

Comparative Efficacy of Drug-Eluting Stents vs Bare-Metal Stents in Peripheral Arterial Diseases

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Abstract

There is currently no demonstrated patency advantage of a drug-eluting stent (DES) over bare metal stents (BMSs) for the treatment of marginal pathway disease of the femoropopliteal the component. In order to compare the patency of BMSs for the treatment of femoropopliteal artery wounds to the Eluvia DES (Boston Scientific, Marlborough, MA), a polymer-coated paclitaxel-eluting stent, the EMINENT study (Trial Comparing Eluvia Versus Bare Metal Stent in Treatment of Superficial Femoral and/or Proximal Popliteal Artery) was conducted. Blinded participation and outcome evaluation are features of the prospective, randomized trials, controlled, multicenter European study EMINENT. For measuring the research study used smart PLS software and generate result included descriptive statistic, correlation also that smart PLS Algorithm model between them. A decrease in Rutherford classification of ≥ 1 categories from baseline without repeat target lesion revascularization was considered sustained clinical improvement. Walking capacity and health-related quality of life were assessed. Since important meta-analyses of randomized controlled trials in interventional cardiology suggested that drug-eluting stents might reduce the rates of restenosis and reintervention, the use of active protecting technology in peripheral arterial interventions is one of the next steps in the treatment of arterial occlusive disease complying with coronary artery stenting. Overall result found that direct and significant relation in between Drug eluting stents and bare-metal stents in peripheral arterial diseases. Examining the literature on the current uses of drug-eluting stents in peripheral (lower limb, renal, and supra-aortic) settings, examining the financial ramifications, and offering recommendations for future therapeutic approaches in this area of research are our goals.

Keywords

Efficacy (EE), Drug-Eluting Stents (DES), Bare-Metal Stents (BMS), Peripheral Arterial Disease (PAD)

Disclosure: The authors have no conflicts of interest to declare.

Received: 14 May 2024 **Accepted:** 19 October 2024 **Citation:** *Vascular & Endovascular Review* 2024;7: e02. **DOI:** <https://doi.org/10.15420/ver.2024.07.02.02>

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The efficiency of an organization is the comparison between the services or products produced by an organization and the inputs that they utilize to synthesize products. The construction and manufacture of all this evidence play a significant role in comparing the advantages and disadvantages of methods that are substitutes for one another to diagnose, protect, treat, and monitor a clinical condition, which is called comparative effectiveness research. Another purpose of all such practices is to improve the delivery of care. The rate related to the control of Amy's disease using a vaccine is known as efficacy. The transmission also comes in this category if carried out with excellent care and in an ideal environment. The comparison is involved in this phenomenon, which usually occurs between the vaccinated and placebo groups. Effectiveness is related to the performance within the real world¹. The level of appearance of desired results comes under the term of efficacy. Even if one does not like the taste of broccoli, he cannot raise any questions about its effectiveness as it has excellent health benefits. A

type of mesh that is small and placed within an artery to keep it open. The stent is covered with the medicine that is released slowly and proves helpful in stopping the formation of blood clots. Blood clotting also proves to be a stent that can block an artery in the future, known as restenosis. This condition becomes the cause of heart attack. All those stents which are not covered with the drug come under the category of bare metal stents. As time changes, stents that go into the drug category Eluting Stents are advancing. These stents prove very beneficial and effective, along with using anti-clotting medicines, which doctors suggest². One of the benefits of using the drug Eluting stents is that they do not cause hindrance by creating a blockage, unlike bare metal stents. A drug-eluting stent is commonly utilized to treat blockage of heart arteries. Most people who suffer from heart diseases can be treated easily by applying the Eluting Stents. These stents have brought a lot of ease in medicine as there will be no need for complicated procedures in the presence of these drug Eluting

