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The Classification, Comparison and Behavior of Coronary Stents: A Focused Review on Materials and Clinical Studies & Complications

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Abstract

In the past two decades, cardiovascular disease has become one of the leading causes of death in the world. For treatment of these diseases, according to the patient's conditions, methods such as drug therapy, balloon angioplasty, stent implantation, and bypass surgery are used. Stent implantation can be considered the most common way to treat these diseases. In this article, considering the special importance of stents, we examine them. We classify the stents based on their design and point out the effect of the design on some of the properties of the stents. Also, we introduce the different generations of stents and compare them. Finally, we will examine some of the features of the artery wall and the behavior of the stent in the arteries. And we talk about the bad effects the stents can have on the body.

Introduction

The main task of the circulatory system is to provide the materials needed by all the biological cells of the body and to dispose of waste from cellular metabolism. Circulatory system consists of the heart and blood vessels. The heart is a muscular pump that pumps blood into the body. Blood vessels are a network of tubes that carry blood throughout the body and provide oxygen, nutrients, water and hormones, therefore; the presence of any disorder in blood supply can cause serious problems.

In recent decades, due to the progress of the industry, the life style of many people around the world has changed, which hazarded the health of people and made cardiovascular disease the world's leading cause of mortality. Cardiovascular diseases effect on function and structure of the heart and blood vessels. Coronary artery disease is one of the most common cardiovascular diseases, that it affects more than five million Americans each year.

The heart muscle requires a constant supply of oxygen and nutrients for the proper and healthy functioning of the heart; this is the responsibility of coronary arteries. In normal state, the arteries have a smooth, elastic inlay that allows blood to flow freely. Blood consists of fatty substances that are stick to the internal walls of the arteries. The onset of this disease is a gradual process that can begin before a person's adolescence and at older ages can cause the formation of fat masses on the walls of the arteries and, consequently, damage to the walls of the blood vessels. Cells release a kind of white blood cells for repair, but the process itself over time makes the walls of the vessels more sticky; therefore, other substance such as proteins, calcium and inflammatory cells-that are suspended in bloodstream- stick to the walls of the vessels and combine with the fat, the product substance, called plaque. Over time, plaque continues to build upon the walls of the arteries. As the plaque expands, the arteries become narrow and hard. This process is called Atherosclerosis. This process is commonly known as hardening of the vein, because the builds up of plaque, makes the walls of the artery thicker and restricts blood flow through the area that is supplied by the artery, so; the heart can't receive blood, oxygen and nutrients it needs.

There are various therapeutic options for treating coronary artery disease. The doctor's recommended treatment depends on the symptoms of patient and degree of damage to his heart. Treatment options can include:

• Drugs

Blood diluents such as Aspirin, Beta blockers and etc. can prevent arterial occlusion.

• Balloon angioplasty

Coronary balloon angioplasty is a process used to open blocked heart arteries. This method, involve the temporary placement of a small balloon in the artery obstructing area and inflate it to help expand the arteries.

• Coronary stent implantation

About one third of patients who have been using balloon angioplasty to open their vascular obstruction have been restenosis within six months, therefore; in most people

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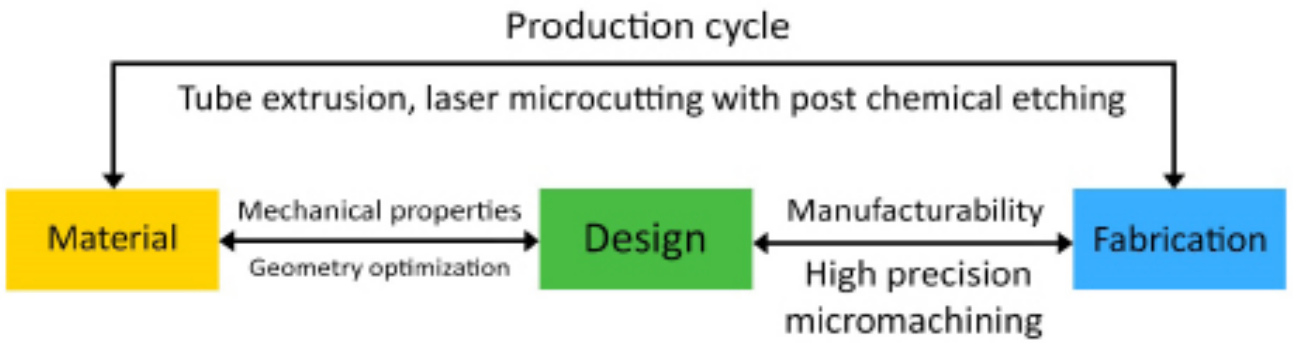

