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Effectiveness of clinical assistive application «Anesthesia Status Indicator»: a randomized controlled trial

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ABSTRACT

Objective. To evaluate the effectiveness of clinical assistant application «Anesthesia Status Indicator» (BoA Panel) for support of clinical decision-making and improving the patient safety.

Material and methods. A single-center, randomized, controlled trial included 66 patients aged 33—74 years (ASA III) who underwent surgery under general anesthesia for thyroid tumors. Patients were randomized into 2 groups: group A (control, *n*=33) — anesthesiologists were guided by current values of advanced monitoring without taking into account the recommendations of clinical application; group B (study, *n*=33) — anesthesiologists were guided only by the recommendations of clinical application. In all cases, we used the Harvard monitoring standard, control of gas-narcotic mixture, depression of consciousness and neuromuscular conduction. Heart rate variability and electrodermal activity were recorded. We also performed internal discrete medical audit of critical incidents. Methods of descriptive and variation statistics were used. The null hypothesis was rejected at $p<0.05$.

Results. We found unidirectional dynamics of parameters of advanced anesthetic monitoring in both groups without significant differences, identical clinical course of anesthesia and the same need for pharmacological load. Internal discrete medical audit revealed higher safety in group B due to significantly lower incidence of arterial hypotension ($p=0.019$) and greater number of cases without critical incidents compared to the control group.

Conclusion. «Anesthesia Status Indicator» (BoA Panel) for clinical decision-making is effective for monitoring of anesthesia and increasing the safety of patients with ASA III physical status undergoing surgery for thyroid tumors.

Keywords: *adequacy of anesthesia, safety of anesthesia, critical incidents, decision-making support, clinical application.*

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Introduction

Patient safety is one of the key issues in medicine. In this regard, increasing the safety of anesthesia is of particular importance in modern surgery. Global priority implies decrease of overall perioperative and anesthesia-related mortality through evidence-based best practices. Undoubtedly, modern anesthesiology has become much safer than before thanks to national and international standards for safe anesthesia adopted in many countries that have adhered to the Declaration of Helsinki on patient safety in anesthesiology [1]. Nevertheless, perioperative modulation of surgical stress response and protection of organs and systems are urgent objectives in anesthesiology of the 21st century. Increasing the safety of anesthesia through targeted effects on the most vulnerable organs and systems has led to justification of new monitoring methods, especially in high-risk patients. This necessitates assessment of their effectiveness. One of these directions is monitoring systems with clinical decision-making support based on real time information about organs and systems. These systems or software products or monitor modules are currently used in intensive care and, less often, in anesthesiology [2—4]. Harutyunyan R. et al. [5] have recently published a systematic review and meta-analysis with estimation of continuous (standardized mean difference [SMD], –0.66; 95% CI [–1.01 to –0.30]; $p<0.01$) and binary outcomes (odds ratio [OR], 0.64; 95% CI, [0.44—0.91]; $p<0.01$). Clinical decision-making support systems insignificantly improve the outcomes of interventions in anesthesiology versus intensive care. The authors justified necessary additional randomized controlled trials (RCTs) for assessment of these systems in intensive care [5].

In this regard, we were interested in auxiliary clinical application «Anesthesia Balance Information Panel (BoA Panel)» (patient monitor «BeneVision N17», «Shenzhen Mindray Bio-Medical ElectronicsCo, LTD», China). According to developers, this device should be effective and simple for monitoring of anesthesia and decision-making support. We found no available data on effectiveness of this clinical application for improving intraoperative patient safety that inspired this study.

The purpose of this study was to evaluate the effectiveness of clinical assistant application «Anesthesia Status Indicator» (BoA Panel) for support of clinical decision-making and improving the patient safety.

Material and methods

The local ethics committee approved this study (protocol dated 02/15/2022).

A single-center, randomized, controlled trial was performed.

Null hypothesis: «Anesthesia Balance Information Panel (BoA Panel)» for clinical decision-making support will not improve patient safety in the same volume of monitoring.

Primary endpoint: 20% decrease in critical incident rate during surgery and anesthesia according to perioperative discrete internal medical audits.

We analyzed necessary sample size using the MedCalc calculator (version 15.2, MedCalc Software Ltd, Belgium). To generate the sample, we compared mean critical incident rates obtained in previous studies:

Significance level (alpha) = 5%.

Power (1-beta) = 80%.

Mean difference (clinically significant) — 0.22

Standard deviation in group 1 — 0.35

Standard deviation in group 2 — 0.25

Necessary sample size per a group = 31.

