Evaluation of post-operative development of mediastinitis in patients undergoing isolated coronary artery bypass grafting surgery: A single-center experience

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ABSTRACT

BACKGROUND: In this study, we aimed to evaluate mediastinitis cases developed after isolated coronary artery bypass graft surgery performed by median sternotomy to determine the causative microorganisms, risk factors, and clinical features.

METHODS: Between March 2009 and December 2018, a total of 44 patients (32 males and 12 females; mean age 62.84±6.95 years; range, 46–78 years) who underwent isolated coronary artery bypass grafting surgery with median sternotomy and developed mediastinitis postoperatively were included in the studying our cardiovascular surgery (CVS) department. Patients demographic information, comorbidities, habits, pre-operative hospital stay, elective or emergency surgery, perioperative internal mammary artery use, perioperative blood or blood product, operation and cardiopulmonary bypass times, suitability of antibiotic prophylaxis, medical and surgical treatment, clinical data, and laboratory results were retrospectively analyzed. Purulent discharge cultures obtained directly from the mediastinal space and microbiological examination notes made from the material obtained from the surgical site or surgical repair were recorded.

RESULTS: In isolated coronary artery bypass grafting surgery performed over a period of approximately 10 years, the rate of mediastinitis was 1%. There was no statistically significant difference between patients with and without mediastinitis in terms of age, sex, smoking habits, duration of operation and cardiopulmonary bypass, and intraoperative blood transfusion. The presence of diabetes mellitus and high mean body mass index was significantly higher in patients with mediastinitis compared to those without. Mediastinitis was diagnosed in 38 (86.3%) patients in the 1st month, 5 (11.3%) in the first 3 months, and 1 (2.2%) in the 1st year. Twenty-five (56.9%) Gram-positive bacteria, 13 (29.6%) Gram-negative bacteria, and 1 (2.3%) fungi were the microorganisms grown in purulent discharge cultures. Pathogen microorganisms could not be produced in 5 (11.4%) cases. The three most commonly isolated agents were methicillin-resistant coagulase-negative staphylococci (MRCNS) (50%), Escherichia coli (9.1%), and Klebsiella pneumoniae (6.8%).

CONCLUSION: Attention should be paid to surgical site infection in patients undergoing CVS. Following discharge, follow-up is important and empirical treatment should be determined by considering the presence of MRCNS as the leading infectious agent in our hospital when infection occurs.

Keywords: Cardiovascular surgery; coronary artery bypass grafting; mediastinitis.

INTRODUCTION

Infections following cardiovascular surgery (CVS) may necessitate further medical therapy and surgical interventions, increasing the length of hospital stay.1 Post-operative mediastinitis is a rare complication of CVS but the most critical and feared one. Mediastinitis is an organ-space infection listed among surgical site infections (SSIs), seen in 0.4–2.4% of patients undergoing a median sternotomy. Mortality rates of up to 40% are reported in the literature in association with mediastinitis.2 Several risk factors are involved in the develop-
opment of mediastinitis, including advanced age, male sex, obesity, smoking habits, diabetes mellitus, chronic obstructive pulmonary disease (COPD), prolonged surgery and cardiopulmonary bypass time, sternal detachment, and the bilateral use of internal mammary arteries (IMA).[^3] In this study, we aimed to evaluate mediastinitis cases that developed this infection after isolated coronary artery bypass graft (CABG) surgery performed with median sternotomy in the CVS clinic of our hospital to determine the causative microorganisms, risk factors, and clinical features.

