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INTRAOPERATION PROCEEDING OF IMPLANTATION LVAD IN DIFERENT COAGULATION GRUP OF PATIENTS

Mazurenko O.[1]
Tarabrin O.[2]

[1]*Silesian Centre Heart Diseases, Department Cardiac anesthesiology SUM, ICU SCCS, Poland*

[2]*International University, Odesa, Ukraine*

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The work was carried out within the framework of a bilateral agreement on scientific cooperation between the department of Anesthesiology&Intensive Care in National Medical Academy of Post-Graduate Education Named After P.L. Shupik and the Silesian Center for Heart Diseases (Poland).

Introduction. That work is probe of analisis response and complications e introperation LVAD patients on some intraoperative infusion and transfusion tactic fifty patients with implanted devices for mechanical support of the left ventricle, left ventricle assist device, LVAD, in the Silesian Heart Disease Center (Śląski Centrum Chorób Serca – SCCS), Poland. Patients were divided into two groups, a control group receiving classical anticoagulation targeted therapy (ATT), which included the most controlled monotherapy with heparin, after reaching the target values of APTT, the addition and transition to monotherapy with warfarin until reaching the target INR and ASA, and the main, research group, who received an alternative ATT consisting of the previous one with the addition of P2Y12-receptor blockers and Xa-factors.

The result of the work demonstrated the benefit of the modified anticoagulant treatment scheme against the classical approach with clear confirmation by correlation-regression indicators of a significant degree of reliability. A prognostic assessment of the dynamic state of the patient was also proposed to reduce clinical complications after this intervention.

Key words: left ventricle assist device (LVAD), anticoagulant targeted therapy (ATT), surgical, infectious, renal, pulmonary, ischemic-hemorrhagic complications.

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ВНУТРІШНЬООПЕРАЦІЙНИЙ ПЕРЕБІГ ІМПЛАНТАЦІЇ LVAD У ПАЦІЄНТІВ ІЗ РІЗНИМИ КОАГУЛЯЦІЙНИМИ ПРОФІЛЯМИ

Мазуренко О., Тарабрін О.

Робота виконана в рамках двосторонньої угоди про наукову співпрацю між кафедрою анестезіології та інтенсивної терапії Національної медичної ака-

демії післядипломної освіти ім. П. Л. Шупика та Сілезьким центром захворювань серця (Польща).

Вступ. Дана робота є спробою аналізу реакції та ускладнень у пацієнтів з LVAD під час операції на тлі різних внутрішньоопераційних інфузійних і трансфузійних тактик у п'ятдесяти пацієнтів з імплантованими пристроями для механічної підтримки лівого шлуночка (left ventricle assist device, LVAD) у Сілезькому центрі захворювань серця (Śląski Centrum Chorób Serca – SCCS), Польща. Пацієнтів було поділено на дві групи: контрольну, яка отримувала класичну таргетну антитромботичну терапію (АТТ), що включала керовану монотерапію гепарином із подальшим додаванням та переходом на монотерапію варфарином до досягнення цільових значень МНВ та АСК, і основну, дослідницьку групу, яка отримувала альтернативну АТТ, що складалася з попередньої схеми з додаванням блокаторів P2Y12-рецепторів і інгібіторів фактора Ха.

Результати роботи продемонстрували переваги модифікованої схеми антитромботичної терапії порівняно з класичним підходом із чітким підтвердженням за кореляційно-регресійними показниками значного ступеня достовірності. Також було запропоновано прогностичну оцінку динамічного стану пацієнта для зменшення клінічних ускладнень після даного втручання.

Ключові слова: пристрій допомоги лівому шлуночку (LVAD), таргетна антитромботична терапія (АТТ), хірургічні, інфекційні, ниркові, легеневі, ішемічно-геморагічні ускладнення.

