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Therapy area: Other

Evaluation of virtual reality combining music and a hypnosis session to reduce anxiety before hand surgery under axillary plexus block: A prospective study

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Abstract

Aims: Preoperative anxiety, which can affect postoperative recovery, is often present in patients undergoing surgery under loco-regional anaesthesia (LRA). Minimising preoperative anxiety with premedication can be effective but results in drug-related side effects. Therefore, the use of non-pharmacological techniques should be encouraged.

Methods: We evaluated whether a virtual reality (VR) incorporating music and a hypnosis session, provided during the performance of LRA, can reduce preoperative anxiety. Fifty patients scheduled for elective hand surgery under an axillary plexus block were enrolled (March-June 2019). The primary outcome measure was the change in the Amsterdam Anxiety and Preoperative Information Scale (APAIS) questionnaire 5 min after the VR session as compared to before the VR session. The secondary outcome measures were the visual analog scale (VAS) for anxiety before and 2 h after the surgery and the Evaluation du Vécu de l'ANesthésie—LocoRégionale (EVAN-LR) satisfaction score.

Results: Data from 48 patients were analysed. The APAIS score as well as VAS for anxiety were significantly reduced after a VR session ($p < .001$ for both scores). Patients were very satisfied (EVAN-LR: 92 (88, 94)).

Conclusions: The use of VR incorporating music and a hypnosis session could be an effective tool in the management of a patient's preoperative anxiety during the performance of an axillary plexus block.

1 | INTRODUCTION

Anxiety is often present in patients undergoing surgical procedures and can affect their postoperative recovery and per-operative experience. Indeed, preoperative anxiety can influence the severity of postoperative acute pain, analgesia requirements and the development of chronic pain. It can moreover result in postoperative complications.[1-3] Anxiety can occur due to fear for anaesthesia, for surgery, but also due to concerns about possible discomfort and pain as well as related health problems that have necessitated surgery.[4,5] Up to 85% of day surgery patients can present a high level of preoperative anxiety.[1] Anxiety may even increase in specific cases such as during the performance of loco-regional anaesthesia (LRA).[1,6] It may therefore be difficult for some patients to tolerate the performance of the LRA block and to undergo surgery under LRA. Moreover, it has been shown that anxiety level before axillary brachial plexus can impact the success rate of the block.[7] Minimising preoperative anxiety is therefore an important goal for anesthesiologists. Premedication can be effective in reducing anxiety but the desire to avoid drug-related side effects, particularly in the context

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of day surgery as well as the increasing popularity of complementary medicine has led to the development of new non-pharmacological anxiolytic techniques such as music therapy and hypnosis. Both techniques have demonstrated their effectiveness in reducing preoperative anxiety.[1,8] Additionally, the use of the virtual reality (VR) technique combined with relaxant music allows complete immersion in a three-dimensional artificial environment. VR shows distracting effects and has been therefore shown to be highly effective in reducing pain and anxiety in adult and paediatric patients treated for burn injuries.[9,10] More recently, hypnosis has been introduced in these VR devices allowing patients to benefit simultaneously from VR and hypnotic sessions in addition to relaxant music. To date, no studies have investigated the efficacy of combining VR with a hypnotic session and music in a population of patients undergoing surgery under LRA. The purpose of this study was to investigate the anxiolytic effect of a VR session combined with hypnosis and music delivered to day surgery patients during the performance of an axillary plexus block for hand surgery.

What's known

Premedication can reduce preoperative anxiety with drug-related side effects.

What's new

A virtual reality incorporating music and a hypnosis session can reduce preoperative anxiety.

2 | MATERIALS AND METHODS

The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of Cliniques universitaires Saint-Luc, Brussels, Belgium (Chairperson Prof J.-M Maloteaux, approved this study) on July 20, 2016 (2016/20JUL/345) and was registered prior to patient enrollment (Trial Registration Clinical Trial gov.NC T03905915).

Written informed consent to participate in the study was obtained for all subjects.

