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LEAD EXTRACTION RISK SCORES AND PRACTICAL USE: LITERATURE REVIEW

S.A.Aivazian[1], O.V.Sapelnikov[2], I.R.Grishin[2], I.N.Sorokin[1]

[1]Volga regional medical center of the Federal Medico-Biological Agency, Russia, Nizhniy Novgorod, 2 Nizhnevolzhskaya emb; [2]Federal State Budgetary Institution National Medical Research Center of Cardiology Ministry of Health of the Russian Federation, Moscow, 15a 3rd Cherepkovskaya str.

The number of implantations of cardiac electronic devices is increasing. Along with this, there is an increase in complications requiring lead extraction. As we know, lead extraction is associated with the risk of complications, including fatal ones. This review considers seven risk stratification scores for transvenous lead extraction. Their advantages and disadvantages and importance of their use in practice are discussed in this article.

Key words: transvenous lead extraction; complications; risk stratification score; cardiac implanted electronic devices

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Corresponding author: Aivazian Sergei, E-mail: sergei_aivazyan@mail.ru

S.A.Aivazian - ORCID ID 0000-0002-9642-9754, O.V.Sapelnikov - ORCID ID 0000-0002-5186-2474, I.R.Grishin - ORCID ID 0000-0002-2689-2751, I.N.Sorokin - ORCID ID 0000-0002-7350-8353

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The number of cardiac implantable electronic devices (CIEDs) has been steadily increasing over the last few years. For the last 10 years in Russian Federation, the number of CIEDs increased from 26,500 to 50,000 per year and keeps growing [1, 2]. It is important to notice that an increasing number of CIEDs occur due to elderly patients with severe comorbidities as a result of population aging and improving the quality of health care [3]. Accordingly, the number of complications, infectious and non-infectious, associated with electrodes dysfunction is increasing [3-5].

Transvenous lead extraction (TLE) is considered the first-line strategy for the management of complications associated with CIEDs. TLE is considered a gold standard in the treatment of CIED-related infective complications. In some cases, extraction of noninfected abandoned leads should be performed as well [6].

According to previous studies, the rate of major complications during TLE ranges from 1.4% to 2.0%, including most often damaging to the myocardium or veins (including superior vena cava). Superior vena cava damage is related to a 50% rate of mortality. In case of heart or vessels damage, to avoid intraoperative mortality, an emergency surgical procedure should be performed within 5-10 min [6]. It is a controversial question who and where should perform TLE (interventional cardiologist in the catheterization laboratory or cardiovascular surgeon in the hybrid operating room) [7].

To prevent life-threatening complications, it becomes relevant to assess the risk of lead extractions. The risk stratification system is important for patients with non-infectious complications if TLE should be performed. Several protocols have been proposed to predict the occurrence of serious perioperative complications and to provide the availability of necessary tools.

To identify and study proposed risk scores for TLE in MEDLINE / PubMed, Google Scholar, Cochrane Central Register of Controlled Trials (CENTRAL), there was a search using the keywords in English: “transvenous lead extraction”, “risk stratification”, “risk score”. To balance the specificity and sensitivity of the searching strategy, groups of keywords were combined using the AND operator. The search was performed by one researcher and included sources published in English up to 01/24/2022. The primary selection of studies was performed according to the title and abstract. The selected studies were read to determine whether their content met the criteria of acceptability. Studies were selected according to the use of lead scores. We searched publications for the last 10 years. 320 relevant articles were found. After reading the title and abstract, 313 articles were excluded. Seven articles were identified in which one or another risk stratification score for TLE was proposed (Table 1).

This article aims to review existing risk scores for specialists, who are involved in device implantation and TLE. It can help to decide in the following situation: perform TLE by yourself and right now; perform the intervention after the additional technical and organizational preparation and correction of risk factors associated with the patient; refer the patient to a high-volume center.

LED score

This is the first TLE risk score which was developed and published in 2014. The main goal is to identify patients who should be referred to a medical center with greater

Table 1.

