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Coronary laser with simultaneous contrast injection for the treatment of stent underexpansion

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Abstract

Background: *Stent underexpansion is a challenge in interventional cardiology. Some off-label treatments, such as rotational atherectomy, intravascular lithotripsy and coronary lasing, have been used to overcome the problem. The purpose of this study is to evaluate the safety and efficacy of coronary laser atherectomy with simultaneous contrast injection and subsequent balloon dilation to optimize stent expansion.*

Methods: *Coronary laser atherectomy with simultaneous contrast injection was used. After lasing, non-compliant balloon dilation at high pressure was performed to overcome the underexpanded point. The average increase in the minimum stent area (MSA) was measured by intravascular ultrasound (IVUS), and any complication related to the technique was evaluated. Additionally, major adverse cardiovascular events (MACE), consisting of death from any cause, new myocardial infarction (MI) and target lesion revascularization, were scrutinized in a long-term follow-up.*

Results: *Sixteen underexpanded stents were treated with laser between August 2017 and November 2022. In all cases but one, IVUS was used to evaluate the MSA before and after lasing. The MSA showed an average increase of 2.34 ± 1.57 mm*^{2} *(95% confidence interval [CI]: 1.47–3.21;* $p < 0.001$*) after laser application and balloon inflation. No complication related to the technique was detected. During a follow-up period of a median (interquartile range) of 457 (50–973) days, the combined MACE assessed by Kaplan-Meier estimator showed an event-free rate of 0.82 (95% CI: 0.59–1).*

Conclusions: *Coronary laser with simultaneous contrast injection is a safe method to optimize a stent underexpansion, with an acceptable event-free rate in long-term follow-up.* (Cardiol J 2024; 31, 2: 235–242)
Keywords: percutaneous coronary intervention, excimer laser coronary angioplasty

Introduction

Percutaneous coronary intervention (PCI) with eventual stent implantation is the standard therapy for significant atherosclerosis lesions in most cases. Plaque preparation before stenting, especially in calcified lesions, is crucial to obtaining optimal results after stent deployment. Interventional cardiologists are increasingly dealing with more complex lesions, which demand, in some circumstances, careful debulking using specific techniques before stent implantation.

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Figure 1. Koninklijke Philips N.V. (San Diego, CA, USA) CVX-300 excimer laser coronary atherectomy system with its monorail catheter.

Stent underexpansion is associated with a higher risk of stent thrombosis and restenosis [1, 2]; therefore, ensuring adequate lesion debulking is crucial for optimal stent deployment. Some balloon undilatable lesions are easily identified under fluoroscopy by visualizing a waist in the balloon; however, at other times, a precise diagnosis requires intravascular imaging [3]. Indeed, optimal stent expansion using intravascular ultrasound (IVUS) has been associated with lower target vessel revascularization compared with angiographic guidance alone [4]. The ideal scenario is to avoid stent underexpansion, but if the stent remains constrained following implantation despite appropriate inflation pressure, typical conventional treatment is limited to high-pressure non-compliant (NC) balloon inflation. However, a few off-label therapies have been described in interventional cardiology to solve this unexpected problem, such as rotational atherectomy and intravascular lithotripsy (IVL) [5, 6]. IVL is safe to perform in freshly implanted stents and it does not significantly damage the polymer [7], with reported low effectiveness in lumen diameter gain in case of IVL therapy directly after stenting and in ostial location [8]. Excimer laser coronary atherectomy (ELCA™ Coronary Laser Atherectomy Catheter; Koninklijke Philips N.V. San Diego, CA, USA) can potentially debulk and ablate the tissue around the underexpanded stent and subsequently assist in balloon dilation within the stent as evidenced in several studies [9, 10].

The purpose of this study is to report a single-center experience in the efficacy and safety of ELCA with simultaneous contrast injection in a series of patients with underexpanded stents.

