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# Impact of a preoperative conversational hypnotic session on propofol consumption using closed-loop anesthetic induction guided by the bispectral index

## A randomized controlled trial

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**Abstract**

**Objective:** The automated administration of propofol in a closed loop could be used to objectively evaluate the nonpharmacological anesthetic action of hypnotherapy. The objective of this study was to evaluate the impact of a conversational hypnosis session on the consumption of propofol for anesthetic induction.

**Design:** A randomized, usual care-controlled, single-center, patient-blind trial.

**Setting:** Tertiary care center in France from November 2012 to December 2013.

**Participants:** Adult patients scheduled for a surgical procedure under general anesthesia.

**Interventions:** Before surgery, patients were randomized with a computer-generated random list for a preoperative conversational hypnosis session or for usual care. The conversational hypnosis session was conducted and individualized by the therapist with an academic degree in hypnosis in a quiet environment. Anesthetic induction was automatically performed by propofol without opioids and was assisted by the bispectral index in a closed loop.

**Outcome:** Primary endpoint was the propofol dose required for anesthesia induction, defined as a Bispectral index less than 60 for at least 30 seconds.

**Results:** The study included 48 patients in the hypnosis group and 49 patients in the control group. No difference in propofol consumption to obtain anesthesia induction was observed between the groups (total dose: 138.6 [67.5] and 130 [47.9] mg, $P = .47$; adjusted dose: 2.15 [1.09] and 1.95 [0.66] mg/kg, $P = .28$, for the hypnosis and control groups, respectively). Hetero-evaluation of arm movement during propofol injection (no reaction: 98% and 74%; $P = .004$, in the hypnosis and control groups, respectively) and face reaction at venous access placement (no reaction 59% and 30%; $P = .017$, in the hypnosis and control groups, respectively) were lower in the hypnosis group. No adverse event was reported.

**Conclusions:** No difference in propofol consumption was observed in this study designed to evaluate the effect of a hypnotic conversational session on anesthesia induction using an automated tool for propofol administration.

**Abbreviations:** ASA = American Society of Anesthesiology, BIS = bispectral index.

**Keywords:** anaesthetics i.v., hypnosis, propofol, suggestion

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## 1. Introduction

Although data on the biological physiology of hypnosis are accumulating,[1,2] lack of assessment regarding the benefits of hypnotic techniques and their generalization at the patient's bedside hampers their wider use. In the setting of interventions with general anesthesia, hypnosis appears effective in lessening anxiety and postoperative pain.[3] Among hypnosis techniques used by practitioners, the preferred methods are positive suggestion and focalization of attention.[4] It has been shown that empathic attention and positive communication, when they are used during interventional procedures without anesthesia, are beneficial for anxiety[5] and general morbidity.[6] Before induction of general anesthesia, this form of conversation with the patient is often performed to obtain a reduction of anxiety.[4] One could call it a premedication effect. However, the action of hypnosis during the intraoperative period has been investigated less, although preoperative suggestion appears to be more efficient for dreaming during anesthesia when propofol induction is used.[7]

Modification of blood flow distribution and activation of several cortical regions can be observed during the hypnotic state.[8] Electro-encephalographic data regarding hypnosis are complex and even if there is no specific electro-encephalographic signature of hypnosis, a decrease in cortical electrical activity has been reported in certain spectral bands.[9] The interaction of these changes with general anesthesia needs to be determined.

We have developed an automated tool for anesthetic drug administration.[10] In a nutshell, intravenous anesthetic drugs are automatically administered using an algorithm that determines syringe-pump speed using the bispectral index (BIS) signal. The use of this closed loop tool overcomes the inherent heterogeneity of caregivers. This automated system is available as an objective and unbiased tool that could be used to evaluate the effect of a non-pharmacological hypnotic action.

This study attempted to assess the impact of a conversational hypnosis session before anesthetic induction on the consumption of anesthetic drugs. Our hypothesis is that conversational hypnosis could reduce the propofol consumption required to achieve deep anesthesia as defined by a BIS less than 60 for at least 30 seconds.