Transvenous lead extraction risk stratification scores

Risk score title	LED score	-	-	RISE protocol	SAFeTY score	MB score	EROS
Authors	Bontempia L et al. [8]	Fu HX et al. [10]	Kancharla K et al. [11]	Afzal MR et al. [12]	Jacheć W et al. [13]	Bontempi L et al. [14]	Sidhu BS et al. [15]
Year of publication	2014	2015	2019	2019	2020	2020	2021
Number of patients in the study	469	652	187	1200	2049	973	3510
Number of extracted leads	889	1378	349	1687	3425	1960	6493
PL/ICD lead (%)	42 / 58	73 / 27	61,7 / 38,3	61,9 / 38,1	84,9 / 15,1	67 / 33	70,6 / 29,4
The principle of risk gradation	Points	Intermediate / high	Intermediate / high	Low / high	Low / intermediate / high / very high	Points	Low / intermediate / high
The main risk factors	Number of leads, lead age, dual-coil ICD lead	Lead age	Lead age, congenital heart disease, lead implantation if patient age is < 15 years old, hemodialysis, CT data, sepsis, CHF NYHA IV	Lead age, StarFix lead model	Sum of ages of all leads, lead implantation if patient age is < 30 years old, hemoglobin level, female, number of previous procedures	Lead age, number of leads, passive fixation leads, ICD leads	Lead age, congenital heart disease, lead implantation if patient age is < 15 years old, hemodialysis, sepsis, CHF NYHA IV
Lead extraction technology	Mechanical/ laser/ femoral approach	Mechanical/ laser	Mechanical/ laser	Laser / mechanical	Mechanical	Mechanical/ laser/ femoral approach	Mechanical/ laser/ femoral approach
Lead age median (years)	4,6	4,8	11,2	6,5	11,6	5,8	5,3
Deadlines for lead survival evaluation	30 days	30 days	30 days	30 days	Less than 10 years, Mmedian 3 year	30 days	30 days
Group of validation	No	No	No	Yes	Yes	Yes	No

Note: PL - pacing lead. ICD - implanted cardioverter-defibrillator, CHF - congestive heart failure, NYHA - New-York Heart Association.

experience in TLE. The score was developed based on the experience of TLE with 889 leads in 469 patients [8, 9].

LED score is equal to the number of leads to extract + years from implant of the oldest lead to remove + 1 (if a dual coil implantable cardioverter-defibrillator (ICD) lead must be removed) +1 (if vegetation is confirmed along the lead body).

The LED score proposed to use the fluoroscopy time as a measure of complexity of extraction (extraction considered to be difficult when the fluoroscopy time was more than 31.2 minutes). The median of LED score in our population was 6, ranging from 0 to 32. The LED score of more than 10 (35,6% of patients) was associated with higher risk of TLE and prolonged procedure time. The sum of LED score points is an independent predictor of fluoroscopy time [odds ratio (OR) 1.22, 95% confidence interval (CI) 1.15-1.30, P<0.0001]. Moreover, an increase in the LED score by one point leads to an increase in the time of fluoroscopy by 12%. Sensitivity and specificity of the score was 78.3% and 76.3% respectively.

Fu NX et al score

Fu NX et al score is created by authors from the Mayo Clinic (USA) [10]. The main goal of the score is to divide patients into two groups: those who can be operated in a cath lab, and those who should be operated in a hybrid operating room with immediate cardiovascular team assistance available, including a surgeon, an assistant, a perfusionist, and a nurse. It allows for reducing risk, prevents major complications, and regulates clinic resources. The score based on the experience of TLE of 1378 leads in 702 patients. In 44% of cases, leads were removed using a laser sheath. The number of major complications was 1.9%, which were associated with the age of lead (OR 1.2, 95% CI 1.1-1.3, P<0.001). All patients were divided into 3 groups: high, intermediate, and low-risk groups. The high-risk group included patients with pacing lead (PL), age of the lead of more than 10 years, dual coil ICD lead, and age of the lead of more than 5 years. The intermediate-risk group included patients with PL, lead age from 1 to 10 years, and ICD lead - from 1 to 5 years. A low-risk group included patients with lead age of less than 1 year (if extraction tools were not used, terminologically it is more correct to define this group as lead deimplantation) [6]. Emergency surgical procedure was performed in 5.3%, 1.2%, and 0%, respectively (P<0.001). Therefore, all patients were divided into two groups: high and intermediate-risk groups.

The authors concluded that an available hybrid operating room is the best option for TLE. In case it is not possible, TLE in the intermediate-risk group should be performed in a well-equipped cath lab using a balloon for temporary hemostasis in case of superior vena cava damage.

