Trends in aortic stenosis diagnosis and treatment in the years 2006–2016

according to the SILesian CARDiovascular (SILCARD) database

Authors: Tomasz Roleder, Michał Hawranek, Tomasz Gąsior, Daniel Cieśla, Marian Zembala,
Wojciech Wojakowski, Mariusz Gąsior, Zbigniew Gąsior

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Title: Trends in aortic stenosis diagnosis and treatment in the years 2006–2016 according to the SILesian CARDiovascular (SILCARD) database.

Short Title: Aortic stenosis at Silesian district

Authors: Tomasz Roleder¹, Michał Hawranek², Tomasz Gąsior³, Daniel Cieśla², Marian Zembala⁴, Wojciech Wojakowski³, Mariusz Gąsior², Zbigniew Gąsior¹

¹Department of Cardiology, SHS, Medical University of Silesia, Katowice, Poland
²3rd Department of Cardiology, School of Medicine with the Division of Dentistry in Zabrze, Medical University of Silesia, Katowice, Silesian Centre for Heart Disease in Zabrze, Poland
³Department of Cardiology and Structural Heart Diseases, 3rd Division of Cardiology, Medical University of Silesia, Katowice, Poland
⁴Department of Cardiac, Vascular and Endovascular Surgery and Transplantology, Medical University of Silesia, Katowice, Poland

Conflict of Interest: none declared

Corresponding Author:
Tomasz Roleder, MD, PhD; Department of Cardiology, SHS, Medical University of Silesia, Katowice, Poland; 45/47 Ziolowa Street, Katowice, Poland; email: troleder@sum.edu.pl; Telephone number: +48884096034
Abstract

Introduction: During the last decade, aortic stenosis (AS) has emerged as one of the most significant subjects in cardiovascular diseases.

Objective: The following study extracted data from the local registry to present the characteristics of AS patients.

Patients and methods: The report referred to the SILCARD database, which is based on the agreement between Silesian Centre for Heart Diseases in Zabrze and the Regional Department of National Health Fund in Katowice to conduct a comprehensive analysis of patients with cardiovascular diseases in the Silesian Province.

Results: There were 15158 patients (pts) hospitalized with a diagnosis of AS between 2006 to 2016. 7644pts (50.43%) were male with average age 69.87±11.97. Heart failure was reported in 4187pts (27.62%), and coronary artery disease was diagnosed in 6217pts (41.01%). During the first hospitalization an intervention on aortic valve was performed in 2137pts (14.10%), and during the 12-month follow-up it was reported in 3416pts (25.32%). During the first hospitalization percutaneous coronary intervention (PCI) was performed in 666pts (4.39%) and coronary artery bypass grafting (CABG) in 1071pts (6.71%). At 12-month follow-up 560pts (4.15%) had PCI and 560pts (4.15%) had CABG. 30-day mortality between 2006 and 2016 was 4.35% (659 pts) and remained stable (5.4% in 2005 vs. 4.0% in 2016, p=0.278). The one-year mortality was 15.88% (2142pts) and it increased from 14.3% in 2006 to 16% in 2015 (p=0.07).

Conclusions: According to the SILCARD registry, the number of diagnosed AS increases. Presented data proofs that AS became one of the most critical aspects of cardiovascular diseases in Silesia district.
Keywords: aortic stenosis, registry, mortality
Introduction

The population is aging, and the problem of aortic stenosis (AS) has emerged in recent years as one of the most significant subjects of all cardiovascular diseases [1, 2]. The broad spectrum of AS symptoms is not only a concern of cardiovascular units but also of intensive cardiac care and internal medicine departments. Thus, it makes AS an interdisciplinary matter [3].

Most commonly the severe AS requires surgical intervention, but as a high-risk procedure, it excludes those who are highly vulnerable to periprocedural complications. However, in last ten years percutaneous transcatheter aortic valve implantation (TAVI) was introduced as an alternative to the surgery, which made possible treatment of patients with a high perioperative complications risk [4, 5]. Such shift in patients’ treatment changed physicians’ approach significantly by increasing the number of AS patients considered as curable [6]. Therefore, the knowledge about the AS prevalence in population and about treatment trends over the last decade is essential to establish the most appropriate treatment strategy.

