

Minimizing Guidewire Unwilling Passage and Related Perforation: Prevention is Better Than Cure

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Technical advance

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Abstract

Background: Current guidewires for transradial coronary angiography had defects of passage difficulty or branch injury. This study sought to investigate the safety and efficiency of a novel method of active knuckle angle 0.035-inch hydrophilic guidewire in transradial coronary angiography.

Methods: Patients who underwent a transradial coronary procedure from August 2015 to June 2020 were consecutively noted. Of them, 1457 patients were allocated into the Traditional group, while the following 1322 patients were allocated into the Knuckle group to investigate the safety. In addition, 239 patients were randomly divided to evaluate its efficiency.

Results: Unwilling passage of guidewire into branches occurred more in Traditional group than in Knuckle group (9.5% vs. 0.08%, $p < 0.001$). Of them, 2 patients experienced guidewire associated perforation in Traditional group. Covered stent was used for 1 patient with internal mammarian artery perforation, and the other was treated with compression for brachial branch perforation. Furthermore, duration of guidewire advancement from the sheath to aortic root significantly decreased in the Knuckle group (22.6 ± 8.0 s vs. 33.4 ± 16.9 s, $p < 0.001$).

Conclusions: Active knuckle angle guidewire was a novel method to prevent unwilling passage and associated perforation, which also improved the efficiency and reduced radiation exposure.

Introduction

Radial artery access has been widely applied as a default route for diagnostic and interventional coronary procedures as its reduced vascular complications, shorter hospital stays and improved outcomes compared with femoral approach [1–5]. Effective hemostasis of radial artery was on account of its superficial course and small luminal caliber. However, anatomic variations of radial artery and S-shaped configuration of the subclavian-innominate-aorta axis often disabled J-tip 0.035-inch guidewire passage [6, 7]. An angle tip 0.035-inch hydrophilic guidewire (Radifocus, Terumo, Japan) is commonly used for its superiority in tortuosity and direction change [8], which can glide into small side branches without appreciable resistance, heightening the risk of subintimal dissection and perforation [9, 10]. Sometimes the branch is apparently mimicking the main artery due to its lengthy and parallel course [7, 11]. Thus unwilling passage of guidewire could not be avoided absolutely and may cause different complications such as hematoma, dissection and perforation [12, 13]. Perforation is rare but terrible, which could result in radial, cervical, mammary and mediastinal hematoma [9, 14–16]. Nonetheless most doctors are reluctant to report their complications. Artery perforation occurs in lower than 1.0% of patients undergoing transradial coronary intervention [9, 17, 18]. Immediate recognition of the complication and prompt action is of utmost importance to prevent fatal outcomes. We all know that prevention is better than cure for minimizing injury [19]. So combination of changing direction and controlling unwilling passage is a promising method to improve the safety and efficiency. We investigated a novel method of

active knuckle angle 0.035-inch hydrophilic guidewire (knuckle guidewire) to prevent guidewire unwilling passage and related complications.

Materials And Methods

Study population and transradial puncture.

Patients who underwent a transradial coronary procedure from August 2015 to June 2020 were consecutively noted. Procedures were performed by two experienced operators via radial arteries. The selected arm was positioned appropriately and sterilized. After local subcutaneous anesthesia with 1% lidocaine, radial artery puncture and 6F hydrophilic sheath (Radiofocus Introducer II, Terumo, Tokyo, Japan) was introduced. After sheath insertion, 100 microgram (mcg) nitroglycerin was given to prevent vasospasm and subsequently 2,500 IU heparin diluted in 10-ml saline was injected into the radial artery.

Active knuckle angle 0.035-inch hydrophilic guidewire (knuckle guidewire).

