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Guidezilla Guide Extension Catheter Use During Retrograde Chronic Total Occlusion Percutaneous Coronary Intervention: Procedural Success and Long-Term Outcomes

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Abstract

Background: The role of the Guidezilla guide extension catheter during retrograde chronic total occlusion (CTO) percutaneous coronary intervention (PCI) remains uncertain. We examined its associations with procedural success, reported complications, and subsequent clinical events. **Methods:** This retrospective single-centre study included 819 patients undergoing elective retrograde CTO PCI between January 2011 and April 2023. Procedural associations were evaluated using logistic regression and propensity score matching. Long-term outcomes were evaluated using Kaplan–Meier analysis and Cox regression. **Results:** The Guidezilla guide extension catheter was used in 281 patients (34.3%). Retrograde technical success was 95.0% versus 87.0%, and final recanalisation success was 96.1% versus 88.3% (both $p < 0.001$). Corresponding adjusted odds ratios (ORs) were 3.80 (95% confidence interval [CI] 2.11–7.32) and 4.30 (95% CI 2.26–8.94; both $p < 0.001$). Associations persisted in 259 matched pairs (ORs 2.54, 95% CI 1.34–4.82, and 2.90, 95% CI 1.41–5.95; both $p = 0.004$). Reported in-hospital complications did not differ significantly, but rare events limited comparative safety assessment. In the fully adjusted Cox model, hazard ratios (HRs) were 0.99 (95% CI 0.48–2.04; $p = 0.976$) for cardiovascular events and 1.28 (95% CI 0.81–2.03; $p = 0.295$) for major adverse cardiovascular events. **Conclusions:** Guidezilla guide extension catheter use was associated with higher procedural success. These observational findings remain susceptible to selection bias and residual confounding, while limited event numbers preclude firm conclusions regarding comparative safety and long-term outcomes. Prospective confirmation is warranted.

Keywords: chronic total occlusion; percutaneous coronary intervention; retrograde; Guidezilla guide extension catheter

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1. Introduction

Percutaneous coronary intervention (PCI) for chronic total occlusion (CTO) remains technically demanding, particularly in long, calcified lesions or when antegrade crossing is unsuccessful. The retrograde approach expands the options for recanalisation but

introduces additional challenges related to equipment delivery, antegrade–retrograde connection, and wire externalisation [1,2]. Procedural adjuncts that address these barriers are therefore relevant to contemporary CTO practice, provided that their potential benefits are considered alongside the risks of vessel instrumentation.

Guide extension catheters increase guide support and facilitate device delivery during complex PCI. In retrograde CTO procedures, an extension positioned within the antegrade system may also provide a conduit for the retrograde guidewire during reverse controlled antegrade and retrograde tracking (reverse CART) [3]. These applications are distinct from conventional stent delivery, and their utility depends on the anatomical setting, procedural stage, and device characteristics [4]. Early comparative experience with the Guidezilla guide extension catheter suggested that this technique could facilitate recanalisation of long and tortuous CTOs [5].

The clinical evidence remains predominantly observational. The LATAM CTO registry reported higher procedural success with guide extension catheter use after propensity score matching [6], whereas a broader PROGRESS CTO analysis found similar technical success despite greater lesion complexity and more frequent complications in cases requiring these devices [7]. A separate PROGRESS CTO study of reverse CART included only procedures with successful retrograde CTO crossing, limiting its ability to assess whether guide extension use improved final recanalisation success [8]. Differences in patient selection, devices, procedural indications, and endpoint definitions complicate comparisons across studies. Evidence linking Guidezilla guide extension catheter use specifically during retrograde CTO PCI to subsequent clinical outcomes is particularly limited.

We examined the associations of Guidezilla guide extension catheter use with retrograde technical success, final recanalisation success, in-hospital safety, and long-term clinical outcomes in a single-centre cohort undergoing elective retrograde CTO PCI. We also evaluated characteristics associated with device use and performed propensity score–matched analyses to assess whether the procedural associations persisted after accounting for measured differences between groups.

2. Methods

2.1. Study Design and Population

This retrospective cohort study used the CTO PCI registry at Guangdong Provincial People's Hospital. We screened 898 consecutive patients undergoing elective retrograde PCI for at least one CTO between January 2011 and April 2023. Exclusions were active malignancy (n = 1), maintenance dialysis (n = 8), and missing essential covariates, including left ventricular ejection fraction (LVEF) or Multicenter CTO Registry of Japan (J-CTO) score (n = 70), leaving 819 patients for procedural analyses. An additional 69 patients with incomplete follow-up were excluded from long-term analyses but retained in procedural analyses, leaving 750 patients (91.6%; Supplementary Figure S1). The study complied with the Declaration of Helsinki and was approved by the Institutional Review Board of Guangdong Provincial People's Hospital. Written informed consent was obtained from all participants. Reporting followed STROBE recommendations [9].

2.2. Data Collection and Definitions

Baseline demographic and clinical data were retrospectively collected for all participants. These included age, sex, cardiovascular risk factors, comorbidities, smoking status, previous myocardial infarction (MI), and previous revascularisation by PCI or coronary artery bypass grafting (CABG). Physical examination findings, laboratory measurements, imaging results, and discharge medications were also recorded.

Venous blood samples were obtained on the morning before or the morning of PCI after an overnight fast of ≥12 h. Samples were analysed at the hospital's core laboratory using standardised quality control procedures. Resting LVEF was assessed using the modified biplane Simpson's method [10]. Diabetes mellitus was defined as a previous diagnosis, use of glucose-lowering medication, fasting plasma glucose ≥7.0 mmol/L, glycated haemoglobin ≥6.5%, or 2-h plasma glucose ≥11.1 mmol/L during an oral glucose tolerance test [11]. Hypertension was defined as a previous diagnosis, current antihypertensive treatment, or measured systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg [12].

