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Use of volatile anesthetics for sedation in the intensive care unit after the COVID-19 pandemic: a national survey in France. VOL'ICU 2 study

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UNIVERSITÉ CLERMONT AUVERGNE
UFR DE MÉDECINE ET DES PROFESSIONS PARAMÉDICALES

THÈSE D'EXERCICE

pour le

DIPLÔME D'ÉTAT DE DOCTEUR EN MÉDECINE

par

BALDE Aïssatou

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USE OF VOLATILE ANESTHETICS FOR SEDATION IN THE INTENSIVE CARE UNIT
AFTER THE COVID-19 PANDEMIC: A NATIONAL SURVEY IN FRANCE.
VOL'ICU 2 STUDY

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Figure 5. Overall satisfaction of respondents regarding the use of inhaled sedation before and since the COVID-19.

ABBREVIATIONS

ARDS: Acute respiratory distress syndrome

COVID-19: 2019 Coronavirus Disease

ICU: Intensive care unit

STROBE: Strengthening the reporting of observational studies in epidemiology

ABSTRACT

Background: Sedation is performed routinely in intensive care units (ICUs) to manage patients. Current sedation guidelines suggest strategies using non-benzodiazepine sedatives. The COVID-19 pandemic has suddenly increased the number of patients hospitalised in ICUs due to respiratory failure leading to a global shortage of the main intravenous sedative agents. Physicians had to find alternatives to intravenous sedation including inhaled sedation. The use of inhaled sedation in French ICU has been previously explored before the beginning of COVID-19 pandemic two years ago (*VOL'ICU study*). This survey was designed to explore and describe the use of inhaled sedation two years after the beginning of the COVID-19 pandemic and to evaluate how the pandemic has impacted the use of inhaled sedation by French physicians working in ICUs.

Methods: We designed a national survey, contacting medical directors of French ICUs by phone or email between June and September 2021. Over a 50-item questionnaire, the survey covered four categories: general characteristics of the ICU; general data of COVID-19 patients in ICU, general data on inhaled sedation, and the practical aspects of inhaled ICU sedation for both COVID-19 and non-COVID-19 patients. Some answers were compared with the previous survey, VOL'ICU.

Results: Among the 405 ICUs contacted, a total of 27% (102/374) of the questionnaires were recorded (the 31 paediatric ICUs were excluded). Most ICU directors (87%, (89/102)) knew about the use of inhaled ICU sedation and 63% (56/89) of them has an inhaled sedation's device in their unit, mostly the *Anaesthetic Conserving Device (AnaConDa, Sedana Medical)*. The main indications to use inhaled sedation sustained by the respondents were "failure of intravenous sedation", "severe asthma or bronchial obstruction", and "acute respiratory distress syndrome". Sevoflurane and isoflurane were mainly used (94%, (90/92) and 22%, (7/32) respectively). The main reasons for not using inhaled ICU sedation were "device not available"

(76%, (47/62)), “lack of familiarity about the technique” (60%, (37/62)) and “no training for medical and paramedic team” (58%, (36/62) each). The COVID-19 pandemic increased the use of inhaled sedation in French ICUs. The main reasons said by the respondent to use inhaled sedation in COVID-19 patients were “need to additional sedative” (50%, (28/56)), “shortage of intravenous sedatives” (30%, (17/56)) and “involved in a clinical trial” (21%, (12/56)). More than 70% of respondents were overall satisfied with the use of inhaled sedation. Almost 80% of participants stated that inhaled sedation was a seducing alternative to intravenous sedation and to manage COVID-19 patients.

Conclusion: The use of inhaled sedation in ICU has increased quickly in the last 2 years, always with a good satisfaction among the users. Even if the COVID-19 pandemic could have impacted the widespread use of inhaled sedation, the use of inhaled sedation represents an alternative to intravenous sedation for more and more French physicians. Nonetheless, both lack of devices available in the units and insufficient training of ICU teams remains the two major restraining factors highlighting the importance of staff formation about inhaled sedation in ICU.

INTRODUCTION

Sedation is used daily in intensive care units (ICUs) to manage patients. It improves comfort and tolerance during mechanical ventilation, therapeutic interventions, or nursing care [1]. Sedation is usually performed with intravenous drugs such as propofol or midazolam [2]. However, these products can cause serious side effects including delirium, propofol infusion syndrome and hemodynamic failure and increase the time to liberation from mechanical ventilation and the duration of stay in the ICU. All these effects are associated with increase in hospital morbidity and mortality. Therefore, clinical practice guidelines for analgesia and sedation in the ICU (e.g., the Pain, Agitation/sedation, Delirium, Immobility and Sleep disruption (PADIS) guidelines [1]) have consistently focused on early rehabilitation and rapid ventilator liberation and have suggested the use of non-benzodiazepines drugs. The ideal sedative drug should sedate effectively with few adverse effects, low accumulation and a quick awakening at the end of administration.

Since the beginning of 2020, an unprecedented pandemic changed the daily management of ICUs worldwide: coronavirus disease 2019 (COVID-19) [2]. The pulmonary infection is caused by the severe acute respiratory syndrome coronavirus (SARS-CoV) -2 and has suddenly increased the number of patients hospitalized in ICUs due to respiratory failure. In France, almost 100 000 persons were admitted in ICU [3] and most of them needed intubation to support respiratory function. The pandemic posed a major challenge to health-care systems because of the need for intensive care therapy and mechanical ventilation including sedation. Because of this unusual situation, intensivists had to use more sedative products leading to a global shortage of the main intravenous sedative agents [4]. Consequently, physicians had to find alternatives to intravenous sedation including inhaled sedation [4]. Inhaled sedation is performed with volatile agents such as sevoflurane, desflurane or isoflurane. Inhaled volatile agents are an abundant resource and an easily implementable solution for providing ICU

sedation. The recent development of anesthetic reflectors, such as the *Anaesthetic Conserving Device* (AnaConDa, Sedana Medical, Danderyd, Sweden) and the *Mirus* (Carelide GmbH, Mouvaux, France), has allowed inhaled sedation to become in the ICU [5–7]. Indeed, in some national guidelines including Germany's, the use of volatile agents in the ICU is an option [8]. Furthermore, using volatile anesthetics could now be considered for specific acute respiratory distress syndrome (ARDS) patients to reduce emergent delirium and cumulative propofol doses [9]. Recently, isoflurane received national approval from the French Agency for the Safety of Health Products (ANSM for *Agence nationale de sécurité du médicament et des produits de santé*) for inhaled sedation in ICU.

