

# **Protocol: Assessment of intervention reporting in RCTs**

## **ambulatory anesthetics procedure: a cross sectional study**

**1 jun 2019**

### **Background**

Ambulatory anesthesia consists in providing an anesthetic procedure to a patient receiving a surgical procedure and leaving the hospital on the same day. There is no planned hospitalization for this type of patient. This type of care has been expanding in recent years<sup>1</sup>. It offers the advantages of improved quality of life for patients with early return home, lower risk of nosocomial infections, reduced hospitalization costs and higher turnover with more possible interventions<sup>3 4 5</sup>. There is a real financial issue in the reduction of cost related to the reduction of hospitalization costs and the increase in the number of practicable interventions<sup>6</sup>. Such care system requires a specific organization, with an entire patient circuit adapted to the outpatient, compatible premises and dedicated and trained staff. This has also required the development of a multitude of anesthesia protocols providing quality and safety for patients who do not stay in hospital, particularly in terms of reducing the risks of perioperative complications: nausea and vomiting, cardiovascular complications, pain, behavioral disorders, fatigue, immobilization<sup>8 9</sup>.

The choice of anesthesia molecules and techniques has a direct impact on these events, on the patient's discharge, and on the potential failure of the ambulatory. For example, the use of loco-regional anesthesia in place of or in combination with general anesthesia improves the

effectiveness of analgesia and anesthesia as well as the quality of life of patients<sup>10 11</sup>. Similarly, the availability of ultrashort-acting anesthetics reduces complications related to the consumption and accumulation of anesthetic products and therefore side effects such as nausea, vomiting, arterial hypotension, respiratory depression<sup>12</sup>. Outpatient anesthetic management of patients remains complex, due to this non-pharmacological dimension, the multitude of stakeholders and the need for a specific patient path. Anesthesia procedures need to be correctly reported in the trials in order to ensure reproducibility<sup>13</sup>.

Interventional pharmacological trials have been the subject of recommendation on how to conduct them and how to report them in the publications. Thus, The Consolidated Standards of Reporting Trials (CONSORT), the first version of which was created in 1996 and revised in 2010, is a checklist of items designed to improve the quality of the report of trial information in publications<sup>14 15</sup>. Non-pharmacological trials are complex interventions because they present the problem of reproducibility. To facilitate effective and comprehensive reporting of interventions, guidelines have been developed for non-pharmacological trial interventions in order to improve reproducibility. The CONSORT-NPT (Consolidated Standards of Reporting Trials for Non-Pharmacological Treatment) and TIDieR (Template for intervention Description and Replication) recommendations have been approved and recognized by most peer-reviewed journals<sup>16 17</sup>. These guidelines mention essential elements to report in the trials in order to allow clinicians to reliably replicate the interventions. It has been shown that adherence to these recommendations improves the quality of randomized controlled trials' reporting<sup>18 19</sup>. However, since their creation, many gaps in the reporting of interventions remain<sup>20-22</sup>.

Anesthesia ambulatory procedures is an emergent procedure and lead to an increasing number of publications. As a compelling example of complex interventions, these trials should follow the CONSORT-NPT and TiDIER. Therefore, we decide to perform a cross-sectional study evaluating the quality of reporting of randomized controlled trial interventions in ambulatory anesthesia. We will conduct first a systematic review to identify randomized controlled trials assessing ambulatory procedures, and a mapping of the publications, the type of institution, the type of surgery procedures and the outcomes used in trials.

## Methods

### *1- Search strategy*

We will use Medline database for our research on RCTs.

The search strategy is detailed in table 1.

