

Original Research Article

Impact of coronary stent pricing regulation in a private sector health care system in India: a retrospective cohort analysis

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ABSTRACT

Background: National pharmaceutical pricing authority of India slashed prices of coronary stents by up to 80% (February 2017) to increase affordability of percutaneous coronary interventions (PCI). This study aimed to assess its impact.

Methods: A retrospective cohort study in a private sector tertiary care hospital in Mumbai, India evaluating data of patients admitted for PCI from 13 February 2015 to 12 January 2019. Cost of undergoing PCI before and after price capping of coronary stents was analysed and studied under different subgroups along with other associated parameters.

Results: Of 1015 patients included, 514 of them underwent PCI before and 497 after the price capping. 967 stents at an average 1.88 stents/case and 1011 stents at average 2.03 stents/case were implanted before and after the price capping respectively. Cost of PCI decreased by 11.64% and 28.14% in non GIPSA (private insurance providers and self-paying) and GIPSA (public sector insurance providers) category respectively under single room class and by 2.79% and 19.87% in non GIPSA and GIPSA category respectively under twin sharing room class. In multi sharing room class cost of PCI increased by 3.99% in non GIPSA category and decreased by 26.87% in GIPSA category. Usage of adjunct devices and number of complex PCIs increased significantly.

Conclusions: Cost of undergoing PCI has dropped significantly after price regulation of coronary stents in most subgroups despite increased usage of adjunct devices like IVUS, FFR/iFR for better patient outcomes. There was no effect on number of PCIs performed.

Keywords: Medical devices, Stents, Price regulation, PCI, IVUS, FFR

INTRODUCTION

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 are significantly higher in men than women.¹ Both

morbidity and mortality from IHD are seen at a much younger age in South Asian population compared to the West. 53.4% of crude deaths due to IHD in India in 2016 were among persons younger than 70 years of age.²

With a predominantly younger population and a stressed-out health care system, IHD remains highly underdiagnosed. By the time the patients knock on the healthcare system, they might have already suffered an ischemic event, which in most if not all cases probably mandate a vascular intervention. These interventions are

in a way lifesaving but exerts a significant toll on patient's savings which subsequently leads to economic burden on themselves and their families. Central Government of India and various State Governments of India over the last few years have introduced various health schemes in order to accommodate such patients so as to reduce their economic burden.

With the ever-increasing number of patients suffering from CVD, the field of interventional cardiology has expanded rapidly through the length and breadth of the country. As a result, the number of interventional catheterization labs (Cath labs) and percutaneous coronary interventions (PCIs) increased from 539 Cath labs and 177240 PCIs in 2012 to about 1200 Cath labs and 373579 PCIs in 2016.^{3,4} Total stents used increased from 215662 in 2012 to 478770 in 2016 with drug eluting stents making up 94.86% (454159 stents) in 2016 compared to 74.52% (160668 stents) in 2012. Primary angioplasty has seen growth from 21343 primary PCIs in 2012 to 56276 in 2016 which has grown from 12.04% to 15.06%.^{3,4}

With an eye on the ever increasing numbers of patients undergoing PCIs and repeated complaints regarding multilevel profiteering; India's national pharmaceutical and pricing authority (NPPA) fixed a ceiling price for coronary stents at INR 7260 (\approx USD 100) for bare metal stents and INR 29600 (\approx USD 400) for drug eluting stents on February 13, 2017.⁵ Before that the average retail price for bare metal stents was INR 45000 (\approx USD 600) while drug eluting stents were priced at around INR 1.2 lakh (\approx USD 1600).⁶ 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.⁵ A significant amount of time has passed since implementation of this order and probably the market forces have adjusted to new pricing dynamics and now would be a right time to study impact of this price regulation policy.

This study assesses the impact of coronary stent price regulation on number of PCIs done per year and number of stent usage per case. It also aims to study whether there has been any cost benefit to the patient/insurance provider and whether it has led to usage of additional technologies to give optimal results (better outcomes) and increase practice of evidence-based medicine.

