

## RENAL FAILURE IN PATIENTS WITH IMPLANTED LVAD IN EARLY POSTOPERATIVE PERIOD AND AFTER

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### RENAL FAILURE IN PATIENTS WITH IMPLANTED LVAD IN EARLY POSTOPERATIVE PERIOD AND AFTER

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**Introduction.** Diseases of the cardiovascular system occupy a leading place in the statistics of morbidity and mortality of the population not only in Ukraine, but throughout the world as a result of heart failure. Cardiovascular insufficiency of varying degrees, in turn, as well as cardio-renal syndrome cause renal failure, which is one of the main complications in the group of cardiac surgery patients in the world. LVAD, as a result of the development of radical treatment of heart failure, is sometimes the only treatment option for this category of patients in the form of city therapy or targeted therapy. But in patients with implanted LVAD in the short and long postoperative period, the situation with such a complication as renal failure, which is associated with destabilization of hemodynamics, fluctuations in the parameters of the hemostasis system, etc.

**The purpose** of this scientific work is to analyze the state of the excretory renal system in 50 patients with implanted LVAD with various targeted anticoagulant maintenance therapy and its correction with complications in the early postoperative period treated at the Silesian Heart Disease Center, Poland. There were two groups of patients to investigate the state of the coagulation system and its response on correction, the control group receiving classical anticoagulation targeted therapy (ATT), which included the most controlled heparin monotherapy, after reaching the target APTT values, addition and switch to warfarin monotherapy before reaching the INR and ASA goal, and the main, research group that received an alternative ATT, consisting of the previous one with the addition of P2Y<sub>12</sub>-receptor blockers and Xa-factors. The results of the article are analytics of correlation between renal complications in the perioperative period in both groups of patients and the final results of persistent renal failure in these patients and their impact on further treatment and prognosis of their state of health.

**The results** showed that the control group of patients with classical anticoagulant targeted therapy had a greater mortality associated with renal failure than the patients of the study group, and it was also demonstrated that initially greater duration of surgery and intraoperative polyuria gave a greater percentage of the

first new acute kidney complications in the postoperative period and more results of permanent kidney diseases after the study period.

**Key words:** left ventricle assist device (LVAD), anticoagulant targeted therapy (ATT), renal failure, acute kidney injury (AKI), chronic kidney diseases (CKD).

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## **НИРКОВА НЕДОСТАТНІСТЬ У ПАЦІЄНТІВ З ІМПЛАНТОВАНИМ LVAD У РАНЬОМУ ПІСЛЯОПЕРАЦІЙНОМУ ПЕРІОДІ ТА НАДАЛІ.**

**Мазуренко О. П., Тарабрін О.О.**

**Вступ.** Захворювання серцево-судинної системи займають провідне місце у структурі захворюваності та смертності населення не лише в Україні, а й у всьому світі, що пов'язано з розвитком серцевої недостатності. Серцево-судинна недостатність різного ступеня, а також кардіо-ренальний синдром призводять до розвитку ниркової недостатності – одного з основних ускладнень у групі кардіохірургічних пацієнтів у світі. Імплантація LVAD (пристрою допомоги лівому шлуночку) як один із результатів еволюції радикального лікування серцевої недостатності, іноді є єдиним варіантом терапії для цієї категорії пацієнтів – у вигляді міст-терапії або цільової терапії. Водночас у пацієнтів з імплантованим LVAD як у ранньому післяопераційному періоді, так і в подальшому, досить часто виникає таке ускладнення як ниркова недостатність, що зумовлена дестабілізацією гемодинаміки, коливаннями параметрів системи гемостазу тощо.

**Мета дослідження:** проаналізувати стан екскреторної системи нирок у 50 пацієнтів з імплантованим LVAD, яким проводилась різна цільова антикоагулянтна терапія, з її корекцією в умовах ускладнень у ранньому післяопераційному періоді на базі Сілезького центру хвороб серця, Польща. Пацієнти були поділені на дві групи для оцінки стану системи коагуляції та її реакції на корекцію:

**Контрольна група** отримувала класичну цільову антикоагулянтну терапію (ЦАТ), яка включала монотерапію гепарином з подальшим переходом на монотерапію варфарином після досягнення цільових значень АЧТЧ та INR у пододенні з ацетилсаліциловою кислотою.

