

World Journal of *Clinical Cases*

World J Clin Cases 2019 April 26; 7(8): 908-1005





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World Journal of Clinical Cases (*World J Clin Cases*, *WJCC*, online ISSN 2307-8960, DOI: 10.12998) is a peer-reviewed open access academic journal that aims to guide clinical practice and improve diagnostic and therapeutic skills of clinicians.

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The *WJCC* is now indexed in PubMed, PubMed Central, Science Citation Index Expanded (also known as SciSearch®), and Journal Citation Reports/Science Edition. The 2018 Edition of Journal Citation Reports cites the 2017 impact factor for *WJCC* as 1.931 (5-year impact factor: N/A), ranking *WJCC* as 60 among 154 journals in Medicine, General and Internal (quartile in category Q2).

**RESPONSIBLE EDITORS
FOR THIS ISSUE**

Responsible Electronic Editor: Yun-Xiaojuan Wu Proofing Editorial Office Director: Jin-Lei Wang

NAME OF JOURNAL

World Journal of Clinical Cases

ISSN

ISSN 2307-8960 (online)

LAUNCH DATE

April 16, 2013

FREQUENCY

Semimonthly

EDITORS-IN-CHIEF

Dennis A Bloomfield, Sandro Vento

EDITORIAL BOARD MEMBERS

<https://www.wjgnet.com/2307-8960/editorialboard.htm>

EDITORIAL OFFICE

Jin-Lei Wang, Director

PUBLICATION DATE

April 26, 2019

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<https://www.wjgnet.com/bpg/gerinfo/208>

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<https://www.wjgnet.com/bpg/gerinfo/242>

STEPS FOR SUBMITTING MANUSCRIPTS

<https://www.wjgnet.com/bpg/GerInfo/239>

ONLINE SUBMISSION

<https://www.f6publishing.com>

Retrospective Study

Optimal use of fielder XT guidewire enhances the success rate of chronic total occlusion percutaneous coronary intervention

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Author contributions: All authors helped to perform the study; Jing QM, Liao YL and Wang QC contributed to study conception and design; Jing QM, Wang QC, Dong H, Xu K, Guan SY and Han Y contributed to performing the procedures and collecting the data; Bin JP, Lin HR, Chen ZH and Hao HX contributed to interpreting the data and statistical analysis; Wang QC and Liao YL contributed to manuscript writing and made critical revision on the manuscript; All authors reviewed the manuscript and completed final approval.

Supported by the National Natural Science Foundation of China, No. 81570464 and No. 81770271; Special Fund for the Cultivation of College Students' Science and Technology Innovation in 2018, No. pdjha0095; and Municipal Planning Projects of Scientific Technology of Guangzhou, No. 201804020083.

Institutional review board

statement: This study was reviewed and approved by the Ethics Committee of the General

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Abstract

BACKGROUND

Chronic total occlusion (CTO) is found in 18-31% of patients who undergo coronary angiography. Successful recanalization of CTOs is associated with reduced recurrent angina pectoris rates and increased long-term survival. Although the success rate of CTO percutaneous coronary intervention (CTO-PCI) has improved, CTO-PCI remains technically challenging. The Fielder XT guidewire was designed for CTO lesions. To validate whether the use of the guidewire increases the success rate, we compared the results of CTO-PCI with or without the guidewire. We hypothesized that the use of Fielder XT guidewire can increase the success rate of CTO-PCI.

AIM

To investigate whether the use of Fielder XT guidewire increases the final procedural success of CTO-PCI *via* the antegrade approach.

METHODS

Between January 2013 and December 2015, a retrospective study was conducted on 1230 consecutive patients with CTO who received PCI *via* the antegrade approach at the General Hospital of Northern Theater Command. The patients were divided into an XT Group ($n = 686$) and a no-XT Group ($n = 544$) depending on whether Fielder XT guidewire was used. Both groups were compared for clinical parameters, lesion-related characteristics, procedural outcomes and in-hospital complications. The data were statistically analyzed using Pearson's χ^2 test for categorical variables, and Students' t test was used to compare the

Hospital of Northern Theater Command.

Informed consent statement:

Patients were not required to provide informed consent to participate in this study because the analyses used anonymous clinical data that were obtained after each patient had agreed to treatment based written consent.

Conflict-of-interest statement: The authors declare no conflicts of interest regarding this manuscript.

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Manuscript source: Unsolicited manuscript

Received: January 30, 2019

Peer-review started: January 31, 2019

First decision: March 10, 2019

Revised: March 22, 2019

Accepted: April 9, 2019

Article in press: April 9, 2019

Published online: April 26, 2019

P-Reviewer: Abadi ATB, Aseni P, Elhamid SMA

S-Editor: Ji FF

L-Editor: Filipodia

E-Editor: Wu YXJ



quantitative data. Significant independent factors and a risk ratio with 95% confidence interval (CI) were assessed by multivariate logistic regression analysis.