Patients ≥18 years scheduled for elective ambulatory hand surgery under axillary plexus block were prospectively included between March 2019 and June 2019. Patients were recruited during preoperative surgical or anaesthesia visit.

Exclusion criteria were chronic use of antidepressant, antipsychotic or pain relief treatment, patients who experienced hearing or visual difficulties, those who did not fluently speak French and patients who refused LRA.

Patients included in the study were treated in a dedicated outpatient surgery centre. At their arrival in the operating theatre, patients completed a baseline visual analog scale (VAS) for anxiety on a scale of 0–10 (0 = no anxiety;10 = very anxious) a baseline Amsterdam Anxiety and Preoperative Information Scale (APAIS) questionnaire [Appendix 1].[11,12] The APAIS questionnaire has been validated in French.[13] The APAIS is a self-assessment questionnaire containing 6 items. Each item is rated from 1 ("not at all") to 5 ("extremely"). Four items assess anxiety (the patient with a score ≥11 is considered to be very anxious), 2 items assess the desire for information (the patient with a score >8 is considered to be very anxious because there is a correlation between the need for information and anxiety). The score may range from 6 ("no anxiety") to 30 ("very anxious"). In addition to the desire for information, the 4 items assessing a global anxiety index are divided into two items assessing anxiety related to anaesthesia technique being APAIS-Anaesthesia (APAIS-A) and two assessing anxiety related to surgery being APAIS-Surgery (APAIS-S). For the purposes of this study, we separately analysed anxiety related to these two items.

Thirty minutes before the surgery, patients were taken in charge by a research nurse and were brought into a quiet room. Standard monitoring was used throughout the procedure (electrocardiogram, non-invasive blood pressure and pulse oximetry) and an intravenous access was established.

2.1 | Virtual reality combined with music and a hypnosis session

The VR device consisting of the Oncomfort ™AQUA module was offered to the patient after the insertion of the intravenous line. AQUA module is an immersive experience focused on inducing relaxation in an undersea environment (Figure 1). The VR device consists of a video headset displaying images and regular headphones playing sounds or music. Both elements are connected to a smartphone (Figure 2). The VR device provides a clinical hypnosis session with suggestions for progressive muscle relaxation and deep breathing for 15 min on a relaxing music background (integrated into the VR device). The patient experiences a feeling of real immersion through visual and auditory stimuli because the headset has sensors that can track the movements of the head giving the illusion of movement in a virtual space. The VR performs a kind of distraction technique.[14,15] A distraction technique redirects the mind far from the current emotion such as anxiety. When the attention is diverted, resources available for processing pain are reduced. The highly immersive nature of VR is allowed by the layout of the headset, which prevents the user from interacting outside the virtual environment, limiting unwanted visual or auditory signals.

Immediately after the start of the VR session, the axillary block was performed by an anesthesiologist experienced in performing VR under ultrasound guidance. None of the patients received any sedative medication and no complications during the execution of the axillary plexus were observed. The local anaesthesia protocol used was identical for all patients, i.e. a mixture of Ropivacaine 0.5% and Mepivacaine 1%, without adjuvant (for an injection not exceeding 4 mg/kg). The surgery was performed and 2 h after the surgery, patients were asked to complete the Evaluation du Vécu de