Stents, like bypass surgery of the coronary artery³. During coronary angioplasty, a cardiologist or a heart doctor places a stent to solve the blockage of an artery. A skinny, flexible tube, a catheter within a balloon on its top, is placed inside a blood vessel. The balloon's inflated phenomenon quickly opens blocked arteries and improves blood flow. A few times, there is a need for the drug-coated balloon. To treat the problem of chest pain, which usually happens due to the blockage of an artery, a drug-eluting stent is utilized⁴. This stent has the caliber to reduce the symptoms; it can treat the problem to such an extent that there will be no need for further angioplasty procedures. Drug-eluting stents are not beneficial for people who face the difficulties of bleeding. Certain medicines, such as aspirin and blood thinner medicine like clopidogrel, are prescribed in that situation. A stent is made up of a skinny type of metal that is not coated and is formed within a mesh-like tube. The first one is stents, which are utilized for treating diseases of cardiac arteries and are of bare metal type⁵. The stents of bare metal type are covered with a layer of endothelial cells, which are then sealed into the wall of a vessel after the specific weeks of implantation. A stent is placed for a lifetime so that our body can work with it smoothly. The role of bare metal stents is that they are self-expanding and have a wide range of applications in cardiology to maintain the working of the coronary arteries. After the insertion process, the lumen, which is found inside the stent, becomes epithelized, and with time, these are then integrated so that endothelium can be seen with time. The danger of restenosis can be reduced by applying a stent, known as the drug Eluting Stents. It hinders the building of scar tissue building within the artery lining. So, it can reduce the chances of blockage of an artery⁶. To prepare a report about bare metal stents, paclitaxel-coated balloons, and drug Eluting stents along with balloon angioplasty within the arteries known as infra popliteal. There is no clear demonstration of the benefit of drug-eluting stents, considered more beneficial than bare metal stents for treating peripheral artery diseases. The EMINENT study was made to know the complete information about Eluvia DES and a paclitaxel Eluting stent, which is coated with a polymer; these are compared with BMSs to treat the femoropopliteal artery lesions⁷. EMINENT is a study made in Europe, and it is a random, controlled, and multicenter in which blinded participants are involved along with the observation of results. Patients who are bearing peripheral artery disease in which symptoms are also obvious are prescribed to be treated with DES or BMS. All the articles about these stents describe the working of DES versus BMS. The endpoints, which are all about efficacy, mention the loss of lumen, binaries restenosis, and the fracture in the stent⁸. Endovascular interventions are a primary treatment for peripheral artery disease (PAD) as well as an aggressive risk factor reduction and exercise program for patients who have favorable anatomy or who are deemed to be at high risk for surgery. The treatment with Percutaneous Transluminal Angioplasty (PTA), as well as bare-metal stents (BMS), is limited due to high rates of intrastent restenosis (ISR), which requires revascularization several times⁹. Drug-eluting Stents (DES) designed and designed to decrease ISR offer an additional viable solution to the problems currently faced in managing

endovascular PAD. Numerous clinical trials randomized to participants have found improvement in both short- and long-term outcomes when using DES compared to both PTA and BMS. This article prepares the most current review of the latest research concerning DES application in PAD¹⁰.

Research Objective

Analyzing the distinctions between bare metal and drug-eluting stents—which are typically used to treat peripheral artery diseases—is the primary goal of this study. The effectiveness of these two stents is also compared in this study in order to ascertain which is better for treating serious cardiac conditions. The study establishes the relative effectiveness of bare metal and drug-eluting stents in peripheral artery disease. There were five sections in the study article. The first section serves as an introduction that includes the research study's goal. The literature review is represented in the second part, and the approach, including tools and procedures, is described in the third. That outcome and its explanation are shown in the fourth part. The final section provided a summary of the entire research investigation and offered some research recommendations.