Methods

This is a retrospective, single-center study of consecutive patients with underexpanded stents in whom ELCA with concurrent contrast injection was used to assist posterior balloon inflation and to optimize the minimum stent area (MSA) assessed by IVUS. Stent underexpansion was defined as a focal angiographic stenosis of ≥ 30% after stent deployment. Calcification was assessed with fluoroscopy examination and checked by IVUS as a calcified ring surrounding the stent underexpanded point. MSA was assessed by IVUS before laser application except in one case in which the IVUS probe was unable to cross the lesion. After laser delivery and subsequent balloon inflation, MSA was measured once again by IVUS. An ELCA 0.9 mm or 1.4 mm X-80 Vitesse RX Catheter (Koninklijke Philips N.V.; Fig. 1) was used with simultaneous contrast injection during laser delivery. After 2–3 rounds of ELCA within the underexpansion area, a NC balloon inflation fit for stent size was performed until a considerable improvement in the waist or stent underexpanded point was appreciated. Laser energy was applied using an on-off method consisting of laser energy activation for 10 s with a 5 s pause after each lasing period. The laser catheter was slowly advanced over a 0.014 inch coronary guidewire at a speed of 1 mm/s, through the underexpanded point and not beyond the stent, according to the recommendations of the device manufacturer [11, 12]. Final residual stenosis after laser delivery and balloon inflation was assessed by visual inspection.

The main purpose of the present study was to evaluate the efficacy of ELCA with simultaneous contrast injection for stent underexpansion in terms of MSA improvement. Additionally, the procedural safety was evaluated with the assessment of the following variables: coronary dissection, vessel perforation, slow-flow or no-reflow phenomenon and peri-procedural myocardial infarction (MI). Moreover, clinical follow-up in all patients was performed in order to assess any major adverse cardiac events (MACE), consisting of the combination of all cause-mortality, new MI or target lesion revascularization (TLR). To evaluate the procedural efficacy, MSA was measured before and after ELCA, plus balloon dilation and the mean increase in this parameter was assessed in the entire series. Additionally, an increase of at least 1 mm^2 in MSA after coronary lasing plus balloon inflation was evaluated individually in all cases. Patient follow-up was caried out through a clinical history review and phone call if needed. All patients signed an informed consent before undergoing the procedure.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation and compared with a paired Student t-test. Categorical variables were represented as proportion and percentage and compared using a chi-square or Fisher exact test as appropriate. The paired t-test was used to find the gain in MSA measured by IVUS after lasing and balloon dilation. The MACEs were assessed as time-to--event data using the Kaplan-Meier statistic. Data analyses were performed using SPSS Statistics v.23 (IBM Corp., Armonk, NY, USA). A p-value < 0.05 was considered statistically significant.

Table 1. Basal and procedural details

Parameters	N = 16
Age	71 ± 11
Female	2 (12.5%)
Hypertension	14 (87.5%)
Diabetes	13 (81.3%)
Vessel:	
LAD	3 (18.7%)
RCA	13 (81.3%)
Diagnosis:	
Stable angina	8 (50%)
NSTEMI	7 (43.8%)
STEMI	1 (6.2%)
Size of excimer laser:	
0.9 mm	13 (81.3%)
1.4 mm	3 (18.7%)
Intravascular ultrasound	15 (93.8%)
Balloon (pre-laser):	
Yes	9 (56.3%)
No	7 (43.7%)
Lasing:	
Acute phase	10 (62.5%)
Staggered procedure	6 (37.5%)
Fluency [mJ/mm^2]	57.8 ± 11.1
Frequency [Hz]	42.2 ± 18.5

LAD — left anterior descending coronary artery; NSTEMI — non--ST-segment elevation myocardial infarction; RCA — right coronary artery; STEMI — ST-segment elevation myocardial infarction