Figure 1: The interactions and aspects used in the design and fabrication of the biodegradable stents

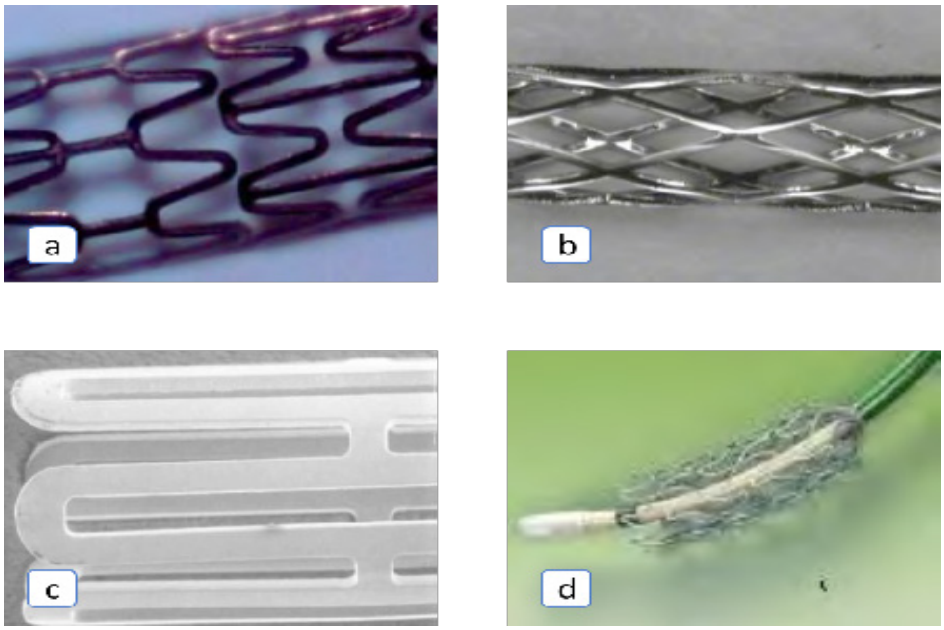

Figure 2: Different type of stents base on design: a) Tubular wire; b) Tubular mesh; c) Slotted tube; d) Coil [2]

undergoing angioplasty, during a process similarly, a tool called a Stent is also placed in the blocked artery. The stent is usually inserted into the artery after expansion of the artery by inflating the balloon. A stent is a latticed, metal scaffold that keeps the artery open and stays there permanently. Stent also reduces the odds of heart attack.

• Bypass surgery

Another treatment for the narrowing of the arteries is Bypass surgery; this involves the graft of a blood vessel from the chest, leg, or forearm to the coronary artery to redirect the blood around the blockage area. As result of this surgery, blood will reach the heart.

Coronary Artery Stents: Clinical Practice, Identification and Evaluation

The efficacy of medical devices such as stents depends on different factors such as material, design of mesh geometry and fabrication as demonstrated in Figure 1. Although; the role of these three aspect seem discrete, but they are highly connected to each other. The design of stent is required to exploit the material characteristics in order to fulfill most duties of stents. The method of fabrication should incorporate realizing and maintaining the material with design properties, which tolerance levels and quality reflect the biocompatibility of the stent [1].

As demonstrated in Figure 2 on the basis of stent design, stents divided into four types:

1. Slotted tube (made from tubes of metal)
2. Coil (characterized by metallic wires or strips which are formed into circular coil)
3. Tubular mesh (wires wound together in order to form a tube)
4. Tubular wire

These designs may have some differences in different aspects such as width or overall diameter, strut pattern and etc. Design of stents affects some properties such as elastic radial recoil and rigidity, it also has influence in on Neointima proliferation, late lumen loss and restenosis rates. Some stent characteristics such as flexibility and trackability (ability to conform to tortuous vessels) rely on stent design but radiological visibility and biocompatibility depend on stent material. Other noticeable characteristics are low crossing profile, easy deployment, minimal Foreshortening, low metallic surface area, minimal Elastic Longitudinal Recoil, optimum Scaffolding, high radial strength [2].