LITERATURE REVIEW

Researchers claim that treatment of different types of artery disease is possible using endovascular-based treatment techniques. These techniques generally include stents implants and angioplasty to treat femoropopliteal artery disorders. The BMS technique is adopted by surgeons. For more advanced and safe treatment the use of DES techniques is adopted. Studies provide mixed results about the effectiveness of the use of DES and BMA techniques for carrying out endovascular therapy sessions⁴. Studies reveal that data related to the effectiveness of DCB stents for treating endovascular disease is obtained from IN. PACT global study. This study provides evidence that treating femoropopliteal disorder using the DCB along with bare metal stent shows improved treatment outcomes as compared to the use of DCB alone¹¹. Studies suggest that the first treatment approach used for PAD is DES. The quality and types of DES present in the market are diverse. The type of DES used for treatment purposes depends on the type of artery disorder. For PAOD treatment the DES is used to provide positive outcomes¹². Studies reveal that the number of deaths due to peripheral artery disease is higher as compared to cardiovascular diseases. Peripheral artery disease is characterized by causing damage to the person's lower limb thereby impacting his ability to walk properly. Patients having peripheral artery disorder have higher chances of losing their limb functioning. Drug-eluting technology is effective for peripheral arterial disorders¹³. Studies claim that people with ischemia are at risk of developing life-threatening conditions. This disease condition can also result in infrapopliteal artery disorder. Two treatment approaches used for infrapopliteal artery disease are PAT and DES. The comparative studies made on the use of PTA and DES show that the efficacy of DES for therapeutic purposes is more¹⁴. Scholars reveal that open surgery for endovascular disease treatment is very risky. Surgeons prefer to use endovascular therapy as an alternative treatment approach instead of open surgery. The two drug-

coated stents used for femoropopliteal artery disorders are heparin-coated and the second is paclitaxel-coated. The clinical results improved by using paclitaxel and heparin-coated stents as compared to Bare metallic stents¹⁵. Different studies reveal the effect of using eluvia-coated stents for treatment purposes. The results of these studies suggest that the use of eluvia-coated stents reduces the mortality rate in patients in comparison to the use of DES³. Studies suggest that less complex types of femoropopliteal artery disorders are treated with DCS. The use of DCS as compared to DES for therapy purposes is because of the effectiveness of DCS against less severe forms of artery diseases⁷. Scholars conclude that higher treatment potency is shown by DCB use. Also, combining AT+ DCB shows high effectiveness against the primary infection. For the FP lesions therapy process, the drug-coated implants are preferred by doctors as they are more suitable to use than Bare metal stents^{16, 17}.

Also, the two main stents base techniques used for Ealey treatments of FP is DES as well as DCB. The results of studies made on FL affected patients suggest that DES shows more promising outcomes shown used as primary stents¹⁸. Studies explain that for small coronary arteries, the use of drug-coated balloons is preferred while for overall CAD treatment, the use of drug-coated stents is preferred by surgeons. Most CAD patients are provided with individualized therapies to improve the effectiveness of treatment¹⁹. Also, the risk associated with CAD disease makes the disease more complex, severe, and difficult to treat. DES and DCB are used for CAD patients as effective treatment strategies²⁰. Studies reveal that below knee arteries associated disorders are treated using the SESs. In some BMS is used in patients with knee diseases, but the most preferable and safest technique for BTK arterial disease is SES²¹. Studies predict that the use of drug-eluting stents is increasing in surgical operations. The effectiveness and safety of the drug-coated stents make them the preferable choice for most arterial disease treatment. Studies suggest that femoropopliteal artery disorders treated with paclitaxel drug-coated stents and the patients treated with it in the United States show eighty-two percent improvement chances²². Studies claim that in the past ten years, the trend of using traditional stents has been replaced with modern stents. Modern stents treat superficial arterial disease. The drug-coated stents are digitized devices that target the site of arterial infection and treat the lesions²³. Studies suggest that endovascular disorders require revascularization