Introduction. The use of a device for mechanical support of the left ventricle, LVAD, as the only chance for patients with severe degrees of heart failure to live to heart transplantation on the waiting list, is recommended by the American and European Associations of Cardiology and Cardiac Surgery. Currently, the use of these devices in patients receiving donor heart transplantation is approximately 46%, according to literature data, and the median time of LVAD support in patients awaiting heart transplantation is an average of 300 days (147–537 days). The number of implanted LVADs in the United States is currently approaching the number of heart transplants [1]. The transition from pulsatile to continuous-flow, centrifugal LVADs is associated with significantly lower overall adverse event rates, longer stable device performance, and much better long-term patient survival rates. In the first year, the incidence of complications in patients implanted with an LVAD is up to 30%, within two years after implantation in 80% of patients there is at least one event [2], which is a complication that arose in connection with the operation of implanting the device LVAD. According to world experience, the average time of re-hospitalization due to events in patients was 35 days after device implantation, the average duration of patient follow-up was eleven months [3]. The main complications after LVAD implantation include: bleeding, thrombosis of the device, ischemic and hemorrhagic strokes, acute kidney damage, multiple organ failure, infections, etc. The timing of complications after LVAD placement is classified as early (up to 30 days after implantation) or late (after 30 days until 3 years). Carrying out optimal therapy aimed at correcting the hemostasis system in such patients is an important component of intensive therapy, especially in the early postoperative period. The state of the hemostasis system, the development of thromboembolic and hemorrhagic complications, and the effectiveness of the mechanical blood circulation support system depend on the correctly chosen tactics of anticoagulant therapy. The most common complications include surgical and non-

surgical ones (infections, ischemic and hemorrhagic lesions of the brain, acute renal failure occurring in the postoperative period, etc.). Most complications manifest in the early postoperative period. An individualized approach with preventive strategies is crucial for improving treatment outcomes for patients in this category.

This work analyzed the frequency of adverse surgical events and complications in the operative period in time of implantation of a left ventricular mechanical support device in fifty patients treated at over a three-year period from 2016 to 2018, inclusive, aged 55± 13.5 years old, with a body mass index of 30.8±8.3 m2, with a left ventricular ejection fraction of 8–28%. Comparison of the analyzed survey results refers to qualitative and quantitative assessments of adverse events and complications in patients with different approaches to anticoagulation targeted therapy.

Materials and methods. The study included 50 patients with various degrees of heart failure, all of whom had a device for mechanical support of the left ventricle of the heart installed, either planned or emergency. The average age of the patients was 52.8±1.7 years, with a predominance of patients older than 50 years (asymmetric type of distribution). The youngest patient was 19 years old, the oldest was 69 years old, Me=56.0 (1q: 47.0 3q: 62.0). The studied sample was characterized by a negative value of the asymmetry coefficient (A_s=-1.0 σ_{As}=±0.3), the kurtosis coefficient had a positive value (k=0.4 σ_k=±0.6), the average BMI values were at the level of 26 ,1±0.9 kg/m2 (Me=25.0 (1q=21.7; 3q=30.7). Patients were divided into two groups (Table 1), the control group and the main study group. In the control group (21 patients), patients received monotherapy with heparin or warfarin or in combination with aspirin, due to the impossibility of switching to another stage of anticoagulant therapy. In the study group (29 patients), after controlled anticoagulant therapy with heparin, patients received warfarin up to a target value of 2.5 IU and then additionally received a blocker of blood coagulation Xa-factor and blockers of P2Y12 receptors. All patients were equally subjected to all possible analyzes of the blood coagulation system after taking the medication.

In the control group of the study, 8 patients received heparin therapy in the first two weeks by continuous submission at the infusomat on rate until 6 to 11 Units/kg/h. (Me-9.05 Units/kg/hour), and 2 patients were on monotherapy with heparin until the end of

Table 1

Characterization of patient groups and targeted anticoagulation therapy

Medication of ATT:	Control group of patients with classic ATT (N= 21)			Examinate group of patient with modificate ATT (n= 29)		
	n=6	n=1	n=14	n=6	n=20	n=3
Heparyn	+	–	+	+	+	+
Varfaryn	–	+	+	+	+	+
ASA	–	–	+	–	–	+
P2Y12 blocker	–	–	–	+	–	+
anty-Xa factor	–	–	–	–	+	+

Note: Ts ACT is targeted anticoagulant therapy; anti-Xa – calcium nadroparin or fondaparinux; ASA – aspirin; P21Y12-bl. – clopidogrel.

their stay in the intensive care unit. Eleven patients during the first week and 7 patients during the second week received warfarin indirect anticoagulant in a dose of 1.5-7 mg/day (Me-3.45 mg/day).

As an alternative to the standard ATT, the following drugs were used: 5 patients received aspirin in doses of 1.4±0.7 mg/kg/day during the entire period; 3 patients during the first week and 5 patients during the second week received clopidogrel 1.3±0.8 mg/kg/day; nadroparin calcium (0.3–0.6 ml/ 2 times a day) and fondaparinux Na (2.5–5 mg/ 2 times a day).