## 2. Materials and methods

### 2.1. Patients

After approval by the Institutional Review Board (Comité de Protection des Personnes Ile de France VIII, 2012-A00369-34, April 10, 2012), we conducted a single-center 1:1 randomized, placebo-controlled study that included 2 groups: a standard care or control group, and an intervention or hypnosis group. The trial was registered at ClinicalTrials.gov under the number NCT 01648725.

The inclusion criterion was adult patients who were scheduled for a surgical procedure under general anesthesia. Information about the protocol was given during the preanesthetic visit on the day before surgery or on the morning of the surgery for ambulatory care. Exclusion criteria were pregnancy and breast-feeding, allergy to propofol, soya or peanuts, a history of central nervous system disease or receiving psychotropic treatment as a patient, treatment by a psychiatrist or a psychologist, hemodynamic instability or high cardiovascular risk, and presence of a pacemaker.

Randomization was performed using a computer-generated random list that was available through a dedicated web page. After obtaining a written informed consent, an inclusion number was assigned to each patient, and the related number was attached to the medical file. Investigators in charge of the patient could log onto the web page on the day of surgery when the patient arrived at the preanesthetic room. Patients were blinded to their assignment.

### 2.2. Study protocol

No premedication was performed before the anesthetic procedure on any of the patients. Four healthcare providers performed the hypnotic sessions: 2 senior anesthetists and 2 anesthetic nurses. Each of the healthcare providers holds an academic degree in hypnosis and had practical experience of over 1 year. Chronologically, the healthcare provider established contact with the patient before entering the operating room, evaluated the anxiety of the patient according to the Covi Scale[11] (1–12) and recollected a pleasant memory in the pre-anesthetic room. Randomization to allocate the patient to one of the groups was then performed using the dedicated web site.

For the hypnosis group, the intervention consisted in a hypnotic session once the patient had entered the operating room. The session was conducted and individualized by the therapist in a quiet environment. During the session, the patient was supported – without intrusive suggestion and fully respecting his mental environment – in such a way as to help plan the intervention in terms of reducing the anxiety of the event. Therapeutic communication used reformulation of the words of the patient and avoided negative suggestions. For example, the conversation could cover work: "What do you do for a living? Ah well, it must be interesting, or absorbing, or tiring" (to be adapted according to patients), around the environment: "I suggest you do something that you have done for a long time: to breathe... Let the air come and go naturally and maybe you can realize by focusing on your breathing that the air coming in is cooler than the air coming out. This is because the air is warming in the nose . . . the throat... the body... And the more you breathe, the more the parts of your body are relaxed: the head, neck, shoulders, back, legs... You feel that all these parts are well rested on the bed... comfortably... And you are warm, well covered up, safe... Enjoy this moment of quiet, rest, security. Perhaps the eyelids close alone or maybe not... They can remain open to know when they will close... just now, or later...". The sessions were variable, individualized, and were adapted to the personal experiences of the patient and to their defense mechanisms. A mental focus on the previously chosen pleasant memory was progressively obtained. The sessions therefore varied somewhat.

This dedicated time continued from entry into the operating room, through monitoring, intravenous access device placement, until loss of consciousness after anesthetic induction. Attention focusing was performed for each patient as they entered the operating room, after randomization. For the control group, the patients received usual care.

Propofol (Propofol Fresenius 10 mg/mL; Fresenius Kabi France, 92316 Sevres Cedex, France) was used to induce general anesthesia using an automated administration system. Details of the controller have been described previously.[10] Briefly, the controller has a cascade structure including a dual proportional-integral-derivative algorithm that steers a target-controlled infusion system for the administration of propofol. The total body weight was set in the target-controlled infusion system based on the pharmacokinetic of Schnider et al[12] for propofol. The controller modified the calculated effect-site concentrations according to BIS changes and performed tight control of adequate

anesthesia (as measured based on the BIS) and avoided the propofol overdosing that is related to the use of inappropriate pharmacokinetic models.

