# ORIGINAL CONTRIBUTION The Safety and Feasibility of Live-Stream Proctoring for CTO Procedures

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<u>Iotal Occlusion</u> <u>CTO</u> <u>Complex</u> <u>Coronary</u> <u>Percutaneous</u> <u>Interventions</u> <u>Proctoring</u> <u>Telemedicine</u>

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## Abstract

**Objective.** To assess the technical feasibility of a new method of educational training, based on audio-video (AV) communication between an interventional cardiologist and the cath lab staff members in one location and a remote expert proctor. **Methods.** Overall, 9 patients underwent a percutaneous coronary intervention (PCI) targeting a chronic total occlusion (CTO) between June 2021 and January 2022 at a single Belgian center using the virtual proctoring approach. For this assessment, the strategic planning of the CTO PCI and all the decisions throughout the intervention were the responsibility of the proctor. The operator was guided via an AV link, by the proctor throughout the procedure. **Results.** The operator performed each procedural step, guided by the remote proctor, who had continuous access to all relevant interventional details. No major adverse cardiac events (MACE) occurred during the index hospitalization or within 6 months follow-up. **Conclusions.** A new method of virtual proctoring based on live AV communication is feasible, even in the case of highly complex CTO PCI procedures. This strategy also appears safe and may provide the patient the benefit of incremental expertise. This approach is facilitated by advances in AV communication and allows physicians to share expertise irrespective of location. It could increase global interaction between colleagues and facilitate sharing of knowledge, which are both key aspects in the development of CTO PCI. This preliminary experience could serve as a basis for future large studies to study the potential role and benefits of virtual proctoring for complex CTO PCI procedures.

## Introduction

Compared with other PCI, CTO PCI carries a higher complexity with an increased risk of complications, lower success rates, and higher costs.<sup>1-3</sup> Implementation of CTO programs require specific educational training for operators and cath lab staff.<sup>4,5</sup>

There are multiple steps to address these learning needs, which have included primarily didactic learning programs and live case demonstrations. While these remain foundational, in isolation, these are less effective than interactive learning, either ex vivo or in vivo. A challenge remains of how to safely expose the trainee to sufficient complexity. To date, this has been achieved by on-site direct supervision, also referred to as proctoring.<sup>6-8</sup>

Although effective, it is resource intensive, both in time and economics.

Teleproctoring or virtual proctoring may supplement in-person proctoring, due to advances in audio-visual (AV) technology, allowing the virtual proctor to connect to all cath lab members in real time. The fundamentals underpinning the success of on-site proctoring remain the same.

Yet, questions about the ability of the technology to replace the on-site experience remain: Is the information transmitted to the proctor sufficiently granular to permit accurate interpretation of the clinical scenario, and is the flow of information from proctor to cath lab sufficiently seamless?

Hence, we aimed at assessing the feasibility and monitor the safety of virtual proctoring during CTO PCI procedures.

## Methods

**Study population.** Consecutive patients undergoing a CTO PCI under teleproctoring between June 2021 and January 2022 at the Jolimont Hospital, La Louvière, Belgium were enrolled in a prospective registry.

The patient selection for CTO PCI was based on clinical symptoms and documented ischemia or viability. Patients were systematically discussed at the heart team and all members agreed with the performance of CTO PCI. All PCI were performed according to the hybrid algorithm.<sup>9</sup> A CTO was defined as total occlusion of a coronary artery for 3 months or longer based on angiographic evidence. The morphological characteristics of the occlusion were determined according to the Japanese-Chronic Total Occlusion (J-CTO) score.<sup>10</sup>

Baseline patient characteristics, procedural details and techniques, success and possible complications, in-hospital outcomes, and proctor evaluation of AV communication quality were prospectively recorded.

All clinical events were reported by the operator who performed the CTO-PCI. This study was approved by the ethical committee of the institution and all patients provided written informed consent.

