

Conference paper

TiNi-based Mesh Implant Sternal Resynthesis in Patients with Postoperative Sterno-Mediastinitis

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Abstract

The article presents analysis of the results of surgical treatment in patients with postoperative sterno-mediastinitis based on originally developed approach for sternal resynthesis using TiNi mesh implants compared with routine method of sternoraphy with metallic wire. The study showed that routine sternoraphy with metallic wire did not result in healing of more than a half of patients while worsening of sternal fragmentation occurred. The method of sternal resynthesis using TiNi mesh implants was developed in the Department of Hospital Surgery with Cardiovascular Surgery Course at the Siberian State Medical University. This method allowed to achieve good short-term results, reliable fixation of sternal fragments, and restoration of sternal integrity. However, this method is contraindicated to patients with severe sternal fragmentation. The efficacy of the proposed approach significantly exceeds that of the routine method of sternal osteosynthesis with metallic wire.

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1 Introduction

Sternal sternotomy still remains the method of choice for surgeries of the heart, great vessels, and large airways as well as for one-step bilateral surgeries of the lungs [1].

Postoperative sternal dehiscence is one of the most alarming complications of cardiac surgery. Unsuccessful treatment followed by fatal outcome occurs often despite all efforts aimed at elimination of sternal diastasis, removal of infected tissue, muscle flap interposition, and placement of wire sutures [2]. Sternal nonunion after sternotomy is associated with the substantial economic expenses requiring healthcare system resources and affects patient's survival [3]. The postoperative sterno-mediastinitis after open-heart surgery is a severe surgical complication which develops with frequency of 0.7-6% cases according to international literature. It is characterized with high lethality rate, prolonged duration of hospitalization, necessity of repeated surgical procedures, and high cost of treatment. During recent years, there is tendency to an increase in the number of patients with postoperative sterno-mediastinitis due to growing number of thoracic surgeries [4, 5, 6]. The course of postoperative sterno-mediastinitis is often chronic and persistently recurrent. Patient's disability in case of repeated surgical interventions progresses due to an increase in the deficit of thoracic wall tissues [2, 3]. Improvement of the methods for treatment of postoperative complications of median sternotomy is a relevant task of current thoracic surgery. The aim of the study was to investigate the efficacy of new method for sternal osteosynthesis in postoperative sterno-mediastinitis by using TiNi implants compared with routine method of sternoraphy with metallic wire.

2 Experimental

A total of 33 patients with postoperative sterno-mediastinitis were studied during six-year period from 2011 to 2016. Patients were divided to two groups depending on the type of surgical treatment.

Group 1 comprised patients ($n = 16$) who received surgery for sternal re-osteosynthesis using TiNi mesh implants according to original method developed in the Department of Hospital Surgery with Cardiovascular Surgery Course at the Siberian State Medical University in collaboration with the Research Institute of Medical Shape-Memory Materials and Implants. Surgical treatment according to this method was performed after wound revision and debridement and removal of sternal fragments affected by osteomyelitis if necessary. After that, sternal integrity was restored: a special curved trocar was introduced retrosternally and TiNi mesh implants woven of nickelid titanium alloy fibers were placed in the 2nd, 3rd, and 4th intercostal spaces. After that, an assisting surgeon performed lateral

chest compression to achieve sternal half union while single-coil triple knots were tied one-by-one (laterally to the sternum to prevent discomfort after operations) followed by fixation by suture material. Drainage tube was placed into surgical wound through separate puncture. Wound was closed layer-by-layer.

Group 2 (control group) comprised 17 patients who received surgery consisting in wound revision and debridement and osteosynthesis by metallic wire according to various schemes such as: 1-1-1-1-1-1; 1-X-1-1-1-1; 1-X-X-X; 1-1-X-X-1-1, etc.

Groups did not significantly differ in patients' gender, age, duration of disease, severity of initial condition, and comorbidities. Group 1 included 11 men (68.7%) and 5 women (31.3%). Group 2 included 12 men (70.6%) and 5 women (29.4%). Mean age was 62.65 ± 7.32 and 61.09 ± 7.79 years for group 1 and 2, respectively.

