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Initial experience with the Expressman™ guide catheter extension in a high-volume tertiary cardiology center

Experiência inicial com a extensão de cateter-guia Expressman™ em um centro terciário de cardiologia de alto volume

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ABSTRACT - **Background:** Guide catheter extensions provide increased support in complex percutaneous coronary interventions. The Expressman™ is a novel guide catheter extension and the objective was to assess the impact of its use on procedural success and complications in a high-volume reference center. **Methods:** We analyzed data from all consecutive procedures in which the Expressman™ guide catheter extension was used. The decision to use a guide catheter extension was at operator's discretion. Device success was defined as the successful positioning of the guide catheter extension in the coronary vessel and procedural success was defined as <20% residual stenosis and TIMI 3 flow, with no loss of significant side branches. Major adverse cardiac and cerebrovascular events were defined as the composite of all-cause death, myocardial infarction, target vessel revascularization and stroke. **Results:** From April 2022 to January 2023, 34 procedures were included. The majority of the patients were male (59%) and the mean age was 66.5 years. Guide catheter extension use was not planned pre-procedure in 17 procedures (50%). The most common reasons for guide catheter extension use were target vessel angulation or tortuosity and unfavorable coronary ostium position. Device success was obtained in 88% and revascularization success in 91%. There were three side branch occlusions. During in-hospital clinical follow-up, no major adverse cardiac and cerebrovascular events or major bleeding occurred. **Conclusion:** The device success and procedural success were high and the rate of complications was low. Guide catheter extension use as bailout technique in complex anatomies allowed procedural success in the vast majority of otherwise untreatable patients.

Keywords: Percutaneous coronary intervention; Cardiac catheters; Coronary artery diseases; Equipment design; Treatment outcome

RESUMO - **Introdução:** As extensões de cateter-guia fornecem maior suporte em intervenções coronárias percutâneas complexas. O Expressman™ é uma nova extensão de cateter-guia, e nosso objetivo foi avaliar o impacto de seu uso no sucesso do procedimento e nas complicações ocorridas em um centro de referência de alto volume. **Métodos:** Analisamos os dados de todos os procedimentos consecutivos em que foi usada uma extensão de cateter-guia Expressman™. A decisão de usar uma extensão de cateter-guia ficou a critério do operador. O sucesso do dispositivo foi definido como o posicionamento bem-sucedido da extensão de cateter-guia dentro do vaso coronário, e o sucesso do procedimento foi definido como <20% de estenose residual e fluxo TIMI 3, sem perda significativa de ramos laterais. Eventos adversos cardíacos e cerebrovasculares maiores foram definidos como a combinação morte por todas as causas, infarto do miocárdio, revascularização do vaso-alvo e acidente vascular cerebral. **Resultados:** Foram incluídos 34 procedimentos entre abril de 2022 e janeiro de 2023. A maioria dos pacientes era do sexo masculino (59%), e a média de idade foi 66,5 anos. O uso da extensão de cateter-guia não foi planejado antes do procedimento em 17 procedimentos (50%). Os motivos mais comuns para o uso da extensão de cateter-guia foram angulação ou tortuosidade do vaso-alvo e posição desfavorável do óstio coronário. O sucesso do dispositivo foi obtido em 88% e o da revascularização, em 91%. Houve três oclusões de ramo lateral. Durante o acompanhamento clínico intra-hospitalar, não ocorreram sangramento e nem eventos adversos cardíacos e cerebrovasculares

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maiores. **Conclusão:** O sucesso do dispositivo e do procedimento foi alto, e a taxa de complicações foi baixa. O uso da extensão de cateter-guia como técnica de resgate em anatomias complexas permitiu o sucesso do procedimento na maioria dos pacientes que, de outro modo, não poderiam ser tratados.

Descritores: Intervenção coronária percutânea; Cateteres cardíacos; Doença da artéria coronária; Desenho de equipamento; Resultado do tratamento

INTRODUCTION

Patients undergoing complex percutaneous coronary interventions (PCI) more frequently present adverse clinical and angiographic features, such as advanced age, increased vessel tortuosity and extensive calcification. To achieve procedural success in those complex situations, guide catheter extensions (GCEs) have been increasingly used.[1-3] These devices allow deep seating within the coronary artery, providing increased support for guidewire and microcatheter advancement, and improving deliverability of balloons and stents.[4] Guide catheter extensions may also allow selective visualization of the vessel and improve the stability of the guide catheter. Despite all those theoretical benefits and experience of interventional cardiologists, there are still relatively few published data addressing the use of these devices. The Expressman™ GCE is a novel guide extension featuring side holes near the tip, designed to ensure antegrade blood flow and diminish coronary ischemia, a possible complication of deep intubation with these devices.[5] Also, it has a long exchange segment (35cm) to facilitate stent delivery with less resistance.