CTO PCI was undertaken for persistent symptoms despite medical therapy or evidence of viable or ischaemic myocardium in the CTO territory. Procedural techniques have been described previously [5,13]. Femoral, radial, or combined access was used. Crossing strategy, guide catheters, stents, and intravascular imaging were selected by the operator. All operators had performed >300 CTO PCI procedures and undertook at least 50 annually as the primary operator. Guidezilla guide extension catheter use (Boston Scientific, Natick, MA, USA) was defined as deployment at any stage of the index procedure, according to procedural records. Use was discretionary, including for inadequate guide support or difficulty connecting the retrograde wire to the antegrade system. In guide extension-assisted reverse CART, an extension within the antegrade system provides a target for the retrograde wire [3,5]. Collateral traversal precedes engagement of the extension by the retrograde wire, but uncertainty regarding initial deployment timing and intent limits distinction between planned, rescue, and bailout use. Exposure classification reflected eventual device use, creating potential time-dependent selection, including immortal-time bias [14].

The patient was the unit of analysis, with procedural outcomes referenced to the index retrograde CTO PCI. Patients with multiple CTOs contributed one patient-level observation. CTO was defined as Thrombolysis in Myocardial Infarction (TIMI) grade 0 antegrade flow for an estimated ≥3 months [1]. Complexity was assessed using the J-CTO score [15], and the attempted collateral channel was classified using the Werner system [16]. Collateral channel (CC) crossing success required guidewire passage through the channel to the distal CTO cap. Retrograde technical success required successful retrograde CTO crossing followed by residual stenosis <30% and TIMI grade 3 antegrade flow [13]. Final recanalisation success required the same final angiographic criteria irrespective of the successful crossing strategy. Failed retrograde attempts followed by successful antegrade crossing were classified as retrograde technical failures but final recanalisation successes. Antegrade balloon or stent delivery after successful retrograde crossing or wire connection was considered completion of the retrograde strategy, rather than antegrade conversion.

2.3. Follow-Up and Clinical Endpoints

Procedural efficacy outcomes comprised retrograde technical success and final recanalisation success. In-hospital safety outcomes included any coronary perforation, target-vessel perforation, cardiac tamponade, pericardiocentesis, emergency cardiac surgery, and all-cause death during the index hospitalisation. Any coronary perforation encompassed perforation of any coronary vessel during the index procedure, whereas target-vessel perforation was restricted to the artery containing the index CTO.

Follow-up data were obtained through medical record review, outpatient visits, and structured telephone interviews conducted by trained researchers blinded to baseline data. The primary clinical endpoint was cardiovascular events (CVEs), defined as a composite of cardiac death, non-fatal MI, or non-fatal stroke. The secondary clinical endpoint was major adverse cardiovascular events (MACEs), defined as a composite of all-cause death, non-fatal MI, non-fatal stroke, or unplanned revascularisation.

Deaths were classified as cardiac unless a clear non-cardiac cause was established. Non-fatal MI required a rise in cardiac troponin accompanied by ischaemic symptoms, ischaemic electrocardiographic changes, angiographic coronary thrombus, or imaging evidence of new myocardial injury [17,18]. Non-fatal stroke required a new focal neurological deficit lasting >24 h and neuroimaging confirmation. Unplanned revascularisation included unplanned repeat coronary revascularisation irrespective of vessel; planned staged procedures were excluded. Two physicians independently verified clinical endpoints using available records.

2.4. Statistical Analysis

Continuous variables are presented as mean ± standard deviation (SD) or median (interquartile range), and categorical variables as n (%). Normality was assessed using the Shapiro–Wilk test. Comparisons used the Wilcoxon rank-sum test and Pearson's χ^2 or Fisher's exact test, as appropriate. Analyses used complete cases for the required covariates. Baseline p values described observed group differences and were not measures of covariate balance.

Logistic regression estimated odds ratios (ORs) and 95% confidence intervals (CIs) for procedural success. Model 1 was unadjusted; Model 2 included age, sex, previous PCI, and multivessel disease; Model 3 additionally included Werner collateral grade and J-CTO score. Characteristics associated with Guidezilla guide extension catheter use were examined using exploratory logistic regression, with variables meeting univariable $p < 0.05$ entered into the multivariable model. These estimates were interpreted as associations. Adjusted probabilities of procedural success were estimated from Model 3 by marginal standardisation over the analysis cohort. Absolute probability differences were calculated by subtracting the standardised probability under no use from that under Guidezilla guide extension catheter use and were expressed in percentage points. Corresponding 95% CIs were calculated using the delta method (Supplementary Table S1). These estimates were interpreted as adjusted associations rather than causal effects.

Propensity scores were estimated using logistic regression incorporating age, sex, previous PCI, multivessel disease, Werner collateral grade, J-CTO score, and procedural calendar time, defined as elapsed years since the earliest procedure in the cohort. Patients were matched 1:1 using greedy nearest-neighbour matching without replacement and a caliper width of 0.2 SD of the estimated propensity score on the probability scale. Unmatched patients were retained in analyses of the original cohort. Covariate balance after matching was summarised using standardised mean differences (SMDs; Supplementary Table S2). Procedural outcomes were analysed using conditional logistic regression stratified by matched pair, with results reported as odds ratios and 95% confidence intervals (Supplementary Table S3).

Kaplan–Meier event estimates were calculated as 1 minus survival, and curves were compared using the log-rank test. Cox proportional hazards regression was used to examine the associations between Guidezilla guide extension catheter use and long-term outcomes and to estimate hazard ratios (HRs) with 95% CIs. Each composite was analysed as time to the first qualifying event. Time was measured in days from the index PCI; event-free patients were censored at their last documented event-free assessment or the administrative end of follow-up, whichever occurred first. Full available follow-up was used; only the curve display was restricted to 1080 days. Model 1 was unadjusted. Model 2 included age, sex, smoking, hypertension, diabetes, dyslipidaemia, previous MI, and previous stroke. The main adjusted Model 3 additionally included serum creatinine, multivessel disease, J-CTO score, and LVEF. The model additionally including final recanalisation success is presented as a secondary analysis (Supplementary Table S4). The proportional hazards assumption was assessed using Schoenfeld residuals.

All analyses were performed using R version 4.2.1 (R Foundation for Statistical Computing, Vienna, Austria). All tests were two-sided, and $p < 0.05$ was considered statistically significant.

