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Research Article

Development and Psychometrics of Safe Anesthesia Evaluation, Three-Step Checklist (Pre-Induction of Anesthesia, Maintenance of Anesthesia, Post-Anesthesia): A Cross Sectional Study

Alireza Babajani[1], Parisa Moradimajd[1]*, Azam Saei[1], Jamile Abolghasemi[2]

[1]Department of Anesthesia, Allied Medical School, Iran University of Medical Sciences, Tehran, Iran.

[2]Department of Biostatistics, School of Public Health, Iran University of Medical Sciences, Tehran, Iran.

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ABSTRACT

Background: Patient safety is one of the main elements of the quality of health services. Our aim of this study was to compile a complete checklist for the three stages of anesthesia.

Methods: This research was a cross-sectional descriptive-analytical study. First, an internet search was conducted in databases to identify checklists related to safe Anesthesia. The WHO Safe Anesthesia Checklist was designated as the main checklist. Then, a brainstorming session was held with experts and according to the determined fields, the initial draft was compiled. Face and content validity were conducted. The reliability of the checklist was measured with Cronbach's alpha and intra class correlation index (ICC) methods.

Results: The initial draft was compiled with 34 items. 29 items scored higher than 0.79 in terms of CVI (content validity index) The value of CVI of 5 items was less than the permissible limit and the edge of the border, which was revised and corrected by the research group. 2 items were returned to the research process according to the survey of experts and their necessity CVR (content validity ratio) (value >0/62) and 3 items were removed from the research process. Cronbach's alpha was calculated as 0.876 for the first evaluator and 0.870 for the second evaluator, and the percentage of agreement between the evaluators was 0.956 (P<0.001).

Conclusion: We developed and evaluated a checklist for the three stages of anesthesia through an evidence-based study. We hope this checklist can reduce and prevent clinical errors.

Introduction

Patient safety is one of the main elements of the quality of health services and means preventing any injuries and accidents to the patient during the provision of nursing and medical care, which are called clinical errors. Especially in developing countries, the amount of injuries caused during the implementation of medical care is one person per 10 thousand people [1]. Clinical errors can cause complications such as death, lifelong disability, or long-term hospitalization of patients [2]. The time of anesthesia is one of the most important moments during the provision of health services. Risks at this time can be 22% to 33% due to the fact that the anesthesia room equipment is not ready for unusual situations and before the induction of anesthesia, 26%, haste, distraction and boredom of the treatment staff, 26% accidents during anesthesia occur. It means that in anesthetizing patients, not only the stage before

The authors declare no conflicts of interest.
*Corresponding author.
E-mail address: alirezababajani1368@gmail.com

induction of anesthesia, but also the conditions during anesthesia and after anesthesia are very important [3].

Checklists are actually a set of consecutive tasks that take place under the supervision of a special group [4]. Checklists are being developed in many clinical fields with the aim of reducing human error in stressful situations by optimizing preparation and structured management [5]. Using anesthesia checklists has made tremendous progress in sharing critical information, improving teamwork, and understanding safety by anesthesia teams [6].

In Iran's health system, more emphasis has been placed on the implementation of the checklist before induction of anesthesia. Our goal in carrying out this study was to develop a checklist that fits the needs of our society and culture and that includes not only the pre-induction stage, but also all the stages of anesthesia and improves patient safety and reduces clinical errors.

Methods

This cross-sectional study was carried out in order to develop a checklist for safe anesthesia evaluation, taking into account the ethical points in the research and obtaining the code of ethics from the Iran University of Medical Sciences (IR.IUMS.REC.1400.931) from January 2021 to June 2022 (Table 1). Inform consent obtain from all of participants.