A previous study from our group explored inhaled sedation practices in French ICUs in 2019 and demonstrated that even if inhaled sedation was familiar to most physicians it was underused because of a lack of available device, physicians knowledge and literature [10]. Since March 2020, few studies have cared about the potential benefits of inhaled sedation in COVID-19 patients. Nevertheless, extant data suggest that inhaled sedation could be used safely in these patients [4,11,12]. Indeed, due to their intrinsic characteristics, volatile agents may also provide important pulmonary benefits for COVID-19 patients with ARDS that could improve gas exchange and reduce the time spent on a ventilator [11].

Therefore, this survey was designed to explore and describe the use of inhaled sedation two years after the beginning of the COVID-19 pandemic and to evaluate how the pandemic has impacted the use of inhaled sedation by French physicians working in ICUs.

METHODS

Survey development

This investigator-initiated survey was approved by an independent Ethics Committee (CERAR IRB 00010254 - 2021-128). The survey was registered at ClinicalTrial.gov. A 50-item questionnaire was developed with questions designed by the authors (RB, AB, MJ) (**Supplemental Content 1**); The survey covered four categories: general characteristics of the ICU; general data of COVID-19 patients in ICU, general data on inhaled sedation, and the practical aspects of inhaled ICU sedation for both COVID-19 and non-COVID-19 patients. Some answers were compared with the previous survey, VOL'ICU.

Survey sample

All French ICUs were identified and contacted. Paediatric ICUs were excluded from the survey. All the same ICUs were surveyed in this study as were surveyed in the VOL'ICU study [10]. The current survey was conducted between June and September 2021. Almost all responses were recorded by the online survey. After short information about the survey design and objectives, the medical director of each ICU was questioned exclusively. Completion of the survey took approximately ten minutes. The first contact with the ICU directors was by email. In the case of non-response, a second attempt at contact was made by email or phone with the ICU director and followed by a last call when necessary.

Statistical analysis

Statistical analysis was performed in compliance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist [13]. Responses to each question were recorded into a Microsoft Excel database. Statistical analysis was performed with Stata software (version 15; StataCorp, College Station, Texas, USA), considering a 5% two-sided

first-species risk of error. Categorical data were described by numbers and percentages and quantitative data by the mean \pm standard deviation or median [1st quartile ; 3rd quartile], depending on statistical distribution. Results from both surveys (qualitative variables only) were compared using either the Chi2 test or Fisher's exact test. The associated qualitative data were compared using the Stuart-Maxwell test.

RESULTS

General characteristics

Among the 405 French ICUs^[14] , 31 paediatric ICUs were excluded and 374 adult ICU directors were questioned. A total of 27% (102/374) of the questionnaires were recorded, 95% (97/102) electronically and 5% (5/102) orally. Of the answers, 52% (53/102) came from general hospitals, 38% (39/102) from teaching hospitals, 9% (9/102) from private medical centres and 1% (1/102) from military hospitals. Among the participating ICUs, 89% (91/102) were mixed (medical and surgical) ICUs, 10% (10/102) were only medical ICUs and 1% (1/102) was a burn center. The majority of the ICU respondents managed COVID-19 patients (95%, (97/102)). The general characteristics of ICU respondents are reported in **Supplemental Contents 2 and 3**.

Practical aspects of inhaled ICU sedation

Among the respondents, 87% (89/102) stated that they knew about the use of inhaled sedation in the ICU. Among the 89 respondents, 9% (8/89) discovered inhaled sedation during the COVID-19 pandemic. Of these, 91% (81/89) knew about the *AnaConDa* device and 10% (9/89) knew the *Mirus* device. Sixty-three percent (56/89) of respondents who knew about the use of inhaled sedation in the ICU reported disposing of a specific device in their unit. Among these respondents, 84% (47/56) declared they performed inhaled sedation with *AnaConDa* and

14% (8/56) used *Mirus*. Five percent of respondents (3/56) declared to own both. Thirty-four percent (19/56) of respondents answered that they had acquired a device since the pandemic. If neither the AnaConDa nor the *Mirus* were available in their hospital, 11% (6/56) of respondents declared that they borrowed anesthesia ventilators from the operating room to deliver halogenated agents in the ICU.

According to all respondents, 35% (36/102) reported performing inhaled sedation in the ICU before the beginning of the COVID-19 pandemic and 47% (48/102) of respondents reported using inhaled sedation in the ICU since the COVID-19 pandemic began. Twenty-five percent of the respondents (25/102) declared that they had modified their use of inhaled sedation during COVID-19. The two main reasons for changing the use of inhaled sedation were: a more frequent use independent of COVID-19 and a more frequent use with ARDS patients. Among the respondents who did not use inhaled sedation, 34% (20/58) said they were favourable to developing inhaled sedation in their unit within the next two years.

During the COVID-19 pandemic, the reasons declared by the respondents to use inhaled sedation were in descending order: the need for additional sedative (50%, (28/56)), a shortage of intravenous sedatives (30%, (17/56)), the unit was involved in a clinical trial about inhaled sedation (30%, (17/56)) and interest in the system (21%, (12/56)).

Indications and contraindications for inhaled ICU sedation

Twenty-seven percent of respondents (15/56) declared that inhaled sedation was performed by all physicians working in their units. The majority of the respondents answered they used inhaled sedation in the ICU in less than 20 patients per year before and after the beginning of COVID-19 (**Figure 1**).

Main reasons for not using inhaled ICU sedation were as follows: “device not available” (76%, (47/62)), “lack of familiarity about the technique” (60%, (37/62)), “lack of formation for both the physicians and the nurses” (58%, (36/62) each) and “halogenated-induced atmospheric pollution” (27%, (17/62)) (**Figure 2**).

About indications, the main reported by respondents were: “failure of intravenous sedation” (74%, (39/53)), “severe asthma” (64%, (34/53)), and ARDS (49%, (26/53)). The other indications mentioned are summarised in **Figure 3**. The main advantages for using volatile sedation answered by respondents were: bronchodilation (83%, (44/53)) and usability (64%, (34/53)).

Absolute contraindications for inhaled sedation were reported by 94% (68/72) of the respondents (**Figure 4**). Thirty-nine percent (22/57) of the respondents declared that they had already at least one adverse effect attributable to volatile anesthetics, mainly reporting diabetes insipidus, malignant hyperthermia, and hypercapnic acidosis.