Guidewire and catheter advancement was monitored with fluoroscopy all the time. The angle guidewire has a higher tendency to enter small side branches (Fig. 1A&B), and sometimes it was hard to adjust into main branch (Online video 1). Occasional knuckle guidewire, similar to J tip, avoiding inadvertently slipping into branch inspired us to improve advancing guidewire. Knuckle guidewire operation was applied and illustrated in Fig. 1. First, advance guidewire until 1.5 ~ 2.0 cm protrusion outside the 5F Tiger catheters (Terumo, Tokyo, Japan). Then, manually insert the catheter tip and protruding guidewire together into but not beyond the sheath (Fig. 1C). Next, fix the guidewire tail and pull back the catheter 2 ~ 3 cm to loosen guidewire from catheter in the sheath (Fig. 1D). Finally, advance the knuckle guidewire to aortic root under fluoroscopy (Fig. 1E&F, Online video 2). Coronary angiography (CAG) was first attempt using 5F Tiger catheters as 6F catheter was hard to be inserted into the 6F sheath with knuckle guidewire. Judkins or Amplatz catheters were used in the presence of unsuccessful selective cannulation of the coronary arteries with Tiger catheter. Guidewire entering branches and its frequency were recorded. Hemorrhage, arteriovenous fistula, and pseudoaneurysm related to access site were not noted as it was associated to puncture and hemostasis process. Perforation was defined as the rupture of the artery wall characterized by contrast extravasation demonstrated by angiography during the transradial procedure. All patients were followed in hospital stay. Efficiency and safety of knuckle guidewire were compared. The study protocol was approved by the local ethics committee.

Statistical analysis

Variables are presented as mean \pm SD or as absolute numbers (percentage). Data analysis was carried out using SPSS version 22.0 (IBM, Armonk, New York). A 2-tailed p value $<$ 0.05 was considered to indicate statistical significance. The Fisher exact test was used for categorical variables. Student's t-test was used to compare continuous variables.

Results

Baseline characteristics

Table 1 showed the clinical characteristics of enrolled patients. Advancement of guidewire with traditional method in 1457 patients (Traditional group), while the knuckle guidewire was used in the following 1322 patients (Knuckle group). Patients in the Knuckle group were more often male, hyperlipidemia, mellitus diabetes and smoking. Other clinical characteristics showed no significant differences between groups such as age, history of coronary artery disease and treatment, and left ventricular systolic function.

Table 1
Baseline characteristics

| | Knuckle group n = 1322 | Traditional group n = 1457 | p value |
|--|---|---|----------------|
| Male (%) | 881(66.6) | 901(61.8) | 0.008 |
| Age (years old) | 63 ± 10 | 63 ± 9 | 0.51 |
| Hypertension (%) | 723(54.7) | 783(53.7) | 0.62 |
| Hyperlipidemia (%) | 133(10.1) | 90(6.2) | < 0.001 |
| Diabetes mellitus (%) | 306(23.1) | 275(18.9) | 0.006 |
| Smoking (%) | 464(35.1) | 438(30.1) | 0.005 |
| Prior myocardial infarction (%) | 122(9.2) | 136(9.3) | 0.92 |
| Family history (%) | 27(2.0) | 35(2.4) | 0.52 |
| Chronic kidney dysfunction (%) | 27(2.0) | 18(1.2) | 0.09 |
| Prior percutaneous coronary intervention (%) | 263(19.9) | 275(18.9) | 0.50 |
| Prior coronary artery bypass graft (%) | 8(0.6) | 19(1.3) | 0.15 |
| Left ventricular ejection fraction (%) | 62.3 ± 8.8 | 62.3 ± 8.4 | 0.99 |

Table 2 illustrated the procedural features. Access sites were similar between groups. Small knuckle guidewire inadvertently slipped into the right common carotid artery of only 1 patient in Knuckle group. Unwilling passage of guidewire into branches occurred in 139 (9.5%) patients in Traditional group due to its inherent slippery ability. Of them, branches entering occurred once in 76 patients, twice in 28 patients, three times in 27 patients, four times in 5 patients, and up to 5 times in 3 patients.