**Table 1.** Search terms for MEDLINE

#1	"anesthesia"[MeSH] OR "anesthesia methods"[tiab] OR anesthetics[tiab] OR "anesthesia regional"[tiab]
#2	"ambulatory surgical procedures"[MeSH] OR "ambulatory"[tiab] OR "ambulatory care"[MeSH] OR "ambulatory unit"[tiab] OR "outpatient"[tiab] OR "outpatient surgery"[tiab] OR "outpatient surgeries"[tiab] OR "day surgery"[tiab] OR "day surgery unit"[tiab] OR "day care surgery"[tiab] OR "day case surgery"[tiab]
#3	(randomized controlled trial[Publication Type] OR controlled clinical trial[Publication Type] OR randomized[tiab] OR placebo[tiab] OR drug therapy[sh] OR randomly[tiab] OR trial[tiab] OR groups[tiab]) NOT (animals[mh] NOT humans[mh])

#4	"Anesthesiology" [jour] OR "Br J Anaesth" [jour] OR "Pain" [jour] OR "Anaesthesia" [jour] OR "Reg Anesth Pain Med" [jour] OR "Eur J Anaesthesiol" [jour] OR "Anesth Analg" [jour] OR "Int J Obstet Anesth" [jour] OR "Can J Anaesth" [jour] OR "J neurosurg Anesthesiol" [jour]
#5	"N Engl J Med" [jour] OR "Lancet" [jour] OR "JAMA" [jour] OR "BMJ" [jour] OR "JAMA Intern Med" [jour] OR "Ann Intern Med" [jour] OR "Nat Rev Dis Primers" [jour] OR "J Cachexia Sarcopenia Muscle" [jour] OR " PLoS Med" [jour] OR "BMC Med" [jour]
#6	#1 <b>AND</b> #2 <b>AND</b> #3 <b>AND</b> ( #4 <b>OR</b> #5)

The search will be restricted to the 10 most important journals in Anesthesia and 10 most important journals in General Medicine. There will be no restriction on language, country, publication status. We will restrict the search to the last 5 years, from 2013 to 2018. The searches will be conducted using the recommended Mesh terms standardized vocabulary for Medline database. The terms we will use and their definition for the search, according to the International Association for Ambulatory Surgery, are:

- Ambulatory surgery: An operation/procedure, or outpatient operation/procedure, where the patient is discharged on the same working day.
- Outpatient: A patient treated solely in the outpatient department, including such services as ambulatory procedure, interventional radiology, radiotherapy, oncology, renal dialysis, etc....
- Anesthesia or anesthesiology: perioperative medical act providing a state of sedation, analgesia and/or muscle relaxation compatible with the performance of a diagnostic or therapeutic invasive act. this includes general, regional, spinal, epidural, inhaling, intravenous and caudal anesthesia. In our study, this one is performed on an outpatient.

We will perform the search on Jun 2019.

## ***2- Selection of studies***

Two reviewers (C.C and B.P) will examine independently the titles and abstracts of the work resulting from the initial research and exclude obviously studies. Disagreements will be discussed with au third reviewer for find a consensus (C.P).

We will include any randomized controlled trials comparing any anesthetic procedure: -for instance, general anesthesia, regional anesthesia, intravenous anesthesia, spinal anesthesia, caudal anesthesia..., whatever the place of the trial location, whatever the population studied, whatever the period of time, whatever the timing of the surgery (urgent or scheduled).

We will exclude studies on local anesthesia, topical anesthesia, and verbal or hypnosis anesthesia when it was to the single anesthetic act. We then will review the remaining articles in their entirety to determine their eligibility. We will list the reasons of non-eligibility of full text trials. All the selection process will be performed with Covidence software.

## ***3- Data extraction***

The data for each article will be systematically extracted via a pre-established data extraction form. This form will contain the following criteria:

### **General characteristics:**

- The Journal and its impact factor
- Date of publication

- Location of the trial
- Type of center: academic center, public hospital center, private center of public utility, lucrative private center
- Monocentric or multicentric study

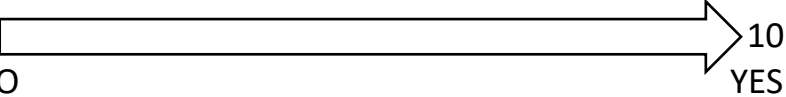
General characteristics of included RCTs:

- Study identification
- The number of patients included
- Population characteristics: age, sex, ASA score, comorbidities (such as cardiopathy, lung cancer...)
- The arms of anesthesia intervention: procedure description (specific checklist below)
- The type of outpatient surgery concerned, for example: inguinal hernia in digestive surgery, hallux valgus in orthopedic surgery, cataract in ophthalmic surgery. We will classify them into surgical categories, presented in Appendix 1.

