การศึกษาประสิทธิผลและความปลอดภัยของการใช้บอลลูนเคลือบยาในผู้ป่วยที่มีรอยโรคที่มีหลอดเลือดหัวใจตีบในประเทศไทย ที่ 1 ปี

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1 Year Outcome of Clinical Efficacy and Safety of Drug Coated Balloon Usage in Coronary Artery Disease in Thailand

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Abstract

Background: Drug coated balloon is indicated as the treatment of in stent restenosis (ISR) and de novo lesion in coronary artery disease. The evidence of drug coated ballon (DCB) used for Thai patient in term of safety and efficacy is limited. **Objectives:** Our real-world cohort study was aimed to evaluate the paclitaxel coated balloon (Sequent please) for 1-year clinical efficacy and safety in Thai population. **Methods:** From June 2020 to January 2022, a total of 97 symptomatic patients with 100 procedures including de novo, bifurcation and in stent restenosis (ISR) were treated with DCB at Central Chest Institute of Thailand. The composite end point was major adverse cardiac events (MACE) which was a composite of cardiovascular death, target vessel related myocardial infarction (MI) and target lesion revascularization (TLR) at 12 months follow-up. **Results:** The majority of patients were presented with chronic stable angina (51%). The most common indication for the use of DEB was ISR (82%) followed by de novo lesion (17%), bifurcation lesions (1%). The mean DEB diameter of 2.88 ± 0.58 mm and average total length of 24.95 ± 8.80 mm. At 12 months follow-up, 4% of patients developed MACE in ISR subgroup only. MACE was mainly driven by TLR (4%) followed by target vessel related myocardial infarction (1%) .No cardiovascular death was occurred in study. **Conclusion:** In our cohort of Thai patients demonstrated that DCB was a safe and effective treatment modality with a low incidence of MACE observed at 12 months follow-up.

Keywords: Drug coated balloon, In stent restenosis, MACE, TLR

บทคัดย่อ

ภูมิหลัง: บอลลูนเคลือบยามีข้อบ่งใช้ในผู้ป่วยที่มีภาวะตีบซ้ำจากการใช้ขดลวดและเส้นเลือดตีบในหลอดเลือดหัวใจ ปัจจุบันข้อมูลเกี่ยวกับประสิทธิผลและความปลอดภัยในการใช้บอลลูนเคลือบยาในคนไข้ไทยยังมีข้อจำกัด **วัตถุประสงค์:** การศึกษานี้จึงเป็นการศึกษาประสิทธิผลรวมถึงความปลอดภัยของบอลลูนเคลือบยาในผู้ป่วยที่มีข้อบ่งใช้ในคนไทย โดยมีการติดตามไปข้างหน้าหลังการใช้ที่ 12 เดือน **วิธีการ:** เก็บข้อมูลผู้ป่วยทุกคนที่มีการใช้บอลลูนเคลือบยาในสถาบันโรคทรวงอก ตั้งแต่ มิถุนายน ค.ศ. 2020 ถึง มกราคม ค.ศ. 2022 จำนวน 97 คน และ 100 หัตถการ ซึ่งข้อบ่งใช้ในการใช้ประกอบไปด้วย รอยโรคหัวใจตีบรวมถึงแขนงเส้นเลือด ขดลวดตีบซ้ำ โดยดูผลรวมของอุบัติการณ์โรคหัวใจซึ่งประกอบไปด้วยการเสียชีวิตจากโรคหัวใจ ภาวะกล้ามเนื้อหัวใจขาดเลือดสัมพันธ์กับเส้นเลือดที่ทำหัตถการ มีการทำหัตถการซ้ำที่เส้นเลือดที่ได้รับการรักษาภายใน 12 เดือน **ผล:** จากการศึกษาพบว่า ผู้ป่วยได้รับการทำบอลลูนด้วยอาการแน่น