Table 2
Interventional characteristics

| | Knuckle group n = 1322 | Traditional group n = 1457 | p value |
|---------------------------------|-----------------------------------|---------------------------------------|----------------|
| Transradial access | 1350 | 1468 | 0.38 |
| Right radial artery (%) | 1264(93.6) | 1386(94.4) | |
| Left radial artery (%) | 86(6.4) | 82(5.6) | |
| Guidewire unwilling passage (%) | 1(0.08) | 139(9.5%) | < 0.001 |
| Once (%) | 1(100.0) | 76(54.7) | |
| Twice (%) | 0 | 28(20.1) | |
| Three times (%) | 0 | 27(19.4) | |
| Four times (%) | 0 | 5(3.6) | |
| Five times and more (%) | 0 | 3(2.2) | |
| Involved branches | | | |
| Radial recurrent artery (%) | 0(0.0) | 5(0.3) | 0.03 |
| Internal mammarian artery (%) | 0(0.0) | 10(0.7) | 0.003 |
| Common carotid artery (%) | 1(0.08) | 13(0.9) | 0.002 |
| Perforation (%) | 0(0.0) | 2(0.1) | 0.18 |
| Covered stent | 0 | 1 | |
| Compression | 0 | 1 | |

Radial recurrent artery always originated from the radioulnar alpha loop and run parallel to the radial artery, which was the first branch to be inadvertently strayed into and hard to see with empirical advancement of guidewire under fluoroscopy. 5 patients complained of discomfort when catheter was passing the elbow introduced by guidewire in the Traditional group. Consequent angiography confirmed that the guidewire entered into the radial recurrent artery, in whom the radial artery originated from a radioulnar loop and run a similar parallel course to the recurrent radial artery. Adjustment of guidewire and catheter successfully passed and straightened the loop to perform CAG. Radioulnar loop was easily observed and crossed in the Knuckle group. No knuckle guidewire slipped into radial recurrent artery due to the small caliber and relative large diameter of knuckle guidewire. Internal mammarian artery (IMA) runs close to sternum and parallel to ascending aorta, which could be supposed mistakenly. In addition, atherosclerotic narrowing and tortuosity at innominate-subclavian artery junction requiring a meticulous manipulation of guidewire increases the risk of inadvertent insertion. In the Traditional group, guidewire inadvertently slipped into the IMA of 10 patients and into the common carotid artery of 13 patients. Of

them, 1 patient occurred IMA perforation and was treated with covered stent (Fig. 2 and Online videos 3–5). The remaining unwilling passages involved other branches, and 1 of them occurred brachial branch perforation with upper arm swelling treated with compression. Guidewire entered into right common carotid artery of only 1 patient due to its small knuckle, and no complications occurred in the Knuckle group. All patients discharged successfully.

As improved safety and rare unwilling passage of knuckle guidewire, we designed a following study to investigate its efficiency. 239 patients were randomly allocated into advancement of guidewire with knuckle method (n = 119) or traditional method (n = 200). Matched baseline characteristics were presented in Table 3 including gender, age, concomitant diseases, and history of coronary artery diseases. Arterial loops had been crossed and straightened, which showed no differences. Unwilling passage of guidewire occurred more in the Traditional group, and consequently adjustment of guidewire increased fluoroscopy time and dose. We calculated the fluoroscopy time of guidewire advancement from sheath to aortic root, which demonstrated significant decrease in the Knuckle group (22.6 ± 8.0 s vs. 33.4 ± 16.9 s, $p < 0.001$). No guidewire related complications occurred in both groups and patients discharged.

Table 3
Efficiency investigation

| | Knuckle group n = 119 | Traditional group n = 120 | p value |
|--|--------------------------|------------------------------|---------|
| Male (%) | 69(58.0) | 81(67.5) | 0.13 |
| Age (years old) | 62 ± 11 | 61 ± 10 | 0.24 |
| Hypertension (%) | 71(59.7) | 63(52.5) | 0.26 |
| Hyperlipidemia (%) | 15(12.6) | 14(11.7) | 0.82 |
| Diabetes mellitus (%) | 25(21.0) | 25(20.8) | 0.97 |
| Smoking (%) | 45(37.8) | 37(30.8) | 0.26 |
| Prior myocardial infarction (%) | 16(13.4) | 8(6.7) | 0.08 |
| Prior percutaneous coronary intervention (%) | 17(14.3) | 18(15.0) | 0.88 |
| Prior coronary artery bypass graft (%) | 1(0.8) | 2(1.7) | 0.57 |
| Left ventricular ejection fraction (%) | 64.1 ± 7.0 | 62.4 ± 8.2 | 0.08 |
| Transradial access | | | |
| First time puncture (%) | 92(77.3) | 96(80.0) | 0.61 |
| Right radial artery (%) | 115(96.6) | 112(93.3) | 0.24 |
| Loops (%) | 2(1.7) | 2(1.7) | 0.99 |
| Guidewire unwilling passage (%) | 0(0.0) | 13(10.8) | < 0.001 |
| Durations (s) | 22.6 ± 8.0 | 33.4 ± 16.9 | < 0.001 |
| Perforation (%) | 0(0.0) | 0(0.0) | NA |