Основна (дослідна) група отримувала альтернативну ЦАТ, до якої, окрім вищевказаної схеми, додавали блокатори рецепторів P2Y<sub>12</sub> та інгібітори фактора Ха.

**Результати дослідження:** наведено аналітику кореляції між нирковими ускладненнями у периопераційному періоді в обох групах пацієнтів, кінцевими результатами формування стійкої ниркової недостатності та впливом цих ускладнень на подальше лікування та прогноз стану здоров'я пацієнтів.

**Висновки:** пацієнти контрольної групи, які отримували класичну ЦАТ, мали вищу смертність, пов'язану з нирковою недостатністю, у порівнянні з дослідною групою. Також було встановлено, що більша тривалість операції та виражена інтраопераційна поліурія асоціювались із вищою частотою вперше діагностованої гострої ниркової недостатності в післяопераційному періоді та частішим розвитком хронічних захворювань нирок після завершення періоду спостереження.

**Ключові слова:** LVAD, цільова антикоагулянтна терапія (ЦАТ), ниркова недостатність, гостра ниркова недостатність (ГНН), хронічна хвороба нирок (ХХН).

**Introduction.** Left ventricular assist devices (LVADs) improve survival in patients with advanced heart failure. As LVAD use increases, so do the number of patients with LVADs who also have kidney disease. To date, there is not a large amount of scientific evidence on common renal complications in large groups of patients with cerebral palsy. After LVAD implantation, kidney function may improve in the short term, especially with the restoration of cardiorenal physiology, but in the long term, the data remain limited. The main complications after LVAD implantation, such as: bleeding, thrombosis of the device, ischemic and hemorrhagic strokes, acute kidney damage, multiple organ failure, infections, etc, increase possibility of evidence on common renal complications. The timing of kidney complications after LVAD placement is classified as early (up to 30 days after implantation) or late (after 30 days until 3 years) [1–5]. 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. This work analyzed the frequency of early adverse non-surgical events and complications in the postoperative period within 14 days after implantation of a left ventricular mechanical support device in fifty patients treated at SCCS over a three-year period from 2016 to 2018, inclusive, aged  $55 \pm 13.5$  years old, with a body mass index of  $30.8 \pm 8.3 \text{ m}^2$ , with a left ventricular ejection fraction of 8–28%. Many questions remain and in addition to comparing the analyzed results of the study refers to qualitative and quantitative assessments of side effects and complications in patients with different approaches to anticoagulation targeted therapy, such as the treatment of anemia, optimization of renal replacement therapy, etc., which indicates the urgency of the problem and the need for further research in the industry.

**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  $52.8 \pm 1.7$  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 ( $As = -1.0 \sigma As = \pm 0.3$ ), the kurtosis coefficient had a positive value ( $\kappa = 0.4 \sigma \kappa = \pm 0.6$ ), the average BMI values were at the level of  $26.1 \pm 0.9 \text{ kg/m}^2$  ( $Me = 25.0$  (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 P2Y<sub>12</sub> 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 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  $1.4 \pm 0.7$  mg/kg/day during the entire period; 3 patients during the first week and 5 patients during the second week received clopidogrel  $1.3 \pm 0.8$  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 [6], 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  $\geq 15$  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.

The decision for renal replacement therapy were given are increase creatinine urinary acid and decrease GFR in accordance with KDIGO – Kidney Diseases Improving Global Output for patients with acute kidney injury [13].

**Results.** This study of patient cohorts demonstrated that in the early postoperative period, patients with different approaches to targeted anticoagulant therapy showed a diverse response pattern to therapy and, as a result, side effects and complications. The results showed that the control group of patients with classical anticoagulant therapy had increased mortality rates associated with ACI than the patients of the study group with the modified targeted therapy; an ananocorrelation between a longer duration of surgery and intraoperative polyuria was also demonstrated, giving a higher percentage of ACI in the short postoperative period. It was determined that chronic renal failure was recorded in five out of fifty patients, that is, 10% of the total number of patients examined, after a total hospital two-week short postoperative period. This burdened these patients with the fifth stage of renal failure, the need for regular dialysis therapy, since the level of creatinine and uric acid increased already outside the intensive care and cardiac surgery departments to appropriate, life-threatening levels. The existing differences in the distribution of hemostasis indicators in the comparison groups are of considerable interest (Table 1). 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.

