https://doi.org/10.48047/AFJBS.6.14.2024.6811-6833

African Journal of Biological Sciences

Journal homepage: http://www.afjbs.com

Research Paper Open Access

CARDIOVASCULAR STENT ADVERSE REACTION: REVIEW AND META-ANALYSIS

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Volume 6, Issue 14, Aug 2024

Received: 15 June 2024

Accepted: 25 July 2024

Published: 15 Aug 2024

doi: 10.48047/AFJBS.6.14.2024.6811-6833

Abstract

According to the degree of risk involved, MDR divided medical devices into four classes: Class A (low risk), Class B (low moderate risk), Class C (moderate high risk), and Class D (high risk). Cardiovascular devices that come under the D Category include bioresorbable vascular scaffold systems, drug-eluting stents, and heart valves. Stents are intricate, tiny, hollow structures with a cylindrical shape that are arranged into a ring pattern using struts and connecting components. The major drawback is postprocedural complications associated with stent implantation such as inflammation, thrombogenesis, and hyper-proliferation of vascular smooth muscle cells. Thus, estimating the prevalence of adverse events following stent implantation is the primary objective of the current research. A meta-analysis of the literature on adverse events resulting from stent implantation was conducted for this study. A computerized search of the primary database literature was conducted from 2000 onwards. In total 102 case studies were selected as per inclusion/exclusion criteria. All studies were thoroughly examined about the type of stent, patient gender, age, reaction start time, adverse event, clinical presentation, treatments, and outcomes. Meta-analysis studies confirmed an incremental rise in adverse events with a significant increase in mortality and the risk of death was almost doubled with the presence of any co-morbidity. A lower target-lesion revascularization and incidence of stent thrombosis with newer-generation devices as compared to 1st generation DES and BMS. With the development and improvement of coronary stents, particularly second-generation DESs, the long-term outcome after PCI has improved dramatically. However, the combination of personalized medicine and an improved stent platform with cell-selective drugs has the potential to solve the remaining challenges and improve the care of coronary artery disease patients.

Keywords- adverse event, coronary stent, cardiovascular disease, meta-analysis

Innovations in automation and wireless technologies, drug-device combination products, advanced clinical use of devices, and other fields have made it possible for the use of medical devices in healthcare settings to grow rapidly [1]. India's medical device market is projected to

grow from US$ 11 billion in 2020 to US$ 65 billion in 2024[2,3] But for a very long time, there was no effective mechanism in place to keep an eye on adverse incidents associated with medical devices [4]. At first, the Drugs and Cosmetics Act of 1940 and the rules of 1945 regulated the marketing of medical devices. In 2017, the Indian government published the 2017 Medical Devices Rules (MDR) which govern the usage of medical devices across the nation. The regulations went into force on January 1, 2018. The Indian Pharmacopoeia Commission will function as the national coordinating centre for the materiovigilance program, which was approved for development by the Indian Health Ministry.

According to the MDR, the devices are divided into four classes: Class A (low risk), Class B (low moderate risk), Class C (moderate high risk), and Class D (high risk), depending on the level of risk entailed. Heart valves, drug-eluting stents, bioresorbable vascular scaffold systems, over-the-wire thrombectomy sets, cardiac pacemakers, cardiac portable monitors, and other devices fall under the D Category of cardiovascular devices. Manufacturers of medical devices, particularly those related to cardiovascular health, are required to comply with the risk-proportionate regulatory requirements set provided in the Rules, which are based on best international practices [5].

Heart conditions are the primary cause of hospitalization and death worldwide, creating an ever-greater threat to human life. In particular, coronary artery disease (CAD) is the third biggest cause of death worldwide, putting a significant financial and medical strain on most developed nations. Plaque accumulation underneath the endothelium causes artery constriction, which is the primary feature of CAD. [6]. Atherosclerosis is the term for the accumulation of plaque that blocks an artery. When the condition progresses, the artery gets significantly narrower, and in the worst scenario, it becomes blocked [7].

In order to restore normal blood flow and stop additional potentially fatal effects of vascular narrowing, specially designed devices known as stents can be inserted into the injured vessel under fluoroscopic and/or endoscopic supervision. This procedure is less invasive than open heart surgery and has been associated with better short-term outcomes for patients in critical condition as well as lower long-term mortality and morbidity [8]. Stents are minuscule, intricate, hollow structures that have a cylindrical form. Several struts and connecting pieces are organized into a sequential ring construction [9]. Their primary function is to clear the obstruction in the artery or to stop elastic arterial reversibility after artery dilatation or balloon angioplasty.

The functionality of stents is dependent on their design, which aids in maintaining the open passage of human arteries throughout the body [10]. Stenting has benefits over other therapies, including less complexity, less pain, quicker healing, and no surgery [11].