Worldwide and local registries sought to identify the local health needs [7]. They give an insight into the epidemiology, morbidity, and mortality of the patients. With the following study, we extracted data from the local registry to present the characteristics of AS patients, treatment trends, and prognosis at Silesian district of Poland in the last ten years.
Patients and methods

The SILCARD database was based on the agreement between Silesian Centre for Heart Diseases in Zabrze and the Regional Department of National Health Fund in Katowice to conduct a comprehensive analysis of patients with CV diseases in the Silesian Province [8]. The inclusion criteria were as follows: each hospitalization at a department of cardiology, cardiac surgery, diabetology, or vascular surgery and hospitalization with a cardiovascular (CV) diagnosis at departments of internal medicine or intensive care. The exclusion criteria were hospitalizations of patients living outside the Silesian Province and patients younger than 18 years on admission. All hospitalizations fulfilling the enrollment criteria in the years from 2006 to 2016 were included in the registry. The initial hospitalization was defined as admission for CV causes, including a potential transfer to another department or hospital. This hospitalization constituted the baseline for follow-up. If the time between hospital discharge and the following admission due to the diagnosed CV disease was shorter than one day, both hospitalizations were treated as one. All data was anonymized. Matching information concerning the individual patient was possible through the hospital register number and encoded national personal identification number (PESEL). Data analysis was conducted at the Science Department of Silesian Centre for Heart Diseases and the Department of Biostatistics of the Medical University of Silesia, Katowice, Poland, according to regulations (Security Policy as of September 1, 2015). The individuals involved in data collection and workup signed a confidentiality clause. Data flow was presented previously [8]. The analyses were conducted as follows: 1) according to the first hospitalization of the patient, depending on primary and/or concomitant diagnosis (ICD-10), where each next admission was analyzed as an event (analysis of first-time hospitalizations); 2) diagnostic and therapeutic procedures were examined according to the ICD-9, presenting all of
them together or attributing to each of the patients with a given disease entity. The reported data come from 310 hospitals’ departments and 1863 outpatient clinics. They contain information on 605920 cardiovascular hospitalizations. In this study, we analyzed the number of hospitalizations, distribution of disease entities, and prognosis up to 12 months in patients with diagnosed AS. The ICD classification codes assigned to the individual disease entities are presented in Table 1.

Statistical analysis

The mortality rate and repeated hospitalizations in a 12-months follow-up were analyzed according to the first hospitalization of the given patient. Descriptive statistics were also applied. Compilations were generated directly from the Oracle database using the SQL Developer tool. The excel spreadsheet was used for graphics development. The obtained data distribution was assessed by Kolmogorov – Smirnov analysis. For normally distributed values data are presented as mean with standard deviation (SD), for non-normally distributed values data was presented as median with interquartile intervals (IQR, 25 percentiles, 75 percentiles). Continuous variables were compared using the 1-way analysis of variance. The differences in the number of patients and mortality rate over the years were verified using the Cochran-Armitage Trend Test.
Results

Aortic stenosis patients’ hospitalizations

Among all 605920 patients reported with the CV disease, there were 15158 (2.5%) patients hospitalized with AS diagnosis in the last ten-years period, and the rate of patients with diagnosed AS increased from 0.95% in 2006 to 4.64% in 2016 (p<0.001). Most of the AS patients were hospitalized at the cardiology units (8268 pts, 54%). The rest were treated at the internal medicine departments (4471 pts, 29%), the cardiac surgery units (2406 pts, 16%), the intensive care units (8 pts, 0.05%) and the vascular surgery units (5 pts, 0.03%) (Figure 1). The study shows that forty-four percent of patients required urgent hospitalization (data from 2011-2016). Among all the AS patients 7715pts (50.9%) they were male, and they were younger than women with the AS (66±12 vs. 73±11; p<0.001). The average hospital stay for a single patient was 9.65±1.24 days, and 492 (3.24%) died during the hospitalization. The in-hospital mortality rate dropped from 4.5% in 2006 to 3.0% in 2016 (p=0.024) (Figure 2).

