

# R-HEC: Registry of complications - Hospital El Cruce. Two-year analysis in a high complexity national health center

R-HEC: Registro de complicaciones - Hospital El Cruce. Análisis a 2 años en un centro público nacional de alta complejidad

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## ABSTRACT

**Objective.** To analyze the rate of complications of patients undergoing diagnostic and therapeutic procedures at the Interventional Cardiology Department of Hospital El Cruce - Dr. Néstor Carlos Kirchner SAMIC.

**Methods.** From August 2019 to October 2021, a total of 2055 patients were admitted to undergo diagnostic and/or therapeutic procedures—whether elective or emergency procedures—and then were prospectively and consecutively included. Demographic, clinical and complication data were collected through an application for mobile devices. Complications included in the analysis were categorized into minor (arrhythmias, hypersensitivity, heart failure, others) and major complications (bleeding, vascular complications, stroke, and death).

**Results.** Of the 2055 patients included in the registry, 77.46% were men with a mean age of 54.9 ± 10.45 years. Coronary artery disease was the most frequent cause for which a study was requested. A total of 2529 procedures were performed: 1820 diagnostic (71.96%) and 709 therapeutic (28.04%). A total of 89 adverse events were recorded in 83 patients (4.03%). Diagnostic procedures had a rate of complications of 0.98% (18/1820), and therapeutic procedures, 10.01% (71/709). Among these events, vascular complications were the most frequent (n = 35) followed by death (n = 22), and bleeding (n = 13). The overall mortality rate was significantly higher in patients with femoral access (P = .0001). The overall mortality rate of acute myocardial infarction was 6%.

**Conclusions.** The overall adverse event rate in the Interventional Cardiology Unit of Hospital El Cruce - Dr. Néstor Carlos Kirchner SAMIC was < 5% being vascular complications the most common occurrence. The overall rate of complications in a public center in Argentina compares favorably with national data and the results of other international registries.

**Keywords:** Registry, Complications, Endovascular procedures.

## RESUMEN

**Objetivo.** Analizar las complicaciones de pacientes sometidos a procedimientos diagnósticos y terapéuticos en el Servicio de Hemodinamia y Cardiología Intervencionista del Hospital El Cruce - Dr. Néstor Carlos Kirchner SAMIC.

**Materiales y métodos.** Desde agosto de 2019 a octubre de 2021 se incluyeron en forma prospectiva y consecutiva 2055 pacientes que ingresaron, de forma electiva o de urgencia, para la realización de un procedimiento diagnóstico y/o terapéutico. Los datos demográficos, clínicos y complicaciones fueron recolectados a través de una aplicación para dispositivos móviles. Las complicaciones que se incluyeron dentro del análisis fueron divididas en menores (arritmias, hipersensibilidad, insuficiencia cardíaca, otras) y en mayores (sangrado, complicaciones vasculares, accidente cerebrovascular y muerte).

**Resultados.** De los 2055 pacientes incluidos en el registro, 77,46% eran hombres con edad promedio de 54,9±10,45 años. La enfermedad coronaria fue el cuadro clínico más frecuente por el que se solicitó estudio. Se realizaron en total 2529 procedimientos: 1820 diagnósticos (71,96%) y 709 terapéuticos (28,04%). Se registraron 89 complicaciones en 83 pacientes (4,03%). Los procedimientos diagnósticos tuvieron una tasa de complicaciones del 0,98% (18/1820) y los procedimientos terapéuticos tuvieron una tasa de complicaciones del 10,01% (71/709). Entre las 89 complicaciones, las vasculares fueron las más frecuentes (n=35), seguido por muerte (n=22) y sangrados (n=13). La mortalidad global del infarto agudo de miocardio fue del 6%.

**Conclusiones.** La tasa de complicaciones globales en el Servicio de Hemodinamia y Cardiología Intervencionista del Hospital El Cruce - Dr. Néstor Carlos Kirchner SAMIC fue del 4%, siendo las complicaciones vasculares las más frecuentes. La incidencia general de complicaciones en un centro de referencia en Argentina se compara favorablemente con los escasos datos nacionales y los resultados de otros registros internacionales.