The most concerns about implanting stents are risk of stent thrombosis and delayed endothelialization [3]. There are other complications such as:

1. In stent restenosis
2. Side branch occlusion
3. Poor stent biocompatibility
4. Poor radiographic properties
5. Post-implantation stent foreshortening
6. Post-implantation stent expansion
7. Post-implantation stent migration [2]

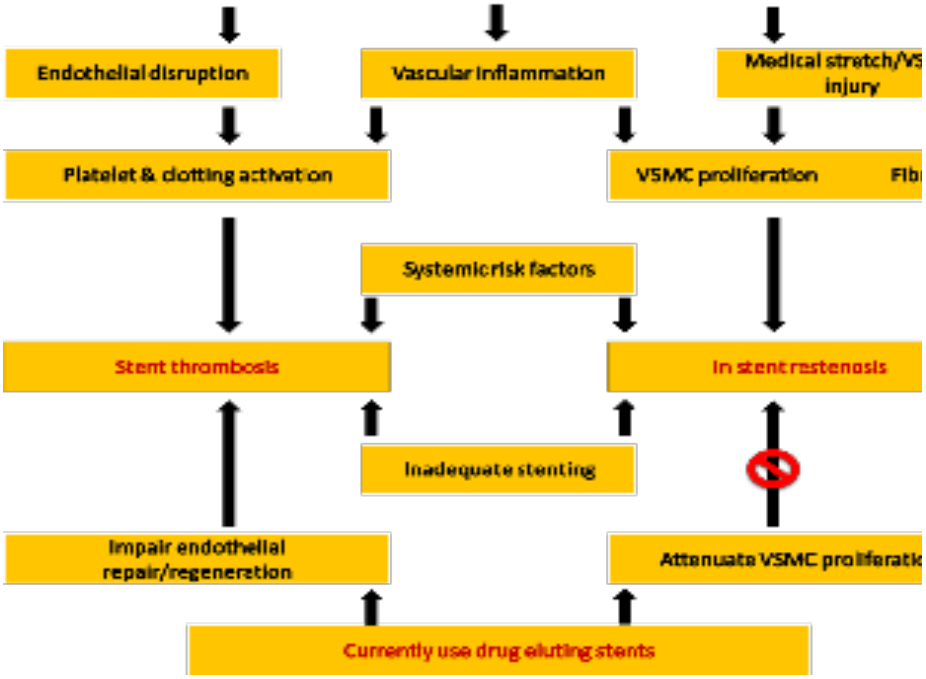

Figure 3: Pathophysiological impact of angioplasty, stenting and drug-eluting stents. Angioplasty and stenting induces initially induced medial vascular smooth muscle cell (VSMC) necrosis, which leading to in stent restenosis (ISR).

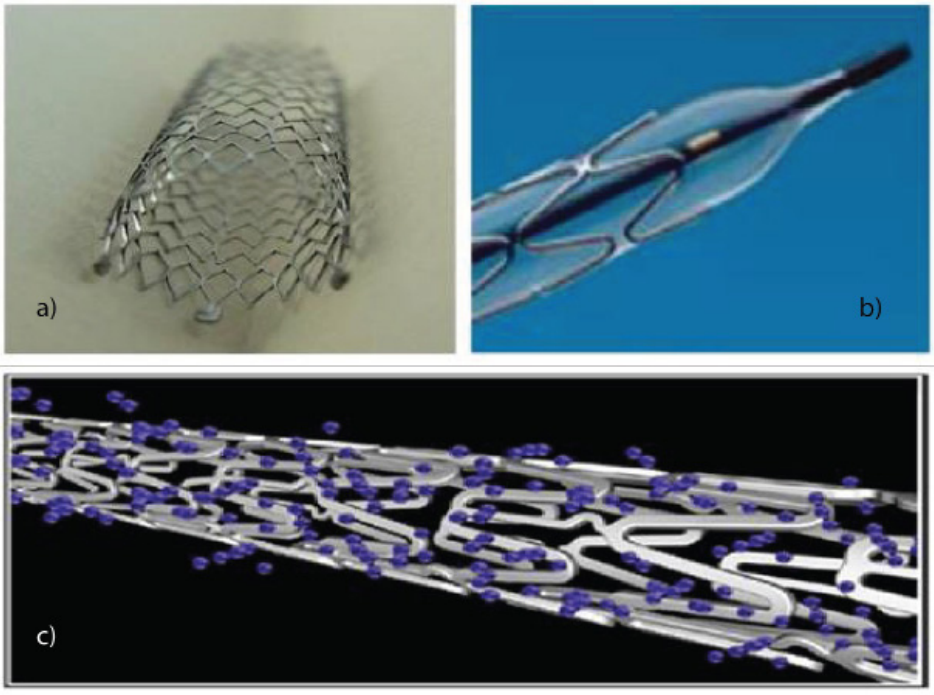

Figure 4: Different generation of stents, a) the schematic of bare metal stent (BMS), b)the BMS with inflated balloon and c) the drug eluting stent (DES) [6]

The Figure 3 shows impact of angioplasty, stenting and drug-eluting stents.

