Patient outcomes in GuideLiner facilitated percutaneous coronary intervention stratified by the SYNTAX score: A retrospective analysis

Shuangbo Liu, Christopher Parr, Hannah Zhang, Basem Elbarouni, Ashish Shah, Malek Kass and Amir Ravandi

Abstract

Objectives: To determine patient outcomes in GuideLiner facilitated percutaneous coronary intervention stratified by the SYNTAX score.

Design: Single centre retrospective cohort analysis.

Participants: A total of 540 consecutive cases facilitated by GuideLiner at a single center.

Main outcome measures: Successful stent delivery, in-hospital, 30 day and 1 year mortality rates stratified by SYNTAX score.

Results: The most common indication for GuideLiner was need for increased support for balloon or stent delivery (82%), 6% for non-coaxial guide, 9% for chronic total occlusion and 3% for selective vessel engagement. Successful stent delivery was achieved in 91% of all cases, with no complications occurred due to GuideLiner use. In-hospital, 30 day and 1 year mortality rates were 2.8%, 2.1% and 4.5%, respectively. The high SYNTAX group was associated with higher rates of initial TIMI score of 0–1; however, the final TIMI score rate of successful delivery and complications did not differ between groups. In-hospital and 1 year mortality rates were higher in the higher SYNTAX groups.

Conclusions: The GuideLiner is an easy to use guide catheter extension system with high rates of success and low rates of complications, across all SYNTAX groups.

Keywords

Acute myocardial infarction, catheter-based coronary interventions, complex coronary intervention

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Introduction

Coronary artery disease (CAD) is one of the most prevalent causes for death in the world, leading to over 65% of all cardiovascular-related deaths and accounting for an estimated 7.4 million global deaths in 2012 alone. With the expansion of percutaneous coronary intervention (PCI) to high risk patients with complex coronary lesions, new techniques and equipment are needed to perform successful procedures. The GuideLiner (Vascular Solutions) is a rapid exchange “child in mother” catheter that aids stent delivery through complex coronary segments with extreme tortuosity, severe calcification and offers better support in situations with poor coaxial alignment.

The SYNTAX score is a semi-quantitative anatomical method to assess CAD complexity. It was initially developed to help risk stratify based on CAD burden and optimize the method of revascularization. Despite
having a high SYNTAX score, many patients are not suited for surgery due to comorbidities. As a result, the number of coronary artery bypass grafting (CABG) surgeries performed in the United States has decreased nearly 30% in the last decade, and the number of complex PCI cases has increased significantly. New technologies like the GuideLiner can facilitate successful revascularization despite complex anatomy with high SYNTAX score.

The ACC/AHA lesion classification groups lesions into three categories based on individual characteristics such as length, calcification, tortuosity, chronic total occlusion, etc. This classification was originally published in 1988 and has remained a standard method to assess rate of success and risk of procedure.

The objective of this study is to evaluate the indications, procedural success and safety outcomes of the GuideLiner for PCI, as stratified by SYNTAX groups.

**Results**

A total of 5033 PCIs between January 2013 to December 2014 were performed at St. Boniface Hospital; 10.7% of these procedures required a GuideLiner (n = 540), in 497 total patients. The median age was 70 (IQR 61–78) years, with 77% males (Table 1). Approximately 36% of the patients were diabetics. Up to half of the patients had prior myocardial infarction (45%) and 36% had previous PCI. The majority of the procedures were elective (36%), while 27% for non-ST elevation myocardial infarction (NSTEMI) and 21% for ST elevation myocardial infarction (STEMI). Approximately 12% of patients were diagnosed with cardiogenic shock at initial presentation with the radial approach utilized in 48% of cases. Approximately half the lesions (47%) were ACC/AHA lesion classification Type C. The SYNTAX score was calculated in 428 patients, with 110 patients excluded due to previous CABG. The mean SYNTAX score was 21 ± 11, with 61% in the low risk category (≤22), 24% in the intermediate category (23–32) and 15% in the high-risk category (≥33).

