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Patient Safety and Outcomes From Live Case Demonstrations of Interventional Cardiology Procedures

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Objectives The goal of this study was to examine the safety and results of interventional procedures performed during the broadcast of live case demonstrations.

Background Professional meetings using live case demonstrations to present cutting-edge technology are considered a valuable educational resource. There is an ongoing discussion on whether patients who are treated during live case demonstrations are exposed to a higher risk.

Methods Between 1998 and 2010, 101 patients were treated during live transmissions from a single center in 15 invasive-cardiology conferences. Technical success was defined as the ability to effectively perform the planned procedure without any major complication. The primary endpoint of the study was the composite occurrence of death, myocardial infarction, or stroke.

Results The interventional procedures included coronary (n = 66), carotid (n = 15), peripheral (n = 1), valvular (n = 2), congenital heart disease (n = 12), and complex electrophysiological mapping and ablation interventions (n = 7). In 4 cases, the intended procedure was not done. The procedure was technically successful in 95%. In 5 cases, the procedure was unsuccessful because of the inability to cross a chronic total occlusion. There were no deaths during the hospital stay, and the composite primary endpoint occurred in 2 patients: a minor stroke following an atrial fibrillation ablation and a rise in serum troponin levels after percutaneous coronary intervention. These results were no different from those of 66 matched controls who underwent procedures performed by the same operators but not as live case demonstrations (relative risk: 0.32; 95% confidence interval: 0.02 to 3.62, p = 0.62).

Conclusions In this consecutive series of interventional cardiology procedures that were performed by expert operators during live demonstration courses, the procedural and 30-day clinical outcomes were similar to those found in daily practice and to those that have been reported in the contemporary published data. These results suggest that broadcasting live case demonstrations in selected patients from selected centers may be safe. (J Am Coll Cardiol Intv 2012;5:215–24) © 2012 by the American College of Cardiology Foundation

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The number of transcatheter cardiovascular interventions has increased dramatically and the technique has improved significantly during the past decades. Newer and better devices, improved pharmacological treatments, and enhanced visualization, guidance, and monitoring now enable a safer and more efficacious procedure. As a result, the periprocedural event rate has fallen over the past years (1,2).

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The training in interventional cardiology involves direct mentoring by experienced cardiologists during an actual clinical procedure, as well as learning from peers during professional meetings and focused courses. Rapid advances in technology, the demand to improve quality and safety, and the dissemination of information on new tools, equipment, and state-of-the-art interventional techniques have led to the development of courses with live case demonstrations around the world for dissemination of information and training purposes.

Abbreviations and Acronyms

CI = confidence interval
CTO = chronic total occlusion
EP = electrophysiological
FDA = Food and Drug Administration
MCRS = Mayo Clinic Risk Score
MI = myocardial infarction
PCI = percutaneous coronary intervention
RR = relative risk
VF = ventricular fibrillation
VT = ventricular tachycardia

The growth in the number of meetings with live case demonstrations of interventional procedures is true not only in cardiology, but also in surgery, gastroenterology, and other medical disciplines. In cardiology, the procedure is performed in the catheterization laboratory and is transmitted to a conference hall, which can be in the same medical center, but often is at another location on the globe.

It is assumed that during live case demonstrations, the operators perform the procedure in a more stressful environment than in daily routine work. There are cameras and production personnel in the catheterization laboratory, and an expert panel in the conference hall interacts with the operator and team, discusses the case, and advises what they think should be done. Every step of the procedure is broadcast onto large screens. Frequently, novel devices are used, and the cases that are chosen for the demonstration are exceptionally challenging because the "regular" cases are not as educational or informative. The operator and the team are required to discuss their plans and rationale with the panel or the audience while still in the midst of the procedure. Thus, the operator and the team have to deal, not only with a complex procedure, but also with an expert panel that may often criticize the interventional plan, and may even suggest an alternative approach.

There has been an ongoing discussion about the ethics of live demonstration and the patient safety of these procedures from the early days of live demonstration broadcasts of interventional procedures (3–10). Despite the increasing use of this educational modality in medical meetings, there are only 2 published reports that have investigated the patients' safety during live case demonstration in transcatheter therapeutics: 1 report from 1992 on coronary procedures, and a second report from 2009 on carotid interventions (4,5). Therefore, we sought to examine the results of transcatheter cardiovascular procedures that were performed during live demonstration transmissions at our center since 1998.