Stents are a smart substitute for surgery, which was initially proposed by Grüntzig in 1977 with balloon angioplasty (BA) [12]. Nowadays, angioplasty or percutaneous coronary intervention is used to implant three main types of coronary stents in coronary arteries. These types of stents are as follows:[13].

- Bare-Metal Stent (BMS): These are tubular, mesh-like devices without any medication incorporated in them. They are composed of platinum chromium, cobalt chromium, or stainless steel. Heart stents were first implanted using BMSs made of stainless steel. They were effective in reducing the occurrence of abrupt arterial closure and restenosis in comparison to balloon angioplasty, which therefore reduced the rate of target lesion revascularization [14,15].
- Drug-eluting stents (DES): These stents are covered with drugs that deliver medicaments directly to the arterial wall. A medication is gradually released by DES to

lower the chance of stent restenosis, stop scar tissue from growing, and prevent re-blockage of the artery. The first DES entered European markets in 2002. DES development changed over several generations. The stainless-steel scaffolding of the first generation of DES was coated with either paclitaxel or sirolimus, while the second generation of DES was loaded with either zotarolimus or everolimus. Cobalt-chromium scaffolding with various polymer coatings is used in second-generation DES, enabling reduced strut thickness, better eluting profiles, higher biocompatibility, improved flexibility, and superior re-endothelialization [16,17].

- Bioresorbable Vascular Scaffold (BVS): a non-metallic mesh tube that functions similarly to a stent but gradually dissolves when the clogged artery regains its ability to function normally and remains open. Equivalent to a tiny mesh tube [18,19].

Though stenting is less invasive than other angioplasty treatments, it has gained popularity and acceptance as a safer approach. The multifactorial character of stent failure, including age, gender, and co-morbidity, is still recognized [19]. In-stent restenosis (ISR) and other postprocedural problems, including inflammation, thrombogenesis, and hyperproliferation of vascular smooth muscle cells, are the main disadvantages of stent implantation. Drug-eluting stents (DES) have lower rates of restenosis and target lesion revascularization than bare metal stents (BMS), which has a significant impact on how coronary artery disease is treated interventionally. However, observations in both BMS and early-generation DES also show how important it is for physiological responses brought on by implantation trauma and exposure to stent components [20]. As second and third-generation DES are developed, it can be reduced by as much as 15%, depending on the lesion [18]. Thus, the current study's objective is to conduct a comprehensive review and meta-analysis of adverse events associated with cardiac stents.

METHOD

A comprehensive literature review of published articles was performed using Medline, Embace, and Google Scholar databases from 2000 onwards to identify documented cases of stent failure. The research methodology used is a combination of the following terms "cardiac implant failure", "case study of stent failure" and "adverse event with cardiac stent". Titles and abstracts of all identified studies were carefully reviewed in terms of stent type, patient gender, age, period of onset of reaction, adverse event, clinical presentation, outcome, and treatment. Conference proceedings and conference abstracts were not included in the search because of the limited presentation of results in abstract format. Manuscripts in languages other than English were excluded. Retrieved results were de-duplicated. Unrelated studies were discarded and those potentially eligible were examined for their inclusion.

Inclusion Criteria:

- ✓ Studies that compared the outcome and the incidence of reaction with stent, stent breakage, or any other periprosthetic reaction after the stent implantation were included
- ✓ Patients of both genders regardless of their age will be included.
- ✓ The case should be valid (a suspected medical device, an adverse reaction, an identifiable patient, an identifiable reporter)

Exclusion Criteria:

- ✓ Patients with intentional or accidental breakage or reaction with stent will be excluded.
- ✓ Pregnant women will be excluded from studies.

RESULTS

In total 102 case studies were selected as per inclusion criteria. The patient population was divided into three categories young age (less than 40 years), Mid age (40-60 years), and elderly people (greater than 60 years). Tables 1 and 2 depict demographic details of patients having stent failure cases. The majority of patients are within the age group of 60+ years with a mean age.57 At baseline the male had a higher rate of stent failure as compared to women in each age group (75.4% Vs 24.5%). At baseline, the elderly had higher rates of co-morbid conditions such as hypertension, coronary disease, renal insufficiency, and diabetes. The non-elderly group (41-60) was more likely to have a history of smoking. Almost 29.4% of cases from both elderly and non-elderly groups have no history.