Table 1- Implementation stages of preparation and psychometric evaluation of safe Anesthesia evaluation checklist

Internet search Safe Anesthesia Checklists and Safety in Anesthesia	Development	Development and Psychometrics of safe anesthesia evaluation checklist
Preparing a bank of items from the collected information		
Choosing the WHO Safe Anesthesia Checklist as the baseline checklist		
Translation of cultural equivalence of WHO checklist		
Creation of the first draft by the principal investigator		
Conducting a brainstorming session and determining the necessary areas in anesthesia safety		
Preparing the final draft and reviewing the design, content and layout of the items		
Checking the face validity of the checklist	Psychometrics	
Checking the content validity of the checklist with the CVI method		
Checking the content validity of the checklist with the CVR method		
Checking the reliability of the checklist using Cronbach's alpha methods		
Checking the reliability of the checklist by determining the percentage of agreement between evaluators(ICC)		
Analyzing information and determining the final checklist		

Development

Review study

First, internet search in reliable domestic and foreign databases such as: Google Scholar, PubMed, Scopus and SID using the keywords "checklist", "general anesthesia", "anesthesia", "safe", "safety", "clinical error" and a combination of these Keyword. With logical function "And", "OR", "NOT" and related articles from search from 1990 to 2022 were reviewed and studied. At this stage, the entry criteria of all the checklists used in general anesthesia and the exit criteria were the non-availability of these checklists. 12 anesthesia checklists were prepared and the items of these checklists were extracted and categorized, which was created as a bank of items, the number of which was 290 items. According to the opinion of the research team, the World Health Organization (WHO) safe anesthesia checklist was determined as the basic checklist. Which was translated and confirmed and cross-culturally equivalent by the FORWARD-BACKWARD method, and thus the initial draft of the checklist with 18 items was compiled.

Brainstorming session

In order to prepare the checklist, a brainstorming session was held with the presence of the main researcher and experts. In this meeting, according to the opinions and suggestions of experts, the fields of patient control, equipment control, drug control, anesthetic machine control, airway management, induction of anesthesia, maintenance of anesthesia, intelligence and recovery were defined. According to the designated areas, among the 290 items in the item bank, the items of interest were selected, and the initial draft, which had 18 items, became the final draft with 34 items.

Psychometrics

Face validity

In order to determine the psychometrics of this checklist, first the final draft was measured to check the face validity. Face validity is the expression of how well the tested items can measure the problem in question and are agreed by the examinees [7]. The studied items were evaluated based on features such as simplicity, transparency and importance by 10 anesthesiologists. The experts were requested to record their comments and corrections in writing on the psychometric sheet and provide feedback.

The demographic information of the evaluators in the validation phase is listed in (Table 2).

Table 2- Demographic information of evaluators

Executive stage	Number of evaluators	Specialty	Man (%)	Female (%)	Average work experience(year)
Face validity	10	Anesthesiologist	80%	20%	15
Content validity	10	Anesthesiologist	80%	20%	15
Reliability	2	anesthesia nurse	100%	0%	5

Content validity

After passing the face validity stage, the desired items were evaluated in terms of content validity. The purpose of conducting content validity is to reach the concept of whether the developed test has provided the appropriate concepts to create the drop for which it was created [9]. At this stage, the compiled items were measured by 10 anesthesiologists considering their relationship with the safety of patients during anesthesia in a 4-part spectrum (1= not related, 2=slightly related, 3= related, 4= completely related). Took the scores obtained for each of the developed items were calculated in the following way [10-12].

$$\mathrm{CVI} = \frac{The\ number\ of\ experts\ who\ have\ considered\ the\ item\ to\ be\ completely\ relevant\ and\ relevant..}{N^{a}}$$

[a]N= Total number of experts

In this method, the criterion for each item to remain in the research process is to obtain a score of 0.79, and the items that did not obtain this score were reviewed and modified, and if it was confirmed that it is not necessary with the CVR index, it was removed from the research process were deleted.