Necessary total sample size = 62. Considering 10% dropout rate or possible withdrawal of patients from the study immediately before surgery, we randomized 66 patients (1:1) and analyzed the effectiveness and safety of combined general anesthesia.

Inclusion criteria: informed consent, women aged 18—80 years, surgery (60—120 min) for thyroid cancer, ASA grade III, 18<BMI<40 kg/m^2.

Non-inclusion criteria: males, decompensated diabetes mellitus, decompensation of chronic organ or systemic failure, severe disorders of neuromuscular conduction, neuromuscular diseases (including myasthenia gravis, Eaton-Lambert syndrome, previous poliomyelitis, etc.), contraindications for TOF Watch device (for example, pacemaker, etc.), acute infectious diseases, previous malignant hyperthermia, previous allergy, emergency surgery, combined surgical intervention, repeated surgery within 30 days.

Exclusion criteria: refusal of the study by the patient or inability to continue participating in the study, appearance of non-inclusion criteria during the study, intolerance to anesthetic drugs.

We performed randomization using the envelope method (https://www.sealedenvelope.com/simple-randomiser/v1/lists).

Diagnostic procedures:

1. Clinical assessment.
2. Intraoperative advanced monitoring («BeneVision N17», «Shenzhen Mindray Bio-Medical Electronics Co, LTD», China): Harvard monitoring standard (non-invasive blood pressure measurement, heart rate, pulse oximetry (SpO_2), capnometry, thermometry); bispectral index (BIS) with target values 4060, assessment of neuromuscular conduction (TOF), composition of gas-narcotic mixture.
3. Real time assessment of heart rate variability (HRV) (pulse oximeter ELOX-01m, Russia) with tension index (TI).
4. Real time assessment of electric dermal activity (EDA) (stress monitoring system NeonFSC, Russia).
5. Internal discrete audit of critical incidents (CI) with assessment of their rate equal to the ratio of all incidents at certain stage of the study to the number of observations in the group; critical incident rate index (CIRI) equal to the number of CIs per hour of anesthesia per a patient [6]. We recognized the following values of monitoring as critical incidents [6, 7]:
   - bradycardia (heart rate decrease by more than 20% or <50 min^{-1});
   - tachycardia (heart rate increase by more than 20% or >100 min^{-1});
   - hypertension (systolic blood pressure increase by 20% or >160 mm Hg);
   - hypotension (blood pressure decrease by 20% or <90 mm Hg);
   - moderate hypoxemia (90%<SpO_2<95%);
   - excessively deep anesthesia (BIS < 30);
   - unreasonably superficial anesthesia (BIS > 60).
6. Assessment of post-anesthesia rehabilitation period:
   - time periods (until restoration of consciousness, weaning from ventilator, Aldrete Score 9—10);
   - incidence of postoperative nausea and vomiting according to numerical rating scale (NRS);
   - NRS score of pain.
7. Descriptive and variation statistics:

We analyzed distribution normality using the Shapiro-Wilk test. Continuous data are presented as median and interquartile range for nonparametric distributions, as mean and standard deviation for parametric distributions. Categorical variables are presented as numbers and percentages with their comparison using the χ^2 test. Between-group comparison of means was carried out using the Mann—Whitney test. The Wilcoxon test was applied to estimate significance of changes over time. The null hypothesis was rejected at p-value<0.05. We analyzed the results in electronic database (MS Excel) using the Statistica 10.0 software (Statsoft, USA).

Stages of the study: 1) before surgery (1—2 days); 2) admission to operating theatre (before induction); 3) after induction, intubation and onset of ventilation (stabilization of anesthesia); 4) skin incision (beginning of surgery); 5) 30 min later; 6) 60 min later; 7) 90 min later; 8) end of surgery; 9) restoration of consciousness; 10) weaning from ventilator; 11) Aldrete Score 9—10; 12) 2 hours after transfer to the ward.

According to inclusion/non-inclusion criteria, we examined 66 patients aged 33—74 years with ASA grade III who underwent surgery for thyroid tumors under general anesthesia. We excluded male patients to reduce study error considering gender-related differences in hormones, necessary drugs for anesthesia and pain relief, course of early post-anesthesia rehabilitation period [8—11].

According to study design, patients were randomized (1:1) into 2 groups. Characteristics of groups are presented in **table 1, 2**.

All patients were classified as ASA grade III. There were 2.49 and 2.58 concomitant diseases per a patient in both groups, respectively. Cardiovascular diseases, type 2 diabetes mellitus and metabolic syndrome prevailed. The last ones along with underlying disease allowed us to recognize high-risk patients. Gastrointestinal diseases and some other diseases were more common in group B. Patients with increased BMI significantly prevailed **(table 1)**. All patients were diagnosed with thyroid tumors and indications for surgical treatment **(table 2)**.