RESULTS

In total, 1230 patients were recruited; 75.4% of the patients were male, and 55.8% of the patients were in the XT group. The overall success rate was 83.9%, with 87.8% in the XT group. Based on multivariate logistic regression analysis, factors positively associated with procedural success were the use of Fielder XT guidewire ($P = 0.005$, 95%CI: 1.172-2.380) and systolic blood pressure ($P = 0.011$, 95%CI: 1.003-1.022), while factors negatively associated with procedural success were blunt stump ($P = 0.013$, 95%CI: 1.341-11.862), male sex ($P = 0.016$, 95%CI: 0.363-0.902), New York Heart Association (NYHA) class ($P = 0.035$, 95%CI: 0.553-0.979), contrast amount ($P = 0.018$, 95%CI: 0.983-0.998) and occlusion time ($P = 0.009$, 95%CI: 0.994-0.999). No significant differences were found between the XT group and the no-XT group with respect to clinical parameters, lesion-related characteristics, coronary artery rupture [3 (0.4%) vs 8 (1.5%), $P = 0.056$], in-hospital death [2 (0.3%) vs 6 (1.1%), $P = 0.079$] or in-hospital target lesion revascularization [3 (0.4%) vs 7 (1.3%), $P < 0.099$]. However, there were significant differences between the groups with respect to success rate [602 (87.8%) vs 430 (79.0%), $P < 0.001$], procedure time [(74 ± 23) vs (83 ± 21) , $P < 0.001$], stent length [(32.0 ± 15.8) vs (37.3 ± 17.6) , $P < 0.001$], contrast amount [(148 ± 46) vs (166 ± 43) , $P < 0.001$], post-PCI myocardial infarction [43 (6.3%) vs 59 (10.8%), $P = 0.004$], major adverse cardiovascular event [44 (6.4%) vs 57 (10.7%), $P = 0.007$], side branch loss [31 (4.5%) vs 44 (8.1%), $P = 0.009$], contrast-induced nephropathy [29 (4.2%) vs 40 (7.4%), $P = 0.018$] and no reflow [8 (1.2%) vs 14 (2.9%), $P = 0.034$].

CONCLUSION

The use of Fielder XT guidewire shortens the Procedure and increases the success rate of CTO-PCI, and is also associated with reduced complication rates.

Key words: Chronic total occlusion; Percutaneous coronary intervention; Anterograde wire escalation; Parallel wire technique; Fielder XT guidewire; Success rate

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Core tip: This retrospective study aimed to investigate whether the use of Fielder XT guidewire can increase the final procedural success of chronic total occlusion-percutaneous coronary intervention *via* the anterograde approach. We found that the use of Fielder XT guidewire was positively associated with procedural success based on multivariate logistic regression analysis. We found no significant differences between the XT group and the no-XT group with respect to clinical parameters, lesion-related characteristics, coronary artery rupture, in-hospital death or in-hospital target lesion revascularization. However, we found significant differences between the groups with respect to success rate, procedure time, stent length, contrast amount and in-hospital complications.

Citation: Wang QC, Lin HR, Han Y, Dong H, Xu K, Guan SY, Chen ZH, Hao HX, Bin JP, Liao YL, Jing QM. Optimal use of fielder XT guidewire enhances the success rate of chronic total occlusion percutaneous coronary intervention. *World J Clin Cases* 2019; 7(8): 928-939

URL: <https://www.wjgnet.com/2307-8960/full/v7/i8/928.htm>

DOI: <https://dx.doi.org/10.12998/wjcc.v7.i8.928>

INTRODUCTION

Coronary chronic total occlusion (CTO), defined as a lesion with total occlusion exhibiting thrombolysis in myocardial infarction (TIMI) grade 0 flow in a native vessel for more than 3 mo, is found in 18%-31% of patients who undergo invasive coronary angiography^[1,2]. Successful recanalization of CTOs has been shown to be associated with reduced risks of death, coronary artery bypass grafting^[3], recurrent angina

pectoris^[4] and increased long-term survival^[5,6]. In addition, failure of CTO-percutaneous coronary intervention (CTO-PCI) is reported to be associated with higher subsequent mortality and more frequent major adverse cardiovascular events (MACE)^[7]. Although experience and the introduction of new devices have improved the success rate of PCI^[8], CTO-PCI is still technically challenging. The most common reason for CTO-PCI failure is the failure of the guidewire to cross the occlusion segment^[9]. Recently, the Fielder XT guidewire was specifically designed for CTO lesions. It has a soft, tapered polymer-jacketed tip, and has been introduced and used worldwide.

To validate whether Fielder XT guidewire can increase the success rate of PCI in CTO lesions, we retrospectively compared data from 1230 consecutive patients with CTO who received PCI *via* the antegrade approach at our institution from January 2013 to December 2015. We hypothesized that the use of Fielder XT guidewire can increase the success rate of CTO-PCI *via* the antegrade approach.

MATERIALS AND METHODS

Study population

Between January 2013 and December 2015, 1230 consecutive patients with CTO who received PCI *via* the antegrade approach at the General Hospital of Northern Theater Command. The study protocol was approved by the local ethics committee, and all procedures were performed according to current international guidelines^[10,11]. All patients provided written informed consent. We conducted a retrospective analysis of these 1230 patients.

Definitions

CTO was defined as a lesion with total occlusion exhibiting TIMI grade 0 flow in a native vessel for more than 3 mo. Estimation of the occlusion duration was based on the first onset of angina symptoms, prior history of myocardial infarction (MI) in the target vessel territory, or comparison with a prior angiogram. Procedural success was defined as angiographic success (final residual diameter stenosis < 20% and TIMI grade 3 flow following recanalization of the CTO). Clinical success was defined as successful PCI with the patient discharged alive.