Inhaled sedation in practice

Eighty-two percent of respondents (83/101) declared that they had a written protocol for sedation in their institution whereas 64% (34/53) of units had a specific protocol for inhaled sedation.

Among units using inhaled sedation, 41% (19/46) of the respondents said they received specific training on inhaled sedation, either from the companies developing the devices in 84% (16/19) of the respondents or through scientific conferences in 21% (4/19) of the respondents.

Sevoflurane and isoflurane were the main drugs used, as reported by the respondents (94%, (30/32) and 22%, (7/32) respectively) and 3 respondents (10%, (3/32)) answered they used both. Four respondents (13%, (4/32)) said they used desflurane. To manage sedation,

respondents reported achieving a target exhaled gas fraction with sevoflurane of 1,0 [0,8-1,2] (35/56) and 0,5 [0,4-0,7] (35/56) for deep sedation and light sedation, respectively. All respondents said that they used inhaled sedation with controlled ventilation mode. Forty-six percent of them (25/54) stated that they also used inhaled sedation during pressure support ventilation in intubated patients. Two respondents (4%, (2/54)) declared that they had already used inhaled sedation during non-invasive ventilation.

All the respondents reported that they usually combined opioid-based analgesia with inhaled sedation, 65% (35/54) with sufentanil, 37% (20/54) with remifentanil and 6% (3/54) with fentanyl or morphine. One-third of them (18/54) answered that they combined gas with continuous intravenous sedative hypnotic, such as propofol (94%, (17/18)), midazolam (61%, (11/18)), ketamine (33%, (6/18)) or dexmedetomidine (17%, (3/18)).

When asked how they measured sedation objectives, most of the respondents (92%, (77/83)) answered using validated sedation scales or scores (such as The Richmond Agitation Sedation Scale (RASS)) rather than end-tidal gas concentration monitoring (42%, (35/83)). Forty-eight percent of the respondents (40/83) used the bispectral index (BIS-ASPECT-A-2000; Aspect Medical Systems, Norwood, USA). Only one ICU director reported that he measured plasma concentrations of volatile anesthetics or their metabolites when monitoring inhaled sedation.

According to the ICU directors' answers, 65% (35/54) interrupted inhaled sedation when patients began the process of weaning from ventilation and 37% (20/54) did not specifically set any maximal duration for inhaled sedation in their ICU patients.

Overall satisfaction with the use of inhaled sedation among users is represented in **Figure 5**. Seventy-nine percent (69/87) of the respondents declared that inhaled sedation could be an interesting alternative to intravenous sedation and especially for COVID-19 patients for 76% (62/87) of the respondents.

Evolution of inhaled sedation use compared to VOL'ICU study

The comparison between the data from VOL'ICU and VOL'ICU2 is summarized in **Table 1**. Since the beginning of COVID-19, the respondents declared that they knew more about inhaled sedation in the ICU and disposed more frequently of use at least one of the devices for delivering inhaled sedation. The indications for the use of inhaled sedation declared by the respondents were unchanged between VOL'ICU and VOL'ICU2 except for an increased use for medical indications since the COVID-19 pandemic. The two main halogenated agents used remained sevoflurane and isoflurane, but 13% of respondents declared to use desflurane in VOL'ICU2 compared to zero respondents in VOL'ICU. No significant modification of the rate of adverse effects was shown between the two studies.

DISCUSSION

This survey is the first to re-evaluate the use of inhaled sedation after the COVID-19 pandemic in French ICUs. This survey shows that in 2021, both knowledge of and interest in inhaled sedation are growing significantly among French intensivists. Nonetheless, the lack of devices with which to perform inhaled sedation in units and the insufficient training of both medical and paramedical teams remain barriers to widespread use of inhaled sedation.

The COVID-19 pandemic has led quickly to a worldwide shortage of intravenous sedative drugs prompting intensivists to search for alternatives to sedate ICU patients. Interestingly, French intensivists mainly justified the use of inhaled sedation in their units during COVID-19 with the need for additional sedatives. Thus, COVID-19 patients, especially when they develop an ARDS, need higher doses of sedatives to reach the sedation objective [11]. This element may also explain the increase of use of inhaled sedation with or without another hypnotic. The use of inhaled sedation due to shortages was declared by only one-third of the respondents as

well as the involvement of the unit in clinical trials on inhaled sedation. This point suggests that the popularity of inhaled sedation is increasing because of its intrinsic sedative characteristics. The respondents also reported potential interest in the bronchodilator effect and the manageability of inhaled sedation which could explain why halogenated agents may be a more popular option in the management of COVID-19 patients. Some studies also suggest that halogenated gas has an anti-inflammatory effect, a good manageability and avoids tachyphylaxis [15,16]. For all these reasons, volatile sedation may become, theoretically, an ideal option for intensivists in order to manage sedation. Furthermore, a large number of clinical trials studying the effects of inhaled sedation on major clinical outcomes in both non-COVID-19 and COVID-19 patients are actually enrolling patients. The French study, Sevoflurane for Sedation in ARDS (SESAR) aims to evaluate the efficacy of sedation in patients with moderate-to-severe ARDS with inhaled sevoflurane versus intravenous sedation with propofol (ClinicalTrials.gov: NCT04235608). The primary outcome will be the number of ventilator-free days through day 28, as defined as the number of days alive and off the ventilator at 28 days (thereby considering death as a competing event). Additionally, the Canadian Sedating with Volatile Anesthetics Critically Ill COVID-19 Patients in ICU: Effects On Ventilatory Parameters And Survival (SAVE-ICU) trial is ongoing to study the effects of a strategy of inhaled sedation with isoflurane or sevoflurane compared to intravenous sedation on hospital mortality, ventilator-free days and ICU-free days (ClinicalTrials.gov: NCT04415060). Currently, the Inhaled Sedation in ICU (INASED) investigators are also enrolling patients in a randomized trial of isoflurane vs propofol that was designed to assess the effects of the two sedation strategies on the occurrence of delirium as well as cognitive and functional outcomes at long term [17]. In addition to providing important results about inhaled sedation in ICU, these trials on halogenated agents may contribute to help participating centers to be more familiar with this technique.