The duration of surgical intervention in the main group did not differ significantly from the control group –  $347.8 \pm 17.9$  min and  $459.3 \pm 57.4$  min, respectively ( $p > 0.05$ ). During surgery, diuresis was higher in the control group (on average,  $940.0 \pm 186.5$  ml) than in the main group ( $704.5 \pm 82.5$  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  $693.3 \pm 141.5$  ml. ( $p > 0.05$ ). In the control group, Hemotransfusion was performed in 18 out of 21 patients (85.7%), with an average volume of  $1140.0 \pm 222.0$  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  $811.6 \pm 114.7$  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 ( $p > 0.05$ ).

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.

**Table 1**

*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
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

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

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 renal 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,  $p < 0,05$ ).

**Table 2**

*Characteristics of complications in LVAD patients with different types of ACCT*

ACTT Complication	Heparin	Varfarin	Heparin + Varfarin+ ASA	H/V/ A+P2Y12-bl.	H/V/A + anty-Xa.	H/V/A + P2Y12+ anty-Xa.
Quantity of patients	12%	2%	28%	12%	40%	12%
AKI with CRRT:						
HD–	10%	2%	4%	–	4%	–
HDF–	2%	–	4%	–	4%	4%
CKD	8%	–	–	2%	–	–

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

As shown in Table 2, 100% of patients who received heparin monotherapy developed acute renal failure in the postoperative period, which required the use of renal replacement therapy. In 2% of patients with heparin monotherapy, the postoperative period was complicated by the development of hemorrhagic stroke, liver failure,

aortic and right ventricular failure. 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 have in case of use extracorporeal renal replacement therapy in response to platelet conglomeration, which was evident only on a manual microscopic examination of the patient's blood morphology. As the study demonstrated, preliminary intraoperative data of a long duration of surgery affected the patient's renal complication, such as acute renal failure, which was not previously diagnosed. In total, in the control group of classical targeted anticoagulant therapy, the need for the use of extracorporeal support required 50% more patients than in the study during the entire short postoperative period. The percentage difference between the need for hemodialysis and hemodiafiltration was not significant and depended more on the intensity of the increase in the symptoms of AKI.

As a result of statistical processing of patient data, also after the transfer to other departments after the completion of treatment in cardiac surgery with intensive care, it turned out that five, five patients, 10% of patients, according to the results of non-improving indicators of creatinine and uric acid levels, glomerular filtration rate and others, received the G5 stage of chronic renal failure according to the CDIGO CKD. Of this number of patients, 4, that is, 80%, had a previously classic anticoagulant therapy regimen and only one, 20%, was modified.

As shown in Table 3, timely acute renal replacement therapy (CRRT) in a short period of time helps to restore kidney function and further limit the manifestations of renal dysfunction. According to the obtained data, in all patients, the level of creatinine in the blood decreased in comparison with the previous values, also, against the background of renal replacement therapy, an increase in the rate of glomerular filtration was noted. Continuous renal replacement therapy was had by 43% patient from control group and 10% from main research group.

**Table №3**

*Kidney function failures and disorders and CRRT in patients with LVAD*

Indications	Kind of CRRT	Hemodialise	Hemodiafiltration
Duration of CRRT day		2	10
Mediane of Creatinine in start\end of therapy CRRT in mmol/L.		294±24 /95±62	384 /100
Mediane of GFR in start\end of therapy CRRT in mmol/L (ml/min1.72m <sup>2</sup> )		19±42 /56,2±12	18,2 />60
Mediane of 24 hour diuresis in start\end of therapy CRRT in mL.		346±640 /2516±1430	510 /3800
Middle velocity of blood filtration in CRRT in mL\h.		105,1± 10,3	139
Quantity of CRRT-seat useless during therapy.		2,8 set/period	2,1 set/period
Quantity of CRRT-seat thrombosis during CRRT therapy.		2	0

The data are statistically significantly different from the original, p<0.05.

Table 3 clearly demonstrates that in acute renal failure in patients using HDF, in contrast to HD, qualitatively less sets were used during the therapy period, the median recovery of diuresis was significantly higher and the number of thrombosis sets was also lower.