Concomitant diseases of patients with aortic stenosis

The aortic regurgitation was reported in 3877pts (25.58%), the mitral regurgitation was reported in 615pts (4.1%), the mitral stenosis was reported in 201 pts (1.32%), and the tricuspid valve regurgitation was reported in 74pts (0.5%). The Heart failure (HF) was reported in 4187pts (27.62%), the coronary artery disease (CAD) was diagnosed in 6217pts (41.01%). The number of HF and CAD diagnosis increased over the ten-years period (p<0.001) (Figure 2). The hypertension was reported in 6020pts (39.72%) and other valvular diseases in 3231pts (21.32%).
3425 (22.6%) patients had diabetes, 485 (3.2%) suffered from renal insufficiency, and 1015 (6.7%) had chronic obstructive pulmonary disease diagnosed.

The Pulmonary embolism was diagnosed in a tiny number of AS patients (45 pts, 0.3%). The distribution of the aortic stenosis hospitalization with concomitant cardiovascular diseases is presented in Table 2.

Interventions on the aortic valve

During the first hospitalization an intervention on the aortic valve was performed in 2137pts (14.10%), which from the level of 20.9% in 2006 dropped to 10.1% in 2010 and increased again to 17.6% in 2016 (p<0.001). During the first twelve months after the initial hospitalization the interventions on the aortic valve were performed in 3416pts (25.32%) and remained stable over 10-years observation period. Although, the number of surgical treatments dropped from 20.34% to 16.54% in 2016 (p<0.015). 13017pts (85.88%) were only on the optimal medical therapy between 2006 and 2016.

Myocardial revascularization

During the first hospitalization, the coronary angiography was performed in 5702pts (37.62%), the percutaneous intervention was performed in 666pts (4.39%), and PCI increased over the observation period from 2.6% in 2006 to 5.0% in 2016 (p<0.001) (Figure 2). 1071pts (6.71%) underwent CABG. The rate dropped to 4.3% in 2010, but in 2016 came back to the same level as it was observed in 2006 (7.8%). At 12-months follow-up, 1623pts (12.06%) underwent the
coronary angiography, 560pts (4.15%) had the percutaneous coronary intervention. PCI increased from 1.0% in 2006 to 4.9% in 2015 (p<0.001) and 560pts (4.15%) had CABG, which decreased from 8.1% in 2006 to 5.8% in 2015 (p<0.001) (Figure 2).

Other procedures

The cardiac pacemaker was implanted in 239pts (1.58%), and either ICD implantation or cardiac resynchronization (CRT) therapy was performed in 34 pts (0.22%) during the first hospitalization. During the first twelve months after initial hospitalization 77pts (0.57%) required either ICD or CRT implantation.

The prognosis of AS patients

Among 13489 AS patients hospitalized between 2006 and 2015, 1551 pts (11.50%) were hospitalized because of the heart failure symptoms, 274pts (2.03%) had a diagnosis of the myocardial infarction, and 244pts (1.81%) had a stroke. The one-year mortality rate was 15.88% (2142pts), and it increased during the observation periods from 14.3% in 2006 to 16% in 2015 (p=0.070). On the other hand, 30-day mortality rate for all AS patients hospitalized between 2006 and 2016 was 4.35% (659 pts) and did not decreased over the observation period (5.4% in 2005 vs. 4.0% in 2016, p=0.278) (Figure 3). In patients over the 70 years old the one-year mortality dropped from 20.73% in 2006 to 15.20% in 2016. However, during the 10-year period the mortality was significantly higher in patients more than 70 years old as compared to the younger ones [8601 (20.5%) vs. 6557 (8.7%), p<0.001]. Furthermore, the one-year mortality was smaller in women as compared to men [2384pts (7.93%) vs. 4173pts (9.24%), p<0.001]
Discussion

The following study presented for the first time the prevalence and trends in the treatment of patients with AS in Poland over the ten-year period. This data is the most important in terms of giving the insight into AS epidemiology. Such a reliable data is essential for to planning the local health needs. The data presented in the report shows that 15158 of AS patients were hospitalized in years 2006-2016. Our data presented in this report significantly expanded data from previous Scottish report on AS prevalence also based on ICD-10 classification [9].