**AV system description and streaming.** The Sonar (Incathlab, COM&CO Group) AV system was employed for every procedure. This system includes a local storage server and 2 high-definition Power over Ethernet (PoE) robotic cameras. Similar to traditional security cameras, they are wired for power, video transmission, and internet connection, and can rotate 180° on 2 axis, being controlled by a joystick. The audio communication between interventional cardiologists, nurses, and other cath lab staff members is warranted by a dedicated high frequency audio system with 3 microphones. Both the CTO PCI operator and the proctor use headsets to communicate with each other.

The Sonar (Incathlab, COM&CO Group) audio-video system was employed for every procedure. This system includes a local storage server, 2 high-definition power over Ethernet (PoE) robotic cameras. Similar to traditional security cameras, they are wired for power, video transmission, and internet connection. Also, they can rotate 180° on 2 axis, being controlled by a joystick. The audio communication between interventional cardiologists, nurses, and other cath lab staff members is warranted by a dedicated high frequency audio system with 3 microphones. Both the CTO PCI operator and the proctor use headsets to communicate with each other.

Four specific converters allow simultaneous streaming of video data from angiography, hemodynamic monitoring, highdefinition intravascular ultrasound (IVUS), echocardiography, and the local personal computer (**Figure 1**). The field of view and zoom function is controlled remotely and the resulting image is of high resolution and quality. Access to the platform is secured with a password, and data transfer is encrypted, in order to entirely respect all high standards in terms of patient confidentiality. The system is easy to use and doesn't require an AV professional team. The streaming from the Sonar system needs a current video conferencing application, being compatible with virtually any current AV software, and in our case, the Cisco Webex software was used to settle the communication between the proctors and the cath lab operator.

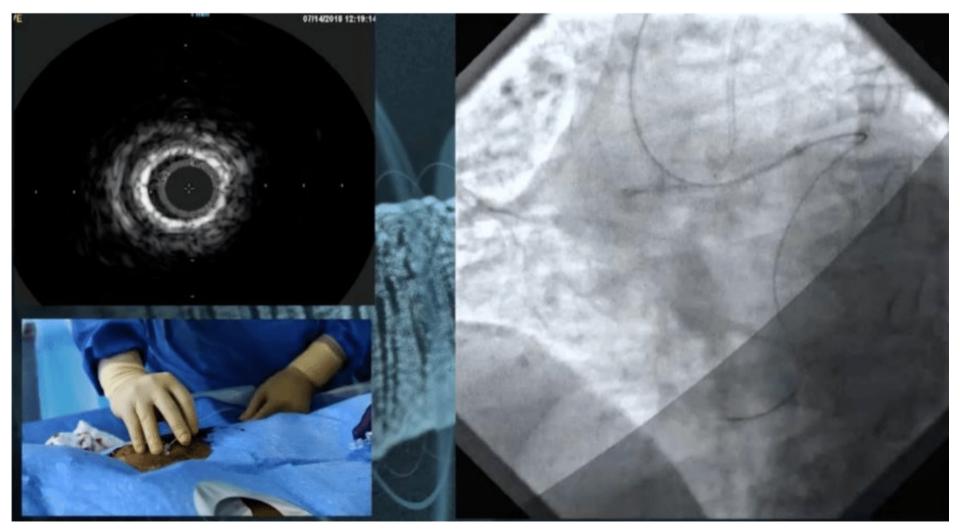


Figure 1. Four specific converters allow simultaneous streaming of video data from angiography, hemodynamic monitoring, high-definition intravascular ultrasound (IVUS), echocardiography, and the local personal computer

**Teleproctoring approach.** After establishing a connection between the proctor and the operator using the Cisco Webex Meetings or Cisco app and the Sonar system, the proctor received all the clinical information and was able to carefully analyze the diagnostic angiograms.

The proctor devised the strategy of the CTO PCI procedure and took all the decisions throughout the intervention. Through his headset, the operator received all the technical explanations from the proctor and was guided step by step throughout the entire procedure. All information from the cath lab was immediately available to the proctor via 2 cameras. At any time, live audio transmission also allowed interaction with any other member of the cath lab team.