Criteria for choice of donors

Patients were candidates for intervention if they had sufficient cardiac function to lie in the supine position for at least 2 h. To minimize confounding factors, only patients undergoing primary antegrade CTO-PCI whose target vessel was ≥ 2.5 mm in diameter were included in this study. Patients were excluded if they had more than one CTO treated during the same PCI procedure, or if there was no clear evidence for CTO duration ≥ 3 mo.

Study design

Based on the use of Fielder XT guidewire, the patients were divided into two groups: the XT group ($n = 686$) and the no-XT group ($n = 544$). Both groups were compared for clinical parameters, lesion-related characteristics, procedural outcomes and in-hospital complications.

CTO-PCI procedure

All interventional procedures were performed using standard techniques. The selection of arterial access depends on the characteristics of the target lesions. Generally, puncture of one of the right radial arteries or right femoral arteries was performed. If necessary, puncture of two arteries among the right radial artery, left radial artery, right femoral artery and left femoral artery were performed. We preferred the Amplatz Left guiding catheter when performing CTO-PCI of the right coronary artery, and we preferred the EBU or the Extra Backup guiding catheter when performing CTO-PCI of the left anterior descending (LAD) and left circumflex artery. The antegrade wire escalation (AWE) strategy was employed for antegrade crossing of the CTO. AWE was usually started with a soft (tip load = 0.8 g), tapered polymer-jacketed guidewire (such as Fielder XT, Asahi Intecc, Japan), a tapered polymer-jacketed guidewire (such as Pilot 50, Abbott, United States), a stiff guidewire (such as Miracle 6, Asahi Intecc), or a stiff, tapered guidewire (such as Conquest, Asahi Intecc).

AWE technique was always performed using an over-the-wire system (such as Finecross microcatheter, Terumo, Japan, or Corsair microcatheter, Asahi Intecc) to support the guidewire. A microcatheter allowed rapid exchange of guidewires, while maintaining wire position and improving guidewire torque response. Microcatheters

also improve support and enable dynamic alterations of the penetration power of the guidewire by changing the distance between the microcatheter tip and wire tip. Some of the preferred wires are able to cross the CTO lesions either directly or with the support of the over-the-wire system. If the first soft wire entered the subintimal space of the occlusion segment and failed to cross the CTO lesion, we upgraded to a stiff, tapered wire for crossing using the parallel wires technique. If the first wire could not enter the proximal cap of the CTO lesion, we used a higher-tip-load tapered wire to puncture the proximal cap and then downgraded to a softer, tapered polymer-jacketed guidewire to cross the occlusion. If the CTO had tortuous vessels or unclear vascular anatomy, the knuckle wire technique was usually attempted with a polymer-jacketed guidewire (such as Fielder XT or Pilot 50). Other techniques including the buddy wire technique, multiwire plaque crushing, subintimal tracking and reentry, and balloon jailing were also employed as required. All PCI procedures were performed by experienced interventionists who handled at least 50 cases of CTO-PCI annually.

Statistical analysis

Continuous variables are presented as the mean \pm SD, and categorical data are presented as numbers (proportions). The data were statistically analyzed using Pearson's χ^2 test for categorical variables, and Students' *t* test was used to compare the quantitative data. Significant independent factors and risk ratio with 95% confidence interval (CI) were assessed by multivariate logistic regression analysis. Analyses were performed using SPSS software (version 21.0; SPSS Inc., Chicago, IL, United States), and $P < 0.05$ (2-sided) was considered statistically significant.

RESULTS

Patients

A total of 1230 patients aged from 31 to 88 years were enrolled, with 74.8% (898/1230) of the patients being male and 55.8% (686/1230) of the patients in the XT group. The overall success rate was 83.9% (1032/1230).

Arterial access

The right radial arterial access percentage is 38.4% (472/1230); the right femoral arterial access percentage is 6.3% (77/1230); the right and left radials arterial accesses percentage is 33.1% (407/1230); the right radial arterial and right femoral arterial accesses percentage is 17.1% (210/1230); the right and left femoral arterial accesses percentage is 5.2% (64/1230).

Parameters predicting the success of CTO-PCI

According to backward logistic regression analysis by Wald's method, the following factors were positively correlated with successful CTO-PCI: Use of Fielder XT guidewire ($P = 0.005$, 95%CI: 1.172-2.380) and systolic blood pressure ($P = 0.011$, 95%CI: 1.003-1.022), while factors negatively associated with procedural success were blunt stump ($P = 0.013$, 95%CI: 1.341-11.862), male sex ($P = 0.016$, 95%CI: 0.363-0.902), New York Heart Association (NYHA) class ($P = 0.035$, 95%CI: 0.553-0.979), contrast amount ($P = 0.018$, 95%CI: 0.983-0.998) and occlusion time ($P = 0.009$, 95%CI: 0.994-0.999) (Table 1).

