Original Article

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Impact of Coronary Stent Price Regulation on the Interventional Cardiology Landscape of India: An Assessment of Health Economics Outcomes

Internal Medicine Section

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ABSTRACT

Introduction: The cases of Coronary Artery Diseases (CAD) are on the rise in India, this can be attributed to various factors such as ageing, lifestyle, smoking, food habits, and higher income levels. Although, a large proportion of India's population has access to some form of health insurance but the out of pocket expenditure is still extremely high as a percentage of total health spendings.

Aim: To assess the impact of coronary stent price regulation on the interventional cardiology field in India.

Materials and Methods: In this retrospective study, data was collected from online search at google and various other external data sources such as websites and published reports of World Health Organisation (WHO), Niti Aayog, National Pharmaceuticals Pricing Authority (NPPA) and Economic Times (ET) Health World. Line graphs for the percentage change in the number of percutaneous coronary intervention procedures, usage of Drug Eluting Stents (DES) pricing for government and private hospitals for the period 2016-2021 were plotted using Microsoft excel.

Results: A high cost of coronary stents ranging from Indian Rupee (INR) 40,000 to INR 1,25,000 was a major contributor to a very high out of pocket expenditure in the field of interventional cardiology. In order to curtail this cost, a ceiling limit of INR 29,600 was imposed with respect to the prices of coronary stents in the year 2017 by the NPPA. Ever since a ceiling limit was imposed on the prices of coronary stents in India, there has been an annual increase of 3.7%, 13.1%, 12.6%, and 12.9% in the number of coronary intervention procedures for the years 2017, 2018, 2019 and 2021, respectively. Similarly, the usage of DES has also shown an annual increase of 8.9%, 14.7%, 10.5%, and 13.3%, respectively for the same years.

Conclusion: At this juncture when the burden of CAD is on a rise in India, the efforts to make coronary stents more affordable will go a long way in the efficient management of CAD in the country.

Keywords: Coronary angiography, National pharmaceutical pricing authority, Percutaneous coronary intervention, Stent pricing

INTRODUCTION

Cardiovascular Diseases (CVD) accounted for 17.9 million deaths in the year 2019 which inturn represents 32% of all global deaths [1]. Of the 17.9 million deaths, 15.2 million people died of heart attack and stroke. CVD accounts for 31.5% of all deaths in females and 26.8% of all deaths in males. It is predicted that for low-income countries, Non Communicable Diseases (NCD) will contribute half of the total disease burden leading to 23.3 million deaths from CVDs alone by the year 2030 [2-4]. India accounts for 60% of the world's heart disease cases with a projection of around 70 million cases by the year 2025. The rise of CVD is directly linked to various factors such as ageing, lifestyle, smoking, food habits, higher income levels, and improvement in the healthcare system. The average life expectancy in India has increased from 48.8 years in 1970 to 69.9 years in 2020 and the number of people above 60 years of age is expected to double by the year 2030 [5,6].

Coronary Artery Diseases (CAD) is the most common form of CVD. With an increasing prevalence of CAD, the interventional cardiology field is witnessing an exponential growth. The foundation of the interventional cardiology was laid down by Gruntzig A, by performing the balloon angioplasty in the year 1977 [7]. The first documented evidence for the use of coronary stents dates back to 1986 when a self-expanding, stainless-steel wire-mesh structure was implanted in a human coronary artery [8]. The development of stents continued, and Drug Eluting Stents (DES) were introduced to address the problem of restenosis encountered with Bare Metal Stents (BMS). The first sirolimus-eluting stent was implanted by Eduardo Sousa in the year 1999 and the same became commercially available for clinical use in Europe in the year 2002 [9]. Thereafter, a number of DES has been introduced after a careful evaluation of safety and efficacy in large clinical trials.

Health Insurance Landscape-India

It is estimated that around 70% of India's population has access to some form of health insurance. These include government subsidised schemes, social health insurance schemes, and private voluntary health insurance schemes [10,11].