Kancharla K et al score

This score was also created by authors from the USA in 2019. The main goal of this work was similar - to divide patients into those who can be operated in cath lab and those who should be operated in a hybrid operating room. The score is based on TLE of 349 leads in 187 patients [11].

In this score authors divide all patients into two groups: intermediate and high-risk groups. Authors marked that TLE can't be performed without any risk. In this study all patients with PL with lead age more than 10 years, patients with ICD lead with lead age more than 5 years, patients with severe comorbidity and those who have lead age less than 10/5 years, are proposed to be operated in a hybrid operating room with the assistant of a surgeon (Table 2).

There were no major complications among patients who were operated in cath lab. In the high-risk group of patients (38.5% of the total number of patients) operated in a hybrid operating room, the rate of major complications was higher than 6.9% (P=0.007).

Authors of Kancharla K et al score concludes that providing TLE in a cath lab. or hybrid operating room is acceptable, safe, and effective. Intermediate-risk group patients can be operated without additional surgical assistance.

RISE score

RISE score (RIsk Stratification before lead Extraction) was created by a group of authors from the USA in 2019. The authors divided patients into two groups: high-risk and low-risk TLE [12]. The high-risk group included dual coil

Table 2.

Kancharla K et al transvenous lead extraction risk stratification score [11]

Procedure Risk for Lead Extraction	
Intermediate risk	Pacemaker lead 1-10 years implant duration, ICD lead 1-5 years implant duration
High risk	Pacemaker lead >10 years (≥1 lead), ICD lead >5 years (≥1 lead) or pacemaker lead 1-10 years, ICD lead 1-5 years implant duration, with: congenital heart disease, initial implant when patient was age <15 years (growth into vessel wall), hemodialysis, chest radiograph/CT scan showing calcified SVC or myocardium adjacent to lead, active sepsis, heart failure, NYHA functional class IV

Note: CT - computed tomography; ICD - implantable cardioverter-defibrillator; NYHA - New York Heart Association; SVC - superior vena cava.

Table 3.

SAFeTY TLE score

S	Sum of the dwell times of leads planned for extraction per patient (>16.5 years)	6,095 points
A	Age	2,291 points
Fe	Female gender	2,740 points
T	Number of previous CIED procedures per patient	1,364 points (for each procedure)
Y	Young patient (first implantation under the age of 30)	2,174 points
TLE	Transvenous lead extraction	

ICD lead with lead age ≥ 3 years, PL or single coil ICD with lead age ≥ 5 years, as well as all left ventricular leads in the StarFix model (Medtronic, USA) (Fig. 1).

After the introduction of the RISE score, patients of the high-risk group were operated in the hybrid operating room with cardiac surgeon assistance, perfusion, and blood-saving equipment. The study included a pre-RISE group (449 patients, 632 leads) and a post-RISE group (751 patients, 1055 leads). Application of the RISE score reduced the major complications - from 3.34% to 1.6% (P=0.04), and mortality from 0.89% to 0.13% (P=0.04) [12].

SAFeTY TLE Score

The score was developed by Polish authors in 2020. SAFeTY TLE Score is based on a prospective analysis of 2049 patients and 3425 leads undergoing TLE [13]. More often for TLE were used Byrd dilators (Cook Medical, USA) were placed through the subclavian vein (1758 procedures (85.8%)). Other techniques included simple traction (360 leads (10.5%)), combined approach (upper and lower access, 65 leads (1.9%)), lead extraction from a femoral approach using various devices (45 leads (1.3%)), and extraction through the jugular approach (4 leads (0.1%)). The study also included a TLE of 9 leads (0.26%) in patients who were initially referred for open-heart surgery due to large vegetations or comorbidity of cardiac valve disease.

The major complications were developed in 37 (1.81%) cases, including death in 8 (0.39%) cases. Based on the results, the authors calculated an extraction risk score and developed and presented a scoring system using the abbreviation SAFeTY TLE (Table 3). The sum of the risk points correlated with the probability of developing major complications during a TLE and the relationship was expressed as the logistic function in the following equation:

risk of major complications (%) = 100/(1 + 644/(1.3213x)), where "x" is the number of points obtained.

