Cardiovascular Revascularization Medicine 17 (2016) 15–18

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

The learning curve in treating coronary chronic total occlusion early in the experience of an operator at a tertiary medical center: The role of the hybrid approach☆

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ARTICLE INFO

Article history:
Received 6 July 2015
Received in revised form 25 September 2015
Accepted 30 September 2015

Keywords:
Chronic total occlusion
learning experience
resource utilization
outcome

ABSTRACT

Background: Treatment of chronic total occlusion (CTO) is complex and has a low adoption rate by interventional cardiologists. The introduction of the hybrid approach has provided a systematic step-by-step approach to treat complex CTO lesions with a high success rate. We describe the overall experience with the use of the hybrid approach of a non-CTO operator and analyze differences in the procedural and long term outcomes before and after the initial 30 cases performed.

Methods: A total of 67 unselected, consecutive patients (68 lesions) underwent PCI of a CTO between January 2012 and June 2013 by a non-CTO operator. Patients were followed up for 1 year using office and hospital medical records and death certificates. Cases were divided into the first consecutive 30 patients and compared to the subsequent 37 patients. The primary endpoint was acute procedural success defined as residual narrowing of ≤30% with no major adverse events. Secondary endpoints included the independent outcomes of death, major bleeding, perforations with cardiac tamponade, acute stent thrombosis (ST), target lesion revascularization (TLR) and target vessel revascularization (TVR). Descriptive analysis was performed on all variables. Univariate analysis was used to compare both groups.

Results: Baseline characteristics were as follows: mean age 63.9 ± 10.6 years, males 80.6%, diabetes 41.8%, de novo lesions 100%, ejection fraction 49.9 ± 13.8%, CTO length 76.9 ± 45.7 mm, number of drug eluting stents per CTO 2.8 ± 1.6 (median 3), contrast use 397 ± 161.3 ml, fluoroscopy time 51 ± 32 min and procedure time 134.3 ± 74.7 min. Lesions were crossed using an antegrade approach in 70.6% and a combined retrograde/antegrade approach in 29.4%. Crossing was intraluminal in 83.8% and subintimal in 16.2%. Acute procedural success was 95.5%. MAE included pericardial effusion with tamponade in 4.5%. On follow-up, TLR occurred in 6.6% of patients and TVR in 13.1%. There were no definite ST, one (1.6%) probable ST and one (1.6%) possible ST. Cardiac death occurred in 4.8% and non-cardiac death 1.6%. When comparing early experience (first 30 cases) with subsequent one, there were no differences in CTO length (60 ± 47.6 mm vs 83.2 ± 43.7 mm, $p = 0.206$) or coronary distribution of the CTO. The number of drug eluting stents used per CTO (2.6 ± 1.7 vs 3.0 ± 1.5, $p = 0.289$), contrast use (401 ± 141.2 ml vs 393.7 ± 177.8 ml, $p = 0.856$), fluoroscopy time (48.9 ± 25.6 min vs 52.9 ± 36.5 min, $p = 0.617$), or procedure time (116.8 ± 48.6 min vs 148.5 ± 88.7 min, $p = 0.068$) were statistically similar between the 2 groups. Less crossing catheters were used (1.1 ± 1 vs 0.6 ± 0.7, $p = 0.024$) and more lesions were crossed via antegrade approach after the initial experience (antegrade crossing: 53.3% vs 84.2% respectively, $p = 0.008$). There was numerically more procedural success after the initial experience (90 vs 100%, $p = 0.085$). MAE, TLR and TVR were similar on 1 year follow-up.

Conclusion: A high success rate was seen using the hybrid approach to treat CTO by a non-CTO operator. Although less crossing catheters were used and more lesions were treated via the antegrade approach after the initial experience, procedural and long term outcomes were otherwise similar between the early versus the late experience.

1. Purpose

Coronary chronic total occlusion (CTO) is defined as complete occlusion of the coronary artery for at least 3 months prior to revascularization based on history, symptom onset or prior angiography [1]. Collaterals are typically present but in some patients they are

☆ Conflict of Interest. Relevant disclosure: Educational and research grants from Abbott, Boston Scientific, Cordis, Medtronic. Full disclosure at www.mcrfmd.com. Presented at Cardiovascular Research Technologies (CRT) 2015 in Washington, DC.

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http://dx.doi.org/10.1016/j.carrev.2015.09.004
1553-8389/

suboptimal in providing adequate blood flow, relieving symptoms or maintaining good left ventricular function. Treatment of CTO may improve quality of life, symptoms and ejection fraction [2–4]. CTO is present in 15% to 30% of patients [1], a large proportion of whom are either asymptomatic or have no impairment to left ventricular function. Treatment of CTO is appropriately reserved for patients with continued limiting symptoms or large area of ischemia and/or hibernating myocardium despite optimal medical therapy [5].

The choice of treating CTO is either percutaneous coronary intervention (PCI) or coronary artery bypass surgery (CABG). PCI emerged as a viable option in treating CTO effectively and safely but less operators have adopted this treatment likely because of complexity and lack of a standardized approach to treatment [6]. Treatment of a CTO is generally complex and requires significant amount of time and resources. The learning curve for treating a CTO by an experienced non-CTO interventionalist has not been well defined but it is thought that it requires a high level of dedication and the performance of over 200–300 cases before establishing expertise in this treatment along with 50 cases per year to maintain acquired skills [7,8].

The advent of the hybrid approach in treating CTO [9], however, has provided a systematic algorithm that can be followed successfully by a non-CTO operator after appropriate training and early preceptorship by a CTO expert [6]. We analyze our own experience with the hybrid approach use by a non-CTO operator (JR) and evaluate whether there is a learning curve between the first 30 cases and subsequent cases.