Government subsidised health insurance schemes: These provide fully or partially subsidised insurance coverage to the low-income earners in the country. The prominent schemes include Rashtriya Swasthya Bima Yojana (RSBY) and Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) in 2018. RSBY was initiated in the year 2008 to provide hospitalisation coverage upto Rs. 30,000 for most of the diseases that require hospitalisation for Below Poverty Line (BPL) families. AB-PMJAY was launched in 2018 to provide a fully subsidised comprehensive secondary and tertiary healthcare package with an annual coverage of Rs. 5 lakhs per family for low-income earners in the country [12,13].

Social health insurance schemes: These are compulsory health insurance schemes for organised sector employees requiring contribution by both the employer as well as the employee. The

prominent schemes include Employer State Insurance scheme (ESI), 1948; Central Government Health Insurance Scheme (CGHS), 1954; Ex-servicemen Contributory Health Scheme (ECHS), 2003 etc. Of the various social health insurance schemes, CGHS and ESIS are the only schemes that provide comprehensive healthcare coverage, including outpatient care, preventive care and hospitalisation [14].

Private voluntary health insurance schemes: These are either individual or group insurance schemes that are contributory and voluntary in nature. While 50% of the country's population is covered under Government Subsidised Health Insurance Schemes and nearly 20% of the population is covered under Social Health and Private Voluntary [10].

Health Insurance Schemes, a large segment i.e., 30% of population lack any financial protection for health. It is this segment that accounts for a very high out of pocket expenditure of 63% as a percent of current health spending [10,11].

Interventional Cardiology Landscape-India

According to an editorial from Cardiological Society of India (CSI), the largest association of cardiologists in India, 62 million people in India have some form of CVD [15]. What is more alarming is that, there is almost a two third rise in the number of CVD cases as compared to 36 million people around a decade ago. Further, the report estimates that around 1500 interventional cardiologists are working across 4185 cardiac catheterisation labs in the country [15]. A relatively high cost of coronary stent could be a major barrier for offering coronary intervention services to a large proportion of CVD patients. To address this, Government of India has put a ceiling limit on the price of coronary stents in the year 2017 [16]. Thus, this study was undertaken to assess the impact of coronary stent price regulation on the interventional cardiology field in India.

MATERIALS AND METHODS

The present study was a retrospective study, in which data for the period 2013-2021 was collected between December 2021 to January 2022, from online search at google and various other external data sources such as websites [11,15,17,18] and published reports of WHO [1], Niti Aayog [10], NPPA [16,19-22] and ET Health World [23].

Data on the pricing of DES for the period 2013-2015 both for government and private hospitals was collected from the medical device industry sources. Since, there was a variation in the pricing of different companies/institutions, a range of lowest and highest price have been included to give an idea of the price range prior to the implementation of fixation of ceiling price by the NPPA.

STATISTICAL ANALYSIS

Line graphs for the percentage change in the number of percutaneous coronary intervention procedures, usage of DES as well as DES pricing for government and private hospitals for the period of 2016-2021 were plotted using Microsoft excel. Graphs were plotted considering 2016 as the base year as this was the immediately preceding year prior to the implementation of the price regulation and the number of participating centres in the coronary interventional registry remained relatively uniform from this point onwards.

RESULTS

Data from the industry sources revealed that prior to February 2017 the cost of coronary stents was very high ranging from INR 40,000 to INR 65,000 for government hospitals and INR 90,000 to INR 1,25,000 for private hospitals. [Table/Fig-1] represents the coronary interventional registry data for the period 2013 to 2021 [16,18,19]. The number of participating centres in the coronary interventional registry rose from 404 in the year 2013 to 751 in the year 2020 [15,17,18]. While the number of PCI procedures increased from 0.22 million in the year 2013 to 0.4 million in the year 2021, the corresponding usage of DES increased from 0.26 million to 0.54 million during the same period. The data on the pricing of DES for the period 2013 to 2021 is presented in [Table/Fig-2] [17,20-23].

With the exception of year 2020, there has been an annual increase of 3.7%, 13.1%, 12.6% and 12.9% in the number of coronary intervention procedures for the years 2017, 2018, 2019 and 2021, respectively [Table/Fig-3]. Similarly, the usage of DES has also shown an annual increase of 8.9%, 14.7%, 10.5% and 13.3%, for the years 2017, 2018, 2019 and 2021, respectively [Table/Fig-4]. The data in [Table/Fig-3,4] has been presented considering 2016 as the base year for two reasons viz., it was the immediately preceding year prior to the price regulation and the number of participating centres in the coronary interventional registry remained relatively uniform after 2016 thereby limiting the chances of any potential interpretation bias.

