The COSTA Study: Sternal Closure in High-Risk Patients - A Prospective Randomized Multicenter Trial

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Abstract

Background  Median sternotomy in patients with risk factors for wound healing is associated with high rates of postoperative wound infections and sternum instability.

Methods  A total of 338 patients with elective first median sternotomy and at least four predefined risk factors were randomized between Sternal Talon (Gebrüder Martin GmbH & Co. KG—KLS Martin Group, Tuttingen, Germany) and wire cerclage. The primary end point was mediastinitis and/or sternal instability within 30 ± 5 days, and the secondary end points were mediastinitis and/or sternal instability within 60 ± 5 days; incidence of pneumonia during hospitalization within the first 30 ± 5 days and chest pain intensity.

Results  The primary end point was reached in 10 Sternal Talon and 7 wire cerclage patients (6.2 vs. 4.7%, odds ratio [OR]: 1.3, 95% confidence interval [CI]: 0.5–3.6, p = 0.57) from 338 randomized patients. Sternal Talon group, n = 170 patients versus wire cerclage group, n = 168 patients. The differences between treatment groups with regard to the incidence of mediastinitis/sternum instability within the first 60 ± 5 days after the primary sternum closure and the incidence of pneumonia during the hospitalization within the first 30 ± 5 days were not statistically significant, either. We observed comparable rates of superficial surgical site infection (SSI) in Sternal Talon and wire cerclage patients (16.1 vs. 12.1%, OR: 1.4, 95% CI: 0.7–2.7, p = 0.31).

Conclusion  According to these data, there is no statistically significant difference between Sternal Talon closure and wire cerclage in reducing the incidence of mediastinitis and superficial SSI after primary closure of median sternotomy in high-risk patients.

Introduction

Sternal wound complications following median sternotomy influence in-hospital mortality, postoperative morbidity, and health care costs. It is especially important to reduce postoperative sternal wound complications in patients with risk factors for wound healing such as age, diabetes mellitus, bilateral use of the internal mammary artery for coronary bypass grafting, renal insufficiency, or a higher than average body mass index (BMI), chronic obstructive pulmonary disease (COPD), and others.1–4 The conventional method used for sternal closure usually involves the use of stainless steel wires. It is a nonrigid fixation technique that may be associated with significant disadvantages.

Many clinical studies have reported the effects of different sternal closure techniques after median sternotomy on postoperative wound healing.5–7 In recent years, new alternative sternal closure methods have been developed which in considering the biomechanics of the sternum could improve postoperative wound healing and prevent sternal instability in high-risk patients.

One of the newly developed devices is the Sternal Talon (Gebrüder Martin GmbH & Co. KG—KLS Martin Group, Tutlingen, Germany). It is made of biocompatible titanium. The device covers a large bone area of the sternum and it allows the closure of the sternum without bone penetration. This technique promises significant sternal stability and decrease of postoperative wound complications in patients with risk factors such as age, obesity, diabetes, COPD, and others. The system is easy to implant and can be opened fast and easily in emergency immediately after the operation.8–12

Methods and Participants

The COSTA Study (Closure of median sternotomy in high-risk patients using Sternal Talon implants or conventional wire closure) is a randomized controlled open multicenter study for investigating the incidence of mediastinitis and sternal instability with the use of Sternal Talon implants compared with conventional wire cerclage for primary sternal closure after median sternotomy. The identification of superficial surgical site infection (SSI) involves interpretation of clinical and laboratory findings and is classified as being either incisional or organ/space with purulent drainage from the superficial incision or positive swabs (see definition 1).

Supplementary Material [available online only]).4,13

Mediastinitis was defined as a wound infection from mediastinal tissue with sternal instability/sternum fracture and positive microbiological swabs. In addition, a deep dehiscence was diagnosed if the sternum was unstable, even if swabs were negative and there were no clinical signs of infection (see definition 1).4,13

Pneumonia was defined as a lung infection and involves interpretation of clinical symptoms and radiological findings (see definition 1).