Discussion

The incidence of unwilling passage of guidewire was as high as 9.5% in transradial CAG, and its related perforation was rare but serious. There's hardly any unwilling passage of guidewire in the Knuckle group, which improved the safety. Shorter fluoroscopy duration decreased radiation exposure and increased efficiency.

High incidence of unwilling passage of guidewire has not been reported for various reasons, but it is an inevitable problem in daily practice. Based on a similar parallel course of pericardiophrenic artery [7] and radial recurrent artery [20] to the normal arteries, the guidewire must have inadvertently entered at some point during repeated manipulation without early recognition. Sometimes hydrophilic guidewire may slip into the same branch recurrently and hard to be corrected. Meticulous advancement and

unrecognized abnormalities could result in dissection and perforation. Early recognition and prompt action may prevent fatal outcomes. Asymptomatic dissection was hard to see without routine angiography and self-healing over time [21]. Immediate recognition of perforation and prompt action including neutralization of heparin, crossing with a wire, and deployment of either a diagnostic or guide catheter across and external compression by sphygmomanometer cuff may help seal the perforation. Furthermore, invasive solutions including prolonged balloon inflation, embolization, and covered stents should be entertained according to the patient's hemostatic response after abovementioned noninvasive therapy has clearly failed [7, 9, 17, 18]. Though the incidence of perforation is low [9, 22], its consequence may be serious for the patient [7, 13]. And we all know that prevention is always more effective than cure.

We have designed a novel approach to prevent guidewire associated unwilling passage and complications. Knuckle guidewire exhibits some superiorities, consisted mainly of preference for main artery not small branches and friendly to vessel wall with smooth tip [23, 24]. Predefined knuckle could avoid slipping into the small branches and the knuckle may enlarge and unfasten in a large luminal caliber. Recurrent radial artery branch always originated from the radioulnar alpha and runs parallel to the radial artery, which was easy to be strayed into and hard to see with empirical advancement of guidewire under fluoroscopy. Maneuvering catheter passage may cause pain, vessel spasm, even perforation [6, 9, 17]. The most loops were easily crossed and straightened using knuckle guidewire, while the traditional method was sometimes hard to cross through the loop due to multiple branching patterns along the loop [11]. IMA is far smaller than and nearly perpendicular to the subclavian artery, which prompts knuckle guidewire to keep away from IMA. More often male, hyperlipidemia, mellitus diabetes and smoking indicated more atherosclerosis in the Knuckle group, which could cause difficult passage of J-tip guidewire [15]. However, knuckle guidewire exhibited equal passage with original angle hydrophilic guidewire. Smooth tip could be friendlier to the vessel wall than original angle tip, especially when encountering tortuosity and loop. The angle tip contacting with vessel wall increases risk of dissection and perforation [9, 10, 17]. According to its preference for main artery and smooth tip, advancement of guidewire becomes more efficient. Fluoroscopy dose is linear correlation with fluoroscopy time so that shorter duration of guidewire advancement will protect both the doctor and patient due to decreased radiation exposure.

Some interventional doctors prefer J-tip guidewire, whose tip is partly similar to the knuckle guidewire with decreased branch enter. However, it was designed for transfemoral approach of large lumen, and indicated some limitations in transradial access. First, the safe J tip formed when it entered in a large vessel or encountered a branch. Before that, the tip kept straight in the small radial artery so that potential risk remained [17]. Furthermore, J tip is smaller than our knuckle tip, which entered into branches and lead to perforations [6, 12, 17, 25]. Finally, J-tip guidewire was difficult to pass tortuosity and severe angle of subclavian-innominate-aorta axis at times, which was dealt with hydrophilic angle guidewire [7, 15]. Knuckle guidewire could enlarge and unfasten its knuckle in large lumen, possessing the ability of direction change to accomplish angiography in patients (Online video 6).