The internet connection round-trip time (the duration, measured in milliseconds, from when a browser sends a request to when it receives a response from a server) was less than 60 ms. The Webex application from Cisco was used for virtual video conferencing, allowing simultaneous audio and video interaction between all the participants taking part in this project.

To fully assess the teleproctoring approach, a different proctor was involved in each procedure. All were highly experienced in CTO PCI procedures. All proctors were far from the hospital, 7 of them even abroad. **(Figure 2)** 

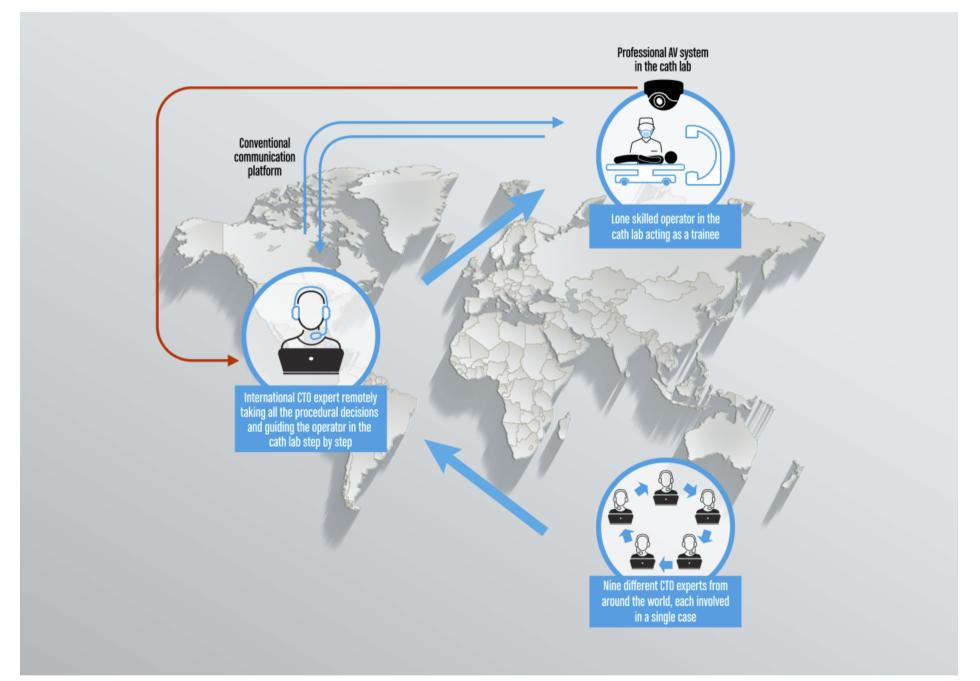


Figure 2. Detailed pictogram with the complex PCI materials needed and with the main procedural techniques employed.

The single operator in this study has performed >100 CTO PCI procedures per year for 7 consecutive years and has proctored >40 CTO PCI per year. As the main goal of this study was to assess the technical feasibility of the AV system, the involvement of an experienced operator fully qualified to independently complete the procedure at any moment was mandatory to warrant an optimal security standard. Regarding the fact that the personal strategy of the first operator could had been different that the proctor's one, the first operator pretended in all cases, to be a trainee and purposely waiting for proctor instructions.

**Study endpoints.** The primary endpoint was the feasibility of this approach, which was defined according to the decisions taken by the operator alone.

According to the CTO-Academic Research Consortium (ARC), technical success was defined as achievement of Thrombolysis in Myocardial Infarction (TIMI)  $\geq$  grade 2 antegrade flow in all  $\geq$ 2.5 mm distal branches with <30% residual stenosis of the target CTO lesion and procedural success was defined as technical success plus the absence of an inhospital MACE, a composite endpoint including death, myocardial infarction (MI), or clinically driven target vessel revascularization (TVR).<sup>10,11</sup>

