Short-term results of the first-in-man new non--compliant balloon catheter clinical study

Krótkoterminowe wyniki pierwszego klinicznego badania dotyczącego nowego cewnika niepodatnego

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ABSTRACT

Objective: Nowadays, non-compliant (NC) balloon catheters are used to predilate heavily calcified lesions before stenting to postdilate the implanted stent to optimize its parameters, to finalize bifurcation treatment in final kissing balloon technique as well as to treat restenosis, especially in implanted earlier stents. The aim of this paper was to verify clinical effectiveness and safety profile of the new non-complaint balloon catheter (Balton, Poland).

Methods: It was the first-in-man analysis of the use of Balton NC balloon angioplasty catheter in patients undergoing percutaneous coronary interventions. There were included consecutive patients with age ≥ 18 years old, with coronary artery disease undergoing percutaneous coronary interventions in lesion requiring predilatation or postdilatation and who signed the informed consent. The local IRB approved the study protocol (No 135/2017). The primary endpoint was to compare balloon diameters obtained in QCA to diameters declared by the producer reached at certain pressures.

Results: A total of 21 patients were enrolled. In most cases patients presented with the multivessel disease (61.9%) and lesions of the moderate complexity (type B1 — 71.4%, type B2 — 4.8%). Lesions were located most frequently in the left circumflex artery (47.6%, n = 10). The device success rate was 100%. All procedures were performed via the 6F guiding catheter (100%) and in 95.2% (n = 20/21) the radial access was preferred. There were no significant differences between QCA and expected balloon diameters when applied the nominal pressure both in predilatation (2.32±0.31 mm vs. 2.38 ± 0.43 mm, Δ 2.5%) as well as in postdilatation (2.90±0.38 mm vs. 2.96 ± 0.47 mm, Δ 2.0%). There were only two dissection cases (1 type A and 1 type B).

Conclusions: The presented data confirm the effectiveness and safety profile of Balton NC balloon catheters. There the device success rate was 100%, and there were no severe complications. In QCA analysis Balton NC balloon catheters reached assumed diameters and lengths at given pressures.

Key words: balloon angioplasty, non-compliant balloon, quantitative coronary angiography

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STRESZCZENIE

Cel: Obecnie niepodatne cewniki (NC, *non-compliant*) balonowe stosuje się do przygotowania silnie uwapnionych zmian przed stentowaniem, do doprężenia implantowanego stentu w celu zoptymalizowania jego parametrów, do sfinalizowania zabiegu poszerzenia bifurkacji w technice *kissing*, a także w leczeniu nawrotu zwężenia, szczególnie w przypadku wszczepionych wcześniej stentów. Celem niniejszej pracy była weryfikacja skuteczności klinicznej i profilu bezpieczeństwa nowego niepodatnego cewnika balonowego (Balton, Polska).
Metody: Jest to pierwsza analiza zastosowania cewnika do angioplastyki balonowej Balton NC u chorych poddawanych przezskórnej interwencji wieńcowej. Do badania włączono kolejnych pacjentów w wieku co najmniej 18 lat z chorobą niedokrwienną serca poddawanych przezskórnej interwencji wieńcowej w zmianach wymagających pre- lub postdilatacji

i którzy podpisali świadomą zgodę. Lokalna Komisja Bioetyczna zatwierdziła protokół badania (nr 135/2017). Pierwszorzędowym punktem końcowym było porównanie średnic balonów uzyskanych w ilościowej ocenie angiograficznej (QCA, *quantitative coronary angiography*) do średnic deklarowanych przez producenta, osiągniętych przy określonych ciśnieniach. **Wyniki:** Do badania zakwalifikowano 21 pacjentów. U większości przypadków zdiagnozowano chorobę wielonaczyniową (61,9%) i zwężenia o umiarkowanym stopniu złożoności (typ B1 — 71,4%, typ B2 — 4,8%). Zmiany zlokalizowane były najczęściej w tętnicy okalającej (47,6%, n = 10). Wskaźnik skuteczności urządzenia wyniósł 100%. Wszystkie zabiegi wykonano za pomocą cewnika prowadzącego 6F (100%), a w 95,2% (n = 20/21) zastosowano dostęp promieniowy. Nie było znaczących różnic między QCA a oczekiwanymi średnicami balonu przy zastosowaniu ciśnienia nominalnego ani w predilacji (2,32 ± 0,31 mm w porównaniu z 2,38 ± 0,43 mm, Δ 2,5%), ani w postdilatacji (2,90 ± 0,38 mm w porównaniu z 2,96 ± 0,47 mm, Δ 2,0%). Odnotowano tylko dwa przypadki dyssekcji (1 typ A i 1 typ B). **Wnioski:** Przedstawione dane potwierdzają skuteczność i profil bezpieczeństwa cewników balonowych Balton NC. Wskaźnik skuteczności urządzenia wyniósł 100% i nie było poważnych powikłań. W analizie QCA cewniki Balton NC osiągnęły założone średnice i długości przy określonych ciśnieniach.