หน้าอกเรื้อรังมากที่สุดร้อยละ 51 มีการใช้บอลลูนเคลือบยาในข้อบ่งชี้เส้นเลือดหัวใจตีบซ้ำในขดลวดร้อยละ 82 เส้นเลือดหัวใจตีบร้อยละ 17 แขนงเส้นเลือดหัวใจร้อยละ 1 ขนาดบอลลูนเคลือบยาที่ใช้เฉลี่ยที่ 2.88±0.58 มิลลิเมตร และความยาวเฉลี่ย 24.95±8.80 มิลลิเมตร ที่ 12 เดือน พบว่าอุบัติการณ์โรคหัวใจอยู่ที่ร้อยละ 4 และพบเฉพาะในกลุ่มที่ใช้บอลลูนเคลือบยาในขดลวดตีบซ้ำเท่านั้น โดยเป็น ภาวะกล้ามเนื้อหัวใจขาดเลือดสัมพันธ์กับเส้นเลือดที่ทำหัตถการร้อยละ 1 มีการทำหัตถการซ้ำที่เส้นเลือดที่ได้รับการรักษาร้อยละ 4 ไม่พบผู้ป่วยเสียชีวิตจากโรคหัวใจ **สรุป:** บอลลูนเคลือบยามีประสิทธิผลและความปลอดภัย ในผู้ป่วยไทยที่มีข้อบ่งชี้ในการใช้ โดยมีผลรวมการเกิดภาวะแทรกซ้อนต่ำในโรคหัวใจที่ 1 ปี

คำสำคัญ: บอลลูนเคลือบยา, อุบัติการณ์โรคหัวใจ, ภาวะกล้ามเนื้อหัวใจขาดเลือด

Introduction

Coronary artery disease and acute myocardial infarction was one of the most cause of death worldwide. In 1978 transluminal dilatation of coronary was introduced in the world which reduced the mortality rate from acute coronary syndrome. The latter drug eluting stent (DES) was introduced to reduce recoil and restenosis after balloon angioplasty. However, DES has other problems like neointimal hyperplasia causing stent restenosis (ISR). So, drug coated balloon (DCB) was introduced for the first time in 1999 by Herdeg C, et al. The local paclitaxel delivery was used for the prevention of coronary restenosis[1-3]. After that in 2002 the first randomized trial of sirolimus eluting stent (RAVEL trial) was published and shown promising result in prevention of restenosis[4, 5]. The meta-analysis showed that in bare metal stent (BMS) ISR using DCB or DES had the same result in target lesion revascularization at 1 year and at 3 years respectively. However, from this same study demonstrated that DES ISR corrected with using another DES has less target lesion revascularization at 1 year[8].

For de novo small vessel coronary lesion there are several evidence showed that DCB has favorable result in late lumen gain[9]. The PICCOLETO (Drug Eluting Balloon Efficacy for Small Coronary Vessel Disease Treatment) trial compared between a paclitaxel-DCB with paclitaxel-eluting stent showed that DCB was increased in percentage diameter stenosis at the angiographic follow-up significantly compared to DES[9]. In RESTORE SVD and PICCOLETO 2 which compared DCB with new generation DES (Zotarolimus and Evalolimus eluting stent respectively) showed that there were non inferiority of luminal diameter angiographic follow up at 6-9 months[10-11]. And in BASKET-SMALL[2] trial which compared DCB and Zotarolimus eluting cobalt chromium stent resulted in non-inferiority of clinical effectiveness and safety[12].

However, there is limited data and evidence using DCB in both in stent restenosis and de novo small vessel lesion in Thailand. We therefore sought to evaluate the clinical efficacy and safety of SeQuent Please DEB (B. Braun, Melsungen, Germany) in our cohort of Thai patients in “real world” clinical practice.

Materials and methods

2.1 Study population

From June 2020 to January 2022, a total of 97 symptomatic patients with 100 procedures including de novo, instent restenosis (ISR) were treated with 109 SeQuent Please DCBs at Central Chest institute of Thailand.

2.2 Study design

Prospective study of the patients who had indication for DCB usage and received treatment using sequent please DCB. Clinical follow up and patient information were collected at 1, 6, 9 and 12 months respectively. Due to prospective study design, inform consents were required from all patients.

2.3 Interventional procedure

All PCIs were performed using standard techniques and according to current practice guidelines. The instent restenosis lesions are encouraged to use intravascular imaging. All patients were pretreated with optimal antiplatelet including aspirin gr. V and other P2Y12 (clopidogrel, prasugrel and ticagrelor) before the procedure. All patients will receive dual antiplatelet according to current guideline, followed by a minimum of 1 month of dual antiplatelet in patients who DCB

was used. Additional duration of clopidogrel, prasugrel and ticagrelor treatments were at the discretion of the attending physician.

