From Sterile Debate to Burning Issue: The Economics and Safety Dichotomy
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Surgical instruments are thought to be capable of transmitting spongiform encephalopathies from patient to patient, even after sterilization. At the same time, there is an increasing trend to reuse devices intended for single use. This article discusses certain aspects of that apparent contradiction.

Disease transmission versus cost

It has always been necessary to ensure cleanliness and sterility when using medical devices. Although the epithelial surfaces of our bodies are effective barriers to microorganisms, once that protective layer is breached during an operative or interventional procedure, these ubiquitous microorganisms are capable of rapid penetration, and risks of infection are rapidly increased. It is bad enough leaving ourselves exposed to opportunistic air- borne infections during and following these procedures, but the simple penetration of the body by a medical device is tantamount to an open invitation to purulent disaster. Asepsis has been a fundamental principle of operative medicine since the days of Lister, and every healthcare professional and student should know and appreciate its importance. Moreover, we know that every medical device permanently sited within the body, from suture to major prosthetic replacement, significantly increases the pathogenicity of any bacteria that are present, thereby increasing the risk of infection. Prosthetic heart valve endocarditis and infected total hips are the nightmares of cardiac and orthopedic surgeons.

None of this is new. The need for the technology to achieve medical device sterility has been with us for decades. The debate is resolved, and all agree that sterility is essential. However, the issues involved with sterility and medical devices have become more complex rather than less, and are a matter of considerable current controversy. We discuss here two of the important facets of the current debate: the question of reuse of single-use devices and the role of surgical instruments in the transmission of infectivity in relation to prions. These two aspects are clearly related, and the connection between the two is illustrated in an examination of the underlying problem.

Judging risk

Sterilization is aimed at minimizing risks of infection through the destruction of all or virtually all potentially infective microorganisms or agents in or on a device. Intuitively, this is a simple problem because these agents are organic and all organic matter can be decomposed if you apply enough physical energy, especially via heat or ionizing radiation. Everything could be sterilized by heating to a high enough temperature to be certain of sterility, for example, to 300°C, at which point the molecular structure of all microorganisms disintegrates. The problem is that many of the materials used for the construction of medical devices also suffer

molecular disintegration on exposure to this temperature. Most plastics will have melted or vaporized. Even if that is not the case, components will warp or creep or have their mechanical properties changed beyond all recognition. If gamma irradiation is used instead, the intensity of the radiation dose is sufficient to cause damage to many materials; damage that is often insidious because the changes will not necessarily be obvious at the time. The result may be an appreciable change in a crucial property, such as the wear resistance of the same polyethylene materials used in joint-replacement prostheses after some forms of gamma irradiation.[1]

The selection of sterilization technique for a medical device, depending on the materials of construction, is still an extremely important factor in medical device design and manufacture, even though much more is known now about the effects of sterilization on material properties. The two controversial issues raised in this article impinge on this basic problem: reuse of so-called single-use devices inevitably involves increased doses of the sterilization regime; and the infectious agents in transmissible encephalopathies are prions that are resistant to the type of molecular disintegration that causes the destruction of bacteria

Prions and sterilization

Everyone now knows of bovine spongiform encephalopathy (BSE), and it has become obvious in recent months that BSE does not respect national boundaries, even though some countries are apparently still BSE-free. Public health concerns have centered around the possibility of transmission of a form of encephalopathy to humans via the food chain or, to a much lesser extent, through the use of bovine products in certain pharmaceutical preparations. The risks here relate to the possibility of humans contracting a form of Creutzfeldt-Jakob Disease (CJD), referred to as variantCJD (vCJD) as opposed to the more standard form of sporadic CJD. This has little do to with sterilization and all to do with agricultural and food-hygiene policies. However, as far back as 1977 it was shown that the agents that cause sporadic CJD are highly resistant to sterilization procedures.[2] A cerebral electrode was used in a patient that subsequently developed CJD. The electrode had then been sterilized in benzene and alcohol and was used on two further patients who went on to develop the same disease. The same electrode was then presterilized using the same routine and implanted into the brain of a chimpanzee, which also developed a spongiform encephalopathy.

