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Comparison between stainless steel stent and cobalt chromium stent in patient undergoing primary percutaneous coronary intervention (PCI) for coronary artery disease.

Bharat Bhushan[1]* , Satish Kumar Sharma[1], Lalit Singh[1], Komal Gupta[2], Hema Arya[3]
1.Sunder Deep Pharmacy College, Ghaziabad, UP, India- 201001
2.Indira College Of Pharmacy,Pune, Maharshtra, India-411033
3,Rameesh Institute of Voc. and Technical Education of Pharmacy, Greater Noida, U.P, India

ABSTRACT

The observational study was a retro-selective, unicenter, nonrandomized study to evaluate the clinical safety and efficacy of the stainless steel and cobalt-chromium alloy stent. Use of the cobalt-chromium alloy in place of stainless steel offers enhanced visibility and radial strength with thinner structural elements. The study enrolled 128 patients with symptomatic ischemic heart disease attributable to de novo or restenotic nonstented native lesions of a single vessel amenable to percutaneous stenting. The primary composite end point was the incidence of major adverse cardiac events (death, myocardial infarction, emergency bypass surgery, or target lesion revascularization) 365 days after PCI. The mean age of patient was 56.17 ± 10.43 years, with 50.81% and 47.36% of unstable angina patient. No difference in most clinical angiographic characteristic between two groups. At 1 month follow up there was no significant difference between two groups (p = 0.96). The individual clinical component showed no difference in occurrence of death (p = 0.29), MI (p = 0.29) and TLR (p = 0.96) at end of 6 month. At 1 year MACE occurred 8.1% in cobalt chromium group and 14.0% in stainless steel stent (p = 0.31). Rate of TLR was 0 % in cobalt chromium group and 3.5% in stainless steel stent (p = 0.14). The incidence of restenosis was 3.27 % in cobalt chromium group and 7.01% in stainless steel stent (p = 0.35).

Keywords: PCI, CABG, CAD, MACE, MI, TLR

*Corresponding Author Email: bharatarya12@yahoo.co.in
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INTRODUCTION

To compares safety and efficacy between stainless steel stent and cobalt chromium stent in patient undergoing primary percutaneous coronary intervention (PCI) for coronary artery disease.

Background:

Cobalt chromium and stainless steel coronary stents are increasingly being used in percutaneous coronary interventions. Although huge work has been done in the area of DES. However no reliable data is available for comparison of sirolimus eluting stainless steel stent and cobalt chromium stent.

Method

This study involves single centre recruitment of patients undergoing percutaneou coronary intervention (PCI) at Artemis Health Institute, Centre received approval from its Institutional Review Board. 118 subjects have been enrolled who met the inclusion and exclusion criteria and followed retrospectively for 1 year.

Data on baseline demographic, clinical, and angiographic characteristics and procedural characteristics during the index PCI, as well as the occurrence of death, myocardial infarction, and the need for coronary-artery bypass grafting (CABG) during hospitalization, were collected. Follow-up status was ascertained at 1 month, 6 months, and 1 year after intervention.

Table: 1: **Demographic, history & angiographic parameter comparison of different population**

Characteristic	**Group-I Cobalt Chromium stent**	**Group-II Stainless Steel Stent**
Total no. of Patients	61	57
Male	56	50
Female	5	7
Age (Mean) (+ SD)	56.88 ± 10.16	55.84 ± 10.71
Height (cm) (+ SD)	172.5 ± 9.42	173.1± 9.80
Weight (Kg) (+ SD)	73.26 ± 10.33	72.14± 9.44
BMI (± SD)	24.77 ± 2.42	24.28 ± 2.59
Age Distribution		
31-40	4.91% (03)	7.01% (04)
41-50	27.86% (17)	28.07% (16)
51-60	32.78% (20)	36.84% (21)
61-70	26.22% (16)	19.29% (11)
71-80	6.55% (04)	8.77% (05)
81-90	1.63% (01)	0
Risk Factor and medical History		
Smoker	18.03% (11)	15.78% (09)

Tobacco	9.83% (06)	8.77% (05)
Diabetes mellitus	31.14% (19)	26.31% (15)
Hyperlipidemia no.	32.78% (20)	29.82% (17)
Hypertensive no.	32.78% (20)	28.07% (16)
MI	14.75% (09)	12.28% (07)
Unstable Angina	50.81% (31)	47.36% (27)
Stable Angina	34.42% (21)	40.35% (23)
Angiographic Parameter		
Left Anterior Descending Artery	55.73% (34)	52.63% (30)
Left Circumflex Artery	13.11% (08)	14.03% (08)
Right Coronary Artery	22.95% (14)	26.31% (15)
Obtuse Marginal	8.19% (05)	7.01% (04)
Lesion length, mm	26.26 ± 8.88	28.68 ± 8.51
Reference vessel diameter	2.94 ± 0.34	2.90 ± 0.31

Study Population

For this analysis, only patients who received a stent as part of index PCI were included. The study was divided in to two groups: patients receiving drug eluted stainless steel stent and patients receiving drug eluted chromium cobalt stent.