The most common indication for GuideLiner use was increased support for equipment delivery (91%) (with 9% of cases were chronic total occlusion (CTO) procedures), non-coaxial guide alignment (6%) and 3% for other indications such as selective coronary visualization (Table 2). A total of 210 lesions (49%) were ACC/AHA lesion classification Type C lesions. CTO represented 12% of the study population. The rate of successful stent delivery was 91%. There were...
no procedural complications from GuideLiner use. In-hospital, 30-day and 1 year all-cause mortality was 2.7%, 2.1% and 4.5%, respectively. Repeat PCI was 5% at 30 days and 14% at 1 year.

Baseline characteristics, angiographic characteristics, procedural and clinical outcomes were stratified
by SYNTAX score and compared (Tables 3 and 4). The high SYNTAX group was older (73 years, IQR 62–83) compared to the lower and intermediate SYNTAX groups (68 years, IQR 61–80; 68 years, IQR 60–73, respectively, p = 0.005). Rates of prior cerebrovascular accidents (19% for high SYNTAX, 9.7% for intermediate SYNTAX, 8% for low SYNTAX, p = 0.004), peripheral vascular disease (21% for high SYNTAX, 12% for intermediate SYNTAX, 5% for low SYNTAX, p < 0.001) were higher in the high SYNTAX group. Chronic kidney disease was higher in the high (18%) and intermediate (21%) SYNTAX groups than the low SYNTAX group (8.7%, p < 0.0001). Previous PCI rates were lower in the high SYNTAX group (11%) in comparison with the intermediate (39%) and low (40%) SYNTAX

Table 3. Study characteristics stratified by SYNTAX score.

| Variable                  | SS ≤ 22   | SS = 23–32 | SS ≥ 33   | p-Valuea |
|---------------------------|-----------|------------|-----------|----------|
| Age (years)               | 68 (60–75)| 68 (61–80) | 73 (62–83)| 0.005    |
| Male gender               | 69 (26%)  | 24 (23%)   | 12 (19%)  | 0.498    |
| BMI (kg/m²)               | 29.7 (26.4–33.4) | 28.0 (25.3–32.4) | 27.2 (25.0–30.3) | 0.003    |
| Medical history           |           |            |           |          |
| Hypertension              | 176, 67%  | 76, 74%    | 44, 71%   | 0.28     |
| Dyslipidemia              | 151, 57%  | 54, 52%    | 32, 52%   | 0.96     |
| Stroke                    | 21, 8.0%  | 10, 9.7%   | 12, 19%   | 0.004    |
| Diabetes                  | 84, 32%   | 38, 37%    | 26, 42%   | 0.17     |
| Smoking                   | 59, 22%   | 14, 14%    | 13, 21%   | 0.24     |
| PVD                       | 13, 5%    | 12, 12%    | 13, 21%   | <0.001   |
| CKD                       | 23, 8.7%  | 22, 21%    | 11, 18%   | <0.001   |
| CHF                       | 23, 8.7%  | 8, 7.8%    | 9, 15%    | 0.20     |
| Prev MI                   | 108, 41%  | 38, 37%    | 19, 31%   | 0.45     |
| Prev PCI                  | 106, 40%  | 40, 39%    | 7, 11%    | <0.001   |
| Reason for angio          |           |            |           |          |
| STEMI                     | 54, 21%   | 28, 27%    | 26, 42%   | 0.003    |
| NSTEMI                    | 81, 31%   | 25, 24%    | 16, 26%   |          |
| Elective                  | 106, 40%  | 36, 35%    | 17, 27%   |          |
| Other                     | 22, 8.4%  | 14, 14%    | 3, 5%     |          |
| At presentation           |           |            |           |          |
| VT/VF                     | 11, 5%    | 1, 1%      | 3, 6%     | 0.25     |
| Cardiogenic shock         | 19, 8%    | 16, 18%    | 13, 24%   | <0.001   |
| Creatinine (μmol/L)       | 86 (72–119)| 99 (73–205)| 103 (79–137)| 0.036   |
| LVEDP (mmHg)              | 19 ± 8    | 19 ± 8     | 22 ± 9    | 0.01     |
| LVEF (%)                  | 55 ± 14   | 48 ± 16    | 48 ± 15   | <0.001   |
| Access                    |           |            |           |          |
| Femoral                   | 81, 31%   | 53, 52%    | 31, 49%   | 0.003    |
| Radial                    | 165, 63%  | 44, 31%    | 29, 46%   |          |
| Both                      | 16, 6%    | 5, 5%      | 3, 5%     |          |
| Fluoroscopy time (min)    | 21 (14, 32)| 23 (18, 35)| 26 (21, 34)| 0.008   |
| Total contrast (mL)       | 200 (150, 250)| 208 (160, 260)| 230 (160, 280)| 0.05   |
| GuideLiner used for       |           |            |           |          |
| Left main                 | 3, 1%     | 2, 2%      | 4, 6%     | 0.05     |
| LAD                       | 44, 17%   | 31, 30%    | 17, 25%   |          |
| Circumflex                | 42, 16%   | 16, 15%    | 15, 24%   |          |
| RCA                       | 172, 66%  | 55, 52%    | 28, 45%   |          |
| Ramus                     | 1, 0%     | 1, 1%      | 0         |          |
| LIMA                      | 0         | 0          | 0         |          |
| SVG                       | 0         | 0          | 0         |          |