3. Results

3.1. Baseline Characteristics

Among 819 patients undergoing retrograde CTO PCI, 281 (34.3%) received the Guidezilla guide extension catheter and 538 (65.7%) did not (Table 1). The median age was 60 years (interquartile range, 52–67), and 747 patients (91.2%) were men. Compared with patients treated without the Guidezilla guide extension catheter, those receiving the Guidezilla guide extension catheter more frequently had a history of PCI (58.4% vs. 49.1%; $p = 0.014$) and less frequently had dyslipidaemia (74.7% vs. 81.8%; $p = 0.023$). Patients receiving the Guidezilla guide extension catheter had lower white blood cell counts and lower levels of C-reactive protein, troponin T, total bilirubin, aspartate aminotransferase, and fibrinogen, but higher levels of apolipoprotein A1, albumin, and creatine kinase isoenzyme (all $p < 0.05$).

Table 1. Baseline characteristics.

Characteristic	Overall N = 819	Without Guidezilla Guide Extension Catheter N = 538	With Guidezilla Guide Extension Catheter N = 281	*p* Value
Demographic and Clinical Characteristics				
Age, years	60.00 (52.00–67.00)	60.00 (52.00–67.00)	60.00 (52.00–67.00)	0.3
Male, n (%)	747 (91.2)	491 (91.3)	256 (91.1)	>0.9
Systolic blood pressure, mmHg	131.00 (121.00–144.00)	132.00 (122.00–144.00)	130.00 (120.00–144.00)	0.3
Diastolic blood pressure, mmHg	78.00 (70.00–84.00)	78.00 (70.00–85.00)	77.00 (70.00–84.00)	0.4
Heart rate, beats/min	73.00 (66.00–81.00)	74.00 (68.00–81.00)	72.00 (66.00–81.00)	0.2
Current smoker, n (%)	298 (36.4)	203 (37.7)	95 (33.8)	0.3
Hypertension, n (%)	498 (60.8)	322 (59.9)	176 (62.6)	0.5
Dyslipidaemia, n (%)	650 (79.4)	440 (81.8)	210 (74.7)	0.023
Diabetes, n (%)	339 (41.4)	219 (40.7)	120 (42.7)	0.6
CKD, n (%)	162 (19.8)	111 (20.6)	51 (18.1)	0.5
Previous MI, n (%)	240 (29.3)	167 (31.0)	73 (26.0)	0.2
Previous PCI, n (%)	428 (52.3)	264 (49.1)	164 (58.4)	0.014
Previous CABG, n (%)	35 (4.3)	22 (4.1)	13 (4.6)	0.9
Previous stroke, n (%)	57 (7.0)	32 (5.9)	25 (8.9)	0.2
Laboratory Results				
TC, mmol/L	3.93 (3.30–4.65)	3.98 (3.37–4.70)	3.90 (3.21–4.60)	0.065
TG, mmol/L	1.49 (1.06–2.10)	1.52 (1.11–2.12)	1.46 (1.02–1.97)	0.11
LDL-C, mmol/L	2.46 (1.91–3.02)	2.46 (1.92–3.02)	2.45 (1.87–3.03)	0.7
HDL-C, mmol/L	0.92 (0.80–1.06)	0.92 (0.80–1.05)	0.92 (0.80–1.07)	0.6
Lipoprotein(a), mg/L	202.00 (83.00–412.00)	195.00 (86.00–402.00)	224.00 (74.00–429.00)	>0.9
Apolipoprotein A1, g/L	1.10 (0.99–1.22)	1.10 (0.98–1.20)	1.11 (1.03–1.25)	0.003
Apolipoprotein B100, g/L	0.78 (0.63–0.91)	0.78 (0.65–0.91)	0.77 (0.61–0.93)	0.4
FBG, mmol/L	5.57 (4.96–7.03)	5.58 (4.99–6.90)	5.55 (4.84–7.36)	0.8

Table 1. *Cont.*

Characteristic	Overall N = 819	Without Guidezilla Guide Extension Catheter N = 538	With Guidezilla Guide Extension Catheter N = 281	*p* Value
HbA1c, %	6.16 (5.70–6.80)	6.11 (5.70–6.70)	6.20 (5.60–6.90)	0.7
White blood cell count, 10^9/L	7.03 (5.85–8.40)	7.11 (5.94–8.59)	6.80 (5.71–8.06)	0.011
Haemoglobin, g/L	135.00 (124.00–146.00)	136.00 (125.00–146.00)	134.00 (122.00–145.00)	0.3
C-reactive protein, mg/L	2.56 (0.70–7.29)	2.99 (1.19–7.77)	2.00 (0.50–5.55)	<0.001
NT-proBNP, pg/mL	272.70 (86.70–903.00)	312.40 (95.50–915.62)	228.00 (73.30–816.70)	0.2
Troponin T, pg/mL	23.30 (11.20–73.20)	28.05 (12.60–89.30)	17.00 (9.40–38.60)	<0.001
Total bilirubin, µmol/L	12.20 (9.60–15.50)	12.50 (9.70–16.10)	11.70 (9.40–14.50)	0.006
Albumin, g/L	38.12 (35.80–40.50)	38.00 (35.60–40.26)	38.34 (36.60–40.88)	0.006
CK, U/L	87.00 (63.00–124.00)	86.00 (62.00–123.00)	89.00 (66.00–125.00)	0.2
CK-MB, U/L	10.10 (10.00–13.20)	10.00 (9.50–13.20)	10.30 (10.00–13.00)	0.010
AST, U/L	22.00 (18.00–27.00)	22.00 (18.00–27.00)	21.00 (17.00–26.00)	0.019
ALT, U/L	23.00 (16.00–32.00)	23.00 (16.00–33.00)	21.00 (15.00–30.00)	0.035
Fibrinogen, g/L	3.60 (3.17–4.25)	3.66 (3.18–4.37)	3.49 (3.13–4.06)	0.010
D-dimer, ng/mL	370.00 (270.00–597.00)	360.00 (270.00–597.00)	370.00 (270.00–660.00)	0.8
BUN, mmol/L	5.50 (4.39–6.77)	5.42 (4.26–6.70)	5.62 (4.70–6.77)	0.050
Serum creatinine, µmol/L	85.00 (72.77–101.78)	85.00 (72.80–104.00)	84.70 (72.50–100.46)	0.7
Uric acid, µmol/L	409.00 (346.40–489.31)	409.35 (348.00–488.00)	408.00 (345.50–494.90)	0.8
LVEF, %	57.00 (46.00–63.00)	57.00 (46.00–63.00)	56.00 (46.00–63.00)	0.8
Angiographic and Procedural Characteristics				
Target vessel, n (%)				0.001
RCA, n (%)	486 (59.3)	293 (54.5)	193 (68.7)	
LAD, n (%)	316 (38.6)	232 (43.1)	84 (29.9)	
LCX, n (%)	15 (1.8)	12 (2.2)	3 (1.1)	
LM, n (%)	2 (0.2)	1 (0.2)	1 (0.4)	
Multivessel disease, n (%)	708 (86.4)	461 (85.7)	247 (87.9)	0.4
Multiple CTOs, n (%)	227 (27.7)	139 (25.8)	88 (31.3)	0.11
J-CTO score ≥ 3, n (%)	598 (73.0)	369 (68.6)	229 (81.5)	<0.001
In-stent CTO, n (%)	31 (3.8)	20 (3.7)	11 (3.9)	>0.9
Previous attempt, n (%)	336 (41.0)	218 (40.5)	118 (42.0)	0.7
Blunt stump, n (%)	571 (69.7)	360 (66.9)	211 (75.1)	0.019
Moderate or severe calcification, n (%)	415 (50.7)	247 (45.9)	168 (59.8)	<0.001
Bending > 45°, n (%)	510 (62.3)	322 (59.9)	188 (66.9)	0.057
CTO length ≥ 20 mm, n (%)	692 (84.5)	442 (82.2)	250 (89.0)	0.014
Werner classification of collateral connections, n (%)				<0.001
CC0	187 (22.8)	110 (20.4)	77 (27.4)	
CC1	337 (41.1)	208 (38.7)	129 (45.9)	
CC2	295 (36.0)	220 (40.9)	75 (26.7)	
Septal CC, n (%)	597 (72.9)	384 (71.4)	213 (75.8)	0.2
IVUS, n (%)	177 (21.6)	106 (19.7)	71 (25.3)	0.081