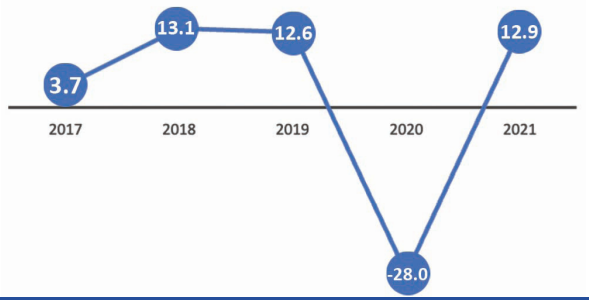
[Table/Fig-5,6] presents the percentage change in the DES pricing for the period 2016-2021 for government as well as private

Variable	Year								
	2021	2020	2019	2018	2017	2016	2015	2014	2013
Number of participating centers	-	751	748	709	705	698	620	396	404
Number of Percutaneous Coronary Intervention (PCI) procedure	401118	355326	493684	438351	387416	373579	355451	248152	216817
Total stents used	-	482778	631915	578164	511389	478770	433650	310190	-
Drug eluting stents (DES)	537498	474571	627050	567295	494769	454159	415350	299078	262349

[Table/Fig-1]: The coronary interventional registry data (2013-2021).

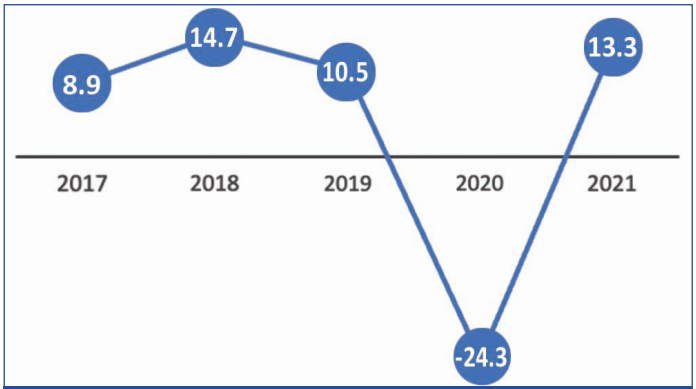
Year	Price (INR)
2021	30811
2020	30647
2019	30080
2018	27890
2017	29600
2016-2013*	40000-65000 (Government Hospitals) 90000-125000 (Private Hospitals)

[Table/Fig-2]: DES price comparison (2013-2021).
*Data from industry sources

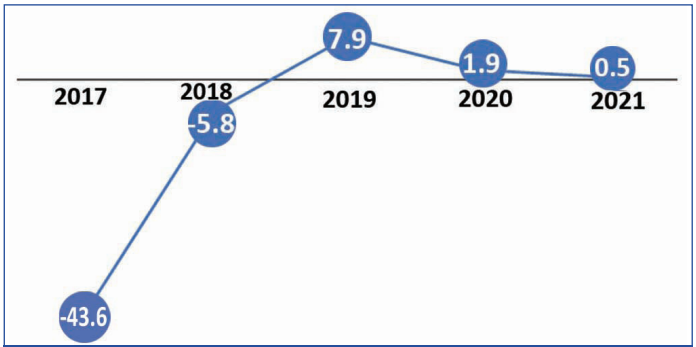


[Table/Fig-3]: Percentage change in the number of PCI procedures for the period 2016-2021.

