COMMENT

The controversy of drug-eluting cardiac stents

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On September 19, 2005, the Bombay High Court asked the Central government to fix standards for drug-eluting cardiac stents. Till standards are developed, only four companies, with either US or European certification, are allowed to sell stents in Maharashtra. The High Court decision followed press reports that the Maharashtra state government's JJ hospital had been using untested cardiac stents on its patients. It has been suggested that the controversy was created by competing stent manufacturing and distributing companies. In any case, it has raised a number of issues of concern to medical ethics, of both practice and research, in India.

The background

The story goes back to June 2005 when it was reported that the state-run JJ hospital in Mumbai was using unapproved drug eluting stents; this had been done on at least 60 high-risk cardiac patients. Axxion drug-eluting stents were manufactured by Occam, a Netherlands-based company. They were not approved for use in the Netherlands, but were being marketed in India by the Mumbai-based Shruti Medi Sciences (1).

In the course of an official investigation, it was learnt that the department had been using unapproved stents since February 2004. While the hospital dean indicated that the stents were bought directly from the market by patients, the payments were recorded in the hospital's accounts. In other words, the government hospital could not evade responsibility for this practice.

Further, the investigating committee found that government departments gave conflicting opinions on the legal status of the stents. The Drugs Controller General of India said drug-eluting stents were not drugs and therefore were not covered under the Drugs and Cosmetics Act. The Indian Food and Drug Administration described as "illegal" the use of imported stents that don't have approval from either their own country or the regulatory authority of the United States. It also held that the very description "drug eluting stent" implies that it is a drug (2).

As a result of the investigation, government ministries have started discussions on standardising medical devices in the country. Devices used in treatment are now defined as drugs and regulated under the Drugs and Cosmetics Act. This will include pacemakers, valves, stents, catheters – both medicated and non-medicated – as well as implants for hip and knee replacements. These high value implants will be brought under government regulation like any other new drug being introduced in the country. It may be pertinent to mention that in the USA, devices used there must be approved by the country's regulatory body.

Cardiac care and stents

This controversy must be seen in the context of the quality of cardiac care in the country. Insufficient cardiac care in the midst of scientific abundance is a ground reality in countries with limited resources. In India instances illustrating this point are reported daily. At the same time, the cost of cardiac care continues to rise with the expanding role of technology in surgical and medical cardiac interventions. Some of these technologies have such short shelf lives that any investment may be misplaced in developing countries like ours.

There are two issues to be considered regarding the phenomenal growth of cardiac surgery and catheter-based therapeutics for treatment of coronary artery disease (CAD) in recent years. First, the quality of activist cardiac care in most parts of the world is of varying standards. Economics and politics play a major role in this. Second, while major technological advances occur in developed countries, the large health-care markets being eyed are in China, Brazil and India. The burgeoning middle class in these countries is being wooed.

Practising cardiologists project drug-eluting stents as the most significant advance in the non-surgical management of CAD. However, one must remember that devices are much more expensive than bare metal stents. Further, in certain circumstances, coronary artery bypass surgery can be a more economical option than implanting of stents in patients with multi-vessel coronary artery disease.

Indeed, it is alleged that doctors or hospitals receive incentives for their use. Most DES are used in patients who are reimbursed by government or private insurance as few people can afford them when paying from their own pocket.

Medical devices and research

Further, in this rapidly expanding market of percutaneous coronary interventions, there has been no regulatory body in India controlling the use of stents and other devices. At least half of the 60,000 patients undergoing angioplasty every year in India receive unapproved stents, according to Abhay Raj of the Delhi-based non-governmental organisation Prahar (3). Though the current controversy concerns a government hospital, private institutions and cardiologists have been using devices that are not approved by appropriate authorities – not in the US or Europe, and not in India. In the JJ case, the stents were acquired

directly from the company through the Indian distributor and used in patients without seeking permission of the Indian FDA or any hospital ethics committees.

Devices that are not tested or approved in the US or European countries should not be used on the ill-informed and poor population of India. Using untested medical devices can present a serious risk to the health, safety and welfare of the patient. The only indigenous heart valve, the Chitra-TTK heart valve, developed at the Sree Chitra Thirunal Centre at Thiruvanthapuram, underwent strict scrutiny including multi-centric clinical trials before being allowed for use in patients. At the same time, one may recall the Barua heart valve that was used without scrutiny.

The Indian Council for Medical Research (ICMR) has a set of guidelines for the investigational use of medical devices (4).

Devices manufactured abroad that are not approved in the country of manufacture may not be used in India. Further, clinical trials of foreign devices may not be conducted in India alone; in certain circumstances, they may be a part of a multi-centre clinical trial.

All the research ethics principles relevant to drug trials apply for trials of medical devices. Clinical trials being conducted for approval of a new drug or device must follow all the relevant regulations: they must obtain regulatory clearance, the trial protocol must undergo ethics review, patients' consent should be taken, they must be informed of the experimental nature of the device, the drug or device should be offered free of cost, and so on. Safety procedures to introduce a medical device in the patient should also be followed as the procedure itself may cause harm to the patient. As for drugs, safety evaluation and pre-market efficacy of devices with data on adverse reactions should be obtained before certification.

The current status of such regulation in India cannot give much confidence to patients. This should be changing. The chief executive of the Society of Biomedical Technology, set up under the Defence Research Development Organisation, has drafted a proposal for setting up a regulatory authority, tentatively named the Indian Medical Devices Regulator Authority. This regulatory body must be given teeth to be effective. Penalties for violators should be documented and ensured. This would be a deterrent to unscrupulous elements amongst the industry and the profession and do away the need of setting up various inquiry committees every time such a case comes up.

Conclusion

Cardiac care is controlled globally by an group of multinationals. The pressure of capital-intensive market forces can threaten clinical decisions and the correct delivery of health care. The nexus between the industry and doctors always existed; it has only become more intense. Doctors need to reclaim their earlier role of being initiators of good practice, changing from their current status as clinical validators of industry handouts. The latest or the most expensive is not always the best (5).

References

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