**Discussion.** As for the activity of the 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  $123.8 \pm 3.7$  units, and in the control group –  $132.9 \pm 15.0$  units. ( $p > 0.05$ ).

A similar situation was observed with regard to the final kreaatinine level in the observation groups. So, in the main group, the cretinin content exceeded  $2.7 \pm 0.9$ , and in the control group it reached  $1.6 \pm 1.5$  units. ( $p > 0.05$ ), which may be due to a higher percentage of AKI. The risk of death in the control group was 3.5 times higher than in the main group ( $p < 0.05$ ).

After use in acute renal failure, renal replacement therapy in the main group compared to the control group was parametrically better, which requires explanation, despite the fact that the discrepancy between the increase in the indicator after correction of anticoagulant therapy was more pronounced in the main group ( $\Delta = +140\%$  versus  $+58\%$ ).

Also, the analysis of this group of patients with daily fluid balance showed that during the stay in intensive care 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 incidence of renal complications and mortality rate in patients whose IABP and ECMO support was more intensive during the first two days of postoperative ICU stay ( $\Delta = +105\%$  versus  $+19\%$ ). Further analysis showed that, depending on the applied anesthetic support, the duration of the surgical intervention, the volume of blood transfusion, postoperative renal complications of various structures are recorded in patients. Similar factors caused postoperative mortality. When looking for the most significant predictors, survival was defined as such activated clotting time and lactate levels at the end of surgery.

The development of AKI and CKD is quite common in patients with heart failure, especially in patients with implanted left ventricular mechanical support systems. INTERMACS reported that 876 of 7,286 (12%) LVAD implanted patients developed acute renal failure requiring dialysis or hemofiltration. Also, in these patients, an increase in the concentration of creatinine in the serum more than 3 times compared to the initial level or an increase in the concentration of creatinine above 5 mg/dL for more than 48 hours was noted [14]. There are also observational data describing the short-term effects of LVAD implantation on renal function, but insufficient data on long-term renal function outcomes. For example, a retrospective study of 220 patients showed [15] that in patients whose creatinine clearance improved by more than 50 ml/min. after LVAD implantation, the 30-day survival rate was 84%, while patients with lower creatinine levels had a 30-day survival rate of 66%. In our study, it was shown that the level of creatinine in the blood decreased in all patients compared to the previous values before the implantation of LVAD systems. During renal replacement therapy for patients who needed it, an increase in the rate of glomerular filtration and an improvement in central hemodynamics were noted, which was combined with a reduction in the doses of drugs used for adrenomimetic correction.



## Conclusions:

1. The highest percentage of acute renal complications, in the form of bleeding and thromboembolic events, was observed in the control group of patients who received monotherapy with heparin or warfarin or their combination and correlated with right ventricular failure in 20% of cases and an increase in the diameter of the portal vein, which, when using modified ACTT, allowed reduce this indicator by 50%.
2. Investigation was demonstrating that in acute renal failure in patients using HDF, in contrast to HD, qualitatively less sets were used during the therapy period, the median recovery of diuresis was significantly higher and the number of thrombosis sets was also lower.
3. AKI develops in patients with implanted LVAD systems in 40% of cases and requires SRPT mainly due to thrombosis of the proximal part of the renal tubules due to a decrease in perfusion pressure due to the production of exclusively laminar blood flow of a mechanical circulatory support apparatus. 10% of patients in the distant period received CKD and after treatment had permanent dialysis procedures. The use of an alternative anticoagulation scheme developed by us reduces the incidence of this complication by 90% in AKI case and 80% CKD, respectively.
4. Regardless of the monitoring methods used, the possibility of predicting serious complications in these patient cohorts is analytically complex, which is mostly associated with the function of the blood coagulation system, its morphology, and imbalance of hemodynamic parameters. It is clearly demonstrated by this work that the significant advantages of multimodal anticoagulant therapy regimens, which require complete control of the main parameters of the coagulogram as often as possible, are economically advantageous due to fewer complications and a rarer use of less renal replacement therapy. Further studies of the problems of this field will expand the possibilities of analytical structural analysis of prognostic methods for their everyday use in the practice of related medical specialties of doctors of these groups of patients.

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