Results

Between August 2017 and November 2022, 16 cases of underexpanded stents were treated in our cath lab using ELCA with simultaneous contrast injection technique. The mean age of patients was 71 ± 11 years, 2 (12.5%) were women and 13 (81.3%) were diabetics. In terms of diagnosis, 8 (50%) presented with stable angina and 7 (43.8%) with non-ST-segment elevation MI; 1 (6.2%) had recently suffered a ST-segment elevation MI. A 0.9-mm laser catheter was used in 13 (81.3%) cases and a 1.4-mm one in 3 (18.7%). The laser energy and frequency mean values were 57.8 ± 11.1 mJ/mm^2 and 42.2 ± 18.5 Hz, respectively, with laser application duration a median of 100 (80–115) s. In 13 (81.3%) cases, the treated artery was the right coronary artery and in 3 (18.7%), the left anterior descending coronary artery. The average vessel reference diameter was 3 mm and the mean stent diameter and length where laser energy was applied were 3.33 mm and 35.5 mm, respectively. In 10 (62.5%) out of 16 cases, the ELCA technique with simultaneous contrast administration was used as soon as stent underexpansion was detected, and in 6 (37.5%), the procedure was performed in a second step, an average of 18.8 ± 11 days after the first procedure. In 9 (56.3%) cases, the ELCA technique was used after a NC balloon failed to overcome the underexpanded point, and in the remaining 7 (43.7%) cases, a coronary laser was used without prior balloon dilation (Table 1). The MSA assessed by IVUS showed an average increase of 2.34 ± 1.57 mm^2 (confidence interval [CI]:

Table 2. Quantitative intravascular ultrasound features

	Pre ELCA (n = 15)	Post ELCA (n = 15)	P
MSA	5.79 ± 2.24	8.13 ± 2.4	< 0.001
↑MSA ≥ 1 mm²		11 (73.3%)	

ELCA — excimer laser coronary atherectomy; MSA — minimum stent area

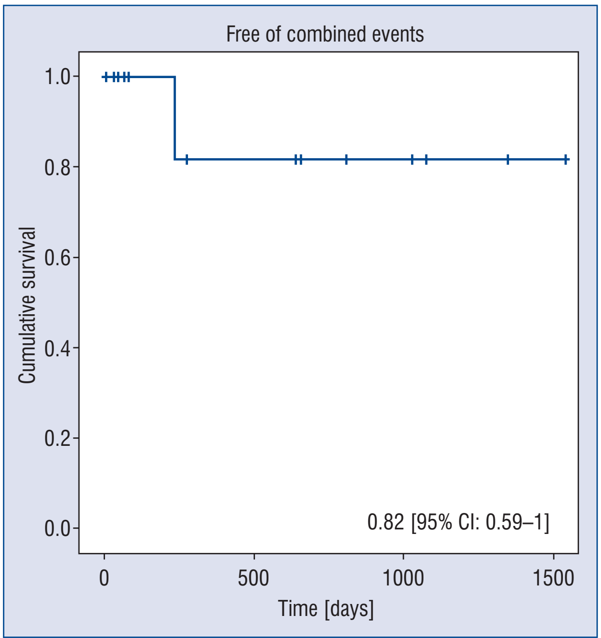

Figure 2. Kaplan-Meier estimator illustrating the event--free rate of the combined major adverse cardiovascular events including death from any cause, new myocardial infarction and target lesion revascularization during a median (interquartile range) follow-up of 457 (50–973) days; CI — confidence interval.

1.47–3.21; p < 0.001) after laser application and NC balloon inflation (Table 2). The average final residual stenosis was 15%. No complications related to the procedure, such as coronary perforation, dissection, slow flow, the no reflow phenomenon or peri-procedural MI, were experienced in the present series. Upon a median (interquartile range) follow-up of 457 (50–973) days, the combined MACE, consisting of all-cause mortality, new MI or TLR assessed by the Kaplan-Meier estimator, showed an event-free rate of 0.82 (95% CI: 0.59–1; Fig. 2) mainly at the expense of 2 (12.5%) deaths due to non-cardiovascular cause. Any new MI or TLR was detected during the follow-up period.

Discussion

The main finding of this single-centre study was that ELCA with simultaneous contrast injection is safe and efficacious as an adjuvant therapy for the treatment of stent underexpansion with an acceptable patient prognosis during the follow-up period.

Excimer laser coronary angioplasty transmits ultraviolet light energy with the ability to ablate inorganic material via a photochemical, photothermal and photomechanical mechanism [9, 13]. Moreover, the interaction of laser energy with the contrast medium can generate microbubbles with pressure pulses > 100 atm [14]. As a result, ELCA can weaken or ablate the underlying tissue surrounding the underexpanded stent, facilitating posterior balloon dilation within the stent.

