Early and Intermediate Outcomes of Left Main Coronary Intervention

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Objective: *We examined the immediate and long-term outcomes after stenting of all comers for left main coronary artery (LMCA) stenoses.*
Background: *Left main coronary artery disease is regarded as an absolute contraindication for coronary angioplasty. Recently, several reports on protected or unprotected LMCA stenting, or both, suggested the possibility of percutaneous intervention for this prohibited area.*
Material and Method: *Eighty-one consecutive patients with LMCA stenoses were treated with stents. The post-stent antithrombotic regimens were aspirin and clopidogrel. The major adverse cardiac events (MACE) including death, Q-wave myocardial infarction, or repeat target lesion revascularization were followed. Patients were followed very closely and all attended office visit at 12 months.*
Results: *The procedural success rate was 86.4%, with no episodes of acute thrombosis. Follow-up angiography was performed in 30 of 65 eligible patients (46.2%). Angiographic restenosis occurred in eight patients (9.9%). Cumulative death occurred in 16 patients (19.7%). MACE at 30 day and 12-month was 12.3% and 33.3% respectively. From multivariate analysis, dialysis (HR =3.22, p = 0.048), urgent PCI (HR =2.39, p = 0.036), post-procedure TIMI flow < 3 (HR =25.99, p = 0.001) and final kissing balloon inflation (HR = 0.30, p = 0.04) were independent predictors of MACE at 12-month. There was one definite late stent thrombosis (1.2%).*
Conclusion: *Stenting of LMCA stenosis may be a safe and effective alternative to CABG in carefully selected patients. Further studies in larger patient populations are needed to assess late outcome.*

Keywords: *Left main coronary artery (LMCA), Left main PCI, Drug-eluting stent (DES), Outcomes, Survival*

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Despite improvements in the safety and long term efficacy of percutaneous coronary intervention (PCI), the presence of a significant narrowing of left main coronary artery (LMCA) has remained one of the last bastions of surgical dominance. Despite the statement of the 2005 European Society of Cardiology guidelines for PCI[1] that the use of PCI for patients with significant unprotected LMCA stenosis is indicated in the absence of other revascularization options (IIb, level C) and the 2005 AHA/ACC guidelines for PCI[2] in patients not eligible for CABG and in carefully selected patients (IIa, level C), the ongoing registry of LMCA intervention as a viable alternatives to bypass surgery has been evaluated with short and long term follow-up and is promising[3-11].

Patients with "unprotected" left main coronary artery (ULMCA) disease treated medically have an estimated 3-year mortality rate of 50%[12,13]. We sought to demonstrate the option of LMCA intervention as alternative in patients who are not candidate for

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bypass surgery or are not willing to undergo this major operation. However, PCI of ULMCA is associated with a high rate of early restenosis, especially when the procedure involves the distal left main bifurcation[14]. With the evolution of PCI techniques and the wide experience of drug-eluting stent (DES) placement for complex, high risk lesion in preventing restenosis and reduced the target lesion revacularization (TLR) over use of bare metal stent (BMS), the challenging part remaining to be addressed is for LMCA intervention[15,16]. The answer to the question is that LMCA PCI is effective among Thai patients.

Material and Method

This is a retrospective observational, single center study with prospective data registration which was conducted using CALYSTO IV Cardiac Cath Image IV Database. The present study included all consecutive patients who had a stenosis in the ostium and/or mid shaft, including distal, of all LMCA treated with PCI. The decision to perform PCI was an intention to treat based upon physician discretion. Patients were informed of the risk of left main PCI. The procedures were performed according to the practice of complete coverage of the diseased segment. At the start of the procedure, a bolus of heparin (100 IU/kg) or 7,500 IU was administered to achieve an activated clotting time > 250 seconds. Glycoprotein IIb/IIIa inhibitors were administered at the discretion of the operator. Clinical follow-up was scheduled for all patients at 1,6 and 12 months at our PCI clinic (office visit) as per usual practice or by direct telephone call to the patients. Dual antiplatelet therapy (aspirin 300 mg/d for the first three months and reduced to 81 mg/d afterward and clopidogrel 75 mg/d) were administered once daily for twelve months. All patients were advised to maintain lifelong use of asprin (81 mg/d). Clinical driven coronary arteriography follow-up was allowed and necessity for repeat target revascularization was decided by the operator. This study was approved by Siriraj Institute Review Board for this retrospective data collection and analysis.