The following data revealed the equal distribution of AS between males and females, which is not in keeping with American and Japanese data presented previously. Women tend to have less likely the AS as compared to men [10, 11]. Previous studies presented that AS prevalence and mortality rate is higher in women as compared to men in patients more 65 years old [11]. In our report the one-year mortality was slightly higher in men as compared to women and higher for elder patients. At Silesian district of Poland, the rate of patients diagnosed with the AS increased almost five times over the ten-years period. It cannot be explained by the extended life expectancy, as it did not change significantly in the recent years, and the mortality rate from cardiovascular diseases remained at the same level [8]. Thus, such growing trend in AS identification may be caused by more perspicacious analysis of hospitalized patients, probably due to the broad application of echocardiography in both ambulatory and in-hospital patients’ care. The SILCARD data presented a significant increase in the ratio of the AS diagnosis at the internal medicine departments, where the application of echocardiography significantly increased over last years.

Almost one-third of the AS patients were reported to present symptoms of HF. Since the ICD-10 does not distinguish patients with or without severe AS, the reported HF symptoms might have
represented the AS population with the poorest prognosis. It was previously documented that the incidence of heart failure in the AS patients increased five-years mortality rate for both moderate and severe aortic stenosis [12]. SILCARD registry provided the rate of patients subjected to aortic intervention, so as the result of that it might be suspected that around 25% of patients had significant AS. Interestingly that rate of AS related to interventions has not changed over the ten-years period, but the number of procedures increased over the observed time. The number of the aortic interventions represents all procedures performed on the aortic valve from balloon valvuloplasty to surgical aortic valve replacement and TAVI. As the number of TAVI procedure increases in Poland, the presented date supposedly reflects future population needs [13].

The aortic stenosis has a significant impact on patients’ prognosis, and when it coexists with another cardiovascular comorbidity, it adds fuel to the fire [14, 15]. CAD coexistence worsened AS patients’ prognosis [16, 17]. With the presented registry half of the patients had been diagnosed with CAD, but only around 10% required percutaneous or surgical revascularization. Interestingly the number of PCI increased over the observation period. It may be explained by the increased number of TAVI procedures which are accompanied by the percutaneous revascularization of the coronary artery disease. The management of significant CAD in patients with the AS is safe and improves their outcomes either in those referred for the aortic valve replacement plus coronary artery bypass grafting or for TAVI plus PCI [16, 18, 19]. From the preventive point of view, appropriate control of common cardiovascular risk factors in mid-life decreased AS and atherosclerosis prevalence in late-life [20, 21]. However, the prevention should concern a broad spectrum cardiovascular risk factors, since the only aggressive lipid-lowering therapy is not enough. It decreases the CAD incidents and reduces the number of
coronary revascularizations in AS patients, but it does not have any impact on AS prevalence [22].

Although the number of patients with diagnosed AS increased over last decade, the 30-day in-hospital mortality rate has dropped. One-year mortality rate was still high and stayed at around 15% level, but it should be contemplated concerning increasing age and increasing rate of coexisting extracardiac diseases. Furthermore, it is many patients, as compared to data from other publications. Japanese registry presented that not treated AS characterized 6.7% mortality at 16-month follow-up [23]. SILCARD AS patients had probably a very diverse clinical characteristic at baseline, which could have impacted their general prognosis. It mostly involves patients with symptomatic aortic stenosis omitting those with poor clinical symptoms but increased risk of adverse events [24]. As mentioned below, SILCARD registry also has significant limitations, which undoubtedly might have affected the results. Nevertheless, further thorough studies are needed to identify the cause of death in AS patients in the Silesian district in Poland.