Comparison of different generation of stents

There are three different types of stents. The first type is bare-metal stents (BMS); second and third types are drug eluting stents (DES). Classification of DES stents are in two generations, first and second generation DES. Although they have same general components but their difference is in drug, which coats the surface of stent, polymer and stent platform. We can notice sirolimus-eluting stent (SES), approved in 2003, and paclitaxel-eluting stent (PES), received FDA approval in 2004, as first generation DES [4]. The Zotarolimus-eluting stent (ZES) and an everolimus-eluting stent (EES) are two types of second generation DES [5].

The Figure 4 demonstrates the different generation of stents. Each type of stents has some complication and causes inflammation [6].

There are two different type of stent BMS and DES. Each type has some complication and causes inflammation. The use of BMS over the past two decades has become a common method for the treatment of coronary artery occlusion. These metal stents have many drawbacks, such as:

1. Due to the high surface tensile of metals, their surface is clotting

2. In long run cause corrosion, instability and perforation of the vessel wall

3. In long term; additional tissue builds up occurs

4. The restenosis is a problem it is common among patients with this stents [7].

Metal alloys of bare metal stent, initially 316 L stainless steel (316 L SS), are incompatible with the vasculature, in which promoting thrombosis due to their surface properties. Death attributed to stent implantation within the first 30 days, adjudicated as stent thrombosis [8]. After the early thrombosis risk has abated restenosis, a major cause of bare metal stent failure, driven by an uncontrolled immune response [9].

After implantation of BMS, the patient must use special drugs in order to reduce restenosis but because of low drug concentration and non-specifically targeting the lesion revascularisation, the Systemic drug administration was unsuccessful [10].

Using DES provides both biological and mechanical solution is promising approach in treatment of in stent restenosis [11,12]. In order to have successful drug delivery should face with different challenges such as:

1. Decision of using the most appropriate agent

2. Determining proper dose which needed locally

3. Identifying biocompatible device in order to deliver drugs [13].

There are four different classes of drugs: anti-inflammatory, antiproliferative, immunosuppressive and antithrombogenic. These drugs inhibit some pathways that leads to restenosis [14,15].

Paclitaxel, rapamycin-Zotarolimus, Tacrolimus, Biolimus A9 and Everolimus are some of drugs that used in DESs [16].

In comparison to BMS, drug eluting stents significantly reduce restenosis rate due to locally releasing anti-proliferative agents [17]. The use of drug-eluting stents led to a tremendous transformation in the treatment of coronary artery disease due to reduction in the rate of in-stent restenosis from 20-40 percent, but by using BMS reduction rate is 6-8 percent [18]. Contrary to expectations, studies have shown that the use of DES has been accompanied by increased mortality in long run after surgery. Although; these findings are not statistically notable. Since DES were widely used, several safety concerns related to them. For example one of the most concerns raised in this kind of stent is thrombosis, an issue that results coronary artery closure, which can lead the patient to death significantly after first year of implantation [19], so it may be necessary to treat antithrombotic for a longer period in these patients [20]. These stents also due to require blood diluents, to prevent from artery blockage by blood clotting, less recommended for people with bleeding problems and persons that require some types of surgery during one year after stenting.

Regarding the observation of long term stent thrombosis in first generation DES, second generation DES was developed with the new generation polymer. These stents use a permanent but biocompatible polymer that based on Cobalt or Platinum chromium alloys [21,22]. They are thinner and more tolerable than first generation. In addition; the second generation is more biocompatible than the first generation and may produce less inflammatory response. There is also a quicker recovery and endothelialization of the vessel. These features are due to the advancement of polymer technology [23].

Performance of EES and ZES are similar to SES, but PES is more effective. EES can be considered as the safest DES; because it reduces the incidence of myocardial infarction significantly.

Due to the need for temporary support of the artery, and that beyond the first few months, there are potential disadvantages of a permanent metal prosthesis, so PCI with bioabsorbable stents was considered and the third generation of stents was introduced [7,24].