Previously, all patients received surgery of the heart and/or great vessels performed through median sternotomy. Patients of group 1 and 2 did not significantly differ in regard to the type of primary surgery that involved median sternotomy. Duration of sterno-mediastinitis from its onset to the study surgery did not significantly differ between groups and lasted for 157.38 ± 120.87 days in group 1 and 141.23 ± 117.31 days in group 2.

All patients had combination of sternal dehiscence and anterior mediastinitis. Sternal osteomyelitis was diagnosed in all patients of group 1 and in 16 patients (94.1%) of group 2.

Fistulous form of osteomyelitis was observed in 6 patients (37.5%) of group 1 and in 7 patients (41.2%) of group 2. Open wound was observed in 2 patients (12.5%) of group 1 and in 3 patients (17.6%) of group 2.

The entire course of the disease was studied in all patients showing that 62.5% of patients (n=10) of group 1 and 52.9% of patients (n=9) of control group underwent unsuccessful attempts of surgical interventions on the anterior chest wall (serial wound debridement, wound revision and debridement, necrectomy, sequestrectomy; sternal re-osteosynthesis with metallic wire according to various schemes) which did not result in healing.

Patient's condition during the preoperative and postoperative periods was evaluated based on data of X-ray examinations, spiral computed tomography (CT) of the thoracic organs, ^{99m}Tc -Technetritil-based scintigraphic indication of the inflammation, ultrasound study of the sternum and the anterior mediastinum, echocardiography, spirometry, bacterial examination, and routine clinical and laboratory tests. In the presence of fistulous form of sternal osteomyelitis, fistulography was performed.

During postoperative period, patients were managed in accordance with standard approaches to therapy including administration of antiseptic solutions and

ointments and correct antibiotic therapy based on the results of bacteriological culture tests of wound fluid for determination of bacterial populations and sensitivity to antibiotics.

Statistical processing of data was performed using PSPP 0.8.2 software package. To determine significance of differences between qualitative characteristics, contingency table analysis was performed (Pearson's chi-squared (χ^2) test and Fisher's exact test in case if expected value of at least one cell of contingency table was less than 5). Values were considered statistically significant when P was < 0.05.

3 Results and discussion

Durations of surgery did not significantly differ between groups and were 113.15 ± 29.93 min in group 1 and 115.29 ± 38.86 min in group 2.

One case of intraoperative bleeding was documented in each group: bleeding from a. Thoracica interna was documented in one patient of group 1; bleeding from a. Intercostales occurred in one patient of group 2. Bleedings were stopped by additional suturing. Intraoperative damage of pleura was observed in control group (sutures were placed to lung tissue). Sternal fractures during sternotomy occurred in one patient of group 1 and in two patients of control group. The results of surgeries in group 1 and 2 are presented in Table 1.

Table 1. Immediate results of surgery in groups 1 and 2

Parameters	Group 1, n=16	Group 2, n=17
Uneventful postoperative period	9 (56.2%)*	3 (17.6%)*
Recurrence of sternal closure disruption	3 (18.7%)*	10 (58.8%)*
Recurrence of mediastinitis	3 (18.7%)	8 (47.0%)
Recurrence of osteomyelitis	3 (18.7%)	6 (35.3%)
Disruption of cutaneous and subcutaneous fat sutures	4 (25.0%)	6 (35.3%)
Death	1 (6.25%)	-

In group 1 (n=16), restoration of sternal integrity was achieved in 13 patients; mediastinitis was cured in 13 patients; healing by the first intention was observed in 12 patients. No specific complications due to placement of implants (rupture, migration, sternal cheese-wire effect, severe pain syndrome) were observed.

