



2019年 Research proposal

採択演題

冠動脈バイパスグラフトに対するPCIの短期成績 末梢保護デバイスの使用

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背景



冠動脈バイパスグラフトに対するPCI (**GV-PCI**) は、通常PCIと比べて治療成績が不良である可能性がある。(1)-(4)

大伏在静脈グラフトに対するPCI (**SVG-PCI**) は、ガイドラインでは末梢保護デバイスの使用が推奨されているが、近年の報告では有用性は示されず、議論の余地がある。(5, 6)

- (1) Brilakis ES, et al. JACC Cardiovascular interventions. 2016;9(9):884-93.
- (2) Mavroudis CA, et al. International journal of cardiology. 2017;228:563-9.
- (3) Al Suwaidi J, Am Heart J. 2001;142(3):452-9.
- (4) Welsh RC, et al. JACC Cardiovascular interventions. 2010;3(3):343-51.
- (5) 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention.
- (6) Paul TK, et al. Circulation Cardiovascular interventions. 2017;10(12).



背景



しかしながら、我が国におけるGV-PCI予後、及びそれに関わる臨床的特徴に関して十分に検討されていない。



目的



J-PCIレジストリーにおけるビッグデータを用いて、我が国におけるGV-PCIの短期予後、及びそれに関わる臨床的背景、至適治療戦略について検討する。



Study flow

GV-PCIの割合は少ない



PCI cases from J-PCI registry between
January 2016 and December 2018
N=761,177

Missing data for age (N=7), prior CABG (N=11,161), in-hospital complication (N=89), <20 or >100 years old patients (N=246), PCI for both GV-PCI and NV-PCI at the same time (N=1,445) were excluded.

PCI cases with complete data collection
N=748,229

Group 1
GV-PCI
N=2,745

GV-PCI
全体の0.4%

Group 2
NV-PCI in patients
with prior CABG
N=23,932

CABG既往あり

Group 3
NV-PCI in patients
without prior CABG
N=721,552

CABG既往なし



フローチャート

CABG既往のある症例の9割はNV-PCI



PCI cases from J-PCI registry between
January 2016 and December 2018
N=761,177

Missing data for age (N=7), prior CABG (N=11,161), in-hospital complication (N=89), <20 or >100 years old patients (N=246), PCI for both GV-PCI and NV-PCI at the same time (N=1,445) were excluded.

PCI cases with complete data collection
N=748,229

Group 1
GV-PCI
N=2,745

10.3%

CABG既往あり

Group 2
NV-PCI in patients
with prior CABG
N=23,932

89.7%

Group 3
NV-PCI in patients
without prior CABG
N=721,552

CABG既往なし



患者背景①

CABG既往の症例はハイリスク

CABG既往あり

| | Group 1 N=2745 GV-PCI | Group 2 N=23932 NV-PCI | Group 3 N=721552 | P value |
|--|------------------------------------|-------------------------------------|---------------------|---------|
| Patient characteristics | | | | |
| Age, y | 72.74 (9.47) | 72.13 (9.38) | 70.45 (11.20) | <0.001 |
| Female sex, n (%) | 564 (20.5) | 4924 (20.6) | 172252 (23.9) | <0.001 |
| Hypertension, n (%) | 2173 (79.2) | 19066 (79.7) | 536068 (74.3) | <0.001 |
| Diabetes mellitus, n (%) | 1557 (56.7) | 13880 (58.0) | 314796 (43.6) | <0.001 |
| Hyperlipidemia, n (%) | 2006 (73.1) | 17208 (71.9) | 463600 (64.3) | <0.001 |
| Smoker, n (%) | 597 (21.7) | 5620 (23.5) | 222345 (30.8) | <0.001 |
| Chronic kidney disease, n (%) | 951 (34.6) | 8076 (33.7) | 130034 (18.0) | <0.001 |
| Hemodialysis, n (%) | 456 (16.6) | 4219 (17.6) | 46106 (6.4) | <0.001 |
| Chronic lung disease (%) | 69 (2.5) | 654 (2.7) | 17221 (2.4) | 0.002 |
| Peripheral artery disease (%) | 459 (16.7) | 3867 (16.2) | 52536 (7.3) | <0.001 |
| History of previous PCI, n (%) | 1758 (64.3) | 15653 (65.6) | 329956 (45.8) | <0.001 |
| History of previous CABG, n (%) | 2745 (100.0) | 23932 (100.0) | 0 (0.0) | <0.001 |
| History of previous myocardial infarction, n (%) | 1366 (50.5) | 10849 (45.9) | 157372 (21.9) | <0.001 |
| History of previous heart failure, n (%) | 887 (32.8) | 8020 (34.1) | 96179 (13.5) | <0.001 |



