

One Ring to Revascularize Them All: Assessing The End Results of Coronary Bioresorbable Vascular Scaffolds as Revascularization Approach for Chronic Total Occlusions

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Systematic Review

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Abstract

Following the era of percutaneous coronary intervention (PCI), the occurrence of revascularization in chronic total occlusions (CTO) is correlated with positive and longstanding echocardiographic and clinical outcomes. The beneficial outcomes of bioresorbable vascular scaffolds (BVS) treatment to manage CTO are currently inconclusive, since patients presenting with CTO were frequently ruled out from a vast number of randomized clinical trials (RCTs) which assess BVS. This systematic review is aimed to review and recapitulate available reports on the clinical outcomes of CTO with BVS treatment. Available data in the Cochrane Library, EMBASE, MEDLINE, and, clinicaltrials.gov are being examined to gather investigations on BVS-treated CTO. Outcomes of concern involved vessel restenosis, scaffold thrombosis, target lesion revascularization, myocardial infarction, major adverse cardiac events (MACE), and all-cause mortality. Thirteen papers have met the criteria for inclusion. All papers were written based on observational studies cumulative population samples of 1,077. Two papers were found to involve retrospective comparison of drug-eluting stents (DES) group with BVS group. The investigations had varying group size and duration of follow-up. This review presented beneficial results for BVS-treated CTO. In double-arm studies, the recorded MACE incidence diverged from 0% to 6.7% with no notable differences between DES and BVS populations. While reports on the implantation of the first-generation BVS in CTO populations are infrequent and recruited only insufficient observational studies samples, the available data is promising. The data shows satisfactory results which are analogous to second-generation DES. However, additional investigation by means of RCTs and the application of more novel scaffolds is necessitated.

Introduction

In coronary artery diseases, the condition of chronic total occlusion (CTO) is described as a fully occluded vessel with thrombolysis in myocardial infarction (TIMI) patients, with a grade of flow 0 and persisting for longer than three months [1]. CTOs exist in roughly 20% of individuals who are receiving elective angiography due to coronary artery disease [2]. CTO revascularization approach by percutaneous coronary intervention (PCI) is correlated with a relief of chest pain (angina), moderation in infarct expansion of the myocardium, better function of the left ventricular, smaller probability for the need of future coronary artery bypass grafting, and greater patients survival despite existing manifestation of collateral circulation [3-5]. However, since the use of multiple, consecutive, and extended stents (known as the vessel caging) are usually needed to administer a vessel with CTO, the vessel is predisposed to hazards of delayed restenosis and stent thrombosis [6-8]. A substitute choice for treatment is offered by the bioresorbable vascular scaffolds (BVS). The novel characteristics of BVS enable them to advance the healing process of vessel, facilitating for the remodelling of the vascular system, preventing delayed lumen enlargement, and reviving the normal vasomotion. All these effects result in escaping the issues of vessel caging and the hazard of delayed thrombosis [9, 10]. The beneficial outcomes derived from incorporating bioresorbable vascular scaffolds (BVS) to manage CTO are currently inconclusive since patients presenting with CTO were frequently ruled out from a vast number of randomized clinical trials

(RCTs) assessing BVS. This systematic review is aimed to compile available reports on the clinical outcomes of CTO with BVS treatment.

Materials And Methods

This review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [11]. Systematic electronic searches were implemented in the Cochrane library, EMBASE, MEDLINE, and clinicaltrials.gov for systematic reviews, observational studies, case series, and clinical trials on Abbott Vascular's Absorb bioresorbable vascular scaffolds in patients presenting with chronic total occlusions. Extensive search keywords were incorporated: "chronic total occlusion" and "bioresorbable vascular scaffold". These keywords were consolidated employing the Boolean operator. Furthermore, to gather supplementary references, additional publications were sought from the chosen papers and papers that cited the chosen investigations.

Studies were chosen to review once they satisfied the following criteria of inclusion: patients with age of equal to or more than 18 years; chronic total occlusion (CTO) manifestations of one or more coronary arteries; incorporating bioresorbable vascular scaffolds implantation; disclosed a minimum of one efficacy and safety outcomes: vessel restenosis, stent or scaffold thrombosis (ST), target lesion revascularization (TLR), myocardial infarction (MI), major adverse cardiac events (MACE), cardiac death, and all-cause mortality; having a minimum of three months of patients follow-up.