**MATERIALS AND METHODS**

A retrospective review of 4349 patients who underwent isolated CABG surgery with median sternotomy in the CVS clinic of our hospital from March 2009 to December 2018 revealed that 44 patients developed mediastinitis in the post-operative period. Demographic information, comorbidities, and lifestyle habits of the patients, their length of pre-operative hospital stay, the nature of the surgical intervention whether elective or emergency, perioperative IMA use, perioperative transfusion of blood and blood products, the length of operation, and cardiopulmonary bypass times, and the adequacy of antibiotic prophylaxis were retrieved from the patient files retrospectively. The surgical prophylaxis administered to the patients included cefazolin sodium 1–2 g given intravenously 3 times a day. It was administered 60 min before the operation and continued for 48 h in the post-operative period. Alternatively, cefuroxime was administered to the patients at an intravenous dose of 1.5 g 2 times a day. In the evening before the operation, the body hair of the patients was shaved with a 3M Remington 9604 medical razor, and the patients were bathed with Hibitanol, an antiseptic solution, to avoid potential infections. During the intervention, necrotic skin and subcutaneous tissue were debrided. If the sternum was intact and strong after plain rewiring, aggressive re-exploration was employed with debridement and cleaning of the mediastinum. After preparing the site of the surgery thoroughly and draping the chest, the median sternotomy incision was opened completely, and all sutures and sternal wires were removed. Intraoperative cultures and Gram stain were obtained. The soft tissues were debrided as required, but as minimally as possible. The sternal edges were freshened using curettes and rongeurs. The wound was copiously irrigated with warm saline or an antibiotic solution. One or more drainage and irrigation catheters were placed in the mediastinal posteriorly to the sternal edges. The sternal edges were reapproximated carefully and securely with multiple heavy stainless steel wires. The skin edges and soft tissues were then reapproximated with monofilament propylene sutures. Dilute antibiotic solution (povidone-iodine 40 ml/h) is irrigated continuously into the mediastinum over the next few days. This is continually dripped into the inflow drain and removed with the outflow drains which are removed in the next few days if it remains sterile and minimum. The antibiotic choice is directed by the culture and sensitivity results and continued for 3–6 weeks. It was found that the patients were routinely called for outpatient control visits on the 10th day after the hospital discharge to be followed up for any potential development of nosocomial infections. The second follow-up visits were performed in the 1st month after the hospital discharge. Fever, pain on the sternum, the presence of purulent discharge in the surgical site with or without sternal detachment, and medical and surgical treatments were noted as clinical findings. Any findings from purulent discharge cultures obtained directly from the mediastinal space and the microbiological examination notes of the material obtained from the surgical site or the surgical repair area were recorded. SSI was diagnosed according to the definitions recommended by the Centers for Disease Control and Prevention.[^6] Isolated microorganisms were identified using standard methods.[^3]

This study was approved by our institution with the decision number 2019-9/8 on the date 09.05.2019.

**Statistical Evaluation**

For the statistical analysis of the study data, IBM SPSS Statistics for Windows Version 24.0 (Statistical Package for the Social Sciences, IBM Corp., Armonk, NY, USA) was used to quantify frequencies and percentages. The Chi-square test and the t-test were used for the significance test of the difference between the two means. P<0.05 was considered statistically significant. A multiple logistic regression analysis was used to determine the risk factors associated with mediastinitis.

This study was approved by our institution with the decision number 2019-9/8 on the date May 09, 2019.

**RESULTS**

Of the 44 patients included in the study, 32 (73%) were male and 12 (27%) were female. The mean age of the patients was 62.84±6.951 years (range: 46–78 years). The age and sex of the patients were not statistically significantly different between the patients with and without mediastinitis. The pre-operative characteristics, demographic characteristics, and perioperative findings of the patients included in the study are presented in Table 1. The rate of mediastinitis was found out to be 1% in patients who underwent isolated CABG surgery during a period of approximately 10 years. The most common finding detected in all patients who developed mediastinitis after surgery was marked purulent discharge in the sternal region. Fever was detected in 24 (55%), sternal detachment in 23 (52.2%), and pain in the sternal region was detected in 30 (68%) patients. The white blood cell counts of the patients with mediastinitis ranged from 5470 to 21800/mm³ (mean: 11,548.1/mm³). The presence of diabetes mellitus and a high mean body mass index (BMI) were significantly more common in patients with mediastinitis compared to those without mediastinitis (Table 1). Gram-positive bacteria were more prevalent than Gram-negative bacteria.
and fungi in purulent discharge cultures. Gram-positive bacteria and Gram-negative bacteria grew in 25 (56.9%) and 13 (29.6%) purulent discharge cultures, respectively. Fungi grew only in 1 (2.3%) purulent discharge culture. Pathogenic microorganisms could not be cultured in the samples collected from 5 (11.4%) patients. The three most isolated agents were coagulase-negative staphylococci (CNS) (50%), Escherichia coli (9.1%), and Klebsiella pneumoniae (6.8%). Of the Gram-positive bacteria, CNS was found to be associated with the most critical outcomes and all the isolated strains were resistant to methicillin. Methicillin-resistant coagulase-negative staphylococci (MRCNS) were the causative agent in 61% of the patients with internal detachment. The distribution of microorganisms grown in purulent discharge cultures is presented in Table 2.