In the next step, the necessity of items for safety was measured by evaluators. In order to measure the necessity of the items used in the safe anesthesia evaluation checklist, the content validity ratio was used. To determine CVR, 10 experts were asked to check each item based on a three-part spectrum (necessary=3), (useful but not necessary=2), (not necessary=1), then the answers were calculated according to the following formula [13-15].

$$CVR = \frac{ne^{b} - N/2}{\mathrm{N}/2}$$

[b]The number of experts who considered the item essential

Based on the number of experts who evaluated the questions, the minimum passing score for each subject was determined to be 0.62 [13]. The items that did not get the required score and recorded I-CVI value <0.79 were removed from the checklist.

Reliability

Cronbach's Alpha and percentage of agreement between evaluators (intra class correlation index) ICC were used to measure the reliability of the safe anesthesia evaluation checklist [16-18]. After compiling and evaluating the validity of the safe anesthesia evaluation checklist and implementing the resulting changes in it. 2 Anesthesia nurse under the supervision of an anesthesiologist were used to measure reliability. Research environment Rasool Akram and Firozgar hospitals were randomly selected, where surgeries such as orthopedics, general surgery, gynecology and obstetrics, neurology and urology were performed.

To measure the reliability during a test session, the evaluators were taught how to complete the checklist, and after it was experimentally used for a surgery, they were asked to consistently, independently and simultaneously rate 155 available surgeries. In this stage, the entry criteria were all the available procedures, provided that the patients were over 18 years old, and the exit criteria was failure to complete one of the steps in the checklist for various reasons, such as the cancellation of the surgery. And finally, data collection and analysis was done by SPSS version 22 software in the validity and reliability stage. Demographic information is shown in (Tables 3-4).

Table 3- The demographic information of Anesthesia method

Anesthesia Type	N	Mean age	Std. Deviation	Std. Error	95% Confidence Interval for Mean	
					upper bound	Lower bound
GA[c]	138	45.59	16.098	1.370	42.88	48.30
RA[d]	13	45.69	18.648	5.172	34.42	56.96
MAC[e]	3	62.33	12.662	7.311	30.88	93.79
NB[f]	1	69				
Total	155	46.08	16.386	1.316	43.48	48.68

[c]General Anesthesia
[d]Regional Anesthesia
[e]Monitor Anesthesia Care
[f]Nerve B lock

Table 4- The demographic information of surgeries

Type of surgery		Gender female	male	Total
Orthopedics	Count	13	16	29
%Within Gender		13.5%	27.1%	18.7%
Obstetrics and Gynecology	Count	28	0	28
%Within Gender		29.2%	0.0%	18.1%
ENT	Count	6	6	12
%Within Gender		6.3%	10.2%	7.7%
Neurosurgery	Count	16	9	25
%Within Gender		16.7%	15.3%	16.1%
Open heart	Count	1	3	4
%Within Gender		1.0%	5.1%	2.6%
Urology	Count	2	4	6
%Within Gender		2.1%	6.8%	3.9%
General	Count	29	18	47
%Within Gender		30.2%	30.5%	30.3%
Thorax	Count	1	3	4
%Within Gender		1.0%	5.1%	2.6%
Total	Count	96	59	155
%Within Gender		100.0%	100.0%	100.0%

Results

Checklist validity

In the face validity phase, the initial draft was approved by experts. According to the opinions and requests of experts and with the coordination of the research group, 4 items were slightly modified. The items were evaluated based on their relationship with safety by anesthesia specialists, the I-CVI value was determined separately for each item. The lowest value of I-CVI was 0.60 and the highest value was 1. I-CVI value of 29 items was determined to be greater than 0.79, the value of 5 items was less than the permissible limit and borderline, which was reviewed and corrected by the research group. The S-CVI scores for the entire instrument was 0.87

According to the survey of experts and their necessary assignment, 2 items returned to the research process and 3 items were removed from the research process. The items whose scores were less than 0.62 and their relationship with safety was not within the permissible limits were excluded from the research process, and their number was 3 items. The S-CVR scores for the entire instrument was 0.69. The resulting changes in the items based on the relevance and necessity of the items are stated in (Table 5).