TABLE 1: MALE VS FEMALE CARDIAC STENT REACTION

	Age Range					
Gender	**0-40**		**41-60**		**60+**	
Female	3	38%	11	24%	11	22%
Male	5	63%	34	76%	38	78%
Total	**8**		**45**		**49**	

TABLE 2: DEMOGRAPHIC DETAILS OF PATIENTS INCLUDED IN THE STUDY

	Age Group		
Patient History	0-40	41-60	60+
Hypertension	1	13	12
Coronary Disease	1	5	6
Renal Disease	1	0	4
Smoking	4	5	4

Diabetes	0	2	5
Allergic Reaction	0	1	1
No History	0	16	14
Other	1	3	3
Total	**8**	**45**	**49**

Table 3 depicts the incidence of stent reactions. A majority of Adverse events were of Thrombosis (48%) followed by stent migration (12.7%), Aneurysm (10.7%), Stent fracture (9.8%), occlusion of the stent (5.8%) and cardiac shock (5.8%). Less frequently reported adverse events were allergic reaction (2.9%), hemopericardium (0.98%), stenosis (0.98%), stent balloon not deflating (0.98%), and death (0.98%). Thirty-six ADRs required discontinuation of the device. out of 102 patients. Figure 1 shows the association of stent reaction with different age groups and it was observed that the most commonly adverse reaction is thrombosis in the elderly age group that is greater than 60 years. The relationship between age, gender, and adverse reaction is graphically shown in Figure 2.

TABLE 3: INCIDENCE OF ADVERSE REACTION

	Age Range			**% Total**
Reaction Type	**0-40**	**41-60**	**60+**	**Cases**
stent balloon does not deflate	-	1	-	0.98%
Thrombosis	4	19	26	48.04%
Stent Fracture	2	3	5	9.80%
Occlusion of stent	-	3	3	5.88%
Stent Migration	-	8	5	12.75%

Cardiac Shock	-	2	4	5.88%
Stenosis	-	-	1	0.98%
Aneurysm	1	6	4	10.78%
Hemopericardium	-	1	-	0.98%
Death	-	1	-	0.98%
Allergic Reaction	1	1	1	2.94%
Total	**8**	**45**	**49**	**100.00%**