For endpoint collection, a dedicated healthcare provider was present in the operating room and assessed the patient's reaction and collected the data. Obviously, the healthcare providers – both the healthcare provider conducting the hypnotic session and the healthcare provider responsible for data collection – were aware of the group to which the patient had been allocated. However, the patients were not told which group they were in.

In both groups, the pursuit of anesthesia beyond induction was at the discretion of the anesthetist in charge of the patient. A visit to the postinterventional surveillance room was performed for the subjective assessment of the care given before the anesthetic induction.

### 2.3. Endpoints

The primary endpoint was the administered propofol dose required to obtain the induction of anesthesia (BIS < 60 for at least 30 seconds).

Secondary outcome measures included the following: calculated target plasma concentration corresponding to anesthesia induction (BIS < 60 for at least 30 seconds); hetero-evaluation of pain during propofol injection as assessed by the following criteria: withdrawal of the infused arm (no withdrawal = 0; withdrawal = 1; violent withdrawal = 2); and spontaneous expression (no expression = 0; frown = 1 grin = 2); the hemodynamic consequences of induction: heart rate and blood pressure were measured immediately before the induction of anesthesia and after it had been realized (BIS < 60 for at least 30 seconds); characteristics of the hypnotic procedure: for speed: focus obtained very rapidly (1), rapidly (2), medium (3), delayed (4), impossible to obtain (5); for quality: very deep (1), deep (2), medium (3), superficial (4), not obtained (5); and patient assessment of the induction of anesthesia on a 4-point scale, as given postoperatively in the recovery room.

Other endpoints were assessed: hetero-evaluation of pain during intravenous device access (as assessed by the following criteria: withdrawal of the infused arm [no withdrawal = 0; withdrawal = 1; violent withdrawal = 2] and spontaneous expression [no expression = 0; frown = 1 grin = 2]); BIS before preoxygenation and BIS before propofol infusion; propofol consumption for BIS = 50; ephedrine injection during induction; post-operatively, a numerical verbal scale for propofol injection pain (0: no pain, 10: maximal pain) and a numerical verbal scale for perioperative anxiety (0: no anxiety, 10: maximal anxiety).

### 2.4. Statistical analysis

On the basis of a previous study on the potency of various propofol formulations,[13] the mean propofol dose required to obtain anesthesia induction (BIS < 60 for at least 30 seconds) was 2.2 mg/kg (standard deviation 0.6). Considering a statistical power of 90% and an alpha risk of 5% to detect a dose reduction of 25%, the number of patients needed in each group was 40. A total number of 100 patients was chosen to ensure sufficient enrolment considering a predicted attrition rate of approximately 15%. Data are given as frequencies and percentages for categorical variables, and as the mean and standard deviations for quantitative variables unless otherwise stated.

Comparisons were made using the *t* test or a chi-square test as appropriate. All tests were 2-sided at the 0.05 significance level. Analyses were performed using R 3.1.2 (R Core Team [2014]. R: A language and environment for statistical computing; R Foundation for Statistical Computing, Vienna, Austria; http://www.R-project.org/).

## 3. Results

### 3.1. Patients

From November 2012 to December 2013, a total of 124 patients were considered for trial eligibility; of these, 103 patients were randomized, and 48 and 49 patients in the hypnotic and control groups, respectively, were considered for data analysis (Fig. 1). Trial ended after reaching the previous number of participants. Primary endpoint data were available for all these patients. Demographic data and perioperative characteristics are presented in Table 1. The study population mainly comprised women (87%), and gynecological surgery was performed in most cases (84%). No regional analgesia was performed. Regarding security endpoints, no memorization was found after anesthesia, and no significant (>500 mL) bleeding occurred.

### 3.2. Characteristics of the hypnotic session

The hypnotic session was qualified as acceptable or good by the healthcare provider for 90% of the patients (Table 2). However, focalization was not obtained for 9/48 patients. The same 9 patients were considered unreceptive. Incidents related to the hypnosis session were 2 very rapid losses of focalization (distraction from the pleasant memory).