However, we noted that scarcity was not the main reason for the increased use of volatile sedation in ICUs since the pandemic started: indeed, respondents reported that they used halogenated gas to achieve better sedation and to manage patients with ARDS.

Halogenated gas contraindications in ICU seem known by almost all participants even if answers varied. Malignant hyperthermia was the contraindication mainly responded by the physicians and clearly documented by studies in the literature [18]. The other contraindications remained unclear for ICU's practitioners and it could be explained by a very scarce literature about at-risk patient categories. However, inhaled sedation should be avoided when there is a risk of increased intracranial pressure. During pregnancy, the use of sevoflurane seems safe, but the "precautionary principle" should be applied to limit exposure as much as possible[19]. Interestingly, the number of adverse effects reported by the users of inhaled sedation did not statistically change between VOL'ICU and VOL'ICU2. Some respondents reported suspected or confirmed cases of diabetes insipidus, but also malignant hyperthermia and hypercapnia with acidosis. Unfortunately, the literature about adverse events related to inhaled sedation use is limited and the most often, the causality remains under debate. Nevertheless, the prolonged use of inhaled sedation (e.g., for >48 h) has shown good safety with equivalent effects on hemodynamic stability, no hepatorenal toxicity, and possibly less agitation compared to intravenous agents [20–23]. Even if large-scale studies are urgently needed to confirm safety of inhaled ICU sedation, randomised controlled SEDACONDA study suggests that isoflurane in ICU is safe and efficacious as a sole sedative and non-inferior to propofol in maintaining targeted sedation levels with good up to 54h [24].

Surprisingly, the major restraining factors for a more widespread use of inhaled sedation remains the availability of the device and the training of both medical and paramedical teams.

The same restraining factors were answered by the respondents in 2019 in the VOL'ICU study.

These points strengthen the importance of the initial and continuous formations of the

caregivers who work in ICUs to decrease the fear of using a “new” sedation technique. One other element that could explain this result is that a distinct specialty track trains French “medical intensivists” who can work in ICUs but are not anesthesiologists. Perhaps, anesthesiologists-intensivists are more likely to be trained to use volatile anesthetics during their residency program which involves more time in the operating room. These elements should encourage the practitioners to reinforce the training and pedagogical requirements for themselves and their teams about inhaled sedation in their units. It appears essential to integrate inhaled sedation into multifaceted bundles of care in the management of sedation in the ICU [9]. The education of both practitioners and nurses is crucial to developing the use of inhaled in the ICU. Hopefully, the use of volatile anesthetics can now be considered for specific ARDS patients to reduce emergent delirium and cumulative propofol doses [9]. Furthermore, isoflurane received national approval from ANSM for inhaled sedation in ICU which will result in an increased use of inhaled sedation. This increase in the use of inhaled sedation should be supported by the writing of a specific protocol for inhaled sedation which is insufficiently present in the units to date. Another point is that even if the industries had provided many devices all around France during the COVID-19, some ICU could have had shortages of some products restraining the use of inhaled sedation.

The risk of room and environmental pollution remains a limiting factor among the respondents for the use of inhaled sedation in ICU. It is true that average threshold limit concentrations for halogenated agents differ significantly between countries or are not even defined at all, leading to raising concerns among teams who work in ICU [25]. Actually multiple studies reported room pollution far below the recommended exposure limits even in countries with lowest recommendations [19,26,27]. Concerns are often historically founded, when personnel were exposed to high concentrations of evidently toxic substances, which were used in rooms without air-conditionings and gas scavenging systems. However, based on currently available

data, there is no significant pollution when the anaesthetic reflectors are correctly set up and used in accordance with recommendations from their manufacturers. Besides, in order to decrease room pollution, the Swedish and American authorities recommend that ICU rooms are equipped with air conditioning that has at least 6 air changes per hour. Indeed effective air conditioning is an effective system to maintain low values of waste halogenated agents below the recommendations [19,27]. Additionally, devices such as the AnaConDa reflects moisture back to the patient, but also reflects 90% of the halogenated agent by adsorbing and releasing the volatile using a proprietary carbon filament reflecting medium. This reflection reduces the total amount of halogenated agent needed, reducing that which is exhausted or scavenged [28].

Our survey has several limitations. First, with 102 survey responses, the participation rate in this second survey was lower than in our previous survey (n = 187, 50% response rate). With the second survey, we were only able to reach about 25% of potentially eligible adult ICUs in France [16]. Since the beginning of the COVID-19 crisis, French health-care has been challenged with reorganizations of critical care all around the country including major physician turnover [29]. Furthermore, lower interest in this survey could be explained by the amount of work for some ICU directors due to a number of COVID-19 cases that remaining high in some regions. Nevertheless, the characteristics of the answering ICUs were comparable to those of our previous survey. Furthermore, we used the same information channels to distribute the survey link and the time-period (summer) was identical to our first survey. Second, declarative surveys can only provide limited information due to intrinsic bias which could be avoided with an observational study. Nevertheless, the validity of our findings is highlighted by the design of the study in which only ICU directors were questioned to limit both the non-response rate and the response bias. Finally these findings, which reflect the use of inhaled sedation as reported by French intensivists, may not be extrapolated to other countries with distinct ICU organizations.

CONCLUSION

In conclusion, our study strengthens that the use of inhaled sedation in ICU has increased quickly in the past 2 years, always with a good satisfaction among the users. Even if the COVID-19 pandemic could have impacted the widespread use of inhaled sedation, the use of inhaled sedation represents an alternative to intravenous sedation for more and more French physicians. Nonetheless, both lack of devices available in the units and insufficient training of ICU teams remains the two major restraining factors highlighting the importance of staff formation about inhaled sedation in ICU.

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Clermont-Ferrand, le 21/09/2021

Le Président du Jury



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TABLES AND FIGURES

TABLES

Table 1. Comparisons between the answers provided by the respondents in the VOL'ICU (n=187) and VOL'ICU2 (n=102) studies. Results are presented as numbers (with associated percentages). Percentages were rounded to the nearest whole number depending on whether the value after the decimal was greater than or less than 5.