The secondary endpoint was the occurrence of in-hospital major adverse cardiac and cerebrovascular events (MACCE), a composite endpoint including all-cause death, periprocedural MI, TVR and stroke, and peri-procedural and in-hospital complications.<sup>1</sup> Other complications monitored for included: coronary perforation resulting in cardiac tamponade with or without the need of pericardiocentesis, aortic dissection, access site-related nerve injury, life-threatening or major bleeding (defined as any bleeding associated with one of the following: hemoglobin drops of  $\geq$ 3 g/dL, transfusion of whole blood or packed red blood cells; or procedural intervention/surgery at the bleeding site to reverse, stop, or correct the bleeding),<sup>12</sup> vascular complications (defined as pseudoaneurysm, arteriovenous fistula, femoral neuropathy, retroperitoneal hematoma, hematoma at the access site requiring transfusion/prolonged hospital stay or causing a drop in hemoglobin  $\geq$ 3.0 g/dL; or any access site complication requiring surgical repair), and contrast-induced nephropathy (defined as impairment in renal function, resulting in a 0.5 mg/dL absolute increase in serum creatinine from baseline).<sup>13</sup>

## Results

Nine patients were included in this study, and their demographic and clinical characteristics are shown in **Table 1**. Angiographic characteristics of the treated lesions are shown in **Table 2**. The average J-CTO score was 2.6, implying moderate to difficult CTO PCI. Bi-distal transradial access using the RailTracking technique<sup>14</sup> was used in 8 patients and femoral access in 1 patient who required mechanical circulatory support with an Impella CP (Abiomed) during the procedure (**Table 3**). Antegrade dissection reentry was attempted in 2 patients and antegrade wiring in 7 patients; IVUS was used in 4 patients for stent optimization and revealed subintimal tracking in 2 patients (**Figure 3**).

TABLE 1. BASELINE CHARACTERISTICS	
Age (yrs)	64±12
Male gender	88,8 %
BMI (Kg/m2)	25,9±5,2
Diabetes mellitus	33,3 %
Smoking	66,6 %
Hypertension	88,8 %
Dyslipidemia	100 %
Creatinine (mg/dl)	1,2±0,7 %
LVEF (%)	45±11

Prior MI	33,3 %
Prior PCI	33,3 %
Cerebrovascular disease	11,1 %
Chronic lung disease	11,1 %

TABLE 2. ANGIOGRAPHIC CHARACTERISTICS OF STUDY LESIONS	
Target Vessel	
RCA	5 (55,5%)
LAD	4 (44,4%)
LCx	1 (11,1%)
CTO length (mm) average	36,5
Vessel diameter (mm) average	2,49
Proximal cap ambiguity	8 (88,8%)
Side branch at proximal cap	7 (77,7%)
Blunt stump	6 (66,6%)
Interventional collateral vessels	4 (44,4%)
Moderate/Severe calcification	8 (88,8%)
Moderate/Severe Tortuosity	1 (11,1%)
In-stent restenosis	0
Previously failed CTO PCI	0
J-CTO score average	2.6
Progress CTO score average	1.4

# **TABLE 3. PROCEDURAL CHARACTERISTICS**

## Access site

Distal Radial Artery	8 (88,8%)
Femoral	1 (11,1%)
Crossing Strategies Used	
AW	9 (100%)
ADR with Stingray System	2 (22,2%)
ADR Wire-Based	2 (22,2%)
Retrograde	0
Successful crossing strategy	8 (88,8%)
AW	5 (55,5%)
ADR with Stingray System	1 (11,1%)
ADR Wire-Based	2 (22,2%)
Retrograde	0
Non-CTO vessel treated at same setting	2 (22,2%)
Bifurcation lesion	3 (33,3%)
DK Crush	1 (11,1%)
Nano Crush	2 (22,2%)
Left Main PCI	1 (11,1%)
Number of stents in CTO vessel	1,8±0,8
Total stent length (mm)	58±21
Hemodynamic support	1 (11,1%)
Fluoroscopy time, min	38±24
Contrast volume, mL	161±54
Radiation exposure dose, Gy	1.8±2.2