METHODS

This retrospective single centre cohort based analytical study was carried out at Dr. L. H. Hiranandani Hospital - a private sector tertiary care hospital in Mumbai, India evaluating data for patients admitted for PCI from 13 February 2015 to 12 January 2019, i.e. 2 years prior to and 2 years after coronary stent price capping. Requisite permissions were taken from the concerned authorities of the institute. The data of all PCIs done in this institute during above mentioned period was generated from the

hospital electronic health records (EHR). PCIs done using BVS (bio-absorbable vascular scaffolds), bare metal stents and balloon angioplasties i.e. without stent implantation, were excluded from the study. Also, cases which required additional non coronary interventions were excluded from the study.

Cost of undergoing PCI in a corporate hospital depends mainly on whether they are self-paying or insured. In India there are mainly two groups of insurance providers, the government backed insurance companies i.e. those that come under General Insurers Public Sector Association (GIPSA) and private sector insurance providers (which we would term as non GIPSA or private providers). GIPSA has created closed packages for specific surgeries in specific rooms and the packages have remained unchanged for several years irrespective of the price control. Non GIPSA packages or self-paying packages are usually set by the hospitals/private insurance providers. The cost also depends on the type of room selected, i.e. multi sharing room, twin sharing room or single/private room. Thus, the data of patients who underwent PCI during the above-mentioned time frame were divided into groups based on the type of rooms selected and further subdivided into GIPSA or non GIPSA and compared pre and post implementation of coronary stent price capping.

The data was entered into Microsoft Excel and the total cost to undergo a PCI pre and post coronary stent price capping was analysed and studied under different subgroups along with other associated parameters. Appropriate statistical tests were applied to assess statistical significance. The results were considered significant when p value <0.05.

RESULTS

A total of 1137 patients underwent PCI from 13 February 2015 to 12 February 2019 which included 860 men and 277 women. Among them 126 patients either underwent PCI with BVS or bare metal stent or only underwent plain balloon angioplasty (without stent implantation) and were excluded from the study. Of the 1011 patients included in the study, 514 patients underwent PCI from 13 February 2015 to 12 February 2017 i.e. prior to coronary stent price capping with 967 stents implanted at an average 1.88 stents per case and include 379 men's and 135 females with mean age of 61.5 ± 11.7 years. 497 patients underwent PCI from 13 February 2017 to 12 February 2019 i.e. post coronary stent price capping with 1011 stents implanted at an average 2.03 stents per case and which included 382 men and 115 women with mean age of 60.3 ± 11.8 years (Table 1).

Pre stent price capping, the average cost to undergo PCI was INR 587561 (\approx USD 7940) (N=78) and INR 592661 (\approx USD 8000) (N=59) in single room category under non GIPSA and GIPSA category respectively. Under twin

sharing room class, it cost on an average 459216 (≈USD 6200) (N=103) and 483536 (≈USD 6530) (N=63) under non GIPSA and GIPSA category respectively. In multi sharing room class it cost on an average 386152 (≈USD

5220) (N=148) and 464393 (≈USD 6275) (N=63) under non GIPSA and GIPSA category respectively to undergo PCI.

Table 1: Demographics of patients that underwent PCI pre and post stent price capping.

Variables	Pre stent price capping (n=514) N (%)	Post stent price capping (n=497) N (%)
Mean age	61.5±11.7 years	60.3±11.8 years
No. of males	379 (73.7)	382 (76.9)
No. of females	135 (26.3)	115 (23.1)
No. of self-paying patients	225 (43.8)	172 (34.6)
No. of insured/govt. assisted patients	248 (48.2)	269 (54.1)
No. of govt. assisted patients	41 (8.0)	56 (11.3)
1 stent PCI	227 (44.2)	212 (42.6)
2 stent PCI	170 (33.1)	148 (29.8)
3 stent PCI	77 (14.9)	74 (14.9)
≥4 stent PCI	40 (7.8)	63 (12.7)
LMCA stenting	10 (1.9)	37 (7.4)
IVUS guided PCI	41 (7.97)	168 (33.8)
FFR/iFR guided PCI	16 (3.1)	43 (8.65)

Table 2: Comparison of cost of PCI* and number of stents used per case pre and post stent price capping.