**Palabras clave:** registro, complicaciones, procedimientos endovasculares.

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## INTRODUCTION

Over the past few decades, interventional cardiology has experienced an exponential growth from performing simple diagnostic studies<sup>1</sup> to more complex therapeutic procedures like transcatheter aortic valve implantations or percutaneous coronary interventions to treat chronic total coronary occlusions.<sup>2-4</sup> In Argentina this growth has been confirmed, annually, in the voluntary registry of general procedures performed in Argentina as reported by the Argentine College of Interventional Cardiology (CACI) that has been collecting data since 2007.<sup>5</sup>

Although refinement in the materials used, the increased number of procedures performed, and the experience gained by operators themselves has had a positive impact on the rate of complications, the approach of the most difficult cases associated with more powerful antiplatelet and anticoagulant therapies has impacted the occurrence of such complications negatively.<sup>6,7</sup>

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The objective of this study is to analyze the complications of patients treated with diagnostic and therapeutic procedures in the cath lab of a high complexity health center.

## MATERIALS AND METHODS

This registry was started back in 2019 at the cath lab of Hospital El Cruce - Dr. Néstor Carlos Kirchner SAMIC (HEC), Buenos Aires, Argentina. Data mining took place from August 2019 through October 2021.

An app was built for smartphones with AppSheets (a tool built by Google) that provides a platform to develop applications for smartphones. The data entered in the app were sent to a confidential database.

All the patients admitted to the center to undergo a diagnostic and/or therapeutic procedure on an elective or emergency basis were prospective and consecutively included. The registry was completed 24 hours after finishing the procedure in patients admitted to the HEC and when they were discharged from this center (both in ambulatory patients and in those coming from other centers who were sent back to their centers of origin once the procedure was completed).

Cardiovascular risk factors were also included like arterial hypertension, smoking, dyslipidemia, and diabetes. The past medical history studied included previous acute myocardial infarction (AMI), previous percutaneous coronary intervention (PCI), previous myocardial revascularization surgery, and chronic kidney disease. The clinical signs that triggered the procedure were included within the following categories depending on which was considered the most appropriate one: non-ST-segment elevation acute coronary syndrome (NSEACS) or ST-segment elevation acute coronary syndrome (SEACS), the patient's hemodynamic status based on the Killip-Kimball (KK) classification, discard chronic coronary artery disease (CAD), postinfarction angina (PIA), post-AMI stratification/evolving AMI, coronary artery disease, sudden death/ventricular arrhythmia, dilated cardiomyopathy (DCM), valvular heart diseases, peripheral vascular disease, heart transplant follow-up, other conditions.

For better analysis, the procedures available at the cath lab to treat all vascular territories were categorized into diagnostic and therapeutic. In relation to other procedural technical aspects, the access route was registered as well (radial, humeral, femoral, and venous accesses), as well as the French size used. The complications included in the analysis were categorized into minor (arrhythmias, hypersensitivity, heart failure [HF], other), and major complications (bleeding, vascular complications, stroke, and death). Hemorrhages were assessed according to the criteria established by the Bleeding Academic Research Consortium (BARC),<sup>8</sup> and those  $\geq 2$  were registered. The vascular complications included were pseudoaneurysm, arteriovenous fistula (AVF), perforations, emboli/thromboses, dissections, radial artery occlusions, acute stent thromboses,<sup>19</sup> and perioperative Q-wave/enzymatic infarction.

### Statistical analysis

Categorical variables were expressed as absolute values, percentages, and associations. The quantitative ones as mean and standard deviations with their maximum, minimum, and ranges, when appropriate. The statistical comparison

among the different qualitative variables was conducted using the chi-square test with or without Yates Correction. In all the analyses, *P* values  $< .05$  were considered statistically significant.

## RESULTS

A total of 2055 patients were included in the analysis. The demographic characteristics, prevalence of cardiovascular risk factors, and the patients' past medical history are shown on **Table 1**. A total of 77.46% ( $n = 1592$ ) of the patients were men with a mean age of  $54.9 \pm 10.45$  years (range, 15-89). **Table 2** shows the clinical signs that triggered the procedure, among others, coronary artery disease was the most common clinical sign in 56.91% of the cases (STEACS, NSTEACS, chronic CAD, post-AMI stratification, and PIA). Among the patients with STEACS, ( $n = 231$ ), ( $n=231$ ), KK-A was the most prevalent classification in 64.93% while 9.95% of the patients were categorized as KK-D.