Mean ± SD or Median ± IQR for continuous variables. Frequency, % for categorical variables. BMI: body mass index; CABG: coronary artery bypass grafting; CHF: congestive heart failure; CKD: chronic kidney disease; LAD: left anterior descending; LIMA: left internal mammary artery; LVEDP: left ventricular end diastolic pressure; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NSTEMI: non-ST-segment myocardial infarction; PCI: percutaneous coronary intervention; PVD: peripheral vascular disease; RCA: right coronary artery; SS: syntax score; STEMI: ST-segment myocardial infarction; SVG: saphenous vein graft; TIMI: thrombolysis in myocardial infarction; VT: ventricular tachycardia; VF: ventricular fibrillation.

aComparing SS < 22, SS = 23–32 and SS > 33 groups.
patients with high SYNTAX score were more likely to present with cardiogenic shock (24% vs. 18% and 8% in the intermediate and low SYNTAX groups, respectively, \(p < 0.001\)) and had higher LVEDP (22/16 mmHg in high SYNTAX group vs 19/16 mmHg in both intermediate and low SYNTAX groups, \(p = 0.01\)). LVEF was higher in the low SYNTAX patients (55 ± 14%) in comparison with the intermediate (48 ± 16%) and high SYNTAX groups (48 ± 15%, \(p < 0.001\)). More patients in the low (95%) and intermediate (86%) SYNTAX group had final TIMI grade 3 compared to high SYNTAX patients (79%, \(p < 0.001\)).

However, the rates of successful stent delivery were comparable despite the SYNTAX score (91% in low SYNTAX, 90% in both intermediate and high SYNTAX). In-hospital mortality was higher in the high SYNTAX group (8.1%) in our cohort compared with low (1.5%) and intermediate groups (2.9%, \(p = 0.025\)) but not 1 year mortality rates (3.6%, 7.3% and 1.8% for low, intermediate and high SYNTAX groups, respectively). Repeat revascularization at 1 year was highest in the high SYNTAX group (24%).

We stratified the data by clinical presentation (STEMI, NSTEMI or elective procedure, Table 5). The rate of cardiogenic shock (\(< 0.0001\)) was higher in