The anesthetic protocol was the same for all patients: intravenous induction with propofol 2 mg/kg and fentanyl 2 μg/kg; tracheal intubation after myoplegia with rocuronium 0.6—1.0 mg/kg, maintaining of muscle relaxation at a dosage of 0.6 mg/kg/h; protective ventilation with a gas-narcotic mix-

Table 1. **Characteristics of patients**

Parameter	Group A (n=33)		Group B (n=33)		p(U)	
	$M\pm SD$	Med (Q_{25}; Q_{75})	$M\pm SD$	Med (Q_{25}; Q_{75})	Z	p
Age, years	51.4±13.5	53 (39; 63)	56.2±10.4	60 (49; 63)	−1.374	0.169
Height, cm	164.3±5.9	165 (160; 167)	161.6±5.9	164 (157; 165)	1.501	0.133
Weight, kg	70.9±12.1	72 (61; 81)	79.2±14.3	80 (70; 85)	−2.240	0.025
BMI, kg/m^2	26.3±4.5	25.5 (22.4; 30.8)	30.1±5.1	31.0 (24.8; 33.3)	−2.995	0.003

Table 2. **Diseases in all patients**

Disease	Group A (n=33)	Group B (n=33)	$\chi 2$ test	p
Main diagnosis:				
thyroid carcinoma	2	0	2.063	0.151
multinodular nontoxic goiter	2	4	0.733	0.392
multinodular toxic goiter	5	6	0.109	0.742
thyroid cancer	8	9	0.079	0.779
follicular neoplasia of the thyroid gland	16	14	0.244	0.622
Concomitant diseases:				
cardiovascular diseases	27	30	1.158	0.282
respiratory diseases	2	2	0.000	1.000
kidney diseases	3	3	0.000	1.000
obesity	9	14	1.668	0.197
diabetes mellitus type 2	8	10	0.581	0.581
gastrointestinal diseases	24	7	17.580	<0.001
other diseases	9	19	6.203	0.013

ture (oxygen, air, sevoflurane with MAC 0.8—1.0), tidal volume 6 ml/kg, PEEP 5 cm H2O; analgesia through bolus administration of fentanyl 3—5 μg/kg/h.

There were different methodological approaches to the management of anesthesia and assessment of quality.

— In the control group (A), the anesthesiologist was guided by advanced monitoring data (BP, HR, BIS, TOF) in decision-making. The recommendations from the «Anesthesia Status Indicator» application were not displayed on the monitor screen.

— In the main group (B), the anesthesiologist was guided only by the recommendations of the «Anesthesia Status Indicator» application displayed on the monitor screen. We present an example of recommendations based on analysis of the following parameters **(fig. 1)**: pain severity — difference between systolic blood pressure (ΔBPs) and heart rate (ΔHR); consciousness depression depth — BIS value; neuromuscular blockade — response to four-discharge stimulation (TOF). Color of branches of each indicator indicates appropriate parameter: standard range (adequate anesthesia) — green, parameters outside the range of standard values (necessary correction) — red, invalid or unavailable value of parameter — gray [12].

At all intraoperative stages, we additionally monitored HRV and EDA for real time and retrospective assessment of autonomic nervous system. We also filled electronic anesthetic records with monitoring data and other information. The following parameters were considered to evaluate the effectiveness and safety of «Anesthesia State Indicator» application.

Performance criteria:

1. Stability of hemodynamic and gas exchange parameters;
2. Minimum incidence of excessively deep and superficial anesthesia;

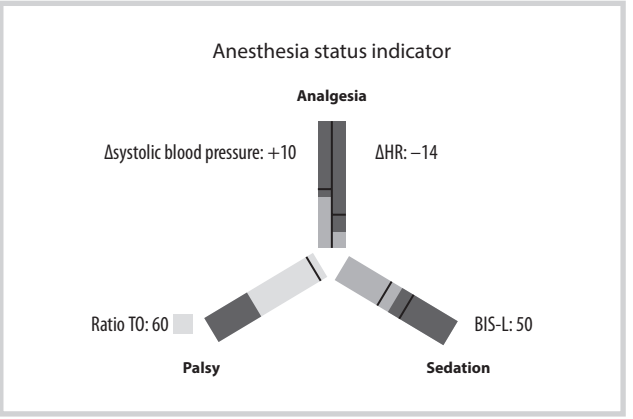

Fig. 1. **Anesthesia balance dashboard of application «Anesthesia Status Indicator».**

3. Stable parameters of vegetative homeostasis;
4. Minimal postoperative pain, nausea and vomiting in early postoperative period.