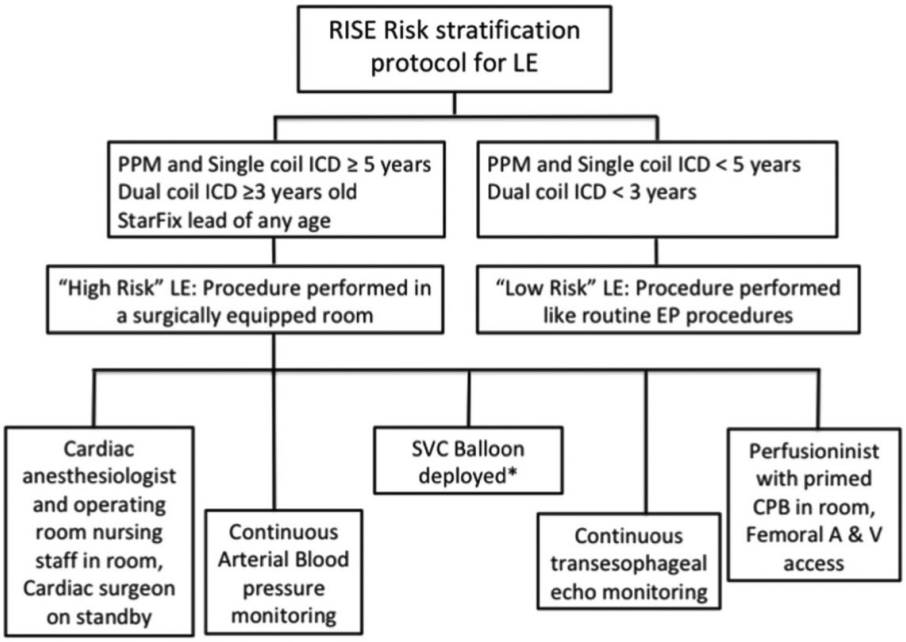

Figure 1. Flow chart depicting various components of high- and low-risk stratification during RISE protocol [12]. Note: CPB - cardiopulmonary EP - electrophysiological; ICD - implantable cardioverter-defibrillator; LE - lead extraction; PPM - permanent pacemaker; SVC - superior vena cava.

Based on this formula a simplified calculator was created to predict the risk of major complications during the TLE procedure (the calculator is available online at http://usuwanieelektrod.pl/akalkulator/).

MB score

A group of authors from Italy proposed a validated risk stratification score for TLE, which is called MB-Score (named by the initials of the developers). The score based on a prospective analysis of 973 patients and 1960 leads undergoing TLE. The validation cohort consisted of 486 patients [14].

Risk factors were associated with the lead age (≥3, ≥5, and ≥10 years), number of leads (high-risk procedure means removal of more than one lead), passive fixation leads, and dual coil ICD leads (Fig. 2). The aim was to derive and validate a scoring system to efficiently predict the need for advanced tools (mechanical and laser sheaths) to achieve TLE success [14].

In cases with MB score 0 point, leads were always extracted by simple traction with or without locking stylet (prediction accuracy, according to the authors, - 100%). These patients are truly low-risk and may be safely operated in low-volume centers without additional equipment and staff. Even with an index value of 1 - with a probability of 75.9% - the procedure should be simple and not require the use of additional devices (Fig. 3). Such operations (according to the authors) can be performed in clinics with a low volume of extractions and in the absence of special equipment (hybrid operating room, heart-lung machine, etc.).

EROS score

The ELECTRa Registry Outcome Score (EROS) was developed by a group of European experts in 2021 and applied to ELECTRa Registry in 2017. The aim was to determine if it could appropriately risk-stratify patients underwent TLE [15]. Overall, 3510 patients underwent TLE in 73 European centers in 19 countries [16]. Lead dwell time was available in 3485 patients.

All medical centers where TLE was performed were divided into two groups: 1) high-volume centers (performing > 30 TLE per year); 2) low-volume centers (performing < 30 TLE per year).

This score should be reviewed in more detail. The EROS score is based on the Kancharla K et al score. Patients were assigned to ELECTRa Registry Outcome Score (EROS) 1, 2, or 3 depending on whether their predicted risk of major complications was low, intermediate, or high (Table 4). The score was based on patient characteristics, comorbidities, lead characteristics, and lead age.

In this analysis, the authors compared the characteristics and

outcomes of EROS 3 with both EROS 1 and 2 combined and also EROS 1 with EROS 2 separately, since this would help identify whether the risk score could distinguish between high- and intermediate-risk patients. Overall, 2004 (57.5%) patients were EROS 1, 1109 (31.8%) EROS 2, and 372 (10.7%) EROS 3 retrospectively in ELECTRa Registry. The operating room or hybrid operating room was both considered a high-risk setting since this environment can facilitate urgent surgical intervention and the catheterization laboratory a low-risk setting.