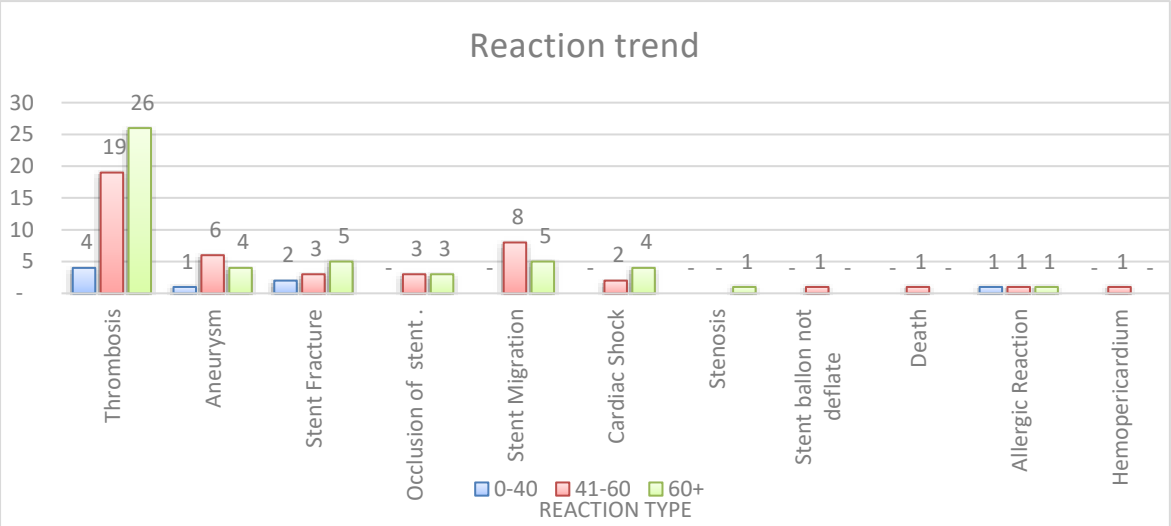

Fig.1: Age-wise incidence of stent reaction

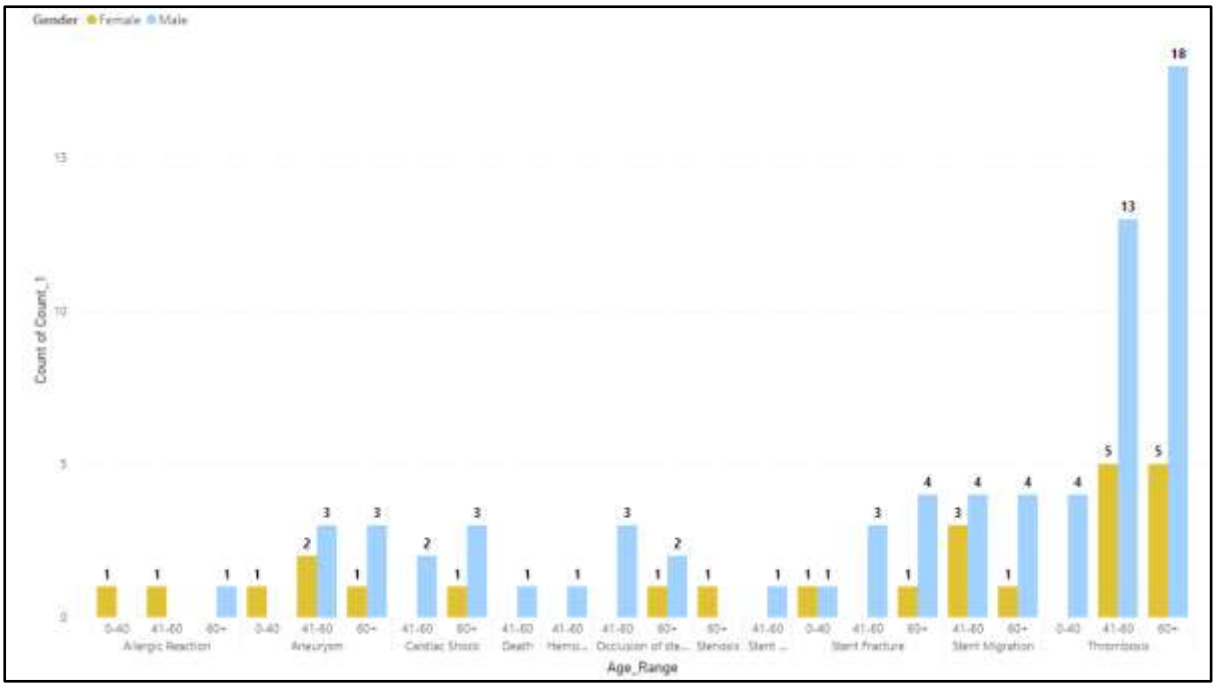

Fig. 2: Association of Gender, Age, and adverse reaction

The patient demographics of those having DES implants and BMS implantations were largely comparable. Sixty-five percent of the reactions in the 102 reaction cases came from first-generation DES, which includes paclitaxel- and sirolimus-eluting stents. Thrombosis accounts for 55% of reported reactions with first-generation DES. 20% of responses to bare metal stents are mostly related to stent migration (37%). Following BMS, thrombosis adverse response rates are remarkably low (8.33%) for second-generation DES (everolimus-eluting stent, biolimus eluting stent, zotarolimus-eluting stent) and multiple stents. Figure 3 displays the percentage of response cases by type of implant, and Table 4 illustrates the association between reaction nature and implant type. The percentage distribution of history by implant type is shown in Figure 4. The percentage distribution of age by implant type is displayed in Figure 5.

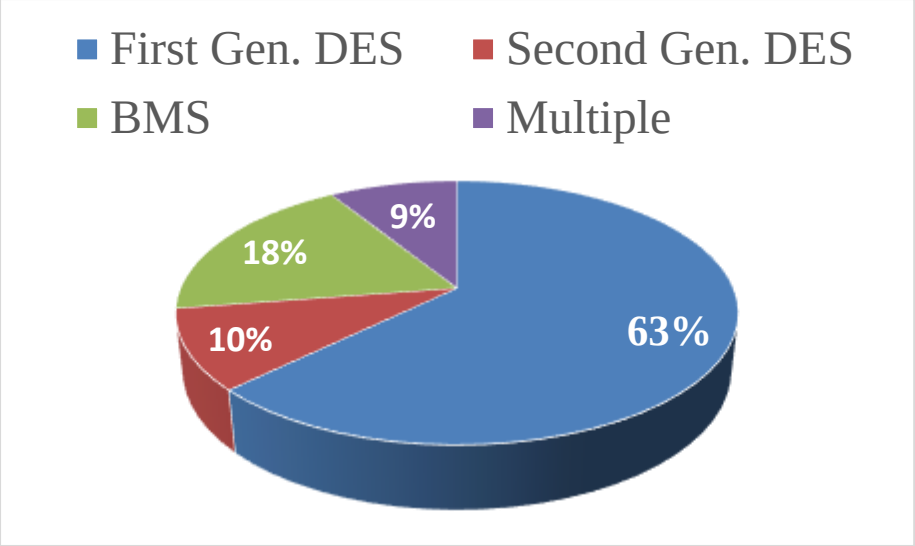

Fig. 3: Reaction percentage for various implant type

TABLE 4: RELATIONSHIP B/W NATURE OF REACTION AND IMPLANT TYPE

Nature of Reaction	**First Gen. DES**	**Second Gen. DES**	**BMS**	**Multiple**
Allergic Reaction	2	1	-	-
Aneurysm	8	-	1	2
Cardiac Shock	5	-	1	-
Death	1	-	-	-
Hemopericardium	-	-	1	-
Occlusion of stent	-	-	-	-
Stenosis	-	-	1	-
The stent balloon not deflate	1	-	-	-
Stent Fracture	5	3	2	-
Stent Migration	6	-	7	-