Table 1. *Cont.*

Characteristic	Overall N = 819	Without Guidezilla Guide Extension Catheter N = 538	With Guidezilla Guide Extension Catheter N = 281	*p* Value
Rotational atherectomy, n (%)	29 (3.5)	14 (2.6)	15 (5.3)	0.07
Intra-aortic balloon pump, n (%)	11 (1.3)	8 (1.5)	3 (1.1)	0.9
Antegrade failure, n (%)	782 (95.5)	505 (93.9)	277 (98.6)	0.004
CTO crossing strategy, n (%)				<0.001
Retrograde wire crossing, n (%)	181 (22.1)	141 (26.2)	40 (14.2)	
Kissing-wire crossing, n (%)	23 (2.8)	22 (4.1)	1 (0.4)	
Reverse CART, n (%)	531 (64.8)	305 (56.7)	226 (80.4)	
Conversion to an antegrade strategy, n (%)	10 (1.2)	7 (1.3)	3 (1.1)	
Number of stents ≥ 3, n (%)	494 (60.3)	294 (54.6)	200 (71.2)	<0.001
Total stent length, mm	90.00 (65.00–108.00)	81.50 (56.00–100.00)	99.00 (72.00–114.00)	<0.001
Medication at Discharge				
Aspirin, n (%)	801 (97.8)	529 (98.3)	272 (96.8)	0.2
Clopidogrel, n (%)	631 (77.0)	455 (84.6)	176 (62.6)	<0.001
Ticagrelor, n (%)	182 (22.2)	80 (14.9)	102 (36.3)	<0.001
Statin, n (%)	807 (98.5)	535 (99.4)	272 (96.8)	0.007
β-Blocker, n (%)	686 (83.8)	460 (85.5)	226 (80.4)	0.077
Dual antiplatelet therapy, n (%)	793 (96.8)	526 (97.8)	267 (95.0)	0.055
ACEI/ARB, n (%)	515 (62.9)	361 (67.1)	154 (54.8)	<0.001
CCB, n (%)	195 (23.8)	150 (27.9)	45 (16.0)	<0.001

Values are median (interquartile range) or n (%). Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ALT, alanine aminotransferase; ARB, angiotensin receptor blocker; AST, aspartate aminotransferase; BUN, blood urea nitrogen; CABG, coronary artery bypass grafting; CART, controlled antegrade and retrograde tracking; CC, collateral channel; CCB, calcium channel blocker; CK, creatine kinase; CKD, chronic kidney disease; CK-MB, creatine kinase myocardial band isoenzyme; CTO, chronic total occlusion; FBG, fasting blood glucose; HbA1c, glycated haemoglobin; HDL-C, high-density lipoprotein cholesterol; IVUS, intravascular ultrasound; J-CTO, Multicenter CTO Registry of Japan; LAD, left anterior descending artery; LCX, left circumflex artery; LDL-C, low-density lipoprotein cholesterol; LM, left main coronary artery; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NT-proBNP, N-terminal pro-B-type natriuretic peptide; PCI, percutaneous coronary intervention; RCA, right coronary artery; TC, total cholesterol; and TG, triglycerides.

The target vessel distribution differed between groups (overall $p = 0.001$), with the right coronary artery more frequently targeted in the Guidezilla guide extension catheter group (68.7% vs. 54.5%) and the left anterior descending artery less frequently targeted (29.9% vs. 43.1%). Patients receiving the Guidezilla guide extension catheter had higher J-CTO scores ($p < 0.001$), with more frequent blunt stumps (75.1% vs. 66.9%; $p = 0.019$), CTO length ≥ 20 mm (89.0% vs. 82.2%; $p = 0.014$), and moderate or severe calcification (59.8% vs. 45.9%; $p < 0.001$). The distribution of Werner collateral grades also differed (overall $p < 0.001$), with a lower proportion of grade CC2 collaterals in the Guidezilla guide extension catheter group (26.7% vs. 40.9%).