strategies for treatment. The studies based data suggest that certain stents devices have high quality that make them suitable for immediate treatment²⁴. Studies have shown that arterial diseases are becoming complex in developing countries. Ischemia is a complex limb arterial disease that makes the disease treatment a complex process. All the peripheral arterial disease are categorized as prevalent disease. This high prevalence rate makes the treatment procedure complicated. Strategizing before the implant of stent require per [management of the surgery process. The pathophysiology of peripheral disease is studied to before the stent implantation in patients. Surgical procedure followed for drug based stent implant results in positive therapeutic outcomes in patient of peripheral arteries disease²⁵. Studies suggest that efficacy of various endovascular therapies varies in different patient. The data obtained from the randomized studies predict that infra-inguinal arterial disorder if not properly treated results in chronic condition that increase death risk in person. The use of best endovascular therapy for infra-inguinal disorder provide promising outcomes²⁶. Studies reveal that alone BMS does not provide promising results. For obtaining efficient treatment response. Combining DCB with BMS improves the overall efficiency. Drug coated balloons are commonly use in surgical operations rather than bare metal stents. The chances of artery lesions gets treated with bare metal rod is comparatively low then DCB. The comparative studies reveal that using a more favorable method for treatment purposes yield better therapeutic responses in patients with TASCII²⁷. Studies claim that restenosis is a condition that requires favorable treatment approach. The use of polymer-based stents is suitable as polymer material is safest material to use for femoropopliteal disorder. A comparative based study reveal that drug coated balloons have high drug dosage for acting a therapeutic agent for arterial diseases. The effect of using polymer and drug coated stents in patients after one year was estimated. The results predict that the rate of restenosis in polymer based DES group is lower in comparison to the high dose DCB group²⁸.

METHODOLOGY

The research study determines that comparative analysis between the drug eluting stents and bare metal stent. The research study based on primary data analysis for determine the research used smart PLS software and generate result included descriptive statistic, the correlation coefficient analysis also that it describes smart PLS Algorithm model between them.

DESCRIPTIVE STATISTICAL ANALYSIS

Table 1(a): Result of Descriptive statistical analysis

Name	No.	Mean	Median	Scale min	Scale max	Standard deviation	Excess kurtosis	Skewness	Cramér-von Mises p value
DES1	1	1.571	2.000	1.000	3.000	0.606	-0.545	0.567	0.000
DES2	2	1.490	1.000	1.000	3.000	0.576	-0.453	0.703	0.000
DES3	3	1.633	2.000	1.000	3.000	0.596	-0.623	0.358	0.000
DES4	4	1.592	2.000	1.000	3.000	0.569	-0.756	0.312	0.000
BMS1	5	1.633	2.000	1.000	3.000	0.629	-0.603	0.490	0.000
BMS2	6	1.531	2.000	1.000	2.000	0.499	-2.070	-0.127	0.000

Table 1(b): Result of Descriptive statistical analysis

Name	No.	Mean	Median	Scale Min	Scale Max	Standard Deviation	Excess Kurtosis	Skewness	Cramér-Von Mises P Value
BMS3	7	1.633	2.000	1.000	3.000	0.523	-1.052	-0.120	0.000
BMS4	8	1.408	1.000	1.000	3.000	0.531	-0.509	0.803	0.000
BMS5	9	1.490	1.000	1.000	3.000	0.539	-1.002	0.445	0.000

The previous outcome of table 1 illustrates how mean values, median rates, and standard deviation values are defined in descriptive statistical analysis, as well as providing an explanation of the probability value of each variable, both dependent and independent. Every result from the comparison studies of DES1, 2, 3, and 4 is regarded as an independent variable. 1.571, 1.490, 1.633, and 1.592 are its mean values. 60%, 57%, 59%, and 56% of the standard deviation rate deviates from the mean. The results indicate that 1.000 is the overall minimum value. Each indicator has a maximum value of 3.000 and a median rate of 2.000. The result indicates that there is a 100% significant rate between them, with an overall probability value of 0.000. The results show that the BMS1, 2, 3, 4, and 5 are all regarded as dependent variables, with mean values of 1.633, 1.531, 1.408, and 1.490, respectively. This indicates a positive mean value.