The somatic condition of the patients corresponded to 6-14 points of the European System for assessing the risk of preoperative interventions, or 4-5\E. ASA. Depending on the status according to INTERMACS, Level 1 (cardiogenic shock) was observed in 15 patients, Level 2 (progressive circulatory failure) – in 6 patients, Level 3 – 17 patients, Level 4 – 10 patients, Level 5 – 2 patients. Severe pretransplantation pulmonary hypertension (transpulmonary gradient ≥15 mmHg. and/or pulmonary vascular resistance greater than 3 Wood's Units) was detected in 8 patients. Fifteen patients were operated on in a state of circulatory arrest with cardiopulmonary resuscitation, and ventricular fibrillation was noted in five patients.

Patients were implanted under artificial circulation (ECC) and without such, and moderate hypothermia with t = +31C°. The productivity of ECC device was 2.6 l/min/m^2. Schtoker alternating current systems (Germany) were used to protect the myocardium, which created artificial fibrillation at a frequency of 50Hz, 12V/25A.

Monitoring of systemic hemodynamics was carried out using the IntellsVue X2 Philips® systems (Netherlands), cardiac index indicators – using the A7 Vigileo Monitor-Acsesories EDWARDS® systems, cerebral oxygenation – using the INVOS Oximetr Somanetics® Inc. (USA) system «.

The operation was performed under conditions of combined endotracheal anesthesia using a semi-closed circuit with targeted maintenance of the concentration of inhalation anesthetics according to the age-related indicators of the minimum alveolar concentration. Fentanyl was used for analgesia at a dose of 1.7±0.8 μg/kg/min. or sufentanil 0.015±0.03 μg/kg/min.

In patients with high pulmonary hypertension, inhaled NO was used under the control of electronic measurement device of molecules, in a dose of 30-200 p\m, this technique was also used for several days in the postoperative period.

After the end of the operation, artificial ventilation in the intensive care unit (IT) was carried out by the Drager Evita V300 device with an air-oxygen mixture with an oxygen concentration depending on the degree of need and pulmonary hypertension, under the control of blood gas analysis indicators, which were determined by the ABL800 device (France)". The analysis of the dynamics of the myocardium was determined by the analysis of blood lactate, troponin I and MV fraction of creatine phosphokinase.

All the above-mentioned analyzes and studies of the blood coagulation system were carried out at the system laboratory station "Multiplate® Roche (France)". The average duration of blood circulation support with LVAD was 49.7±28.2 days. The duration of support for three patients with the pulsatile pneumatic system POLVAD ranged from 102 to 156 days, and for forty-seven patients with the centrifugal constant-flow LVAD ranged from 20 to 78 days.

Control of the drained fluid from the pericardial and thoracic cavities was carried out by a system of two-chamber active drainage systems connected to a constant nega-

tive pressure, which simplified the outflow of fluid and improved the hourly calculation of its amount.

Results. During the early postoperative period, in patients with different approaches to anticoagulant therapy, a rather diverse pattern of response to the therapy and, as a consequence, adverse events and complications was observed.

The existing differences in the distribution of hemostasis indicators in the comparison groups are of considerable interest (Table 2). As can be seen from the above, normalization of the hemostasiogram was observed in both the control and main research groups, which was more pronounced in the main group.

Attention is drawn to the multidirectionality of changes in the indicator of sensitivity to acetylsalicylic acid, which decreased by 10.3% in the control group, and increased by 5.6% in the main group at p>0.05.

The higher level of D-dimer in the control group in comparison with the main group requires explanation, also after the correction, their level was more pronounced in the control group (Δ=+12.5%).

The duration of surgical intervention in the main group did not differ significantly from the control group – 347.8±17.9 min and 459.3±57.4 min, respectively (p>0.05). During surgery, diuresis was higher in the control group (on average, 940.0±186.5 ml) than in the main group (704.5±82.5 ml). One of the patients in the control group received only warfarin as anticoagulant therapy, and he had the lowest levels of diuresis (200 ml) due to decompensation of chronic kidney injury. This patient later died.

Hemotransfusion was performed in 16 out of 29 patients of the main group (55.2%) in an average volume of 693.3±141.5 ml. (p>0.05). In the control group, Hemotransfusion was performed in 18 out of 21 patients (85.7%), with an average volume of 1140.0±222.0 ml (p<0.05). Thus, already at the intraoperative stage, the use of a polymodal scheme of anticoagulant therapy demonstrated certain advantages.