Patients of four centers in Germany and one in Austria were enrolled (Heart Center, University of Freiburg; Heart Center, Bad Oeynhausen; Department of Cardiovascular Surgery, Cologne, Tuebingen, and Vienna). Data were collected during hospitalization and/or in a telephone follow-up after 30 and 60 days. For some patients, records from other hospitals or institutions or primary physicians were obtained. Patients were recruited from November 20, 2008, to February 28, 2014. We have the summary of risk factors for each group currently calculated: in the Sternal Talon group (n = 170), there were 122 (72%) patients with ≤4 risk factors and 48 (28%) with 5 to 6 risk factors; in the wire cerclage group (n = 167) had 113 (68%) patients ≤4 and 54 (32%) 5 to 6 risk factors.

Every patient, who survived up to 16th day and beyond, received postoperative follow-up. The mortality rate was 5.3% (9 patients) in the Sternal Talon group and 11.3% (19 patients) in the wire cerclage group. The most frequently reasons in both groups were multiorgan failure and heart failure. The trial ended when the number of planned study patients was reached.

Eligibility criteria were a planned median sternotomy and age >18 years. Except six patients from the beginning, we included patients with at least 4 of the following 12 risk factors: age ≥65 (as a separate risk factor); age ≥80 (as a separate risk factor); myocardial infarction within previous 90 days and/or ejection fraction ≤35%; extracardiac arteriopathy (claudication intermittent, carotid stenosis >50%, previous or indicated operation of aorta, lower extremities arteries, or carotid artery); diabetes mellitus (dietary, drug, or insulin regulated); chronic pulmonary disease (therapy with steroids and bronchodilators); creatinine ≥200 μmol/L and/or dialyses; patient on immune suppression/cytostatic drug; critical preoperative state (one or more points: state after mechanical reanimation, artificial respiration, preoperative intra-aortic balloon pump support, preoperative catecholamine support, renal failure, oliguria <10 mL/h, ventricular tachycardia, and ventricular fibrillation); planned use of bilateral mammary artery; BMI ≥30 kg/m² (as a separate risk factor); BMI ≥40 kg/m² (as a separate risk factor).

Exclusion criteria were hypersensitivity to titanium, any thoracic anomaly preventing Sternal Talon application, systemic antibiotic therapy for current infection, pregnancy or breastfeeding, concomitant participation in another clinical study, or inability of the patient to understand study and provide informed consent.

Inclusion criteria were twice changed and adapted to the study; per example female gender was removed from the list of risk factors because that produced predominant randomization of women. After randomization of six patients, BMI ≥40 kg/m² was included as another risk factor in addition to BMI ≥30 kg/m², aiming to recruit more potential patients for the study. Between November 20, 2008, and February 28, 2014, 338 patients were randomized between Sternal Talon and wire cerclage.

Surgical Procedures

The Sternal Talon system is available in a single and double version (Fig. 1A, B), sterile and separately packed. The single version is available in five widths (XS, S, M, L, and XL) and the double version in two widths (S and M). Both
versions are available in four foot-plate depths: 11, 14, 17, and 20 mm.

Intraoperative placement of the Sternal Talon was performed in four steps: (1) The width and thickness of the sternum were measured to determine the correct size of the implants to be selected. (2) The two parts of the Sternal Talon were inserted in the intercostal spaces at an angle of 45 degrees. (3) A reduction clamp was then used to press the two halves together which were locked in place by the ratchet (Fig. 1C). (4) Once the implant had been firmly closed, the three-position screw was turned to the locked position.

For controls, sternal wire closure was performed according to the hospitals’ manuals or standard operating procedures (SOPs) of the participating hospitals. Preoperative prophylaxis against infection, perioperative antibiotics therapy, anesthesia, and postoperative wound care are performed for both closure techniques according to the hospitals’ manuals or SOPs.

The random allocation sequence was generated by one independent researcher by means of the “Random Sequence Generator” (https://www.random.org/sequences/). Sequences were created in a 1:1 ratio in block sizes of 10. Blinding was not applicable.

Sheets containing the allocation to the group were provided in continuously numbered closed envelopes. Each center received its own packs of envelopes.

Patients were enrolled by the physician in charge. After inclusion of the patient, the envelopes were opened at the center in sequential order and the assignment was revealed.

