Proceedings of
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Science and Technology for Future Health

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Organized By:
Proceedings

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November 2-3, 2015
Institut Teknologi Bandung
Bandung, Indonesia

Organized by:
Preface

Wilujeng Sumping,

Welcome to 2015 Fourth International Conference on Instrumentation, Communications, Information Technology, and Biomedical Engineering (ICICI-BME), in Bandung, Indonesia.

On behalf of the organizing committee, we are delighted to welcome all of the participants to the ICICI-BME 2015. This biennial conference is organized under the auspices of the Institut Teknologi Bandung (ITB), Indonesian Sensor and Actuator System Society (ISASS), Indonesian Biomedical Engineering Society (IBES), and sponsored by the School of Electrical Engineering & Informatics, the Faculty of Mathematics & Natural Sciences, together with IEEE Indonesia EMB and CAS Chapters.

ICICI-BME is dedicated to the presentation and discussion of the latest developments and ideas in instrumentation, measurements, communications, information technology, and biomedical engineering, in both theory and application.

This conference also aims to strengthen the collaboration among international researchers, scientists, engineers, and industrial players in the fields of science and engineering. It is designed to be a meeting point for those who are involved, to globally exchange and share their views, ideas, and advances in science, technology, and industrial aspects.

Our gratitude to many people which helped making this conference a reality, to all of our invited speakers and guests, and for all of our committee members for their effort to ensure the success of this conference. Finally, we hope that all of participants will learn new things, make new contacts, get new ideas, and have fruitful discussion while having a pleasant experience during our conference in Bandung.

Hatur Nuhun, Thank You

Mitra Djamal & Tati L. R. Mengko
Chairs of ICICI-BME 2015
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Evaluation of Various Alloys for Stent on Platelet Aggregation Activity

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Abstract: Nowadays coronary atherosclerotic disease becomes a primary health problem due to its high morbidity and mortality rate. Such disease is related to the poor coronary blood flow quality. Coronary stent implantation is widely accepted to overcome the problem. There are various alloys available for stent commercially by different prices. This study was aimed to evaluate the various alloys for stent on platelet aggregation activity. The materials used under research were stainless-steel of SS 316L (Otocompo, Sweden) and cobalt-chromium of CoCr L605 (Remanium Star, Germany). Twenty eights alloys (14 SS 316L and 14 CoCr L605) were shaped as discs with 10 mm diameter and 2 mm thickness respectively. Venous blood was drawn from medial cubit vein from 14 subjects of healthy people with neither established atherosclerotic disease nor risk factors. The drawn blood from each subject further be divided into three parts: one part was left without any induction (control), the other two parts were contacted to SS 316L and CoCr L605 respectively. Platelet aggregation activity in all of the samples were then calculated and analyzed by Anova. The result showed the average of platelet aggregation activity in percentage (%) were 89.96±17.93 (control), 80.16±22.04 (CoCr L605), and 80.91±20.68 (SS 316L). The Anova showed p<0.05. In conclusion, stainless-steel of SS 316L and cobalt-chromium of CoCr L605 did not affect platelet aggregation activity on healthy subject; therefore, both of the alloys were potential to be used as material choices for stent devices. Further research is needed to evaluate the effect of both alloys on atherosclerotic patients.

Keyword: cobalt-chromium, stainless-steel, stent, platelet aggregation, healthy people

I. INTRODUCTION

Atherosclerotic changes in cardiac vasculatures is known as Coronary Atherosclerotic Disease (CAD). The treatment of CAD is targeted to alleviate related symptoms as well as to prevent more severe event such as unstable angina, myocardial infarction and death. Among the CAD treatment options is Percutaneous Coronary Intervention (PCI) [1, 2].

Percutaneous Coronary Intervention is a procedure which is aimed to restore the caliber of narrowed coronary artery lumen due to atherosclerotic process. Narrowed part of coronary vessels will be dilated (angioplasty) by applying pressure at particular measure through balloon catheter against the stenotic wall. In order to preserve the lumen caliber once angioplasty is done, a net-like frame (struts) made up of metal or similar material, known as stent, will be deployed. The use of stent to maintain narrowed coronary vessels patency has been clinically proven to improve morbidity and mortality rate in CAD patients. Several advancements in materials used in coronary stent have been made, from the use of stainless steel to cobalt chromium, up to recently known as biodegradable materials (stainless steel, cobalt-based alloy, tantalium, nitinol, inert coating, active coating, or biodegradable) [3]. Each of stent materials has its own special features on vessel wall.