The presentation of degradable polymers in DES technology has caused the potential to complete the degradation of polymer immediately or at the same time after the release of the immunosuppressive medicine, after which a BMS remains in site [25]. This type of stents that called BIO, are superior from first generation durable polymer DES in reduction target vessel revascularization.

Clinical studies of stenting's outcomes

There was study in two different hospitals in Netherland and Switzerland which 8146 patient underwent coronary investigation. The data assessed between April, 2002 and Dec, 2005 the rationale was to ascertain time course, incidence and difference between late and early stent thrombosis. Early stent thrombosis assigned 0-30 day after implantation and late stent thrombosis assigned to over 30 days after implantation. Two type of DES were used in this study, sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES). Conclusion documented that stent thrombosis occurred in 2.9% (cumulative 152 patients) of patients in 3 years, which 60% of them had early stent thrombosis and 40% of them had late stent thrombosis. There was no diminution up to 3 years in late stent thrombosis. Incidence of late stent thrombosis was more frequent with PES type stent but early stent thrombosis was similar in both types of stents [26].

Other study for determining long term effect of polymer-based sirolimus-eluting and paclitaxel-eluting stents, the only DES approved by the Food and Drug Administration of U.S (FDA), on coronary arterial healing examined these two types of drug-eluting stents. In this study 23 DES cases were compared with matched autopsies of 25 BMS cases. Data showed that 14 of DES cases had late stent thrombosis after 30 days. In similar implant duration DES showed greater delayed arterial healing characterized in comparison to BMS [27].

The Examination of the Artery and the Behavior of the Stent Inside it

The Healthy arterial wall

All blood vessels have some common properties, for an example they consist of three different but dependent layers:

The tunica intima: This is thin endothelial layer that lines inside walls and covers very thin lamina of collagen type IV [28] and it's thickness is about 80 nm. Because of semipermeability of this layer, from the bloodstream nutrients and chemical signals can reach the cells which exist in the vessel wall [29]. As a membrane, Intima has key role in aspect of regulating the active response of the vessel [30]. The endothelium is a monolayer organ, in order to help control vascular tone, for relaxation of smooth muscle cells in a nonproliferative states, endothelial cells produce many vasoactive substances, such as NO (nitric oxide) [31,32]. NO is a key factor which associated with inhibition of platelet and leukocyte activation [33]. When considering the different layer contributions, the intima layer, due to its small thickness, is usually neglected. the intima is separated from next layer, the media layer, by a fenestrated sheet of elastin called internal elastic lamina [34].

The tunica media: This layer is formed by smooth muscle cells, that are embedded in an extracellular plexus of elastin and collagen types I and III [35].

The tunica adventitia: This the outmost layer and consist of dense network of type I collagen fibers, nerves, elastin and fibroblasts [36].

Arterial mechanics

Vascular mechanical behavior has different characteristic such as:

Residual stresses: If a you cut arterial ring radially, from vessel axis, springs open and an axial strip excised from the artery that expose existence of residual stresses and shows that luminal part is under compression but the external part is under tension [37]. In conclusion by comparing components of the arterial wall, it has been demonstrated that elastin is responsible for the residual stress, however internal pressure equilibrates these stresses.

Anisotropy: This characteristic indicated by different behavior in both the circumferential and axial directions.