Stent underexpansion is a challenge for interventionists, and all efforts must be made to avoid such unexpected complications. Calcific coronary lesions require adequate debulking necessitating in some cases the use of high pressure NC balloon dilation instead of conventional NC [15]. MSA > 80% of the average (proximal and distal) reference lumen area has been considered as a target for stent optimization and is associated with low adverse event rate and consequently the latter cut-off is recommended by experts to be adopted in clinical practice [16]. There are some non-conventional treatments to overcome stent underexpansion if post-dilation with a NC balloon fails. The rotational atherectomy technique, academically termed stent ablation, has been used to resolve this complication. However, this strategy runs the potential risk of burr entrapment within the stent, which requires specific techniques aimed to retrieve the device trapping [17, 18]. Cui et al. [5] described an elegant method for the use of stent ablation with a rotablator guided by IVUS and based on the burr size selection principle of 'downsize first and upsize last'. The latter technique consists of using a first burr 0.1–0.2 mm smaller and a second burr 0.1–0.2 mm larger than the minimum lumen diameter. The authors did not experience any burr entrapment, although in 81.8% of procedures, a new stent was implanted.

Intravascular lithotripsy delivers a pulsatile sonic pressure wave via a balloon positioned within the coronary artery with the ability to fracture intimal and medial calcification and energy passing atraumatically through the surrounding noncalcified tissue [19]. IVL has been used as an off-label technique to treat underexpanded stents with