VARIABLE	VOL'ICU	VOL'ICU 2	p value
Knowledge of inhaled sedation, n (%)			
Yes	137 (73)	89 (87)	0,006
No	50 (27)	13 (22)	
Availability of the device in the unit, n (%)			
Yes	40 (21)	56 (55)	< 0,001
No	147 (79)	46 (55)	
Indications, n (%)			
Medical	13	36	0,01
Post-operative	13	13	0,92
ARDS	65	49	0,13
Trauma	3	6	0,63
Failed sedation	75	74	0,88
Asthma	75	64	0,26
Status epilepticus	10	13	0,64
Cardioprotection	13	2	0,08

No specific indication	3	6	0,63
Reasons declared for not using inhaled sedation, n (%)			
No device available	39	76	< 0,001
Lack of medical training	22	58	< 0,001
Lack of paramedic training	16	58	< 0,001
Complexity	12	19	0,14
Ecological concern	7	27	< 0,001
Adverse effects	1	13	< 0,001
Lack of familiarity	35	60	< 0,001
Cost	21	18	0,58
Sedation protocol, n (%)			
<i>Intravenous sedation</i>			
Yes	157 (84)	83 (82)	0,7
No	30 (16)	18 (18)	
<i>Inhaled sedation</i>			
Yes	17 (45)	34 (34)	0,23
No	21 (55)	67 (66)	
Halogenated agent, n (%)			
Sevoflurane	88	94	0,45
Isoflurane	20	22	0,85

Desflurane	0	13	0,04
Adverse effects, n (%)			
Yes	11 (28)	22 (39)	0,26
No	29 (73)	35 (61)	

FIGURES

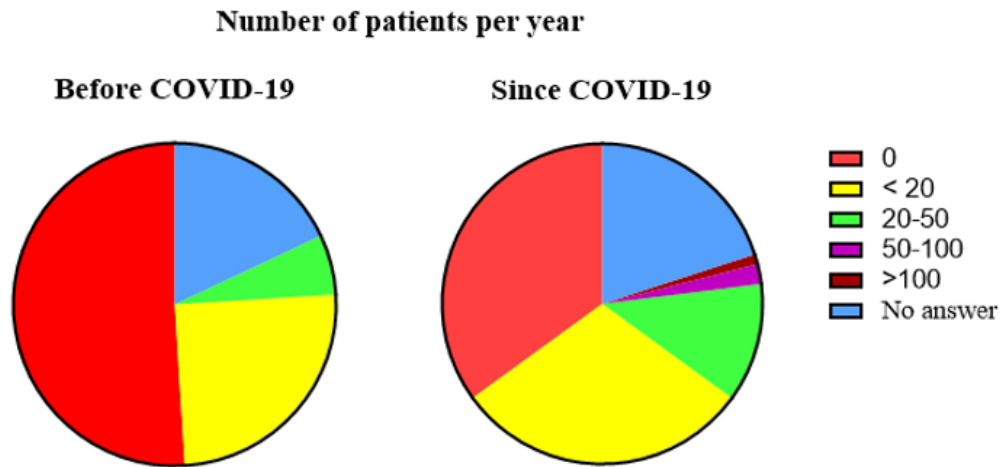


Figure 1. Follow-up number of patients per year sedated with volatile sedation in ICU among the respondents (n=56). Data are represented in number of patients

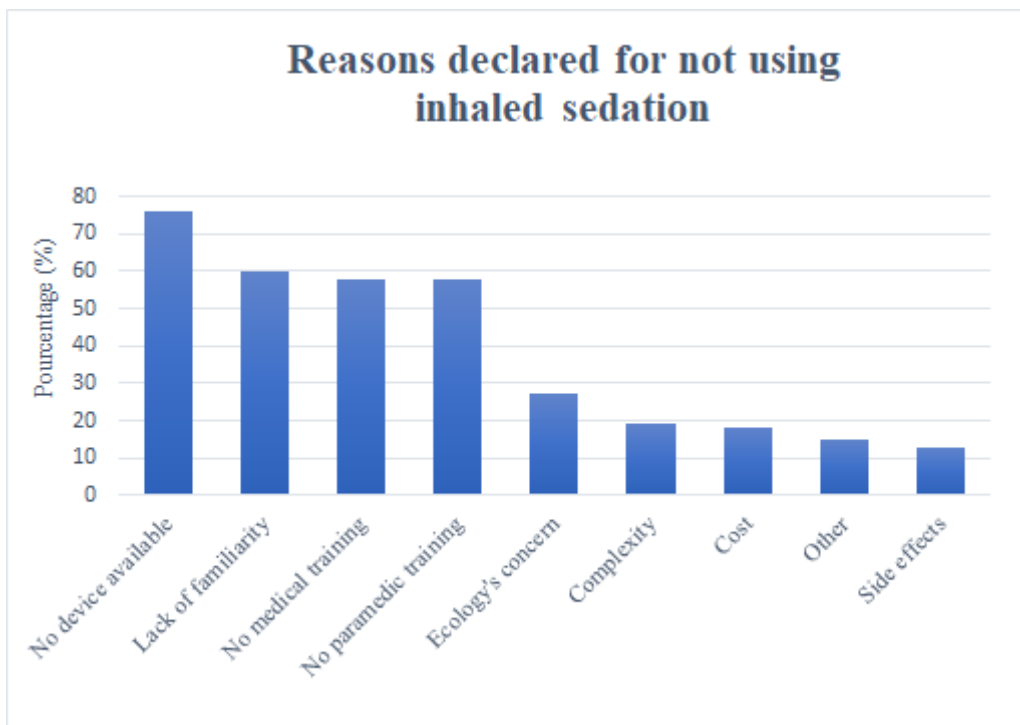


Figure 2. Reasons declared by the respondents for not using inhaled sedation in ICU (n=62). Data are represented in %