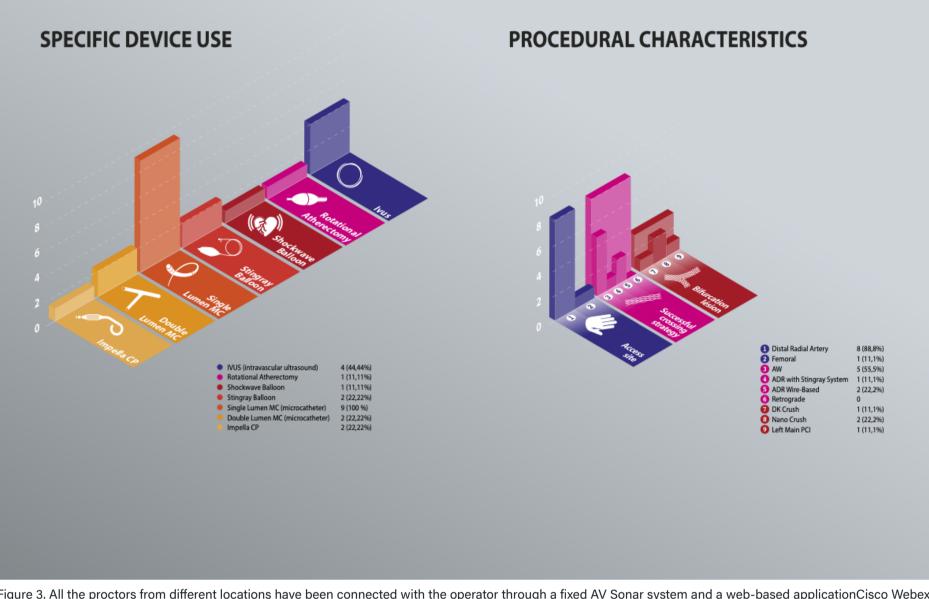


Figure 3. All the proctors from different locations have been connected with the operator through a fixed AV Sonar system and a web-based applicationCisco Webex software.

All the procedural steps were performed by the operator guided by the remote proctor, and the proctor guided the operator through unexpected technical issues. No single decision was taken by the operator alone as the proctor was able to notice perfectly all the angiographic details and other important parameters recorded by the AV system.

All the strategy proposals from the proctor were recorded and the most important ones are described here: For all patients, the proctors highly recommended the use of dual injection and a systematic angiographic review to determine the initial CTO crossing strategy.

*Case 1:* RCA CTO with J-CTO 2 (length and a proximal cap ambiguity). After evaluating all of the options, the proctor proposed an anterograde approach. The collateral channels were considered inappropriate to be used, regarding their sizes and tortuosity. The first operator had the same evaluation as the proctor, who considered the quality and resolution of the images being optimal for the analysis.

After using a balloon-assisted subintimal entry (BASE), a polymer jacket wire (Gladius MG, Asahi Intecc) was crossed in a knuckle fashion with the intention to define and mark the vessel course. During the anterograde dissection-reentry (ADR) with a Stingray device (Boston Scientific), the proctor decided to try multiple highly penetrative wires as Confianza 12 or Astato 20 (Asahi Intecc) after seeing the behaviors of the wires and receiving all the explanations that he asked from the operator. Unfortunately, the true lumen was not found and the proctor proposed a subintimal angioplasty and a subintimal

tracking and reentry (STAR) as a final attempt in full agreement with the operator, who would have proceeded in that same manner had he been acting alone.

*Case 2:* Left anterior descending (LAD) artery CTO with J-CTO 2 (length and a proximal cap ambiguity) was occluded just after the origin of the first diagonal. Following the proctor suggestion, an IVUS probe was placed into the diagonal branch to guide the wiring with a Gaia 3.

Again the proctor gave positive feedback regarding the quality of the IVUS images. After advancing the microcatheter into the CTO body, the proctor strongly advised the de-escalation with a low penetrative wire as Fielder X-TR, which was able to wire the distal LAD correctly. The first operator admitted that he would have continued with the same wire. The procedure was completed after the implantation of one drug-eluting stent (DES) by provisional technique.