Exclusion criteria for studies elimination were: investigations using a language other than English; case series and case reports having fewer than ten samples; investigations recruiting subjects other than human. The collection of papers for fitness of criteria and data harvesting was performed by PHW. Selected evidence included study design, study type, publication year, clinical and demographic features, primary and secondary outcomes, and follow-up duration. Selected outcomes were successful procedure approach, ST, TLR, target vessel revascularization (TVR), MI, MACE, and deaths by non-cardiac and cardiac causes. Outcomes were recorded quantitatively and published as the total study population percentages. On account of the heterogeneity of study design among the included investigations, meta-analysis of evidence was not conducted. Selected papers were assessed for possible biases utilizing the Cochrane risk of bias assessment tool (ROBINS-I).

Results

Applying the strategy for evidence search as outlined, we distinguished potential data, and 95 identical papers were spotted and eliminated. The remaining papers were filtered. Papers using a language other than English, editorials, review articles, conference abstracts, case series and case reports having fewer than ten samples were further eliminated. A sum of thirteen papers fulfilled the criteria of inclusion for investigation.

Features of Selected Studies

All investigations selected were observational study. A total of 1,077 patients were included, having a median size of the population of 41, with interquartile range (IQR) of 29.5 to 67.5 individuals. The median follow-up period was 3.3 months to 23.5 months. Male patients were dominant in the population (77.5% to 98%), comprising a mean age of 56.9 years to 65.7 years. Of 13 papers selected, 11 were retrospective cohort investigations, and therefore did not constitute a control population. The remaining two were double-arm investigations which constituted comparator populations which retrospectively contrasted drug-eluting stents (DES) with BVS. All investigations described the term CTO identically as a complete vessel occlusion with TIMI flow of zero for longer than three months period. The primary and secondary outcomes differ moderately from one investigation to another, as seen in Table 1. However, they were primarily concentrated on the effect of combination or individual impact of major adverse cardiovascular events such as ischemia-driven target lesion revascularization, myocardial infarction, and cardiac death.

Table 1. A comparison table of clinical studies which investigated the primary and secondary outcomes of Bioresorbable Vascular Scaffolds and Drug-Eluting Stents

Author	Year	Type and Design	Population, Follow-up Duration	Primary Outcomes	Secondary Outcomes
Manna al. [12]	2018	Prospective single center series (sub-study GHOST-CTO)	N=21. Median of 447 days (IQR 365 to 713 days)	One-year outcomes of optical coherence tomography	MACE at one year is described as compound of TLR, MI, and death
tomo et [13]	2017	Retrospective international multi-center registry	N=65. Median of 453 days	Target lesion failure is described as a compound of clinically driven TLR, target vessel MI, and cardiac death	Scaffold thrombosis, clinically driven target vessel revascularization, and all-cause mortality
ieremans al. [14]	2017	Prospective multi-center single arm study	N=41. Twelve months follow-up	TVF incidence (in-stent re-stenosis or occlusion with or without TVR)	BVS patency and performance of quantitative MSCT imaging to assess area and diameter of stenosis at one-year follow-up
gler et [15]	2017	Retrospective single center study, two-arms, BVS compared with DES (Ulm-CSI CTO)	BVS (n=14 with 15 CTO); DES (n=15). Angiographic follow-up at nine month in 96.7%. Clinical follow-up at twelve months in all patients	Compound of target lesion revascularization, MI not clearly related to a nontarget vessel, and cardiac death	None
m et al. [16]	2017	Prospective multi-center single-arm registry	N=105. Six months follow-up	Scaffold thrombosis, clinical TLR, non-TLR, MI, cardiac death	None
maç al [16]	2016	Prospective single-center	N=30. Median of 542 days	All-cause mortality; MACE (BVS thrombosis, symptom-driven TLR, non-fatal target	None