Out of 118 subjects, 61 patients received Cobalt chromium stent (Group-I), where as 57 patients received Stainless steel stent (Group- II)

Endpoint

Efficacy parameters include rate of target lesion revascularization, target vessel revascularization and restenosis at 1 month, 6 months and 12 months Target lesion revascularization, target vessel revascularization and restenosis rates from angiography, (repeat PTCA, PCI or CABG).

Safety parameters include incidence of major adverse cardiac events (MACE), MACE is defined as the composite endpoint of death, myocardial infarction, and coronary intervention, and angina, abnormalities in ECG and mortality rates.

After history or no history of PCI, history or no history of CABG, presence or absence of chronic kidney disease, history or no history of congestive heart failure, presence or absence of diabetes mellitus, number of involved vessels, number of lesions for which revascularization was attempted, reason for revascularization, and medical regimen on discharge,

Statistical Analysis

Patient characteristics pertaining to the index PCI, including demographic characteristics, medical history, cardiac presentation, periprocedural medications, procedural characteristics, and in-hospital outcomes were compared between stent types with the use of chi-square test for categorical variables.

RESULTS AND DISSCUSSION

To the best of our knowledge, this is the first study that compares the use of sirolimus cobalt chromium stents versus sirolimus stainless steel stents in patients with CAD

This retrospective non randomized open label study compared the use of sirolimus cobalt chromium stent and sirolimus stainless steel stent in patient with CAD. The purpose of this study was to compare clinical outcome in the same drug eluting in different metal material. Our study included patients who were undergoing PCI from January 2011 to march 2012.

The major findings of this study were that at the 1 month, 6 month, and 1 year follow up clinical outcomes were not significantly different for sirolimus cobalt chromium stent and sirolimus stainless steel stent group. At 1 year TLR and TVR were higher in stainless steel stent group compared to cobalt chromium stent group but the difference was statistically insignificant.

Treatment with sirolimus cobalt chromium stents was associated with similar risk of target vessel revascularization and no risk of death at the end of 30 days compared to sirolimus stainless steel stents whereas MACE was observed in one patient in both stent groups

Table: 2. Clinical outcome at 1 month follow up:

Parameters	Cobalt chromium stent (n=61)	Stainless steel stent (n=57)	P value
Death	00	00	
MI	00	00	
Unstable Angina	00	00	
Stable Angina	1.63% (01)	1.75% (01)	0.96
Post CABG	00	00	
Re-PCI	00	00	
Restenosis	00	00	

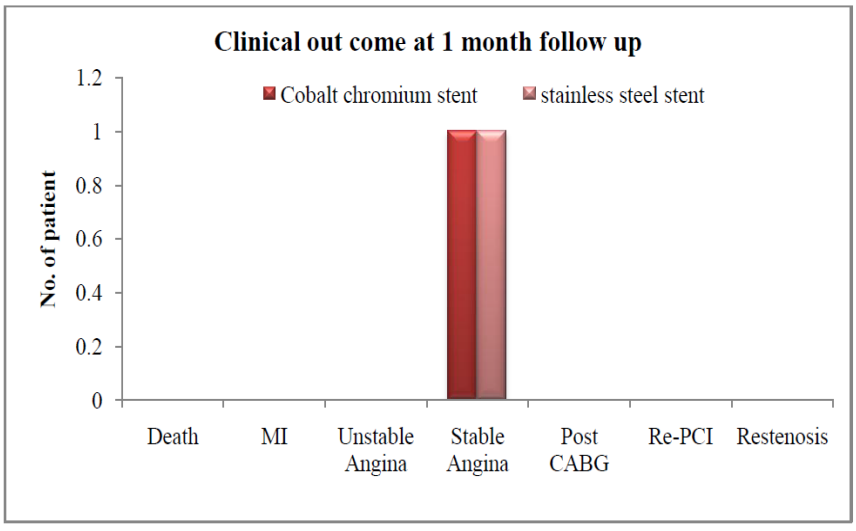

Figure. 1: Clinical Outcome at 1 month follow up

As shown in Table 1 and Figure 1 at end of 1 month follow up there was no significant difference between two groups (p = 0.96). Major clinical event during 6 month follow up were similar between groups (p = 0.20). The individual clinical component also showed no difference in occurrence of death (p = 0.29), MI (p = 0.29) and TLR (p = 0.96) as shown in Table 2 and Figure 2. At 1 year the incidence of individual and MACE did not significantly differ between two groups. MACE occurred 8.1% in cobalt chromium group and 14.0% in stainless steel stent (p = 0.31). Rate of TLR was 0 % in cobalt chromium group and 3.5% in stainless steel stent (p = 0.14). The incidence of restenosis was 3.27 % in cobalt chromium group and 7.01% in stainless steel stent (p=0.35) as shown in Table 3 and Figure 3.