Procedural and lead outcomes:

1. Patients with EROS 3 compared with EROS 1 and 2 combined, were more likely to require a femoral approach, powered sheaths including laser sheaths, but a prolonged procedure time and hospital stay and less likely to achieve clinical success.
2. Patients with EROS 3 compared with EROS 1 and 2 combined, were more likely to suffer procedure-related major complications including deaths. Group EROS 3 was associated with procedure-related major complications including deaths (OR 3.333, 95% CI 1.879-5.914, P<0.0001), cardiac avulsion or tear (OR 7.111, 95% CI 3.382-14.949, P<0.0001) and cardiovascular lesions requiring pericardiocentesis, chest tube, or surgical repair (OR 3.860, 95% CI 2.095-7.113, P<0.0001).
3. Patients with EROS 2 compared with 1 were more likely to require the use of powered sheaths, particularly laser sheaths and require a femoral approach, but a prolonged procedure time and hospital stay. Both groups were matched in terms of procedure-related major complications including deaths. However, patients with EROS 2 were more likely to suffer all-cause in-hospital major complications including deaths [15].

DISCUSSION

It is necessary to determine a risk assessment for safety TLE. Risk assessment provide an ability to identify the high-risk patients and refer them to high-volume center. The proposed scores, especially SAFeTY TLE and EROS scores, are based on the data analysis of large population and the risk management of major complications is multifactorial.

The great advantage of SAFeTY TLE score is an easy-to-use calculator which is available online and become a useful option for making decision of TLE in clinical situation.

The SAFeTY TLE score showed that the sum of the dwell times of leads planned for extraction per patient is the most sensitive parameter, which depended both on the age of the lead and on their number.

The authors of the EROS score proposed a 'traffic light system' to risk stratify patients into low (EROS 1: green), intermediate (EROS 2: yellow), and high risk (EROS 3: red). They proposed that the highest risk patients (EROS 3) should be considered to have their TLE performed in a high-risk environment (hybrid operating room) with immediate surgical assistance available, with a cardiac surgeon present in procedures. Patients with EROS 2 are at intermediate risk of complications could have TLE performed in an environment with formalized surgical back-up (nominated cardiac surgeon available to perform thoracotomy/sternotomy but not present during the procedure). EROS 1 patients may be suitable for a low-risk environment however surgical back-up is still required. The decision of where to perform EROS 1 and 2 should also consider frailty, additional important comorbidities, and adverse lead characteristics such as dual-coil ICD leads

Table 4.

Risk score EROS [15]

EROS 1	EROS 2	EROS 3
Pacemaker lead 15 years from implant ICD lead ≤10 years from implant	Pacemaker lead ≤15 years or ICD lead ≤10 years from implant and either: congenital heart disease, initial implant when the patient was <15 years old, chronic kidney disease and serum creatinine >2 mg/dL, infectious indication for extraction and any one of the following: white cell count > 12 × 10^9/L, positive blood culture, vegetation on transoesophageal echocardiogram	Pacemaker lead > 15 years from implant ICD lead > 10 years from implant

Note: ICD - implantable cardioverter-defibrillator.

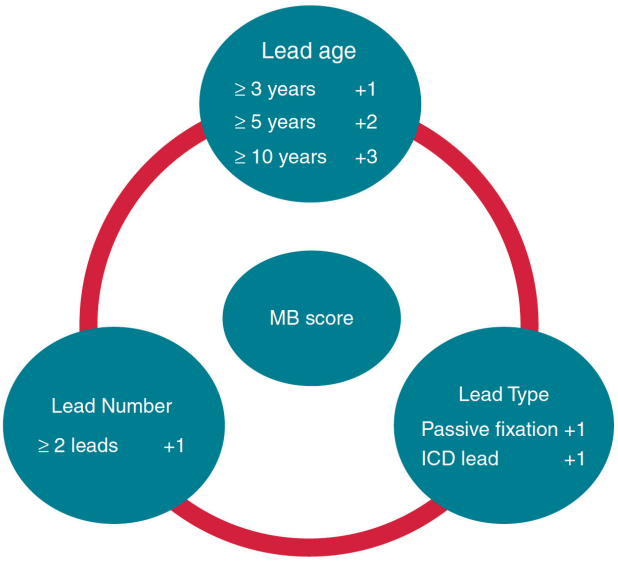

Figure 2. Scheme for calculating the extraction complexity index MB-Score [14].