Diabetes mellitus and BMI were determined as independent risk factors of mediastinitis based on the results obtained from the multiple logistic regression analysis (Table 3). Thirty (68.2%) patients had hypertension, 25 (57%) were smokers, and 3 (12%) had COPD. The mean length of hospitalization in the pre-operative period was 1.14 days. The left internal mammary artery was used in all patients. The median length of surgery was 120.9±23.3 minutes (62–200) and the mean length of cardiopulmonary bypass was 70.95±22.88 min (20–147). The duration of the operation and cardiopulmonary bypass was not different across the patients with and without mediastinitis (Table 1). Operations were performed electively in all patients except one. No blood transfusions were performed in 31 patients (70.5%). Twelve patients (27.3%) received blood transfusions at least once. Pre-operative nasal swab cultures were collected from all patients to investigate the nasal carriage of microorganisms. Staphylococcus aureus growth was not detected in any of the nasal swab cultures. Cautery and bone wax were used perioperatively in all patients.

Mediastinitis was diagnosed in 38 (86.3%) patients in the 1st month, while it was diagnosed in 5 patients (11.3%) in the first 3 months and 1 patient (2.2%) in the 1st year. All patients with mediastinitis underwent revision surgery and purulent discharge cultures were obtained from the surgical site perioperatively. All patients received long-term treatment with parenteral antibiotics based on the antibiogram results of surgical drainage and debridement cultures. The mean duration of treatment was between 3 and 6 weeks. In 43 (97.7%) patients, the parenteral antibiotic treatment was successful; however, 1 patient (2.2%) died due to sepsis.

### Table 1. Pre-operative, demographic characteristics, and perioperative findings of the patients

| Characteristics          | Mediastinitis cases | Mediastinitis non-cases | p   |
|--------------------------|---------------------|-------------------------|-----|
| Number of patients       | 44                  | 4305                    |     |
| Mean age (years)         | 62.8±6.951          | 60.19±10.015            | 0.08|
| Male/female (%)          | 72.7/27.3           | 72.2/27.8               | 0.94|
| Body mass index (kg/m²)  | 32.0±5.28           | 28.93±4.59              | <0.05|
| Diabetes mellitus (%)    | 70.4                | 38                      | <0.05|
| Smoking (%)              | 57                  | 54                      | 0.54|
| Operation time (min)     | 120.9±23.3          | 118.3±22.7              | 0.87|
| Cardiopulmonary bypass   | 70.95±22.88         | 69.72±29.81             | 0.78|
| Perioperative blood       | 27.3                | 24.8                    | 0.45|
| transfusion (%)           |                     |                         |     |

### Table 2. Distribution of microorganisms grown in purulent discharge cultures

| Reproduction microorganisms | n (%) |
|-----------------------------|-------|
| Coagulase-negative staphylococci (CNS) | 22 (50) |
| Escherichia coli            | 4 (9.1)|
| Klebsiella pneumoniae       | 3 (6.8)|
| Enterobacter aerogenes      | 2 (4.5)|
| Enterococcus faecalis       | 2 (4.5)|
| Acinetobacter baumannii     | 1 (2.3)|
| Morganella morganii         | 1 (2.3)|
| Pseudomonas aeruginosa      | 1 (2.3)|
| Proteus mirabilis           | 1 (2.3)|
| Staphylococcus aureus (MSSA)| 1 (2.3)|
| Candida albicans            | 1 (2.3)|
| No reproduction             | 5 (11.4)|

MSSA: Methicillin susceptible Staphylococcus aureus.