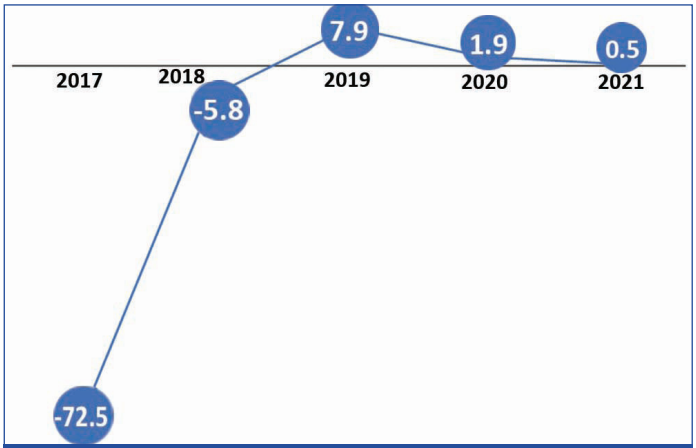
hospitals. The numbers in [Table/Fig-3-6] has been shown to reflect the percentage change on an annual basis based on the data for the preceding and the next year.



[Table/Fig-4]: Percentage change in the usage of DES for the period 2016-2021.



[Table/Fig-5]: Percentage change in the DES Pricing for the period 2016-2021 based on the data for the preceding year (Government hospitals).



[Table/Fig-6]: Percentage change in the DES Pricing for the period 2016-2021 based on the data for the preceding (Private hospitals).

DISCUSSION

The 4A's i.e., Awareness, Availability, Accessibility and Affordability are playing a major role in increasing the number of intervention cardiology procedures over the past few years. The coronary interventional registry established by the National Interventional Council (NIC); CSI is the largest source of coronary intervention data in the country [15]. The data on coronary interventions from centres spread across the country is collected, analysed and published periodically. The high cost of coronary stents was perceived to be a major contributor to a very high out of pocket expenditure in the field of interventional cardiology. Therefore, in order to curtail this high out of pocket expenditure on healthcare, Government of India included coronary stents in the National List of Essential Medicines (NLEM) 2015 on 19th July 2016.

Further, the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, by notification dated 21st December 2016 has incorporated coronary stents as 'scheduled formulations' under the provisions of the Drug Prices Control Order (DPCO), 2013. Finally, the NPPA fixed the ceiling prices in respect of coronary stents via Gazette notification dated on 13th February 2017 [17]. Ever since the NPPA put a ceiling limit on the prices of coronary stents, there has been an annual increase in the number of coronary intervention procedures for the years 2017, 2018, 2019 and 2021, respectively. The only exception being year 2020, where the number of coronary intervention procedures marked a decrease of 28%. This may be attributed to the fact that most of the cardiac catheterisation labs in the country were closed for almost six months owing to the emergence of COVID-19 pandemic. The impact continued in the year 2021 also, when the cardiac catheterisation labs operated to a very little capacity for almost three months.

With the exception of year 2020, the usage of DES has also shown an annual increase for the years 2017, 2018, 2019 and 2021. A decrease in the usage pattern of 24.3% in the year 2020 can be attributed to COVID-19 pandemic. Of the overall stents used, the usage pattern of DES was 97.3% whereas only 2.7% stents deployed are BMS. The NPPA after putting a ceiling limit in the year 2017 reviewed the stent prices on an annual basis. While there has been a significant reduction of 43.6% and 72.5%, respectively in the prices of DES for government and private hospitals in the year 2017, there has been only a marginal increase owning to the fluctuation in the prices of the raw material [16,19-22].

Limitation(s)

One of the major limitations of the study was the lack of financial data to assess the economic impact of coronary stent price regulation on the interventional cardiology field in India. No such financial data is currently available from any reliable data source. Future studies in this regard seem warranted as and when the required financial data becomes available in the public domain.

CONCLUSION(S)

The coronary stent price fixation has played a major role in the exponential growth of coronary intervention procedures as well as the usage pattern of stents in India. NPPA has fixed the prices of different categories of stents in an attempt to make it more affordable with the ultimate aim of reducing the overall healthcare spent by different stakeholders. The same is evident by the steadily increasing number of percutaneous coronary intervention procedures as well as the usage of DES over the years. An increase of 12.9% in the number of coronary intervention procedures and 13.3% in the usage of DES for the period 2016 and 2021, clearly demonstrate the effectiveness of coronary stent price regulation in India. At this juncture when the burden of CAD is on a rise in India, an effective participation of various stakeholders (government, healthcare providers, insurer, medical device/pharmaceutical companies) to make the coronary stents more affordable will go a long way in the efficient management of CAD in the country.

