Original Article

A Comparative Study of Coronary Stent Utilization Pattern with respect to Coronary Stent Price Regulation: A hospital-based study from Mumbai, India

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Abstract

Introduction: India's National Pharmaceutical and Pricing Authority (NPPA) fixed a ceiling price for coronary stents on 13th February 2017. In this study we compare the coronary stent usage patterns in a hospital in India before and after the coronary stent price regulation was implemented.

Methodology: A retrospective cohort study at a private-sector tertiary care hospital among patients that underwent PCI from 13th February 2015 to 12th February 2019, i.e., two years before and after the price regulation of coronary stents. Sampling was done by complete enumeration of the study population & those fulfilling eligibility criteria. Data were collected from the hospital's electronic health records and Cath-lab registry following the inclusion & exclusion criteria. Data on coronary stent utilization patterns were analyzed under different subgroups using descriptive statistics. The Chi-square test was applied to assess statistical significance. The results were considered significant when p value <0.05.

Results: 1135 patients were included in the study of which 604 of them underwent PCI before the price regulation of coronary stents, and 531 after. 1154 and 1092 stents at an average of 1.91 and 2.05 stents were used per case before and after the price regulation respectively.

Conclusion: The use of DES has increased after the coronary price regulation. Also, more third-generation DES which is the gold standard in coronary revascularization is being used compared to before. The use of superior imported stents also saw an increase after the coronary price regulation. There was only a marginal increase in stents used per case.

Keywords: Coronary stents, price regulation, medical devices

Introduction

Percutaneous transluminal coronary angioplasty (PTCA) also called percutaneous coronary intervention (PCI) is a minimally invasive procedure to open blocked coronary arteries allowing unobstructed blood flow to the myocardium.(1) Coronary stents (CS) are expandable

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tubular metallic devices that are introduced into the coronary arteries that show stenosis due to an underlying atherosclerosis disease. Various types of stents are available including traditional bare-metal stents (BMS) and drug-eluting stents (DES) and bioabsorbable vascular scaffolds (BVS). The most common metal used in coronary stents is stainless steel or cobalt-chromium which gives long-term mechanical stability to counteract vascular recoil. DES consists of three components: a metallic stent platform, an active pharmacological drug agent, and a carrier vehicle in form of a polymer coating that enables sufficient drug loading and release for a long time. The first-generation DES contains sirolimus or paclitaxel coating on a stainless steel base. In contrast, the second-generation DES has zotarolimus or everolimus coating on top of a biocompatible cobalt-chromium or platinum-chromium platform. Newer third-generation DES have ultrathin strut (defined as strut thickness <70 μm) & biodegradable polymer coating which further reduce vascular injury and accelerate reendothelialization as well as reduce polymer-associated inflammation.[2,3] BVS are devoid of metallic structure and are entirely resorbed in a few months after serving their purpose. These are also referred to as fourth-generation DES.[4]

Cardiovascular disease (CVD) continues to be the leading cause of morbidity and mortality worldwide and in sync with global trends, India is not far behind. Ischemic heart disease (IHD) is a leading cause of mortality and disability-adjusted life years (DALYs) in India contributing to 17.8% of total deaths and 8.7% of total DALYs. The proportion of deaths and DALYs from IHD is significantly higher in men than women. With the progressive increase in the number of patients suffering from CVD, the field of interventional cardiology has rapidly expanded throughout the country.[5] In the year 2020 the coronary interventional registry in India included 751 centers which together performed 355326 PCIs implanting 482778 stents. In the pre-pandemic year of 2019, 493684 PCIs were performed implanting 631915 stents.[6,7]

In developing countries, growing populations and efforts by governments to expand universal health coverage have posed a challenge to meeting healthcare expenditures. As a result, countries have implemented increased regulation for healthcare technologies, including price regulation for medical devices. Price regulation is the practice of restricting the minimum or maximum prices in the market by imposing legal requirements. The regulation of prices typically involves establishing a price cap for a predefined category of devices. India's National Pharmaceutical and Pricing Authority (NPPA) fixed a ceiling price for coronary stents at INR 7260 (≈USD 88) for bare metal stents and INR 29600 (≈USD 358) for drug-eluting stents on 13th February 2017.[8] Before this average retail price of bare metal stents was INR 45000 (≈USD 544) and drug-eluting stents INR 120000 (≈USD 1450). In issuing its order, the NPPA stressed that margins had become exorbitant and irrational and profiteering was rampant at various levels in the supply chain.[9] Multiple yearly revisions followed and the current price stands at INR 9373 for bare metal stents and INR 34128 for drug-eluting stents.[10]