Methods

This study was performed in compliance with the local human studies committee. The study is comprised of all patients in whom a procedure was attempted and transmitted live to interventional cardiology conferences, which our center organized or participated in between 1998 and 2010. The primary operators were experienced cardiologists from our center and, in only a few cases, international guest operators. Overall, 8 primary operators participated in coronary procedures, 2 operators in pediatric procedures, and 4 in electrophysiological (EP) procedures. In all cases, 1 or 2 additional secondary operators participated. The medical conferences were international and national. Written informed consent for treatment and live transmission of the procedure was received from all patients before the procedure. The procedure was performed in the standard way, and all medications were given in the customary manner.

The operators were connected to microphones, and the filming staff was present in the room. The operators discussed each step of the procedure and responded to the many comments of the expert panel. The discussion took place before the procedure was done, during the procedure, and after completion. In the annual local meetings, which have been organized by our center since 1998, there were parallel transmissions of live demonstrations from 3 catheterization laboratories. In these cases, the operators needed to pause according to the scheduled transmission slot. Hence, some of these procedures took longer than usual to complete. In all these cases, patient safety was always the top priority. When scheduling caused a significant delay, parts of the procedure were not transmitted live, and the procedure presentation, as well as the discussion, were done at the end of the procedure.

Data were collected from the medical records, procedure notes, catheterization films, conference programs, live case schedules, and follow-up visits.

Definitions

Successful intervention. A procedure was defined as successful when the intended goals were achieved and the procedure was completed in the absence of any major complications.

Partial success. If the intended coronary procedure involved the treatment of multiple lesions, and not all planned lesions were eventually treated, the procedure was classified as being partially successful. For example, if 4 lesions were planned to be stented during the live demonstration, and not all of the lesions were treated, the procedure was defined as being partially successful.

Major complications and the primary and secondary endpoints. The primary endpoint was the composite of all-cause death, myocardial infarction (MI), and stroke. The secondary endpoints were death, MI, stroke, or repeat procedure within 30 days after the first procedure.

Diagnosis of MI. The diagnosis was based on the definition at the time of the intervention and was based on the joint definition of the European Society of Cardiology/American College of Cardiology for acute MI in 2000, then adapted to the definition of European Society of Cardiology/American College of Cardiology Foundation/American Heart Association/World Heart Federation in 2007 (11,12).

Elevations of troponin above the 99th percentile of the upper reference limit after percutaneous coronary intervention (PCI), assuming a normal baseline value, indicated post-procedural myocardial necrosis for noncoronary procedures. Increases more than 3 times the 99th percentile of the upper reference limit were classified as PCI-related MI (type 4a). MI was determined according to the change of troponin together with at least 1 of the following: symptoms of ischemia; electrocardiographic changes indicative of new ischemia (new ST-T changes or new left bundle branch block) or new left bundle branch block; development of pathological Q waves in the electrocardiogram; imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.

Minor complications. These were defined as any result or event that occurred during or after the procedure that was unexpected or unwanted, such as vessel closure, significant arrhythmias, perforations, tamponade, need for urgent surgery, access site complications, and hemodynamic instability.

Control Group and Statistical Methods

The number of EP and congenital abnormalities procedures is small, and thus it is difficult to compare the outcomes of these patients to parallel routine cases. We compared our coronary patients treated during live transmission (n = 66) to our daily experience during 1 year (n = 2,039) and to a matched control group (n = 66).

The following variables were used for matching the control group: extent of coronary artery disease, anginal status, age, sex, and hyperlipidemia. Data are expressed as mean ± SD. Baseline characteristics of the groups were compared using unpaired *t* test for continuous variables and by the chi-square statistic for noncontiguous variables. A 2-sided exact Fisher-Irwin test with a 5% significance level was applied for comparison of specific events between the groups. The relative risk (RR) and 95% confidence intervals (CI) comparing the live case demonstration group and the 2 control groups were determined. All statistical analyses were performed using the SPSS statistical software (Version 15.0, IBM, Armonk, New York).

Results

Between 1998 and 2010, we identified 120 patients at our center who were scheduled for live case transmission during 15 interventional conferences. Because of time constraints or schedule changes due to urgent cases during the meetings, 19 live cases were not done at the scheduled time, but were treated later on the same day or the next day.