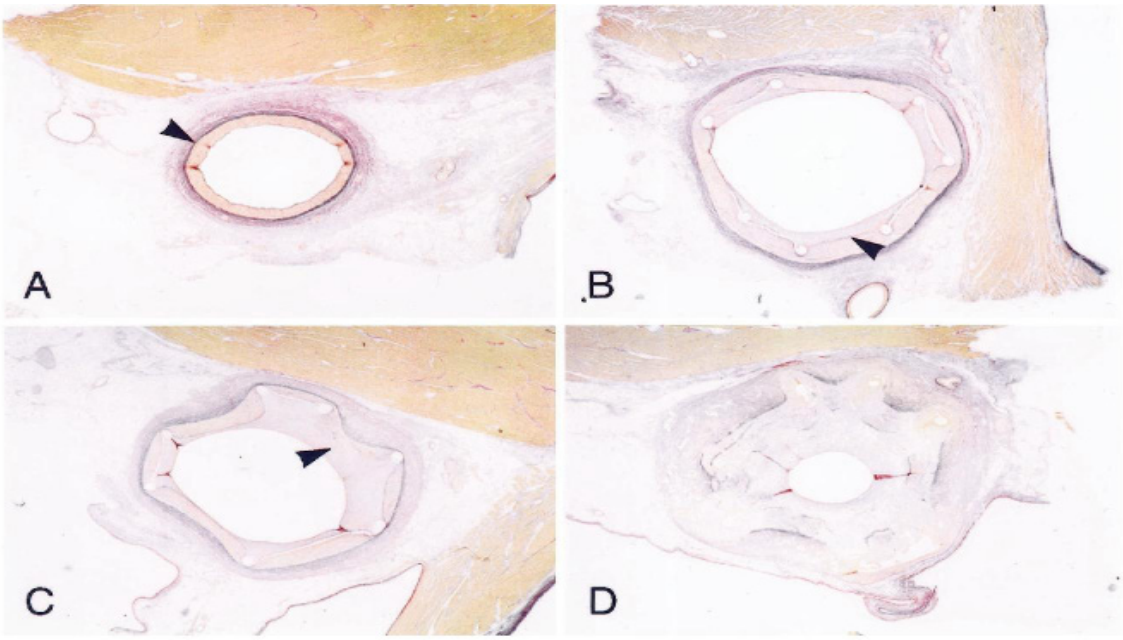

Figure 5: The injury in artery's wall due to stent; A. Injured vessel and arrowhead indicates external elastic lamina; B. Vessel with mild injury and arrowhead shows internal elastic lamina; C. Moderate injury and arrowhead points to neointima; D. Severe vessel injury [45]

Stent behavior inside the arteries

Some problems and conditions such as the environment, stent deformation and fracture decrease performance of stents [38,39]. Under biomechanical forces stents may face with deformation in other hand fracture in stents could disrupt a drug delivery system and fractured stents may result in vessel injury [40]. Mechanical stress may delay vessel healing. A metal device such as stent may take apart by some arteries such as SFA and popliteal undergo severe conformational changes [41].

In some cases, depend on stent type, the rigidity of arteries may be increased which reduces ability of the arteries to accommodate Foreshortening and so adds stress to stent which possibly contributing to stent kinking or fracturing [42].

Production cycle

Tube extrusion, laser micro cutting with post chemical etching

The Destructive Effects of Stent on the Arteries

When a stent is placed in a blood vessel, the new tissue grows within it; this new tissue that passes through the stent's struts initially contains healthy cells from the arterial wall cover (endothelium). The development of this natural coating on the stent has a beneficial effect, because it allows blood to pass slowly and without clotting onto the stenting area. Later, the wound tissue may form underneath a new healthy coating. In about 25% of patients, the growth of the wound tissue under the artery's coating may be very thick and may damage the flow of blood and cause significant obstruction [43].

Planting and expanding the stent leads to coronary artery damage, which is much more severe than the lesion caused by an angioplasty balloon [44]. The long-term intense pressure (in which stent enlargement causes a larger luminal diameter) causes severe structural changes in the coronary artery wall. The Figure 5 shows the severity of the injury caused by the stent in the vascular wall [45].

The presence of a metal mesh in the coronary artery as an external object causes the appearance of a permanent granuloma inflammatory response. Finally, endothelial dysfunction to the inflammatory response causes thrombosis and ischemic phenomena, by inhibiting vascular synthesis, in particular nitric oxide, and increasing endothelin release [46].

Although stenting is a common method for the treatment of cardiovascular patients, vascular restenosis is the main limitation of this method. Many stents are made of stainless steel. Some researchers believe that the allergic response to nickel and molybdenum ions released from these stents can lead to the onset of restenosis within the stent. Although this has not yet been fully proven, some studies have shown that the chance of restenosis is greater in patients with hypersensitivity [47-52].

Conclusion

There are various ways to treat cardiovascular disease, each with its own characteristics. Today, using stents is one of the new and common ways to treat cardiovascular diseases. This treatment method has the best results and performance that has come with many advances. In this paper, coronary stents were examined based on design type and compared in terms of advantages and disadvantages. As mentioned, the stents are designed in three different types, which, according to the type of design, have different properties. The first type is bare-metal stents (BMS); second and third types are drug eluting stents (DES).

Each stent is designed to improve the previous generation and has advantages and disadvantages and is used according to the patient's condition and extent of the disease. For example, although drug-eluting stents reduce the rate of restenosis compared to a metal stent, but stent thrombosis still remains, also the use of these stents has some disadvantages.

Although stents are widely used to treat cardiovascular patients, they can also have bad effects on the body; Such as: the growth of extra tissue within the stent and in result of arterial cramps; severe structural changes in the artery wall; allergic responses to their materials.

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