Patient

Using computerized cardiac catheterization database system (CALYSTO Cardiac Cath-Image IV system), terms were searched from October 1, 2006 to March 31, 2008 using the following keywords; left main coronary artery, percutaneous coronary intervention. All patients who had LMCA stenosis and received PCI were recruited; those for whom PCI was abandoned after insignificant LM lumen area from intra-vascular ultrasound (IVUS) evaluation were excluded from the study. After the name was retrieved, the diagnostic catheterization and percutaneous coronary intervention registry form (NCDR® CathPCI Registry® v4.0) were searched, baseline demographics and all peri-procedural angiographic data were collected. Events at 30 days and 12 months were collected from medical records.

Definitions

Unprotected left main coronary artery (ULMCA) stenosis was defined as the absence of functioning grafts to the left anterior descending artery and/or to the left circumflex coronary artery. *Major adverse cardiac event (MACE)* was defined as combination of death of all causes, MI, or TLR. The MACE at 30 day and 12 months during follow-up will be collected. *Death* was defined as any post-procedural death or during the follow-up period. *Myocardial infarction* was based on the rise and fall of biochemical markers (CK-MB) of myocardial necrosis more than 3 times of the upper reference limit (URL) with at least one of the following: ischemic symptom, development of pathologic Q waves on the ECG, non-Q wave with ST-segment depression. *Target lesion revascularization (TLR)* was defined as a repeat revascularization to treat a stenosis within the stent or 5 mm distal and/or proximal segments adjacent to the stent, including the ostium of the left anterior descending artery and/or left circumflex artery.

Statistical analyses

Descriptive analysis has been performed. Continuous data were reported as means and standard deviation (SD), the categorical data were counted, reported as per cent. Parameters were entered for an univariate analysis using a Log-rank test. Variables with a univariate value of $p < 0.10$ were entered into the Cox proportional hazards model for multivariate analysis. Event-free survival during follow-up was evaluated according to the Kaplan-Meier survival analysis. All data were analyzed by using a SPSS statistical software package version 13.0.

Results

During the study period, a total one-hundred and eight patients underwent LM intervention at our institution. Of these, twenty seven patients whom IVUS showed insignificant stenotic lumen area were excluded. Eighty-one patients underwent coronary intervention. All patients had complete follow-up at 12

months.

The baseline characteristics are listed in Table 1. The average age was 67.9 years and 76.5% were male. Thirty patients (40.7%) had prior history of myocardial infarction, 20 patients (24.7%) had heart failure. Thirty-six patients (46.9%) present with acute coronary syndrome. Thirty-seven patients (45.7%) were treated because of a EuroScore $\geq$ 6 and/or prior bypass surgery failure in one or more of conduits to either LAD or LCX territories (n = 16, 19.8%). All patients receive both aspirin and clopidogrel either before or at start time of PCI. Glycoprotein IIb/IIIa inhibitor was used in twenty-six patients (32.1%); most of them received abciximab (n = 17). Baseline angiographic findings were summarized (Table 2). In 27 patients (33.3%) the stenosis was located at the ostium, in 8 patients (9.9%) the stenosis was located at mid shaft and in 46 patients (56.8%) was at distal left main bifurcation. Small left main caliber < 3 mm was observed in 14 patients (17.3%). Sixty-seven patients (82.7%) had unprotected left main coronary artery (ULMCA) disease. Fifty-seven patients (70.4%) underwent treatment including both runoff vessels and 48.1% received final kissing balloon inflation. Among these, 27 patients (33.3%) underwent the two-stent technique. One-hundred and eighteen stents were implanted in 81 patients (1.46 stent per patient). Among these 97 stents (82.2%) were DES. In 61 patients (75.3%) received exclusively DES implantation, 16 (19.8%) received BMS implantation. Angiographic success was achieved in 79 of 81 (97.5%), two patients who met the angiographic failure had final TIMI flow grade 2. There was one intra-procedural death, 2 patients had new Q-wave MI, 6 patients (7.4%) underwent TLR.