Thrombosis	33	4	6	6
Total	**61**	**8**	**19**	**8**
Percentage	**63.54%**	**8.33%**	**19.79%**	**8.33%**

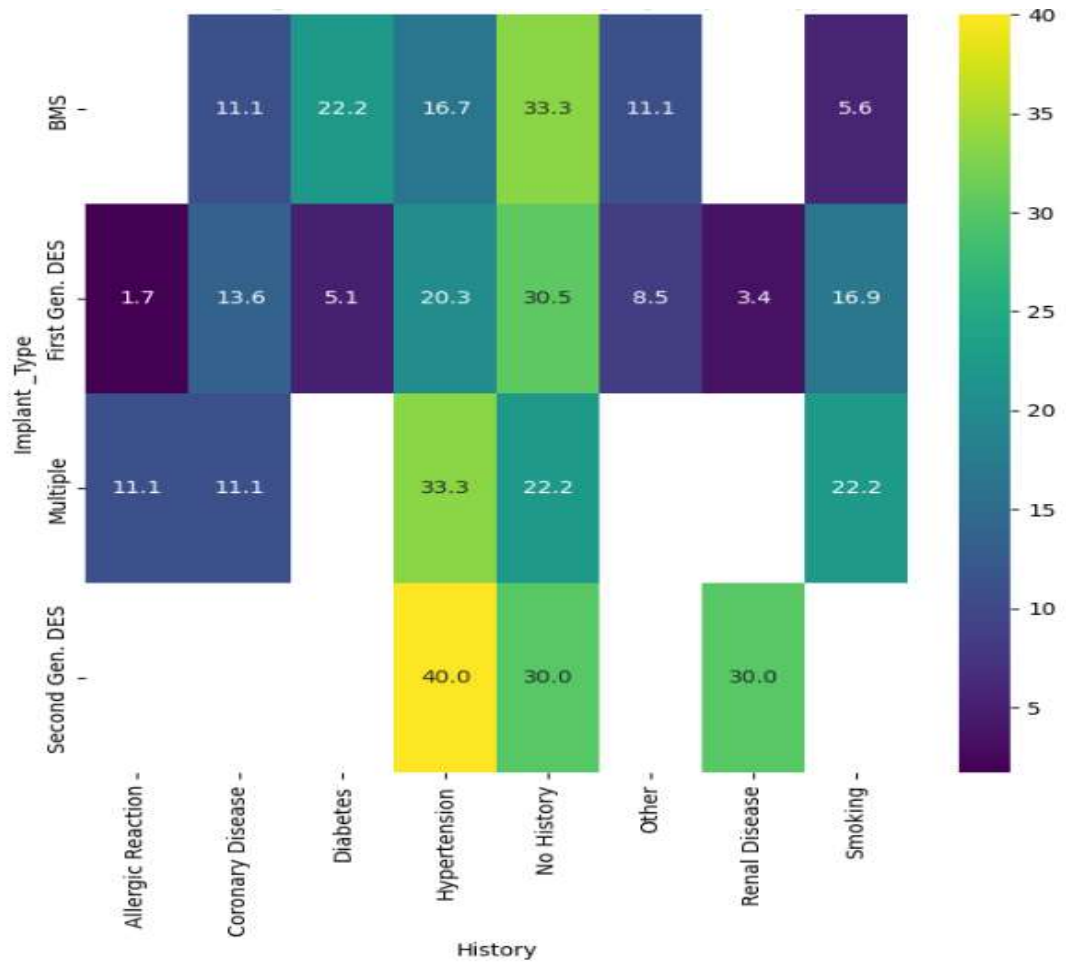

Fig. 4: Percentage distribution of history by implant type

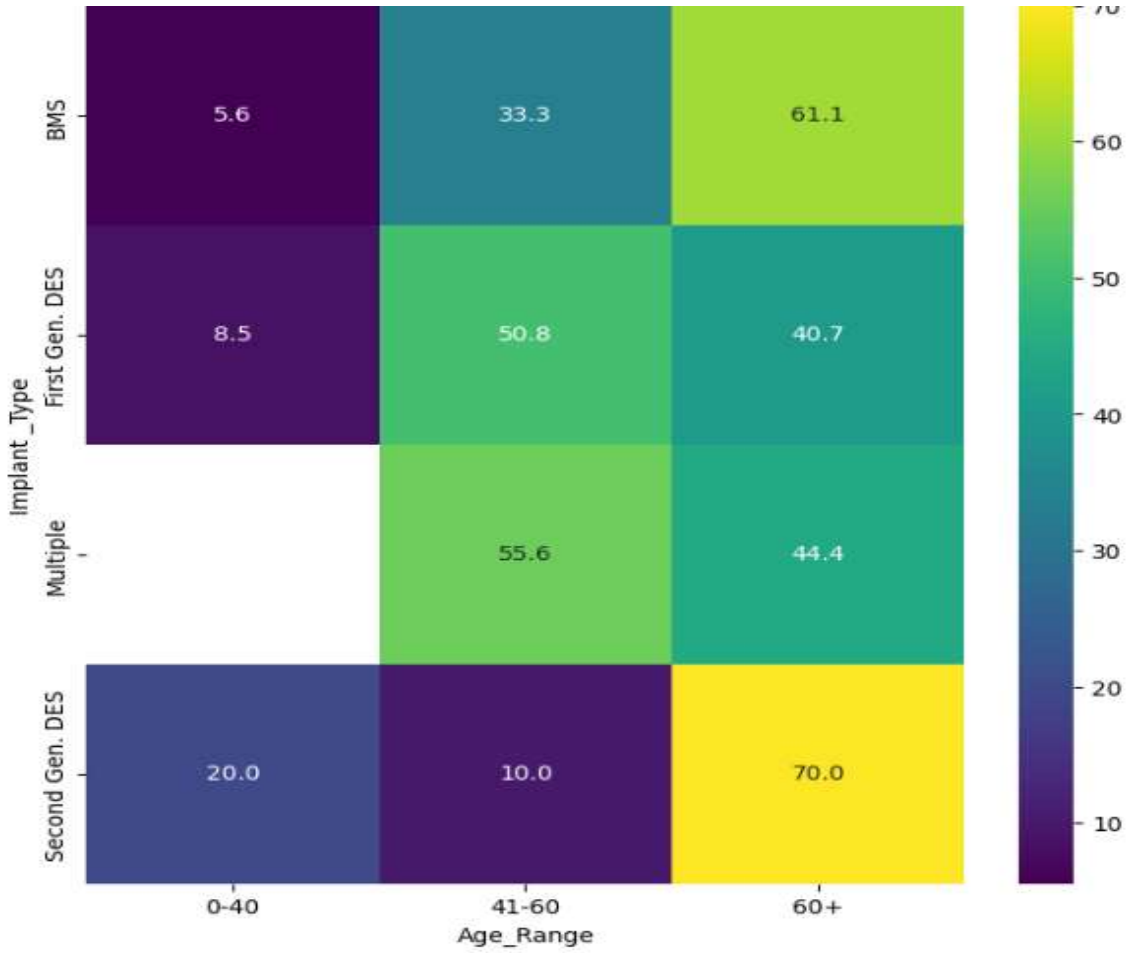

Fig 5: Percentage distribution of age by implant type

The various management techniques for stent reactions are shown in Table 5. Findings indicate that the main side effect of a cardiac stent is thrombosis. Therefore, thrombosis can be mitigated by Antiplatelet treatment. Triple antithrombotic therapy, which combines dual antiplatelet therapy with an oral anticoagulant (OAC), is an alternative to dual antiplatelet therapy, which consists of aspirin and clopidogrel. Additional treatments for treating thrombosis include thrombectomy and balloon angioplasty. For managing various types of stent reactions, additional treatment options such as stent removal, coronary