Safety criteria:

1. Internal discrete medical audit of critical incidents;
2. Postoperative morbidity according to the ISOS criteria (2016) [13].

Results and discussion

Final statistical analysis included 66 patients (33 ones in each group). In the control group, 87.9% and 12.1% of patients underwent thyroidectomy and hemithyroidecto-

my, respectively. In the main group, these values were 84.8% and 15.2%, respectively (p=0.535). Mean surgery time was 71.79 and 75.82 min (p<0.05), anesthesia time — 91.39 and 97.76 min, respectively (p=0.469) **(table 3)**. Thus, extent and duration of intervention, as well as surgical trauma were comparable.

Effectiveness of combined general anesthesia

We found completely identical characteristics of anesthesia in both groups according to a single protocol. The need for intravenous anesthetic, narcotic analgesic and muscle relaxant was similar **(table 3)**. End-tidal concentration of sevoflurane (EtSev) was identical at different stages of surgery (p=0.204—0.412). Therefore, the «Anesthesia State Indicator» application did not affect pharmacological load in the main group.

Assessing the hemodynamic parameters, we note minimal changes in blood pressure and heart rate within normal values in both groups **(fig. 2, 3)**. With the exception of mean blood pressure prevalence in group B by 12.5% at the end of surgery (p=0.016), all circulatory parameters were similar in both groups throughout the entire intraoperative period.

Parameters of combined neurophysiological monitoring were similar in both groups and typical for adequate general anesthesia. Mean BIS was 40—60 at various stages of surgery in all patients **(fig. 4)**. Incidence of intraoperative episodes of excessively deep (<30) or superficial (>60) anesthesia was insignificant in both groups (7 and 5, respectively, p=0.552). Mean tension index did not exceed 250 **(fig. 5)** in both groups that indicated adequate anesthetic protection without signs of severe sympathicotonia.

Neuromuscular conduction differed significantly only at the beginning of surgery (TOF 0 (0; 1) and (0; 0), respectively, p=0.034). Subsequently, we observed good muscle relaxation with target TOF in both groups.

Early post-anesthesia rehabilitation in both groups was characterized by almost simultaneous restoration of consciousness and spontaneous breathing followed by weaning from ventilator and transfer from the operating theater after adequate recovery (Aldrete Score 9—10). There was no significant between-group difference in any time period. There was almost no need for additional pain relief and clinical symptoms of postoperative nausea and vomiting under stable hemodynamics and gas exchange in 2 hours after surgery in both groups. Mean VAS score of pain was 15.2±22.1 and 9.7±17.0 mm, PONV — 11.5±16.6 and 11.5±19.7 mm, respectively **(table 3)**.

Table 3. **Perioperative characteristics**

Characteristics	Group A (n=33)			Group B (n=33)			p(U)
	Med	Q_{25}	Q_{75}	Med	Q_{25}	Q_{75}	
Surgery time, min	65.00	60.00	85.00	75.00	54.00	90.00	0.653
Duration of anesthesia, min	86.00	73.00	109.00	95.00	71.00	126.00	0.469
Loss of consciousness, s	41.00	35.00	47.00	43.00	37.00	51.00	0.738
Tracheal intubation, s	210.00	185.00	226.00	218.00	200.00	264.00	0.106
Total							
propofol, mg/kg/h	1.79	1.46	2.13	1.54	1.21	2.03	0.144
fentanyl, μg/kg/h	3.77	3.33	4.36	3.52	2.90	4.50	0.568
rocuronium, mg/kg/h	0.61	0.48	0.74	0.57	0.44	0.74	0.438
Infusion volume, ml/kg/h	7.55	6.25	10.00	7.05	5.75	7.94	0.137
Recovery of consciousness, s	736.00	497.00	865.00	733.00	555.00	960.00	0.526
Weaning from ventilator, s	720.00	558.00	899.00	817.00	564.00	1003.00	0.560
Aldrete Score 9—10, s	994.00	819.00	1133.00	997.00	825.00	1305.00	0.526
After 2 hours							
NRS score of PONV	0.00	0.00	2.00	0.00	0.00	2.00	0.678
NRS score of pain	0.00	0.00	3.00	0.00	0.00	2.00	0.353