Table 1. Clinical Characteristics of the Study Population (n = 81 Patients)

	n = 81
Age (Yr)	67.9 $\pm$ 10.6
Male	62 (76.5%)
DM	33 (40.7%)
HT	62 (76.5%)
Dyslipidemia	62 (76.5%)
Smoker	21 (25.9%)
Prior MI	33 (40.7%)
Prior HF	20 (24.7%)
Prior CABG	16 (19.8%)
Body mass index	23.6 $\pm$ 3.0
EuroSCORE $\geq$ 6	37 (45.7%)
Presentation	
-Asymptomatic	4 (4.9%)
-Stable angina	39 (48.2%)
-UA/NSTEMI	36 (44.4%)
-STEMI	2 (2.5%)
Cardiogenic shock in 24 hr	5 (6.2%)
PCI status	
-Elective	53 (65.4%)
-Urgent	21 (25.9%)
-Emergency	7 (8.64%)
Aspirin	81 (100%)
Clopidogrel	81 (100%)
GPIIb/IIIa Inhibitor	26 (32.1%)
Abciximab	17 (21.0%)
Eptifibatide	9 (11.1%)

In-Hospital and Long Term MACE

The post-procedure events were summarized (Table 3). Sixteen patients (19.8%) had non-Q wave MI by positive biomarkers (CK-MB $\geq$ 3 URL), eight patients (9.9%) had cardiogenic shock, 5 patients (6.2%) had heart failure. Major events at 30 day and 12 months were summarized (Table 4). Clinical success (angiographic success without any MACE) was achieved in 86.4%. Two patients (2.5%) had Q-wave MI, 9 patients (11.1%) died within 30 days (one patient died in the

Table 2. Lesion and Procedural Characteristics of the Study Population (n = 81 Patients)

	n = 81
Left main characteristic	
Unprotected left main	67 (82.7%)
Lesion location	
Ostial lesion	27 (33.3%)
Mid-shaft lesion	8 (9.9%)
Distal lesion	46 (56.8%)
Post procedure TIMI flow	
0/1	0 (0%)
2	2 (2.5%)
3	79 (97.5%)
RVD $\leq$ 3mm	14 (17.3%)
Provisional stenting	57 (70.4%)
Two-stent technique	27 (33.3%)
Final kissing balloon inflation	39 (48.1%)
Total stent usage, n	118
Drug-eluting stent	97 (82.2%)
Bare metal stent	21 (17.8%)
LM stent strategy	
Drug-eluting stenting only	61 (75.3%)
Combined stenting	4 (4.9%)
Bare metal stenting only	16 (19.8%)

Table 3. In-Hospital Events

	n = 81
Myocardial Infarction (Positive Biomarkers)	16 (19.8%)
Cardiogenic Shock	8 (9.9%)
Heart Failure	5 (6.2%)
CVA/Stroke	1 (1.2%)
Tamponade	3 (3.7%)
New Requirement for Dialysis	2 (2.4%)
Bleeding Event within 72 Hours	3 (3.7%)

Table 4. Cumulative Events at 30-Day and at 12-Month Clinical Follow-Up

	30-day (n = 81)	12-month (n = 81)
Death	9 (11.1%)	16 (19.8%)
MI	2 (2.5%)	11 (13.6%)
TLR	2 (2.5%)	11 (13.6%)
MACE	10 (12.3%)	27 (33.3%)

MI = myocardial infarction, TLR = target revascularization, MACE = major adverse cardiac event