Study Limitations

There are some limitations in this study. The incidence of guidewire related perforation was really low and the sample size was relatively small. Yet the consequences of perforation are serious and need to be managed timely. Unwilling passage of guidewire occurs frequently, so prevention of our knuckle guidewire is effective and necessary to avoid severe complication. In addition, knuckle guidewire changes its original tip may influence the use. In our experience, the knuckle guidewire would be unfastened in large vessels spontaneously or by pulling back guidewire, and thus it still possessed the angle tip and ability of changing direction. Where there is a wire, there may be a complication! We should still pay more attention to its operation.

Conclusions

Unwilling passage of guidewire was frequent of 9.5% in transradial angiography, and consequently perforation was rare but serious. Active knuckle angle guidewire was a novel method to prevent unwilling passage and associated perforation, which also improved efficiency and reduced radiation exposure.

Abbreviations And Acronyms

CAG=coronary angiography

knuckle guidewire= Active knuckle angle 0.035-inch hydrophilic guidewire

IMA= internal mammarian artery

Declarations

Ethics approval and consent to participate

All patients signed written informed consent form. Fudan University affiliated Zhongshan Hospital Ethics Committee had approved the work and received all the written informed consent.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

All authors declare no competing financial interests.

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Authors' contributions

HY, JC and FZ conceived the idea and design for the study. MZ, CL and YD analyzed the data. All authors contributed to interpret the data. HY and JC drafted the manuscript. All authors contributed to revise the draft critically for important intellectual content and approved the final manuscript. HY, JC, and FZ contributed equally to this work.