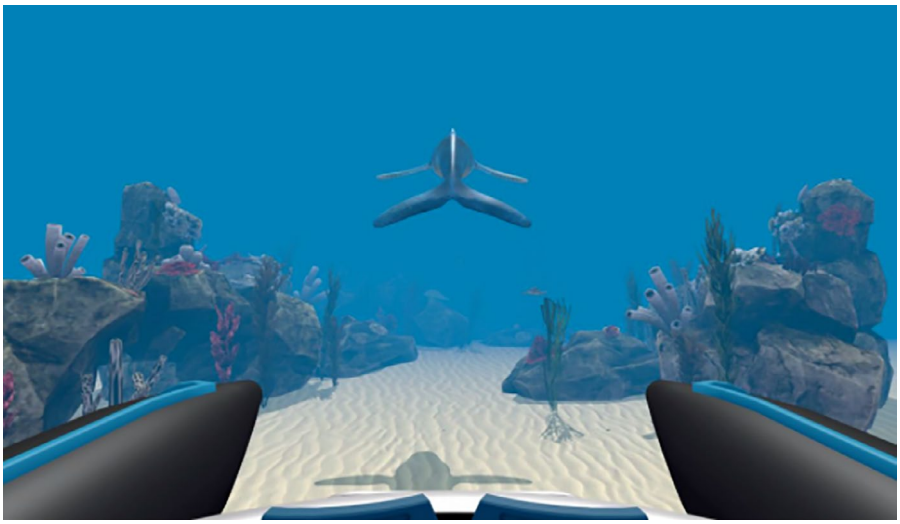

FIGURE 1 Undersea environement seen by the patient with the permission of Oncomfort

FIGURE 2 The VR device was composed of a visual headset and regular headphones, both connected to a smartphone

l'ANesthésie–LocoRégionale (EVAN-LR) questionnaire [Appendix 2]. EVAN-LR is a specific questionnaire validated in French language in order to assess patients' satisfaction in the perioperative period of an LRA technique.[16] The EVAN-LR questionnaire consists of 19 items structured into a global index and five dimensions: attention, information, discomfort, waiting and pain. Each element is rated from 1 ("not at all") to 5 ("extremely"). The score may range from 18 (unsatisfied) to 95 (very satisfied).

The primary outcome of this study was the change in the APAIS score 5 min after the VR session as compared to baseline. Secondary outcome measures were the evaluation of the change in Visual Analog Score for anxiety 5 min after the VR session and the EVAN-LR satisfaction score 2 h after the surgery. We also evaluated whether age and gender could influence the APAIS score.

2.2 | Statistical analysis

The Kolgomorov–Smirnov test was used to check the normality of the data. Continuous variables are expressed as median (Percentile 25, Percentile 75). Categorical variables are expressed as numbers

(%). The Wilcoxon signed-rank test was used to compare before and after treatment for continuous variables. A multiple linear regression analysis was performed with the enter method to analyse whether age and gender predicted baseline APAIS score. The predicted model was checked for validity. The power of the study was calculated based on an internal analysis performed before the start of the study and revealed a decrease in the mean APAIS score from 23 to 11 (SD = 0.9) by using the current VR technique. In order to answer the primary outcome, a minimum of 40 patients were required for a two-tailed $\alpha = 0.05$ and a power of 80%. We planned to include a total of 50 patients taking into account any eventual dropouts. A two-tailed $p < .05$ was considered statistically significant. All analyses were performed using IBM® SPSS® Statistics Version 25.

3 | RESULTS

3.1 | Analysis of the results

Figure 3 illustrates the study flowchart. A total of 91 patients were assessed for study eligibility of which 50 met the inclusion criteria and were enrolled in the study. Two patients were excluded from the final analysis after having been included. In one patient there were technical problems with the VR device. The second patient could not tolerate the device and described a visual intolerance with a feeling of oppression similar to claustrophobia. Data from the remaining 48 patients were further analysed. Demographic characteristics of the 48 patients are shown in Table 1. The axillary plexus block was successfully performed in all the patients.

As shown in Table 2 the total APAIS score was significantly reduced 5 min after a VR session [median (Percentile 25, Percentile 75)] [16 (11, 19) before VR session vs. 9 (6, 13) after VR session; $p < .001$]. This significant reduction was observed for the APAIS—anaesthesia ($p < .001$) as well as for the APAIS—surgery score ($p < .001$). Baseline APAIS-A scores were significantly lower compared to the APAIS-S scores ($p = .004$). The VR session significantly reduced the VAS score for anxiety [5 (4, 7) before VR session vs. 2 (1, 6) after VR session; $p < .001$]. Patients were highly satisfied as shown by the EVAN-LR score, which was 92 (88, 94).