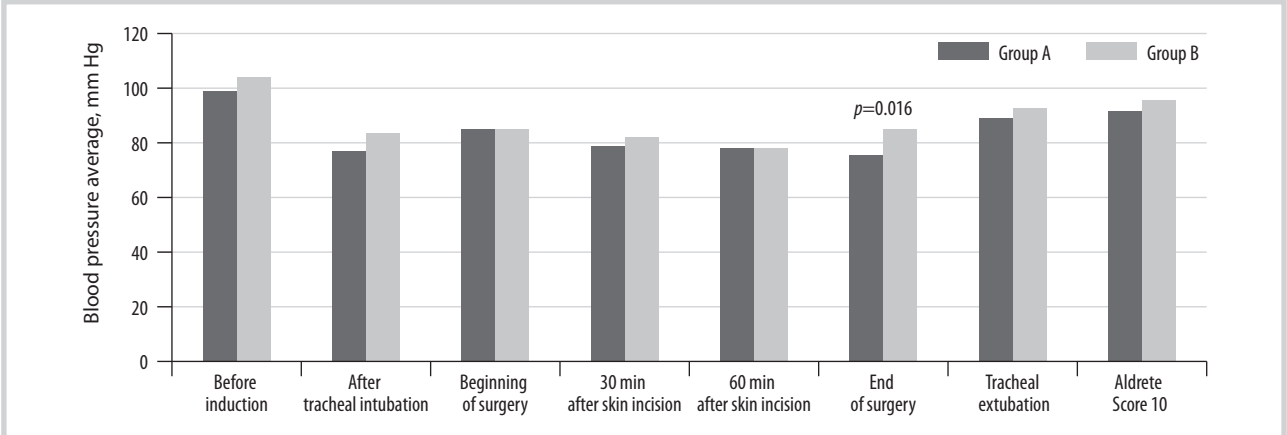

Fig. 2. **Mean blood pressure at various stages of surgery (mm Hg).**

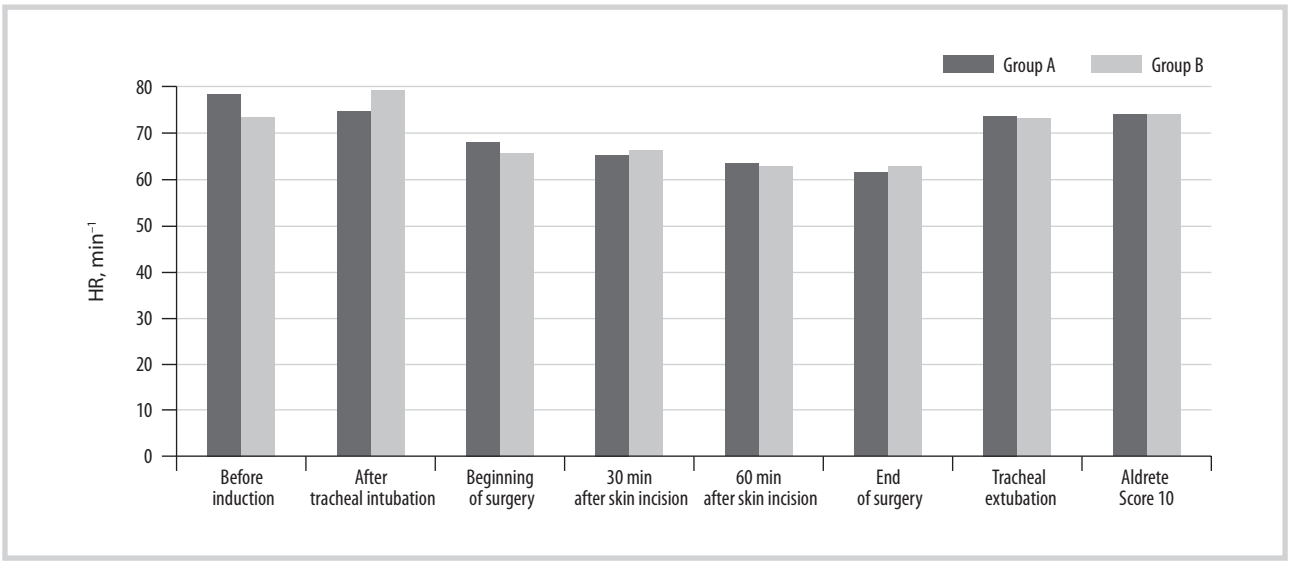

Fig. 3. **Mean heart rate at various stages of surgery (min^{-1}).**

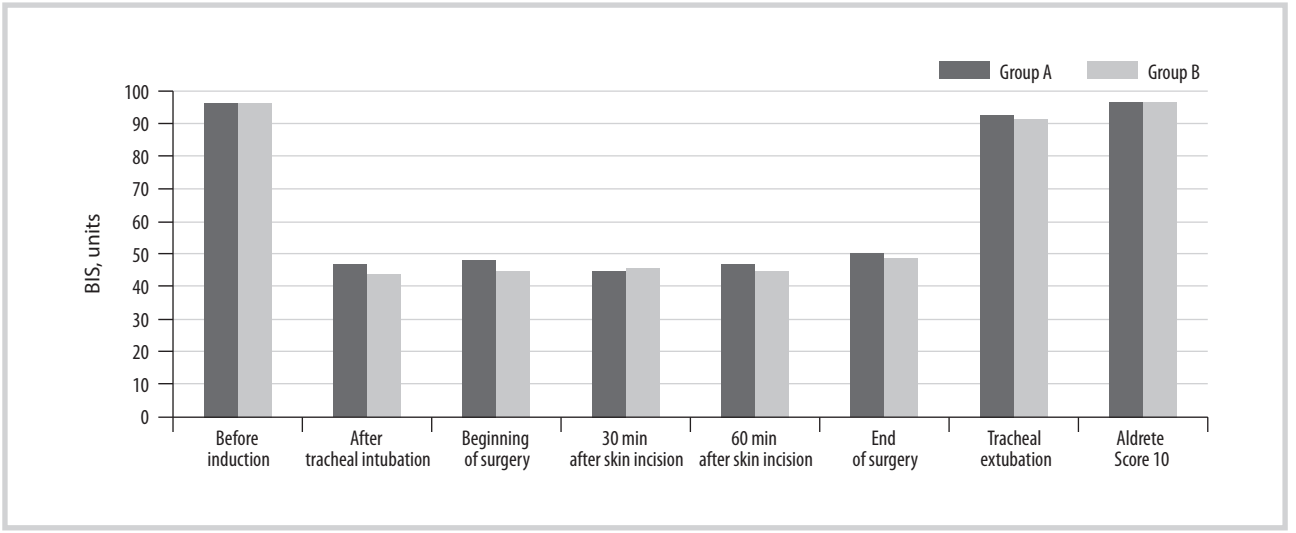

Fig. 4. **Mean BIS values at various stages of surgery.**

Thus, the effectiveness of combined general anesthesia in patients with ASA grade ⩾III undergoing surgery for thyroid tumors and monitoring with clinical application «Anesthesia State Indicator» fully complied with all accepted criteria. Parameters of hemodynamics, gas exchange and neurophysiological monitoring were similar in both groups that confirmed advisability of this application for intraoperative monitoring. Anesthesiologists noted that graphical concentration of important parameters with color indication of changes reduced response time and facilitated decision-making.

Safety of combined general anesthesia

Retrospective internal discrete medical audit of critical incidents was based on electronic anesthetic cards with assessment of critical incident rate and mean critical incident rate index [6]. Results are presented in **fig.**, **table 4—6**.

Median of critical incident rate index was 1.20 (0.00; 1.85) and 0.72 (0.00; 1.58), respectively (p=0.366). Within-group analysis revealed different dynamics of critical incident rate at the stages of the study. In the control group, significant decrease in critical incident rate compared to the value before induction of anesthesia was observed only after achievement of Aldrete score 9-10 (from 0.21 to 0; p=0.028), i.e. before transfer to the ward. At other stages, critical incident rate did not significantly decrease in this group **(table 4)**.

In group B, critical incident rate significantly decreased (from 0.24 to 0.03) 1 hour after onset of surgery (p=0.038) and upon transfer from the operating theatre (p=0.038) compared to baseline values **(table 4)**. Step-by-step between-group comparison of critical incident rate revealed significant difference 1 hour after onset of surgery (0.21 and 0.03 in both groups, respectively, p=0.047) and by the end of surgery (0.39 and 0.12 in both groups, respectively, p=0.021) **(table 4)**.

A thorough analysis of critical incidents **(table 5)** revealed that decrease of their incidence in the main group was due to 2.8-fold decrease in the number of episodes of arterial hypotension (p=0.019) compared to the control group.

Thus, decision-making based on the recommendations of the Anesthesia State Indicator significantly improved safety of patients in the main group.

Number of patients with critical incidents at various stages of the study confirms this conclusion. This value was similar at the first stages. In 60 min after skin incision, the number of patients with critical incidents decreased in group B (3% and 18%, respectively, p=0.046). This difference persisted until the end of surgery (12.1% and 36.4%, respectively, p=0.022) and disappeared as soon as Aldrete Score 10 was achieved **(table 6)**.