Coronary stent implantation has been widely accepted, although this procedure is still poses potential clinical hazards such as in stent restenosis (ISR) and in stent thrombosis (IST). The latter can occur shortly after stent implantation (acute stent thrombosis) or take place weeks to years afterward (late stent thrombosis). Clinical consequence of stent thrombosis is mostly catastrophic and fatal due to disturbance of coronary blood flow which might eventually lead to patient death. Physiological response varies to different coronary stent materials. This study was aimed to evaluate various coronary metal stent materials in term of platelet aggregation activity which was thought to be an underlying process in intra-stent thrombosis. The determination of the platelet aggregation was based on ISO 10993.4 [4].

II. MATERIALS AND METHODS

A. Materials and Patients
The materials used in this research were listed as in Table I. All the other chemicals to evaluate platelet aggregation were analytical or pharmaceutical grade and obtained from Sigma-Aldrich Chemicals (Bormem, Belgium).

The stainless-steel and cobalt chromium alloys were cut by dental steel bur for discs shape of size 10 mm in diameter and 2mm thickness (figure 1 and 2). The alloys were sterilized by UV light for 24 h. This research had the Ethics Committee Approval Letter from MHREC (Medical and Health Research Ethics Committee Gadjah Mada University) with Ref. No. KE/FK/929/EC.

<table>
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<tr>
<td>Stainless-steel</td>
<td>SS 316L</td>
<td>Otocompo, Sweden</td>
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<tr>
<td>Cobalt-Chromium</td>
<td>CoCr L605</td>
<td>Remanium Star, Germany</td>
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**TABLE I**
MATERIALS USED

![Figure 1. Samples of SS 316 L](image1)

![Figure 2. Samples of Co Cr L 605](image2)

**B. Platelet Aggregation Evaluation**

Evaluation of platelet aggregation was done based on ISO 10993:4 [4]. Venous blood was drawn from medial cubiti vein of 14 healthy subjects. Inclusion criteria of the subjects were: young adults, being in good health condition and neither established atherosclerotic disease nor risk factors.

Each blood collected from the subject samples were divided into 3 parts. The first part was for platelet aggregation evaluation of blood without alloy induction. The second part was for stainless steel induction, and the third part was for cobalt chromium induction ones. The evaluation procedure of the blood without stent induction was as follows: 1 ml EDTA was added to the blood, then run for complete blood count by ADVIA machine. In another tube, 1 ml citric acid was added to the blood, then added 10 µL of 20µmol ADP and run for complete blood count by ADVIA machine. Platelet aggregation activity was then calculated by the formula [5]:

$$\text{EDTA platelet count} \times 100%$$

$$\text{Citric acid platelet count}$$

$$\text{EDTA platelet count}$$

(1)

The evaluations of platelet aggregation from the blood of 14 healthy patients after induction of cobalt chromium or stainless steel alloys were as follows: 1 ml blood containing EDTA was induced by cobalt chromium or stainless steel alloys for 60 minutes, then determine for complete blood count by ADVIA machine. On other tube, 1 ml blood containing citric acid was induced by cobalt chromium or stainless steel alloys then added by 10 µL of 20µmol ADP and run for complete blood count by ADVIA machine. Platelet aggregation activity was determined by the formula (1). The data were presented as means ± standard deviation of platelet aggregation.

**C. Statistical Analysis**

The data on platelet aggregation were analyzed by one way analysis of variance (ANOVA). The level of statistical significant p was set as 0.05. The data normality was examined by Kolmogorov-Smirnov test.

**III. RESULTS AND DISCUSSION**

Coronary atherosclerotic disease (CAD) becomes the main health problem among people throughout the world due to its high morbidity and mortality rate. In 1999, one third of world’s mortality was caused by CAD. It is estimated that by 2020 the mortality rate due to CAD will raise from 17 million to 25 million death people per year [6].

Atherosclerotic process in cardiac vasculatures begins as early as young adolescent age until the clinical symptom occurs in acute or chronic fashion. Clinical symptom of CAD occurred in acute fashion is commonly called heart attack [7]. Atherosclerotic process is affected by several factors such as hypertension, hyperglycemia (diabetes mellitus), dyslipidemia,
and unhealthy life styles (for instance: cigarette smoking and sedentary lifestyle) [8, 9]. Inflammation in atherosclerotic plaque and fissure of plaque rise to platelet aggregation and in turn causes thrombosis [10, 11]. Healthy young adults without established atherosclerotic disease or risk factors were chosen as the subjects under this research in order to minimize the risk of platelet aggregation activity.

It was known that thrombosis problem could be overcome with the administration of double antiplatelet [12]. However, the problem remains questioned in mind whether various stent materials (alloys) available commercially also play roles in the development of thrombosis?

The current research aimed to evaluate the various alloys for coronary stent on platelet aggregation activity. The alloys under research were stainless-steel of SS 316L and Cobalt-chromium of CoCr L605. The mean and standard deviation of platelet aggregation activity in percentage (%) were in Table II.