The multiple linear regression analysis was performed on 48 data and included baseline APAIS as outcome variable and age and gender as predictors. There was a significant correlation between age and baseline APAIS score ($r = -0.418$, $p = .002$) and between gender and baseline APAIS score ($r = 0.152$, $p = .018$). The model was statistically significant as follows: $F(2, 45) = 4791$; $p = .013$. The adjusted r^2 was 0.176 indicating that only 17.6% of the variability of the APAIS score was explained by the predictors. The Variance Inflating Factor was 1.102 indicating that there was no collinearity among independent variables. The maximum Cook's Distance was 0.099 excluding the presence of too many outliers. The linearity assumption and the homoscedasticity assumption were valid. Gender was not predictive of baseline APAIS score (unstandardised Beta Coefficient: 0.287; $p = .853$). However, higher age was predictive of lower preoperative APAIS scores with unstandardised Beta Coefficient (95% Confidence Interval): −0.136 (−0.232, −0.041); $p = .006$.

4 | DISCUSSION

This study shows that a 15-minutes-lasting VR session incorporating music and a hypnosis session given during the performance of a

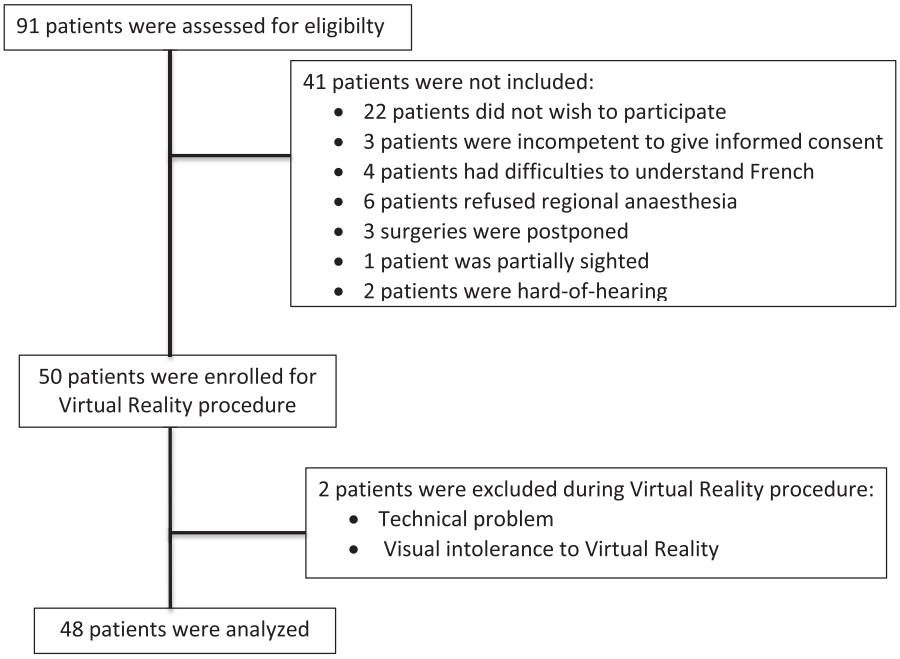

FIGURE 3 Flow diagram

TABLE 1 Baseline patients' characteristics

	N = 48
Age (years)	49 (19, 76)
Female gender	27 (56.3)
Body mass index	27 (23, 28)
Education at university	9 (18.7)
ASA 1	19 (39.6)
ASA 2	29 (60.7)
Any previous surgeries	10 (20.8)
History of alcohol consumption	5 (10.4)
Active smoker	11 (22.9)

Note: Values are presented as numbers (%) and median (Percentile 25, Percentile 75).

Abbreviation: ASA, American Society of Anesthesiologist score.