The distribution of CTO crossing strategies differed between groups (overall $p < 0.001$), with reverse CART more frequently used in patients receiving the Guidezilla guide extension catheter (80.4% vs. 56.7%). Antegrade failure was also more frequent in the Guidezilla

guide extension catheter group (98.6% vs. 93.9%; $p = 0.004$). The number of implanted stents differed between groups ($p < 0.001$), and median total stent length was greater in patients receiving the Guidezilla guide extension catheter (99.0 vs. 81.5 mm; $p < 0.001$). At discharge, ticagrelor was more frequently prescribed in the Guidezilla guide extension catheter group, whereas clopidogrel, statins, angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, and calcium channel blockers were less frequently prescribed (all $p < 0.05$).

3.2. Procedural Characteristics and In-Hospital Outcomes

Patients receiving the Guidezilla guide extension catheter had higher recorded CC crossing success (97.9% vs. 91.6%), retrograde technical success (95.0% vs. 87.0%), and final recanalisation success (96.1% vs. 88.3%; all $p < 0.001$). CC crossing may have preceded device deployment and was interpreted descriptively. All comparisons used the 819-patient procedural cohort. Ten patients achieved final success after conversion to antegrade crossing (7 without and 3 with the Guidezilla guide extension catheter), accounting for the difference between 735 retrograde technical successes and 745 final recanalisation successes. Reported complication proportions did not differ significantly: any coronary perforation, 12.8% vs. 13.6%; tamponade, 4.3% vs. 3.0%; pericardiocentesis, 1.8% vs. 2.4%; emergency surgery, 0% vs. 0.4%; target-vessel perforation, 4.6% vs. 2.8%; and in-hospital death, 1.1% vs. 0.4% (all $p > 0.05$; Table 2).

Table 2. Procedural outcomes and in-hospital safety according to Guidezilla guide extension catheter use.

Outcome	Without Guidezilla Guide Extension Catheter N = 538	With Guidezilla Guide Extension Catheter N = 281	*p* Value
Collateral channel crossing success	493/538 (91.6)	275/281 (97.9)	<0.001
Retrograde technical success	468/538 (87.0)	267/281 (95.0)	<0.001
Final recanalisation success	475/538 (88.3)	270/281 (96.1)	<0.001
Any coronary perforation	73 (13.6)	36 (12.8)	0.8
Cardiac tamponade	16 (3.0)	12 (4.3)	0.4
Pericardiocentesis	13 (2.4)	5 (1.8)	0.7
Emergency cardiac surgery	2 (0.4)	0 (0.0)	0.8
Target-vessel perforation	15 (2.8)	13 (4.6)	0.2
In-hospital death	2 (0.4)	3 (1.1)	0.5

Values are n/N (%) or n (%). *p* values were calculated using Pearson's χ^2 test or Fisher's exact test, as appropriate.

3.3. Association Between Guidezilla Guide Extension Catheter Use and Procedural Success

In the unadjusted model (Model 1), Guidezilla guide extension catheter use was associated with higher odds of retrograde technical success (OR 2.85, 95% CI 1.62–5.37) and final recanalisation success (OR 3.26, 95% CI 1.76–6.62; both $p < 0.001$). These associations persisted after adjustment for clinical and angiographic characteristics. In the fully adjusted model (Model 3), the corresponding ORs were 3.80 for retrograde technical success (95% CI 2.11–7.32) and 4.30 for final recanalisation success (95% CI 2.26–8.94; both $p < 0.001$; Table 3). After marginal standardisation, the adjusted probability of retrograde technical success was 95.7% with the Guidezilla guide extension catheter and 86.0% without the Guidezilla guide extension catheter, corresponding to an absolute difference of 9.6 percentage points (95% CI 5.9–13.3). The adjusted probabilities of final recanalisation success were 96.6%

and 87.5%, respectively, corresponding to an absolute difference of 9.1 percentage points (95% CI 5.6–12.6; both $p < 0.001$; Supplementary Table S1).

Table 3. Associations of Guidezilla guide extension catheter use with retrograde technical success and final recanalisation success.

Outcome	Model	OR (95% CI)	*p* Value
Retrograde technical success	Model 1	2.85 (1.62–5.37)	<0.001
	Model 2	2.84 (1.61–5.36)	<0.001
	Model 3	3.80 (2.11–7.32)	<0.001
Final recanalisation success	Model 1	3.26 (1.76–6.62)	<0.001
	Model 2	3.22 (1.72–6.58)	<0.001
	Model 3	4.30 (2.26–8.94)	<0.001

All models included 819 patients. ORs compare patients treated with versus without the Guidezilla guide extension catheter. Model 1 was unadjusted. Model 2 was adjusted for age, sex, previous PCI, and multivessel disease. Model 3 was additionally adjusted for Werner collateral grade and J-CTO score. CI, confidence interval; J-CTO, Multicenter CTO Registry of Japan; OR, odds ratio; and PCI, percutaneous coronary intervention.

3.4. Characteristics Associated with Guidezilla Guide Extension Catheter Use

The five reported variables selected after univariable screening were previous PCI, blunt stump, CTO length ≥20 mm, moderate or severe calcification, and CTO bending >45° (Table 4). Their multivariable ORs were 1.40 (95% CI 1.04–1.88; $p = 0.029$), 1.54 (95% CI 1.11–2.15; $p = 0.011$), 1.61 (95% CI 1.04–2.57; $p = 0.037$), 1.72 (95% CI 1.28–2.32; $p < 0.001$), and 1.37 (95% CI 1.00–1.89; $p = 0.051$), respectively. These exploratory, data-selected associations do not establish an exhaustive set of determinants or validated selection criteria for device use.

Table 4. Reported characteristics associated with Guidezilla guide extension catheter use after univariable screening.

Variable	Univariable OR (95% CI)	*p* Value	Multivariable OR (95% CI)	*p* Value
Previous PCI	1.45 (1.09–1.95)	0.012	1.40 (1.04–1.88)	0.029
Blunt stump	1.49 (1.08–2.07)	0.016	1.54 (1.11–2.15)	0.011
CTO length ≥ 20 mm	1.75 (1.15–2.74)	0.011	1.61 (1.04–2.57)	0.037
Calcification	1.75 (1.31–2.35)	<0.001	1.72 (1.28–2.32)	<0.001
CTO bending > 45°	1.36 (1.00–1.84)	0.048	1.37 (1.00–1.89)	0.051

Guidezilla guide extension catheter use was the dependent variable. The table reports the five reported variables selected after univariable $p < 0.05$ screening. CI, confidence interval; CTO, chronic total occlusion; OR, odds ratio; and PCI, percutaneous coronary intervention.