Table 1. Procedures Performed During Live Transmissions

Coronary procedures	66
Carotid procedures	13
ICA	10
CCA	2
Aborted	1
Congenital heart procedures	12
ASD closure	4
PFO closure	3
VSD closure	2
PDA closure	2
COA angioplasty	1
EP procedures	7
Ablation of VPBs/short VT of RV outflow	2
Ablation of foci of PAF around PV	2
Ablation of EP foci originating in scar	1
EPS mapping to detect right ventricular dysplasia	1
Ablation using Carto mapping for SVT	1
Stent insertion in subclavian artery	1
Combined coronary and pediatric procedure: stent insertion into RCA with ASD occlusion	1
Combined coronary and carotid procedures	2
Stenting of LAD with stenting of LCCA	1
Stenting of RCA with stenting of RICA	1
Transcatheter aortic valve implantation	2

ASD = atrial septal defect; CCA = right common carotid artery; COA = coarctaion of aorta; EP = electrophysiology; EPS = electrophysilogic study; ICA = internal carotid artery; LAD = left anterior descending coronary artery; LCCA = left common carotid artery; LV = left ventricle; PAF = paroxysmal atrial fibrilation; PDA = patent ductus arteriosus; PFO = patent foramen ovale; PV = pulmonary veins; RCA = right coronary artery; RICA = right internal carotid artery; RV = right ventricle; SVT = supraventricular tachycardia; VPBs = ventricular premature beats; VSD = ventricular septal defect; VT = ventricular tachycardia.

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Therefore, our study population comprised 101 patients in whom the procedure was done during a live transmission. The age of the patients ranged from 5 to 86 years (62 ± 14 years), and 21 (21%) were females. Table 1 summarizes the interventional procedures, which consisted of a range of coronary interventions, carotid stenting, valvular interventions, congenital heart diseases, and EP interventions. Sixty-six patients (66%) underwent coronary interventions. We performed a combined coronary and congenital heart defect procedure in 1 patient, and a combined coronary and carotid procedure in 2 patients.

The clinical characteristics of the patients that underwent coronary interventions are presented in Table 2. The majority of patients were smokers and had hypertension and hyperlipidemia. The target vessels of the planned coronary procedures are detailed in Table 3. Sixty-two percent of the coronary patients had multivessel disease, and the left anterior descending coronary artery was involved in 48%.

Major Complications

The rate of major complications was 2 of 101 (2%). There were no deaths during the procedure or during the hospital stay. In 1 patient following PCI, the serum troponin levels increased above the upper reference limit, and the patient was classified as having a PCI-related MI (type 4a) (11). There was 1 case of a stroke in a 61-year-old patient who underwent pulmonary vein isolation for atrial fibrillation. Following the EP ablation, a disturbance in the patient's speech and a right hemiparesis appeared. Brain computed tomography did not demonstrate cerebral bleeding. The patient was discharged with a mild disturbance of speech, which had completely resolved at follow-up.

Procedure Completion and Success Rate

Of the 101 live transmitted procedures, 4 patients were not treated after the angiography (Fig. 1). In a 72-year-old man with an ST-segment elevation MI scheduled for PCI intended to be transmitted live, coronary angiography demonstrated 3-vessel coronary artery disease, and the operators and the expert panel decided not to proceed with PCI, and instead referred the patient for coronary artery bypass surgery. A planned carotid procedure was not done because the stenosis previously diagnosed by Doppler in the left internal carotid artery was proven to be in the left external carotid artery after several angiographic views. An EP procedure was not continued in a 52-year-old man who was scheduled for right ventricular outflow tract tachycardia ablation because ventricular premature beats could not be provoked even after an aggressive pacing induction protocol. A second EP procedure was aborted in a 25-year-old patient with right ventricular dysplasia that was referred for ablation, because 2 sources of ventricular tachycardia (VT) were identified, and it was decided to treat the patient with an implantable cardioverter-defibrillator rather than with the intended ablation.

Intervention success. The overall success rate was 95% (in 92 of 97 procedures attempted). However 8 procedures (8%) were classified as being partially successful, 6 of these partial successes were coronary interventions (Online Table 1). Thus, in 83% of patients, the procedure was classified as successful by our strict definition of intended procedure completed fully and in the absence of any major complications.