### 3.3. Primary endpoint

No difference in propofol consumption was observed between the groups (Table 3). The propofol dose required to obtain anesthesia induction (BIS < 60 for at least 30 seconds) was 138.6 mg (67.50) in the hypnosis group and 130 mg (47.90) in the control group ($P = .4716$). Adjusting for the weight of patients did not yield any difference: 2.15 mg/kg (1.09) and 1.95 mg/kg (0.66) ($P = .28$) were required to obtain induction in the hypnosis and control groups, respectively.

### 3.4. Secondary endpoints

No difference was observed in the drug target plasma concentration corresponding to anesthesia induction (Table 3). Among the secondary endpoints, arm reaction was the only item that differed between the 2 groups: hypnotic intervention significantly reduced arm reaction to propofol injection ($P = .0035$). Patient hemodynamic status was similar between the groups. No difference was observed in the patients' assessment of the period before anesthesia; a high satisfaction rate was obtained in both groups (went well or very well: 88% and 91% in the hypnotic and control groups, respectively; $P = .61$).

### 3.5. Other endpoints

Hetero-evaluation of the patients' reaction to propofol infusion and to introduction of the intravenous access device showed a significant reduction in the hypnosis group (no reaction 59% and 30% in the hypnosis and control groups, respectively; $P = .017$). Postoperatively, the mean numerical verbal scale score for perioperative anxiety was significantly lower in the hypnosis group (5.2 [2.8] vs 6.7 [2.6]; $P = .012$). Other measured endpoints did not differ between the groups (Table 4).