Clinical characteristics in the two groups

Based on the use of Fielder XT guidewire, the patients were divided into two groups: The XT group ($n = 686$; 55.8%) and the no-XT group ($n = 544$; 44.2%). When clinical characteristics from the two groups were compared, we found no significant differences based on male sex ($P = 0.313$), age ($P = 0.062$), height ($P = 0.064$), body weight ($P = 0.645$), body mass index ($P = 0.112$), systolic blood pressure ($P = 0.146$), diastolic blood pressure ($P = 0.365$), hypertension ($P = 0.782$), diabetes mellitus ($P = 0.988$), previous stroke ($P = 0.521$), old MI ($P = 0.587$), previous PCI ($P = 0.431$), previous renal insufficiency ($P = 0.513$), smoking ($P = 0.325$), alcohol drinking ($P = 0.887$), left ventricular ejection fraction ($P = 0.587$), left ventricular end-diastolic diameter ($P = 0.559$), serum creatinine ($P = 0.577$), cardiothoracic ratio ($P = 0.089$), NYHA heart function class ($P = 0.643$) or age ≥ 65 years ($P = 0.585$) (Table 2).

Lesion-related characteristics in the two groups

The groups were further compared for lesion-related characteristics. The two groups did not differ significantly in terms of multivessel coronary artery disease ($P = 0.609$), lesion calcification ($P = 0.423$), tortuosity ($P = 0.124$), bridging collaterals ($P = 0.665$), blunt stump ($P = 0.787$), J-CTO score ($P = 0.077$), Rentrop class ($P = 0.686$), CTO vessel

Table 1 Parameters predicting success of chronic total occlusion-percutaneous coronary intervention

	β coefficient	Wald	Exp (β)	P-value	95%CI of OR
Clinical predictors					
Sex, male	-0.559	7.780	0.572	0.016	0.363~0.902
Systolic blood pressure	0.012	6.405	1.012	0.011	1.003~1.022
NYHA class	-0.307	4.445	0.735	0.035	0.553~0.979
Contrast amount	-0.009	5.555	0.991	0.018	0.983~0.998
Lesion-related predictors					
Occlusion time	-0.003	6.848	0.997	0.009	0.994~0.999
Blunt stump	-1.382	6.192	3.982	0.013	1.341~11.862
Use of Fielder XT	0.513	8.060	1.670	0.005	1.172~2.380
Constant	-5.668	0.127	0.003	0.722	

NYHA: New York Heart Association; CI: Confidence interval; OR: Odds ratio.

($P = 0.570$), occlusion length ($P = 0.876$), or occlusion time ($P = 0.796$) (Table 3).

Procedural outcomes and in-hospital complications

When the procedural outcomes and in-hospital complications were compared between the two groups, there were no significant differences in coronary artery rupture [3 (0.4%) *vs* 8 (1.5%), $P = 0.056$], in-hospital death [2 (0.3%) *vs* 6 (1.1%), $P = 0.079$] or in-hospital target lesion revascularization (TLR) [3 (0.4%) *vs* 7 (1.3%), $P < 0.099$] (Table 4); however, there were significant differences with regard to success rate [602 (87.8%) *vs* 430 (79.0%), $P < 0.001$], procedure time [(74 \pm 23) *vs* (83 \pm 21), $P < 0.001$], stent length [(32.0 \pm 15.8) *vs* (37.3 \pm 17.6), $P < 0.001$], contrast amount [(148 \pm 46) *vs* (166 \pm 43), $P < 0.001$], post-PCI MI [43 (6.3%) *vs* 59 (10.8%), $P = 0.004$], MACE [44 (6.4%) *vs* 57 (10.7%), $P = 0.007$], side branch loss [31 (4.5%) *vs* 44 (8.1%), $P = 0.009$], contrast-induced nephropathy (CIN) [29 (4.2%) *vs* 40 (7.4%), $P = 0.018$] and no reflow [8 (1.2%) *vs* 14 (2.9%), $P = 0.034$] (Table 4).

DISCUSSION

This retrospective study investigated the use of Fielder XT guidewire in CTO-PCI *via* the antegrade approach. We focused on the relationship between the use of Fielder XT guidewire and the success rate of CTO-PCI, and evaluated the occurrence of in-hospital complications in two groups. The main novel findings of this study are as follows: (1) The use of Fielder XT guidewire contributes to increasing the success rate of CTO-PCI *via* the antegrade approach; and (2) The use of Fielder XT guidewire is associated with reduced rates of in-hospital complications and stent implantations.

The AWE technique is the most common strategy for CTO-PCI, and polymer-jacketed guidewires are most frequently used to implement this strategy. Although Karatasakis *et al*^[12] recently reported that the use of stiff polymer-jacketed guidewires results in a high CTO crossing rate without increasing the incidence of MACE or perforation^[12], we found that a soft, tapered polymer-jacketed Fielder XT (Figure 1) guidewire was also effective in crossing the occlusion. Consistent with our results, the Euro-CTO club has recommended starting with a soft (tip load < 1 g), tapered polymer-jacketed guidewire, not only because of high success rates but also because of the low risk of distal vessel damage if the wire fails to cross the lesion^[13]. The existence of microchannels, which partly or completely connect from the proximal cap to the distal end of CTO lesions^[14] (Figure 2A), has also been reported to predict procedural success^[15]. Single wiring displays a high success rate as the initial PCI strategy for CTO of the LAD, and is generally performed with a tapered guidewire such as Fielder XT^[16] (Figure 2B). The diameter of the Fielder XT guidewire is 230 μm , while the diameters of the microchannels range from 160 to 230 μm ^[14]. Therefore, it is reasonable to select Fielder XT as the initial guidewire. Additionally, microchannels frequently end at the sidewall of the coronary artery or connect to the side branches far proximal to the distal end of the CTO lesion. Some of these microchannels may run longitudinally through the lesion from the proximal to the distal lumen for up to 85% of the total length of the CTO (Figure 2A). The initial soft, tapered polymer-jacketed guidewire can easily enter the proximal cap through microchannels, but the wire