**End Points**

The aim of our study was to compare the closure with Sternal Talon implants and conventional wire closure in high-risk patients. The primary end point of the study was defined as incidence of mediastinitis or sternal instability (including crepitation of sternum/transversal sternal fracture) within the first 30 (±5) days after the primary sternum closure.

Secondary end points were as follows:

1. Incidence of mediastinitis or sternum instability within the first 60 (±5) days after primary sternum closure.
2. Incidence of pneumonia during hospitalization within the first 30 (±5) days after primary sternum closure.
3. Chest pain intensity at the first and third postoperative days, and during ongoing hospitalization at days 7, 14, 21, and 30.

**Safety Analyses**

All adverse and serious adverse events (AE and SAE) were recorded throughout the study and classified according to the Medical Dictionary for Regulatory Activities (MedDRA) system (see definition 2). MedDRA is a rich and highly specific standardized medical terminology developed by International Conference on Harmonization of Technical
Requirements for Registration of Pharmaceuticals for Human Use to facilitate sharing of regulatory information internationally for medical products used by humans. It is used for registration, documentation, and safety monitoring of medical products both before and after a product has been authorized for sale (http://www.ich.org/products/meddra.html).

**Statistical Analysis**

Statistical analysis was performed according to a prespecified plan using the Statistical Analysis System (SAS Institute GmbH, Heidelberg, Germany), Version 9.3. Data are expressed as total n, percentage, odds ratios (ORs), and 95% confidence intervals (CIs) as appropriate.

Samples size was estimated according to publications. It was assumed that the probability of mediastinitis or sternum instability is equal to 11% in the wire closure group. The study should have a power of 80% to show a difference between treatments at a two-sided significance level of 5% if in the Sternal Talon group the probability of mediastinitis or sternum instability is decreased to 3%. This required the randomization of ~320 patients in total. The number of randomized was increased slightly to 338 to account for some protocol deviations.

Three analysis sets were considered: the full analysis set (FAS), the per protocol (PP) set, and the safety set. The FAS includes all randomized patients according to the intention-to-treat principle, and patients are analyzed as belonging to their randomized arm, regardless of whether they refused therapy, or whether other protocol deviations are known. The PP set is a subset of the FAS including only patients for whom no major protocol violations are known. Patients were excluded from the PP set when one of the following protocol violations was present: (1) median sternotomy was not planned; (2) patients had less than four risk factors; (3) patients received wire cerclage against randomization; (4) patients received wire cerclage; (5) patients had no primary closure; (6) median sternotomy was not performed; (7) sternotomy < 3 intercostal spaces; (8) patients underwent rethoracotomy for other reasons; and (9) patients had a previous sternotomy. The safety set is a subset of all randomized patients and includes patients for whom median sternotomy was performed and one of the sternal closure methods under study was used. Patients in the safety set were analyzed as belonging to the procedure received. The primary efficacy analysis was conducted in the FAS. As a sensitivity analysis, the analysis was performed also in the PP set. Patients for whom the status of efficacy end points was not known after 25 days after surgery were excluded from the analysis. The incidences of the efficacy end points were calculated as percentage of patients for whom the respective end point occurred.

A statistical comparison of treatment groups was performed using univariable logistic regression models. As estimate of the effect size, the OR was calculated with 95% CI, and the hypothesis of equality of treatment groups was tested using the Wald's test. Safety analyses were performed in the safety set.

**Additional Analyses**

Additional analyses of superficial wound infection were performed with the FAS and PP set between both arms.

**Results**

A total of 338 patients with planned first median sternotomy and predefined risk factors for wound healing were included in our study. All demographic and clinical characteristics are presented in → Table 1. Patient allocation after randomization—a CONSORT flow diagram—is shown in → Fig. 2.

The FAS consisted of 170 patients with Sternal Talon and of 167 patients with wire cerclage, since 1 patient withdrew his/her informed consent before surgery. Since 51 patients in the Sternal Talon group and 18 patients in the wire cerclage group had major protocol deviations, the PP population contained 119 patients with Sternal Talon and 146 patients with wire cerclage.