bypass grafting, catheter intervention, stent covered, etc are also available. Figure 6 shows the percentage distribution of reactions per category of treatment.

TABLE 5: MANAGEMENT STRATEGIES FOR REACTIONS TO STENTS

Nature of Reaction	**Ballon Angioplasty**	**Dual /Triple Antiplatelet Therapy**	**Stent removal**	**Coronary bypass grafting**	**Aneurysm removal**	**Thrombectomy**	**Covered stent**	**Death**	**Catheter intervention**	**Others**
Stent ballon not deflate	1	-	-	-	-	-	-	-	-	-
Thrombosis	9	19	1	1	1	9	1	2	4	2
Stent Fracture	2	1	3	1	1	-	-	-	-	2
Occlusion of stent	-	2	1	1	-	-	-	-	1	1
Stent Migration	-	2	9	-	-	-	-	1	-	1
Cardiac Shock	1	-	-	2	-	-	2	-	-	1
Stenosis	-	1	-	-	-	-	-	-	-	-
Aneurysm	-	3	1	3	2	-	1	-	-	1
Hemopericardium	-	-	-	-	-	1	-	-	-	-

Death	-	-	-	-	-	-	-	1	-	-
Allergic Reaction	-	1	-	-	-	-	-	-	-	2
Total No's of Cases	**13**	**29**	**15**	**8**	**4**	**10**	**4**	**4**	**5**	**10**