		single-arm study	(IQR 175 to 961 days)	vessel MI, TVR), and cardiac death	
querizo al. [17]	2016	Prospective single-arm registry (ABSORB-CTO pilot)	N=33. Twelve months follow-up	Device patency assessed by various modalities of imaging	None
el et al. 3]	2016	Prospective single-center single-arm study	N=41. Twelve months follow-up	TLR, TVR, rates of MI, angina, CABG, and rates of death	None
siak et [19]	2016	Prospective non-randomized clinical pilot registry	N=40. Median 556 days (274 to 932 days; IQR 374 to 706 days)	TVF is described as the mixture of clinically driven TVR, target vessel MI, or cardiac death. Device success (successful deployment at intended area), and procedure success rate (TIMI flow grade 3, residual stenosis <30% without major procedural complications)	Scaffold thrombosis incidence
zalini et [20]	2016	Retrospective multi-center registry	BVS group (n=153) compared to DES group (n=384). Median of 703 days (IQR 426 to 989 days)	TVF incidence is described as the combination of ischemia-driven TLR, target-vessel myocardial infarction, and cardiac death	None
eda et al. 1]	2015	Single-center observational study	N=42. Mean of 13±5 months, median of 12 (IQR 9.75 to 16) months	Technical success is described as TIMI flow grade 3 and patent vessel having <30% residual stenosis achieved. MACE is described as a mixture of TLR, MI, and cardiac death, Scaffold thrombosis. Periprocedural MI.	None
ktekin et [22]	2015	Multi-center registry	N=70. Median of 11 (IQR 7 to 18) months	Compound of non-fatal MI and all-cause death. A combination of safety outcomes of MACE, including symptom-driven TLR, MI, and death	None
ebe et al.	2014	Observational	N=23. Median	Procedural success is described as	None

3] study of 108 (79.5 to 214.5 days) estimated residual stenosis of $\leq 30\%$ on angiography and optical coherence tomography, and successful deployment of the scaffold at target area. MACE is described as MI, unscheduled percutaneous and surgical target lesion, and cardiac death. TVF included percutaneous or surgical TVR, target vessel MI, and cardiac death.

Note: CTO = chronic total occlusion; IQR = Interquartile range; MACE = Major adverse cardiovascular event; TLR = Target lesion revascularization; MI = Myocardial infarction; TVF = Target vessel failure; TVR = Target vessel revascularization; BVS = Bioresorbable vascular scaffolds; DES = Drug-eluting stents; MSCT = Multi-slice computer tomography; CABG = Coronary artery bypass grafting; TIMI = Thrombolysis in myocardial infarction.

Single-Arm Studies

Eleven single-arm investigations were selected, most of which were small retrospective and prospective studies [6, 12-14, 16-19, 21-23]. Clinical and demographic features were alike in all investigations as do with their published end results.

The median duration of follow-up in this population ranged from 108 days to 556 days. A combination of target lesion revascularization, target vessel MI, and cardiac death was published in five investigations, resulting in 2.64% (95% CI: 1.04% to 4.24%). Yamaç et al. conducted an investigation which recorded one cardiac death (3 percent of their samples) throughout the period of follow-up [16]. However, only Maeremans et al. recorded one non-cardiac mortality (2.4% of their samples) [14]. The non-fatal myocardial infarction incidence was reported to be 1.07% (95% CI: 0.09% to 2.06%). Target lesion revascularization incidence was reported to be 2.51% (95% CI: 0.86% to 4.16%). The greatest rate of target lesion revascularization was 8.6% as recorded by Yamaç et al. [16]. The scaffold or stent thrombosis incidence was reported to be 1.3% (95% CI: -0.09% to 2.39%). The combined restenosis rate, as reported in six investigations, was 4.45% (95% CI: 2.04% to 6.86%). Using the primary tool of ROBINS-I to evaluate the non-randomized investigations, each paper went through a detailed assessment of possible biases. Considering that a minimum of one evaluated areas of every investigation was concluded to possess a risk for critical bias, the tool revealed that twelve investigations had an overall risk for critical bias. The report by Azzalini et al. was assessed to possess a severe bias risk.

Double-Arm Studies

Two double-arm investigations were selected, comparing DES with BVS in detailed evidence of follow-up as seen in Table 2. The bigger investigation was conducted by Azzalini et al. in a multi-center retrospective registry, involving 537 subjects [20]. The study juxtaposed the end results of patients

(n=153) who were implanted with the first-generation Absorb BVS and compared them to another group (n=384) who were treated with second-generation DES.