Safety population consisted altogether 318 patients: 138 patients got Sternal Talon and 180 had wire cerclage. Eleven patients in the Sternal Talon group and 8 patients in the wire cerclage group received none of the treatments to be compared, 22 patients received wire cerclage against randomization, and 1 patient received Sternal Talon against randomization.

**End Points**

An overview of the primary and secondary outcomes for the FAS and PP populations is shown in → Fig. 3A, B. The primary end point, mediastinitis, and/or sternum instability within the first 30 (± 5) days after the primary sternum closure was observed in 10 of 161 Sternal Talon and 7 of 148 wire cerclage patients of the FAS with known status of end point (6.2 vs. 4.7%), OR was 1.3 (95% CI: 0.5–3.6), p = 0.57. Nine patients in the Talon group and 15 patients in the wire cerclage group were excluded from this analysis (8 and 15 died within 25 days, 1 and 4 patients had a follow-up time of less than 25 days, Talon and wire cerclage groups, respectively). The primary end point was observed in six patients each in the PP (5.2 vs. 4.5%), OR was 1.2 (95% CI: 0.4–3.7), p = 0.80.

Incidence of mediastinitis or sternum instability within the first 60 (± 5) days after the primary sternum closure was noticed in 12 Sternal Talon and 10 wire cerclage patients of the FAS (7.5 vs. 6.8%), and in 7 patients each in the PP (6.0 vs. 5.2%), OR were 1.1 (95% CI: 0.5–2.6) for FAS and 1.2 (95% CI: 0.4–3.4) for the PP set with no difference between the treatment arms (p = 0.8 and p = 0.8, respectively).

Pneumonia during hospitalization within the first 30 (± 5) days after the primary sternum closure was observed in 22 Sternal Talon and 25 wire cerclage patients of the FAS (13.6 vs. 16.7%) and in 13 Sternal Talon and 20 wire cerclage patients of the PP (11.1 vs. 14.8%). ORs were 0.8 (95% CI: 0.4–1.5) for FAS and 0.7 (95% CI: 0.3–1.5) for PP with no difference between treatment arms (p = 0.45 and p = 0.39, respectively).

Chest pain intensity as a secondary end point was excluded from statistical analysis because the patients’ statements were not reliable and too incomplete for a valid statistical analysis.
Incidence of superficial SSI within the first 30 (± 5) days after the primary sternum closure was noticed in 26 Sternal Talon and 18 wire cerclage patients of the FAS (16.1 vs. 12.1%), and in 21 Sternal Talon and 17 wire cerclage patients of the PP (18.1 vs. 12.6%). ORs were 1.4 (95% CI: 0.7–2.7) for FAS and 1.5 (95% CI: 0.8–3.1) for the PP set with no difference between the treatment arms ($p = 0.31$ and $p = 0.23$, respectively).

**Safety Analysis**

Total number of AEs was 699 in population SAF and 538 in population PP. We saw similar allocation between sternal talon and wire cerclage groups in both populations. An overview of all AEs and SAEs is presented in -Tables 2 and 3.

Total number of AEs possibly related to device was noted in 64 Sternal Talon and 54 wire cerclage patients in the SAF and in 44 Sternal Talon and 41 wire cerclage patients in the population PP. We noted a total of 367 SAEs in population SAF (166 in Sternal Talon and 201 in wire cerclage patients) and 260 in population PP (116 in Sternal Talon and 144 in wire cerclage group). SAEs possibly related to device were observed in 23 patients (16.7%) in the Sternal Talon group and in 16 patients (8.9%) in the wire cerclage group of the SAF ($p = 0.05$ and $p = 0.03$, respectively). Most frequently, AEs such as cardiac arrhythmias, low-output cardiac syndrome, renal failure, and pneumonia were expected to a high-risk profile of randomized patients. The listing of most frequently AEs is presented in -Table 4.