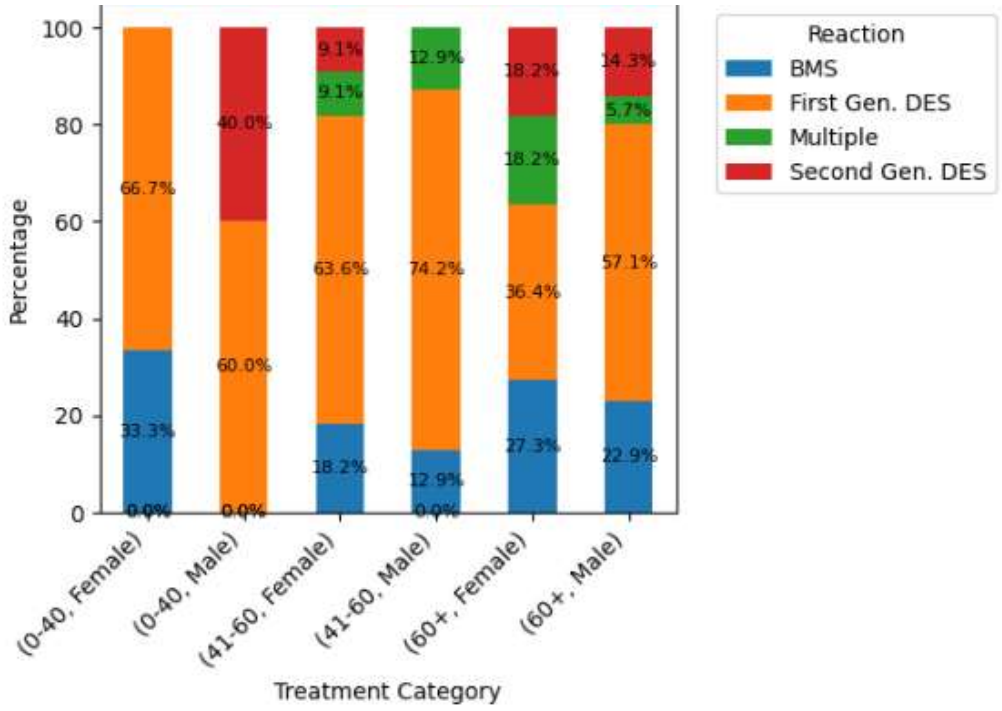

Fig. 6: Percentage distribution of reactions by treatment category

DISCUSSION

Heart valves, drug-eluting stents, bioresorbable vascular scaffold systems, over-the-wire thrombectomy sets, cardiac pacemakers, cardiac portable monitors, and other devices fall under the D Category of cardiovascular devices. Manufacturers of cardiovascular-related products must adhere to the risk-proportionate regulatory standards outlined in the Rules, which are based on best worldwide practices [21].

We assessed the frequency and prognostic significance of co-morbidities in CHD patients in the current study, and we found a significant co-morbidity burden in CVD patients. Since older patients have multivessel disease compared to younger patients, there were differences in the baseline features between elderly and non-elderly PCI patients. Compared to younger patients, they have a higher prevalence of comorbidities like heart failure, renal insufficiency, and hypertension. The elderly are therefore more likely to experience adverse reactions from coronary stents [22,23]. Comorbidities also contribute to a higher rate of in-hospital complications in older patients receiving modern PCI.

Multiple studies have demonstrated that hypersensitivity to alloy components in metal stents causes local inflammation. Bare-metal stents can experience in-stent restenosis (ISR), and restenosis may be aggravated by metal hypersensitivity. Whether metal allergy causes ISR directly is unknown. It is distinguished by the gradual, steady development of a fibrotic extracellular matrix, which usually takes place in the first 7-9 months following implantation. Acute coronary syndrome (ACS) was commonly caused by ISR, and the use of DESs, as compared with BMSs, dramatically decreased the frequency of ISR and target lesion revascularization [24]. Therefore, DESs are recommended over BMSs, except for the requirement of prolonged dual antiplatelet medication. The risk of instent restenosis was reduced by first-generation DES, such as the Cypher sirolimus-eluting stent (SES, Cordis Corp., Miami Lakes, FL, USA) and the Taxus paclitaxel-eluting stent (PES, Boston Scientific, Natick, MA, USA); however, the safety of these devices became compromised by an increase in the risk of late in-stent thrombosis due to delayed arterial healing and undesirable hypersensitivity reactions.[25].