There is a 62%, 49%, 52%, and 53% divergence from the mean in the standard deviation rate. Accordingly, their skewness values are 12%, 80%, and 44%. The use of a polymer-based paclitaxel-eluting stent as a first-line stent-based intervention for patients with symptomatic peripheral artery disease brought on by femoropopliteal lesions is supported by the findings of the EMINENT randomized research, which showed improved 1-year primary patency. Peripheral artery occlusive disease (PAOD) has been treated using endovascular interventional methods since their beginning, despite a number of advancements. Although percutaneous transluminal angioplasty (PTA) and stenting are gradually replacing open peripheral artery surgical therapies, post-angioplasty and in-stent restenosis remain a significant drawback. When compared to bare metal stents (BMS), the use of drug-eluting stents (DES) in coronary artery disease reduces restenosis and reintervention rates, according to significant meta-analyses of randomized controlled trials (RCTs) in interventional cardiology. The results, which vary depending on the drug coating, suggest that stents that elute

sirolimus are more efficacious than those that elute paclitaxel and its derivatives. This study reviews the literature on the potential use of DES to treat PAOD and offers suggestions for novel therapeutic modalities. When compared to bare-metal stents, prospective, randomized clinical trials have shown that the use of drug-eluting stents lowers in-stent restenosis. Based on prospective trials involving around 4500 participants, the US Food and Drug Administration authorized the use of drug-eluting stents for patients with coronary lesions that were less than 30 mm in length and had a reference-vessel diameter of 2.50 to 3.75 mm.

Compared to bare-metal stents, drug-eluting stents appeared to be safe in these studies, with no discernible rise in cardiovascular events. However, the use of drug-eluting stents has quickly expanded to a range of patients, including those in acute conditions and those with more complicated coronary lesions. Concerns about inadequate neointimal coverage, which raises the risk of late stent thromboses in patients with drug-eluting stents, have been brought up by recent pathoanatomical studies and meta-analyses of randomized trials and registries. According to one randomized research, the implantation of drug-eluting stents was associated with an early reduction in myocardial infarction and death; however, this impact was lost during the next 6 to 18 months because of a late rise in both occurrences. We concluded that assessing large clinical registries may offer crucial insights into the long-term safety and effectiveness of these devices, as there are currently no prospective, randomized clinical studies with long-term follow-up of "off-label" usage of drug-eluting stents. Thus, we used data from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) to evaluate the long-term outcomes of all patients who had stent implantation in Sweden between 2003 and 2004. We also used data from other national registries to perform a follow-up study of myocardial infarction and death.

CORRELATION COEFFICIENT

Table 2: Result of Correlation coefficient

	DES1	DES2	DES3	DES4	BMS1	BMS2	BMS3	BMS4	BMS5
DES1	1.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
DES2	-0.042	1.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
DES3	0.016	-0.249	1.000	0.000	0.000	0.000	0.000	0.000	0.000
DES4	-0.093	-0.262	0.220	1.000	0.000	0.000	0.000	0.000	0.000
BMS1	-0.038	0.159	0.239	-0.191	1.000	0.000	0.000	0.000	0.000
BMS2	0.077	0.303	0.038	-0.100	0.491	1.000	0.000	0.000	0.000
BMS3	0.018	0.259	-0.368	-0.093	-0.162	0.043	1.000	0.000	0.000
BMS4	-0.281	-0.120	0.022	-0.192	0.204	0.184	-0.268	1.000	0.000
BMS5	0.205	0.213	-0.202	-0.147	-0.131	-0.207	0.059	-0.057	1.000

The results of table 2 mentioned above show that the correlation coefficient analysis as a whole describes both positive and negative interactions between bare metal and drug-eluting stents in peripheral artery disease. Based on the previously published criteria of the Academic Research Consortium, the late occurrences in our study are associated with "possible stent thrombosis." Recent data from randomized trials and meta-analyses of registries further supports the timing of these events. Stent thrombosis is now more likely to be the cause of late stent thromboses in patients with drug-eluting stents as inadequate neointimal coverage has been identified as a potential contributing factor.