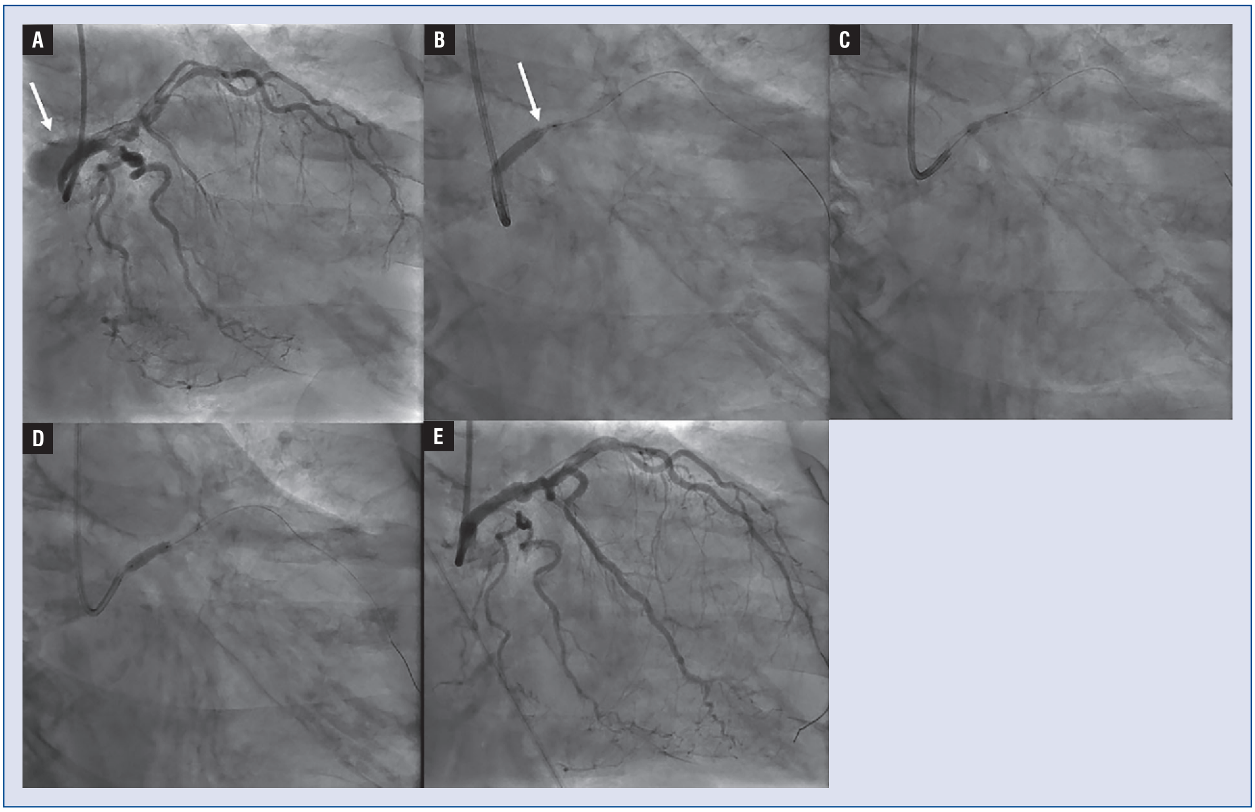

Figure 3. An 87-year-old woman admitted to the documented center due to non-ST-segment elevation myocardial infarction underwent a coronary angiogram. A severe calcified stenosis of the left anterior descending coronary artery (LAD) proximal segment was appreciated during the coronary angiogram, although the injection provoked left main (LM) dissection, which spread antegradely as well as retrogradely to the sinus of Valsalva and ascending aorta (**A**). Any additional injection was avoided, and in order to seal the dissection, the operator decided to implant a direct 3.5 × 16 mm drug eluting stent (DES) in LM-LAD after verifying the correct positioning of the guidewire into the true lumen by intravascular ultrasound (IVUS). However, an important underexpansion in the distal part of the stent was detected (**B**). Dilation with a non-compliant 3.5 × 12 mm balloon could not overcome the underexpanded point (**C**), and an intravascular lithotripsy (IVL) balloon was unable to cross the lesion. The IVUS probe did not cross the tight point either. Excimer laser coronary atherectomy 0.9 mm with a fluency and frequency of 45 mJ/mm^2 and 25 Hz, respectively, and simultaneous contrast injection was used. Afterward, the same non-compliant balloon overcame the stent underexpansion (**D**). The proximal and mid segment of the LAD was significantly diseased, so the procedure was completed by applying a cutting balloon and IVL and implanting a second DES, overlapped with the previous one. A successful angiographic result was achieved with a complete sealing of the dissection at the level of the sinus of Valsalva (**E**), and the patient had an uneventful hospital stay.

promising results [6], although in some severe underexpanded cases, the placement of balloon lithotripsy can be challenging [3], such as in a case illustrated in the present series (Fig. 3). Besides, its effect can be partly attenuated by metal rings of freshly implanted stent [8].

Wańha et al. [20] used IVL aimed to optimize stent underexpansion in 62 patients and achieved a relative stent expansion > 80% as a primary efficacy endpoint in 72.6% of the cases.

One of the basic rules of ELCA usage in the coronary artery is the need to wash out the blood and contrast media with saline serum before laser delivery. The combination of pulsed-wave application of an ultraviolet wave in an on-off method with saline flushing during energy delivery prevents side effects such as dissection or perforation due to coronary wall heating [14, 21]. In fact, both blood and iodinated contrast media contain non-aqueous cellular macromolecules, such as proteins, which can absorb the majority of the excimer laser, creating cavitating microbubbles at the site of energy delivery, which increase the risk of coronary wall injury [22]. By contrast, saline flushing during laser

