

Hippocrates

When surgeons experiment

The discrepancy between the rigid demands which society feels it must impose on those who experiment with drugs and those who experiment with surgical techniques is a recurrent topic of debate. One can think of reasonable arguments for the discrepancy; some surgical “experiments” are for example in fact innovative methods devised in the operating theatre to deal with an otherwise insoluble problem; but there is no denying that medical and surgical experiments have too much in common to be dealt with in an entirely different manner.

In 1990 the *Lancet* [1] reviewed the pioneering work by Starzi and colleagues [2] at the University of Pittsburgh, who in ten patients with extensive abdominal cancers carried out multi-organ replacement. Liver, stomach, spleen, pancreas, duodenum, proximal jejunum, terminal ileum and ascending and transverse colon are removed from the recipient; the gap left is partly filled by a cluster graft. At the time they reported, eight of their ten patients were alive and out of hospital 3–9 months post-transplant. Is this an experiment? No one, presumably, would argue against the attempt to save life by such heroic measures. The advance which may have been made here could be as substantial as that in earlier and less radical forms of transplant surgery to save life.

The balance is a little different where a surgeon is dealing with a situation for which there is already an accepted surgical treatment giving fair results, and where he proposes to introduce a modification in the hope of securing an even better outcome. Here there seems no doubt that a committee of peers, or an ethical review group, will have a role to play, just as it does where medicines are concerned.

References

- 1 Editorial: When surgeons experiment. *Lancet* 1990; 335: 199–200.
 - 2 Starzi TE, Todo S, Tzakis A et al., Abdominal organ cluster transplantation for the treatment of upper abdominal malignancies. *Ann Surg* 1989; 210: 374–386.
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Experience and the quality of diagnosis

A doctor must be good enough to exercise his profession; lack of experience is (with a few valid exceptions – where he is called on in an emergency to do more than he is capable of doing) no valid excuse if he is arraigned before court for making mistakes.

The issue was touched on in a Swedish disciplinary case, actually heard in 1986, which has now been published [1]. A patient in his sixties had been diabetic for half his life. At a routine checkup in May 1986 a red patch had been observed on his right large toe; the diabetic nurse referred him to the associate department for foot care where he was seen two days later; the foot was now swollen and painful; between the toes a cleft had formed which was exuding fluid. He was sent to the casualty department where he was thoroughly examined and told that the pulse in the right groin was barely detectable; arteriography was advised. Accordingly he returned to the diabetes clinic which could arrange with a senior physician for the examination to be performed. On June 3rd he indeed saw the senior physician who, according to the law report, merely “glanced at the foot” and declared that there was no immediate reason for arteriography.

On June 17th the patient returned for follow-up; on this occasion the senior physician did not even see the foot. The district nurse thereafter painted and bandaged it on several occasions, but the condition deteriorated. Referred to a health centre the patient was given analgesics for the pain. In the night of 29th June the pain nevertheless became intolerable and the toe was nearly black. The district nurse referred him at once to the health centre and he was admitted to hospital. Severe pyrexia delayed surgery, but as soon as possible the toe was amputated. Gangrene however continued to spread upwards, and radiography showed arterial occlusion in the groin. An arterial by-pass was created and a further portion of the foot amputated.

Not surprisingly, the patient raised the matter in the disciplinary court, accusing the senior physician of gross negligence and nonchalance. In his defence the physician argued that he had worked in diabetic care for many years and was accustomed to evaluating diabetic ulcers. In this case he had not regarded the situation on June 3rd as alarming; the patient merely exhibited a small ulcer between two toes; there was no discoloration and the peripheral pulse was palpable, though difficult to assess exactly because of oedema. The patient had been given good advice, his insulin dose had been adjusted, and he had been requested to see the diabetic nurse again two weeks later. On that occasion the nurse saw no reason to call on the physician. The aggravation of the condition thus occurred some three weeks after the senior physician had last seen the patient, presumably as a result of a rapid deterioration in the peripheral circulation within that time. Control by a diabetic nurse, the physician argued, was adequate to keep the situation under review.

The disciplinary tribunal was not impressed; the physician had on June 3rd all too readily attributed the ulcer to an ill-fitting shoe; there had been no proper investigation of the condition of the peripheral circulation. Particularly bearing in

mind the physician's long experience with diabetics he should have been alert to the possibility that a peripheral ulcer in such a patient demanded thorough examination. Not surprisingly, the tribunal issued a reprimand.