3.5. Propensity Score-Matched Analysis

Matching retained 259 patients in each group (518 overall). A further 22 patients treated with and 279 treated without the Guidezilla guide extension catheter were unmatched and remained in the original-cohort analyses. Matched characteristics and SMDs are presented in Supplementary Table S2. Matched procedural success was 95.0% versus 87.3% for retrograde technical success (OR 2.54, 95% CI 1.34–4.82) and 96.1% versus 88.8% for final recanalisation success (OR 2.90, 95% CI 1.41–5.95; both $p = 0.004$; Supplementary Table S3).

3.6. Long-Term Outcomes

Long-term follow-up was available for 750 patients: 256 treated with and 494 without the Guidezilla guide extension catheter. Overall median follow-up was 1039 days (in-

terquartile range 536–1509), but was shorter with device use: 775 (424–1125) versus 1220 (710–1757) days ($p < 0.001$; Table 5). Crude MACE proportions were 12.5% versus 18.0% (32 vs. 89 events; $p = 0.051$), and CVE proportions were 4.7% versus 7.9% (12 vs. 39 events; $p = 0.098$). Kaplan–Meier comparisons did not show statistically significant differences (log-rank $p = 0.666$ for CVEs and $p = 0.288$ for MACE; Figure 1). Unadjusted HRs were 1.04 (95% CI 0.53–2.02; $p = 0.912$) and 1.42 (95% CI 0.93–2.17; $p = 0.102$), respectively. In the fully adjusted models, corresponding HRs were 0.99 (95% CI 0.48–2.04; $p = 0.976$) and 1.28 (95% CI 0.81–2.03; $p = 0.295$; Table 6). With additional adjustment for final recanalisation success, HRs were 1.13 (95% CI 0.54–2.34; $p = 0.747$) for CVEs and 1.44 (95% CI 0.90–2.30; $p = 0.128$) for MACE (Supplementary Table S4).

Table 5. Long-term clinical outcomes according to Guidezilla guide extension catheter use.

Outcome	Without Guidezilla Guide Extension Catheter N = 494	With Guidezilla Guide Extension Catheter N = 256	*p* Value
Follow-up duration, days, median (IQR)	1220 (710–1757)	775 (424–1125)	<0.001
CVEs	39/494 (7.9)	12/256 (4.7)	0.098
MACE	89/494 (18.0)	32/256 (12.5)	0.051
All-cause death	37/494 (7.5)	13/256 (5.1)	0.209
Cardiac death	28/494 (5.7)	7/256 (2.7)	0.071
Non-fatal MI	3/494 (0.6)	3/256 (1.2)	0.416
Non-fatal stroke	9/494 (1.8)	2/256 (0.8)	0.348
Unplanned revascularisation	44/494 (8.9)	15/256 (5.9)	0.142

Follow-up duration is presented as median (interquartile range); other values are n/N (%), representing crude event proportions over the available follow-up. CVEs, cardiovascular events; IQR, interquartile range; MACE, major adverse cardiovascular event; MI, myocardial infarction.

Table 6. Association between Guidezilla guide extension catheter use and long-term outcomes.

Outcome	Model	HR (95% CI)	*p* Value
CVEs	Model 1	1.04 (0.53–2.02)	0.912
	Model 2	1.14 (0.57–2.29)	0.712
	Model 3	0.99 (0.48–2.04)	0.976
MACE	Model 1	1.42 (0.93–2.17)	0.102
	Model 2	1.46 (0.94–2.26)	0.089
	Model 3	1.28 (0.81–2.03)	0.295

All models included 750 patients, with 51 CVEs and 121 MACE. Model 1 was unadjusted. Model 2 included age, sex, smoking, hypertension, diabetes, dyslipidaemia, previous MI, and previous stroke. The main adjusted Model 3 additionally included serum creatinine, multivessel disease, J-CTO score, and LVEF. HRs compare Guidezilla guide extension catheter use with no use. Models additionally including final recanalisation success are presented in Supplementary Table S4. CI, confidence interval; CVEs, cardiovascular events; HR, hazard ratio; J-CTO, Multicenter CTO Registry of Japan; LVEF, left ventricular ejection fraction; MACE, major adverse cardiovascular event; and MI, myocardial infarction.