Platelet aggregation is the process by which platelets adhere to each other at sites of vascular injury. Platelet aggregation has long been recognized as critical for hemostatic plug formation and thrombosis. Nowadays it becomes widely accepted that platelets play a pivotal role in the development of cardiovascular disease [13]. As a consequence, inhibitors of platelet aggregation have become increasingly important part of the armamentarium for the prevention and treatment of many atherothrombotic disorders.[14, 15].

Table III showed that the ANOVA had p<0.050. It means that both of the alloys had no difference effect with the control group on platelet aggregation activity although their means on platelet aggregation activity showed less percentages.

This study proved there was no significant difference in platelet aggregation activity among groups treated with different stent materials. Thrombosis process was assumed to be similar by platelet aggregation measurement. Higher platelet aggregation activity was observed in the group of stainless steel induction than that of cobalt chromium one, although the difference was not statistically significant. Type of stent material did not prove to play a role in thrombosis process. The result of this study was in line with that of clinical trial conducted by Angeline et al. [16] which was proved there was similar effect of platelet aggregation activity between cobalt chromium stents to stainless steel in primary percutaneous coronary intervention for acute myocardial infarction. However, further research with higher sample number was needed to ensure the result.

One advantage of cobalt chromium based alloy to be used as coronary stent compared to stainless steel one is that such stent material can be manipulated in thinner stent shape [17]. This thinner shaped was assumed to decrease the incidence in stent restenosis. Jabara et al [18] stated that ultra thin strut cobalt chromium Protea stent which features fixed geometry, uniform cell size, and ultra smooth surface exhibited favourable arterial responses with significant reduction of neointimal formation in porcine coronary arteries, when compared to a commercially available cobalt alloy bare metal stent (BMS). By this research, it seems that improvement and innovate further to the BMS cobalt chromium based alloy might improve substantial biological responses as well.

Cobalt alloys has been used since 1937 in medical implants, but the used as stents material is a recent advancement. In cardiovascular implants, cobalt alloys were used in aneurysm clips, septal occlude and pacemaker leads. In coronary stent, the cobalt alloy shows higher strength than that of stainless steel, allowing thinner struts while maintaining radial strength. This characteristic improves to prevent in stent restenosis [17].

The other advantage of cobalt chromium as stent based material was the phenomenon of cobalt chromium which was not influenced by magnetic wave effect [19]. Once such stent was deployed in the coronary vessel, was not affected by magnetic wave that was frequently used in clinical practice.

The biocompatibility and safety profile of the cobalt chromium alloy and stainless steel has been evidenced by over a decade of incorporation into manufacturing of surgical implants [20, 21, 22]. Regarding to the alloy of CoCr L605 and SS 316L under current research, it was proved from the research by Sunarintyas et al. [23] on the biological effects of cobalt-chromium and stainless-steel on fibroblast cells and rabbits that the SS 316L and cobalt chromium L605 did not show any cytotoxic effect and acute toxicity characteristic. Although the SS 316L showed more cytotoxic and acute

<table>
<thead>
<tr>
<th>Group</th>
<th>Platelet aggregation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control (no induction)</td>
<td>89.96 ± 17.93</td>
</tr>
<tr>
<td>CoCr L605</td>
<td>80.16 ± 22.04</td>
</tr>
<tr>
<td>SS 316L</td>
<td>80.91 ± 20.68</td>
</tr>
</tbody>
</table>

Table II revealed that CoCr L605 induced platelet aggregation less than SS 316L. It was also showed that both of alloys induction on healthy blood caused less platelet aggregation activity than the blood without induction (control group). Further statistical analysis of the platelet aggregation activity of the current research was as table III.

<table>
<thead>
<tr>
<th></th>
<th>Sum of squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between groups</td>
<td>832.73</td>
<td>2</td>
<td>416.36</td>
<td>1.012</td>
<td>0.37</td>
</tr>
<tr>
<td>Within groups</td>
<td>16050.82</td>
<td>39</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>411.56</td>
<td>42</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TABLE III
SUMMARY OF ONE-WAY ANOVA OF PLATELET AGGREGATION ACTIVITY
toxicity characteristic but the difference was not significant. Both alloys were potential for medical devices materials.

Furthermore, robust data substantiate the clinical safety and efficacy in the coronary circulation. In addition to enhance radiographic visibility, cobalt chromium appears devoid of adverse proliferative responses that accompany implant of stents fashioned from other alloys (gold, martensitic nitinol [24, 25, 26]). Favorable biocompatibility profile is desirable for coronary stents materials.

IV. CONCLUSION

By this study, it can be concluded that stainless-steel of SS 316L and cobalt-chromium CoCr L605 and did not affect platelet aggregation activity on healthy subject. Both of the alloys were potential to be used as material choices for coronary stent devices. Further research is needed to evaluate the effect of both alloys on atherosclerotic patients and different of risk factors.

V. ACKNOWLEDGMENT

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