TABLE 2 Primary and secondary outcome variables

	Before VR session	After VR session	*p*
APAIS total	16 (11, 19)	9 (6,13)	<.001
APAIS-A	7 (4, 8)	3 (3, 5)	<.001
APAIS-S	8 (5, 12)	5 (3, 8)	<.001
VAS anxiety (0–10)	5 (4, 7)	2 (1, 6)	<.001

Note: Values are presented as median (Percentile 25, Percentile 75).

Abbreviations: APAIS, Amsterdam anxiety and preoperative information scale; APAIS-A, amsterdam anxiety and preoperative information scale for anaesthesia items; APAIS-S, amsterdam anxiety and preoperative information scale for surgery items; VAS, Visual Analog Scale 0–10, 0 = not anxious −10 = very anxious; VR, virtual reality.

plexus block for hand surgery significantly decreases the total APAIS score as well as both APAIS-A and APAIS-S scores. Moreover, VAS anxiety score was also significantly reduced. In addition, the LRA was successful in all patients, and the very high EVAN-LR scores collected during this study show that patients were highly satisfied with the proposed technique.

Several studies have shown that anxiety before surgery is very common. Anxiety needs to be identified routinely in order to implement effective interventions to reduce it and to avoid complications associated with its occurrence.[6,7,17] Fuzier et al. reported that in patients undergoing an axillary brachial plexus block performed with a nerve stimulator the level of anxiety before the performance of the block was a predictor of technique failure, especially in an emergency context.[7] Preoperative anxiety is often treated with pharmacologic agents such as midazolam,[18,19] hydroxyzine,[20] anti-hyperalgesia agents such as gabapentin[21] and clonidine.[22] These drugs may have delayed effects, particularly undesirable in the context of day surgery.[23] Therefore, recently researchers have used non-pharmacologic alternatives such as music therapy, hypnosis and VR with the aim to reduce preoperative anxiety.[8,24-26]

In this study, we used for the first time a combination of three methods (VR, hypnosis, music therapy) to reduce anxiety in patients undergoing surgery under LRA alone. Music therapy, hypnosis and VR alone have been each shown to be effective in reducing anxiety and pain.[8,24,26] However, the combined use of each of these three approaches may not always be feasible to show the expected effect. Cooke et al. showed that music significantly reduced the level of preoperative anxiety in patients undergoing day surgery.[27,28] However, a recent study comparing intravenous midazolam (1–2 mg) and noise-cancelling headphone delivering music prior to peripheral regional anaesthesia showed a similar change in the State Trait Anxiety Inventory-6 anxiety scores from after compared to before the procedure in addition to a higher satisfaction score in the midazolam group.[29] Nikolajsen et al. who compared audiovisual stimulation with music and nature sounds compared to control group (no intervention) during femoral nerve blocks found similar results. Pain and discomfort during placement of the block were not reduced by the audiovisual device, probably because many patients were distracted by sounds in the environment (alarms, conversation of staff members).[30] To avoid these inconveniences our patients were installed in a quiet room. Nevertheless, the conflicting results regarding the use of music in reducing anxiety highlight that music alone might not be consistently effective. Recently, VR therapy has extremely gained in popularity in the non-pharmacological treatment of anxiety-related disorders.[31] Indeed, a meta-analysis looking at the effectiveness of VR based interventions outperformed control conditions for anxiety and depression but did not improve treatment drop-out.[32] However, even if promising results have been brought by the use of VR in drug savings for pain and stress in general, its distractive effect has been studied only to a limited extent in the specific management of preoperative anxiety.[8,15,25,28] In addition, its use has not yet demonstrated sufficient potency on its own to completely avoid additional medication.[25,33]

The effectiveness of a hypnosis session has been evaluated in the preoperative period and has been shown to dramatically reduce anxiety in patients undergoing ambulatory surgery. Indeed, patients who received a preoperative hypnotic intervention (30 min) were significantly less anxious after the intervention as compared with patients who had received attentive listening and support or a standard care.[8] Moreover, upon entrance into the operating room, anxiety level decreased again by 56% in the hypnosis group whereas in the two other groups, anxiety level increased by 10%–47%. However, hypnosis is rarely used in the management of preoperative anxiety probably because of health professionals' lack of training and because it is time consuming.