### Table 4. Procedural characteristics and outcomes of patients stratified by SYNTAX score.

| Variable | SS \(\leq 22\) | SS = 23–32 | SS \(\geq 33\) | p-Value* |
|----------|----------------|------------|---------------|----------|
| Indication | | | | |
| Increased support | 184, 81% | 86, 83% | 53, 85% | 0.85 |
| Non-coaxial guide | 26, 9.8% | 6, 6% | 5, 8% | |
| CTO | 41, 16% | 10, 10% | 3, 5% | |
| Other | 10, 3.8% | 1, 1% | 1, 2% | |
| Lesion length (mm) | 8 (5–15) | 10 (6–20) | 14 (10–20) | <0.001 |
| bifurcation or trifurcation | 31 (11.8%) | 20 (19.4%) | 15 (24.2%) | 0.023 |
| CTO | 35 (13.3%) | 15 (14.7%) | 3 (4.8%) | 0.138 |
| Proximal lesion | 95 (36.1%) | 45 (43.7%) | 30 (48.4%) | 0.132 |
| Extreme tortuosity | 66 (25.1%) | 30 (29.1%) | 17 (27.4%) | 0.720 |
| Severe calcification | 67 (25.5%) | 46 (44.7%) | 34 (54.8%) | <0.001 |
| Thrombus | 32 (12.2%) | 10 (9.7%) | 13 (21.0%) | 0.097 |
| Anomalous takeoff | 22 (8.4%) | 7 (6.8%) | 6 (9.7%) | 0.795 |
| ACC/AHA lesion classification | | | | |
| A | 36 (14%) | 9 (9%) | 8 (13%) | 0.43 |
| B | 104 (39%) | 41 (39%) | 20 (32%) | |
| C | 123 (47%) | 53 (52%) | 34 (55%) | |
| Successful delivery | 239 (90.9%) | 91 (90.1%) | 56 (90.3%) | 0.971 |
| Final TIMI grade flow 3 | 251 (95.4%) | 89 (86.4%) | 49 (79.0%) | <0.001 |
| Need for additional support | | | | |
| None | 239, 91% | 93, 90% | 49, 79% | 0.03 |
| Device (IABP, Impella, ECMO) | 2, 1% | 1, 1% | 4, 2% | |
| Vasopressors | 22, 8% | 9, 9% | 9, 14% | |
| Cath complications | | | | |
| None | 262, 100% | 105, 100% | 63, 100% | – |
| In-hospital mortality | 4 (1.5%) | 3 (2.9%) | 5 (8.1%) | 0.025 |
| 30 day mortality | 5 (1.9%) | 4 (4.0%) | 2 (3.5%) | 0.408 |
| 1 year mortality | 9 (3.6%) | 7 (7.3%) | 1 (1.8%) | 0.237 |
| 30 day repeat MI | 8 (3.1%) | 4 (3.9%) | 2 (3.2%) | 0.925 |
| 1 year repeat MI | 9 (3.5%) | 2 (2.0%) | 4 (6.7%) | 0.353 |
| In-hospital CABG | 4 (1.5%) | 4 (3.9%) | 0 (0.0%) | 0.244 |
| 30 day revascularization | 11 (4.3%) | 6 (5.9%) | 6 (9.8%) | 0.228 |
| 1 year revascularization | 33 (12.6%) | 8 (7.8%) | 15 (24.2%) | 0.010 |
| 30 day CHF | 3 (1.2%) | 1 (1.0%) | 1 (1.8%) | 0.820 |
| 1 year CHF | 3 (1.2%) | 3 (3.0%) | 3 (4.8%) | 0.116 |

Mean ± SD or Median ± IQR for continuous variables. Frequency, % for categorical variables. ACC: American College of Cardiology; AHA: American Heart Association; CABG: coronary artery bypass grafting; CHF: congestive heart failure; CTO: chronic total occlusion; ECMO: extracorporeal membrane oxygenation; IABP: intraaortic balloon pump; MI: myocardial infarction; TIMI: thrombolysis in myocardial infarction.

*Comparing SS<22, SS = 23–32 and SS >33 groups.
STEMI patients (42%) compared to NSTEMI (4.8%) and elective procedures (1.5%). The distribution of ACC/AHA lesion classification is different, with more Type C lesions requiring GuideLiner in elective cases (63% vs. 37% in STEMI, 41% in NSTEMI, p < 0.0001). The final TIMI grade 3 flow was lower in ACS patients (82% in STEMI, 79% in NSTEMI, 89% in elective, p = 0.038); however, the rate of successful stent delivery was similar. Unsurprisingly, STEMI patients had the highest in-hospital mortality (9.7%, vs 1.4% in NSTEMI, 0% in elective, p = 0.0012).