患者背景②

CABG既往の症例はtrans-radialの割合が少ない。
DES留置の割合が少なく、DCBの使用割合が多い。

CABG既往あり

| Target vessel | GV-PCI | NV-PCI | | |
|--|-------------|--------------|---------------|---------|
| Right coronary artery, n (%) | 0 (0.0) | 10422 (43.5) | 241478 (33.5) | <0.001 |
| Left main-left anterior descending artery, n (%) | 0 (0.0) | 8850 (37.0) | 381573 (52.9) | <0.001 |
| Left circumflex artery, n (%) | 0 (0.0) | 8461 (35.4) | 177295 (24.6) | <0.001 |
| Saphenous vein graft, n (%) | 2125 (77.4) | 0 (0.0) | 0 (0.0) | <0.001 |
| Artery graft, n (%) | 638 (23.2) | 0 (0.0) | 0 (0.0) | <0.001 |
| Access site | | | | |
| Trans-femoral intervention, n (%) | 1195 (43.5) | 10479 (43.8) | 183556 (25.4) | < 0.001 |
| Trans-radial intervention, n (%) | 1225 (44.6) | 11222 (46.9) | 502894 (69.7) | < 0.001 |
| Using device | | | | |
| Drug-eluting stent, n (%) | 1685 (61.4) | 18105 (75.7) | 618216 (85.7) | <0.001 |
| Bare-metal stent, n (%) | 29 (1.1) | 195 (0.8) | 8181 (1.1) | <0.001 |
| Drug-coated balloon, n (%) | 630 (23.0) | 5064 (21.2) | 89652 (12.4) | <0.001 |
| Rotational atherectomy, n (%) | 10 (0.4) | 2235 (9.3) | 26262 (3.6) | <0.001 |
| Thrombus aspiration, n (%) | 329 (12.0) | 726 (3.0) | 88753 (12.3) | <0.001 |
| Embolic protection devices, n (%) | 387 (14.1) | 928 (3.9) | 25001 (3.5) | <0.001 |



結果① 短期予後

GV-PCI群は院内死亡が多い



GV-PCI

| | Group 1 N=2745 | Group 2 N=23932 | Group 3 N=721552 | P value |
|---|-------------------|--------------------|---------------------|--------------|
| In-hospital mortality, n (%) | 39 (1.4) | 196 (0.8) | 5747 (0.8) | 0.001 |
| Periprocedural myocardial infarction, n (%) | 11 (0.4) | 143 (0.6) | 3791 (0.5) | 0.208 |
| Cardiac tamponade, n (%) | 1 (0.0) | 29 (0.1) | 1084 (0.2) | 0.16 |
| Cardiogenic shock, n (%) | 28 (1.0) | 227 (0.9) | 6784 (0.9) | 0.903 |
| Stent thrombosis, n (%) | 0 (0.0) | 12 (0.1) | 942 (0.1) | <0.001 |
| Emergency operation, n (%) | 1 (0.0) | 20 (0.1) | 628 (0.1) | 0.658 |
| Bleeding complication, n (%) | 17 (0.6) | 114 (0.5) | 2422 (0.3) | <0.001 |
| Non-access-site bleeding, n (%) | 8 (0.3) | 49 (0.2) | 1123 (0.2) | 0.035 |

Group 1: PCI for graft vessel; group 2: PCI for native vessel with prior CABG; group 3: PCI for native vessel without prior CABG; GV: graft vessel; NV: native vessel; PCI: percutaneous coronary intervention; TIMI: thrombolysis in myocardial infarction



