New stents disappear from hospitals for ‘re-labelling’

Times View

If the stents do not come back to hospitals in time after the so-called relabelling, the health ministry must step in and ensure that any attempt to create an artificial shortage of these medical devices is thwarted. Any shortage will negatively affect healthcare and make patients suffer for no fault of theirs.

Mumbai: Manufacturers and distributors have withdrawn the latest generation of cardiac stents from most city hospitals in the name of re-labelling, forcing patients to settle for dated versions. In centres where the stents have not been physically removed, there are verbal orders to not offer the “high-end” varieties to patients.

This is despite the National Pharmaceutical Pricing Authority’s (NPPA) clear orders that manufacturers, importers and retailers are to implement the price cap without trying to create any artificial shortage. The body had capped prices of bare metal stents to Rs 7,260 and that of drug-eluting and bioresorbable stents to Rs 29,600 on Monday. The NPPA has now written to all chief secretaries to ensure compliance of pricing capping and availability.

Cardiologists told TOI on Thursday the bioresorbable vascular scaffold (BVS)—the fourth generation and most recent one that dissolves into the body after healing the diseased artery—is practically unavailable. “The companies have taken it away for pasting the new rates, but our fear is they will not return to hospitals any time soon,” said a senior cardiologist from Bombay Hospital, Marine Lines.

The latest version of the drug eluting stents (DES) too has been whisked away from most centres. Both these categories of stents used to be sold for more than Rs 1.5 lakh to Rs 2 lakh before their price was fixed at Rs 29,600.

Cardiac surgeon Dr Pavan Kumar said many centres had to postpone angioplasties on Wednesday because of confusion at the stentmakers’ and suppliers’ end. An average of over 12,000 angioplasties are carried out in the Mumbai Metropolitan Region every year.

On Thursday, heart procedures resumed in most hospitals albeit with the older version of stents that had disappeared from catheterisation labs for a while now. “The technology available to patients now is the first and second generation of DES that arrived more than two years ago. It is not that they are ineffective but the newer generation offered certain amount of ease in placing them,” said interventional cardiologist Dr Dev Pahlani, who consults at Breach Candy Hospital.

Pahlani explained the first generation DES were polymer-based, which were found to be slightly toxic. The next generation took care of toxicity by replacing polymer with cobalt and chromium as well as altering the type of catheter required to deliver the device in the artery. “But it can be determined only over time whether the treatment outcomes will differ,” he said.

Cardiologist Dr Anand Rao agreed the newer generations have some technical superiority in terms of deployment, make and compatibility with body tissues. “But, there is no solid data to compare the outcomes between the different generations of DES. Every generation has brought in some refinement,” said Rao.

The NPPA called it “puzzling” that a total of 52 imported brands of DES are not superior to each other as per global clinical norms, to justify such a wide price variation. It added that the average landed cost of a DES imported by nine firms was Rs 16,918.

A spokesperson from Medtronic, one of the leading stent players said, “We have not taken any decision on withdrawal of any product. As per the requirement, we have initiated relabelling of all products.”