### Table 3. Multiple logistic regression analysis of independent risk factors associated with mediastinitis

| Variables                      | p-value | Odds ratio | 95% CI       |
|--------------------------------|---------|------------|--------------|
| Body mass index (kg/m²)        | 0.001   | 1.06       | 1.01–1.10    |
| Diabetes mellitus              | 0.006   | 2.35       | 1.27–4.35    |
| COPD                           | 0.03    | 2.06       | 0.62–6.83    |
| Smoking                        | 0.682   | 0.87       | 0.47–1.62    |
| Mean age (years)               | 0.112   | 0.974      | 0.943–1.006  |
| Male/female                    | 0.110   | 0.257      | 0.123–0.538  |
| Operation time (min)           | 0.908   | 1.001      | 0.984–1.019  |
| Cardiopulmonary bypass         | 0.524   | 0.998      | 0.992–1.004  |
| Perioperative blood transfusion| 0.410   | 0.426      | 0.056–3.236  |

OR: Odds ratio; CI: Confidence interval; COPD: Chronic obstructive pulmonary disease.
DISCUSSION

Patients developing mediastinitis after CVS in our hospital during a period of 10 years were retrospectively reviewed to determine the causative microorganisms, risk factors, and clinical features. The incidence of post-operative mediastinitis is reported in the literature, varying in the range from 0.7% to 2.5%. In our study, 1% of the patients who underwent isolated CABG surgery with median sternotomy developed mediastinitis in the study period of approximately 10 years. The reported mortality rate in patients with mediastinitis is reported in the literature at rates ranging from 14% to 40%.

The rate of developing mediastinitis after CABG surgery was found out to be 2.2% in our study. In one patient, drainage was performed after mediastinal debridement. Then, the area was washed. However, this patient died due to sepsis. K. pneumoniae grew in the purulent discharge cultures of this patient.

For SSI control, the ideal approach is reported that patients are visited by infection control nurses regularly both during the hospital stay and at home after the hospital discharge. However, this approach was not possible. Instead, the follow-up visits were scheduled early and at frequent intervals after the hospital discharge of our study patients. The most probable cause of low mortality rates we observed in our study should be the close follow-up of the patients for hospital infections (HI) after the hospital discharge. This approach allowed for making an early diagnosis and administering adequate treatment timely when surgical infections were suspected.

Although cases of mediastinitis have been reported even after 1 year following surgery, post-operative mediastinitis usually occurs in the first 2 weeks of the post-operative period. In our study, the diagnosis of mediastinitis was made in 86.3% of the patients in the 1st month.

Besides local symptoms of infection, such as pain, tenderness, and body temperature elevations, systemic findings can be observed clinically, including fever, sepsis, and elevated levels of sedimentation rate, and high white blood cell count. In our study, fever was present in 55% of our patients and the white blood cell counts ranged from 5470 to 21,800/mm³.

Risnes et al. found mediastinitis in 107 (0.6%) of 18,532 patients who underwent CABG. They reported the independent risk factors as advanced age, male gender, left descending coronary artery stenosis, obesity, COPD, diabetes, and receiving a blood transfusion. In our series, age and sex did not show significant associations with mediastinitis. Systemic diseases such as low cardiac output or diabetes can contribute to the development of mediastinitis after surgery by compromising the immune system of the patient. Diabetes is a risk factor for the development of infection, negatively affecting cicatrization due to microvascular changes, and high blood sugar levels in diabetic patients. The use of bilateral IMA grafts in patients with diabetes increases the risk of wound infections to 5 folds. The use of beta-adrenergic drugs before the onset of infection increases the risk of post-operative mediastinitis by 20 times. As is in our series, obesity and diabetes are risk factors for the development of mediastinitis. The reasons for the high risk of infection in obese patients include the use of inadequate doses in prophylactic antibiotic treatment, inadequacies of skin cleansing, the abundance of adipose tissue creating a favorable environment for infections, and difficulties in vascular graft removal.

The most common causative agents in mediastinitis developing after CVS are Gram-positive bacteria followed by Gram-negative bacteria. While S. aureus was the most common causative agent in some series, other series report CNS as the most common causative agents. In our study, the microorganisms involved in mediastinitis were similar to those previously described in the literature. Despite the positive antibiotic prophylaxis, microorganisms were isolated from the mediastinum, with Gram-positive bacteria isolated more commonly compared to Gram-negative bacteria. Remarkably, 50% of these Gram-positive bacteria were MRCNS. This finding suggests that in surgical antibiotic prophylaxis, some patients might have received inadequate doses due to their high BMI. Therefore, we think that the doses used in prophylactic antibiotic regimens in the CVS department of our hospital should be reviewed.