Table 2 Clinical characteristics in the two groups, *n* (%)

	Overall population, <i>n</i> = 1230	XTgroup, <i>n</i> = 686	No-XT group, <i>n</i> = 544	<i>P</i> -value
Sex, male	928 (75.4)	510 (74.3)	418 (76.8)	0.313
Age, yr	61.9 ± 10.3	62.4 ± 9.9	61.3 ± 10.8	0.062
Height, cm	169.5 ± 6.3	169.2 ± 6.3	169.9 ± 6.4	0.064
Body weight, kg	74.0 ± 10.0	74.4 ± 10.7	74.2 ± 10.0	0.645
Body mass index, kg/m ²	25.8 ± 3.2	26.0 ± 3.3	25.7 ± 3.1	0.112
SBP, mmHg	137.0 ± 20.8	137.7 ± 20.6	136.0 ± 21.0	0.146
DBP, mmHg	81.0 ± 12.9	81.3 ± 13.1	80.6 ± 12.7	0.365
Hypertension	765 (62.2)	429 (62.5)	336 (61.8)	0.782
Diabetes mellitus	405 (32.9)	226 (32.9)	179 (32.9)	0.988
Previous stroke	95 (7.7)	50 (7.3)	45 (8.3)	0.521
OMI	408 (33.2)	232 (33.8)	176 (32.4)	0.587
Previous PCI	328 (26.7)	189 (27.6)	139 (25.6)	0.431
PRI	119 (9.7)	63 (9.2)	56 (10.3)	0.513
Smoking	693 (56.3)	378 (55.1)	315 (57.9)	0.325
Alcohol drinking	445 (36.2)	247 (36.0)	198 (36.4)	0.887
LVEF, %	60.0 ± 9.0	60.0 ± 9.0	59.8 ± 8.6	0.587
LVEDd, mm	48.4 ± 6.3	48.5 ± 6.4	48.3 ± 6.2	0.559
Serum creatinine, μmol/L	73.0 ± 23.0	72.5 ± 23.9	71.8 ± 21.6	0.577
Cardiothoracic ratio, %	54.0 ± 6.0	53.8 ± 6.1	53.2 ± 6.0	0.089
NYHA heart function class				0.643
Class I	923 (75.0)	510 (74.3)	413 (75.9)	
Class II	247 (20.1)	144 (21.0)	103 (18.9)	
Class III	60 (4.9)	32 (4.7)	28 (5.1)	
Age ≥ 65 yr	532 (43.3)	292 (42.6)	240 (44.1)	0.585

Values represent the mean ± SD or number of patients and proportion (%). SBP: Systolic blood pressure; DBP: Diastolic blood pressure; OMI: Old myocardial infarction; PRI: Previous renal insufficiency; PCI: Percutaneous coronary intervention; LVEF: Left ventricular ejection fraction; LVEDd: Left ventricular end-diastolic diameter; NYHA: New York Heart Association.

frequently goes into the sidewall of the coronary artery and results in forming intimal dissection (Figure 2C). It may also go into the side branches of the occlusion segment (Figure 2D). In such situations, the parallel wire technique, which is based on a middle-hard guidewire with a tapered tip, is the best approach to solve the problem. First, the initial guidewire in the false lumen or side branch is left both as a marker and to obstruct the false channel. Second, a second tapered guidewire is used to trace the exact path as the first wire. After the tip of the second guidewire reaches the point where the first guidewire appeared to divert from the true lumen, the tip of the second guidewire is intentionally directed into the true lumen (Figure 2E and F). In this case, the second guidewire usually has a high crossing rate and a low side branch occlusion rate. If the second guidewire fails to enter the true lumen, the AWE strategy for CTO will usually involve switching from a middle-hard guidewire with a tapered tip to a stiff guidewire with a tapered tip. If the initial guidewire had already crossed the occlusion segment and entered the subintimal region of the distal cap (Figure 2G), an antegrade dissection reentry (ADR) strategy can be employed. This is usually attempted to minimize the length of the dissection by reentry into the distal true lumen using a stiff guidewire with a tapered tip immediately after the distal cap of the occlusion segment (Figure 2H). If an initial stiff guidewire has been used to puncture the proximal cap, it is important to downgrade to a soft, tapered polymer-jacketed guidewire, such as Fielder XT, to reduce the risk of perforation and increase the chance of tracking the vessel^[17].