We found no severe perioperative complications in both groups according to the ISOS criteria (2016) [13]. This fact undoubtedly indicates effective and safe anesthesia in high-risk

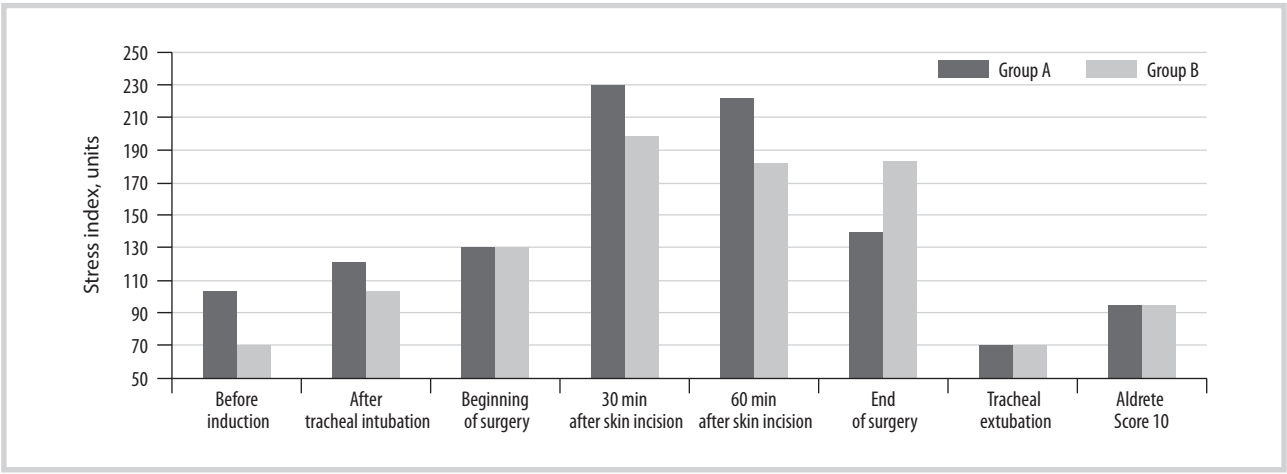

Fig. 5. **Mean stress index values at various stages of surgery.**

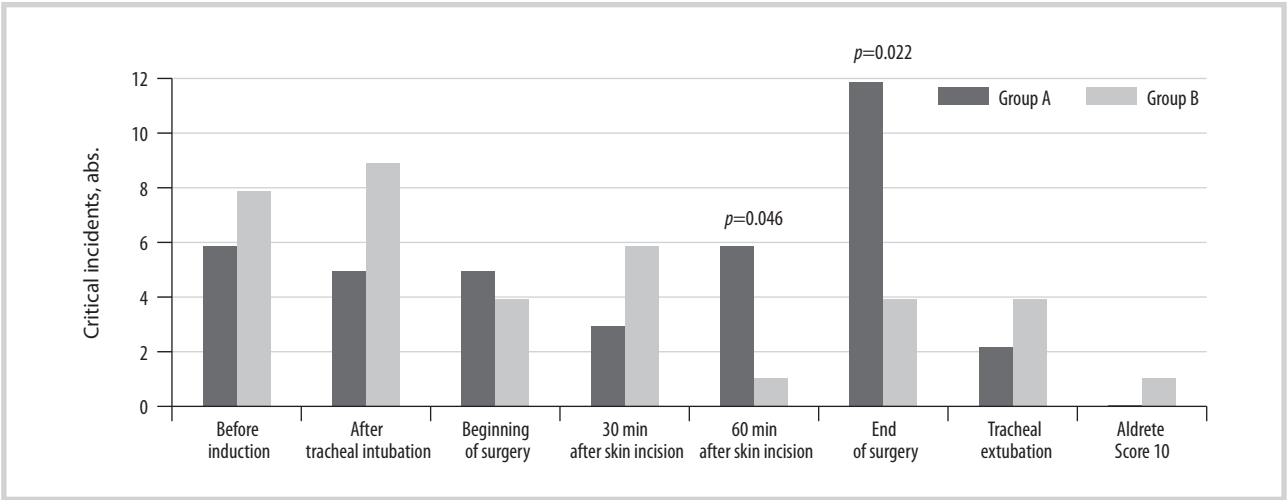

Fig. 6. **Absolute number of critical incidents in groups.**

Table 4. **Incidence of critical incidents**

Stage	Group A	Group B	Z score	p*
Before induction	0.21	0.24	–0.515	0.606
After tracheal intubation	0.18	0.30	–1.146	0.252
Beginning of surgery	0.18	0.15	0.608	0.543
30 min after skin incision	0.09	0.18	–1.057	0.290
60 min after skin incision	0.21	0.03[$]	1.982	0.047
End of surgery	0.39	0.12	2.301	0.021
Weaning from ventilator	0.06	0.12	–0.837	0.403
Aldrete Score 10	0.00[@]	0.03[$]	–0.970	0.332