The risk of death may be affected by stent thromboses even though they seem to affect around 0.5% of patients treated with drug-eluting stents annually, since fatal outcomes have been reported in as much as 45% of these instances. The risk of myocardial infarction and death increase by 0.5 to 1.0% year and around 0.5% annually, respectively, after six months, which is a worrying result. Any early increases in incidence rates will be offset by the continuous decline in late occurrences if this higher risk continues after the three years of follow-up in our research. It was not until the first six months were over that the incidence rate started to rise. Most patients were instructed to take dual antiplatelet medication for six months after drug-eluting stent implantation, but only for one to three months after bare-metal stent insertion, despite the lack of data on long-term antiplatelet usage. Therefore, better clopidogrel protection in the early period and a longer need for such protection after six months may be the cause of the early gain and late loss of clinical events in the drug-eluting stent group. It has been proposed that delayed healing is associated with late stent thrombosis, requiring lifelong dual antiplatelet therapy. Recent results from the duke database, which revealed higher risks of myocardial infarction and death in

patients with drug-eluting stents after stopping clopidogrel, lend credence to this opinion. Throughout the study, the average rate of drug-eluting stent utilization increased dramatically, despite the fact that there were still many different locations and indications. The higher incidence of clinical and angiographic high-risk features in patients with drug-eluting stents suggests that patient selection was focused on restenosis risk factors, even if geographical variances explained the bulk of variations in the usage of these devices.

The clinical restenosis rate was approximately 60% lower in individuals with drug-eluting stents than in those with bare-metal stents. Compared to randomized clinical trials or other registry data, our analysis showed a lower absolute difference in the incidence of restenosis (3%) and reintervention (1%) between the two groups, despite the fact that the restenosis rate after bare-metal stent placement was 5.9%. The need for drug-eluting stents in patients at low or intermediate risk for restenosis is not supported by the low incidence of restenosis and reintervention after bare-metal stent implantation, as well as the minor change after drug-eluting stent implantation. Variations in baseline characteristics or unrecorded selection factors may persist even after applying the appropriate statistical adjustments. Event curve crossings can also be explained by multiple selection biases. Patients with bare-metal stents have greater early-event rates because of a higher percentage of patients who sustained myocardial infarction with ST-segment elevation, whereas patients with drug-eluting stents have higher late-event rates because of a higher percentage of high-risk patients. Changes in incidence rates over time may have been influenced by the smaller number of patients who got drug-eluting stents early in the study period. The absence of information on the length of time that certain patients have been taking clopidogrel is another problem.

SMART PLS ALGORITHM MODEL

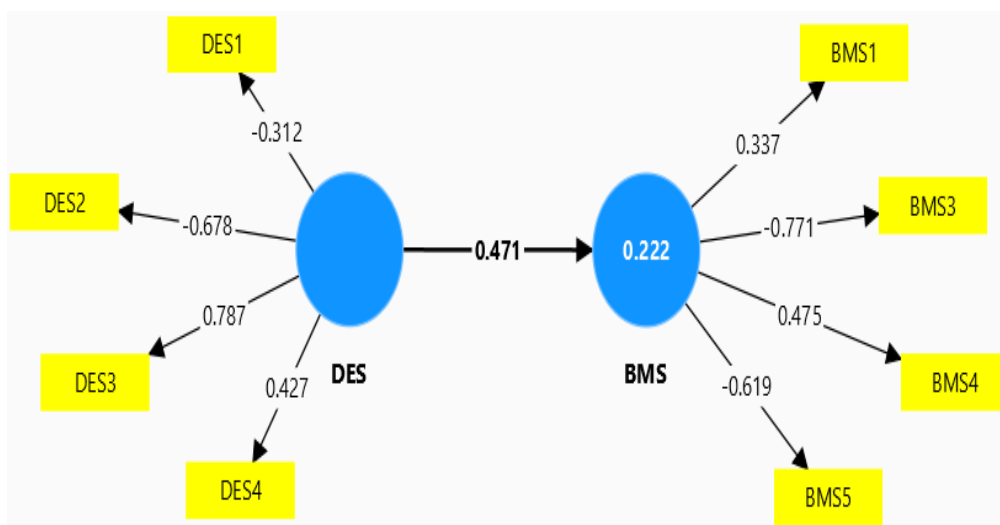


Figure 1: Smart PLS Algorithm Model

The above model of figure 1 represents that smart PLS Algorithm model in between drug eluting stents and bare metal stent. The algorithm model

shows -0.312, -0.678, 0.787 and 0.427 its shows that negative but its significant link between them. the BMS shows that 33%, 77%, 47% and 61% significant also positive relation between them. the DES shows 47% positive and significant relation between DES and BMS.