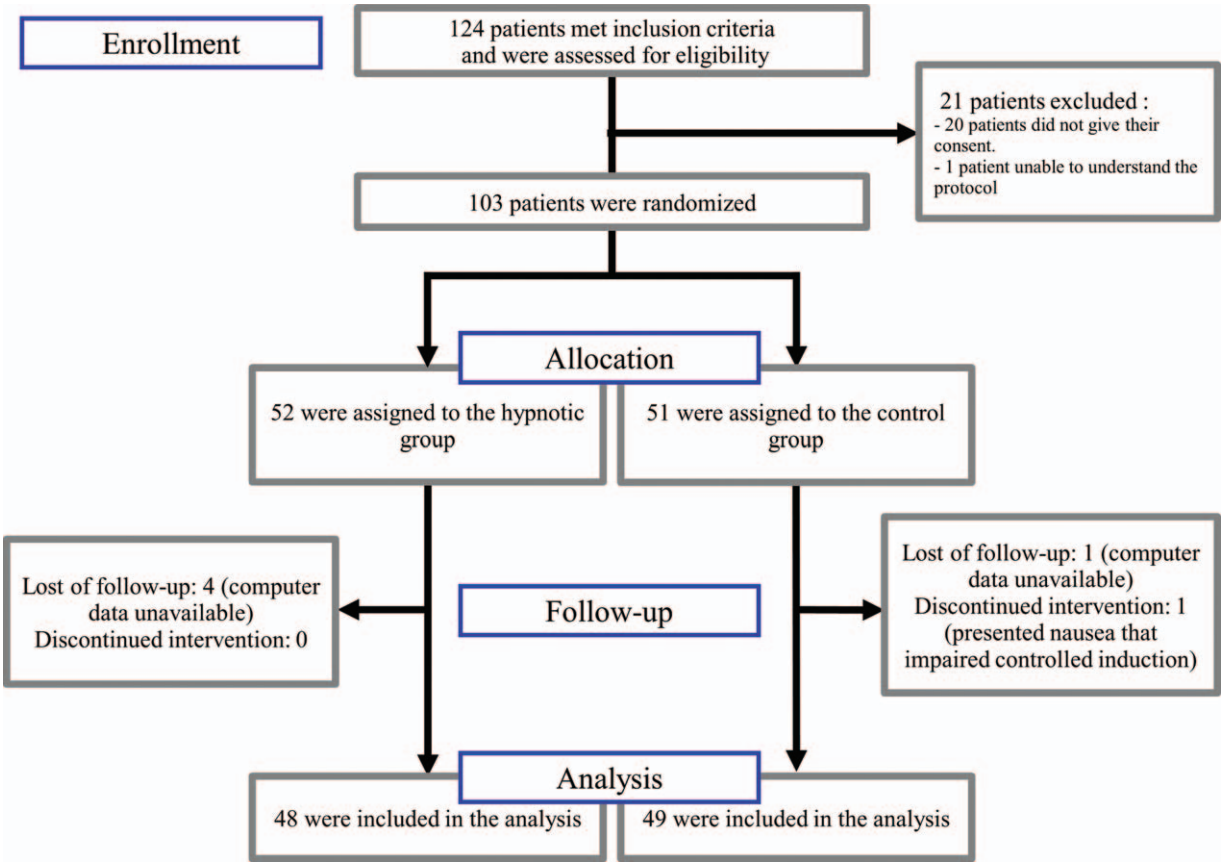


**Figure 1.** Study flow chart.

**Table 1**

**Demographic data.**

| | Hypnosis group (n = 48) | | | Control group (n = 49) | | |
|---|---|---|---|---|---|---|
| | | | Missing values | | | Missing values |
| Age (mean, [min–max]) | 46 | [20–90] | — | 46 | [19–78] | — |
| Women (n) | 43 | 90% | — | 43 | 88% | — |
| Weight, kg | 66.6 | 14 | — | 67.3 | 12.2 | — |
| Height, cm | 165 | 7.3 | — | 165 | 7.9 | — |
| Body mass index, kg/m$^2$ | 24.3 | 4.6 | — | 24.6 | 4 | — |
| ASA score (n) | | | 1 | | | 1 |
| 1 | 35 | 74% | | 35 | 73% | |
| 2 | 10 | 21% | | 10 | 21% | |
| 3 | 2 | 4% | | 3 | 6% | |
| Chronic hypertension (n) | 8 | 17% | 1 | 6 | 13% | 1 |
| Diabetes mellitus type 2 (n) | 2 | 6% | 12 | 0 | 0% | 4 |
| Cancer (n) | 1 | 2% | 2 | 0 | 0% | 1 |
| Type of surgery (n) | | | — | | | — |
| Gynecological | 41 | 85% | | 40 | 82% | |
| Breast | 1 | 2% | | 1 | 2% | |
| Digestive | 6 | 13% | | 8 | 16% | |
| Coelioscopic surgery | 4 | 8% | | 4 | 8% | |
| Moment of surgery (n) | | | — | | | — |
| Morning | 21 | 44% | | 23 | 48% | |
| Afternoon | 27 | 56% | | 26 | 53% | |
| Prerandomization Covi scale (0–12) | 1.4 | 1.6 | 4 | 1.4 | 1.9 | 4 |
| Duration of surgery, min | 81 | 44 | — | 64 | 30 | — |

Data are given in mean and standard deviation or frequencies and percentage, unless otherwise stated.
ASA = American Society of Anesthesiology.

**Table 2**

**Characteristics of the hypnotic session.**

| | | | Missing values |
|---|---|---|---|
| Caregiver's assessment of the session (n) | | | 6 |
| −1: incident | 2 | 5% | |
| 1: without incident | 2 | 5% | |
| 2: quality acceptable | 11 | 26% | |
| 3: good quality | 27 | 64% | |
| Patient being considered as receptive (n) | | | 6 |
| Yes | 33 | 79% | |
| No | 9 | 21% | |
| Speed of focalization (n) | | | 5 |
| Very fast | 11 | 26% | |
| Fast | 20 | 47% | |
| Medium | 4 | 9% | |
| Delayed | 0 | 0% | |
| Impossible to obtain | 8 | 19% | |
| Quality of focalization (n) | | | 7 |
| Very deep | 4 | 10% | |
| Deep | 13 | 32% | |
| Medium | 14 | 34% | |
| Superficial | 1 | 2% | |
| Not obtained | 9 | 22% | |
| Postoperatively, does the patient remember successfully focalizing? (n) | | | 3 |
| Yes | 31 | 69% | |
| No | 14 | 31% | |

Data are given in frequencies and percentage.