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Figures

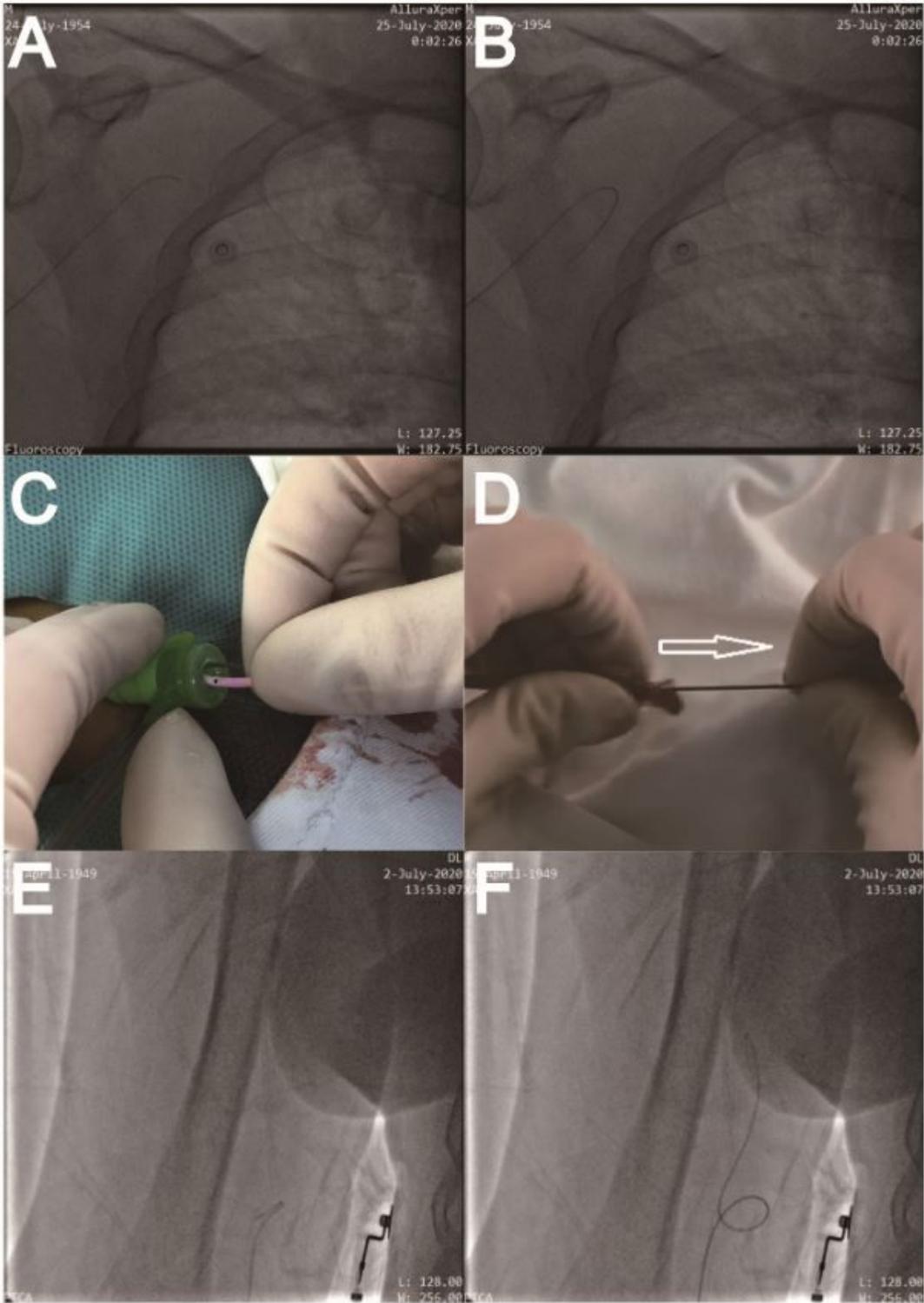


Figure 1

Guidewire performances. (A) Guidewire advancement. (B) Guidewire slipping into a branch artery. (C) Inserting 5F Tiger catheter and protruding guidewire for knuckle use. (D) Fixing guidewire tail and pulling back the catheter to loosen guidewire. (E) Knuckle guidewire advancement. (F) Passing artery loop.

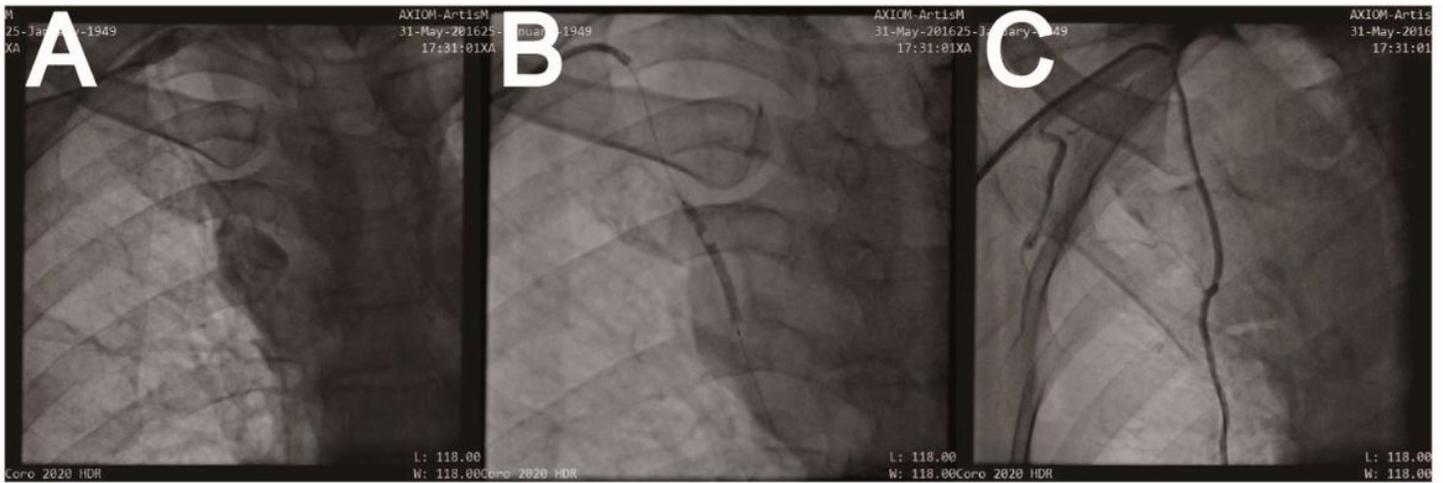


Figure 2

Unexpected perforation of right internal mammary artery (RIMA) and treatment. (A) RIMA perforation. (B) Covered stent implantation. (C) Perforation sealed.

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