Our study shows that VR, which simultaneously incorporates music and a hypnosis session, is very much effective in reducing anxiety in a surgical population and this without the need for any specific training. Anxiety in the perioperative period may result from different reasons and the same patient may perceive anxiety for surgery and anaesthesia differently. Aust et al.[17] proposed that these two aspects should be assessed separately. In our study baseline, APAIS-A scores were significantly lower compared to the APAIS-S

scores. Nevertheless, the VR session was very efficacious in reducing both scores highlighting that it can be used to reduce anxiety regardless of its relation to anaesthesia, to surgery or to a combination of both.

In our study younger patients showed a higher preoperative anxiety level. These results are in accordance with a literature review demonstrating that younger subjects are generally more anxious than older patients before an intervention.[34] We did not find any statistically significant difference in the level of preoperative anxiety according to the patient's gender. The literature review of 34 studies including 3754 patients concluded that women are more anxious than men but, very often, this difference is not statistically significant.[21,35,36]

To our knowledge, our study is the first to evaluate a device combining music, hypnosis and VR in decreasing preoperative anxiety. Several studies have shown the efficacy of anxiety management through hypnosis either with music or with VR, but not when the 3 techniques have been combined. One advantage of this device is that the included hypnosis session does not depend on the availability of a trained person. Moreover, the device is easy to be used by health care teams.

4.1 | Limitations

We considered the patients their own control group. The use of a control group would have been important if the anxiety profiles of the individuals in the study group and the individuals in the control group would have been comparable. Additionally, including a control group and thus possible randomisation would have caused additional stress before surgery and would have therefore biased the results. Indeed, as patients who consent to the study must be informed of its purpose, they will automatically know whether they will use the VR device or not, which might impact their apprehension level. Second, participants who elected to enrol in the study may have been self-selecting to be more likely to benefit from this type of anxiolysis. It is possible that some types of people respond better than others to non-pharmacologic therapy and our study does not differentiate who those people are. However, these patients may actually be the best candidates requiring preoperative anxiety therapy. Lastly, we did not accurately analyse changes in hemodynamic parameters (blood pressure, heart rate, respiratory rate) before and during the VR session. Therefore, we cannot conclude whether this technique influences these parameters.

5 | CONCLUSION

In conclusion, this study shows that the use of VR incorporating music and a hypnosis session could be an effective tool in the management of patient's preoperative anxiety during the performance of an axillary plexus block. In addition, patients were very satisfied with this technique. Future studies need to evaluate the effects of VR with hypnosis on postoperative outcomes.

DISCLOSURES

The authors have declared no conflicts of interest.

AUTHOR CONTRIBUTIONS

Conceptualization, N.T., A.P. and F.R. data curation M.M. All authors have read and agreed to the published version of the manuscript.

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APPENDIX 1

Amsterdam Preoperative Anxiety and Information Scale (APAIS): list of 6 items

Original items	French items
1 I am worried about anaesthesia	Je suis inquiet à propos de mon anesthésie
2 The anaesthesia is constantly on my mind	Je pense continuellement à mon anesthésie
3 I would like to know as much as possible about anaesthesia	Je désire savoir tout ce qui est possible à propos de mon anesthésie
4 I am worried about the procedure	Je suis inquiet(e) à propos de mon opération
5 The procedure is constantly on my mind	Je pense continuellement à mon opération
6 I would like to know as much as possible about the procedure	Je désire savoir tout ce qui est possible à propos de mon opération

Note From Maurice–Szamburski et al.[13] The APAIS is a 6 items self-assessment questionnaire. Each element is rated from 1 ("not at all") to 5 ("extremely"). Four items assess anxiety (the patient with a score ≥ 11 is considered to be very anxious), 2 items assess the desire for information (the patient with a score > 8 is considered to be very anxious because there is a correlation between the need for information and anxiety). The score may range from 6 ("no anxiety") to 30 ("very anxious").

