Assessing Impact

#### [Slide 8 & 9]

After the first heart transplant operation, a 'bandwagon' effect occurred. In the year 1968, more than 100 transplant operations were done worldwide, with Cooley, Shumway and DeBakey performing the greatest number of cases. Transplant operations took place in twenty countries around the world, but the majority of transplant surgery occurred in the United States. The incredible number of operations within this year symbolized the enthusiasm and optimism shared by surgeons, patients and the general public for this procedure. Poor survival rates made it clear that heart transplantation was still an experimental procedure. Medical and public disillusionment with heart transplantation set in. Perhaps surgeons had been too eager to perform this procedure on less than ideal candidates. Perhaps surgeons, feeling helpless, unwisely attempted this risky operation as a desperate measure to save patients who would certainly die otherwise. Perhaps surgeons were too eager to embrace transplant surgery as yet another exciting surgical innovation to be mastered, and did not want to miss out.

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By the end of 1968, mounting medical criticism and poor patient outcomes deterred many surgeons (and patients) from participating in cardiac transplant operations. While some might agree upon the technical ability of surgeons to transplant hearts, both medical and popular press criticized the procedure as being premature due to poor immunological knowledge to prevent organ rejection and no alternative means to sustain life in the event of failure. In 1970, the American College of Cardiology encouraged an unofficial moratorium on heart transplants. Shumway disagreed, determined that his survival rates, which were better than most, would continue to improve with better patient selection and immunosuppression management.

Both of these 'surgical firsts' – cardiac transplantation and the artificial heart implant – raised questions of medical effectiveness (was this a new therapy to be repeated? How best to minimize the uncertainty surrounding experimental procedures?) and medical ethics (which raised questions of informed consent and human experimentation?).

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In the end, Shumway's decision to stay the course was rewarded. With the introduction of the immunosuppressant drug cyclosporine in the early 1980s, more heart transplants were performed with increasing rates of survival. Heart transplantation thereafter became the gold standard treatment for heart failure.

Medical and ethical complexities surfaced for both controversial operations during the 1960s. How best to replace the damaged heart that could not be surgically repaired – with a transplanted human heart or an artificial heart implant? Some researchers in the field preferred one approach over the other, but in the end, the two procedures were used in complementary, rather than competing, ways. Artificial hearts, as bridge-to-transplantation devices, played a supporting role for cardiac transplantation. However, the bridge role of artificial hearts complicated, rather than resolved, several issues raised by heart transplant operations, most notably the shortage of donor organs and priority status for device-implant patients on long waiting lists.

Possible discussion re: Contemporary challenges in heart failure treatment –

- How are the medical and ethical complexities identified with the first clinical cases similar or different today?
- How has the treatment of end-stage heart failure changed since 2000, that may suggest an increased role for mechanical circulatory support systems (the introduction of continuous-flow ventricular assist devices, former U.S. Vice-President Dick Cheney's use of the HeartMate II LVAD as bridge-to-transplant from 2010-12, the tenuous terms of bridge-to-recovery, bridge-to-decision, bridge-to-transplantation or destination therapy in the use of cardiac assist devices)

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