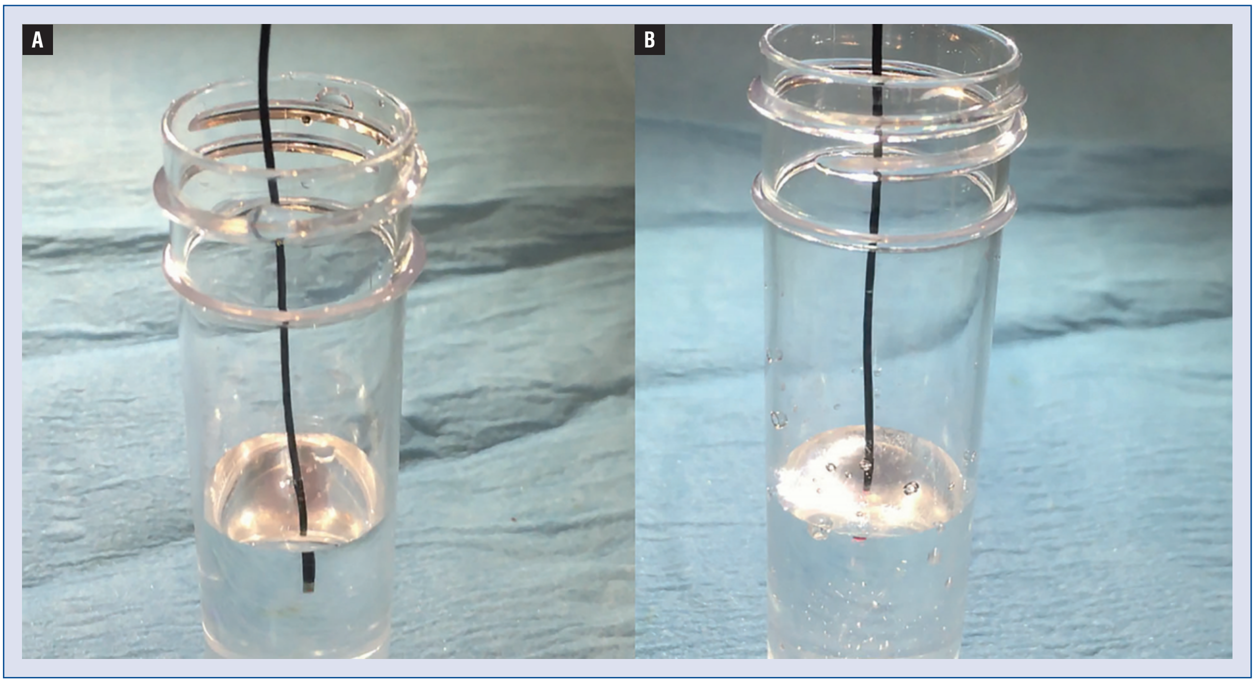

Figure 4. On bench study of laser interaction with saline and contrast milieu. While the saline milieu avoids microbubble formation (**A**), laser interaction with contrast creates a large number of microbubbles (**B**).