2.4 Use of DCB during PCI

The stenosis coronary segment which were ISR and de novo lesions , were optimal lesion preparation predilatation with standard semi-compliant balloon and specialty balloons (scoring, cutting, non-compliant) balloon to vessel ratio of 1:1. To confirm that the vessels were well preparation intravascular imaging such as intravascular ultrasound (IVUS) and optical coherence tomography (OCT) were used on individual operator reference. After the lesion is predilated, the lesion must have an acceptable angiographic result which includes no flow limiting dissections and residual stenosis less than 30%. The SeQuent Please DEB catheter size was chosen at 1:1 balloon to vessel ratio and length of balloon was exceeded the target lesion for at least 2 mm (at both proximal and distal ends). The catheter(s) was inflated at least 8 atm for 30 to 60 seconds. The DES was implanted if the angiographic after DCB alone was not satisfactory due to significant recoil/residual restenosis or flow limited dissection.

2.5 Endpoints and Definitions

The primary endpoint was major adverse cardiac event (MACE) which composed of cardiovascular (CVS) death, target vessel related myocardial infarction (MI) and target lesion revascularization (TLR) at 1 year follow-up. Secondary endpoints include individual components of MACE, target vessel failure and target lesion thrombosis. Death from CVS causes was defined as death due to acute MI, cardiac perforation or tamponade, arrhythmia, a complication of the PCI procedure or as any death in which a CVS cause could not be ruled out.

Target-vessel failure was composed of re-occlusion, restenosis, and target vessel revascularization.

Target-vessel related MI was defined as the presence of new Q waves in at least 2 contiguous leads on electrocardiogram (concordant with the intervened target lesion) with elevation in cardiac troponin or in creatine kinase/creatine kinase-MB above the upper limit of the normal range, or in the absence of pathologic Q waves, MI was diagnosed in the presence of an elevation and rising in cardiac troponin[13]. TLR was defined as any repeat revascularization (percutaneous or surgical) secondary to a stenosis of more than 50% within the stent or within 5 mm proximal or distal to the stented segment. Target lesion thrombosis was defined according to the Academic Research Consortium criteria for definite and probable stent thrombosis[14]. In our study, we defined native coronary artery as small vessel when reference vessel diameter ≤ 2.5 mm and as de novo lesion when reference vessel diameter ≤ 2.5 mm.

Our prospective study conforms to the ethical guidelines of the 1975 Declaration of Helsinki and was approved by the institution's human research committee.

2.6 Statistical analysis

Continuous variables were expressed as mean± standard deviation. Dichotomous variables were expressed as counts and percentages. Statistical comparisons were performed using independent t test or Fisher's exact test, as appropriate. Multivariate regression analysis was performed (using an enter regression model) to evaluate predisposing factors for TLR, in which each entered variable had p-value < .1 based on univariate analysis. Calculations were performed using SPSS software (version 16.0; SPSS, Inc., Chicago, Illinois). All p-values were 2-sided and p-values < .05 were considered statistically significant.

Results

The baseline clinical characteristics were shown in Table 1 demonstrated 69 (71.13%) male patients and the mean age of the study patients was presentation was 64.74 ± 11.42 years. The most common comorbidities were hypertension and dyslipidemia which were 91 (93.81%) patients and 88 (90.72%) patients respectively. Diabetes mellitus (DM) was presented in 49 (50.51%) patients. The prevalence of current smoking in the study is quite low at 5%. Patients were mainly presented with chronic stable angina and NSTEMI at 51 (51%) patients and 26 (26%) patients respectively.

Table 1. Baseline Clinical Characteristics of Patients

Demographics	Overall (n = 97)
Male (%)	69 (71.13%)
Mean Age (years)	64.74 ± 11.42
Mean BW (kg)	67.94 ± 13.52
Mean BMI (kg/m^2)	25.38 ± 4.19
Prior MI (%)	29 (29.90%)
Prior HF (%)	8 (8.25%)
Prior CABG (%)	5 (5.15%)
DM (%)	49(50.51%)
HTN (%)	91 (93.81%)
DLP (%)	88 (90.72%)
Clinical Presentation (CAD Presentation) per procedure	**Overall (n = 100)**
NSTEMI (%)	26 (26.00%)
Chronic Stable Angina (%)	51 (51.00%)
Unstable Angina (%)	15 (15.00%)
Other (%)	8 (8.00%)
Laboratory profile during the procedure (not include 1 ESRD patient)	**Overall (n = 99)**
CKD (eGFR < 60 cc/min/1.73 m^2) (%)	13 (13.00%)
Mean GFR (cc/min)	74.57 ± 21.38
Mean creatinine (mg/dL)	1.01 ± 0.27
Medication	**Overall (n = 97)**
Aspirin (%)	97 (100%)
P2Y12 inhibitor (%)	95 (97.93%)
Clopidogrel (%)	82 (84.53%)
Ticagrelor (%)	8 (8.25%)
Prasugrel (%)	5 (5.15%)
Statin (%)	94 (96.91%)
Number of disease extent	**Overall (n = 97)**
One-Vessel disease (%)	9 (9.28%)
Multivessel coronary artery disease (MVD) (%)*	88 (90.72%)
Two-Vessel disease (%)	16 (16.49%)
Three-Vessel disease (%)	72 (74.23%)