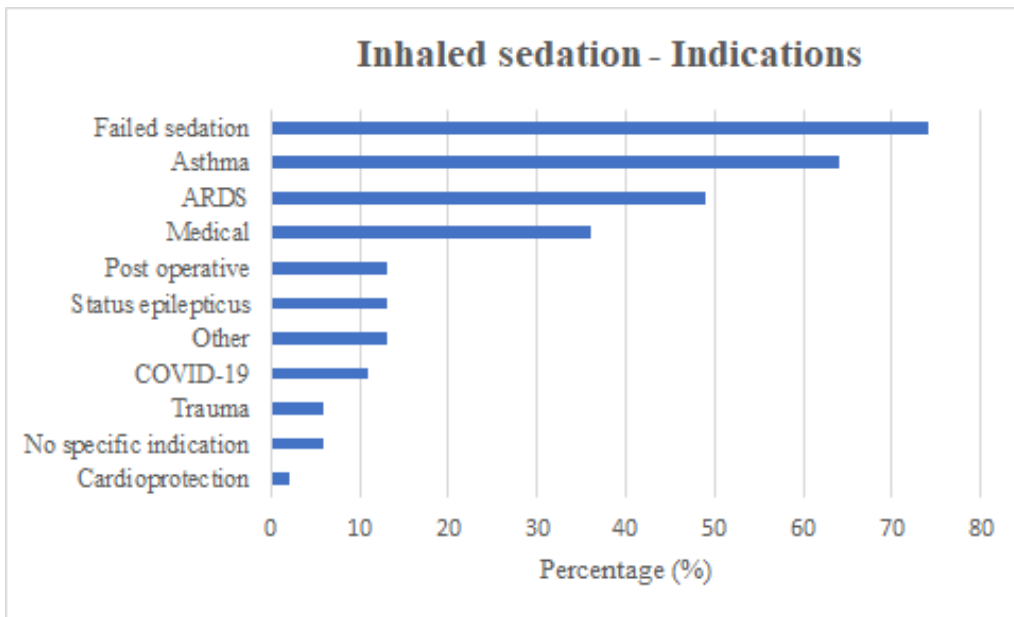


Figure 3. Indications declared by the respondents for using inhaled sedation in ICU (n=53). Data are represented in %

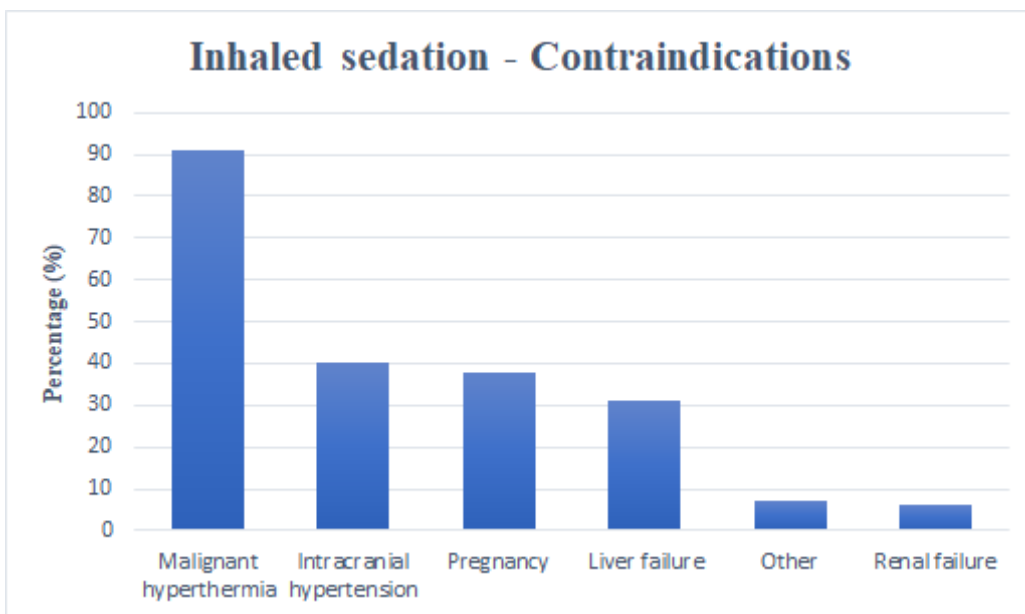


Figure 4. Contraindications declared by the respondents for using inhaled sedation in ICU (n=72). Data are represented in %

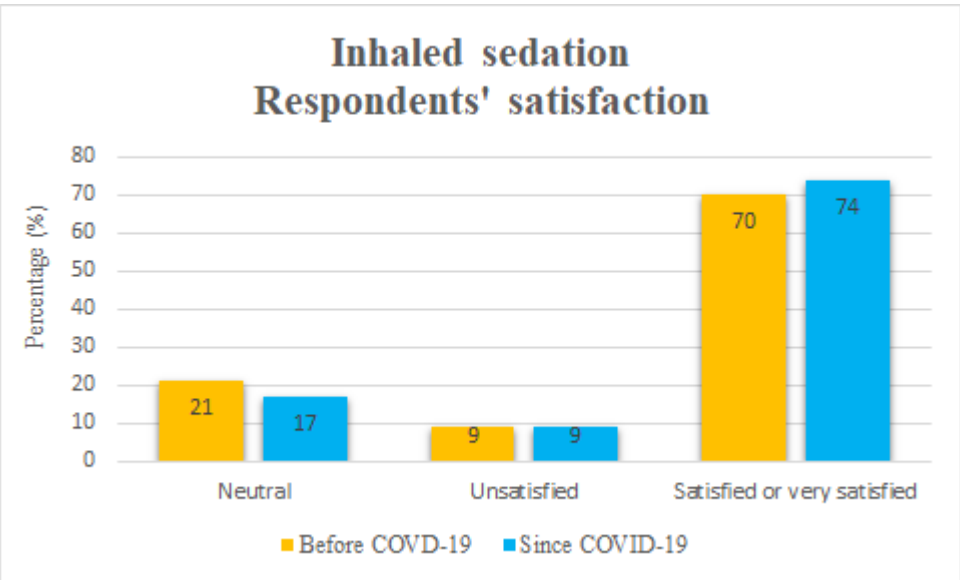


Figure 5. Overall satisfaction of respondents regarding the use of inhaled sedation before and since the COVID-19 (n=87). Data are represented in %.

APPENDIX

Additional file : Supplemental Content 1. Survey questionnaire

I. General characteristics of the ICU

Your place of professional exercise:

- University Hospital
- General Hospital
- Private health structure
- Other

In which type of intensive care unit do you work?

- Medico-surgical / Polyvalent
- Medical
- Step-down unit
- Medical intensive care, such as a coronary care unit
- Other

In which French region do you work?

- Auvergne - Rhône-Alpes
- Bourgogne-Franche-Comté
- Bretagne
- Centre-Val de Loire
- Corse

- Grand-Est
- Hauts-de-France
- Ile-de-France
- Normandie
- Nouvelle-Aquitaine
- Occitanie
- Pays de la Loire
- Provence-Alpes-Côte d'Azur
- Corse
- DOM-TOM

Number of senior physicians in your unit (full-time equivalent): (numerical value)

Number of residents in your unit: (numerical value)

Number of beds in your intensive care unit: (numerical value)

Number of step-down beds in your unit: (numerical value)

Number of patients admitted per year in your intensive care unit: (numerical value)

Have you admitted COVID-19 patients since January 2020 ?