Research using meta-analyses verified that, when compared to first-generation DES, stent thrombosis was less common with these devices. The evolution of coronary stents, especially

second-generation DESs, has significantly improved the long-term prognosis following PCI. Although the exact causes of late thrombosis following DES and BMS implantation are unknown, partial stent expansion, a lack of endothelialization, and inadequate antiplatelet treatment are probable contributing factors. Both the polymeric coating (in the case of DES) and the metal matrix of the stent may induce hypersensitivity reactions. A polymer matrix included in the structure of DES enables the introduction of antiproliferative medications to stop the proliferation of vascular smooth muscle cells. Biostable polymeric drug carriers, such as poly (ethylene-co-vinyl acetate) (PEVA), poly (n-butyl methacrylate) (PBMA), and poly (styrene-b-isobutylene b-styrene) block polymers (SIBS), served as the foundation for the first generation of DES. There have been reports of hypersensitivity reactions and polymer coating persistence following medication release, which results in inadequate reendothelialization and failing late stent thrombosis. Consequently, biodegradable polymers were used in the development of second-generation DES, which can degrade (in 6–24 months) after its purpose has been served. As a result, there were fewer late and extremely late stent thrombosis and hypersensitivity reactions [26].

Chemical and mechanical forces are the causes of coronary artery aneurysms, which are uncommon. Metal allergies, polymer-induced hypersensitivity, and infections are examples of chemical factors. Mechanical factors include SFs, excessive balloon or stent dilatation, residual dissection, and deep artery wall damage from wire insertion into the false lumen. Another possible cause of CAA might be excessive balloon inflation. Appropriate care of CAAs is crucial since consequences such as thrombosis, distal embolization, ACS, and rupture can be deadly [27].

According to this analysis, percutaneous coronary intervention with DES was listed as the second most successful treatment, while PCI with second-generation DES was considered to

be the most effective treatment. Similar results from meta-analyses have shown that second-generation DES is the preferred course of treatment for BMS and reactions related to DES. There are multiple ways to handle stent-related adverse effects. Medications include antiplatelet and anticoagulant treatment, coil embolization, percutaneous covered-stent implantation, and surgical techniques are employed. Nonetheless, there are no established protocols for the handling of stent reactions [28,29].

The evolution of coronary stents, especially second-generation DESs, has significantly improved the long-term prognosis following PCI. To customize healthcare decisions and treatments for each patient, tailored treatment that takes into account the patient's genetic makeup, lifestyle, and surroundings is needed in combination with technological advancements in stent design. In the clinical context, genetic testing will assist doctors in making decisions that will enhance PCI results and reduce overall healthcare costs.

Conclusively compared to younger patients, it is apparent that older patients are more likely to be high-risk patients with comorbidities such as heart failure, renal insufficiency, and hypertension. According to our research, co-morbid burden significantly impacts adverse reactions in PCI patients. When consulting patients on the risks and advantages of treatment, as well as when allocating resources, the assessment of co-morbid burden in PCI patients should be taken into consideration. According to the meta-analysis's findings, stent thrombosis is the most common adverse event among older adults with the highest number of co-morbidities associated with first-generation DES. In contrast to bare-metal stents, PCI for acute ST-segment elevation myocardial infarction patients is safe and enhances clinical outcomes by lowering the risk of reintervention. Our results also show that, in comparison to first-generation DES, more recent DES is turning out to be substantially safer and more effective. Even as interest in bioabsorbable stents grows, DES technology is evolving. The second generation of

DES has demonstrated encouraging outcomes with improved stent design and increased biocompatibility with release kinetics. While ZES and second-generation EES are more effective than PES, they are not as successful as first-generation SES. Only second-generation EES, however, considerably decreased the incidence of MI and ST, and as such, it should be regarded as the safest DES to date.

ACKNOWLEDGEMENTS

We acknowledge the amenities and infrastructure provided by Sushant University, Gurugram, which helped with the creation of this research. We also thank Prof. Rakesh Ranjan, the esteemed vice chancellor of Sushant University, and Prof. Sanjeev Sharma, the dean of the school of health sciences, for their continuous support and guidance in carrying the project forward to completion.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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TABLE AND FIGURE TITLES AND LEGENDS

TABLE 1: MALE VS FEMALE CARDIAC STENT REACTION

TABLE 2: DEMOGRAPHIC DETAILS OF PATIENTS INCLUDED IN THE STUDY

TABLE 3: INCIDENCE OF ADVERSE REACTION

TABLE 4: RELATIONSHIP B/W NATURE OF REACTION AND IMPLANT TYPE

TABLE 5: MANAGEMENT STRATEGIES FOR REACTIONS TO STENTS

Fig.1: Age-wise incidence of stent reaction

Fig. 2: Reaction percentage for various implant types

Fig. 3: Association of Gender, Age, and adverse reaction

Fig. 4: Percentage distribution of history by implant type

Fig 5: Percentage distribution of age by implant type

Fig. 6: Percentage distribution of reactions by treatment category