## 4. Discussion

This randomized controlled trial assessed the effect of a hypnosis intervention on propofol consumption during the induction of general anesthesia. We used an automated closed-loop system guided by the BIS, which has been validated for routine care.[10] We did not observe a difference in propofol consumption after a conversational hypnotic session compared to standard care under randomized and controlled conditions.

Hypnosis is increasingly being used in all aspects of perioperative management.[14] For many years, hypnosis was limited to very specific interventions and used by few anesthetists.[11] The techniques used have been diversified, and the interest of caregivers has increased.[4] In this context, it appears essential to evaluate the benefit of these techniques using randomized controlled unbiased studies. The effect of hypnosis on pain and anxiety has been established by randomized trials during the perioperative period, and the results highlight a measurable and reproductive beneficial effect.[15–17] Our study focused on the induction period and tested hypnosis as a potential agonist for general anesthesia induction and not only to counteract a negative sensation (pain or anxiety). Our study failed to show any effect on propofol consumption. Because our automated tool adapts propofol administration to the BIS signal,[10] our hypothesis implies that our intervention affects cortical electrical activity during or before induction. A potential reduction of the administered propofol dose is a consequence of this effect. As previously said, electro-encephalographic data regarding hypnosis are complex. Because no difference was observed in our primary endpoint, another option would be to study the electroencephalogram or the BIS (decay rate, kinetics); however, such a study would require a different study. Nevertheless, we believe that our approach with an automated drug administration tool eliminates many forms of bias.

As expected from previous studies,[18] our intervention resulted in a difference in the reaction to painful stimuli before induction

**Table 3**

**Primary and secondary endpoints.**

| | Hypnosis group (n = 48) | | | Control group (n = 49) | | | |
|---|---|---|---|---|---|---|---|
| | | | Missing values | | | Missing values | *P* |
| Primary endpoint | | | | | | | |
| Propofol dose required to obtain the induction of anesthesia (BIS < 60 for at least 30 s) | | | | | | | |
| mg | 138.6 | 67.5 | 0 | 130 | 47.9 | 0 | .47 |
| mg/kg | 2.15 | 1.09 | 0 | 1.95 | 0.66 | 0 | .28 |
| Secondary endpoints | | | | | | | |
| Calculated target plasma concentration corresponding to induction of anesthesia (BIS < 60 for at least 30 s) | | | | | | | |
| μg/mL | 5.501 | 3.005 | 2 | 5.904 | 2.617 | 2 | .49 |
| Arm movement during propofol injection (n) | | | 3 | | | 2 | .004 |
| No | 44 | 98% | | 35 | 74% | | |
| Withdrawal | 0 | 0% | | 10 | 21% | | |
| Violent withdrawal | 1 | 2% | | 2 | 4% | | |
| Face reaction during propofol injection (n) | | | 3 | | | 2 | .14 |
| No | 29 | 64% | | 21 | 45% | | |
| Frown | 9 | 20% | | 12 | 26% | | |
| Grimace | 7 | 16% | | 14 | 30% | | |
| Hemodynamic status before induction | | | | | | | |
| Heart rate, bpm | 77 | 12 | 1 | 73 | 12 | 3 | .16 |
| Systolic blood pressure, mm Hg | 136 | 21 | 1 | 142 | 27 | 4 | .053 |
| Diastolic blood pressure, mm Hg | 78 | 11 | 1 | 76 | 12 | 4 | .44 |
| Patient's assessment of the period before anesthesia on a 4-point scale (n) | | | 5 | | | 2 | .61 |
| −1: Did not go well | 0 | 0% | | 1 | 2% | | |
| 1: Went normally | 5 | 12% | | 3 | 6% | | |
| 2: Went well | 16 | 37% | | 16 | 34% | | |
| 3: Went very well | 22 | 51% | | 27 | 57% | | |

Data are given in mean and standard deviation or frequencies and percentage, unless otherwise stated.
BIS = bispectral index.