The primary outcome was a target vessel failure (TVF), being described as the combination of ischemia-driven TLR, target vessel myocardial infarction, and cardiac death. The median duration of follow-up was 703 days with IQR of 426 days to 989 days. There were no notable differences in events rates among the two groups.

The individual comparison of the primary outcome is as follows: TVF (4.6% in BVS versus 7.7% in DES; HR: 0.59, 95% CI: 0.26 to 1.35; p=0.21), ischemia-driven TLR (4.0% in BVS versus 4.1% in DES; HR: 0.95; 95% CI: 0.37 to 2.45; p=0.92), and stent or scaffold thrombosis (0.6% in BVS versus 0.7% in DES, p=0.86). Different inverse probability by Cox regression analysis with intervention weight-adjustment failed to confirm any notable differences in outcomes among the individuals. Nevertheless, when clinical, procedural, and angiographic variables were affixed altogether to the model, the calculation revealed an insignificant rise in TVF and ischemia-driven TLR risks in the BVS population (adjusted HR of 3.45; 95% CI: 0.87 to 13.66; p=0.08). Kugler et al. executed a different double-arm observational study [15] using a modest prospective registry, including 29 samples, and 14 of whom had been implanted with BVS and 15 of whom underwent DES. A clinical follow-up of 12 months period displayed outcomes alike to those published by Azzalini et al. The study did not exhibit any outcomes differences within BVS and DES populations. TVF and ischemia-driven TLR risks, as well as the thrombosis occurrence of the scaffold, were equivalent within two populations.

Table 2. Bias risk assessment in selected studies using Cochrane ROBINS-I

Author	Confounding Bias	Participant Selection Bias	Inter-ventions Classification Bias	Intended Inter-vention Deviation Bias	Missing Data Bias	Out-comes Measurement Bias	Repor- ted Results Bias	Overall Bias
La Manna et al. [12]	Critical	Critical	Serious	Moderate	Serious	Critical	Moderate	Critical
Mitomo et al. [13]	Critical	Serious	Critical	Moderate	Critical	Critical	Moderate	Critical
Maeremans et al. [14]	Critical	Critical	Serious	Moderate	Serious	Critical	Moderate	Critical
Kugler et al. [15]	Critical	Serious	Critical	Moderate	Critical	Critical	Moderate	Critical
Fam et al. [6]	Critical	Critical	Serious	Moderate	Moderate	Critical	Moderate	Critical
Yamaç et al. [16]	Critical	Critical	Serious	Moderate	Moderate	Critical	Moderate	Critical
Vaquerizo et al. [17]	Critical	Critical	Serious	Moderate	Moderate	Critical	Moderate	Critical
Özel et al. [18]	Critical	Critical	Serious	Moderate	Moderate	Critical	Moderate	Critical
Lesiak et al. [19]	Critical	Critical	Serious	Moderate	Moderate	Critical	Moderate	Critical
Azzalini et al. [20]	Serious	Serious	Serious	Moderate	Moderate	Serious	Moderate	Serious
Ojeda et al. [21]	Critical	Critical	Serious	Moderate	Moderate	Critical	Moderate	Critical
Goktekin et al. [22]	Critical	Critical	Serious	Moderate	Moderate	Critical	Moderate	Critical
Wiebe et al. [23]	Critical	Critical	Serious	Moderate	Moderate	Critical	Moderate	Critical

Discussion

DES still leads as the preferred device for percutaneous coronary interventions, however, BVS was invented as a substitute to DES. The theoretical benefit of BVS lies on full resorption of scaffolds or stents after two years of implantation with the resultant vasomotion rehabilitation. This condition avoids the potential “caged vessel” complication which eventually leads to delayed thrombosis of the stent [9, 10]. Theoretically, those features should be favorable for the revascularization procedures of CTO where an extended length of scaffold segment is frequently necessitated. Nonetheless, these favorable features would require confirmation in clinical trials before being approved for comprehensive technology use.