Study limitations

The AS diagnosis was based only on ICD classification reporting to National Health Fund. ICD codes represent the primary cause of hospitalization and, according to Polish regulations, the reporting of coexisting diseases is not mandatory. Furthermore, the order of reported diagnosis is subjective, and some of the imported co-morbidities may be not recorded in the registry. Neither reporting based on ICD classification helps to identify severe aortic stenosis, which has the most significant impact on patients’ prognosis. Some AS patients could have also been lost from
observation or they could continue treatment in other centers not covered by the SILCARD registry. In addition, aortic valve stenosis could be under/over diagnosed in challenging cases such low flow low gradient aortic valve stenosis. These limitations must be considered while drawing conclusions from the data.
Conclusions

According to the SILCARD registry, the number of diagnosed AS patient is increasing. Presented data proofs that AS became one of the most critical aspects of cardiovascular diseases in Silesia district. Although the number of the aortic valve intervention increased, the one-year mortality remains high. It leaves considerable space for intervention to meet local health needs.

Contribution statement:

TR conceived the idea for the study. TR, TG, ZG prepared the manuscript. MH and DC analyzed the data. MZ, WW, MG were involved in data collection. MZ and MG coordinated funding for the project. All authors edited and approved the final version of the manuscript.


Figure 1. The aortic stenosis patients’ hospitalizations

A) The number of patients hospitalized with the diagnosis of aortic stenosis. B) Percentage of the aortic stenosis among the all cardiovascular hospitalizations. C) The rate of patients hospitalized at the cardiology, the cardio surgery, the intensive cardiac care, the internal medicine and the vascular surgery departments. D) The figure presents the mean age of hospitalized aortic stenosis patients.
Figure 2. The Heart failure, the coronary artery disease, the myocardial revascularization, the length of hospital stays and in-hospital mortality rate of patients with aortic stenosis.

A) The figure presents the percentage of the coexisting coronary artery disease and heart failure with aortic stenosis. B) The figure presents the percentage of percutaneous coronary interventions (PCI) and coronary artery bypass grafting (CABG) in patients with the aortic stenosis during the first hospitalization C) the figure presents the trend for the length of the hospital stay and D) presents the trend of in-hospital mortality in patients with aortic stenosis.
Figure 3. Mortality of patients with aortic stenosis

A) The figure presents the 30-day mortality of patients with the aortic stenosis. B) The figure presents (the) one-year mortality of patients with the aortic stenosis.
### Table 1. The ICD-10 codes assigned to individual cardiovascular diseases

<table>
<thead>
<tr>
<th>Cardiovascular Disease</th>
<th>ICD-10 Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic stenosis</td>
<td>I06.02, I06.0, I35.0, I35.2</td>
</tr>
<tr>
<td>Aortic Regurgitation</td>
<td>I35.1 I35.11, I35.111, I35.112, I06.111, I06.112, I06.21</td>
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<td>Mitral Regurgitation</td>
<td>I34.0, I34.1, I05.1, I05.111, I05.112</td>
</tr>
<tr>
<td>Mitral stenosis</td>
<td>I05.0, I05.01, I05.2, I05.21, I34.2</td>
</tr>
<tr>
<td>Tricuspid valve regurgitation</td>
<td>I36.0, I07.0, I07.01, I07.2,</td>
</tr>
<tr>
<td>Heart failure</td>
<td>I50, I51.5, I51.7, J81, R57, I42, I43</td>
</tr>
<tr>
<td>Stable coronary artery disease</td>
<td>I25, I20.1, I20.8, I20.9</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>I20.0, I24.0, I24.8, I24.9</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>I21, I22</td>
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<tr>
<td>Atrial fibrillation</td>
<td>I48</td>
</tr>
<tr>
<td>Arterial hypertension</td>
<td>I10, I11, I12, I13, I15</td>
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<tr>
<td>Pulmonary embolism</td>
<td>I26</td>
</tr>
<tr>
<td>Infective endocarditis</td>
<td>I33, I38, I39</td>
</tr>
<tr>
<td>Grown-up congenital heart disease</td>
<td>Q20-Q28</td>
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<tr>
<td>Valvular heart diseases without aortic stenosis</td>
<td>I05, I06.1, I06.8, I06.9, I07, I08, I34, I35.1, I35.8, I35.9, I36, I37</td>
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Table 2. Distribution of aortic stenosis hospitalization with concomitant cardiovascular diseases.