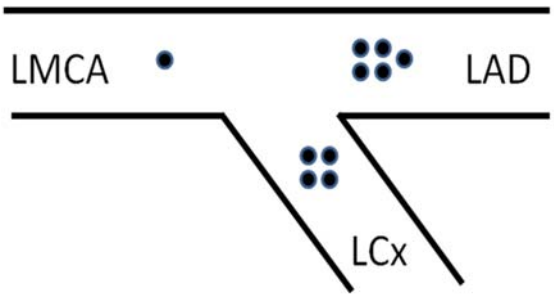

Fig. 1 Sites of in-stent restenosis

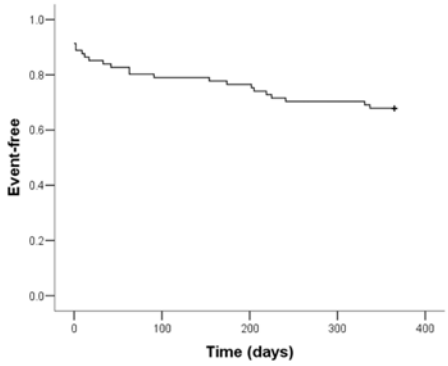

Fig. 2 Kaplan-Meier Survival for MACE at 12-Month

catheterization laboratory). Six patients (7.4%) had urgent repeat TLR. MACE was observed in 10 patients (12.3%). At 12 months follow-up, cumulative MACE were 33.3%, 16 patients (19.8%) died and 11 patients (13.6%) developed new MI and had undergone repeat TLR. One patients had definite late stent thrombosis. Approximately, one-third (37%) of total population underwent controlled coronary arteriography. Eight patients (9.9%) had 10 sites of in-stent restenosis and the locations are shown in Fig. 1. Kaplan-Meier survival of MACE-free patients is shown in Fig. 2.

Predictor of MACE

Table 5 list the univariate predictor of MACE. Variables analyzed were dialysis (p = 0.018), Euro SCORE more than 6 (p = 0.049), non-elective PCI (p = 0.012), post-procedure TIMI flow less than 3 (p = 0.037), bifurcation stenting (p = 0.003), final kissing balloon inflation (p = 0.009). Table 6 list the multivariate predictors of MACE at 12-month. In the overall population, the factors associated with MACE were post-procedural TIMI flow < 3 (HR = 25.99, 95% CI = 3.65-184.72, p = 0.001), renal replacement therapy (HR = 3.22, 95% CI = 1.01-10.31, p = 0.048), final kissing balloon treatment (HR = 0.3, 95% CI = 0.09-0.94, p = 0.04), urgent PCI (HR = 2.39, 95% CI = 1.06-5.41, p = 0.036). Survival at 12 months was analyzed and shown in each predictor analyzed (Fig. 3).

Discussion

Our study was not unique, target LM was unprotected (82.7%). The indications for LM intervention were urgent (25.9%) and emergency procedures (8.7%). The uses of stents were not controlled, our patients received either BMS (17.8%) or DES (82.2%) based on operator discretion. Surprisingly our main findings revealed rather high incidence of MACEs, including death at 30-day (12.3%) and at 12-month (33.3%). We did not investigate the causes of the all-cause mortality, but most were considered cardiac death according to the ARC definition. However, due to the urgent-emergent procedures, STEMI in nature of the clinically driven LM-PCI and cardiogenic shock prior to the LM-PCI (6.2%) could contribute to these results. We reported a 32.1% co-administered GPIIb/IIIa inhibitor during the procedure, unusual for regular practice. In fact, our patients were at very high risk, with many having diabetes (40.7%), Euro Score $\geq$ 6 (45.7%), prior

Table 5. Univariate Analysis of MACE at 12-Month follow-up

	Hazard Ratio	95% CI	p-value
DM	1.75	0.68-4.50	0.244
Renal replacement therapy	9.82	1.04-92.84	0.018
EuroSCORE $\geq$ 6	2.59	1 .00-6.76	0.049
LVEF < 30%	0.75	0.12-4.35	0.730
Urgent/emergency PCI	3.41	1.28-9.09	0.012
Glycoprotein IIb/IIIa inhibitor	1.96	0.74-5.20	0.734
Post-procedure TIMI flow < 3	∞	∞	0.037
Bifurcation stenting	8	1.72-37.32	0.003
Two-stent technique	1.2	0.42-3.44	0.734
Final kissing balloon inflation	3.64	1.35-9.85	0.009
Drug-eluting stent	1.17	0.37-3.76	0.789