*Combination of two vessel disease and three vessel disease

Most of the participants had multivessel coronary artery disease which was predominantly caused by three-vessel disease at 72 (74.23%). For the medication all patients were received aspirin and 97.93% of patients received P2Y12 inhibitor for 1 year. The majority of patients received clopidogrel at 84.53% as P2Y12 inhibitor.

In Table 2 shows the target lesion location, type of lesion and procedural data of our patients. From overall 100 procedures which used DCB were 82 ISRs and 18 non ISR diseases. The non ISR group, DCB was used in De novo lesion 17 cases and 1 case in LCx bifurcation. The left anterior descending artery was the highest target lesion in our study. The usage of DCB in LCx was higher significantly in Non ISR group at 44.4% compared to ISR group at 13.4%, p .002).

The number of IVUS usage in ISR group was 69.5% which was IVUS 41.5% and OCT 28%. In non ISR group IVUS was use only at 50%.

Table 2. Procedure characteristics

	Overall	ISR	Non ISR	p-value
Target vessel location (n = 100 procedures)	**n = 100**	**n = 82**	**n = 18**	
Left anterior descending artery	42 (42.0%)	36 (43.9%)	6 (33.3%)	.411
Left circumflex artery	19 (19.0%)	11 (13.4%)	8 (44.4%)	.002*
Right coronary artery	37 (37.0%)	33 (40.2%)	4 (22.2%)	.152
Left main	2(2.0%)	2 (2.4%)	0 (0.0%)	1.000
Imaging usage (n = 66/100 procedures)	**n = 66**	**n = 57**	**n = 9**	.022*
IVUS	43 (65.2%)	34 (59.6%)	9 (100%)	
OCT	23 (34.8%)	23 (40.4%)	0 (0%)	
PCI approached (n = 109 DCBs usage)	**n = 109**	**n = 91**	**n = 18**	
PCI Procedure success	109(100%)	91 (100%)	18(100%)	
Previous diameter stent (mm)		2.94±0.44		
Previous length stent (mm)		25.22±9.44		
DCB diameter (mm)	2.88±0.54	3.0±0.46	2.3±0.55	< .001*
DCB length (mm)	27.80±8.64	27.8 ± 8.60	27.78±9.11	.991
DCB diameter ≥ 3 mm	55 (50.5%)	53 (58.2%)	2 (11.1%)	<.001*

p values for mean data were calculated with the use of independent t-test, for percentages with the use of chi-square test or Fisher's exact test, * Significant at p-value < .05

The PCI procedures success rate was 100%. The size and length of DCB were 2.88±0.58 and 24.95±8.80 mm respectively. Previous ISR had occurred in stent size 2.94 ± 0.44 mm. The smaller DCB size was used more in the non ISR group compared to ISR group significantly which were 2.3±0.55 and 3.0±0.46 mm respectively, p < .001. However, the length of balloon usage is no statistically significant difference.

The patients were followed up at discharge, 30 days, 180 days and 365 days which totally 7 patients missing the follow up period and were collected data using telephone check. Event free patient at the end of study was 96% as shown in Table 3.

Table 3. Event free patient during follow up period

Follow up	Number of patients	Event free patient	Average day(s) follow up	Min and Max day(s)
At discharge	97 (all patient)	97 out of 97 (100%)		
30 days	97	97 out of 97 (100%)	36.28±10.22	Min 18, Max - 84
180 days	97	95 out of 97 (97.9%)	168.85±34.19	Min 82, Max - 247
365 days	96 (1 patients missing FUP)	93 out of 97 (95.9%)	364.20±61.48	Min 241, Max - 583

FUP = follow up , 1 patient missing FUP due to suicide at 8 months

Table 4. Outcomes at 12 months

Variable	Overall (n = 100)	ISR (n = 82)	Non ISR (n = 18)
Event (MACE) (%)	4 (4.0%)	4 (4.88%)	0 (0.0%)
Cardiac death (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MI	1 (1.0%)	1 (1.2%)	0 (0.0%)
TLR	4 (4.0%)	4 (4.88%)	0 (0.0%)
TVF	1 (4.0%)	1 (1.2%)	0 (0.0%)
Recurrent stenosis	4 (4.0%)	4 (4.88%)	0 (0.0%)