*Case 3:* RCA CTO with J-CTO 3 (proximal cap ambiguity length, calcifications). The proctor preferred a first anterograde attempt with a medium polymeric wire (Gladius), which was used to track the extraplaque space. The visual feedback of the wire distal tip, the retrograde injection, and all the information given by the operator was necessary to confirm the wire position and to let the proctor propose a reentry by Stingray balloon. After a successful puncture with the Confianza 12g, the procedure was completed after 3 DES implants.

*Case 4:* Circumflex artery (Cx) CTO with J-CTO 0. The CTO was wired with Fielder XT-R easily using a microcatheter. The proctor preferred to confirm the position of the wire by advancing it during the contralateral injection. This maneuver has the benefit of better understanding the wire position, avoiding the need for multiple contrast injections, and decreasing the chances of wrong interpretation of the distal course of the wire.

*Case 5:* RCA CTO with J-CTO 1 (length) was attempted successfully with Fielder XT-R, which tracked the true distal lumen of the posterior-descending artery (PDA). The proctor strongly asked for an IVUS run, which showed an extraplaque course of the wire exactly at the level of the crux followed by a reentry directly in the PDA. A Gaia 3 reentry into the posterolateral (PL) branch was possible using a double-lumen microcatheter. In this particular case, the involvement of the proctor was extremely important in order to avoid the stenting of the distal RCA towards the PDA and losing completely the access to the PL.

*Case 6:* A short CTO of the LAD was wired fro an anterograde approach with a Fielder XT-R. The mid and distal LAD were diffusely diseased. The proctor tailored the approach upon IVUS findings, allowing an optimal result after completing the PCI with 2 DES.

*Case 7:* RCA CTO with J-CTO 1 (length). The proctor chose an anterograde approach as a first strategy. After sharing multiple tips and tricks regarding the optimal way to manipulate the Gladius wire by the operator, the distal true lumen was found and the case was successfully completed after implanting 3 DES.

*Case 8:* RCA CTO with J-CTO 1 (calcium). The proctor chose an anterograde approach as the first strategy proposing an Ultimate Bross wire that successfully crossed into the PDA. The distal crux of the RCA was involved and after following all the indications of the proctor regarding the need for a dual lumen microcatheter, the type of wire to use and how to realize the optimal shape of the distal tip, the operator was able to gain access to the true lumen of the PLA and successfully recanalize the RCA CTO.

*Case 9:* LAD CTO with J-CTO 2 (length and calcium). Non-CTO lesions: severe left main (LM) disease and critical highly calcified ostial of a large dominant CX artery in the context of acute coronary syndrome and severely impaired left ventricular dysfunction. The proctor strongly argued for prophylactic hemodynamic support with the Impella CP catheter and to start with the recanalization of the LAD in an anterograde fashion. After wiring the distal true lumen of the LAD with a Fielder XT-R wire and exchanging it with a workhouse wire, an IVUS run showed 2 rings of calcifications in the proximal LAD, which had been treated by rotational atherectomy. The proctor had the opportunity to interpret for himself the IVUS findings as in the previous cases where the proctors took responsibility for all technical decisions. The ostium of the CX was prepared by coronary lithotripsy, as the proctor was reluctant to repeat the rotational atherectomy due to the risk of decreasing the flow in a dominant major vessel. The PCI was successfully ended after a double kissing crush for the LM, and a complete revascularization on the LAD and the CX was achieved. No major complications occurred during the index hospitalization. No MACCE occurred within 6 months of follow up.

## Discussion

Our pilot study showed that remote proctoring for CTO PCI is feasible. The AV system was highly accurate and the proctor

could get all the information needed, even precise angiographic details such as small collateral channels or visual feedback of the coronary wire tip movements.

Regarding the cath lab, the AV system allowed a perfect audio communication without disturbance of the workflow or of the interactions between the people directly involved in the procedure.