**Discussion**

Cardiothoracic literature describes different studies on sternal closure techniques aimed to minimize postoperative sternum instability and wound-healing complications in high-risk patients. Many authors have compared solid wiring closure with double wiring closure, the number of wires, rigid plate fixation, and Robicsek technique with standard wiring closure. For example, Raman et al have described the superiority of rigid plate fixation over wire cerclage in the high-risk patients after the cardiac surgery as a primary sternal closure. Fawzy et al shown that sternal plate fixation is an effective reconstruction option for the treatment of sternal wound dehiscence. Friberg et al demonstrated that additional fixation wires at the lower sternum actually reduce the incidence of deep wound infections. On the contrary, the study by Schimmer et al found no reduction of sternal instability and wound infection in high-risk patients, who received sternal closure by the Robicsek technique. The same authors reported too that the application of InteguSeal or Genta-Coll resorb had no significant influence on the incidence of the sternal SSI rate in cardiac surgery patients.

Nikolaidis et al reported the use of thermal shape-memory nitinol clips following midline sternotomy with considerable reduction of sternal dehiscence and related complications. Tsunekawa et al described the use of Super Fixsorb 30 sternal pins in addition to the standard closure and observed the reduction of anterior-
posterior sternal displacement and development of earlier sternal fusion and osteogenesis. However, Srivastava et al did not observe an advantage of thermoreactive nitinol clips in the prevention of superficial or deep sternal wound infection in obese patients undergoing sternotomy.

There has been a decreasing rate of poststernotomy complications in high-risk patients with optimized wiring.
techniques and the development of many new sternal closure techniques. A device for optimal sternal closure should prevent complications of postoperative wound healing and instability. It would be easily implantable, and quickly removable in case of emergency. For this purpose, the Sternal Talon closure system was engineered. This technique promises significant sternum stability and the potential to improve the postoperative wound complications rate in patients with risk factors such as age, obesity, diabetes, and COPD, among others.

Bennett-Guerrero et al described the results of a pilot study of sternal closure with the Sternal Talon device. The pilot study was a small randomized trial and the primary end point showed no difference between both groups (Sternal Talon vs. standard sternal wiring) related to decreased use of opiates, decreased duration of mechanical ventilation, and hospital length of stay. Cases of deep sternal wound infection or nonunion were not observed in either treatment group. Levin et al observed no sternum instability or dehiscence in 42 patients who had more than three risk factors and underwent surgery with the Sternal Talon closure technique.

With a view to investigate an optimal sternal closure strategy in high-risk patients and to minimize the rate of postoperative wound complications and sternum instability, we started our prospective randomized multicenter study with two different therapy arms. High-risk patients were included in a randomized controlled open multicenter study for analysis of a reduction in the incidence of mediastinitis and sternum instability by the use of Sternal Talon implants as compared with sternal closure with wire cerclages. The postoperative period was monitored after defined primary and secondary end points of study.

Statistical analysis revealed no significant differences between the Sternal Talon closure system and wire cerclage in reducing the incidence of mediastinitis/sternal instability and of superficial SSI after primary closure of median sternotomy in high-risk patients. The primary end point occurred in both the FAS and the PP population with no statistical difference between the treatment arms. Incidence of mediastinitis/sternum instability within the first 60 (±5) days after the primary sternum closure and incidence of pneumonia during the hospitalization until to the maximum 30 days was not statistical significant, either. Most frequently, AEs such as cardiac arrhythmias, low-output cardiac syndrome, renal failure, respiratory complications (pneumonia, respiratory failure, pleural effusion), and symptomatic transitory psychotic syndrome were expected to a high-risk profile of randomized patients.

These results suggest independent decisions by surgeons, for or against the implantation of the Sternal Talon system, according to patient characteristics and the local operative situation.

**Limitations of the Study**

Patient enrollment was very slow and study period (2008–2014) extended over a time of 6 years. In addition, inclusion criteria were changed during the study period and there

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Number of AE and SAE in population SAF and population PP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SAF-ST</td>
</tr>
<tr>
<td>Total no. of patients</td>
<td>138</td>
</tr>
<tr>
<td>Total no. of AEs</td>
<td>320</td>
</tr>
<tr>
<td>No. of patients with at least 1 AE</td>
<td>117</td>
</tr>
<tr>
<td>Total no. of SAEs</td>
<td>166</td>
</tr>
<tr>
<td>No. of patients with at least 1 SAE</td>
<td>71</td>
</tr>
</tbody>
</table>