In the present study, we found that a strategy based on the initial use of Fielder XT guidewire significantly increased the success rate of CTO-PCI *via* the antegrade approach. This may have been partially attributable to the existence of microchannels with a diameter of approximately 160-230 μm in the CTO lesions. The number of microchannels has been reported to decrease with CTO maturation^[18]. Other studies have reported that these channels can exist in loose tissues extending from the proximal to distal fibrous caps in CTOs of any age^[19]. Thus, successful tracking of microchannels in loose tissue may be possible, even in very old CTOs^[20]. Consistent

Table 3 Lesion-related characteristics in the two groups, *n* (%)

	Overall population, <i>n</i> = 1230	XT group, <i>n</i> = 686	No-XT group, <i>n</i> = 544	<i>P</i> -value
Multivessel CAD	530 (43.1)	300 (43.7)	230 (42.3)	0.609
LC	170 (13.8)	90 (13.1)	80 (14.7)	0.423
Tortuosity	105 (10.2)	57 (11.7)	48 (8.8)	0.124
Bridging collaterals	95 (7.7)	55 (8.0)	40 (7.4)	0.665
Blunt stump	107 (8.7)	61 (8.9)	46 (8.5)	0.787
J-CTO score				0.077
0	597 (48.5)	332 (48.4)	265 (48.7)	
1	507 (41.2)	282 (41.1)	225 (41.4)	
2	99 (8.0)	50 (7.3)	49 (9.0)	
3	23 (1.9)	19 (2.8)	4 (0.7)	
4	4 (0.3)	3 (0.4)	1 (0.2)	
Rentrop class				0.686
0	233 (18.9)	126 (18.4)	107 (19.7)	
1	220 (17.9)	117 (17.1)	103 (18.9)	
2	434 (35.3)	245 (35.7)	189 (34.7)	
3	343 (27.9)	198 (28.9)	145 (26.7)	
CTO vessel				0.570
LM	1 (0.1)	1 (0.1)	0 (0)	
LAD	545 (44.3)	302 (44.0)	243 (44.7)	
LCX	173 (14.1)	103 (15.0)	70 (12.9)	
RCA	511 (41.5)	280 (40.8)	231 (42.5)	
Occlusion length, mm	21.6 ± 14.8	21.5 ± 15.1	21.7 ± 14.5	0.876
Occlusion time, mo	82.3 ± 27.1	45.9 ± 60.0	45.0 ± 50.9	0.796

Values represent the mean ± SD or number of patients and proportion (%). CAD: Coronary artery disease; LC: Lesion calcification; J-CTO: Multicenter CTO Registry in Japan; rentrop class definition: Class 1, filling of side branches of the artery *via* collateral channels without visualization of the epicardial segment; Class 2, partial filling of the epicardial segment *via* collateral channels; Class 3, complete filling of the epicardial segment of the artery *via* collateral channels; CTO: Chronic total occlusion; LM: Left main artery; LAD: Left anterior descending artery; LCX: Left circumflex artery; RCA: Right coronary artery.

with these data, we found that the use of Fielder XT guidewire significantly increased the success rate of CTO-PCI, although there were no significant differences in occlusion time between the two groups.

Nevertheless, factors predicting the success or failure of CTO-PCI are context-dependent. In agreement with previous studies, we noted that blunt stump^[21-24] was an independent predictor of the procedural success of CTO-PCI. In recent years, multiple scoring systems have been established to predict the procedural success, efficiency, and complications of CTO-PCI^[21-26]. Both the multicenter CTO registry in Japan (J-CTO) and clinical- and lesion-related (CL) scores include blunt stump as the lesion-related predictor^[21,23]. CTO with blunt stump is a major obstacle to successful intervention. If the proximal cap has a blunt morphology, the occlusion is often more mature^[17]. Older occlusions usually have harder proximal caps and lack microchannels connected to the proximal cap, which prevent the initial soft, tapered polymer-jacketed guidewire from entering the proximal cap. Thus, the blunt stump of proximal cap is an obstacle to the procedural success of CTO-PCI^[17]. In accordance with the results of previous studies, we also found that contrast amount, procedure time and cardiac function were independent predictors of procedural success. Algorithms also provide specific guidance, suggesting that operators should consider stopping a CTO procedure if the procedure time is > 3 h, or more than 3.7 mL × the estimated glomerular filtration rate of contrast has been used^[17]. Systolic blood pressure is closely related to cardiac function, and systolic blood pressure was thus an independent predictor of procedural success in this study. Furthermore, females have lower J-CTO scores than males. The technical success rate is usually higher in females than in males^[27], consistent with our observed outcomes.

In summary, we found in this study that the use of Fielder XT guidewire was associated with a relatively shorter procedure time and lower contrast amount, as Fielder XT guidewire could cross CTO lesions into the distal true lumen by microchannels. The amount of contrast media is closely related to the incidence of

Table 4 Procedural outcomes and in-hospital complications in the two groups

	Overall population, <i>n</i> = 1230	XTgroup, <i>n</i> = 686	No-XT group, <i>n</i> = 544	<i>P</i> -value
Stent length, mm	34.3 ± 16.8	32.0 ± 15.8	37.3 ± 17.6	< 0.001
Contrast amount, mL	156.1 ± 45.6	148 ± 46	166 ± 43	< 0.001
Side branch loss	75 (6.1)	31 (4.5)	44 (8.1)	0.009
CIN	69 (5.6)	29 (4.2)	40 (7.4)	0.018
Coronary artery rupture	11 (0.9)	3 (0.4)	8 (1.5)	0.056
No reflow	22 (1.9)	8 (1.2)	14 (2.9)	0.034
Post-PCI MI	102 (8.3)	43 (6.3)	59 (10.8)	0.004
In-hospital death	8 (0.7)	2 (0.3)	6 (1.1)	0.079
TLR	10 (0.8)	3 (0.4)	7 (1.3)	0.099
MACE	101 (8.3)	44 (6.4)	57 (10.7)	0.007
Success rate	1032 (83.9)	602 (87.8)	430 (79.0)	< 0.001
Procedure time, min	78 ± 23	74 ± 23	83 ± 21	< 0.001

Values represent the mean ± SD or number of patients and proportion (%). CIN: Contrast-induced nephropathy; MI: Myocardial infarction; PCI: Percutaneous coronary intervention; TLR: Target lesion revascularization; MACE: Major adverse cardiovascular event.