LVEF = left ventricular ejection fraction

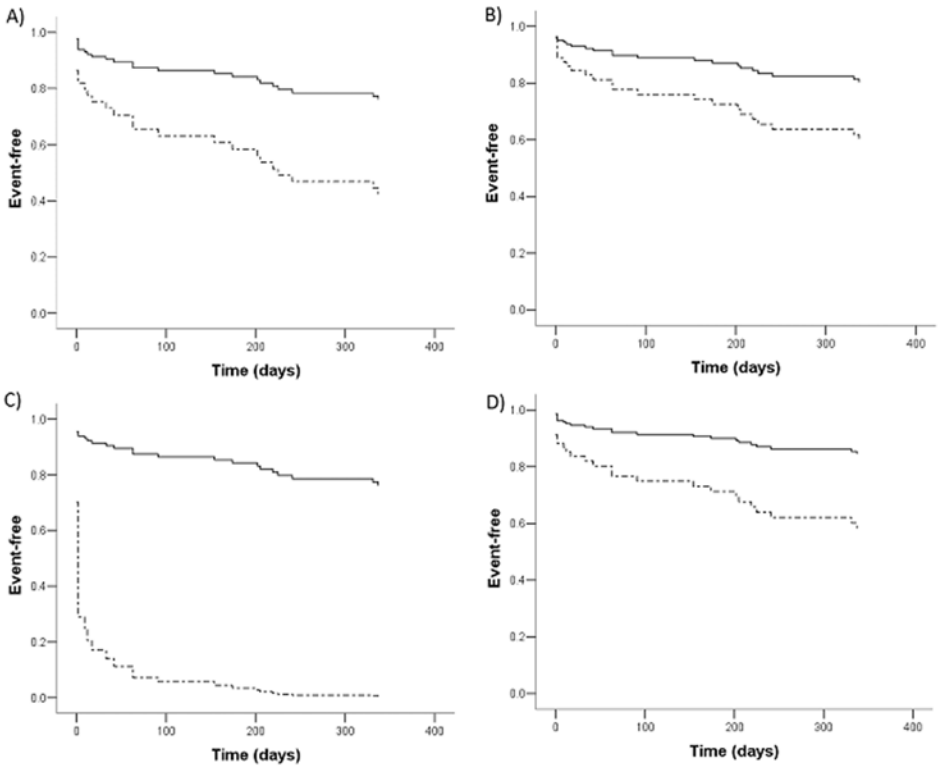

Fig. 3 Kaplan-Meier curve of MACE at 12 months , A) Non-dialysis group is indicated in solid line , dialysis group is indicated in dotted line , HR = 3.22 , p = 0.048 B) Elective PCI group is indicated in solid line, Non-elective PCI group is indicated in dotted line, HR = 2.39 , p = 0.036 C) Post-procedure TIMI flow 3 is indicated in solid line , Post-procedure TIMI flow less than 3 group is indicated in dotted line HR = 25.99 , p = 0.001 D) Final kissing balloon inflation group is indicated in solid line , No final kissing balloon inflation group is indicated in dotted line HR = 0.30 , p = 0.04

Table 6. Multivariate Analysis of MACE at 12-Month

	Hazard Ratio	95% CI	p
Dialysis	3.22	1.01-10.31	0.048
EuroSCORE > 6	1.73	0.72-4.15	0.218
Non-elective PCI	2.39	1.06-5.41	0.036
Post-procedure TIMI flow < 3	25.99	3.65-184.72	0.001
Bifurcation stenting	1.94	0.33-11.36	0.461
Final kissing balloon inflation	0.30	0.09-0.94	0.040