- No
- Yes:

What percentage of patients are admitted with ARDS in your unit?

- during pandemic peak of spring 2020 (numerical value)
- during pandemic peak of autumn 2020 (numerical value)
- during pandemic peak of winter 2021(numerical value)
- between the pandemic peaks(numerical value)

What percentage of patients are admitted with COVID-19 in your unit since January 2020?

- during pandemic peak of spring 2020 (numerical value)
- during pandemic peak of autumn 2020 (numerical value)
- during pandemic peak of winter 2021 (numerical value)
- between the pandemic peaks (numerical value)

What is the average length of stay in the intensive care unit (in days) of your patients?

(numerical value)

What is the average length of stay in the intensive care unit (in days) of your COVID-19 patients? (numerical value)

What is the average duration (in days) of invasive mechanical ventilation in your patients?

(numerical value)

What is the average duration (in days) of invasive mechanical ventilation in your COVID-19 patients? (numerical value)

What is the mortality rate, in the intensive care unit, of your patients? (numerical percentage value)

What is the mortality rate, in the intensive care unit, of your COVID-19 patients? (numerical percentage value)

II. General data on inhaled sedation use

Are you familiar with inhaled ICU sedation?

- No
- Yes, before the COVID_19 pandemic:
 - I am familiar with the AnaConDa System
 - I am familiar with the Mirus System
 - I am familiar with another system

- Yes, since the COVID_19 pandemic:
 - I am familiar with the AnaConDa System
 - I am familiar with the Mirus System
 - I am familiar with another system

Do you have dedicated systems to deliver inhaled sedation available in your institution?

- No
- Yes, before the COVID_19 pandemic:
 - I am familiar with the AnaConDa System
 - I am familiar with the Mirus System
 - I am familiar with ventilator from the operating room to deliver halogenated agents
 - I am familiar with another system
- Yes, since the COVID_19 pandemic:
 - I am familiar with the AnaConDa System
 - I am familiar with the Mirus System
 - I am familiar with ventilator from the operating room to deliver halogenated agents
 - I am familiar with another system

Did you use inhaled sedation in your ICU before the COVID-19 pandemic?

- Never
- Sometimes
- Often

Do you use inhaled sedation in your ICU since the COVID-19 pandemic?

- Never
- Sometimes
- Often

Has your use of inhaled sedation changed since the COVID-19 pandemic?

- No
- Yes
 - I use inhaled sedation more frequently in all patients
 - I use inhaled sedation more frequently in ARDS patients
 - I use inhaled sedation because of the shortage of intravenous sedative
 - I stop to use inhaled sedation
 - Other

If you don't use inhaled sedation, do you think you will develop inhaled sedation in your unit in the next two years ?

What are the reasons to use inhaled sedation since the beginning of COVID-19 pandemic ?

- Shortage of intravenous sedatives
- Add sedative
- Involvement in a clinical trial about inhaled sedation
- Curiosity
- Other

Who uses inhaled sedation in your ICU?

- Nobody
- Some physicians
- All physicians

In how many patients per year do you use inhaled ICU sedation before the COVID-19 pandemic?

- <20
- 20-50
- 50-100
- >100

In how many patients per year do you use inhaled ICU sedation since the COVID-19 pandemic?

- <20
- 20-50
- 50-100
- >100

If you do not use inhaled ICU sedation, what are the reasons? (multiple answers possible)

- No equipment available
- Untrained medical staff
- Untrained paramedical personnel
- No obvious interest
- Heavy organization
- Concerns about air pollution risk or ecological impact
- Undesirable effects
- Lack of habit
- Cost issues

If you use inhaled sedation in your ICU, what is/are the indication(s) for use? (multiple answers possible)

- COVID-19 patient only
- Medical
- Post-surgery
- ARDS
- Traumatology
- Failure of IV sedation (drug or alcohol addicts, etc.)
- Asthma
- Cardioprotection
- Status epilepticus
- Neuroprotection
- No specific indication
- Other(s)

In your opinion, what are the potential benefits of inhaled ICU sedation? (multiple answers possible)

- I don't know
- Ease of use, including “on/off” effects
- Bronchodilating properties
- Anti-inflammatory properties
- Low cost
- Other(s)

III. Practical aspects of inhaled ICU sedation

Do you have a written protocol for inhaled sedation in your ICU?

- No
- Yes

Do you have any specific training in inhaled ICU sedation?

- No
- Yes

What halogenated agent do you use? (multiple answers possible)

- Sevoflurane
- Isoflurane
- Desflurane

For what reason(s) do you use this (these) halogenated agent(s)? (multiple answers possible)

- Availability
- Cost
- Ease of use
- Low metabolism
- Other(s)

With which mode(s) of ventilation do you use inhaled sedation? (multiple answers possible)

- Volume-controlled or pressure-controlled ventilation
- Pressure support (invasive) ventilation
- Pressure support (noninvasive) ventilation
- Other(s)

Do you usually combine an opioid agent with inhaled sedation?

- No
- Yes

If yes, which one(s)? (multiple answers possible)

- Sufentanil
- Fentanyl
- Remifentanyl
- Other(s)

Do you usually combine another sedative agent when you use inhaled ICU sedation?

- No
- Yes

If yes, which one(s)? (multiple answers possible)

- Midazolam
- Propofol
- Ketamine
- Dexmedetomidine
- Other(s)

With what exhaled fraction of halogenated agents do you usually initiate inhaled ICU sedation?

- For sevoflurane: (numerical value)
- For isoflurane: (numerical value)
- For desflurane: (numerical value)

What expired fraction of halogenated agents do you typically target for "deep" ICI sedation?

- For sevoflurane: (numerical value)
- For isoflurane: (numerical value)
- For desflurane: (numerical value)
- Non applicable
- No expired fraction is targeted, I adapt sedation based on a score
- I only set a maximal expired fraction for safety reasons

How do you usually monitor the depth of sedation? (multiple answers possible)

- Sedation scale such as the RASS
- Monitoring of expired gas fraction
- Use of the Bispectral index (BIS)
- Other(s) :

Do you usually perform plasma assays for halogenated agents and/or their derivatives?

- No
- Yes

When do you usually stop inhaled sedation?