Słowa kluczowe: angioplastyka balonowa, niepodatny cewnik balonowy, ilościowa analiza angiograficzna

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INTRODUCTION

Balloon catheters are the basis for everyday catheter laboratory work. The construction of standard products is well established and the principal function of the balloon has not changed much in the last 15 years. The materials, however, are better now and stents and drugs have been added what aim to stabilize the dilatatory effect of the balloon, so that nearly every PCI is now finished with a stent. With the treatment of ever increasingly complicated atherosclerotic disease, predilatation prior to stent deployment and to some degree post-dilatation are now the main indications. The standard construction principle for intracoronary catheters is the monorail system, which is best understood from its function [1].

The evolution of balloon catheter systems was dominated by a consecutive series of essential developments: non-compliant balloons, miniaturization, steerable catheters, catheter exchange and the combination of these developments in one catheter. Grüntzig's solution to treat stenoses in atherosclerotic arteries was a non-compliant "sausage-like" balloon where pressure is transformed into radial force during inflation, evenly distributed over the balloon and directed toward the circumference [2].

Nowadays, non-complaint balloon catheters are used to predilate heavily calcified lesions before stenting to postdilate the implanted stent to optimize its parameters to finalize bifurcation treatment in final kissing balloon technique as well as to treat restenosis, especially in implanted earlier stents. The aim of this paper was to verify clinical effectiveness and safety profile of the new non-complaint balloon catheter (Balton, Poland).

METHODS

Device description

Coronary angioplasty catheter manufactured by the Balton Company is a Rapid Exchange catheter with a high pressure non-compliant balloon near the distal tip. The distal section of the catheter is dual lumen. The outer lumen is used for inflation of the balloon, and the inner lumen is used for guide wire (0.014"/0.36 mm). The proximal section of the catheter is a single-lumen. Catheter includes radiopaque markers aiding in the precision placement of the catheter's balloon in a vessel. The balloon diameter ranges from 1.25 mm to 6 mm and the balloon length — from 8 mm to 40 mm.

Study population and study design

It was the first-in-man analysis of the use of Balton NC balloon angioplasty catheter in patients undergoing percutaneous coronary interventions. There were included consecutive patients with age ≥ 18 years old, with coronary artery disease undergoing percutaneous coronary interventions in lesion requiring predilatation or postdilatation and who signed the informed consent. The study was conducted in August 2018 in the Department of Invasive Cardiology, Central Clinical Hospital of the Ministry of Interior and Administration. The local IRB approved the study protocol (No 135/2017).

Interventional procedure, device description and concomitant medication

There were assessed 21 Balton NC balloon angioplasty catheters, in which 8 were assessed in predilatation and 13 — in postdilatation applications. The example procedure is presented in the Figure 1. The study protocol was as follows:

1. Lesion assessment according to ACC/AHA classification
2. Lesion visualization in two views optimal for QCA measurements. All measurements repeated in the chosen views.
3. Predilatation with the assessed device — QCA measurements including balloon's length, diameter (D) mean, D_{max}, D_{min} with registered applied pressures.
4. QCA measurements after predilatations (2 views).
5. QCA measurements during stent implantation.

6. QCA measurements after stent implantation.
7. QCA measurements during postdilatations.
8. QCA measurements after postdilatations.
9. TIMI blood flow assessment before and after procedure.
10. Operator's assessment including visibility, flexibility, trackability and pushability.