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<tr>
<td>Aortic stenosis, n(%)</td>
<td>939</td>
<td>875</td>
<td>1100</td>
<td>1343</td>
<td>1366</td>
<td>1522</td>
<td>1564</td>
<td>1542</td>
<td>1577</td>
<td>1661</td>
<td>1669</td>
</tr>
<tr>
<td>Coronary artery disease, n(%)</td>
<td>323 (34.4)</td>
<td>318 (36.3)</td>
<td>408 (41.0)</td>
<td>539 (39.5)</td>
<td>681 (44.7)</td>
<td>684 (43.7)</td>
<td>661 (42.9)</td>
<td>678 (43.0)</td>
<td>675 (40.6)</td>
<td>699 (41.9)</td>
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<td>Heart failure, n(%)</td>
<td>213 (22.7)</td>
<td>202 (23.1)</td>
<td>253 (24.6)</td>
<td>365 (26.7)</td>
<td>449 (29.5)</td>
<td>463 (29.6)</td>
<td>464 (30.1)</td>
<td>481 (30.5)</td>
<td>482 (29.0)</td>
<td>484 (29.0)</td>
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<td>Pulmonary embolism, n(%)</td>
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<td>2 (0.2)</td>
<td>3 (0.3)</td>
<td>1 (0.1)</td>
<td>7 (0.5)</td>
<td>2 (0.1)</td>
<td>3 (0.2)</td>
<td>7 (0.4)</td>
<td>12 (0.7)</td>
<td>4 (0.2)</td>
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<td>Other valvular diseases, n(%)</td>
<td>169 (18.0)</td>
<td>156 (17.8)</td>
<td>213 (19.4)</td>
<td>291 (21.7)</td>
<td>304 (22.3)</td>
<td>330 (21.7)</td>
<td>384 (24.6)</td>
<td>324 (21.0)</td>
<td>392 (24.9)</td>
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<td>325 (19.5)</td>
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<td>Congenital heart defect, n(%)</td>
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<td>3 (0.3)</td>
<td>5 (0.5)</td>
<td>4 (0.3)</td>
<td>3 (0.2)</td>
<td>5 (0.3)</td>
<td>11 (0.7)</td>
<td>6 (0.4)</td>
<td>5 (0.3)</td>
<td>3 (0.2)</td>
<td>10 (0.6)</td>
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<td>Hypertension, n(%)</td>
<td>333 (35.5)</td>
<td>317 (36.2)</td>
<td>423 (38.5)</td>
<td>534 (39.8)</td>
<td>564 (41.3)</td>
<td>663 (43.6)</td>
<td>640 (40.9)</td>
<td>615 (39.9)</td>
<td>639 (40.5)</td>
<td>631 (38.0)</td>
<td>656 (39.3)</td>
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<td>Diabetes, n(%)</td>
<td>No data</td>
<td>148 (16.9)</td>
<td>206 (18.7)</td>
<td>285 (21.2)</td>
<td>298 (21.8)</td>
<td>356 (23.4)</td>
<td>375 (24.1)</td>
<td>381 (24.7)</td>
<td>408 (25.8)</td>
<td>390 (23.4)</td>
<td>429 (25.7)</td>
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<tr>
<td>COPD, n(%)</td>
<td>No data</td>
<td>19 (2.2)</td>
<td>22 (2.0)</td>
<td>32 (2.4)</td>
<td>38 (2.8)</td>
<td>53 (3.5)</td>
<td>63 (4.0)</td>
<td>52 (3.4)</td>
<td>64 (4.1)</td>
<td>57 (3.4)</td>
<td>78 (4.7)</td>
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<tr>
<td>Renal insufficiency, n(%)</td>
<td>No data</td>
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<td>64 (5.8)</td>
<td>76 (5.7)</td>
<td>111 (8.1)</td>
<td>93 (6.1)</td>
<td>104 (6.6)</td>
<td>117 (7.6)</td>
<td>108 (6.8)</td>
<td>124 (7.5)</td>
<td>127 (7.6)</td>
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