In line with the increasing focus on price regulation, there is a mounting need for local and international literature outlining arguments for and against regulating the prices of medical devices. However, to date, there has been limited research undertaken on the application of price regulation to medical devices and the impact this has on the healthcare system, patients, and market dynamics. In this study we compare the coronary stent usage patterns in a hospital in India before and after the coronary stent price regulation was implemented.

Methodology

A retrospective cohort study was conducted at Dr. L.H. Hiranandani Hospital, Mumbai, a private-sector tertiary care hospital. The study population was all patients that underwent PCI from 13th February 2015 to 12th February 2019 at the study center. The study population was divided into two cohorts. One, of those that underwent PCI before the price regulation of coronary stents, i.e., during the period 13th February 2015 to 12th February 2017, and the other of those that underwent PCI after the price regulation, i.e., during the period 13th February 2017 to 12th February 2019. Sampling was done by complete enumeration of the study population & those fulfilling eligibility criteria. Patients that underwent PCI with BMS, DES, or BVS were included in the study, and

those that underwent PCI with balloon angioplasty were excluded. Requisite permissions were taken from the concerned authorities of the institute. Data were collected from the hospital's electronic health records (EHR) and Cath-lab registry following the inclusion & exclusion criteria. A predesigned data gathering form comprising items developed according to the objective of the study was used & data was entered into Microsoft Excel 2019. Data on coronary stent utilization patterns were analyzed under different subgroups using descriptive statistics. The Chi-square test was applied to assess statistical significance. The results were considered significant when p value <0.05. All ethical principles as per Helsinki Declaration were followed during the study.

Results

A total of 1137 patients underwent PCI during the study period at the study center. 2 of them underwent PCI each using a drug-eluting balloon (DEB) and plain old balloon angioplasty (POBA) respectively, and did not meet eligibility criteria. The other 1135 of them underwent PCI using coronary stents and were included in the study. Among the 1135 patients included in the study, 604 of them underwent PCI before the price regulation of stents, i.e., during the period 13th February 2015 to 12th February 2017. 531 of them underwent PCI after the price regulation of stents, i.e., during the period 13th February 2017 to 12th February 2019. Study participant general characteristics and the coronary stent usage pattern is given in Table 1.

Table 1. General characteristics of study participants

Variables	Pre-stent price capping (%)	Post-stent price capping (%)
No. of patients	604	531
Age in years	61.6 ± 11.7	60.2 ± 11.6
Male	446 (74)	408 (77)
Female	158 (26)	123 (23)
Total no. of stents used	1154	1092
Average no. of stents used per PCI	1.91	2.05
LMCA PCI	12 (1.9)	43 (8.1)
PAMI	73 (12.1)	119 (22.4)
SVD	268 (44.4)	234 (44.1)
DVD	238 (39.4)	183 (34.5)
TVD	98 (16.2)	114 (21.5)
Average cost of undergoing PCI	INR 496831 ± 88219	INR 437066 ± 68719

LMCA – Left Main Coronary Artery, PAMI – Primary Angioplasty in Myocardial Infarction, SVD – Single vessel disease, DVD – Double vessel disease, TVD – Triple vessel disease

Table 2. Coronary stent usage pattern among study participants

Variables	Pre-stent price capping (%)	Post-stent price capping (%)	Statistical significance
Stent(s) used in each PCI			
1 stent	266 (44)	223 (42)	$x^2 = 6.419$
2 stents	199 (33)	159 (30)	df = 3
3 stents	91 (15)	84 (16)	
4 or more stents	48 (8)	65 (12)	p-value = 0.0939*

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Types of stents			
Bare metal stents (BMS)	2 (0.2)	0	$x^2 = 94.333$
Drug-eluting stents (DES)	1053 (91.2)	1090 (99.8)	df = 2
Bioabsorbable vascular scaffolds (BVS)	99 (8.6)	2 (0.2)	p-value = 0.0001*
Types of DES			
1st generation DES	651 (62)	235 (21)	$x^2 = 464.779$
2nd generation DES	402 (38)	639 (59)	df = 2
3rd generation DES	0	216 (20)	p-value = 0.0001*
Country of origin			
Indian	256 (22)	31 (3)	$x^2 = 188.288$
Other (Imported)	898 (78)	1061 (97)	df = 1
			p-value = 0.0001*

*p-value <0.05 is considered statistically significant.