CTO cases (n = 63) are presented separately in Table 6. The majority of vessels with GuideLiner use was the right coronary artery (RCA, 89%). The rate of successful stent delivery was 89%, and 78% of cases had final TIMI flow grade 3.

**Discussion**

Interventional cardiology continues to improve through development of new technologies, methods and equipment for complex PCI. The main findings of our study are (1) GuideLiner is a safe and easy to use guide catheter extension system in this all-comer study population; (2) GuideLiner leads to similar rates of successfully stent delivery regardless of patient presentation, lesion classification or SYNTAX score.

We demonstrated that use of the GuideLiner was associated with a high rate of successful delivery (91%). This success rate was similar regardless of SYNTAX score or clinical presentation (STEMI, NSTEMI or elective case). This high success rate is comparable to previous studies where procedural success rates range from 80.2 to 98.7%. The wide range of procedural success rate could be related to differences in the patient population as well as lesion specific characteristics. Our study population had a final TIMI score of 3 in 91% of the cases and this is comparable to the 96% in a previous study. Our slightly lower final TIMI score could be due to the higher rate of STEMI (25%) and NSTEMI (29%) patients in our study. Overall, complication rate from GuideLiner use is often quite low (1.6% in a previous study) and we found no complications related to GuideLiner use. One reason for this could be the use of the second generation GuideLiner in our study as compared to first generation GuideLiner in a previous study.

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**Table 5.** Lesion and patient characteristics and outcomes stratified by clinical presentation.

|                | STEMI n=113 | NSTEMI n=145 | Elective n=194 | p-Value |
|----------------|-------------|--------------|---------------|---------|
| Cardiogenic shock | 47 (42%)    | 7 (4.8%)     | 3 (1.5%)      | <0.0001 |
| Bifurcation/trifurcation | 14 (12%)    | 18 (12%)     | 26 (13%)      | 0.95    |
| CTO             | 2 (1.8%)    | 5 (3.4%)     | 53 (27%)      | <0.0001 |
| Proximal        | 48 (42%)    | 60 (41%)     | 75 (39%)      | 0.78    |
| Tortuosity      | 29 (26%)    | 37 (26%)     | 48 (25%)      | 0.98    |
| Calcification   | 34 (30%)    | 49 (34%)     | 69 (36%)      | 0.62    |
| Anomalous       | 8 (7%)      | 14 (9.7%)    | 16 (8.2%)     | 0.56    |
| Type A          | 16 (14%)    | 19 (13%)     | 23 (12%)      | 0.35    |
| Type B          | 55 (49%)    | 66 (46%)     | 49 (25%)      | <0.0001 |
| Type C          | 42 (37%)    | 60 (41%)     | 122 (63%)     | <0.0001 |
| Indication for GuideLiner |            |              |               |         |
| Increase support| 100 (88%)   | 131 (90%)    | 132 (68%)     | <0.0001 |
| Not coaxial     | 7 (6.2%)    | 9 (6.2%)     | 11 (5.7%)     |         |
| CTO             | 1 (0.9%)    | 1 (0.7%)     | 46 (24%)      |         |
| Other           | 4 (3.5%)    | 4 (2.8%)     | 5 (2.6%)      |         |
| Final TIMI 3    | 93 (82%)    | 115 (79%)    | 173 (89%)     | 0.038   |
| Successful delivery | 104 (92%)   | 127 (88%)    | 176 (91%)     | 0.45    |
| In-hospital mortality | 11 (9.7%)  | 2 (1.4%)   | 0 (0%)        | 0.0012  |
| 30 day mortality | 1 (0.9%)    | 4 (2.8%)    | 3 (1.5%)      | 0.5     |
| 1 year mortality | 4 (3.5%)    | 6 (4.1%)    | 4 (2.1%)      | 0.52    |
| 30 day repeat MI | 5 (4.4%)    | 8 (5.5%)    | 5 (2.6%)      | 0.38    |
| 1 year repeat MI | 5 (4.4%)    | 4 (2.8%)    | 5 (2.6%)      | 0.18    |
| In-hospital CABG | 5 (4.4%)    | 2 (1.4%)    | 3 (1.5%)      | 0.18    |
| 30 day revascularization | 7 (6.2%)   | 6 (4.1%)   | 13 (6.7%)     | 0.59    |
| 1 year revascularization | 11 (9.7%)  | 20 (14%)   | 23 (12%)      | 0.61    |
| 30 day CHF      | 1 (0.9%)    | 2 (1.4%)    | 4 (2.1%)      | 0.71    |
| 1 year CHF      | 4 (3.5%)    | 4 (2.8%)    | 1 (0.5%)      | 0.14    |
Our all-comers patient populations allowed inclusion of ACS cases, including a significant number of STEMI patients. It is interesting to note that the majority of STEMI cases that required GuideLiner use was not considered a “difficult” lesion. Only 37% of these cases were Type C ACC/AHA lesions. However, during these emergencies, the key aim of treatment is to restore perfusion to the infarct artery. Using the GuideLiner may facilitate quicker balloon and stent delivery (the main indication for GuideLiner use in this group). Due to local expertise with the GuideLiner, we tend to use this technique with difficult lesions rather than trying other “buddy wire” methods as at other centers.8 We had a high rate of successful stent delivery (92%) with final TIMI 3 flow rate of 82%. As interventionalists encounter more complex cases, especially calcific tortuous or previously stented vessels during STEMI, it is important to be aware of tools that can help facilitate PCI and lead to improved patient outcome.