The volume of intraoperative infusion in the groups also differed. Thus, the patients of the main group received an average of 811.6±114.7 ml of crystalloids, the control group – 656.5±87.1 ml. The existing differences are explained by the clinical situation, when censoring the sample with the removal of excesses, they are completely leveled – 760.6±85.8 ml versus 656.5±87.1 ml (p>0.05).

Table 2

Dynamics of hemostasis indicators in comparison groups

	Control group		Investigate group	
	Before correcting	After correcting	Before correcting	After correcting
APTT, sec.	66,7±8,4	69,2±6,2	59,6±5,2	57,3±4,3
INR, unit	1,8±0,1	2,2±0,2	1,5±0,2	1,8±0,2*
ASPI, au\min.	495,5±62,2	444,8±57,3	625,4±64,2	662,2±58,4#
ADP, mcg\ml.	366,42± 307,33	393,72± 229,65	272,45± 214,04	500,88± 251,99
D-dimer, mcg\ml.	1,6±0,1	7,0±0,2*	1,5±0,2	6,2±0,2*#
Fibrinogen, mg\dl.	269,9±22,4	348,6±26,8*	283,3±23,3	497,7±48,3*#

Note: * – data after correction are statistically significantly different from the original, p<0.05
– differences between groups are statistically significant, p<0.05.

In patients of the control group, the average content of erythrocytes before surgery was 3.9±0.2 1012/l, before discharge – 3.6±0.1 1012/l. This corresponded to hemoglobin levels of 72.2±0.3 g/l and 66.0±0.6 g/l, respectively. In patients of the main group, the dynamics of indicators was similar. At the same time, the degree of anemia was greater than in the control group – the number of erythrocytes before surgery was on average 4.2±0.2 1012/l, before discharge – 3.6±0.1^{x}1012/l ($p<0.05$). Accordingly, the hemoglobin content decreased from 77.9±0.3 g/l to 67.3±0.2 g/l ($p<0.05$). These changes were accompanied by a decrease in hematocrit from 0.37±0.01 g/l to 0.32±0.01 ($p<0.05$).

In the control group, before the start of treatment, the average content of leukocytes was 8.9±1.0 ^{x}109/l (with a maximum value of 22.0 ^{x}109/l), and at the end of the stay in the cardiac center – 11.6±1.4 ^{x}109/l. At the same time, the dynamics of platelet content was less pronounced – 221.8±26.5 ^{x}109/l and 242.7±37.5 ^{x}109/l.

As for the platelet link of hemostasis, before the operation the average platelet content was 259.7±22.5 ^{x}109/l, and before discharge – 341.9±27.9 ^{x}109/l, i.e., with a multimodal effect on the coagulation system, a paradoxical increase of platelets was observed the pool. In our opinion, this indicates the activation of the body's adaptive reserves in response to therapy.

As for the activity of the blood coagulation system according to ACT, it showed significant variability in both clinical groups. So, in the main group, the test corresponded to an average value of 123.8±3.7 units, and in the control group – 132.9±15.0 units. ($p>0.05$).

A similar situation was observed with regard to the final lactate level in the observation groups. So, in the main group, the lactate content did not exceed 4.6±0.8, and in the control group it reached 6.6±1.5 units. ($p>0.05$). We made an attempt to analyze how the values of the above physiological indices are distributed depending on the applied method of blood coagulation correction. During surgery, diuresis was higher in the control group (on average, 940.0±186.5 ml) than in the study group (704.5±82.5 ml). For an extended qualitative analysis of groups of patients, the analyzed data of intraoperative monitoring of patients are given in table No. 3, and in the ICU in table No. 3, which makes it clear the relationship of certain indicators to the postoperative state in the early postoperative period.

As demonstrated in the above data, both the control and experimental groups differed in significant heterogeneity not only in the nature of the applied therapy and the duration of the surgical intervention, but also in the range of physiological responses to the intervention. A significant increase in the lactate content at the end of the operation in patients of the control group who received only heparin for coagulation control, as well as less frequent use of hemotransfusion among patients in the main group, who received complex anticoagulation therapy regimens involving, along with heparins, warfarin, clopidogrel, and ASA, require explanation.