Five procedures, all of them with coronary interventions, were classified as being unsuccessful. All were cases of chronic total occlusions (CTOs) with failure to cross the lesion with either a guidewire or a balloon catheter. Overall, 10 CTOs were attempted, and the success rate in this type of lesion was 50%.

Minor Complications and Other Events

Among the 66 coronary procedures, there were 3 cases of ventricular fibrillation (VF) that were successfully converted to sinus rhythm using direct current shock, and 1 case of guidewire-induced coronary artery perforation that was clinically uneventful. Post-procedural complications included 2 access site bleedings. There was a tamponade during a congenital heart disease procedure, which was treated successfully with pericardiocentesis in the catheterization laboratory, and 1 access site complication.

Other minor events included 2 cases of vasovagal reactions with prolonged hypotension, 4 cases of type B or C dissections of a coronary vessel, allergic reaction (n = 1), and hypertension (n = 1).

Among the patients undergoing EP procedures there was 1 case of complication in a 72-year-old man who was treated for ventricular premature beats that originated from an inferoposterolateral scar. After induction of VT (160 beats/min), the heart rate deteriorated to rapid VT (220 beats/min) with loss of consciousness, and an electrical shock for cardioversion was required. During carotid angioplasty there were 2 cases of vasovagal reactions.

Follow-Up

1 month. During the 30-day follow-up available for all patients, there were no deaths or strokes; repeat coronary angiography was performed in 2 patients: 1 patient with stent thrombosis and another patient with chest pain and without any angiographic findings.

1 year. One-year follow-up was available for all patients, and no deaths, strokes, or MIs were reported. Coronary angiography was performed in 1 additional patient, but no intervention was needed. Routine angiographic follow up was not performed in any patient. There were no cases of clinical restenosis.

Table 2. Patient Characteristics

	Live Transmission (n = 66)	Matched Controls (n = 66)	p Value vs. Matched	Routine (2010 Cohort) (n = 2,039)	p Value vs. Routine
Sex			0.82		0.31
Male	53 (80)	55 (83)		1,525 (75)	
Female	13 (20)	11 (17)		514 (25)	
Age, yrs			0.71		0.75
<49	8 (12)	6 (9)		324 (16)	
50–59	17 (26)	22 (33)		573 (28)	
60–69	24 (36)	15 (23)		613 (30)	
>70	17 (26)	23 (35)		529 (26)	
Risk factors					
Current smokers	17 (26)	15 (23)	0.84	501 (25)	0.82
History of smoking	24 (36)	17 (26)	0.26	858 (42)	0.35
Hypertension	45 (68)	47 (71)	0.85	1,204 (59)	0.13
Renal dysfunction	7 (11)	6 (10)	0.91	122 (6)	0.12
Diabetes	23 (35)	23 (35)	1.00	695 (34)	0.97
Hypelipidemia	52 (79)	51 (77)	0.83	988 (48)	0.03
Family history of IHD	18 (27)	16 (24)	0.84	371 (18)	0.07
Vessel disease					
1VD	24 (36)	25 (38)	0.92	518 (33)	0.52
2VD	22 (33)	22 (33)	1.00	496 (31)	0.71
3VD	19 (29)	19 (29)	1.00	443 (28)	0.86
LMCA involvement	3 (5)	0 (0)	0.97	134 (8)	0.81
Symptoms					
Stable angina pectoris	27 (41)	38 (57)	0.06	418 (21)	<0.001
Unstable angina pectoris/NSTEMI	20 (30)	24 (36)	0.46	790 (39)	0.15
STEMI	3 (5)	3 (5)	1.00	288 (14)	0.009
Atypical angina	5 (8)	1 (2)	0.09	57 (3)	0.06
Other/unknown	11 (16)	0 (0)	0.01	486 (23)	0.18
Past interventions					
PCI	39 (59)	18 (27)	<0.001	985 (48)	0.07
CABG	3 (5)	4 (6)	1.00	172 (8)	0.11
PCI and CABG	10 (15)	5 (8)	0.17	144 (7)	0.02
Use of pressure wire	10 (15)	5 (8)	0.17	69 (3)	0.01
Use of IVUS	23 (35)	8 (12)	0.002	101 (5)	0.049
Irradiation treatment for in stent restenosis	3 (5)	0 (0)	0.08	0 (0)	<0.001
Use of high-speed rotational atherectomy	1 (2)	0 (0)	0.33	3 (0.1)	0.03
Vessel territory*			0.42		
LAD	32 (48)	29 (44)			
RCA	21 (32)	25 (39)			
LCX	25 (38)	19 (29)			
Grafts	6 (9)	2 (3)			
Lesions treated, n			0.31		
0	1 (2)	0 (0)			
1	31 (47)†	42 (63)			
2	18 (27)	18 (27)			
3	9 (14)	5 (8)			
4	2 (4)	1 (2)			
5	1 (2)	0 (0)			