Table 5- Content validity by CVI

Items	CVI
An experienced and trained assistant is available to assist you	0.60
The control of the patient's personal characteristics has been done with the bracelet and the patient's file	1
Preoperative evaluation was done in terms of surgical history, allergies, history of drug use and laboratory values	0.90
The appropriate time period for fasting is included	1
Confirmation of blood group type and sample for cross match has been done	1
The possibility of excessive bleeding and the need to compensate for the lost blood have been evaluated	0.90
There is adequate intravenous access	0.80
The operation position is specified	0.90
The position of the patient is appropriate	0.90
The control of the anesthesia machine is done	0.90
There is enough gas and oxygen cylinders in reserve	1
Suction control is done	0.80
Monitorings (BP, ECG, SPO2, ET CO2) are ready	1
Cardio-pulmonary resuscitation equipment, facilities, and drugs are available	1
The control of the surgical bed, bed attachments and holders has been done	0.60
Necessary measures to prevent hypothermia of the patient are foreseen	0.60
Anesthesia pro-drugs have been injected	0.90
All the necessary drugs and equipment for anesthesia injections are prepared by observing the sterilization tips	1

Medications are drawn into labeled syringes	1
Airway prediction and difficult intubation have been done	0.90
All kinds of equipment and facilities are prepared for laryngoscopy and endotracheal intubation	1
Pre-oxygenation is done	0.90
The correctness of intubation has been checked to start the surgery	0.90
If needed, an additional venous line is installed	0.90
The values of (BP, SPO2, Spo2, ETCO2) are within the normal range	0.70
5-minute interval control	0.90
30-minute interval control	0.90
An experienced and trained assistant is available to assist you	0.60
Vital signs are appropriate for extubation	1
Emergency medicine is ready	1
The return of neuromuscular function has been investigated	0.90
Vital signs were monitored after the operation	1
The following are monitored in the recovery room	1
The time of discharge of the patient from recovery has been done considering the following criteria	0.80
If the value of CVI>0/79, the desired item was kept in the research process	
If the CVI value was <0/79 but the CVR value was >0/60, the target item was retained in the research process	
If the value of CVI was <0/79, but the value of CVR was <0/60, the target item was excluded in the research process	

Checklist Reliability

Cronbach's alpha was calculated as 0.876 for the first evaluator and 0.870 for the second evaluator, and the percentage of agreement between the evaluators was 0.956 (P<0.001). According to the percentage of agreement between the evaluators, which is at an excellent level, as well as the Cronbach's alpha scores obtained for the evaluators, the reliability of this checklist was confirmed. The reliability results are shown in (Table 6).

Table 6- Assessing the reliability of a checklist rated by surgical patients (n=155) via ICC

Possibility	upper bound	Lower bound	ICC	Component
P<0.001	0/968	0/939	0/956	Tool

Discussion

Our aim of this study was to create and psychometrically evaluate a safe anesthesia assessment checklist. A checklist that not only pays attention to the stage before the induction of anesthesia, but also includes the stages of induction, during anesthesia and after anesthesia (consciousness and recovery),), in fact, it is a multi-stage and comprehensive checklist .In the past years, most countries in the world, considering the need they felt for their country, tried to compile a safe anesthesia checklist such as the WHO safe anesthesia checklist [19], Pre-anesthesia assessment checklist [6], FDA Anesthesia Machine Checklist [20], Emergency and trauma anesthesia checklist [21], Checklist for performing anesthesia routines [3], Checklist for safe caesarean delivery in East Africa [22], Ryder's Cognitive Aid Checklist for Trauma Anesthesia [4], Checklist for anesthesia procedure, risk analysis [23], Checklist for safe anesthesia in neurosurgery [24], Neuro-anesthesia handover checklist [25]. Some of these checklists are single-step and some are multi-step, some are general and others are created specifically for specific applications and some are created only for anesthesia equipment. Each of these checklists was superior to the other in some aspect.