All angiograms were recorded after intracoronary administration of 200 μg of nitroglycerin. Two orthogonal views were chosen to visualize the target lesion. A quantitative angiographic analysis was performed using CAAS QCA version 8.0 (Pie Medical, the Netherlands). Catheter calibration was performed in all cases. The following parameters were calculated: lesion length, reference vessel diameter (RVD), minimal lumen diameter (MLD), % diameter stenosis (%DS). All reference diameters were measured 5 mm from the end of angiographically visible plaque without use of interpolations (user defined reference diameters). Percent diameter stenosis (using parameters from each segment) was measured for each vessel using the following formula: %DS = [1 — (MLD/RVD)] *100% [3].

Additionally, the following QCA parameters were recorded [4]:

- stretch, that is, the measured maximal size in diameter of the inflated balloon, assuming uniformity along its entire length during inflation minus the minimal lumen diameter;
- recoil, that is, the difference between the measured maximal balloon size and the subsequent residual minimal lumen diameter.

Additionally, to measure Balton NC balloon compliance we compared the mean diameter obtained during the procedure to the expected diameter assessed in vitro. %Δ was calculated as follows: %Δ = (expected diameter — QCA diameter)/expected diameter * 100%.

Endpoints

The primary endpoint was to compare balloon diameters obtained in QCA to diameters declared by the producer reached at certain pressures.

Statistical analysis:

Continuous variables were presented as mean ± SD. Categorical data were presented as numbers (%). Statistical analyses were performed using R 3.0.2 for OS (R Foundation, Vienna, Austria).

RESULTS

Baseline characteristics

A total of 21 patients were enrolled to assess Balton NC balloon catheters performance in August 2018 in the Department of Invasive Cardiology Central Clinical Hospital of the Ministry of Interior and Administration, Warsaw, Poland. The detailed clinical characteristics is presented below (Table 1).

Table 1. Baseline clinical characteristics

Baseline clinical characteristics		n = 21 (%)
Age [years]		67.3 ± 4.7
Men		21 (100)
Hypertension		20 (95.2)
Hypercholesterolemia		11 (52.4)
Diabetes type 2		10 (47.6)
Prior MI		10 (47.6)
Prior PCI		11 (52.4)
CABG		0
Chronic kidney disease		5 (23.8)
Clinical indication for PCI		
	planned PCI	17 (81)
	UA	0
	NSTEMI	4 (19)
	STEMI	0

MI: myocardial infarction; PCI: percutaneous coronary interventions; CABG: coronary artery bypass graft; UA: unstable angina; NSTEMI: non-ST-elevation myocardial infarction; STEMI: ST-elevation myocardial infarction

In most cases patients presented with the multivessel disease (61.9%) and lesions of the moderate complexity (type B1 — 71.4%, type B2 — 4.8%). Lesions were located most frequently in the left circumflex artery (47.6%, n = 10). More details are presented below (Table 2).

Procedural characteristics

The main procedural variables are presented in Table 3. The device success rate was 100%. All procedures were performed via the 6F guiding catheter (100%) and in 95.2% (n = 20/21). The radial access was preferred.

QCA analysis

Table 4 presents quantitative coronary angiography (QCA) analysis of each step of PCI, with additional marking for mean diameter, minimal diameter and

Table 2. Angiographic characteristics

Parameter		n = 21 (%)
Multivessel disease		13 (61.9)
Lesion type		
	A	2 (9.5)
	B1	15 (71.4)
	B2	1 (4.8)
	C	3 (14.3)
Lesion location		
	LM	1 (4.8)
	LAD	8 (38.1)
	LCx	10 (47.6)
	RCA	2 (9.5)
Vessel tortuosity		
	None — mild	15 (71.4)
	Moderate — severe	6 (28.6)
Calcification		
	None — mild	16 (76.2)
	Moderate — severe	5 (23.8)

LIMA: left internal mammary artery; LAD: left anterior descending artery; LM: left main stem; LCx: left circumflex artery; RCA: right coronary artery; VG: venous graft

maximal diameter for balloons used in predilatations, for stents and for balloons used in postdilatations.

Additionally, in Table 5 data on expected and calculated by QCA mean balloon diameters used in predilatations and postdilatations at nominal pressures applied and on RBP applied are presented.

Safety evaluation

Regarding safety profile there was no severe adverse events, no perforation or systemic bleeding complications (e.g. gastrointestinal bleeding or intracranial hemorrhage). The detailed data are shown in Table 6.