Overall, the rates of adverse clinical outcomes in our patient population were low; however, this varied depending on the clinical presentation. In-hospital mortality was 3%, 30-day mortality was 2% and 1 year mortality was 10%. This is comparable to previous studies, such as Waterbury et al.,9 where in-hospital death in 2.9%, 30-day mortality in 4% and 1-year mortality in 14% of the patients. When the data were analyzed by presentation, in-hospital mortality was 10% for STEMI’s compared to 1.4% for NSTEMI and 0% for elective cases. The high rate of in-hospital mortality for STEMI’s can be accounted for by approximately half of the patients in this group presented with cardiogenic shock.

CTO is often considered the final frontier of percutaneous coronary intervention. A well-established use for GuideLiner support is during chronic total occlusion revascularization. Interventional cardiologists often require both passive (larger guiding catheter, different shaped guide catheter with support from the aortic sinuses or contralateral aortic wall) and active (super stiff wires, buddy wires, anchoring balloons, deep intubation of guide catheter) to achieve successful revascularization. The use of a GuideLiner can provide improved support and deeper intubation of the target vessel, and therefore improve the rate of success.

Previous studies had reported ACC/AHA lesion complexity; however, this does not allow a full assessment of the burden of coronary artery disease. This is the first study to stratify the use of GuideLiner and associated safety and outcomes by SYNTAX score. We found that the higher SYNTAX patients tended to be older and have more cardiovascular risk factors (cerebrovascular accidents, peripheral vascular disease, chronic kidney disease) as well as present more often with cardiogenic shock. They also had higher peak cardiac enzymes, LVEDP and lower LVEF. Hence, it is not surprising that mortality was higher in-hospital as well as at 1 year. However, despite the above, the rates of successful stent delivery and final TIMI flow were similar.

There are limitations to our study. This is a single center retrospective study and results and practice patterns may not be generalizable. As well, there is no non-GuideLiner comparison group which makes it difficult to determine the role GuideLiner played in the high rate of successful delivery.

**Conclusions**

This is the first study to stratify the use of GuideLiner and associated safety and outcomes by SYNTAX score.
score. We found that the GuideLiner is an easy to use guide catheter extension system with high rates of success and low rates of complications, across all SYNTAX groups.

**Contributorship**

All authors made a substantial contribution to: (1) the concept or design of the work; or acquisition, analysis or interpretation of data; (2) drafting or revising the article; (3) approved the version to be published; and (4) participated sufficiently in the work to take public responsibility for appropriate portions of the content.

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**Ethical approval**

The study was approved by the local university (University of Manitoba Research Ethics Board) and hospital (St. Boniface Hospital Research Review Committee).

**Guarantor**

None

**ORCID iD**

Amir Ravandi http://orcid.org/0000-0001-6663-1225

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