Values are n (%). The characteristics of the patients who underwent live transmission coronary procedures are compared with our routine 2010 experience and 66 matched controls. *More than 1 territory was treated in several patients. †A combined procedure was done in 3 patients.

CABG = coronary artery bypass grafting; IHD = ischemic heart disease; IVUS = intravascular ultrasound; LCX = left circumflex coronary artery; LMCA = left main coronary artery; NSTEMI = non–ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction; VD = vessel disease; other abbreviations as in Table 1.

Table 3. Comparison Between Coronary Study Group and Matched Controls

	Live Transmission (n = 66)	Matched Controls (n = 66)	RR (95% CI)	p Value
In-hospital				
Death, MI, stroke	1	3	0.32 (0.02–3.62)	0.62
Death	0	0		
Stroke	0	0		
MI	1	3		
Unsuccessful	5	3	1.72 (0.33–9.57)	0.72
Minor complication	6	4	1.55 (0.36–6.98)	0.74
Discharge to 30 days				
Death, MI, stroke, repeat intervention	1	0	4.42 (0.17–77.7)	1.0
Death	0	0		
Stroke	0	0		
MI	1	0		
Repeat intervention	1	0		

CI = confidence interval; MI = myocardial infarction; RR = relative risk.

Overall, the 1-year event rate free of major events (death, MI, stroke, repeat revascularization) in all patients treated during live case demonstration was 97%.

Mayo Clinic Risk Score

The Mayo Clinic Risk Score (MCRS) (9) has 7 simple clinical and diagnostic variables for predicting in-hospital mortality after PCI. The distribution of the MCRS of the coronary patients in the present study was Gaussian (Fig. 2). The MCRS of 50% of the patients was between 1 and 5, and 40% of the patients had a score between 5 and 8, which correlated to a predicted mortality rate of 2% to 5%. There were no deaths in this cohort of patients.

Comparison to Routine Practice, Non–Live-Transmission Procedures

When we compared the results of the live-transmission coronary patients to our daily experience and patient mix undergoing coronary procedures during 1 year (2010), we observed that baseline characteristics of the 2010 cohort were similar to the present study group with regard to sex, age, and most risk factors. However, not surprising, the live-transmission group presented more often with stable angina compared with the more acute coronary syndromes in daily non–live-transmission cases. In the live-transmission group, there was a more frequent use of intravascular ultrasound and pressure wire (Table 2).

Matched Controls

We compared our study patients to a corresponding matched control group, all from the 2010 cohort (Table 2). The groups were well matched with regard to sex, age, risk factor profile, disease severity, and symptoms.

In the matched control group, there were no in-hospital deaths or strokes, but there were 3 cases of post-intervention myocardial infarction. The primary endpoint of the study was not different between the study group and the matched