A total of 2529 procedures were performed: 1820 diagnostic procedures (71.96%), and 709 therapeutic ones (28.04%). **Table 3** shows the data associated with such procedures. Right radial access and 6-Fr introducer sheaths were the most widely used of all (**table 4**). A total of 45.54% ( $n = 936$ ) of the patients recovered at the hemodynamics and interventional cardiology unit, 34.84% ( $n = 716$ ) were admitted to the HEC, and 19.62% ( $n = 403$ ) were sent back to their referring hospitals once the procedure was completed. During the follow-up of 2055 patients, a total of 89 complications in 83 patients (4.03%) were reported. Among these complications, the most common ones were vascular complications ( $n = 35$ ) followed by death ( $n = 22$ ), and bleeding ( $n = 13$ ) (**Tables 6 and 7**). Acute stent thrombosis and pseudoaneurysm/AVF were the most common complications reported within the group with vascular complications. A total of 7 of these access site-related vascular complications required an active approach (whether surgical or endovascular) for their resolution while 16 were treated conservatively.

In the 2529 procedures performed, diagnostic procedures were associated with a rate of complications of 0.98% (18/1820). A total of 7 minor (2 arrhythmias, 3 patients with hypersensitivity, 2 HFs), and 11 major complications (4 vascular complications, 4 hemorrhages, 3 deaths, and 0 strokes) were described. The rate of complications associated with therapeutic procedures was 10.01% (71/709). A total of 12 minor (6 arrhythmias, 1 hypersensitivity, 3 HFs, and 2 other complications), and 59 major complications (31 vascular complications, 9 hemorrhages, 19 deaths, and 0 strokes) were described. Among the 22 patients who died, 14 developed STEACS (3, 2, and 9 patients were categorized as KK-A, KK-B, and KK-D, respectively). A total of 3 patients developed NSTEACS, 1 chronic CAD, and 2 developed acute aortic syndrome. A total of 2 patients died in the context of hypovolemic shock due to digestive bleeding refractory to treatment. Complications associated with other therapeutic procedures are shown on **Table 5**.

Mortality rates were 0.73% (1/136), 1.12% (2/178), and 6.06% (14/231) for scheduled PCI, PCI to treat NSTEACS, and PCI to treat STEACS, respectively. Out of all PCIs performed, in 76.15% (415/545) the radial access was the route

**TABLE 1.** Characteristics of the population (N = 2055 patients)..

	N°	%
Men	1592	77.46
Mean age	54.9±10.45 years	-
BMI	28.4	-
Body surface area	1.9 m <sup>2</sup>	-
Arterial hypertension	1021	49.68
Smoking	983	47.83
Dyslipidemia	336	16.35
Diabetes mellitus	357	17.37
Previous myocardial infarction	487	23.69
Previous percutaneous coronary intervention	197	9.58
Previous coronary surgery	61	2.96
Chronic kidney disease	27	1.31

of choice followed by the femoral access [23.48% (128/545) of the cases]. Humeral access (0.36%) was used in 2 patients only.

A comparative analysis of the complications described between radial arterial access (RAA) and femoral arterial access (FAA) was conducted (**table 8**). After excluding patients with venous accesses and different arterial accesses, no significant differences were ever reported in the appearance of vascular complications ( $P = .19$ ), arrhythmias ( $P = .32$ ), hypersensitivity ( $P = .34$ ) or bleeding ( $P = .051$ ) in association with the arterial access used. The overall mortality rate, however, was significantly higher in those cases treated via femoral access ( $P = .0001$ ). All critical patients were treated via femoral access, which is why a deviation from the population analyzed should be taken into consideration when analyzing these last results. The highest mortality rate associated with the FAA group could be associated with more baseline morbidities in the patients of the group taking into consideration that 63.63% (n = 14) of all deaths reported occurred in patients with STEACS and 9 out of these 14 patients fell within KK-D.

## DISCUSSION

These are the early results on 2055 patients from the R-HEC, a prospective, longitudinal registry whose primary endpoint was to know current data on the complications occurred through time at the Interventional Cardiology Unit of Hospital de Alta Complejidad El Cruce – Dr. Néstor Carlos Kirchner SAMIC, Buenos Aires, Argentina.