At the end of 6 month the rate of TLR was low in both the stent groups whereas low risk of death was observed in sirolimus stainless steel stent group. Koh et al (2011) reported Stainless steel and cobalt chromium stents are associated with similar and low risk of target vessel revascularization (TVR result at 6 month 3.5% in stainless steel stent and 3.4% in cobalt chromium stent). [1]

At the end 1 year the rate of TLR was high as compared to TVR in sirolimus stainless steel stent group. The risk of death was observed to be similar in both stent groups.

Primary end point of the present study were rate of target lesion revascularization, target vessel revascularization and restenosis, which were statistically insignificant in both stent group at 1 month, 6 month 1 year follow up. The secondary end point was assessment of safety in patient implanted with sirolimus stainless steel stent or sirolimus cobalt chromium stent. Safety parameters included rate of death, myocardial infarction, and coronary intervention, and angina. The results showed that no significant difference in safety profile both treatment groups. Henrique B et al. (2011) study on 316 patient and reported similar efficacy and safety to stainless steel stent compared to cobalt chromium stent.[2] Result of the present study showed that there was no significant difference in efficacy and safety of cobalt chromium stent and stainless steel stent.

Table: 3. Clinical outcome 6 month follow up:

Parameters	Cobalt chromium stent (n=61)	Stainless steel stent (n=57)	P value
Death	00	1.75% (01)	0.29
MI	00	1.75% (01)	0.29
Unstable Angina	1.63% (01)	1.75% (01)	0.96
Stable Angina	1.63% (01)	3.50% (2)	0.51
Post CABG	00	00	
Re-PCI	1.63% (01)	1.75% (01)	0.96
Restenosis	1.63% (01)	1.75% (01)	0.96

The angiographic data was showed there was no incidence of restenosis at end of 1 month in both stent groups. Incidence of restenosis was similar at 6 month follow up in both stent groups. But at 1 year follow up, incidence of restenosis was higher but statistically insignificant.

MACE observed at the end of 6 month, and 1 year was higher in sirolinus stainless steel stent as compared to sirolimus cobalt chromium stent.

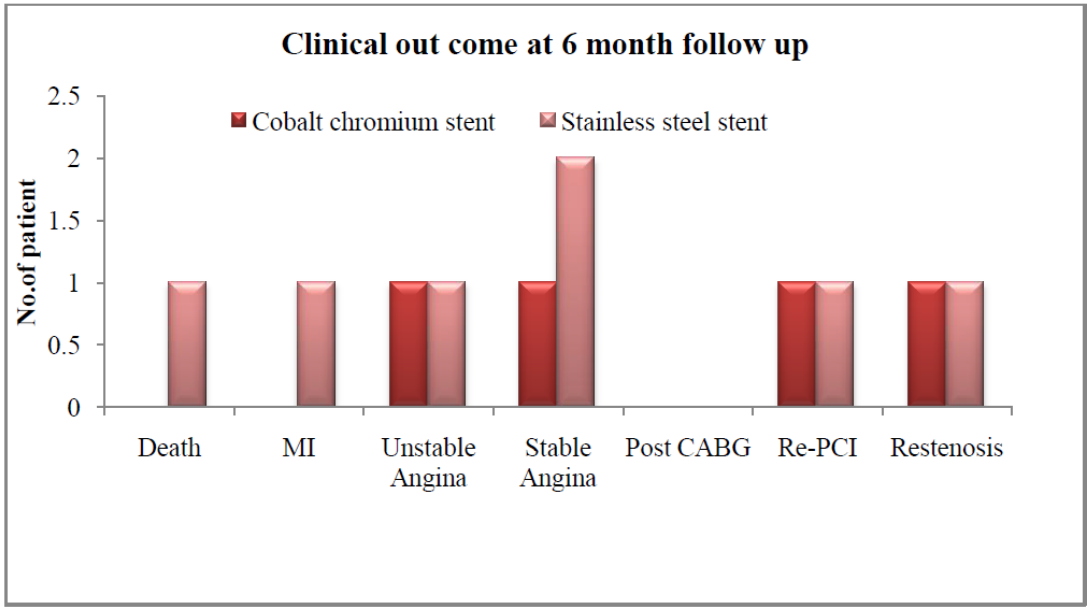

Figure. 2, Clinical Outcome at 6 month Follow up

Previous study compared Everolimus-Eluting Stent and Sirolimus Eluting Stent and reported similar clinical outcome in both stent. [3]Naito et al (2011) reported there was no significant difference in the long term clinical outcome between sirolimus eluting stent and peclitexal eluting stent. [4]Our study found no difference between sirolinus stainless steel stent and sirolimus cobalt chromium stent with respect to the incidence of death and unstable angina during 1 year follow up.