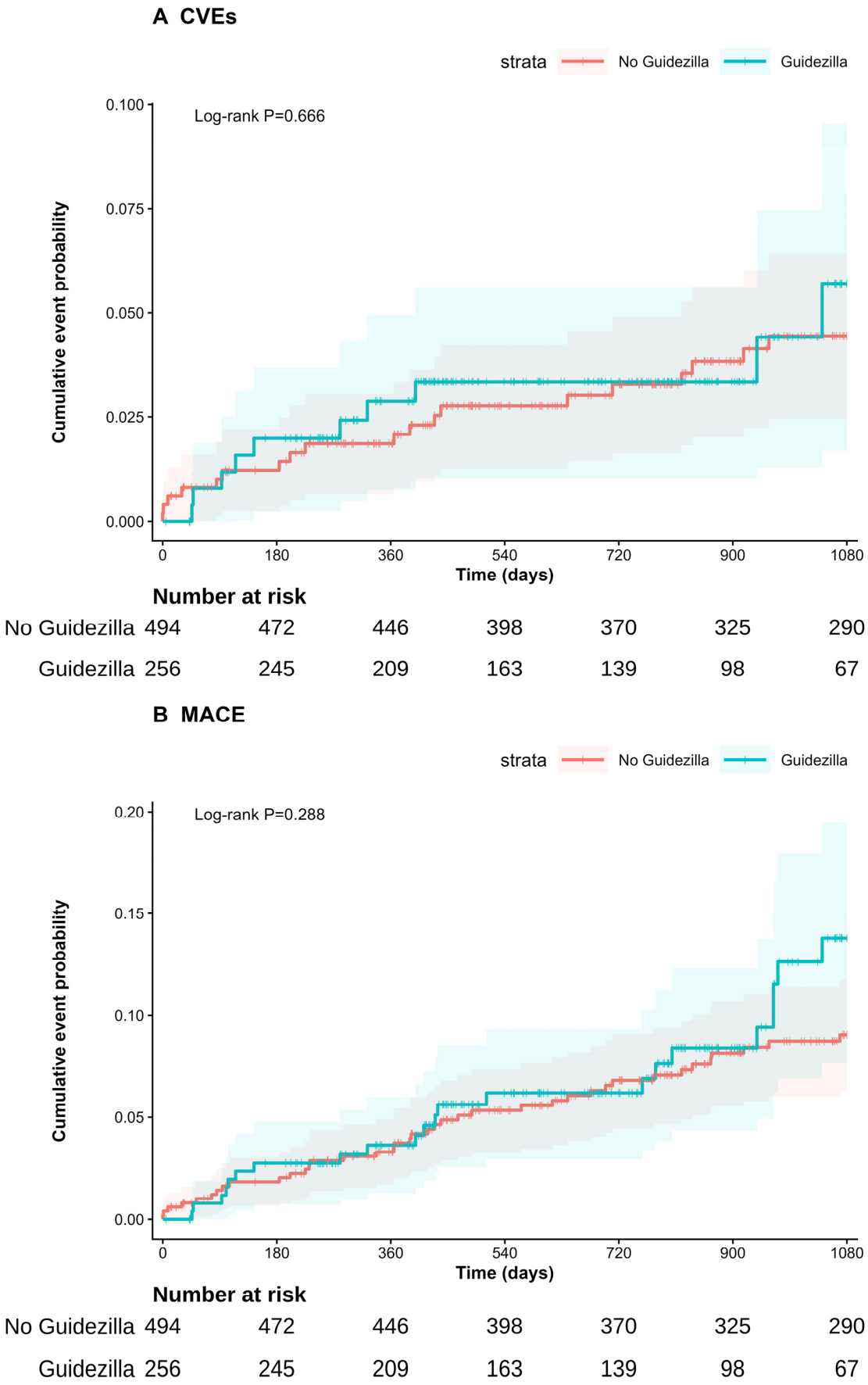


Figure 1. (**A**) Cardiovascular events. (**B**) Major adverse cardiovascular events. Both panels show 1 minus Kaplan–Meier survival from the index PCI: (**A**) cardiovascular events and (**B**) major adverse

cardiovascular events. Shading denotes 95% CIs and p values are from the log-rank test. The plotted labels "Guidezilla" and "No Guidezilla" denote use and no use of the Guidezilla guide extension catheter, respectively. Group sizes at time zero are 494 without and 256 with the Guidezilla guide extension catheter. Event-free patients were censored at last documented event-free assessment or administrative follow-up end. Numbers at risk are shown below each panel. The 1080-day limit applies to the display; Cox models use full available follow-up. CVEs, cardiovascular events; MACEs, major adverse cardiovascular events.

4. Discussion

In this cohort of 819 patients undergoing elective retrograde CTO PCI, Guidezilla guide extension catheter use was associated with higher retrograde technical success and final recanalisation success despite greater lesion complexity. These associations persisted after multivariable adjustment and propensity score matching. Previous PCI, blunt stump, longer occlusion length, and moderate or severe calcification were associated with device use, suggesting selection in response to procedural difficulty. The reported in-hospital safety outcomes did not differ significantly between groups, and a reduction in subsequent CVEs or MACE was not demonstrated. The findings extend the procedural evidence to a device-specific retrograde population with long-term follow-up, while remaining subject to the limitations of observational treatment selection.

Early studies established feasibility but addressed diverse clinical and procedural questions. Duong et al. reported guide extension use in 83 of 1539 PCIs, with device success of 73.3% and procedural success of 90.4% [19]. In 363 GuideLiner-supported procedures, Waterbury et al. reported successful device delivery in 80.2%, with coronary dissection in 3.3% and stent deformation in 2.2% [20]. Guidezilla guide extension catheter series subsequently reported procedural success of 99% in 188 patients and 86% in 165 patients [21,22]. These heterogeneous, predominantly uncontrolled experiences support technical utility but cannot quantify the incremental benefit of device use.

Evidence specific to CTO PCI provides a closer comparison. Huang et al. compared 20 Guidezilla guide extension catheter-assisted reverse CART procedures with 80 conventional reverse CART procedures and reported technical success of 100% and 75%, respectively [5]. The groups were treated during successive periods, and the small sample limited adjustment for selection and temporal changes. In LATAM CTO, guide extensions were used in 438 of 3049 patients; after matching, procedural success was 87.7% with device use and 80.5% without [6]. Our matched final recanalisation rates of 96.1% and 88.8% show a similar direction of association, although differences in population, procedural strategy, success definitions, and operator expertise preclude direct comparison of effect sizes.

Other registries have not shown a higher success rate with guide extension use. The PROGRESS CTO analysis of 14,521 procedures reported technical success of 86.6% with and 86.8% without an extension, despite greater complexity in device-assisted cases [7]. A reverse CART analysis included 467 procedures with successful retrograde CTO crossing, of which 60 used guide extension–assisted reverse CART. Technical success was 100% in the extension group and 99% with conventional reverse CART [8]. Restriction to successful retrograde crossing leaves little scope to demonstrate a difference in final success and excludes procedures in which the retrograde strategy failed earlier. Our cohort included elective retrograde CTO PCI rather than only successfully crossed lesions, addressing a broader procedural question.

These differences do not establish the superiority of a device or deployment strategy. Guide extension use may be planned, rescue an otherwise failing procedure, or follow substantial procedural progress. Pooling these settings obscures temporal ordering and can create time-dependent selection. Differences in endpoint ascertainment also limit compar-

isons across registries. Our findings describe selected procedures and do not establish an indication for routine deployment.

The pattern of device selection in this cohort is consistent with a response to anatomical and technical challenges. Blunt stumps, long occlusions, and calcification can increase crossing difficulty, while inadequate guide support can impede advancement of balloons, microcatheters, or stents. The EuroCTO expert panel describes applications in equipment delivery, dissection and re-entry, and antegrade–retrograde wire connection [3]. Guide extension use is also increasing: the panel reported an increase from 7.8% to 20.0% in the European registry between 2014 and 2021 [3]. Our 34.3% use rate in an exclusively retrograde cohort is compatible with greater procedural demand, although registry differences prevent attributing variation to anatomy alone.