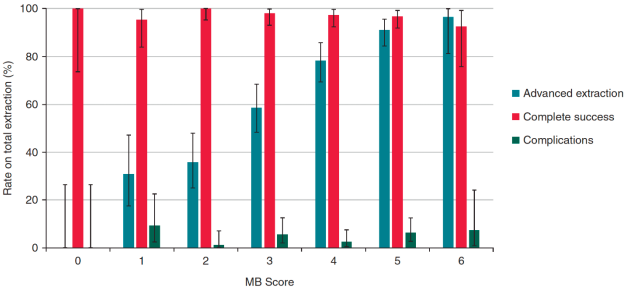

Figure 3. Validation of the MB score: blue - extraction using a laser, rotary dilator or femoral access, red - full efficiency, green - complications [14].

that are associated with an increased risk of procedural-related complications.

In our opinion, this strategy seems to be complicated in risk assessment and planning procedures. Cardiac surgical assistance should be available in all TLE procedures.

We think that Kancharla K et al and RISE scores are easier in use for determination patients in appropriate volume center for TLE. Notably, only Kancharla K et al score used computed tomography to determine a risk-stratification of TLE. Another significant issue is the importance of prediction in postoperative period, which is studied in EROS score. Notably, patients at intermediate risk (EROS 2) compared with low risk (EROS 1) were more likely to suffer all-cause in-hospital major complications including deaths, driven by heart failure and sepsis. These excess nonprocedural-related complications and deaths may also be explained by the significantly higher incidence of systemic infections in EROS 2 patients which is known to result in prolonged hospital admissions and worse long-term outcomes [17]. It suggests these patients should be closely monitored post-procedure to ensure any complications are managed effectively.

There is no doubt if we speak about lead extraction with the present lead or pocket infection. In this case we choose the intervention strategy: who, where and what tools should be taken. Another question is what we should do with abandoned lead without any sings of infection. Shall we extract abandoned noninfected leads and which way? We hope that analyzed scores will help to answer this question. If the risk of extraction is too high, it is better do not touch nonfunctional lead and implant the new one.

We performed 217 TLE for the last 10 years. The mortality rate is 0.9% (2 patients). In the first case, patient died because of TLE of 10-year-old ventricular PL using a rotation dilator sheath. The lead was implanted in the anterior wall of the right ventricular outflow tract, where cardiac avulsion happened during procedure. In the second case, patient also died after TLE of 9-year-old PL using a rotation dilator sheath. Moreover, the lead was implanted in the interventricular septum. Operation was complicated by an extended injury (about 2 cm) of the right atrium with the passage to the inferior vena cava, where the lead loop was fixed.

Both patients were in the low-risk group according to EROS and SAFeTY TLE score, according to LED score 10/11 points, according to MB score - 3 and 2 points out of 6, according to Kancharla K et al score - intermediate-risk, and only in RISE score both patients were in high-risk group. None of the scores doesn't take into account the place of lead fixation, which resulted in adverse outcome in both our cases.

CONCLUSION

Therefore, all considered scores indicate that the main risk factor is the dwell time of lead planned for extraction. In addition to determining the risk of major complications, both directly related to the intraoperation and postoperative period, the main goals are to determine the place of TLE, to predict all the necessity tools (laser sheath, rotational dilator sheath, transfemoral approach of TLE) and the team performing the intervention. Currently, it is recommended to perform the procedure in a hybrid or cardiac operating room equipped with an angiograph, with surgical assistance available (if operation performed by an electrophysiologist).

TLE has been included in the list of high-technical medical care since 2021. As a result, the number of such procedures will continue to increase. According to our experience, we believe that the initial stage of development of TLE procedure, which is currently taking place in the Russian Federation, RISE, and Kancharla K et al. scores are optimal for risk assessment for TLE safety. However, the best strategy would be to use several scores. In our opinion, it should be RISE and EROS scores. The EROS score allows you to predict the postoperative period.

We believe that it will be necessary to search for new risk factors and develop new TLE risk scores in the future.

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