LIMITATIONS

This registry has several limitations that should be acknowledged. First of all, the sample size was relatively small. Another limitation of this registry is due to its non-randomized manner and all known drawbacks of registry studies.

CONCLUSIONS

The presented data confirm the effectiveness and safety profile of Balton NC balloon catheters. There were no severe adverse events, the device success rate was 100%, and there were no severe complications. The dissection incidence was less than 10%. However, this is the normal mechanism of lumen enlargement and the mechanism of action of plain old balloon angioplasty. The rate of complications

Table 3. Procedural characteristics

Parameter	n = 21 (%)
Device success	21 (100)
Predilatation — balloon nominal diameter [mm]	2.38 ± 0.43
Predilatation — balloon nominal length [mm]	16.88 ± 2.50
Stent — nominal diameter [mm]	3.07 ± 0.54
Stent — nominal length [mm]	19.90 ± 5.58
Postdilatation — balloon nominal diameter [mm]	2.96 ± 0.47
Postdilatation — balloon nominal length [mm]	12.92 ± 3.01
Maximal predilatation pressure [atm]	16.4 ± 4.4
Maximal stent deployment pressure [atm]	11.3 ± 3.24
Maxiaml postdilatation pressure [atm]	22.1 ± 3.9
Balloon: artery ratio (predilatation)	0.76 (range: 0.73–0.83)
Balloon: artery ratio (postdilatation)	0.98 (range: 0.95–1.02)
Vascular access radial/femoral	20 (95.2)/1 (4.8)
Guiding catheter 6F/7F	21 (100)/0

Table 4. QCA analysis

	Baseline	Predilatation	Postpredi-latation	Stent impl.	Post stent impl.	Postdilata-tion	Final
MLD	0.72 ± 0.12		1.64 ± 0.21		2.69 ± 0.23		2.92 ± 0.14
%DS	76.4 ± 11.2%	–	45.5 ± 23.1	–	13.4 ± 4.3	–	4.8 ± 1.9
Ref. D	3.05 ± 0.23	–	3.01 ± 0.32	–	3.11±0.23	–	3.07 ± 0.07
Dmean	–	2.32 ± 0.31	–	2.88 ± 0.44	–	3.07 ± 0.12	–
Dmin	–	2.24 ± 0.29	–	2.77 ± 0.32	–	2.99 ± 022	–
Dmax	–	2.36 ± 0.41	–	2.98 ± 0.22	–	3.11 ± 0.12	–
length	–	16.4 ± 3.4	–	19.8±0.12	–	10.9 ± 2.3	–
Stretch		1.6 ± 0.09				0.42 ± 0.04	
recoil			0.68 ± 0.11				0.19 ± 0.02

Table 5. QCA-based and expected balloon diameters

Predilatation, n = 8	Nominal pressure (12 atm)			RBP (20 atm)		
	QCA	Expected	%D	QCA	Expected	%D
Balloon diameter	2.32 ± 0.31	2.38 ± 0.43	2.5%	2.54 ± 0.33	2.59 ± 0.23	1.9%
Postdilatation, n = 13						
Balloon diameter	2.90 ± 0.38	2.96 ± 0.47	2.0%	3.11 ± 0.12	3.22 ± 0.29*	3.4%

*difference statistically significant

Table 6. Procedural complications

Complication		No (%) n = 21
Coronary artery perforation		0
Coronary artery dissection		2 (9.5)
Distal embolization		0
Slow flow/no reflow phenomenon		0
Side branch occlusion after balloon dilatation		0
Systemic bleeding complications		0
Access site complications		0
	hematoma	0
	pseudoaneurysm	0
	a-v fistula	0
	infection	0

Table 7. Coronary artery dissection classification

Type of dissection	No (%) n = 21
A	1 (4.7)
B	1 (4.7)
C	0
D	0
E	0
F	0

and immediate outcomes are similar to other studies describing balloon angioplasty procedures [5–8].

In the QCA analysis Balton NC balloon catheters reached assumed diameters and lengths at given pressures. Additionally, the Balton NC balloon met the non-compliance criteria defined earlier, i.e. compliance < 10%. Worth stressing is the fact that compliance index was no larger than 3.4% [9].

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