MACE = denotes major adverse cardiac events, MI= myocardial infarction, TLR = target lesion revascularization,

TVF = target vessel failure, ISR = in stent restenosis

The end point for 1 year was shown in Table 4. The MACE rate was 4 (4%) patients, and all occurred in ISR PCI, in contrary DCB using in De Novo lesion had 0% MACE rate. No cardiovascular death had occurred during the follow up. Only 1 patient had target vessel related MI and no target lesion thrombosis occurred. We evaluated the factors that could affect the primary endpoint but did not show relatively statistical significance.

Discussion

From our knowledge, this is the first DCB registry trial conducted in Thailand. Due to lack of specific indication and reimbursement issues in Thailand so we could record mainly using DCB in ISR and de no vo small lesion only according to indication recommended by the consensus on DCB usage guideline from Asia pacific group[15].

In our study showed that the MACE rate was 4(4%) and occurred only in the ISR group. To explain this low MACE rate might have resulted from the high number using intravascular imaging in the study population. Secondly, 3 of 4 MACE cases resulted from screening re-coronary angiogram evaluation 9 months after the index PCI which patients did not have symptoms. Our study showed that truly clinical driven MI was only 1 ISR case. The cause of TLR and TVF were low in our study could be from high intravascular imaging using in the patient including of both IVUS and OCT. Lastly, no de no vo lesion using DCB had significantly endpoint at the end of the study this might explained from that almost all patients comply to antiplatelet until end of the study.

In previous Southeast Asia registry study which were recruited all comer DCB usage patients in Singapore show that the result of MACE rate was 5.6% at 9 months16 compared to our study shown 4% MACE rate at 1 year. However in the previous old RCT study, MACE rate for ISR patients at 1 year were 9.1-23.9%. Our study had a significantly lower MACE rate might be from frequently use intravascular imaging and good adherence to antiplatelet medication.

Currently, the myocardial revascularization guideline 2018 from European Society of Cardiology (ESC)17 have given a Class Ia approval to DEB for the treatment of BMS and DES ISR as there is robust clinical data supporting its use in this particular lesion subset.

Favorable results are also seen with the use of DEB in de novo lesion.

However, from American heart association myocardial revascularization guideline[18] which was published in 2021 did not have any recommend regarding using DEB in ISR lesions. The guideline recommended coronary artery bypass graft instead of repeat PCI in ISR. There is a recommendation of using DCB in paragraph as an alternative.

In Asia Pacific we have DCB treatment in coronary artery disease recommended guideline from the Asia Pacific consensus group suggested using DCB in de no vo and ISR lesion. Focus recommends aggressively prepare lesion until residual stenosis before using DCB was less than 30% without flow limited dissection which in our studied protocol was followed by this consensus.

To emphasize the effectiveness of DCB in our study as shown in rate of re coronary angiogram are quite high compared to previous study, the primary end point still low. Our study result supports and emphasizes the DCB benefit in coronary disease and Indication which recommended from the Asia pacific DCB consensus group.

Limitation

In our study there were some limitations. Because we collected data during COVID pandemic cause the case enrollment were slower than usual which the period of case collection extended from 1 year to 2 years. However, we successfully collected complete data according to our precalculated number. Second our study was a single prospective registry study and due to registry study, patient selection and procedural technique were depended on individual operators' technique and experience. Finally, we used only one brand of DCB which was SeQuent Please, we are uncertain that the result of the study could conclude to other DCB which showed from previous study that not all DEBs are equal in terms of efficacy and safety.

Conclusion

Result from our study demonstrated that using Sequent Please DEB in ISR and de no vo lesion for Thai patients had an effective end point in term of low MACE rate, no intralesional thrombosis, no cardiac death at 1 year. Long term clinical follow up is necessary to establish its true clinical efficacy and safety.

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Declaration conflict of interest

Author received proctorship percutaneous coronary intervention in using DCB from Biosensor, Biotronik, B.Braun and Boston company. He also received honorarium in DCB lecture from B Braun, Biosensor, Biotronik and Boston company.

Clinical implication

From our knowledge this is the first prospective study of DCB usage in Thai CAD patient which showed favorable of effectiveness and safety.

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