DISCUSSION AND CONCLUSION

Our study compared the long-term results of bare-metal and drug-eluting stents in a large cohort of consecutive, unselected patients treated with coronary stents in all Swedish interventional facilities. The reliability of data is increased when it is integrated into SCAAR and used as tools for patient therapy. The accuracy was further confirmed by source-data verification, which showed a 95% match to the patients' hospital records. Because the SCAAR database was integrated with the national vital statistics and hospital admission registries, the long-term follow-up was extensive. Selection bias resulting from unidentified confounders is always a possibility, even after the nonrandomized comparison between the research groups was adjusted for all potential confounders. However, our research's main justification for choosing drug-eluting stents over bare-metal stents was the significant variation in hospital and regional acceptance of the devices' indications. Since the selection of either kind of device was frequently random with regard to patient-related variables, we were able to compare the group with drug-eluting stents to a modern, at least mostly nonelected control group of patients with bare-metal stents.

Logistic regression techniques, which take advantage of changes in all pertinent background factors between the groups, are frequently used in nonrandomized group comparisons. However, in order to do appropriate formal statistical comparisons among groups, these investigations require proportionate risks over time. Thus, both unadjusted and propensity-score-adjusted cumulative event rates were used to depict the temporal flow of occurrences across the whole follow-up period. For statistical inference, the groups were compared six months after the fact in landmark analyses. We decided on a 6-month criterion based on two considerations. First, for up to six months after stent implantation, the majority of Swedish hospitals recommend clopidogrel medication. Second, event rates were the same in

all three groups at six months, despite early differences among the primary indications (myocardial infarction with ST-segment elevation, acute coronary syndrome, and stable coronary artery disease). By splitting risk into early and late stages, we were also able to estimate relative risks and confidence ranges, which helped us deal with the problem of nonproportional hazards. Because they were more likely to pass away after six months, patients with drug-eluting stents had a higher long-term risk of dying than patients with bare-metal stents, according to our research. The likelihood of dying rose by more than 30% when we assessed the event rates in the historical sample starting at 6 months, and this increase continued throughout time. The composite of myocardial infarction and death appeared to have less of an incidence during the first six months, but thereafter it increased. The one-stent subgroup, which took into consideration differences in lesion-related characteristics, provided the best evidence in favor of these findings. During the first six months, the composite event rate for this subgroup of patients with drug-eluting stents was lower (18%), but it later increased (23%). Compared to bare-metal stents, drug-eluting stents showed a lower initial incidence of stent-related thrombosis, however this risk eventually rose. This might be the reason for the early increase and late decline in the composite event rate. The results of a prior randomized experiment are corroborated by this observation. After the first six months, the absolute risk of death increased by 0.5% annually, and patients with drug-eluting stents had an 18% greater relative long-term risk of mortality than those with bare-metal stents. The event rate decreased for the first six months before increasing by around 20%, or 0.5 to 1.0% each year, according to the analysis of the mortality and myocardial infarction composite. The absolute decrease was less than 3%, despite the fact that patients with drug-eluting stents had a 60% reduced incidence of clinically obvious restenosis. Therefore, even though long-term follow-up and extensive systematic studies have ruled out any further long-term danger, broad, unselective use of drug-eluting stents should be avoided. The risk-benefit ratio in patient subgroups based on clinical and angiographic risk factors, as well as the length of dual antiplatelet therapy, should also be established clearly by such trials.

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