To describe the anesthesia procedure, we have developed a specific checklist to assess the quality of the procedure report. We used CONSORT reference items, with the CONSORT NPT extension and the TIDieR checklist. Two anesthesiologists and two methodologists participated in the development of this list. The specific checklist we will use is provided below.

Specific checklist for intervention:

Field	Items description	Answers	
<i>1-Surgery</i>	1-Are there any details about the surgery?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	2-Number of providers?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	3-Professional category of providers? ▪ Doctor	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	▪ Resident	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	▪ Nurse	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	▪ Others	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	4-Description of expertise of each provider? (formation or background or training)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	5-Description of surgery procedure used?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>2-Anesthesiology</i>	6-If yes: Name of the surgical technique	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Delivery method	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Sequences of different steps	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	7-Validation of preoperative checklist?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	8-Details on perioperative care?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	9-Number of providers?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	10-Professional category of providers? ▪ Doctor	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	▪ Resident	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	▪ Nurse	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	11-Description of expertise of each provider? (formation or background or training)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	12-Description of each procedure used in the intervention?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	If yes: Name of the anesthesia technique	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Delivery method	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Dosage and adjustment	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Dosage timing	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Sequences of different steps	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Monitoring method	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	13-Validation of preoperative checklist?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	14-Details on post ambulatory follow up?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	If yes, how? Who	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	When	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	How	<input type="checkbox"/> Yes	<input type="checkbox"/> No

<i>3-Organizational stream</i>	15-Precision of the existence of organized care system? If yes, Specialized structure/local? Specialized consultation perioperative? Dedicated staff?	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No
4-Standardization	16-Is there a standardization process of the intervention? If yes, How?	<input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No
<i>5-Modification/ Tailoring</i>	17-If the intervention was planned to be personalized? If yes, How? 18-Are the changes of intervention procedure during the study mentioned? If yes, How?	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No
<i>6-Activity/ Capacity of the center</i>	19-Is mentioned the volume of the center? If yes, How much?	<input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No
<i>7-Reproductibility</i>	20-Is the intervention reproducible? * Note : /10 *Subjective evaluation by an anesthesiologist 0  10 NO YES	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Outcomes:

- Primary outcome: safety or efficacy
- Timing of evaluation of the outcome
- Category of outcomes. The categories are listed in Appendix 2.

**4- Statistical analysis**



Data for qualitative variables will be expressed with frequencies and percentages. Data for quantitative variables will be expressed with median and inter quartile ranges (IQRs). We will use mean and standard deviations. Database management will be done on Excel and all analyses will be conducted using R software, version 3.4.2 (2017-09-28).

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## Appendix 1. Surgical categories

▪ Orthopaedic surgery
▪ Visceral surgery
▪ Vascular surgery
▪ Neurosurgery
▪ Urology
▪ Obstetrical gynecology
▪ Cardiac surgery
▪ Thoracic surgery
▪ Pediatric surgery
▪ Maxillo-facial surgery
▪ Dental surgery
▪ Endocrine gland surgery
▪ Ophthalmology
▪ Ear, nose and throat surgery
▪ Plastic surgery

## Appendix 2. Categories of outcomes

	OUTCOMES
EFFICACY	Peroperative: Peroperative hypnosis, awakening, duration of the intervention, loco regional anesthesia Failure of the procedure Postoperative: pain Outpatient discharge: delayed discharge, hospitalization Quality of life: Return to work, return to driving Patient satisfaction Mortality
SAFETY	Cardiovascular complication Respiratory complication General complication: nausea, vomiting, dizziness, behavioural disorders