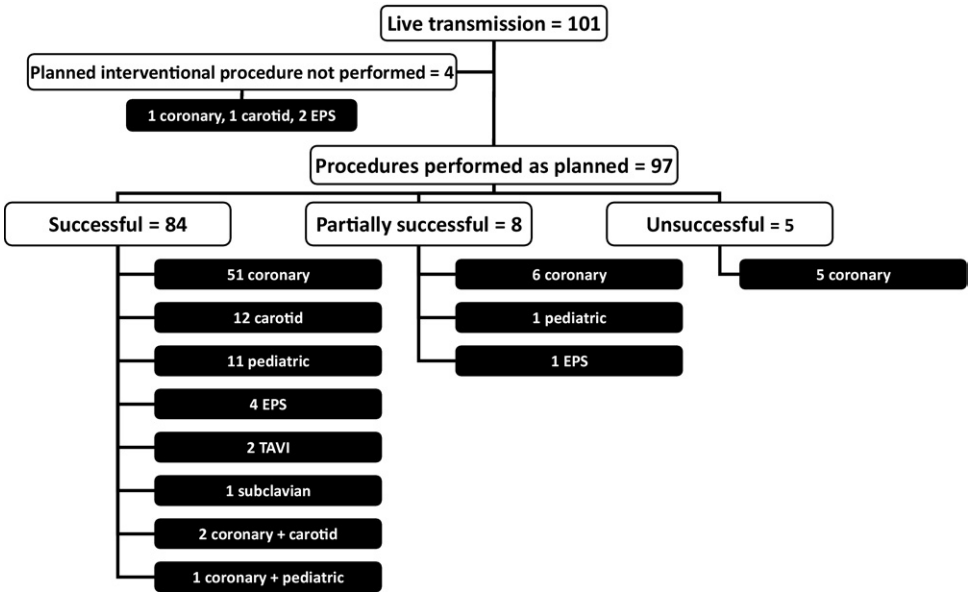

Figure 1. Study Interventions and Success

EPS = electrophysiological study; TAVI = transcatheter aortic valve implantation.

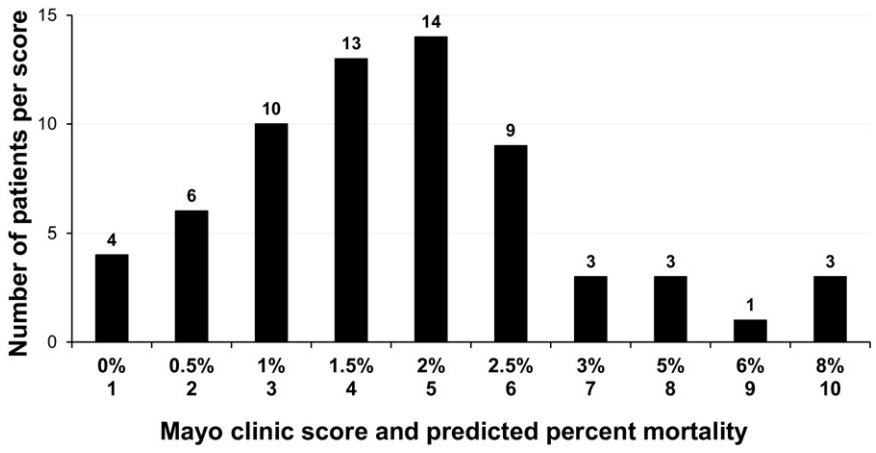

Figure 2. Distribution of the Study Coronary Patients According to the Mayo Clinic Risk Score for Mortality Prediction

The percentages represent the expected in-hospital mortality according to the score. Most patients (n = 46, 70%) were within a score between 3 and 6.

controls: RR: 0.32; 95% CI: 0.02 to 3.62; p = 0.62 (Table 3). The success rate was not different between the study group and the matched controls: RR: 1.72; 95% CI: 0.33 to 9.57; p = 0.72. There were 3 cases in which the procedure was unsuccessful (all due to CTOs) out of 7 CTOs attempted in the matched control group (success rate of 57%).

Minor and other complications in the matched controls included 2 cases of VF, 1 during a primary PCI, 1 access site bleeding, and 1 post-procedure shock. There were 2 cases with type C dissections sealed successfully with stents. There were no perforations. The rate of minor complications was not different: RR: 0.31; 95% CI: 0.04 to 1.81; p = 0.27.

During the 30-day follow-up, which was available for all patients in the matched control group, there were no deaths or strokes. During this period, repeat coronary angiography was performed in 1 patient due to symptoms without any significant findings. The secondary endpoints at 30 days were similar in both groups: RR: 0.42; 95% CI: 0.17 to 7.17; p = 0.97.

Discussion

Live case demonstrations to individuals and to training groups are the heart of teaching surgical and interventional techniques. Transmission of these demonstrations to a large audience with interactive discussion between the operators and the audience opens the procedural details to criticism, allows better training, advances the practice and science of medicine, accelerates the diffusion of new technologies, and promotes the adoption of innovations. Such courses with live case transmission also inform the health professionals on newly available interventions.