Reference

1 Swedish Medical Disciplinary Tribunal HSAN 7007/86.

By-pass and follow-up

A French group headed by Cron at Tours took a look in 1990 at some of the factors affecting survival and long-term mortality in patients with coronary by-pass. Their whole study, covering 867 patients who were followed over a period of ten years, merits reading, particularly because they succeeded in tracking down the causes of all the deaths which occurred. They also had a well-matched control group, comprising a fair cross-section of the French population of similar age, not selected for presence or absence of cardiac disorders.

The mortality rate in the surgical group was slightly higher than in the control group (84 vs 77), but when one discounted the operative mortality (37 cases) the deaths in the post-surgical groups were only 47 as compared with the 77 in the control group. Without any doubt, the mortality would have been far higher in the cardiac group had they not been operated. The surprise provided by this work, however, relates to the causes of secondary mortality. Compared with the control population, the decrease of long-term mortality in patients who survived coronary by-pass was due not only to the decrease in cardiovascular deaths (16 vs 24) but also of deaths due to cancer (15 vs 27), or to other causes (16 vs 26). It all suggests that a more hygienic life and a correct medical follow up contribute, to a large extent, to the long-term survival of these surgical patients.

Unregulated tissue banks in the U.S. come under criticism

Six persons in Virginia recently were found to be infected with HIV as a result of their receipt of transplanted organs and tissue from a donor with AIDS. This sensationalized case has forced a re-examination of the operating standards of tissue banks. In the Virginia case, a 1985 gunshot victim was the source of five organs, two corneas, 54 tissue grafts, and several vials of bone marrow collected by one of the most reputable tissue banks in the country. He was tested twice for AIDS using the most sophisticated screening procedures known at the time. The tests showed, inaccurately, that he was free of the AIDS virus. His organs and tissues were distributed to hospitals throughout the U.S.A.

When the Congress in 1984 required the Food and Drug Administration (FDA) to develop regulations for organ banks, it failed to include tissue banks in the mandate. Left unregulated, some of these suppliers of bone, cartilage, tendon, and other tissues for around 300,000 surgical procedures annually have committed high-risk abuses. Some tissue banks have not collected their materials from the relatively safe environment of a hospital, but instead have gone to morgues where the risks of bacterial or viral infection are much greater. In an attempt to disinfect the materials, they are immersing them in ethylene oxide. This is a toxic chemical widely used with surgical instruments. It also is a known carcinogen. Its use with tissue shortly prior to transplant is criticised by many authorities. And a few banks are just performing generally poor quality work throughout their operation.

By most standards, the risks of infection through transplant of mishandled organ or tissue remains small. Since the initiation of HIV testing, more than 40,000 kidneys have been transplanted and several thousand patients have received heart, liver, and pancreas grafts. Cases of AIDS infection among this group are so rare that they attract national attention when they do occur. In a related area, the odds of AIDS infection through blood transfusion are about one in every 90,000 units of blood.

Despite the minimal risk, the few dramatic cases have prompted a review of the existing regulatory framework. Even organ banks are not under direct government scrutiny. Instead, the FDA in 1987 delegated the responsibility to a private non-profit organization, the United Network of Organ Sharing (UNOS). This group has set standards for how organ banks must do business. It also keeps track of donors and recipients and asks to be notified of any AIDS-related death among donors or recipients. Banks that fail to meet UNOS standards can lose their membership in the group. In addition, the Department of Health and Human Services can withhold Medicare and Medicaid monies. Some health care officials are dissatisfied with even this level of control over organ transplants.

No one has the responsibility for overseeing tissue banks. Several non-profit agencies and private for-profit corporations operating tissue banks have begun to plead for some kind of government regulation. Their pleas are supported by many orthopedic surgeons and other physicians. An aide to Senator Albert Gore Jr., who sponsored the 1984 legislation imposing controls on organ banks, says that the Senator is considering either proposing new legislation or simply asking the FDA to extend its regulatory authority to tissue banks. Either way, it seems likely that such banks will be operating under strict government-enforced guidelines within at least two years.

In the interim, health care providers regularly using tissue transplants should become more curious about their origins. Determine whether the materials came from live patients or corpses. If the latter, ask what steps were taken to control infection. In either case, insist on evidence of thorough, accurate screening to determine the presence of infectious diseases in the donor. Conduct an on-site examination of the tissue bank's facility, equipment, and operations. These steps will minimize the chances of a successful legal action for professional negligence.