Table: 4. Clinical outcome at 1 year follow up:

Parameters	Cobalt chromium stent (n=61)	Stainless steel stent (n=57)	P value
Death	1.63% (01)	1.75% (01)	0.96
MI	1.63% (01)	3.50% (02)	0.51
Unstable Angina	1.63% (01)	1.75% (02)	0.51
Stable Angina	3.27% (02)	5.27% (03)	0.59
Post CABG	00	1.75% (01)	0.29
Re-PCI	00	3.50% (02)	0.14
Restenosis	3.27% (02)	7.01% (04)	0.35

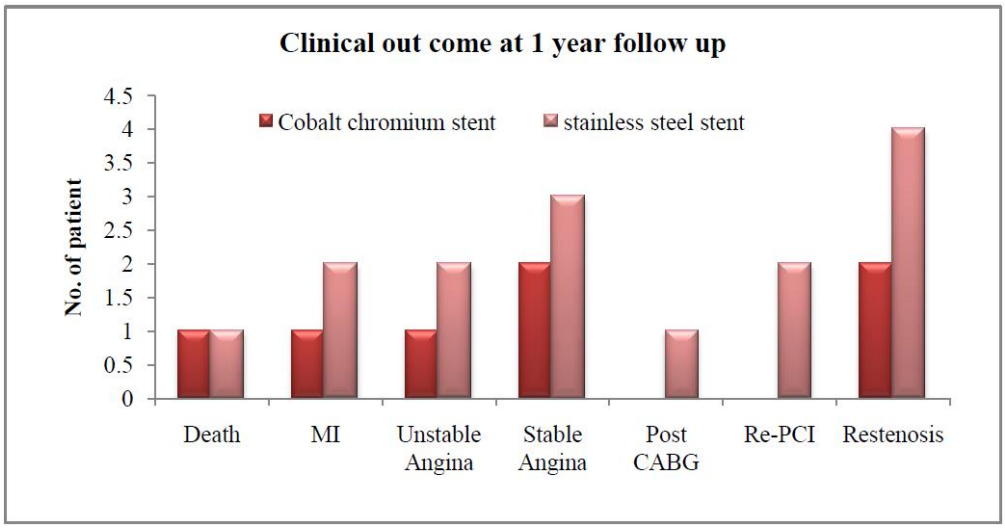

Figure. 3 Clinical Outcome at 1 year follow up

Limitation of the study:

Our study was a single centric, retrospective, observational study with small sample size which seemed not to represent the real world clinical practice as reported in other all-comers trials. [5]The limited sample size may increase the risk of failing to detect differences in both safety and efficacy between the two stents. The choice of stent by the intervention list who performs the primary PCI is a fundamental limitation of a non-randomized, observational analysis. Our study included only patients who have undergone PCI only for single stent and not multiple stents. This limited the sample size greatly.

CONCLUSION:

This study suggested that among CAD patient undergoing primary PCI, sirolimus stainless stent showed similar safety and efficacy profile as compared to sirolimus cobalt chromium stent. Although low risk of TVR was observed in both the stent, it was slightly higher in sirolimus stainless stent group as compared to sirolimus cobalt chromium stent groups. Higher rates of survival amongst the cobalt chromium group require further investigation.

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REFERENCES

1. Koh A. and Choi L., ―Comparing the use of cobalt chromium stents to stainless steel stents in primary percutaneous coronary intervention for acute myocardial infarction: a prospective registry‖, Acute cardiac care, 2011, 13(4):219-22

2. Henrique B., ―Stainless steel versus cobalt-chromium bare metal stents: clinical impact of the metal alloy in a "real world" scenario‖, Revista Brasileira de Cardiologia Invasiva, 2011, vol.19, n.1, pp. 47-52. ISSN 2179-8397
3. Kimura T. and Morimoto T., ―Comparison of Everolimus-Eluting and Sirolimus-Eluting Coronary Stents: 1-Year Outcomes from the Randomized Evaluation of Sirolimus-Eluting Versus Everolimus-Eluting Stent Trial‖, Circulation. 2012 Sep 4; 126(10):1225-1236.
4. Naito R. and Sakakura K., ―Comparison of long-term clinical outcomes between sirolimus-eluting stents and paclitaxel-eluting stents following rotational atherectomy‖, International Heart Journal. 2012; 53(3):149-53.
5. De Boer SP, Lenzen MJ, Oemrawsingh RM, Simsek C, Duckers HJ, van der Giessen WJ, Serruys PW, Boersma E. Evaluating the _all-comers' design: a comparison of participants in two _all-comers' PCI trials with non-participants. *Eur Heart J*. 2011; 32:2161–2167.