Discussion

An average of 1.91 and 2.05 stents were used per case before and after the price regulation respectively. There was no statistically significant change in stent usage pattern in terms of the number of stents used per case. Although a decrease in single stent PCI & two stents PCI by 2% & 3% respectively the change was not statistically significant. Three stents PCI remained the same in both groups while 4 stents PCI increased by 5%. This could be attributed to increased complex LMCA PCI and PCI for TVD.

DES where the most commonly used coronary stent both before and after the price regulation of coronary stents, making up 91.2% & 99.8% respectively. Bare metal stent usage completely stopped after the price regulation so did the usage of BVS stents which fell to a mere 0.2%. At the same time, the market share of DES increased from 95.3% to 97.5% and that of BMS dropped from 4.7% to 2.5% in India.[6] Globally the drug-eluting stents (DES) segment dominated more than 85.4% of the coronary stents market share in 2020 led by the advantages associated with drug-eluting stents. BMS & BVS had 6.3 and 8.3% market shares respectively.[11] Permanent metallic drug-eluting stents (DES) are the current gold standard in percutaneous myocardial revascularization, as they have demonstrated to warrant easy deliverability, good scaffolding, low neointimal hyperplasia, low restenosis rate, and low incidence of major cardiac adverse events (MACE) at long term follow up.[12] BMS were mostly used in government hospitals as various government health schemes did not cover DES in the past. They were also used in cases of financial constraints due to their lower cost.[13]

Use of 1st generation DES decreased by 41% from 62% to 21% while 2nd generation stent usage rose by 21% from 38% to 59%. 3rd generation stent usage rose by 20% from 0% prior to the regulation. The first-generation DESs were another leap forward compared with BMS, but still had concerns about late stent thrombosis and reduced deliverability with the 140μm strut/polymer thickness. The second-generation DESs were designed to overcome these flaws using for example thinner cobalt-chromium alloys, new cell-cycle inhibitors (everolimus/zotarolimus), and more biocompatible polymers. While the first-generation DES released the drug for a prolonged duration, the release kinetics of the second-generation DES was generally shorter. Various studies have consistently exhibited low MACE rates, target vessel failure, and definite or probable stent thrombosis with the 2nd generation DES as compared with first-generation DES. The 3rd generation stents further improved the clinical outcomes with even less late stent thrombosis.[14]

Usage of stents made in India fell by 19% while imported stents increased by 19% making up 97% of all stents used. This is contrary to the notion that the price regulations may allow Indian stent

makers to claim a larger portion of the market and further cultivate domestic production.[15] Two major companies have withdrawn their third-generation high-value DES and a first-generation bio-resorbable stent (BVS). Medtronic filed to remove its Resolute Onyx (DES) stent from the market, while Abbott filed to remove both its Absorb (a first-generation BVS) and Alpine (DES) stents due to financial sustainability concerns. Abbot's Absorb was priced at Rs 190,000 before the cap, whereas Xience Alpine (DES) was priced at Rs 150,000. Boston Scientific has also considered withdrawing its higher-end offerings from the region, due to an expected loss of $7 million in 2017 as a result of the price capping in India. The implication for patients is decreased overall access to the most innovative and effective types of stents. Multiple RCTs show the safety and efficacy data of different imported DES. Indigenously manufactured Indian DES are mostly first-generation DES and lack such supportive data.[16] Although BVS are exempt from price regulation, the newer generation BVS has not made it to the Indian market.

Conclusion

The use of DES has increased after the coronary price regulation. Also, more third-generation DES which is the gold standard in coronary revascularization is being used compared to before. The use of superior imported stents also saw an increase after the coronary price regulation. There was only a marginal increase in stents used per case. The use of PCI for complex coronary artery disease also increased after the price regulation. Price regulation of medical devices has led to overall benefits for the patient.

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