The objective of the present study was to determine the impact of the Expressman™ GCE on procedural success, complication rates and in-hospital outcomes in patients undergoing complex PCI.

METHODS

Study population

All consecutive procedures with an indication for a GCE use in the period of April 2022 to January 2023 were considered for inclusion. The inclusion criteria were age greater than 18 years and written informed consent. There were no clinical or angiographic exclusion criteria, and the decision to use a GCE was at operator´s discretion.

Data collection

Investigators added PCI data to an on-line platform available via Research Electronic Data Capture (REDCap). All investigators received standardized instructions for data entry in REDCap, and clinical, procedural and angiographic information, in addition to post-procedural clinical outcomes were collected on the same platform.

Definitions

Technical success of the PCI was defined as successful revascularization within the treated segment and restoration of Thrombolysis in Myocardial Infarction (TIMI) 3 flow with <20% residual stenosis and without significant side branch occlusion.[6] A significant side branch was defined as one supplying the left ventricle with 1.5mm in diameter or larger. Proximal tortuosity was defined as mild (up to one curve with 70°), moderate (two curves with more than 70° or one with 90°) or severe (more than two curves with 70° or more than one curve with 90°).[7] Procedural success was defined as achievement of technical success with no in-hospital major adverse cardiac and cerebrovascular events (MACCE), and device success was defined as the successful positioning of the GCE within the coronary vessel, so that it achieved the intended use by the operator.

Outcomes

The primary endpoint of the study was procedural success of the index PCI. Secondary endpoints were in-hospital MACCE and procedural complications. Major adverse cardiac and cerebrovascular events included all-cause death, myocardial infarction (MI) and stroke. Myocardial infarction was defined using the fourth universal definition of MI (type 4a).[8] Stroke was defined as a new focal neurological deficit of sudden onset of presumably cerebrovascular irreversible cause (or resulting in death) within 24 hours and not associated with any other easily identifiable cause.

Procedural complications included major bleeding, coronary perforation, cardiac tamponade and urgent revascularization with PCI or coronary artery bypass graft (CABG). Major bleeding was defined as any bleeding causing a reduction in hemoglobin >3g/dL, bleeding requiring transfusion or surgical intervention.[9] Coronary perforation was reported and classified according to the Ellis classification.[10]

Statistical analysis

Categorical data was presented as numbers and percentages, while continuous variables as mean ± standard deviation or median [range]. Since this is an observational study with no control group, no further statistical analysis was presented.

RESULTS

Baseline clinical characteristics

From April 2022 to January 2023, 34 consecutive procedures with the Expressman™ GCE were included in the database. The mean age was 65 years, diabetes mellitus was present in half of the patients, and most of them had dyslipidemia and hypertension (Table 1). Past history of myocardial infarction and previous PCI was referred by half of the patients, and a heart failure diagnosis was present in one out of ten individuals. The majority of the procedures were performed in the setting of acute coronary syndrome (ACS).

Table 2 shows the angiographic and procedural characteristics of the study patients. The left anterior descending and the right coronary arteries were the most common target vessels, and most procedures were performed through the radial artery. A chronic total occlusion as the target lesion occurred in 12% of the cases, and just one procedure was done with adjunctive use of rotational atherectomy. In half of the cases, GCE use was planned upfront; in the remaining, GCE was used as a bailout after the operator facing technical issues to complete the procedure. The main reasons for GCE use were vessel angulation, proximal vessel tortuosity, and unfavorable coronary ostium position. Microcatheters and intravascular ultrasound (IVUS) were infrequently used.

Table 1. Baseline characteristics of the study patients

Clinical characteristics	
Age	65±9.4
Male sex	20 (58.8)
BMI	27.4 [26.2-29.4]
Hypertension	33 (97.1)
Diabetes	16 (47.1)
Dyslipidemia	32 (94.1)
PVD	4 (11.8)
Family History of CAD	1 (2.9)
Smoking (current)	14 (41.2)
Previous MI	16 (47.1)
Previous PCI	16 (47.1)
Previous CABG	6 (17.6)
Previous stroke	2 (5.9)
Heart failure	4 (11.8)
Chronic kidney disease	2 (5.9)
ACS	28 (82.4)

Results expressed as mean ± standard deviation, n (%) or median [range].