結果② 多変量解析

GV-PCI群は有意に院内死亡が多い



GV-PCI

| | Crude analysis | | | Adjusted analysis | | | | |
|------------------------------|----------------|-----------|-------------|---------------------------|------------------|--------------------|----------|-----------|
| | Group 1 | Group 2 | Group 3 | Group 1 | | Group 2 | Group 3 | |
| | N=2745 | N=23932 | N=721552 | N=2745 | | N=23932 | N=721552 | |
| | | | | OR (95% CI) | p | OR (95% CI) | p | |
| In-hospital mortality | 39 (1.4) | 196 (0.8) | 5747 (0.8) | 2.36 (1.66 - 3.36) | <0.001 | 1.07 (0.91 - 1.26) | 0.423 | Reference |
| Procedural complication | 96 (3.5) | 778 (3.3) | 20581 (2.9) | 1.16 (0.93 - 1.44) | 0.18 | 1.04 (0.96 - 1.13) | 0.335 | Reference |
| Bleeding complication | 17 (0.6) | 114 (0.5) | 2422 (0.3) | 1.43 (0.87 - 2.35) | 0.159 | 1.08 (0.88 - 1.32) | 0.452 | Reference |

Group 1: PCI for graft vessel; group 2: PCI for native vessel with prior CABG; group 3: PCI for native vessel without prior CABG; PCI: percutaneous coronary intervention; OR: odds ratio; CI: confidence interval. Adjusted for age, sex (female), ST elevated myocardial infarction, Non-ST elevated myocardial infarction, unstable angina, previous PCI, previous coronary artery bypass grafting, hypertension, dyslipidemia, diabetes mellitus, smoker, chronic kidney disease, peripheral vascular disease, previous heart failure and cardiogenic shock within 24 hours prior to the procedure.

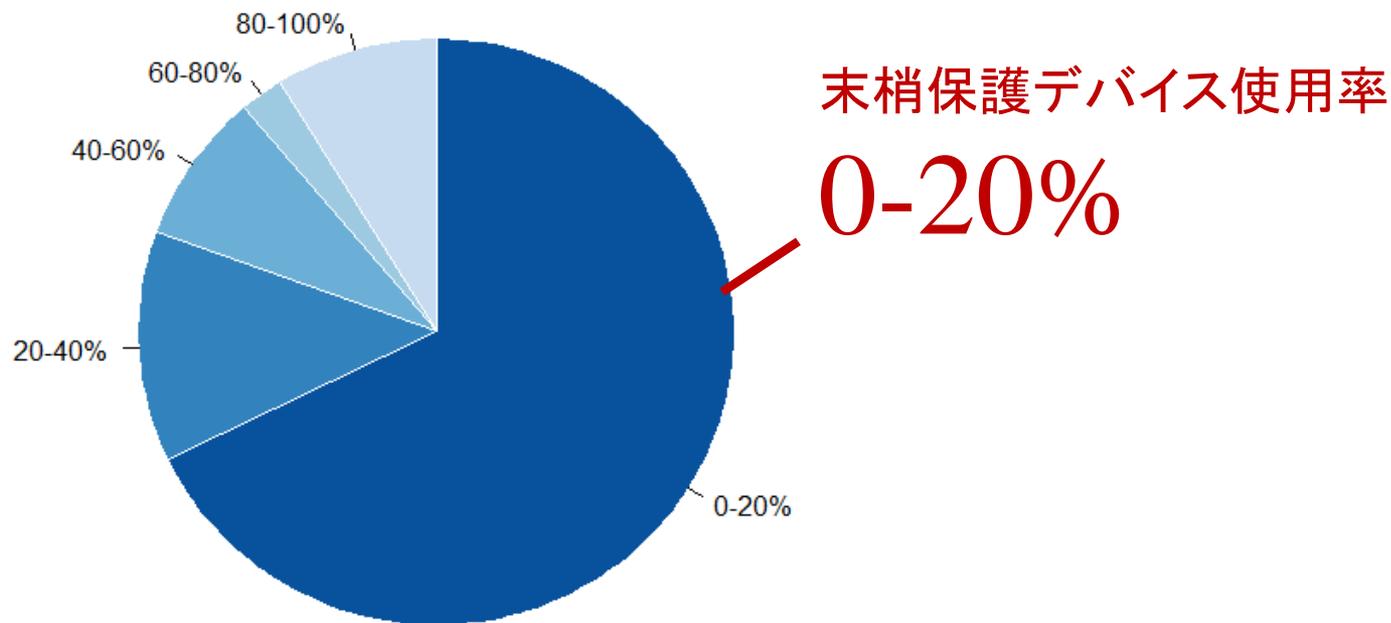


大伏在静脈グラフトに対するPCI (SVG-PCI) 末梢保護デバイスの有効性について



SVG-PCI

末梢保護デバイスの使用率 18%



施設間による使用率の差が大きい

全体の約6割の施設では末梢保護デバイス(EPD)を全く使用していない

low volume施設で使用頻度が少ない

(PCI件数: 全く使用しない施設 vs. 使用する施設 = 240 vs 345,
interquartile range = 163-347 vs. 215-469, $P < 0.001$)