Table 7. Comparison of Characteristics, Procedural Outcomes and Events

	Chieffo et al[10]	Valgimigli et al[17]	Park et al[3]	Siriraj
Patient	85	95	102	81
Age	63 $\pm$ 11.7	64 $\pm$ 12	60.3 $\pm$ 11.1	67.8 $\pm$ 10.64
Male	84.3%	66%	71.9%	76.5%
DM	21.2%	30%	84.4%	40.7%
Acute MI	NA	17%	9.8%	2.5%
Cardiogenic shock	NA	9%	0%	6.2%
Distal location	81.2%	65%	70.6%	56.8%
Bifurcation stenting	74.0%	40%	41.0%	70.4%
Culotte	10.0%	36%	0.0%	15.8%
T stent	8.0%	44%	3.0%	19.3%
Crush	59.0%	12%	38.0%	8.8%
Final Kissing Balloon Inflation	24.0%	8%	59.0%	48.1%
Short term	In-hospital	30 day	In-hospital	30 day
-Death	0.0%	11%	0.0%	11.1%
-MI	5.9%	4%	6.9%	2.5%
-TLR	0.0%	0%	0.0%	0.0%
-MACE	NA	15%	6.9%	12.3%
Long term	6 month	503 day (median)	11.7 $\pm$ 3.4 month	12 month
-Death	3.5%	14%	0.0%	8.7%
-MI	NA	4%	6.9%	11.1%
-TLR	18.8%	6%	2.0%	11.1%
-MACE	20%	24%	7.9%	21%

MI = myocardial infarction, TLR = target revascularization, MACE = major adverse cardiac event

MI (40.7%) and ACS (46.9%). The location of the treated lesions noted as mid and distal LM bifurcation (66.7%), the rather small LM caliber < 3.0 mm (17.3%) and the so called 2-stent technique (47.4%) could be associated with the high TLR rate among our group. The difference in the definition of MI in our study as the post-procedure elevation of CK-MB $\geq$ 3 times the upper normal limit, with or without angina, made the incidence of MI higher than in the other reports. In survival curves analysis of our study, any renal replacement therapy, urgent/emergency PCI, post-procedure TIMI flow < 3, and final kissing balloon inflation are associated with worsening outcomes. In contrast, there was no impact on MACEs with the LV function, the use of GPIIb/IIIa and use of DES. Valgimigli et al[17] report that in their clinical result on LM-PCI, in 95 patients both BMS and DES were used, with the mortality and MACE-free rates at 30 days and 12 months being also similar to our study. At 30 days, death (11% vs. 11.1%), MACE free (85% vs. 87.7%) were observed. At 12 months, death

(14% vs. 9.7%), and MACE-free (76% vs. 76.4%) survival were also observed. He also reported that the use of DES, Parsonnet score, troponin elevation at entry, distal LM location and reference vessel diameter were independent predictors of MACE.

Compared with other real world LM-PCI registries reported earlier using only DES, the MACEs, death rate, MI and TLR& TVR were found to be lower than in our study (Table 7)[3,10,17]. We might conclude that the conflicting result could be attributed to the use of BMS (17.8%) and small LM caliber (17.3%) in our study. Despite these short term follow-up results, if we look for longer term follow-up for remaining MACE-free, during the 3 years follow-up of LM intervention (DELFT registry)[18], only DES were implanted. After 3 years, major adverse cardiovascular events (MACE)-free survival in the whole population was 73.5%. According to the Academic Research Consortium definitions, cardiac death occurred in 9.2% of patients, and reinfarction, target lesion revascularization (TLR), and target vessel revascularization (TVR) occurred in 8.6%, 5.8% and 14.2% of patients, respectively. Lee et al[19] report 5-year follow-up of MACE-free of 77.5%. These data might assist in formulating, designing the LM intervention strategy for our patients and become an alternative choice for revascularization. The limitations of this study are the small sample sizes. The variation of patients LMCA stenosis include the protected and unprotected LMCA interventions. The use of BMS alone for the LM intervention and the mixed usage of both DES and BMS in the same setting could add more MACE in our patients. Despite its high risk nature, lower angiographic study could be pursued; mostly clinical driven angiography could be performed. The technique of distal LM stenting is another area that needs to be evaluated in order to answer the unsolved problems. Comparative study between LM intervention and CABG should also be addressed.