In mediastinitis associated with internal detachment, CNS is the most common etiologic agent. Furthermore, sternal detachment itself is closely related to mediastinitis. The presence of internal detachment may lead to infection initially in a small part of the skin or subcutaneous tissue that can further go deeper resulting in mediastinitis. Skin and subcutaneous tissue infections caused by CNS without internal detachment are associated with favorable results because they are self-limiting and do not cause advanced clinical problems. A sternal detachment was present in 52.2% of our patients and 61% of these patients were infected with MRCNS. This ratio was statistically significant.

In recent years, the incidence of mediastinitis caused by Candida species has been reported to be on the rise. In our study, 2.3% of the microorganisms detected in purulent discharge cultures were fungi and they were identified as Candida albicans.

Smoking and COPD are risk factors for the development of mediastinitis by resulting in the prolongation of mechanical ventilation in the post-operative period. Mediastinitis occurs at 3.3 times higher rates in smokers compared to the non-smoking population. Furthermore, post-operative pulmonary complications occur at high rates in smokers since the immune responses are impaired and the risk of infections is high due to the disturbed nasopharyngeal flora in this pa-
tient population.[133] COPD causes mechanical problems in the thoracic cavity, leading to sternal instability. In our study, 57% of our patients were smokers and 12% of the smokers had COPD. We think that this may have contributed to the development of mediastinitis in these patients. However, no statistically significant differences were found.

Operative risk factors for the development of post-operative mediastinitis have been reported as bypass surgery, emergency surgery, longer time of surgery and cardiopulmonary bypass, and the use of bilateral IMA.[6,8,19] None of these factors were identified as operative risk factors in our study but other factors were identified at different rates. Therefore, we believe that careful follow-up of patients considering potentially associated factors will reduce the likelihood of developing mediastinitis.

The biology of wound infections depends on the interaction between local and systemic immune resistance of the body and bacterial contamination. Excessive use of cautery causing local tissue damage and the use of foreign bodies such as bone wax are involved in the development of infections by reducing the local immune resistance. Indeed, excessive use of cautery and bone wax in experimental animals has led to the development of mediastinitis. Bone wax is a non-biodegradable substance that inhibits bone healing, creating a focus for bacterial reproduction.[22] In our study, perioperative cautery and bone wax were commonly used in all patients, but they were not thought to play a role in the development of mediastinitis.

The use of parenteral antibiotics with surgical drainage and debridement is an accepted approach in the treatment of post-operative mediastinitis.[23] In our study, empirical antibiotic therapy was initiated first to cover a wide spectrum of staphylococci and Gram-negative aerobic bacilli. This empirical antibiotic treatment regimen was then modified, when necessary, based on the findings obtained from cultures. Surgical drainage and debridement were performed in all cases. Vacuum-assisted closure (VAC) has been used in the treatment of post-operative mediastinitis since 1997 to remove infected secretions, reduce edema, increase circulation, and accelerate granulation tissue formation.[24,25] In our series, VAC was used postoperatively in one patient, achieving successful outcomes.

Blood transfusions are thought to increase susceptibility to infection, especially in patients who underwent cardiac surgery. Again, transfusions, as a factor alone, are the best predictor of postoperative infections.[26] In our study, the perioperative blood transfusion rate was found to be 27.3% and it was found out that this variable was not associated with the development of mediastinitis.

Some articles reported successful results of mediastinitis treatment, using mediastinal irrigation solutions and the drainage technique.[27-29] We believe that one of the important aspects of the treatment regimen is high volume irrigation and drainage technique. We concluded that our results are due to, at least partially, continuous use of high-volume irrigation and drainage in our patients.

In CABG surgeries performed in our hospital, factors such as the adequacy of surgical prophylaxis, the absence of prolonged operation and bypass time, no use of bilateral IMA, and low rates of perioperative blood and blood product transfusions were found to be effective in having a low SSI rate (1%). Furthermore, we think that the use of single-patient rooms in the CVS ward, accepting no visitors to the CVS intensive care unit in the operating ward, and compliance with the rules of perioperative asepsis and antisepsis all played significant roles in maintaining the low SSI rate.