Abbreviations: AE, adverse event; PP, per protocol; PP-ST, PP set with Sternal Talon closure; PP-WC, PP set with wire cerclage closure; SAE, serious adverse event; SAF-ST, safety set with Sternal Talon closure; SAF-WC, safety set with wire cerclage closure; ST, Sternal Talon; WC, wire cerclage.
Table 3 Number of AE and SAE possibly related to device in population SAF and PP

<table>
<thead>
<tr>
<th></th>
<th>SAF-ST</th>
<th>SAF-WC</th>
<th>Total</th>
<th>PP-ST</th>
<th>PP-WC</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total no. of patients</td>
<td>138</td>
<td>180</td>
<td>318</td>
<td>119</td>
<td>146</td>
<td>265</td>
</tr>
<tr>
<td>Total no. of AEs (prd)</td>
<td>64</td>
<td>54</td>
<td>118</td>
<td>44</td>
<td>41</td>
<td>85</td>
</tr>
<tr>
<td>No. of patients with at least 1 AE</td>
<td>35</td>
<td>31</td>
<td>66</td>
<td>27</td>
<td>23</td>
<td>50</td>
</tr>
<tr>
<td>Total no. of SAEs (prd)</td>
<td>44</td>
<td>32</td>
<td>76</td>
<td>26</td>
<td>25</td>
<td>51</td>
</tr>
<tr>
<td>No. of patients with at least 1 SAE</td>
<td>23</td>
<td>16</td>
<td>39</td>
<td>15</td>
<td>11</td>
<td>26</td>
</tr>
</tbody>
</table>

Abbreviations: AE, adverse event; PP, per protocol; PP-ST, PP set with Sternal Talon closure; PP-WC, PP set with wire cerclage closure; prd, possibly related to device; SAE, serious adverse event; SAF-ST, safety set with Sternal Talon closure; SAF-WC, safety set with wire cerclage closure; ST, Sternal Talon; WC, wire cerclage.