2. Methods

All consecutive, unselected patients that underwent CTO treatment by a single, non-CTO operator between January 2012 and June 2013 were retrospectively reviewed. The non-CTO operator has performed over 10,000 coronary interventional procedures, attended several dedicated conferences in CTO treatment and was closely supervised on several occasions by a CTO expert. Demographics, clinical, procedural and angiographic variables were collected by reviewing medical records. Angiograms were reviewed by an independent operator. Patients were followed for 1 year using office and hospital medical records and death certificates. Major adverse events (MAE) were defined as death, perforation with or without tamponade, emergency bypass surgery, non-fatal myocardial infarction (either by ST elevation or positive cardiac markers), or major bleeding as defined by thrombolysis in myocardial infarction (TIMI) criteria (intracranial hemorrhage or loss of 5 units of PRBC with a source of bleed).

Cases were divided into 2 cohorts; the first consecutive 30 patients versus the subsequent 37 patients. The primary endpoint was acute procedural success defined as residual narrowing of ≤30% with no MAEs. Secondary endpoints included death, major bleeding, perforations with cardiac tamponade, acute stent thrombosis (ST) as defined by the Academic Research Consortium [10], target lesion revascularization (TLR) and target vessel revascularization (TVR) as independent endpoints.

2.1. Statistical analysis

Descriptive analysis was performed on all variables. Mean ± standard deviation was used for continuous variables. Percentages were used for categorical variables. Univariate analysis was used to compare differences between the early experience group versus the later experience group.

3. Results

A total of 67 consecutive, unselected patients (68 lesions) (age 63.9 ± 10.6 years, males 80.6%) were included. Baseline demographics and clinical variables included hyperlipidemia 83.7%, hypertension 94.0%, diabetes 41.8%, current smoking 22.4%, peripheral vascular disease 10.4%, cerebrovascular disease 6.0%, history of heart failure 11.9%, prior percutaneous coronary intervention (PCI) 58.7% and prior myocardial infarction 23.9%.

CTO was treated because of persistence of symptoms despite 2 antianginal drugs (10.4%), reduced left ventricular function (20.9%), high risk findings on abnormal stress test (41.8%) and part of a staged procedure (26.9%). Angiographic and procedural variables included de novo lesions (100%), ejection fraction 49.9 ± 13.8%, and CTO length 76.9 ± 45.7 mm (Table 1).

Procedural variables (Table 2) showed that the number of drug eluting stents used per CTO was 2.8 ± 1.6 (median 3). Also contrast use was 397 ± 161.3 ml, fluoroscopy time 51 ± 32 min and procedure time 134.3 ± 74.7 min. Lesions were crossed using an antegrade approach in 70.6% and a combined retrograde/antegrade approach in 29.4%. Crossing was intraluminal in 83.8% and subintimal in 11/68 (16.2%). 8 of the 11 subintimal crossing were antegrade dissection/reentry. 3/11 were retrograde reentry. The CrossBoss/Stingray reentry catheter was used in 72.2% to reenter the lumen (7 antegrade and 1 retrograde).

Table 3 shows outcome of patients treated. Acute procedural success was 95.5%. Intraprocedural MAE included pericardial effusion with tamponade in 4.5% of patients treated successfully with pericardiocentesis. TLR occurred in 6.6% of patients and TVR in 13.1%. There were no definite ST, one (1.6%) probable ST and one (1.6%) possible ST. Cardiac death occurred in 4.8% and non-cardiac death 1.6%.

When comparing early experience (first 30 cases) with subsequent one (Table 4), there were no differences in CTO length (60 ± 47.6 mm vs 83.2 ± 43.7 mm, p = 0.206) or coronary distribution of the CTO. The number of drug eluting stents used per CTO (2.6 ± 1.7 vs 3.0 ± 1.5, p = 0.289), contrast use (401 ± 141.2 ml vs 393.7 ± 177.8 ml, p = 0.856), fluoroscopy time (48.9 ± 25.6 min vs 52.9 ± 36.5 min, p = 0.617), or procedure time (116.8 ± 48.6 min vs 148.5 ± 88.7 min, p = 0.068) were statistically similar between the 2 groups. There were no differences in the number of wires and balloons used but less crossing catheters were used after the initial experience (1.1 ± 1 vs 0.6 ± 0.7, p = 0.024). Also more lesions were crossed via antegrade approach with subsequent experience (antegrade crossing: 53.3% vs 84.2% respectively, p = 0.008). Intraluminal vs subintimal crossing of CTO was similar between the 2 groups. There was a trend toward more procedural success after the initial experience (90 vs 100%, p = 0.085). TLR and TVR were similar on 1 year follow-up. MAE was also similar between the 2 groups.

Table 1
Demographics and clinical variables.

	n	Mean	Median
Age	67	63.9 ± 10.6	65
Body mass index	67	32.1 ± 6.9	31.9
Systolic blood pressure (mmHg)	67	128 ± 17	128
Pulse (per min)	67	69 ± 9.9	68
Ejection fraction (%)	65	49.9 ± 13.8	55
	n	**n′**	**%**
Male	67	54	80.6
Prior percutaneous coronary intervention	67	40	59.7
Prior coronary artery bypass surgery	67	19	28.4
Prior myocardial infarction	67	16	23.9
Chronic renal insufficiency (Cr > 1.5)	67	2	3
Chronic lung disease	67	12	17.9
Hypertension	67	63	94
Cerebrovascular disease	67	4	6
Hyperlipidemia	67	61	91
Current smoking history	67	15	22.4
Diabetes mellitus	67	28	41.8
History of atrial fibrillation	67	5	7.5
History of heart failure	67	8	11.9