In group 1, one female patient developed peritonitis seven days after study surgery; diagnostic laparoscopy and then laparotomy were performed, but the source of peritonitis was not found; lethal outcome occurred at day 8. Autopsy did not show recurrences of sternal osteomyelitis, mediastinitis, and soft tissues infection of the anterior chest wall; sternal closure was satisfactory. The most likely cause of peritonitis was primary (hematogenic, lymphogenic) spreading of infection to ascitic fluid as patient suffered from chronic viral hepatitis B. No direct associations between the lethal outcome and specific characteristics of the developed method for restoration of sternal integrity were found.

In control group (n=17), restoration of sternal integrity was achieved in 7 patients; mediastinitis was cured in 9 patients; healing by the first intention was observed in 11 patients. Therefore, the use of routine sternoraphy for sternal osteosynthesis in patients with postoperative complications of median sternotomy did not allow to achieve restoration of sternal integrity in 58.8% of cases due to the development of metallic suture disruption which aggravated sternal fragmentation.

The results of surgical treatment were compared between patient groups. Recurrence of disruption of metallic sutures with the development of sternal dehiscence occurred significantly more often in patients who received osteosynthesis by routine method ($p < 0.05$). Uneventful postoperative period (healing by the first intention without complications and without recurrence of the disease) was documented more often in group 1 ($p < 0.05$).

Note: * $p \leq 0.05$.

In three patients of group 1 who had recurrence of sternal closure disruption, surgery for restoration of sternal integrity with TiNi implants was preceded by unsuccessful attempt for sternal re-osteosynthesis with metallic wire; these patients had sternal fragmentation. The study found a statistically significant association between the development of sternal dehiscence and preceding attempt of a routine re-osteosynthesis with metallic wire in group 1 ($p < 0.05$).

Association analysis of all cases of sternal dehiscence and mediastinitis recurrences (in both groups of patients) showed that there was a significant relationship between the development of mediastinitis recurrence and recurrence of sternal suture failure ($p \leq 0.05$). Among 33 patients who received surgery for sternal re-osteosynthesis, recurrence of mediastinitis occurred in 11 cases; mediastinitis was associated with sternal instability in nine of these cases.

In patients with postoperative sterno-mediastinitis who develop sternal dehiscence, re-osteosynthesis by standard methods (sternoraphy with metallic wire) does not achieve the solution, but contributes to further sternal fragmentation [7, 4] which agrees with data of our study. Keeping this in mind, various alternative methods for sternal integrity restoration have been developed; diverse constructions with shape memory such as TiNi clips became common use. However, available literature presents cases of migration and detachment of clips [1, 8]. These problems affect the quality of treatment and reliability of sternal closure.

Based on comparative analysis of clinical trial results, authors of this article conclude that the use of the proposed method for sternal osteosynthesis with TiNi implants may be a suitable alternative to standard methods of sternal osteosynthesis in the presence of sternal diastasis after surgeries with median sternotomy. This method may be considered for primary sternal closure in patients with high risk for the development of sternal dehiscence [3].

An increase in the quality of treatment and reliability of sternal closure are achieved by the proposed method due to intra operative provision of adequate sizes of the elements for sternal fixation, adequate tension they provide, and the presence of biomechanical compatibility of implant with surrounding tissues. These factors contribute to intergrowth of the connective tissue through the structure of implant with formation of a bone-tissue regenerate integrated with the implant material which guarantees reliable holding of the implant within the tissues and prevents its displacement and, therefore, the recurrence of disease. Implants of this class have super-elasticity, biological inertness, high corrosion resistance, and similarity of their physical-chemical properties with those of the living tissues of the organism. Therefore, the most reliable approaches for restoration of sternal integrity are those that involve the fixation elements with developed surface without tendency to produce chees-wire effect.

4 Summary

The problem of sternal resynthesis in patients with postoperative sterno-mediastinitis currently remains relevant. Results of treatment with standard methods in this category of patients are far from satisfactory. The use of the proposed method of sternal osteosynthesis with TiNi implants demonstrates favorable clinical results and may be recommended for treatment of this category of patients. The applicability of this method may be considered for sternal closure after sternotomy in patients of high-risk group.

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