The development of post-operative mediastinitis increases the cost of hospitalization due to further need for treatment and elevates mortality rates despite all treatment efforts. Therefore, the risk factors for mediastinitis and high-risk patients should be identified, diabetes should be adequately controlled, weight loss of the patients should be promoted, acute episodes of COPD should be treated, and the patient should receive proper antibiotic prophylaxis to reduce the incidence of postoperative mediastinitis. In our study, we shared our SSI outcomes from a single center. Obesity and concomitant diabetes were the most important risk factors for SSI. We have found out that our results are parallel to those reported in the literature. The management of a CVS clinic requires effective collaboration with the infection control committee to prevent and control HI and implement efficient surveillance practices. Further, specifically designed studies to be conducted in this clinic will likely keep the rates of HI at low levels. Identification of the type, frequency, and antibiotic resistance status of isolated infectious agents will help develop specific antibiotic use policies and early revision surgery will contribute significantly to reduce morbidity and mortality rates, enabling the implementation of effective infection control strategies.

**Conclusion**

Attention should be paid to SSI in patients undergoing CVS. Following the hospital discharge, engaging the patient to follow up schedules is critical. Furthermore, empirical antibiotic treatment regimens should be developed to cover MRCNS as these agents were found out to be the leading microorganisms causing mediastinitis in our hospital.

**Ethics Committee Approval:** This study was approved by the Acibadem University Faculty of Medicine Ethics Committee (Date: 09.05.2019, Decision No: ATADEK-2019-09/8).

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**Authorship Contributions:** Concept: Ö.A., Ö.U.; Design: Ö.A., Ö.U.; Supervision: Ö.A., Ö.U.; Resource: Ö.A., Ö.U.;
Materials: Ö.A., Ö.U.; Data: Ö.A., Ö.U.; Analysis: Ö.A., Ö.U.; Literature search: Ö.A.; Writing: Ö.A.; Critical revision: Ö.A.

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İzole koroner arter baypas greft cerrahisi sonrası gelişen mediastinit olgularının değerlendirilmesi: Tek merkez deneyimimiz

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AMAÇ: Bu çalışmada median sternotomi ile yapılan izole koroner arter baypas greft cerrahisinden sonra gelişen mediastinit olgularının, etken olan mikroorganizmalarını, risk faktörlerini ve klinik özelliklerini ortaya koymak amacıyla değerlendirilmesi amaçlanmıştır.

GEREÇ VE YÖNTEM: Mart 2009–Aralık 2018 tarihleri arasında kalp ve damar cerrahisi kliniğinde median sternotomi ile izole koroner arter baypas greft cerrahisi yapılan ve ameliyat sonrası dönemde mediastinit gelişen toplam 44 hasta (32 erkek, 12 kadın; ort. yaş 62.84±6.951 yıl; dağılım 46–78 yıl) çalışmaya alındı. Hastaların demografik özellikleri, eşlik eden hastalıkları, alışkanlıklar, operasyon öncesi yatış süreleri, elektif veya acil cerrahi durumları, perioperatif internal mammarian arter kullanımları, perioperatif kan ve kan ürünü transfüzyonu, operasyon ve kardiyopulmoner baypas süreleri, antibiyotik profilaksisinin uygulandığı, tıbbi ve cerrahi tedavileri, klinik bulgular ve laboratuvar sonuçları dahil olmak üzere genel ve klinik veriler incelendi. Pürülan akıntı kültür alındı ve cerrahi onarım yapıldığı zaman doğrudan mediastinal boşluktan alındı, elde edilen materyalden yapılmış olduğuna 38 (86.3%) % olarak belirlendi. Pürülan akıntı kültürlerinde üreyen mikroorganizmaların %56.9'undan Gram pozitif bakteriler, %29.6'ndan Gram negatif bakteriler ve %2.3'ü mantarlar oluşturmuştur. Beş (%11.4) olguda ise patojen mikroorganizma üretilemedi. En sık izole edilen üç etken metisiline rezistan koagülaz negatif stafilokoklar (MRKNS) (%50), Escherichia coli (%9.1) ve Klebsiella pneumoniae (%6.8) idi.

TARTIŞMA: Kardiyovasküler cerrahi girişim geçiren hastalarda özellikle cerrahi alan enfeksiyonuna dikkat edilmelidir. Taburcu olduktan sonra takip önemlidir ve enfeksiyon ortaya çıktığında ampirik tedavi yaklaşımı hastaneizinde onde gelen enfeksiyoz ajanın MRKNS olduğu dikkate alınarak belirlenmelidir.

Anahtar sözcükler: Kardiyovasküler cerrahi; koroner arter baypas greft; mediastinit.

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