CIN, and several studies have shown that the volume of contrast media is an independent risk factor for the development of contrast-induced acute kidney injury^[28-30]. We observed a similar outcome in which the volume of contrast media was positively associated with CIN incidence. We also found that the use of Fielder XT guidewire was associated with lower rates of in-hospital complications and stent implantation. Furthermore, the initial soft, tapered polymer-jacketed guidewire we used could cross the CTO lesion and reach the distal cap, with lower likelihoods of dissection and a smaller degree of hematoma than stiff guidewires. ADR based on the soft guidewire we used above could also ensure true lumen reentry once through the CTO segment, which decreased the length of the implanted stent and reduced side branch loss. Additionally, MI of perioperative caused by the occlusion of side branches after CTO-PCI was avoided.

In conclusion, the use of Fielder XT guidewire shortens the procedure and increases the success rate of CTO-PCI, and is also associated with reduced complication rates.

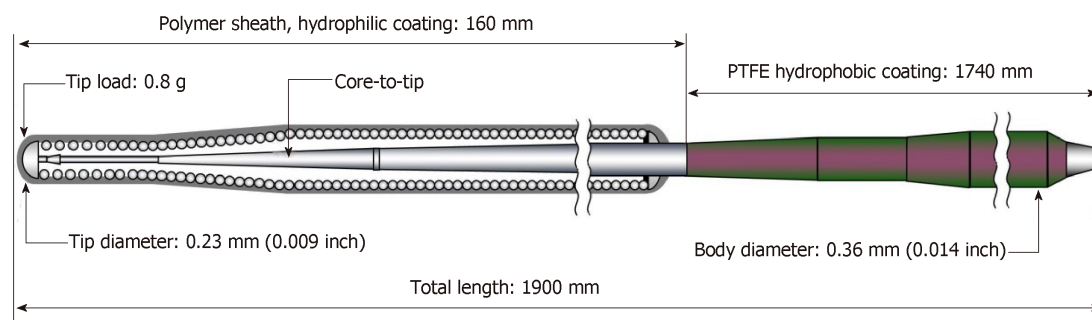


Figure 1 An illustrative image of the Fielder XT guidewire.