Considering all the complications studied, the total percentage was 4.03%. The scarcity of data regarding the overall complications associated with interventional procedures (the registries available mostly evaluate complications associated with a specific procedure)<sup>6,9,10</sup> complicates the possibility of drawing a comparative analysis with data obtained from this registry.

Vascular complications were the most common of all (1.38% of the total). Such rate turned out to be relatively lower compared to results previously published with rates close to 3% that only considered major vascular complications.<sup>6,11</sup> Waldo et al. published a study that included 194 476 cardiac catheterizations and 85 024 PCIs performed in the United States. They confirmed that patients treated with these procedures were progressively older and had more comorbidities. Both the complications and the clinical outcomes remained constant with rates of major and minor complications < 1% during the study period regard-

**TABLE 2.** Clinical signs that triggered the procedure (N = 2055 patients).

	N°	%
NSTEACS* (unstable angina/NSTEMI)	405	19,7
STEACS* (total)	231	11,24
- Killip-Kimball A	150/231 (64.93%)	
- Killip-Kimball B	44/231 (19.04%)	
- Killip-Kimball C	14/231 (6.06%)	
- Killip-Kimball D	23/231 (9.95%)	
Chronic coronary artery disease	330	16,05
Postinfarction angina	25	1,21
Post-AMI stratification/evolving AMI	179	8,71
Discard coronary artery disease	130	6,32
Sudden death/Ventricular arrhythmia	15	0,72
Dilated cardiomyopathy	128	6,22
Valvular heart disease	81	3,94
Peripheral vascular disease	211	10,26
Follow-up heart transplant	42	2,04
Other conditions	278	13,52

STEACS: ST-segment elevation acute coronary syndrome. NSTEACS: non-ST-segment elevation acute coronary syndrome..

ing diagnostic and therapeutic procedures.<sup>12</sup> Since, in this registry, operators reported on the rates of complications voluntarily, these could be under-reported. In Brazil, in a multicenter registry of 2696 patients, the rate of vascular complications was 8.8%<sup>17</sup> (without ever reporting on complications such as AVFs, pseudoaneurysms or retroperitoneal hematomas).

Out of the 13 hemorrhages reported, only 3 (3.37%) were major bleedings according to the BARC. There were 2 BARC type 2B bleedings, 1 in a right cardiac catheterization and the other associated with 1 transcatheter aortic valve replacement procedure, and 1 BARC type IIIC bleeding associated with STEACS. The BARC classification was validated in 12 459 patients treated with PCI from the ISAR trial.<sup>13</sup> Bleeding events (according to the BARC classification) occurred in 1233 patients (9.9%). BARC type > 2 bleedings occurred in 679 patients (5.4%). The ARGENTIAM-ST registry (Study on ST-segment elevation acute myocardial infarction) conducted in Argentina on 1142 patients reported a rate of 3.23% with only 3 patients showing major bleeding.<sup>14</sup>

Regarding complications associated with 2 different access routes, a higher mortality rate was found in FAA compared to RAA (2.47% vs 0.42%;  $P = .0001$ ). However, no statistically significant differences were found in the rate of bleeding between the FAA compared to the RAA, which means that the borderline  $P$  value obtained should be interpreted with caution since it could change with a larger number of individuals included (0.92% vs 0.28%;  $P = .0512$ ). We should mention that all critical patients were approached via femoral access, which is why any deviations from the study population should be taken into consideration when analyzing these outcomes. The higher mortality rate reported in the FAA group could be associated with more baseline morbidities in the patients of the group considering that 63.63% (N = 14) of all deaths occurred in patients with STEACS and that 9 out of these 14 patients fell within KK-D. Mieres et al. published a registry that compared FAA and RAA at 30 days in patients treated with percutaneous coronary intervention. In 988 consecutive patients no significant differences were reported regarding MACCE or death + AMI + stroke between both groups. However, both mortality and cardiac death were numerically higher in the FAA compared to the RAA.<sup>18</sup>