* — p (Mann—Whitney test) — between-group differences. [@] — p=0.028 (Mann—Whitney test) — between-stage differences in group A. [$] — p=0.038 (Mann—Whitney test) — between-stage differences in group B.

Table 5. **Critical incidents in all groups**

Critical incident	Group A (*n*=44)	Group B (*n*=39)	χ^2 test	*p*
HR <50	10	6	0.115	0.735
HR >100	5	7	0.725	0.395
BPsys >160	7	12	2.586	0.108
BPsys <90	17	6	5.580	0.019
SpO_2 <95	0	1	1.142	0.286
BIS <30	0	1	1.142	0.286
BIS >60	5	6	0.291	0.590

Table 6. **Number of patients with critical incidents**

Stage	Group A (*n*=33)	Group B (*n*=33)	χ^2 test	*p*
Before induction	6 (18.2%)	8 (24.2%)	0.363	0.548
After tracheal intubation	5 (15.2%)	9 (27.3%)	1.451	0.229
Beginning of surgery	5 (15.2%)	4 (12.1%)	0.129	0.720
30 min after skin incision	3 (9.1%)	6 (18.2%)	1.158	0.282
60 min after skin incision	6 (18.2%)	1 (3%)	3.995	0.046
End of surgery	12 (36.4%)	4 (12.1%)	5.280	0.022
Weaning from ventilator	2 (6.1%)	4 (12.1%)	0.733	0.392
Aldrete Score 10	0 (0.0%)	1 (3%)	1.015	0.314

patients undergoing surgery for thyroid tumors. None patient had clinical manifestations of agitation and/or acute postoperative delirium.

Unfortunately, we could not compare own findings with data of other researchers. Indeed, screening revealed no studies of similar design. Apparently, this is due to relatively recent start of implementation of the «Anesthesia State Indicator» application (Panel BoA). Most of recent studies were devoted to BalView technology based on combined use of entropy (SE) for analysis of consciousness depression and surgical plethysmographic index (SPI) for assessing the depth of antinociception. M. Gruenewald et al. [14] obtained the most significant results in a multiple-center, single-blind, randomized controlled trial of 494 patients who underwent surgery under intravenous anesthesia with standard or extended monitoring (SE and SPI combined with Harvard standard). BalView technology was accompanied by significantly lower need for propofol, earlier awakening and shorter stay in recovery room. However, the number of adverse intraoperative events was similar. The authors themselves explain this fact by some causes (predominantly young patients without comorbidities (ASA grade I—II); arterial hypo-, hypertension, brady- or tachycardia along with other possible critical incidents before induction of anesthesia as exclusion criteria). On the contrary, we revealed advisability of anesthesia quality control with clinical application «Anesthesia State Indicator» in patients with comorbidities (ASA grade III) and baseline unfavorable hemodynamic status.

Study limitations include small sample size, analysis of only female patients and surgeries with moderate trauma and duration. In the future, we will continue the study in a larger sample including patients of both sexes undergoing highly traumatic procedures. In our opinion, the issue of combined neurophysiological monitoring of anesthesia quality and creation of computer applications for decision-making support are important and require further research.

Conclusion

«Anesthesia Status Indicator» (BoA Panel) for clinical decision-making is effective for monitoring of anesthesia and increasing the safety of patients with ASA grade III undergoing interventions with moderate trauma and duration. In equal pharmacological load, this application reduced the incidence of episodic arterial hypotension by 2.8 times (p=0.019) and increased safety of anesthesia due to significantly lower rate of critical incidents and higher number of cases without critical incidents compared to the control group.

Authors' participation:
Concept and design of the study — Ovezov A.M.
Collection and processing of material — Akhmedova P.M., Pivovarova A.A., Semenova E.V., Gerasimenko O.N.
Statistical analysis of data — A.M. Ovezov, P.M. Akhmedova, E.V. Semenova.
Text writing — Ovezov A.M., Akhmedova P.M.
Editing — A.M. Ovezov, O.N. Gerasimenko.

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