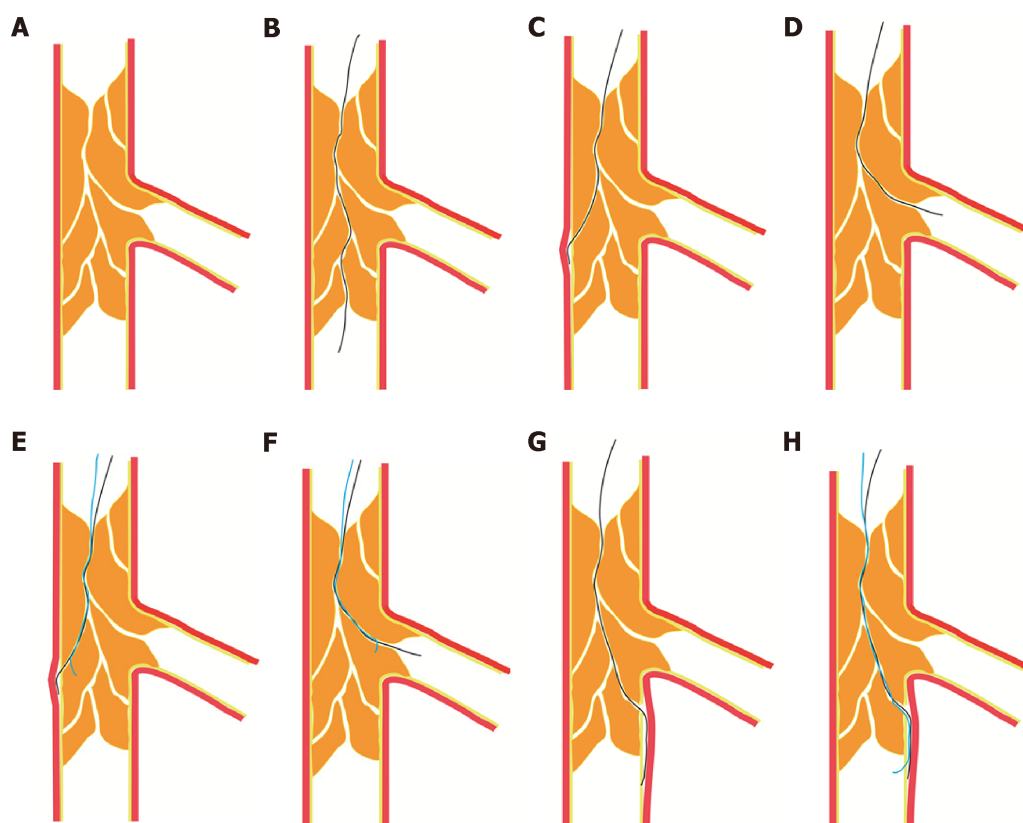


Figure 2 Fielder XT guidewires enter the chronic total occlusion lesions along the microchannels with different anatomical features. A: Microchannels partly or completely connecting from the proximal cap to the distal end of chronic total occlusion (CTO) lesion; B: A Fielder XT guidewire crossing the CTO lesion through microchannels; C: A Fielder XT guidewire entering the sidewall of the coronary artery and resulting in forming intimal dissection; D: A Fielder XT guidewire entering the side branch of the occlusion segment; E-F: After leaving the Fielder XT guidewire in the false lumen, tracing of a second tapered guidewire along the same pathway into the true lumen; G: A Fielder XT guidewire crossing the occlusion segment into the subintimal of the distal cap; H: A stiff guidewire with a tapered tip entering the distal true lumen after the distal cap.

ARTICLE HIGHLIGHTS

Research background

Chronic total occlusion (CTO) is found in 18%-31% of patients who undergo coronary angiography. Successful recanalization of CTOs has been shown to be associated with reduced recurrent angina pectoris rates and increased long-term survival. Although the success rate of CTO percutaneous coronary intervention (CTO-PCI) has improved, CTO-PCI remains technically challenging. The Fielder XT guidewire was designed for CTO lesions. To validate whether the use of the guidewire increases the success rate, we compared the results of CTO-PCI with or without the guidewire. We hypothesized that the use of Fielder XT guidewire can increase the success rate of CTO-PCI.

Research motivation

Although experience and the introduction of new devices have improved the success rates of PCI, CTO-PCI is still technically challenging. We thus wanted to validate whether the use of Fielder XT guidewire increases the success rate of CTO-PCI.

Research objectives

To investigate whether the use of Fielder XT guidewire increases the final procedural success of CTO-PCI *via* the antegrade approach.

Research methods

Between January 2013 and December 2015, a retrospective study was conducted on 1230 consecutive patients with CTO who received PCI *via* the antegrade approach at the General Hospital of Northern Theater Command. The patients were divided into an XT Group ($n = 686$) and a no-XT Group ($n = 544$) depending on whether Fielder XT guidewire was used. Both groups were compared for clinical parameters, lesion-related characteristics, procedural outcomes and in-hospital complications. The data were statistically analyzed using a Pearson's χ^2 test for categorical variables, and a Students' t test was used to compare the quantitative data. Significant independent factors and risk ratios with a 95% confidence interval (CI) were assessed by multivariate logistic regression analysis.

Research results

In total, 1230 patients were recruited; 75.4% of the patients were male, and 55.8% of the patients were in the XT group. The overall success rate was 83.9%, with 87.8% in the XT group. Based on multivariate logistic regression analysis, factors positively associated with procedural success were the use of Fielder XT guidewire ($P = 0.005$, 95%CI: 1.172-2.380) and systolic blood pressure ($P = 0.011$, 95%CI: 1.003-1.022), while factors negatively associated with procedural success were blunt stump ($P = 0.013$, 95%CI: 1.341-11.862), male sex ($P = 0.016$, 95%CI: 0.363-0.902), NYHA class ($P = 0.035$, 95%CI: 0.553-0.979), contrast amount ($P = 0.018$, 95%CI: 0.983-0.998) and occlusion time ($P = 0.009$, 95%CI: 0.994-0.999). No significant differences were found between the XT group and the no-XT group with respect to clinical parameters, lesion-related characteristics, coronary artery rupture [3 (0.4%) *vs* 8 (1.5%), $P = 0.056$], in-hospital death [2 (0.3%) *vs* 6 (1.1%), $P = 0.079$] or in-hospital target lesion revascularization [3 (0.4%) *vs* 7 (1.3%), $P < 0.099$]. However, there were significant differences between the groups with respect to success rate [602 (87.8%) *vs* 430 (79.0%), $P < 0.001$], procedure time [(74 \pm 23) *vs* (83 \pm 21), $P < 0.001$], stent length [(32.0 \pm 15.8) *vs* (37.3 \pm 17.6), $P < 0.001$], contrast amount [(148 \pm 46) *vs* (166 \pm 43), $P < 0.001$], post-PCI myocardial infarction [43 (6.3%) *vs* 59 (10.8%), $P = 0.004$], major adverse cardiovascular event [44 (6.4%) *vs* 57 (10.7%), $P = 0.007$], side branch loss [31 (4.5%) *vs* 44 (8.1%), $P = 0.009$], contrast-induced nephropathy [29 (4.2%) *vs* 40 (7.4%), $P = 0.018$] and no reflow [8 (1.2%) *vs* 14 (2.9%), $P = 0.034$].

Research conclusions

The use of Fielder XT guidewire shortens the procedure and increases the success rate of CTO-PCI, and is also associated with reduced complication rates.

Research perspectives

Larger multicenter studies are required to better understand the relationship between the use of Fielder XT series (such as Fielder XT, Fielder XT-R and Fielder XT-A) guidewires and the procedural success of CTO-PCI *via* antegrade, retrograde, or hybrid approaches.

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