Transmission also enables immediate feedback from large groups of experienced physicians and may thus even improve the quality of patient care. Indeed, in the current study, 4 planned procedures were not performed after further discussions with the panel. There were cases where discussions with the panel led to changes of the intended plan. One example is the diagnosis of a carotid stenosis in the external carotid artery, and another example is the decision to send a patient to surgery rather than perform PCI. There were cases where the length of the stent and the type of stent or procedure were discussed, and the plan was somewhat modified. We found that often this discussion with an expert panel with diverse opinions is highly challenging, but often with excellent educational value, both to the performing operators as well as to the audience.

Nonetheless, reservations and even opposition to the broadcasting of live demonstrations have been raised due to the potential increased risk for the patients (8). We have found from our long-term, multiyear experience that procedures that were done by experienced operators in conjunction with expert panel discussions while being broadcast are safe and are not associated with an increased rate of major complications. In the present study, the procedure was free of major complications in 98% of the treated patients, and the complete or partial success rate was 93%. This clinical success was not different from that found in daily practice (2).

There are substantial obstacles during live case transmissions, such as distraction of the operator by the panel and audience discussions, timing issues due to the limited transmission time windows, or the occasional requirement to pause the procedure until the transmission is online.

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Other possible difficulties are the use of novel investigational devices and the presence of hindering transmission equipment in the catheterization laboratory. Collectively, these obstacles may lead to a stressful environment for the operators and the team. In the present study, we report that 9% of patients experienced a minor complication during the procedure. However, events, such as VF or allergic reactions, can also occur during an interventional procedure, and usually are not even mentioned as a complication in most randomized trials (2).

Although live case transmissions are a powerful educational tool, they also involve organizational and economic challenges, and may provide secondary gain regarding scientific and industrial influence and prestige. Furthermore, there are no objective measures of the educational value of observing live case demonstrations, and there is a paucity of data on the potential safety to patients who are treated during live case demonstrations.

Although there are now numerous courses in which the transmission of live case demonstrations is part of the meeting, and many patients underwent procedures in live transmission, there is a lack of published data on this topic. Data on the outcomes of live case demonstrations are limited to what is shown during the transmission, and there are no reports of the short- and long-term outcomes in these patients. Only rarely, anecdotal follow-up reports on the outcome of the patients that were treated during live case demonstrations are presented at subsequent meetings.

In 1992, Chatelain et al. (5) published the first report of results of live case demonstrations and transmission in cardiac patients in the *Lancet*. Among 104 coronary angioplasty procedures that were demonstrated live in 12 international angioplasty courses during 1991, only 73% of the initially planned procedures were successful. This success rate increased to 93% when the crossover to another device was included. Threatened occlusions occurred in 10%, acute occlusions in 6%, and delayed occlusions in 2% of all cases. No deaths or MIs were reported. Based on their results, Chatelain et al. concluded that "real results of coronary angioplasty are inferior to those found in publications"; furthermore, "interventions done before an audience will be unusually stressful but this will be outweighed by the fact that difficult cases with a low probability of success are rarely tackled during live courses." In contrast to the lesions that were treated in 1991, the cases that we chose to transmit in the present study were typically with more complex coronary artery disease. Yet, the success and complication rates were similar to routine practice and are within the current accepted standards in the literature (2).

Surprisingly, we found no published peer-reviewed papers on live demonstrations until 2009, when Franke et al. (4) described 186 patients treated live by carotid stenting. In this consecutive series of carotid stent cases that were done by expert operators from 3 high-volume centers during live demonstration courses, the procedural and 30-day clinical outcomes were similar to the results that appeared for non–live-transmission results in the contemporary published data. The findings by Franke et al. (4) are opposite to those that were reported by Chatelain et al. (5), and provide evidence of no harm to patients broadcast during live case demonstrations. In an accompanying editorial, MacKay wrote, "Whether the drama of live broadcasts has an educational or other advantage over staged recording of procedures is still to be determined" (3).

Over the past 20 years, the Transcatheter Cardiovascular Therapeutics conference has broadcast 928 live cases from 101 clinical sites, both inside and outside the United States (7). Although many of these cases were high-risk patients or patients with complex anatomy, only 2 procedure-related deaths occurred during these broadcasts. This mortality rate of 0.21% (95% confidence limits: 0.03% to 0.88%) is a rate that is well within acceptable standards for such procedures (9,10).