We did not create the checklist ourselves, but we extracted existing checklists by exhaustive search and used them as puzzle pieces to create our favorite checklist. The checklist was in the form of a clinical scenario and the people who used this checklist knew what actions to take before the onset of anesthesia until the patient left the recovery room. This importance was not evident in other checklists.

We have been looking for a comprehensive, inclusive, scoped checklist that is used in most surgeries. According to the obtained demographic information, this checklist was psychometrically evaluated in a wide range of surgeries such as: orthopaedics, Gynecology and obstetrics, neurosurgery, cardiology, otolaryngology, and thorax. The demographic information of surgeries is shown in (Table 4). We sought to create a complete, concise, clear, confusing, easy-to-use checklist. In order to improve the ability of personnel in emergency situations for patient anesthesia, Tobin and colleagues conducted a study titled "Checklist for Emergency Anesthesia and Trauma" in 2013. A multi-stage checklist was developed, and the use of this checklist with the view that the aspects of medical care and vital stages were not neglected, led to a reduction in the rate of complications and mortality of patients and improved the safety of patients in critical situations [21]. In this study, we also tried to compile a multi-stage checklist that includes most of the necessary measures during anesthesia in the form of a clinical scenario from the beginning to the end of

anesthesia. Kariyoi in 2013 by conducting a study "Challenges of introducing the safe surgery checklist in African countries" and Mahajan in a study in 2011 "Obstacles and strategies for the effective implementation of the safe surgery checklist" pointed out that One of the obstacles to the effective implementation of the checklist and its lack of easy use by the health and treatment staff was the lack of familiarity and vagueness of the items for them [26, 27]. We made the checklist much easier to use by using expert opinions to clarify the items and by placing several activities in a defined framework. Another obstacle to the effective implementation of the checklist is the insufficient time to use the checklist and the lack of priority to use the checklist in the hospital [26, 28]. We were also looking for a checklist to be implemented in the form of a series of tasks, taking into account the priority of doing things and reducing the amount of confusion of the treatment staff during use. Krumbach conducted a study titled "Development and Implementation of a Checklist for Routine Anesthesia Care: A Proposal for Improving Patient Safety" in 2015 and noted that even the simplest tasks assigned to the anesthesia team and performing routine tasks during anesthesia are necessary for patient safety. And failure in its implementation can cause severe and irreparable harm to patients [3]. On the contrary, in 2011, Fouchcad conducted a study entitled "Identification of barriers to the effective implementation of the safety checklist and the development of the best applicable strategy" in 18 French cancer centers, and they noted that the barriers to using the checklist in the health system were time spent to complete the checklist [29]. On the one hand, we tried to make the compiled checklist brief and complete and cover most of the activities and tasks, even simple but needed during anesthesia, and on the other hand, we could not create a checklist with a large number of items. Considering the mentioned topic and the importance of anesthesia machine control, in order to increase the ability of the treatment staff and further training, we put the anesthesia machine control instructions based on the American Society of Anesthesiologists (ASA) recommendations [30] as an attached file at the back of the checklist page. The final form of the checklist is shown in (Figure 1).