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ผลการรักษาผ่านสายสวนหลอดเลือดโคโรนารีย์แขนงซ้ายส่วนต้นตีบระยะแรกและระยะกลาง

ดำรัส ตรีสุโกศล, ศุภเดช สุจริตรักษ์, สุวัจชัย พรรัตนรังสี, ชุณหเกษม โชตินัยวัตรกุล, เรวัตร พันธุ์กิ่งทองคำ, วิวรรณ ทังสุบุตร, ณัฐวุฒิ วงษ์ประภารัตน์, ทิพยวรรณ เลิศวิไล, ประดิษฐ์ ปัญจวีณิน

วัตถุประสงค์: *เพื่อศึกษาผลการรักษาโรคหลอดเลือดหัวใจตีบที่ขั้วซ้ายด้วยการรักษาผ่านสายสวนหลอดเลือดหัวใจด้วยบอลลูนและขดลวดค้ำยันในห้องปฏิบัติการตรวจสวนหลอดเลือดและติดตามทางคลินิกจนครบ 1 ปี*

ภูมิหลัง: *ผู้ป่วยที่มีหลอดเลือดโคโรนารีย์แขนงซ้ายส่วนต้นตีบ ต้องได้รับการรักษาด้วยการผ่าตัดต่อหลอดเลือดหัวใจเท่านั้น ในปัจจุบันการรักษาผ่านสายสวนด้วยบอลลูนและสอดฝังขดลวดค้ำยัน อาจเป็นวิธีรักษาทางเลือกอีกชนิดหนึ่งที่สามารถประยุกต์ใช้ในผู้ป่วยหนักที่อาจทนการผ่าตัดไม่ได้*

วัสดุและวิธีการ: *เป็นการศึกษาเชิงพรรณนาย้อนหลังจากฐานข้อมูลของห้องปฏิบัติการสวนหัวใจ ร.พ. ศิริราช และจากเวชระเบียนผู้ป่วยนอก ตั้งแต่ 1 ตุลาคม พ.ศ. 2549 ถึง 31 มีนาคม พ.ศ. 2551 ติดตามอาการนาน 1 ปี วิเคราะห์ลักษณะผู้ป่วย วิธีรักษาด้วยขดลวด ภาวะแทรกซ้อนหลักที่ 30 วันและ 12 เดือนหลังรักษา*

ผลการศึกษา: *ผู้ป่วย 81 รายได้รับการรักษาผ่านสายสวนและไม่พบภาวะแทรกซ้อนหลักเท่ากับร้อยละ 86.4 เกิดภาวะแทรกซ้อนหลัก ที่ 30 วันและ 12 เดือนเท่ากับร้อยละ 12.3 และ 23.6 ตามลำดับ ปัจจัยที่สัมพันธ์กับภาวะแทรกซ้อนหลักที่ 12 เดือนได้แก่ผู้ป่วยที่ต้องได้รับการรักษาด้วยการฟอกไต (HR = 3.22, p = 0.048) ถูกรักษาเร่งด่วน (HR = 2.39, p = 0.036) อัตราการไหลในหลอดเลือดหัวใจลดลงมากหลังใส่ขดลวด (HR = 25.99, p = 0.001) และการขยายด้วยบอลลูนคู่เมื่อเสร็จสิ้นการรักษา (HR = 0.30, p = 0.04)*

สรุป: *การรักษาหลอดเลือดโคโรนารีย์ส่วนต้นซ้ายตีบผ่านสายสวนได้ผลพอสมควร เกิดภาวะแทรกซ้อนหลักบ้าง อาจนำมาประยุกต์ใช้รักษากับผู้ป่วยที่ไม่สามารถเข้ารับการรักษาด้วยการผ่าตัดต่อหลอดเลือดหัวใจได้ น่าจะวิจัยในผู้ป่วยจำนวนมากกว่านี้*