- When weaning off the ventilator
- During extubation
- Systematically at 48h
- No specific time limit
- Other(s)

In your opinion, what are the absolute contraindications of inhaled sedation?

- I don't know
- Acute renal failure
- Liver failure
- Pregnancy
- History of malignant hyperthermia
- Intracranial hypertension
- Other(s)

Have you ever had any serious adverse events that you believe were caused by inhaled sedation in ICU patients?

- No
- Yes

If yes, please detail: (multiple answers possible)

- Malignant hyperthermia
- Acute renal failure
- Severe respiratory acidosis
- Other(s)

What is your overall satisfaction with inhaled ICU sedation before the COVID-19 pandemic?

- Not satisfied at all
- Unsatisfied
- Indifferent
- Satisfied
- Very satisfied

What is your overall satisfaction with inhaled ICU sedation since the COVID-19 pandemic ?

- Not satisfied at all
- Unsatisfied
- Indifferent
- Satisfied
- Very satisfied

In your opinion, is inhaled sedation an interesting alternative to intravenous sedation in the intensive care setting?

- No
- Yes

In your opinion, is inhaled sedation an interesting alternative to intravenous sedation for COVID-19 patients in the intensive care setting?

- No
- Yes

Free comments, if any:

Additional file: Supplemental Content 2. Characteristics of the centers where respondents worked and characteristics of the non-COVID-19 and COVID-19 patients estimated by the respondents (n=102). *Values are expressed as medians [interquartile ranges] and means (SD). Percentages were rounded to the nearest whole number depending on whether the value after the decimal was greater than or less than 5*

VARIABLE	VOLICU 1 (N=102)
Number of physicians per ICU (n)	
Senior physicians	7,2 [5-9]
Residents	5 [3-7]
Number of beds per ICU (n)	
ICU beds	12 [8-16]
Step-down units beds	6 [4-8]
Patients per year (n)	739 [550-1000]
Patients with ARDS (%)	
<i>during spring 2010</i>	80 [40-100]
<i>during autumn 2020</i>	70 [40-80]
<i>during winter 2021</i>	60 [30-80]
<i>between epidemic peak</i>	20 [10-65]

Patient with COVID-19 (%)	
<i>general</i>	30 [20-60]
<i>during spring 2010</i>	77,5 [39-100]
<i>during autumn 2020</i>	70 [36-85]
<i>during winter 2021</i>	68,3 [32,5-90]
<i>between epidemic peaks</i>	10 [1-20]
Duration of ICU stay (days)	
Non-COVID-19 patients	6,4 [5,3-8]
COVID-19 patients	15 [12-20]
Duration of mechanical ventilation (days)	
Non-COVID-19 patients	5 [4-7]
COVID-19 patients	14 [10-15]
Mortality (%)	
Non-COVID-19 patients	19 [16-23]
COVID-19 patients	25 [19-32]

Additional file: Supplemental Content 3. Geographical distribution and epidemiological data on respondents (n=102). *DOM-TOM: Département d'outre-mer-Territoire d'outre-mer.*

FRENCH REGION	Number of ICU (%)
Auvergne Rhône-Alpes	26 (25)
Bourgogne Franche-Comté	6 (6)
Bretagne	5 (5)
Centre Val de Loire	5 (5)
Corse	1 (1)
DOM-TOM	2 (2)
Grand Est	6 (6)
Hauts-de-France	5 (5)
Ile-de-France	16 (15)
Normandie	4 (4)
Nouvelle Aquitaine	5 (5)
Occitanie	8 (8)
Pays de la Loire	2 (2)
Provence Alpes Côte-d'Azur	11 (11)



Additional file: Strengthening the reporting of observational studies in epidemiology (STROBE).

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1-3	
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3	
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5	
Objectives	3	State specific objectives, including any prespecified hypotheses	5-6	
Methods				
Study design	4	Present key elements of study design early in the paper	6	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7	
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	6	
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6	
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-7	
Bias	9	Describe any efforts to address potential sources of bias	NA	
Study size	10	Explain how the study size was arrived at	NA	

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	5-7
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed	5-7
		<i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
(e) Describe any sensitivity analyses	5-7		
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7-12
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7
		(b) Indicate number of participants with missing data for each variable of interest	7-12
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	NA
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	NA
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	NA
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	7-12
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	1 7	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12
Discussion			
Key results	1 8	Summarise key results with reference to study objectives	12-16
Limitations	1 9	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12-16
Interpretation	2 0	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-16
Generalisability	2 1	Discuss the generalisability (external validity) of the study results	12-16
Other information			
Funding	2 2	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

SERMENT D'HIPPOCRATE (Conseil national de l'ordre des médecins)

Au moment d'être admis(e) à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux.

Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences.

Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

Je donnerai mes soins à l'indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

Admis(e) dans l'intimité des personnes, je tairai les secrets qui me seront confiés. Reçu(e) à l'intérieur des maisons, je respecterai les secrets des foyers et ma conduite ne servira pas à corrompre les mœurs.

Je ferai tout pour soulager les souffrances. Je ne prolongerai pas abusivement les agonies. Je ne provoquerai jamais la mort délibérément.

Je préserverai l'indépendance nécessaire à l'accomplissement de ma mission. Je n'entreprendrai rien qui dépasse mes compétences. Je les entretiendrai et les perfectionnerai pour assurer au mieux les services qui me seront demandés.

J'apporterai mon aide à mes confrères ainsi qu'à leurs familles dans l'adversité.

Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses ; que je sois déshonoré(e) et méprisé(e) si j'y manque.

SERMENT D'HIPPOCRATE

En présence des Maîtres de cette FACULTE et de mes chers CONDISCIPLES, je promets et je jure d'être fidèle aux lois de l'Honneur et de la Probité dans l'exercice de la Médecine.

Je donnerai mes soins gratuits à l'indigent et je n'exigerai jamais un salaire au-dessus de mon travail. Admis dans l'intérieur des maisons, mes yeux ne verront pas ce qui s'y passe, ma langue taira les secrets qui me seront confiés et mon état ne servira pas à corrompre les moeurs ni à favoriser le crime.

Respectueux et reconnaissant envers mes MAÎTRES, je rendrai à leurs enfants l'instruction que j'ai reçue de leurs pères.

Que les HOMMES m'accordent leur estime si je suis fidèle à mes promesses. Que je sois couvert d'OPPROBRE et méprisé de mes confrères si j'y manque.