**Table 4**

**Other outcomes.**

| | Hypnosis group (n = 48) | | | Placebo group (n = 49) | | | |
|---|---|---|---|---|---|---|---|
| | | | Missing values | | | Missing values | *P* |
| Arm movement during venous access placement (n) | | | 2 | | | 2 | .18 |
| No | 45 | 98% | | 43 | 91% | | |
| Withdrawal | 1 | 2% | | 4 | 9% | | |
| Face reaction during venous access placement (n) | | | 2 | | | 2 | .017 |
| No | 27 | 59% | | 14 | 30% | | |
| Frown | 12 | 26% | | 23 | 49% | | |
| Grimace | 7 | 15% | | 10 | 21% | | |
| BIS before preoxygenation (signal, 0–100) | 96 | 3.1 | 6 | 97 | 2.2 | 2 | .75 |
| BIS before propofol (signal, 0–100) | 94 | 4.6 | 7 | 96 | 4.4 | 1 | .07 |
| Delta BIS (signal, 0–100) | 1.6 | 4.3 | 7 | 1 | 3.5 | 2 | .48 |
| Propofol (mg) for BIS = 50 | 133.8 | 68.2 | 6 | 130.8 | 43.6 | 4 | .49 |
| Propofol (mg/kg) for BIS = 50 | 2.036 | 0.937 | 6 | 1.971 | 0.616 | 4 | .51 |
| Ephedrine injection during induction (n) | | | 1 | | | 1 | .84 |
| No | 38 | 81% | | 37 | 77% | | |
| Yes | 9 | 19% | | 11 | 23% | | |
| Postoperatively, numerical verbal scale | | | | | | | |
| For propofol injection pain (0–10) | 2.3 | 3 | 4 | 3.2 | 3.2 | 2 | .21 |
| Postoperatively, numerical verbal scale | | | | | | | |
| For perioperative anxiety (0–10) | 5.2 | 2.8 | 4 | 6.7 | 2.6 | 2 | .012 |

Data are given in mean and standard deviation or frequencies and percentage.
BIS = bispectral index.

(during peripheral vein catheterization and the initial injection of propofol) and for overall perioperative anxiety. Our negative finding regarding the primary endpoint might be explained by the inherent limitations of the study outlined here. Firstly, the hypnotic technique assessed in this study was not deep hypnosis, but that achieved during a conversational session. Dialogue is oriented on directing patient attention using therapeutic communication, avoiding the use of too much information and choosing the words used very carefully. Compared with previous studies, there was not a dedicated extra-caregiver for hypnosis in the intervention group. One anesthetist and 1 anesthetic nurse were in charge of the patient in each group for hypnosis and anesthetic care or for anesthetic care only. Indeed, our goal was to study the actual conditions of support for the potential spread of our intervention using constant human resources. Secondly, the population included in our study was not representative of the general population. For reasons regarding the study design and its single-center character, patient enrolment occurred predominantly in gynecological surgery, resulting in a very low male-to-female ratio. This limit, however, is relative, and previous positive studies on hypnosis were also studied in specific populations. Thirdly and as previously described,[19,20] there is a wide range of suggestibility in the general population. Our data support this finding because 21% of our patients were considered nonreceptive by the caregiver in charge of the hypnotic session. Using an additional indicator to select a patient subgroup a priori might homogenize the quality of hypnosis and give more power to our study. Finally, propofol was used without lidocaine, although lidocaine can reduce pain during injection.[13] Hypothetically, the lack of an observed effect might have been due to a loss of focus and hypnotic state during this painful stimulus and before induction, thus "resetting" the patient, as suggested by the reactions observed during injection in some patients.

Our study failed to demonstrate a decrease in propofol consumption during the induction of general anesthesia, as performed using an automated-tool closed-loop technique after a conversational hypnotic session. A reduction in reactions to preanesthetic painful stimuli and anxiety was nevertheless noted. Our methodology appears promising for the future evaluation of anesthesia-related hypnosis techniques. Further studies are necessary to evaluate the extent of the effects of hypnosis in the perioperative field.

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