This may seem a curious set of circumstances, which are unlikely to be repeated in normal clinical circles. Yet, a brief examination of the structure and prevalence of the causative agent suggests that there are significant dangers associated with surgical instrument contamination. The agent is the prion protein. These proteins are widely distributed in animals, which indicates that normal cellular prion proteins are apparently harmless. They can, however, propagate into a disease-specific form; this propagation causing extensive accumulation of the destructive form of prions in certain tissues. These tissues primarily include brain tissue, which gives rise to the spongiform encephalopathies that involve irreversible changes to the brain tissue and symptoms of cerebellar ataxia and dementia, and lymphoreticular tissue. Transmission by neurological electrodes is therefore understandable. Of even greater significance is the fact that tonsils consist of this lymphoreticular tissue, which is why tonsil biopsies are now used for CJD diagnosis and why tonsillectomies have become a major cause of concern for cross-infectivity. No wonder, therefore, that great emphasis is now being placed on the most thorough cleaning and sterilization procedures for simple tonsillectomy kits[3] and the move towards totally disposable sets of instruments. In January 2001, the British government, which probably has the right to be more concerned about this issue than any other because of the previous prevalence of BSE,

announced a £200-million investment in National Health Service decontamination and sterilization services to reduce the risk of vCJD, and agreed to fund the use of single-use instruments for tonsillectomies.

Reuse of single-use devices

In the light of these comments, it may seem perverse that there has been an increasing trend in hospitals in many countries to reuse medical devices that have been designed and are intended for single use and subsequent disposal. Superficially, this practice appears to be contradictory. However, given that the most powerful regulatory agencies in the world are considering proposals to introduce regulations and guidance on the reuse of single-use devices, this simplistic view is obviously not valid.[4] The United States Food and Drug Administration provides a list of frequently reprocessed single-use devices. Unsurprisingly, this list includes forceps and trochars, burrs and needles, blades and staplers. Perhaps not so obvious are intra-aortic balloon catheters, keratome blades, phacoemulsification needles, electrophysiology catheters and cardiac ablation catheters, which also appear on the list.

It is easy to dismiss the practice of reusing single-use devices as unprofessional and unethical, yet it is important to look at the balance of risks. At one end of the spectrum is the reuse of cardiac pacemakers. One recent study[5] revealed a substantial economic advantage in reusing pacemakers, without any appreciable increased risk of infection, and the European Society of Cardiology believes that the legal and clinical issues this raises need rational debate.[6] At the other end of the spectrum is the situation where a package of devices intended for single use is opened in the operating room, but not all are actually used in the operation. What does the theatre nurse do with the unused, but now nonsterile, devices? They may represent a valuable resource, and economic sense suggests that reuse would be beneficial and risk-free. However, the materials used in the device may be incapable of multiple or even two sterilization procedures. The dilemma of the theatre nurse in this situation has recently been discussed[7] and it is interesting to consider the legal, ethical and economic arguments. Manufacturers, for obvious reasons, are usually opposed to the reuse of devices that are intended to be used only once. They have logic and sound legal reasoning on their side. It is the manufacturer who is responsible (in Europe) for declaring conformity of a medical device to the essential requirements of the relevant medical device Directive, and in doing so he/ she must declare the intended use of the product. If the intended use is the single performance of a procedure, and if the product is only validated for that single use, then permission for the user to carry out the sterilization process more than once or to arrange for reprocessing (that is, cleaning and sterilization) through a third party should only be contemplated with extreme care.

Conclusions

These debates about infectivity and reuse, centered as they are around uncertainties of disease transmission and the cost benefits of instrument reuse, are extremely important and, as yet, unresolved. They require input from all contributing professions and it is important that the medical device industry takes a strong, but scientifically justified, position to achieve a sensible resolution.

References

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