**TABLE 3.** Procedures performed (N= 2055 patients).

	N°	%
<b>TOTAL</b>	<b>2529</b>	<b>100</b>
<b>Diagnostic</b>	<b>1820</b>	<b>71,96</b>
Left cardiac catheterization	1385/1820 (76.09%)	
- Lower limb arteriography	163/1820 (8.95%)	
- Right cardiac catheterization	74/1820 (4.06%)	
- Aortogram	33/1820 (1.81%)	
- Arteriography of neck vessels	40/1820 (2.19%)	
- Endomyocardial biopsy	42/1820 (2.3%)	
- Phlebography / Fistulography	27/1820 (1.48%)	
- Pulmonary arteriography	18/1820 (0.98%)	
- Upper limb arteriography	16/1820 (0.87%)	
- Splanchnic arteriography	16/1820 (0.87%)	
- Other territories	6/1820 (0.32%)	
<b>Therapeutic</b>	<b>709</b>	<b>28,04</b>
- Percutaneous coronary intervention	545/709 (76.86%)	
- Lower limb angioplasty	58/709 (8.18%)	
- TAVI*	11/709 (1.55%)	
- Pulmonary angioplasty/CTPH*	12/709 (1.69%)	
- EVAR/TEVAR*	11/709 (1.55%)	
- Tumor/Bleeding embolization	17/709 (2.39%)	
- Carotid angioplasty	2/709 (0.28%)	
- Angioplasty of venous territory	12/709 (1.69%)	
- VCF implantation/removal*	12/709 (1.69%)	
- Aortic valvuloplasty	1/709 (0.14%)	
- Mitral valvuloplasty	2/709 (0.28%)	
- Other	26/709 (3.66%)	

\* CTPH, chronic thromboembolic pulmonary hypertension; EVAR, endovascular repair of abdominal aortic aneurysm; TAVI, transcatheter aortic valve implantation; TEVAR, thoracic endovascular aortic repair; VCF, vena cava filter.

In our registry, the overall mortality rate of STEACS was 6% (14 patients out of 231), which is somehow similar to that of the French registry FAST MI<sup>15</sup> designed to assess the in-hospital outcomes and mid- and long-term progression being the in-hospital mortality rate associated with STEACS, 5.8%. The Argentine Registry of Coronary Angioplasty (RadAC)<sup>16</sup> was conducted in Argentina from 2010 through 2012. It included a total of 1905 PCIs performed in 67 centers. A total of 752 of these patients showed STEACS. The in-hospital mortality rate reported by the authors for patients with STEACS was 4.6%. However, only 2.6% patients from the RadAC fell within the KK-D category compared to 10% of our registry. In the ARGEN-IAM-ST, the rate of patients who fell within the KK-D category was close of 6%. In such registry, the in-hospital mortality rate of 1142 patients from 247 different Argentine centers was 7.6%.<sup>14</sup> Bono et al.<sup>20</sup> recently published a registry of complications associated with STEACS in a public center from the city of Buenos Aires, Argentina. In 263 patients the overall rate of complications was 47.2% while the 48 hour-all-cause mortality rate was 7.9%. A chronological distribution analysis of the complications was conducted, and it was confirmed that 9 out of every 10 complications occurred within the first day.

## STUDY LIMITATIONS

The R-HEC registry is a single-center, observational, and non-randomized clinical trial. The additional studies conducted and the treatment prior to the procedure were indicated based on the treating cardiologists. The decision on the vascular access, procedural technique used, and thera-

**TABLE 4.** Vascular access (N = 2055).

	N°	%
<b>Total accesses</b>	<b>2253</b>	<b>100</b>
- Right radial artery		62.22
- Left radial artery		0.75
- Right femoral artery		24.81
- Left femoral artery		3.86
- Right humeral artery		0.22
- Left humeral artery		0.08
- Venous accesses		8.03
<b>French (on all accesses)</b>		
- 5	109	4.83
- 6	1833	81.35
- 7	200	8.87
- 8	61	2.7
- 9	12	0.53
- 10	14	0.62
- > 12	24	1.06

**TABLE 5.** Complications per type of procedure (N =2529).

	N°	%	Type of complication	
			Minor	Major
<b>Diagnostic</b>	<b>18/1820</b>	<b>0.98</b>	<b>7</b>	<b>11</b>
- Left cardiac catheterization	13/1385 (0.93%)		5	8
- Right cardiac catheterization	4/74 (5.4%)		2	2
- Splanchnic arteriography	1/16 (6.25%)		0	1
<b>Therapeutic</b>	<b>71/709</b>	<b>10.01</b>	<b>12</b>	<b>59</b>
- Percutaneous coronary intervention	48/545 (8.80%)		7	42
- Lower limb angioplasty	8/58 (13.79%)		2	6
- Angioplasty in CTPH	2/12 (16.66%)		0	2
- Venous Angioplasty	2/12 (16.66%)		1	1
- Tumor/Bleeding embolization	2/17 (11.76%)		0	2
- EVAR/TEVAR	4/11 (36.36%)		0	4
- TAVI	4/11 (36.36%)		2	2

peutics depended on the heart team of the Interventional Cardiology Unit.