This review collected 13 investigations of generally moderate evidence. The analysis of selected papers exhibited promising outcomes for the implantation of BVS in CTO population. The majority of the investigations exhibited a relatively small incidence of combination and individual outcomes after a reasonable period of follow-up.

Azzalini et al. executed a comprehensive double-arm investigation which carried out the unadjusted analysis and the primary adjusted analysis. They did not exhibit any statistically significant difference in the long-term results within the BVS and DES population. However, the investigation revealed an inclination to a greater adjusted risk in the BVS group for ischemia-driven target lesion failure than the DES group [20]. Despite showing moderate-quality evidence in CTO, three new trials have pointed out a heightened stent thrombosis risk in comparison with DES in PCI [24-26]. The differences of conclusions from selected RCTs could be attributed to variable hemodynamics in CTO stenting, selection of patients, inadequate follow-up, and variations in reporting in this review.

This inclination could be described by distinguishing the first-generation BVS with second-generation DES, since the latter is equipped with finer struts and therefore generating lower blood flow turbulence in addition to less thrombosis restenosis risk [27]. As a consequence of flow disturbances, concerns about rising cases of scaffold thrombosis (ST) were brought up and were also confirmed by multiple trials and meta-analysis. Those investigations revealed a heightened scaffold thrombosis incidence in comparison to DES [24-26]. However, this review did not show any distinction in the rate of thrombosis between BVS and DES groups in CTO patients. Additionally, in single-arm observational investigations, the incidence of thrombosis was found to be faint. This finding could be associated with inadequate sample size. It can also be explained by careful selection of lesion for intervention to avoid small vessels with a lower velocity of blood flow and more skillful operators who are exposed to the lesions' complexity using supplementary imaging modalities, such as optical coherence tomography or intravascular ultrasound. Finally, recent concerns should also be examined, especially related to the possible subclinical complication of restenosis in CTO lesion and also stent or scaffold thrombosis [20].

Angiographic follow-up is essential for the aforementioned reason to reveal the accurate incidence rates of scaffold thrombosis and restenosis. In this review, eight investigations conducted a concrete non-invasive or invasive angiographic follow-up after the implantation of BVS. However, in most investigations, this imaging method was performed not in all patients, making the accurate rates of scaffold thrombosis or restenosis to be underestimated. For example, Mitomo et al. in 2017 reported that only as much as 33.8% of patients went through the angiographic follow-up [13] while in 2018, Maeremans et al. recorded approximately 83% of patients went through the multi-slice computed tomography angiographic follow-up [14]. Despite encouraging findings, the first-generation BVS was withdrawn from the guideline for clinical practice in an account of the safety alert issued by Food and Drug Administration to Absorb BVS (Abbott) device owing to its confirmed heightened rates for ST [28]. The next-generation BVS, with enhanced flow parameters and finer struts, is recently undergoing research with promising preliminary outcomes [29]. Simultaneously, published evidence on the effectiveness of second-generation stents or scaffolds for CTO are currently absent.

LIMITATIONS

This review has multiple constraints. First, involved investigations were observational in design, and published RCTs are absent to date. This condition makes the available evidence prone to possible biases, such as confounding and selection biases. The existence of such biases was considered to be of inferior quality in this review. Second, given a notable heterogeneity in studies involved, a meta-analysis could not be executed. Therefore, a systematic review is preferred. Third, the median duration of follow-up for most of the studies was shorter than two years, putting hindrances on the capacity to evaluate the theoretical benefits of BVS after the scaffold or stent resorption. Fourth, involved investigations studied only the first-generation BVS Absorb, which possess unflattering flow characteristics.

Conclusions

The evidence studying the application of the first-generation BVS in CTO patients is not many in number and restricted by inadequate sample in observational studies. Currently, the available evidence is optimistic and implies satisfactory outcomes as compared to the second-generation DES. Additional research and investigation by means of randomized clinical trials and the employment of newer, more superiorly-designed generation of stents and scaffolds is necessitated to control confounders and to determine the existence of a significant distinction among these devices.

Declarations

Funding

None.

Conflict of Interest

The author declares there is no conflict of interest regarding all aspect of the study.

Author Contribution

PHW is responsible for the study from the search of papers and articles, data gathering, data analysis, until reporting the results of the review.

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