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REFERENCES

[1] WHO: Fact sheets/ Details/ Cardiovascular diseases (CVDs), available from: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds) (Accessed: 7 December 2021).
[2] Global status report on noncommunicable diseases 2010. Geneva, World Health Organization, 2011. (Accessed: 7 December 2021).
[3] Global atlas on cardiovascular disease prevention and control. Geneva, World Health Organization, 2011. (Accessed: 7 December 2021).
[4] Mathers CD, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. PLoS Med. 2006;3(11):e442.
[5] Leeder S, Raymond S, Greenberg H, Liu H, Esson K. A race against time: The challenge of cardiovascular disease in developing economies. New York: Columbia University. 2004 Apr 25.
[6] United Nations- World Population Prospects, available from: https://www.macrotrends.net/countries/IND/india/life-expectancy (Accessed: 8 December 2021).

[7] Gruntzig A. Transluminal dilatation of coronary-artery stenosis. Lancet. 1978;1(8058):263.
[8] Sigwart U, Puel J, Mirkovitch V, Joffre F, Kappenberger L. Intravascular stents to prevent occlusion and restenosis after transluminal angioplasty. N Engl J Med. 1987;316(12):701-06.
[9] Serruys PW, Kutryk MJ, Ong AT. Coronary-artery stents. N Engl J Med. 2006;354(5):483-95.
[10] Kumar A, Sarwal R. 2021. "Health Insurance for India's Missing Middle". Available from: https://www.niti.gov.in/sites/default/files/2021-10/HealthInsurance-forIndias MissingMiddle_28-10-2021.pdf (Accessed: 8 December 2021).
[11] The Economic Times (2021, 29 October). Nearly 30% of Indian population don't have any health insurance: Survey. Available from: https://economictimes.indiatimes.com/industry/banking/finance/insure/nearly-30-of-indian-population-dont-have-any-health-insurance/articleshow/87367884.cms.
[12] Rashtriya Swasthya Bima Yojana- Health Insurance for the Poor, available from: https://www.india.gov.in/spotlight/rashtriya-swasthya-bima-yojana#rsby1 (Accessed: 13 December 2021).
[13] About Pradhan Mantri Jan Arogya Yojana (PM-JAY), available from: https://pmjay.gov.in/about/pmjay (Accessed: 13 December 2021).
[14] National Health Insurance Schemes, available from: https://www.nhp.gov.in/national-health-insurance-schemes_pg (Accessed: 13 December 2021).
[15] Mohanan P. Cardiological society of India. Asia Intervention. 2021;7(2):76-78.
[16] National Pharmaceuticals Pricing Authority. (2017, 13 February). Available from: http://www.nppaindia.nic.in/wp-content/uploads/2019/01/so412e-13-02-17-1.pdf.
[17] Arramraju SK, Koganti S, Janapati R, Emmareddy SK, Mandala GR. The report on the Indian coronary intervention data for the year 2017-National Interventional Council. Indian Heart J. 2019;71(2):146-48.
[18] Arramraju SK, Janapati RK, Sanjeeva Kumar E, Mandala GR. National interventional council data for the year 2018-India. Indian Heart J. 2020;72(5):351-55.
[19] National Pharmaceuticals Pricing Authority. (2018, 12 February). Available from: https://www.srms.ac.in/ims/wp-content/uploads/2015/09/stent-ruling-GOI.pdf.
[20] National Pharmaceuticals Pricing Authority. (2019, 29 March). Available from: http://www.nppaindia.nic.in/wp-content/uploads/2019/12/Final-Stent-Notification-WPI-2019-Eng-29.3.19-v2.pdf.
[21] National Pharmaceuticals Pricing Authority. (2020, 25 March). Available from: http://www.nppaindia.nic.in/wp-content/uploads/2020/07/5-2.pdf.
[22] National Pharmaceuticals Pricing Authority. (2021, 25 March). Available from: https://egazette.nic.in/WriteReadData/2021/226134.pdf.
[23] ET Health World. (2015, 08 April) 2014 NIC Registry reveals 68% rise in patients requiring acute coronary interventions. Available from: https://health.economictimes.indiatimes.com/news/industry/2014-nic-registry-reveals-68-rise-in-patients-requiring-acute-coronary-interventions/46850631

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