Although the CTO PCI were highly complex as proven by the J-CTO scores, the technical success was 100% and both the procedural and short-term patient outcomes were excellent. While the proctors were not physically present, they were fully immersed in the cath lab environment and in the procedure due to an easy-to-use AV system and reliable internet connection (**Figure 2**). Using audio feedback from the local operator and smart visualization of all relevant imaging, electrocardiogram (ECG), and hemodynamic data, the experienced proctors were able to guide the operator through a complex procedure (**Figure 3**); the latter actually acting as a "human robot" rigorously following the instructions from the proctor.

Average CTO PCI success rates range between 60% and 70% outside of a few expert centers, highlighting the need for on the job training to improve success rates in a broader interventional cardiology practice.<sup>9</sup> Notably, these aspects strongly emerged in the hands-on proctorship project,<sup>7</sup> where the operators, after being guided in choosing the proper strategy, achieved an excellent success rate regardless of their technical skill levels. Similar experiences have been reported in the surgical field as well, where the rapid pace of technological advancements and the need for professionals to stay up-to-date with the latest tools and techniques have created a need for ongoing education and training. Mentorship programs that pair experienced professionals with less experienced ones can be a valuable resource in helping transfer knowledge and skills, and ensure that new technologies are used effectively and safely.<sup>15,16</sup>

In our study, the operator alone did not purposely take any single decision, thus supporting that the AV system is powerful enough to broadcast high-quality information, allowing the external participation of another physician as if they were physically present in the cath lab.

The CTO-PCI field is very dynamic. Rapid and major improvements, including procedural algorithms, new devices, and therapies have been introduced in routine clinical practice in the last few years. Therefore, readily available means of communication and sharing of medical knowledge targeting a higher frequency of interactions between peers may be valuable.

Despite the high complexity of the CTO-PCI performed, no acute complications occurred during index hospitalization. Despite the limited number of patients included in the study, the teleproctoring conducted in our study appeared to be safe.

In addition, if a catastrophic complication occurs in a complex setting, the life of the patient may be in danger even if the operator is highly experienced. In this particular scenario, having an expert connected to the cath lab could potentially help resolve the complication.

What an operator's level of experience should be to be guided exclusively through remote proctoring has yet to be determined. Some theoretical background and practical experience in CTO PCI and complication management through inperson proctoring are likely to be required.

We strongly recommend that the operator goes through a conventional on-site training proctoring for complex procedures before being guided by a teleproctor. A minimum level of autonomy is certainly required in the event of a technical issue or technical failure, such as a slow internet connection or even sudden connection loss. From the proctor's perspective, teleproctoring is more demanding in terms of expertise and the set of skills required. Since they cannot scrub, some details like the tactical feedback information are missing.<sup>17,18</sup> A clear distinction between on-site proctoring and teleproctoring needs to be highlighted: the on-site proctoring program is mainly designed for operators who are beginning their training, as it provides them with a strong foundation of knowledge and skills and helps them get off to a good start in their careers, or in specific situations where they need an expert in the room to tackle complex or high-risk cases. Teleproctoring, on the other hand, is aimed at a wider audience of physicians, at various levels of experience, with the goal of transferring knowledge, focusing on new techniques or devices, and improving the safety and efficacy of interventions through remote monitoring by an expert who may be located anywhere. This approach can be particularly helpful, as the virtual proctor can provide guidance and support, and help the operators address any questions or concerns they may have.

Educational efforts need to target not only the learner but the whole operating team. Teleproctoring seems particularly efficient in providing a complete image of all the cath lab operations through multiple video cameras, enabling the proctor to observe, oversee, and even actively supervise all the participants at the same time.

Overall, on-site proctoring and teleproctoring each have their own advantages and limitations, and the choice between the 2 will depend on the specific needs and goals of the training program.

### Conclusions

A new method of virtual proctoring based on live AV communication is feasible from both the proctor and the operator perspective, even in cases of highly complex CTO PCI procedures. This modern approach is easy to organize between physicians regardless of their location. It could potentially increase global interaction between colleagues and facilitate the sharing of knowledge, which are both major key aspects in the development of the CTO PCI field.

This study could serve as a basis for future large studies to fully analyze the potential role and benefits of virtual proctoring for complex CTO PCI procedures.

## Affiliations and Disclosures

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