BMI: body mass index; PVD: peripheral vessel disease; CAD: coronary artery disease; MI: myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery bypass grafting; ACS: acute coronary syndrome.

Table 2. Angiographic and procedural characteristics of the study patients

Procedural characteristics	
Radial access	21 (61.8)
Rotational atherectomy	1 (2.9)
Target vessel	
Left main coronary artery	1 (2.9)
Left anterior descending artery	12 (35.3)
Circumflex artery	8 (23.5)
Right coronary artery	12 (35.3)
CTO	4 (11.8)
GCE use planned before the procedure	17 (50.0)
GCE indications	
Proximal tortuosity	22 (64.7)
Vessel angulation	29 (85.3)
Unfavorable coronary ostium position	8 (23.5)
IVUS	6 (17.6)
DES, n	1,6 [1-3]
Lesion length	34 [24-47]
Contrast medium volume	200 [150-250]
Microcatheter use	4 (11.8)

Values are expressed as n (%) or median [range].

CTO: chronic total occlusion; GCE: guide catheter extensions; IVUS: intravascular ultrasound; DES: drug eluting stent.

Procedural and in-hospital outcomes

The overall device success was achieved in 88% of procedures and procedural success in 91%. Acute complications were one coronary dissection and three side branch occlusions; no cardiac tamponade or coronary perforations were reported. During the in-hospital follow-up, there was only one minor bleeding and no deaths, strokes or MI were reported. Table 3 summarizes procedural and in-hospital outcomes.

Table 3. Procedural results, complications and in-hospital clinical outcomes of the study patients

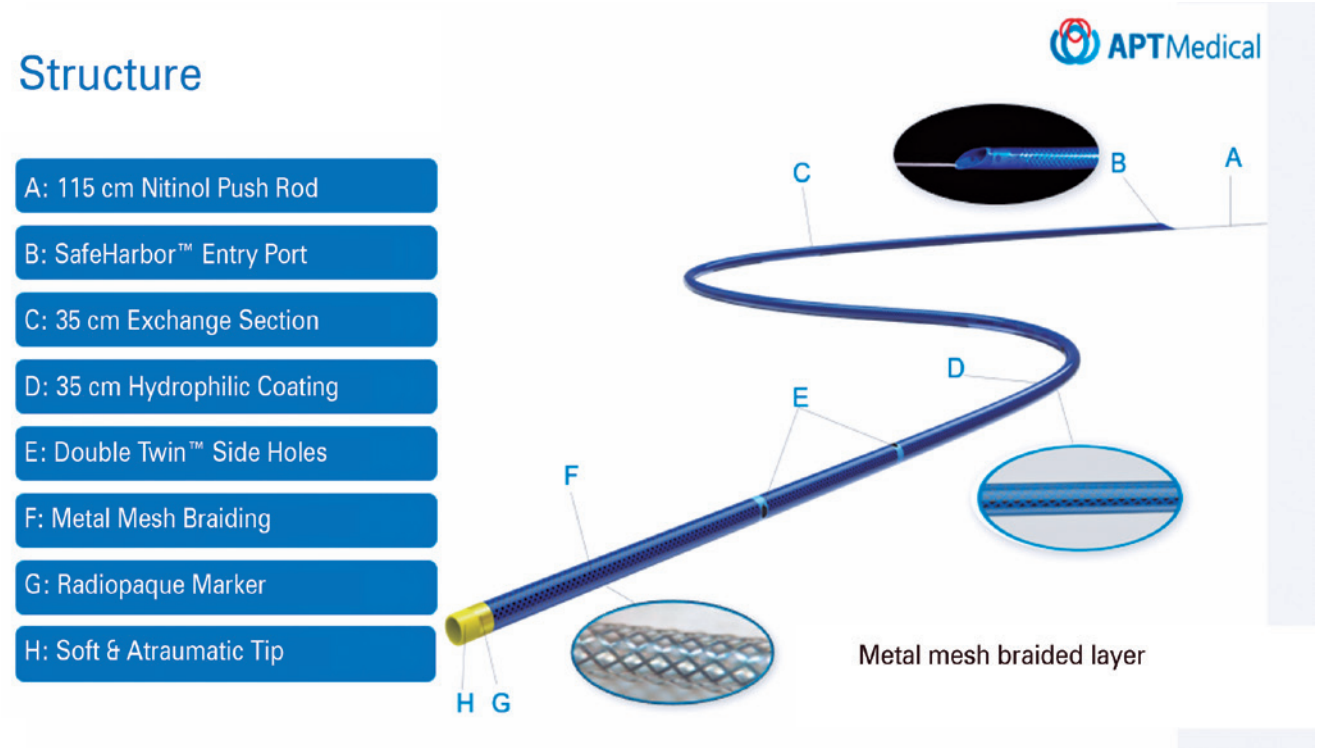
Procedural results	
Device success	30 (88.2)
Procedural success	31 (91.2)
Coronary perforation	0
Unresolved dissection	1 (2.9)
Side branch occlusion	3 (8.8)
Bleeding	
No	2,470 (97.6)
Minor	1 (2.9)
Major	0
Death	0
Stroke	0
MI	0
MACCE	0