The stage before induction of anesthesia			**Stage of induction and maintenance of anesthesia**		**Post anesthesia stage**
Patient control	☐ The control of the patient's personal characteristics has been done with the bracelet and the patient's file	induction of anesthesia	☐ Pre-oxygenation is done	Extubation	☐ Vital signs are appropriate for extubation
	☐ Preoperative evaluation was done in terms of surgical history, allergies, history of drug use and laboratory values		☐ The correctness of intubation has been checked to start the surgery		☐ Emergency medicine is ready
	☐ The appropriate time period for fasting is included		☐ The values of(BP, SPO2, Spo2, ETCO2) are within the normal range		☐ The return of neuromuscular function has been investigated
	☐ Confirmation of blood group type and sample for cross match has been done		☐If needed, an additional venous line is installed	Recovery	☐Vital signs were monitored after the operation
	☐ The possibility of excessive bleeding and the need to compensate for the lost blood have been evaluated	5-minute interval control	☐ Have the following items been checked 5 minutes after anesthesia?		☐ The following are monitored in the recovery room?
	☐ There is adequate intravenous access		☐ Control of ventilator settings (PIP, TV, ETco2 and others) and respiratory status is done		☐ Airway obstruction ☐ Hypoxia ☐ Bleeding: internal and external
	☐ The operation position is specified				☐Increase and decrease blood pressure
	☐ The position of the patient is appropriate		☐ Non-invasive blood pressure control and its measurement times have been done		☐Pain after surgery ☐Hypothermia and shivering
Anesthesia machine control	☐ The control of the anesthesia machine is done ☐ Anesthesia vaporizers are on standby		☐ Transducer path level control is done		☐Vomiting and aspiration

	☐ The breathing circuit is securely connected ☐ The breathing circuits are clean		☐HR and EKG waves have been controlled	☐ Residual drug effect
Equipment control	☐ There is enough gas and oxygen cylinders in reserve ☐ Suction control is done ☐ Monitorings (BP, ECG, SPO2, ET CO2) are ready ☐ Cardio-pulmonary resuscitation equipment, facilities, and drugs are available ☐ The control of the surgical bed, bed attachments and holders has been done	30-minute interval control	☐ Have the following items been checked 30 minutes after anesthesia? ☐ Control of ventilator settings (PIP, TV, ETco2 and others) and respiratory status is done ☐ Non-invasive blood pressure control and its measurement times have been done	☐ The time of discharge of the patient from recovery has been done considering the following criteria? ☐ Awake, open eyes ☐ Extubated ☐ Breathing spontaneously, quietly and comfortably ☐ Can lift head on command ☐ Not hypoxic
Drug control	☐ Anesthesia pro-drugs have been injected ☐All the necessary drugs and equipment for anesthesia injections are prepared by observing the sterilization tips ☐ Medications are drawn into labeled syringes		☐Transducer path level control is done ☐ HR and EKG waves have been controlled ☐ The temperature is checked ☐ Head position and ETT, respiratory circuit connections are checked	☐Blood pressure and pulse rate in the optimal range ☐ Considering the necessary measures to control the patient's pain
Airway assessment	☐Airway prediction and difficult intubation have been done ☐ All kinds of equipment and facilities are prepared for laryngoscopy and endotracheal intubation		☐ Pressure points, cushions, eye condition are checked ☐ Infusion rate, IV cannula location (infiltration) are checked ☐ Foley's duct has been examined	

Figure 1- A three-step safe anesthesia assessment checklist

Limitations

The main limitation of this research and checklist is that it has not been measured clinically (effectiveness). It is necessary to conduct a research project in a pilot hospital in the near future to measure the effectiveness of this checklist in Iran's healthcare system. One of the limitations of the plan is that, according to the demographic information obtained from this research, the compiled items have been psychoanalyzed more in general anesthesia than in other anesthesia methods. From the strength of this research, it can be pointed out that a wide range of surgical procedures were used in the effort to compile and psychometrically assess the checklist. The main strength of this research is the high scores of CVI & ICC, which shows that this checklist has good validity and reliability.

Conclusion

Considering the progress of surgical methods and the number of surgeries performed annually and considering the fact that safety is a relative matter and even forgetting to perform the smallest tasks assigned by the anesthesia team can endanger the lives of patients. Using a complete checklist can promote safety and protect patients from clinical incidents. We were able to develop and psychometrically evaluate a three-step checklist (before induction of anesthesia, induction and during anesthesia, and after anesthesia)

for safe anesthesia. More research is needed to measure the effectiveness of this checklist on patient mortality, risks during anesthesia, and length of hospitalization.

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