結果①

末梢保護デバイス使用群は Slow-flow現象の割合が少ない



| | EPD group (N=383) | Non-EPD group (N=1,742) | P value |
|--|-----------------------------|-----------------------------------|----------------|
| In-hospital mortality, n (%) | 4 (1.0) | 28 (1.6) | 0.557 |
| Periprocedural myocardial infarction n (%) | 2 (0.5) | 7 (0.4) | 1 |
| Cardiac tamponade, n (%) | 0 (0.0) | 1 (0.1) | 1 |
| Cardiogenic shock, n (%) | 3 (0.8) | 17 (1.0) | 0.951 |
| Stent thrombosis, n (%) | 0 (0.0) | 0 (0.0) | NA |
| Emergency operation, n (%) | 0 (0.0) | 0 (0.0) | NA |
| Bleeding complication, n (%) | 3 (0.8) | 11 (0.6) | 1 |
| Non-access-site bleeding, n (%) | 0 (0.0) | 6 (0.3) | 0.536 |
| Access site bleeding, n (%) | 3 (0.8) | 5 (0.3) | 0.33 |
| Slow-flow phenomenon after PCI, n (%) | 7 (1.8) | 72 (4.1) | 0.044 |

EPD: embolic protection devices; SVG: saphenous vein graft; PCI: percutaneous coronary intervention; TIMI: thrombolysis in myocardial infarction.



結果②多変量解析

末梢保護デバイス使用群で有意に Slow-flow現象が少ない



| | EPD group (N=383) | Non-EPD group (N=1,742) | OR (95% CI) EPD group vs. non-EPD group (reference) | P value |
|--|----------------------|----------------------------|--|-------------|
| In-hospital mortality | 4 (1.0) | 28 (1.6) | 0.33 (0.06-1.74) | 0.191 |
| Procedure complication | 11 (2.9) | 65 (3.7) | 0.72 (0.36-1.44) | 0.356 |
| Bleeding complication | 3 (0.8) | 11 (0.6) | 1.30 (0.25-6.71) | 0.758 |
| Slow-flow phenomenon after PCI, n (%) | 7 (1.8) | 72 (4.1) | 0.45 (0.21-0.91) | 0.04 |

PCI: percutaneous coronary intervention; EPD: embolic protection devices; OR: odds ratio; CI: confidence interval; TIMI: thrombolysis in myocardial infarction.

Adjusted for age, sex (female), ST elevated myocardial infarction, Non-ST elevated myocardial infarction, unstable angina, previous PCI, previous coronary artery bypass grafting, hypertension, dyslipidemia, diabetes mellitus, smoker, chronic kidney disease, peripheral vascular disease, previous heart failure and cardiogenic shock within 24 hours prior to the procedure.



まとめ



1. 日本におけるGV-PCIの頻度は0.4%と非常に少ない。
2. CABG既往のある症例の9割はNV-PCI。
3. GV-PCI群はNV-PCI群と比べて有意に院内死亡が多い。
4. SVG-PCIの末梢保護デバイス使用頻度は18%と少なく、使用頻度には施設間格差がある (low volume施設で使用頻度が少ない)。
5. SVG-PCIの末梢保護デバイス使用は、有意にSlow-flow現象の頻度を低下させるが、院内死亡は差がなかった。



論文投稿の現状



2020/8/26 Catheterization and Cardiovascular Interventions (CCI)投稿

2020/10/9 Reject and resubmit

2020/12/8 再解析、論文修正し、再投稿

2021/1/19 Minor revision

2021/2/8 再投稿



おわりに



この研究課題に対する論文作成および発表の機会を頂き、
CVIT関係者皆様に、深く感謝申し上げます。