Values are expressed as n (%).

MI: myocardial infarction; MACCE: major cardiac and cerebrovascular events.

DISCUSSION

The main findings of our study are that patients undergoing complex PCI with the Expressman™ GCE experienced a high rate of procedural and device success, with low rates of complications. Guide catheter extensions have been widely used in contemporary Interventional Cardiology practice given their easiness of use and safety. Nowadays, they are considered a key device in a Catheterization Laboratory for management of tortuous vessels, challenging anatomies and uncrossable lesions during PCI.[2] Expressman™ is a new generation device with excellent deliverability, side holes that allow antegrade blood flow to mitigate GCE-induced coronary ischemia, and a longer exchange segment that positions the transition zone outside the aortic arch and enable equipment delivery (Figure 1). The study results with a small number of patients are encouraging, but further studies with large samples and comparison with different GCE models are needed.



Source: courtesy of APT Medical.
Figure 1. The Expressman Guide Catheter Extension.

Liao et al. have recently reported the performance of the Expressman™ GCE in a sample of more than 600 patients, in which a smaller version (tapered 4F) was compared with a 5F GCE.[5] The authors observed favorable clinical results with both devices, but the 4F version was able to better deeply intubate the target coronary vessel. In the present study, the Expressman™ was offered on demand to operators in case they required such a device. This unique methodological aspect has translated into a selection of a very particular sample of patients, in whom many adverse clinical and angiographic characteristics were common, such as diabetes mellitus, previous heart disease, coronary tortuosity, angulation, calcification and others. Despite not having a control group, the prevalence of such characteristics was much higher than those reported on contemporary studies of PCI in daily practice. The high success rate reported in this context is of note and it can be fair to assume that many cases could not have been done if the GCE was not available, since many operators had requested it as a last resort to successfully perform in the case.

Complication rates with GCE use in general PCI are generally less than 2% and include dissections, coronary ischemia due to deep intubation and gear damage when passing through the transition, or because of the small lumen of the device.[1] Due to its unique design, the Expressman™ GCE device may reduce two of these potential limitations – coronary ischemia and equipment damage – but direct comparisons amongst different GCEs models are not available yet. It is also important to consider that half of the study participants had presented with ACS, a situation where a higher rate of complications is generally expected.

Our study had some limitations. First, this was an observational study with a descriptive purpose of the first group of patients being treated with the Expressman™ in Brazil, and we did not include a control group for comparison. Second, this study had a small number of patients, and the findings may change with a larger sample. Third, the presence of selection bias cannot be excluded as there was no standardization for case selection.

CONCLUSION

In a small sample of high-risk patients submitted to complex percutaneous coronary interventions in a reference center, the Expressman™ guide catheter extensions were safely used, with a high rate of procedural and device success, and low rates of complications. Its use as a bailout technique in complex anatomies allowed procedural success in the vast majority of otherwise untreatable patients. These results warrant further investigation with a larger sample of patients, randomized design and comparison with other guide catheter extensions models available for clinical use.

CONFLICTS OF INTEREST

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CONTRIBUTION OF AUTHORS

Conception and design of the study: ES, JVS, PP and ASQ; data collection: ES and JVS; data interpretation: PP and ASQ; text writing: ES, JVS, PP and ASQ; approval of the final version to be published: AA, CVM, JVT, RSL, AM, HG, CM, EA, JKT and FF.

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