Table 4 Listing of most frequently AEs in population SAF and population PP

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>PP-ST, %</th>
<th>SAF-ST, %</th>
<th>PP-WC, %</th>
<th>SAF-WC, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of patients</td>
<td>119 (100%)</td>
<td>138 (100%)</td>
<td>146 (100%)</td>
<td>180 (100%)</td>
</tr>
<tr>
<td>Cardiac arrhythmias</td>
<td>22 (18.5%)</td>
<td>27 (19.6%)</td>
<td>32 (21.9%)</td>
<td>36 (20.0%)</td>
</tr>
<tr>
<td>Wound infection sternal, superficial</td>
<td>16 (13.4%)</td>
<td>16 (11.6%)</td>
<td>11 (7.5%)</td>
<td>13 (7.2%)</td>
</tr>
<tr>
<td>Symptomatic transitory psychotic syndrome</td>
<td>16 (13.4%)</td>
<td>17 (12.3%)</td>
<td>15 (10.3%)</td>
<td>14 (7.8%)</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>18 (15.1%)</td>
<td>20 (14.5%)</td>
<td>22 (15.1%)</td>
<td>25 (13.9%)</td>
</tr>
<tr>
<td>Low-output cardiac syndrome</td>
<td>17 (14.2%)</td>
<td>19 (13.8%)</td>
<td>24 (16.4%)</td>
<td>28 (15.6%)</td>
</tr>
<tr>
<td>Renal failure</td>
<td>15 (12.6%)</td>
<td>17 (12.3%)</td>
<td>14 (9.6%)</td>
<td>17 (9.4%)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>15 (12.6%)</td>
<td>16 (11.6%)</td>
<td>23 (15.8%)</td>
<td>25 (13.9%)</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>14 (11.8%)</td>
<td>20 (14.5%)</td>
<td>15 (10.3%)</td>
<td>19 (10.6%)</td>
</tr>
<tr>
<td>Chest pain</td>
<td>11 (9.2%)</td>
<td>13 (9.4%)</td>
<td>3 (2.1%)</td>
<td>3 (1.7%)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>10 (8.4%)</td>
<td>13 (9.4%)</td>
<td>11 (7.5%)</td>
<td>14 (7.8%)</td>
</tr>
<tr>
<td>Neurological deficit</td>
<td>9 (7.6%)</td>
<td>12 (8.7%)</td>
<td>8 (5.5%)</td>
<td>11 (6.1%)</td>
</tr>
<tr>
<td>Infection unclear genesis</td>
<td>9 (7.6%)</td>
<td>11 (7.8%)</td>
<td>11 (7.5%)</td>
<td>10 (5.6%)</td>
</tr>
<tr>
<td>Wound infection, another location (leg)</td>
<td>8 (6.7%)</td>
<td>8 (5.8%)</td>
<td>9 (6.2%)</td>
<td>7 (3.9%)</td>
</tr>
<tr>
<td>Sternum instability</td>
<td>7 (5.9%)</td>
<td>12 (8.7%)</td>
<td>7 (4.8%)</td>
<td>9 (5.0%)</td>
</tr>
<tr>
<td>Gastrointestinal complications</td>
<td>6 (5.0%)</td>
<td>6 (4.3%)</td>
<td>8 (5.5%)</td>
<td>8 (4.4%)</td>
</tr>
<tr>
<td>Wound dehiscence sternal</td>
<td>5 (4.2%)</td>
<td>6 (4.3%)</td>
<td>3 (2.1%)</td>
<td>3 (1.7%)</td>
</tr>
<tr>
<td>Mediastinitis</td>
<td>5 (4.2%)</td>
<td>7 (5.1%)</td>
<td>5 (3.4%)</td>
<td>5 (2.8%)</td>
</tr>
<tr>
<td>Wound infection sternal, deep</td>
<td>4 (3.4%)</td>
<td>13 (9.4%)</td>
<td>7 (4.8%)</td>
<td>5 (2.8%)</td>
</tr>
<tr>
<td>Secondary bleeding thoracic</td>
<td>4 (3.4%)</td>
<td>8 (5.8%)</td>
<td>3 (2.1%)</td>
<td>7 (3.9%)</td>
</tr>
<tr>
<td>Anemia</td>
<td>2 (1.9%)</td>
<td>2 (1.4%)</td>
<td>3 (2.1%)</td>
<td>3 (1.7%)</td>
</tr>
<tr>
<td>Multiple organ dysfunction syndrome</td>
<td>2 (1.9%)</td>
<td>7 (5.1%)</td>
<td>2 (1.4%)</td>
<td>3 (1.7%)</td>
</tr>
<tr>
<td>Sepsis</td>
<td>2 (1.9%)</td>
<td>2 (1.4%)</td>
<td>4 (2.7%)</td>
<td>4 (2.2%)</td>
</tr>
<tr>
<td>Pericardial effusion</td>
<td>1 (0.8%)</td>
<td>2 (1.4%)</td>
<td>1 (0.7%)</td>
<td>1 (0.6%)</td>
</tr>
<tr>
<td>Secondary bleeding (peripheral vessels)</td>
<td>1 (0.8%)</td>
<td>1 (0.72%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Surgery-induced complications</td>
<td>1 (0.8%)</td>
<td>3 (2.2%)</td>
<td>3 (2.1%)</td>
<td>4 (2.2%)</td>
</tr>
<tr>
<td>Sternum/rib fracture</td>
<td>1 (0.8%)</td>
<td>3 (2.2%)</td>
<td>2 (1.4%)</td>
<td>2 (1.1%)</td>
</tr>
<tr>
<td>Vascular complications (shunt thrombosis)</td>
<td>0 (0.0%)</td>
<td>1 (0.72%)</td>
<td>1 (0.7%)</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

Abbreviations: AE, adverse event; PP, per protocol; PP-ST, PP set with Sternal Talon closure; PP-WC, PP set with wire cerclage closure; SAF-ST, safety set with Sternal Talon closure; SAF-WC, safety set with wire cerclage closure.
were a great number of protocol violations, which resulted in large differences between FAS and PP population.

Conclusion

Sternal Talon closure system used for primary closure of median sternotomy in high-risk patients is as effective as conventional wire cerclage with a comparable incidence of mediastinitis and sternum instability.

Note

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Clinical Registration Number

German Clinical Trials Register (DRKS): DRKS00000697.

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Conflict of Interest

None declared.

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