Variables	Pre stent price capping (n=514)	Post stent price capping (n=497)	%	P value [#]
Single room class				
Non GIPSA category	N=78	N=69		
Mean cost of PCI±SD	587561±180657	519170±112471	↓11.64	0.00009572
Total stents used	155	143		
Mean stent used/case ±SD	1.987±1.053	2.072±1.130	↑4.2778	0.5464
GIPSA category	N=59	N=60		
Mean cost of PCI±SD	592661±170186	425901±99954	↓28.14	0.00007197
Total stents used	113	115		
Mean stent used/case ±SD	1.915±0.975	1.916±0.920	↑0.0522	0.6578
Twin sharing room class				
Non GIPSA category	N=103	N=171		
Mean cost of PCI±SD	459216±152027	446388±131554	↓2.79	0.09651
Total stents used	186	355		
Mean stent used/case ±SD	1.805±1.156	2.076±1.264	↑15.013	0.3252
GIPSA category	N=63	N=86		
Mean cost of PCI±SD	483536±154221	387436±128433	↓19.87	0.00005772
Total stents used	110	177		
Mean stent used/case ±SD	1.746±0.925	2.058±1.017	↑17.869	0.4335
Multi sharing room class				
Non GIPSA category	N=148	N=92		
Mean cost of PCI±SD	386152±115558	401566±139278	↑3.99	0.04404
Total stents used	277	186		
Mean stent used/case ±SD	1.872±0.942	2.021 ± 1.219	↑7.959	0.005384
GIPSA category	N=63	N=19		
Mean cost of PCI±SD	464393±160337	339622±95235	↓26.87	0.0166
Total stents used	126	35		

*Cost of PCI is mentioned in INR. [#]p value <0.05 is considered statistically significant.

Table 3: Comparison of adjunct devices used (IVUS, FFR, iFR) pre and post stent price capping.

Variables	Pre stent price capping (n=514)	Post stent price capping (n=497)
Single room class		
Non GIPSA category	N=78	N=69
FFR/iFR guided PCI	1	6
IVUS guided PCI	5	21
GIPSA category	N=59	N=60
FFR/iFR guided PCI	3	5
IVUS guided PCI	5	21
Twin sharing room class		
Non GIPSA category	N=103	N=171
FFR/iFR guided PCI	5	12
IVUS guided PCI	9	59
GIPSA category	N=63	N=86
FFR/iFR guided PCI	2	9
IVUS guided PCI	4	24
Multi sharing room class		
Non GIPSA category	N=148	N=92
FFR/iFR guided PCI	5	10
IVUS guided PCI	13	38
GIPSA category	N=63	N=19
FFR/iFR guided PCI	0	1
IVUS guided PCI	5	5

While post price capping it cost on an average 519170 (≈USD 7015) (N=69) and 425901 (≈USD 5755) (N=60) in single room category under non GIPSA and GIPSA category respectively; under twin sharing room class it cost on average 446388 (≈USD 6030) (N=171) and 387436 (≈USD 5235) (N=86) under non GIPSA and GIPSA category respectively. In multi sharing room class it cost an average 401566 (≈USD 5425) (N=92) and 339622 (≈USD 4590) (N=19) under non GIPSA and GIPSA category respectively to undergo PCI. There was a statistically significant decrease in cost of PCI by 11.64% & 28.14% in non GIPSA and GIPSA category respectively under single room class. In twin sharing class there was a drop by 2.79% and 19.87% in non GIPSA and GIPSA category respectively which was statistically significant only in the GIPSA group. In the multi sharing room class there was increase in average cost of PCI by 3.99% in non GIPSA category which was statistically significant (p=0.044) and statistically significant decrease by 26.87% in GIPSA category (Table 2).