During all the procedures and in the postoperative of the patient, hospital ward doctors and residents participated in the healthcare process, which is why results may not be extrapolated to other units without specialist training programs.

The brief follow-up conducted at 24 hours or after hospital discharge confirmed that complications that occurred after that time were not included. There is this possibility of data loss in patients who were sent back to their centers of origin once the procedure was completed. Therefore, a mailbox was created to receive notifications on possible complications, which were the ones that were eventually registered. However, different reports show that most complications occur early as it was the case of the registry conducted by Paganin et al. that confirmed that 97% of all vascular complications occurred within the first 6 hours after the procedure<sup>17</sup> meaning that data loss may not be significant or relevant at all. We should mention, though, how easy it was for the investigators to fill in the forms since they could use the app of their smartphones for that purpose.

## CONCLUSIONS

The rate of overall complications at the Interventional Cardiology Unit of HEC was 4% being vascular complications the most common of all. Results allow us to conclude that the overall rate of complications in a reference center in Argentina holds a favorable comparison given the scarce natio-

**TABLE 6.** Overall complications (N = 2529).

	N°	%
<b>TOTAL</b>	<b>89</b>	<b>3.51</b>
<b>Arrhythmias</b>	<b>8</b>	<b>0.31</b>
- AVB*		
- Supraventricular tachycardia		
- VT/VF*		
<b>Hypersensitivity</b>	<b>4</b>	<b>0.15</b>
<b>Heart failure</b>	<b>5</b>	<b>0.19</b>
<b>Bleeding</b>	<b>13</b>	<b>0.51</b>
- BARC 2	9	
- BARC 3 a	1	
- BARC 3 b	2	
- BARC 3 c	1	
<b>Vascular complications</b>	<b>35</b>	<b>1.38</b>
- Pseudoaneurysm/AVF*		
- Perforations		
- Emboli/Thrombosis		
- Dissections		
- Radial artery occlusion		
- Acute stent thrombosis		
- Perioperative enzymatic infarction		
<b>Stroke</b>	<b>0</b>	
<b>Death</b>	<b>22</b>	<b>0.86</b>
<b>Other (displacement – failed delivery)</b>	<b>2</b>	<b>0.07</b>

AVB, atrioventricular block; AVF, arteriovenous fistula; BARC, Bleeding Academic Research Consortium; VT/VF, ventricular tachycardia/ventricular fibrillation.

nal data available and outcomes of other international registries. Knowing the rate of complications of patients treated with endovascular procedures allows us to plan care before and after the procedure properly. It also gives us the opportunity to give the patient proper information on the risks involved in the procedure planned.

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**TABLE 7.** Analysis of dead patients.

Total	N°	%	Access	
			Radial	Femoral
<b>STEACS</b>	<b>14</b>	<b>63.63</b>		
- Killip-Kimball A	3		2	1
- Killip-Kimball B	2		2	0
- Killip-Kimball C	0		0	0
- Killip-Kimball D	9		1	8
<b>NSTEACS</b>	<b>3</b>	<b>13.63</b>	<b>1</b>	<b>2</b>
Chronic CAD*	1	4.54	0	1
EVAR/TEVAR	2	9.09	0	2
AGIB*	2	9.09	0	2

\*AGIB, acute gastrointestinal bleeding; CAD, coronary artery disease.

**TABLE 8.** Access-related complications.

	Femoral (n=646)	Radial (n=1419)	P
Arrhythmias	0.46% (3)	0.21% (3)	0.3259
Hypersensitivity	0	0.14% (2)	0.3415
Heart failure	0	0.21% (3)	0.2439
Bleeding	0.92% (6)	0.28% (4)	0.0512
Vascular complications	2.01% (13)	1.26% (18)	0.1929
Death	2.47% (16)	0.42% (6)	0.0001
Other	0.15% (1)	0.07% (1)	0.5844

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