The Ethics Committee of the American Association for Thoracic Surgery and the Standards and Ethics Committee of the Society of Thoracic Surgeons (8) have highlighted patient safety and risks and questionable medical ethics that are associated with live case demonstrations. Although these 2 committees recognized that the teaching of surgical techniques by direct observation of live surgery in the surgeon's home operating theater is a time-honored acceptable practice, they concluded that the educational benefits of broadcast live case demonstrations are meager when compared with the potential harms that are faced by the participating patient. Thus, these 2 committees have recommended that national and international cardiothoracic societies consider prohibiting live surgery broadcasts at their annual meetings (13).

Recently, several cardiology associations wrote a statement on the use of live case demonstrations at cardiology meetings (7). They attest to the inherent, but difficult to measure, benefits of live case demonstrations for physician education, improved quality of medical care, increased enrollment in clinical trials, and fostering innovations in medical device development. The writing committee summarizes as follows: "After evaluating the pros and cons of live case demonstrations and the available data, the writing committee cannot determine if the educational benefits of live case demonstrations outweigh any potential negative consequences." The statement presents also a detailed list of measures that are aimed at mitigating patient risks and ethical concerns. The recommendations also describe mechanisms for standardizing the performance of live case demonstrations to enhance patient safety and improve their educational value, and present a code of conduct (7). These recommendations also include a suggestion that an ongoing registry of live case demonstrations be established. The purpose of this registry is to collect objective information to: 1) determine the educational value of live case demonstra-

tions; 2) enable the assessment of immediate, short-term, and long-term patient outcomes; 3) monitor operator and course behavior; and 4) permit review of the feedback from the audience participants.

As a public health regulatory agency, the Food and Drug Administration (FDA) has important oversight of many aspects of live case demonstrations. The FDA has also published its opinion on live case presentations in interventional cardiology (7), stating that their focus is on patient safety and outcomes of patients who participate in live case demonstrations, clinical trial integrity, and improper medical device promotion. Use of investigational devices in live case demonstrations is subject to review and approval by the FDA's Center for Devices and Radiological Health. The agency issues Investigational Device Exemptions for devices to be used in these meetings. In order to improve follow-up of these patients, the FDA is now considering developing further guidance on live case presentations during Investigational Device Exemption clinical trials. In fact, the agency has called for more research on procedural safety outcomes during live case presentations to better define patient risks, particularly at a time when live case presentations have become a cornerstone of many interventional cardiology meetings.

Our report is a single-center experience of 101 consecutive patients who underwent transcatheter cardiovascular interventions under conditions of live case demonstrations. The data inform on the safety of the procedure, the success rate, and the long-term clinical outcomes. It is clear that the selected group of patients were challenging cases that are not the usual daily practice in the catheterization laboratory. This is seen in the relatively high-risk score of our patients according to the MCRS. The fact that all the failures were due to coronary CTOs is biased by the selection of the complex cases for the demonstration purposes.

Study limitations. Being a retrospective, highly selective registry, our findings are obviously limited to the nature of such a collection of patients. Although different interventions, which were indiscriminately grouped, were done in patients, the common denominator for all these patients is that each underwent a transcatheter cardiovascular intervention under live case transmission conditions. It should be emphasized that the cases in the live transmission group were highly selective mainly regarding anatomy and procedure complexity and were chosen after immense screening. Finding matched controls is complex and difficult. The 95% CI around the RR for the rates of adverse events between the live case and control groups were sufficiently wide that meaningful relative differences between them cannot be completely excluded. The outcome analysis is unadjusted as the low event rates limit the statistical power of such adjustment. Larger series of live case transmissions are needed. Finally, the present results apply only to those from our center; whether the safety and patient outcomes from live case demonstrations performed from other institutions is similar, superior or inferior to these results is unknown.

Conclusions

Our report presents evidence that support the view that patient safety is not jeopardized when an interventional cardiology procedure is done as a live case demonstration. Although the audience can see, hear, interact with, and experience all aspects of the case as it is performed, the procedure is not associated with a worse outcome, as judged by the results that are presented in this report. There are potential gains of using communication technology to enhance education. Live case demonstration may even provide a more controlled environment for online decisions during the interventions. Our findings support the notion that for patients who are carefully selected and treated by an experienced team, the stressful conditions that are associated with live case transmissions do not jeopardize patient safety and procedural efficiency.

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Key Words: education ■ interventional cardiology ■ live case demonstration ■ safety ■ stenting ■ training.

APPENDIX

For a supplemental table, please see the online version of this paper.