The analysis of the daily fluid balance showed that during the stay in the ICU there was a decrease in the average daily balance from 9-11 ml/kg/day to 3-5 ml/kg/day. There is also an increase in the frequency of complications and the level of mortality in patients in whom the support of intra-aortic balloon counter pulsation (IABP) and extracorporeal membrane oxygenation (ECMO) was longer than the first two days of postoperative stay in the ICU (correlation +0.76, $p<0,05$).

The data after correction are statistically significantly different from the original ones, $p<0.05$.

Table 3

Comparison of groups of 50 patients with LVAD according to intraoperative management (N=50)

Laboratory and other indicators of the intraoperative period.	Control group of patients (n=21)			The examined group of patients (n=29)		
	n=6	n=1	n=14	n=6	n=20	n=3
TIVA	1	1	4	2	4	0
Inhalation anesthesia: Sevofuran Isoflurane	3 2	– –	5 3	2 2	13 6	2 –
Diuresis in operation in ml.	1160± 728,72	250	1312± 513,26	520±396,6	652±340,4	600±355,5
Operation duration in minutes.	468,33± 302,22	315	383,21± 123,78	311,66± 67,59	325± 80,86	260± 88,88
Transfused colloids, in ml.	1636,5± 1003,16	2100	636,84± 539,96	853,33± 54,4	499,05± 577,79	466± 207,11
Transfused crystaloids, in ml.	791,66± 472,22	50	535,71± 129,33	1033,33± 711,11	718,1± 383,79	466,66± 185,18
ACT final, sec.	157,66± 82,44	134	105,23± 23,47	118,6± 47,44	112,94± 15,29	74,66± 16,59
Final lactate mg/ml.	9,09±7,12	22	3,31±1,68	4,68±2,45	3,82±2,87	1,19±0,79

Data calculated in groups are statistically significant ($p<0.05$).

Table 4

Comparison of groups of 50 patients with LVAD on management in the ICU (N= 50)

Indicators of the period of intensive care and resuscitation	Control group of patients (n=21)			Examined group of patients (n=29)		
	n=6	n=1	n=14	n=6	n=20	n=3
Length of stay, days	13±9,33	14	14,92± 9,91	13,3± 12,11	14,2 ± 7,4	7,66± 5,55
Daily balance, ml.	747,33± 440,55	690	782,28± 368,28	84,66± 187,33	334± 281,78	386,66± 257,77
The days of use simultaneous use of inotrops in ICU is ⩾2.	12,16± 9,16	8	5,92± 3,62	3± 2,4	7,61± 3,61	7,33±8,44
Duration of mechanical ventilation, hours.	240±230,4	120	103,2± 120,5	25,44± 18,6	40,32± 28,08	31,92± 26,6
Pulse Index LVAD	2,65± 1,33	3,5	3,86±0,78	3,56± 0,9	3,45±0,73	2,56±1,71
IABP support, day.	2,5± 1,83	4	–	1,66± 2,44	0,16±0,31	–
ECMO support, day.	4,4±5,84	–	0,11±0,19	–	–	–

As the study showed, in the first days of heparin therapy, one patient developed pronounced heparin-induced thrombocytopenia, which led to a change of strategy to alternative therapy with the use of nadroparin calcium. Subsequently, this patient was diagnosed with infection of the outlet of the LVAD power cable and subsequently developed nosocomial pneumonia.

Conclusions:

1. Patients are difficult to analyze due to the multifactorial effect on a certain researched parameter, which during the statistical processing of a single-dependent complex factor with a certain profitability requires further analysis, but the results clearly state the need for much larger groups of patients, which is unlikely in these studies due to the high cost of equipment and a small number of patients qualified for implantation.The highest percentage of complications, in the form of bleeding and thromboembolic events, was observed in the control group.
2. Patients in the control group of modified anticoagulant therapy had fewer transfusions and related consequences both during and after surgery, the same total tangential to infusion tactics.
3. Indicators of the intraoperative amount of diuresis correlate with the time of the duration of the surgical intervention as well as with the level of blood lactate growth, which clearly indicated an increase in intraoperative events and complications.
4. Inhalation anesthesia had no peculiarities in the correlation to intraoperative events or consequences in relation to different groups, being distinguished by a small difference in application and dosage.
5. The level of increased initial and final activated partial thrombobplastin time correlated with the duration of surgery and affected the increase in transfusion and infusion support levels.

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