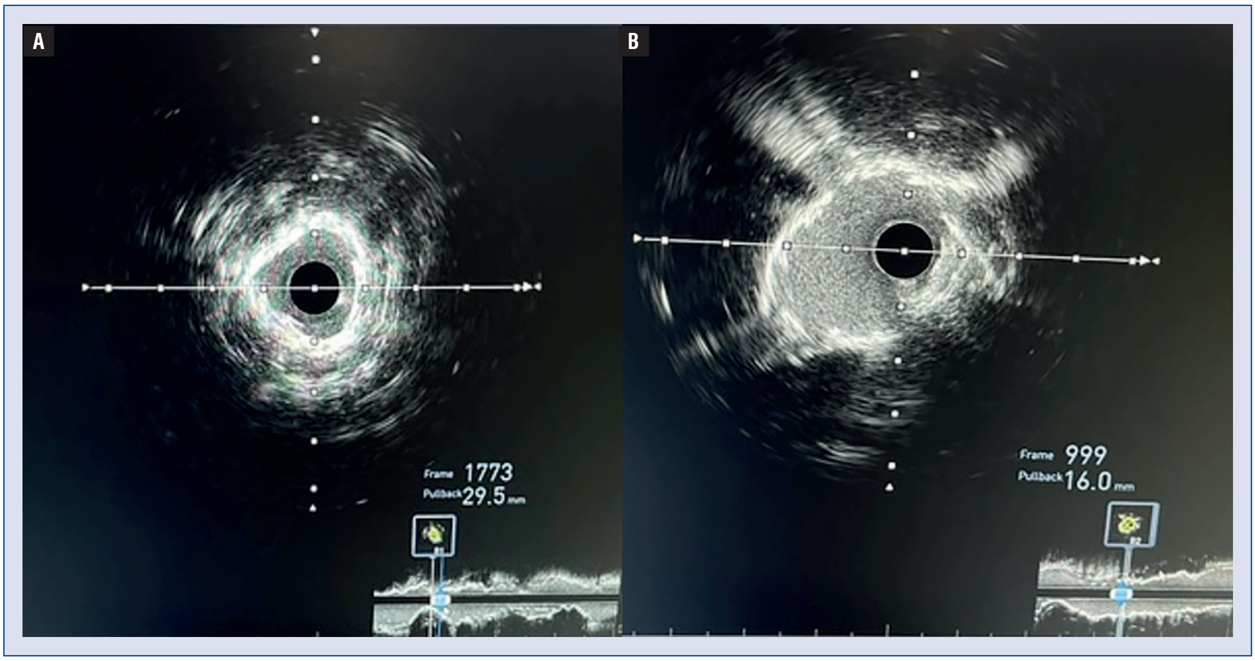

Figure 5. Stent underexpansion circled by a calcified ring (**A**). After laser ablation with simultaneous contrast injection and balloon dilatation the minimum stent area improved significantly (**B**).

delivery avoids the formation of microbubbles in the milieu (Fig. 4).

Concomitant contrast administration during laser delivery and the subsequent creation of microbubbles can weaken and disrupt the fibrotic or calcified tissue beneath the stent strut surrounding the underexpanded stent (Fig. 5) [23]. Indeed, the cardiovascular laser society recommends the use of contrast injection at the highest fluence and repetition rate (80 mJ/mm^2 and 80 Hz), called "explosion technique" in complex lesions such as stent underexpasion, stent restenosis and calcific lesions resistant to balloon dilation for experienced operators [24].

Nan et al. [25] reported the results of 26 patients who underwent ELCA-contrast assisted angioplasty for an underexpanded stent using high energy and a frequency level of 80 mJ/mm^2 and 80 Hz, respectively. The authors achieved ≤ 20% residual stenosis in 58% of cases and a complication rate of 15%, including one acute coronary perforation. Unlike the latter study, a high laser energy level was not used in the current cases and additional intravascular imaging was employed.

Latib et al. [10] used ELCA with concurrent contrast injection in 28 patients with underexpanded stent unsolved despite high-pressure balloon inflation. The authors achieved a successful result in 27 (96.4%) cases, defined as an increase of at least 1 mm^2 in the MSA on IVUS or an increase of at least 20% in the minimal stent diameter by quantitative coronary analysis, following redilation with the same NC balloon. In this series, IVUS could be performed before and after ELCA in 17 out of 28 cases. In the current series, IVUS examination was performed in all but one case in which the IVUS probe could not cross the underexpanded point. Although the mean increase in MSA in our experience was statistically significant in the entire series, using the criteria of an increase of at least 1 mm^2, a procedural success rate of 73.3% was achieved.

One of the main advantages of laser ablation is that the ELCA catheter can be advanced over any 0.014-inch guidewire, in addition to the fact that laser energy delivery does not ablate the stent struts. This is the main difference between laser ablation and the rotational atherectomy technique, which necessarily involves a partial ablation of stent struts and presumably requires implantation of a new stent. In fact, in the present series no new stents were implanted in any underexpanded points.

In order to minimize the risk of the procedure with ELCA ablation in this scenario, precautions must be taken to avoid laser delivery beyond the stent segment, because vessel perforation with this off-label technique is not unlikely, considering that the pressure pulses can exceed 100 atm when simultaneous contrast injection is used, as mentioned earlier.

Limitations of the study

The main limitation of this study is the lack of a control branch using only a NC balloon instead of ELCA plus balloon post-dilatation. The absence of a control group makes it difficult to establish the real efficacy of ELCA as an adjuvant technique for the treatment of stent underexpansion. The definitive facilitating role of laser ablation in stent underexpansion scenarios is limited in the present cohort due to the limited number of cases treated with this adjuvant therapy. Besides, this study has some limitations inherent to any other retrospective studies

Conclusions

Based on our experience, coronary laser with concurrent contrast injection as a coadjuvant therapy aiming to treat stent underexpansion is a safe and effective method and is associated with an acceptable event-free rate in long-term follow-up.

Conflict of interest: None declared

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