During reverse CART, an antegrade guide extension may provide a more accessible target for the retrograde wire and facilitate externalisation [3,5]. These are technical rationales rather than mechanisms directly measured here. In particular, higher CC crossing success cannot be attributed to a catheter that may have been introduced only after crossing. Classification by eventual device use permits reverse temporal ordering and potential immortal-time bias [14]. Baseline adjustment and matching cannot correct an unknown deployment sequence. Because success was common, the reported ORs should not be interpreted as equivalent relative increases in success probability. Standardised probabilities provide an absolute description of the modelled association, without establishing a treatment effect.

Non-significant differences in reported complications do not establish equivalent safety. Tamponade and target-vessel perforation were numerically more frequent with device use, and sparse events constrain comparative inference. LATAM CTO and PROGRESS CTO reported differing safety findings in different populations and with different endpoint definitions [6,7]. Aggregate procedural complications cannot establish device attribution. Published reports describe dissection, equipment damage, and flow impairment related to extension use [4,20]. MAUDE surveillance also identifies potential device failure modes, but lacks a reliable denominator for estimating complication rates [23]. Incomplete characterisation of device-specific injury limits attribution of aggregate procedural complications to the Guidezilla guide extension catheter.

The main adjusted HRs were 0.99 (95% CI 0.48–2.04) for CVEs and 1.28 (95% CI 0.81–2.03) for MACE. These imprecise estimates do not establish either benefit or equivalent prognosis. Shorter follow-up with device use complicates comparison of crude proportions with time-to-event estimates. Although survival methods accommodate unequal observation periods under appropriate assumptions, informative censoring remains possible. Differences in stent length and discharge medications, together with changes in contemporary practice, may influence long-term outcomes. Their temporal relationship to device use also prevents treating them automatically as baseline confounders.

Randomised EuroCTO evidence distinguishes symptomatic benefit from prevention of major events [24,25], but evaluates revascularisation rather than guide extension selection. Because final recanalisation success may be an intermediate, the model omitting it provides the main adjusted long-term comparison; the model including it is secondary. Neither set of estimates establishes a causal effect, and residual confounding and model instability remain concerns.

The present findings support further evaluation of the Guidezilla guide extension catheter when retrograde CTO PCI is limited by inadequate support or difficulty connecting the retrograde wire to the antegrade system. They do not establish an indication for routine deployment or identify a subgroup with proven benefit. Prospective studies should record planned versus bailout use, the reason and timing of deployment, device generation and

size, and the procedural stage at which success or failure occurs. Assessment of device-attributable complications, procedural duration, fluoroscopy time, radiation exposure, contrast use, symptoms, quality of life, and subsequent clinical events would provide a more complete evaluation of its clinical value.

Several limitations merit consideration. First, the retrospective, single-centre design is susceptible to selection bias and residual confounding. Guidezilla guide extension catheter use was determined by operator judgement, and factors influencing device selection may also have influenced procedural success. Although multivariable adjustment and propensity score matching accounted for measured differences, some imbalances persisted after matching, and unmeasured confounding remains possible. Residual imbalance and sensitivity to the probability-scale caliper specification warrant cautious interpretation of the matched estimates. Uncertainty about deployment intent and timing further permits selection according to procedural progress. In particular, collateral crossing may have preceded device introduction, precluding attribution of the observed difference in crossing success to Guidezilla guide extension catheter use. Baseline adjustment and matching cannot resolve this temporal ambiguity, and the findings do not establish causality or justify routine deployment. Second, evolving operator experience, procedural strategies, equipment, intravascular imaging, and secondary prevention during 2011–2023 may have influenced device selection and outcomes. Including procedural calendar time in the propensity score model cannot fully capture these changes, leaving potential temporal and operator-related confounding. Third, sparse major safety events limit precision, and non-significant differences do not establish equivalent safety. Limited characterisation of procedural duration, radiation exposure, contrast use, and device-attributable injury further constrains assessment of procedural efficiency and device-specific safety. The limited number of long-term events relative to the number of model parameters also raises concern about overfitting and unstable estimates, particularly for CVEs. Adjusted long-term associations therefore remain exploratory, with wide confidence intervals compatible with clinically relevant benefit or harm. Fourth, exclusions for missing essential covariates and incomplete follow-up may have introduced selection bias if missingness was related to prognosis. Although time-to-event methods accommodate unequal observation periods, informative censoring remains possible. Competing non-cardiac death and uncertainty about its handling may also affect cardiovascular event estimates. Shorter follow-up among patients treated with the Guidezilla guide extension catheter limits assessment of later events. Finally, the predominantly male population treated by highly experienced CTO operators at a single centre limits generalisability to women, lower-volume centres, and less experienced operators. Prospective evaluation with standardised documentation of deployment timing, procedural efficiency, and device-attributable complications is needed to clarify clinical utility.

5. Conclusions

In this single-centre observational cohort, Guidezilla guide extension catheter use was associated with higher retrograde technical success and final recanalisation success. These associations remain susceptible to treatment selection and residual confounding and do not establish a causal benefit. The safety and long-term outcome estimates were insufficiently precise to establish comparable risks between groups. Larger prospective studies are needed to clarify the procedural and clinical implications of Guidezilla guide extension catheter use.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/jcdd13110581/s1, Figure S1: Patient selection and analysis cohorts; Table S1: Adjusted probabilities and absolute probability differences for procedural success according to Guidezilla guide extension catheter use; Table S2: Baseline Characteristics After Propensity Score Matchings; Table S3: Procedural Outcomes After Propensity Score Matching; Table S4: Secondary analysis of long-term outcomes additionally adjusting for final recanalisation success.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of Guangdong Provincial People's Hospital under approval number GDREC2017196H[R1] on 25 July 2017.

Informed Consent Statement: All participants provided written informed consent before the procedure.

Data Availability Statement: The datasets used during the current study are available from the corresponding author upon reasonable request.

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