Adjunctive interventional devices which are used during coronary intervention were also compared pre and post stent price capping, this include intravascular ultrasonography (IVUS), fractional flow reserve (FFR) and instantaneous flow reserve (IFR), IVUS was used in 41 cases (n=514) i.e. 7.97% pre price capping which increased to 168 (n=497) i.e. 33.8% post price capping. Usage of FFR/iFR increased from 16 (n=514) i.e. 3.11% to 43 (n=497) i.e. 8.65% (Table 1). PCI with >3 stent usage increased from 7.97% to 12.68% post price capping

and left main coronary artery (LMCA) PCI from 1.93% to 7.44% post coronary stent price capping.

DISCUSSION

A statistically significant drop in average cost for undergoing PCI was seen in both GIPSA and non GIPSA category patients under single room class, which was approximately 1000 USD despite no significant change in number of stent usage per case. The drop was more in GIPSA category compared to non GIPSA, probably due to tighter government restriction of prices under GIPSA category with virtually no revision of GIPSA packages post stent price capping. Similarly, there was also a drop in price seen in twin sharing room class under both GIPSA and non GIPSA, but the drop was statistically significant only for the GIPSA group. Even here there was no statistically significant change in number of stent usage per case. Under multi sharing class non GIPSA category the average cost to undergo PCI rose by 3.99% which was statistically significant. We attribute the marginal increase in the cost in this group due to use of adjunct devices like IVUS and FFR/iFR and also more number of stents per case. In GIPSA category there was a statistically significant drop in price despite no statistically significant change in number of stents used per case. Also, it is seen that there was a significant drop in number of patients undergoing PCI in multi sharing class. This indicates that with decrease in costs more patients opted for better hospital services, as evident from the fact there was an increase in the number of patients opting for twin sharing rooms (better room categories).

Ever since NPPA fixed a ceiling price on coronary stents there has been a mixed array of opinions in the print media regarding its impact. There are some authors who are of the opinion that this law had no effect on the cost of undergoing an angioplasty.⁷ This is contrary to findings in our study which is most likely due to the fact that previous case studies were questionnaire based opinions of cardiologists, hospital management, patients and lay persons.

In this study it was seen that post coronary stent price capping there has been an increase in usage of adjunct devices like IVUS and FFR/iFR. This could be due to the fact the cost of undergoing PCI has come down significantly thus allowing the operator for usage of additional newer technologies to give better patient outcomes. The FAME and FAME II trials clearly established that physiology guided PCI (FFR/iFR guided PCI) gives better patient outcomes compared to angiography guided PCI in select subgroups.^{8,9} Also IVUS guided PCI of complex lesions is associated with improved long term outcomes including cardiac death compared to angiographic guided PCI.^{10,11} As reported in the ULTIMATE study IVUS usage also reduces target vessel revascularization, i.e. need for repeat PCI or CABG (coronary artery bypass graft).¹² The increased number of LMCA PCI after stent price capping could be attributed to the increase usage of IVUS. The cost of these additional technologies range from INR 80000 to 100000 (≈USD1000 to 1300) and even with this additional cost, there has been significant drop in cost of PCI in most categories which further ascertains the fact that government decision to fix a ceiling price for coronary stents had a positive impact on both cost and more usage of adjunct devices leading to evidence based treatment.

CONCLUSION

In conclusion coronary stent price capping has not led to significant increase in the number of PCI done. However, the cost of PCI has decreased significantly in most of the categories. This has translated to an increase in the usage of additional interventional technologies like IVUS, FFR/iFR which leads to subsequent improvement in patient outcomes. Despite significant increased usage of adjunct devices like IVUS, FFR/iFR, and also increase in the number of multi vessel PCI and more complex subsets it did not burden the patients or insurance providers in the overall cost of PCIs.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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