APPENDIX 2

Evaluation du Vécu de l'Anesthésie-LocoRégionale (EVAN-LR) questionnaire

French items	Item general meaning
Avant l'opération, lors des visites avec l'anesthésite	*During the preoperative visits with the anaesthetist*
1. J'ai reçu de l'information sur ce qui allait se passer	1. I received information about what was going to happen
2. J'ai pu poser les questions que je voulais	2. I was able to ask questions I wanted
3. Je me suis senti rassuré, détendu, mis en confiance	3. I felt reassured, relaxed, confident
Avant l'opération, lors des visites avec le chirurgien	*During the preoperative visits with the surgeon*
4. J'ai reçu de l'information sur ce qui allait se passer	4. I received information about what was going to happen
5. Je me suis senti rassuré, détendu, mis en confiance	5. I felt reassured, relaxed, confident
6. Le chirurgien a été attentionné	6. The surgeon was attentive
Des premières consultations jusqu'à la descente au bloc	*From the first visit until I entered the operating room*
7. Mon intimité a été respectée	7. My privacy was respected
A l'arrivée au bloc	*When entering the operating room*
8. J'ai été gêné dans mon confort: froid, chaud, mal	8. I felt uncomfortable: cold, warm, badly
A l'arrivée au bloc	*Postured on the operating table*
9. Mon intimité a été respectée	9. My privacy was respected
10. Les médecins ont été attentionnés	10. The medical staff was attentive
En salle de réveil	*In the recovery room*
11. J'ai ressenti des sensations désagréables comme: soif, faim nausées, vomissements, maux de tête	11. I had unpleasant feelings such as: thirst, hunger nausea, headache
12. J'ai été gêné dans mon confort: froid, chaud, mal	12. I felt uncomfortable: cold, warm, badly
Installé dans le lit	*In the recovery room*
9. Mon intimité a été respectée	11. I had unpleasant feelings such as: thirst, hunger nausea, headache
10. Les médecins ont été attentionnés	12. I felt uncomfortable: cold, warm, badly
13. J'ai eu mal	*Postured on the bed*
14. J'ai eu un réveil agréable	13. I had pain
15. Les médecins et le personnel soignant ont été attentionnés	14. I had a pleasant awakening
Depuis mon retour dans le service	15. The medical and nursing staff were attentive
16. J'ai ressenti des sensations désagréables comme: soif, faim, nausées, vomissements, maux de tête	16. I had unpleasant feelings such as: thirst, hunger nausea, headache
17. J'ai été gêné dans mon confort: froid, chaud, mal	17. I felt uncomfortable: cold, warm, badly
Installé sur le lit	*Postured on the bed*
18. J'ai eu des difficultés à effectuer les gestes de la vie quotidienne communiquer, se laver, aller aux toilettes	18. I had difficulty achieving everyday tasks
19. J'ai eu mal	19. I had pain
20. J'ai été soulagé de ma douleur	20. I was relieved of my pain
21. Les médecins ont été attentionnés	21. The medical staff was attentive
22. Le personnel soignant a été attentionné	22. The nursing staff was attentive
23. Mon intimité a été respectée	23. My privacy was respected
Globalement depuis la première consultation jusqu'à ce jour	*Overall, since my first visit until today*
24. J'ai pu voir mon entourage (famille, amis)	24. I was able to meet my family or friends
Les délais d'attente m'ont paru anormalement élévés	*Waiting times in the hospital seemed too long*
25. Pour avoir un rendez-vous avec l'anesthésiste ou le chirurgien	25. To obtain an appointment with the anaesthetist or surgeon
26. Lors des consultations avant l'opération	26. During the preoperative visits

Note From Maurice-Szamburski A et al.[16] The EVAN-LR consists of 19 items, structured into a global index and five dimensions: attention, information, discomfort, waiting and pain. Each element is rated from 1 ("not at all") to 5 ("extremely"). The score may range from 18 (dissatisfied) to 95 (very satisfied).