



Original Article

Impact of hypnosis on patient experience after venous access port implantation



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ARTICLE INFO

Article history:

Available online 1 March 2019

ABSTRACT

Introduction: Hypnosis has been reported to decrease pain and anxiety in surgical context, but data studying its impact on patient experience using a validated scale are scarce. In the present study, we assessed the effect of an audio hypnosis session on patient satisfaction during venous access port implantation under local anaesthesia in adult cancer patients using the EVAN-LR Score.

Methods: After informed consent, patients were randomised to receive either hypnosis or standard care. The hypnosis group listened to a 26 minutes recorded audio hypnosis session through the ongoing implantation procedure.

The primary outcome was the result of the EVAN-LR questionnaire, assessing perioperative experience in patients undergoing anaesthesia without loss of consciousness. This score describes a global index and 5 dimensions of experience: comfort, pain attention, information and waiting. It is scaled from 0 to 100 with 100 indicating the best possible level of satisfaction. Secondary outcomes included patient's anxiety, heart rate before and after procedure, procedure duration and several Visual Analogic Scale to match EVAN-LR dimensions.

Results: Overall, 148 patients were enrolled in the study. The global index of Evan-LR was significantly higher in the hypnosis session group (78 ± 14) compared to the standard care group (71 ± 17) ($P = 0.006$). No difference was reported in secondary outcomes.

Conclusion: A recorded audio hypnosis session during subcutaneous venous port implantation under local anaesthesia in cancer patients significantly improved patient satisfaction.

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1. Introduction

Hypnosis is a non-pharmacological sedation technique that could improve patient experience in the perioperative period.

Hypnosis is usually delivered through a one to one session between the patient and a dedicated caregiver [1]. However, a complete “live” session is time consuming and the spread of such an approach in the perioperative field remains limited [2]. Hypnosis reported beneficial effects in terms of pain, anxiety and drug consumption in the perioperative period [3,4,5,6,7]. But, to date, no

study has assessed the impact of hypnosis on patient experience using a validated scale.

The implantation of a subcutaneous central venous access port such as “Port-A-Cath[®]” is a medical procedure usually performed in cancer patients treated with chemotherapy. This procedure can be performed under local anaesthesia alone or combined with monitored sedation.

We hypothesised that an audio-recorded hypnosis session could improve the perioperative patient experience compared to local anaesthesia alone using the EVAN-LR Score (primary end point).

The HYPNOPAC study is the first randomised trial assessing the impact of a recorded hypnosis session on cancer patients undergoing invasive medical procedure using a validated patient experience and satisfaction scale.

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2. Methods

2.1. Study oversight

The Hypnopac study was funded by Gustave-Roussy Institute (Villejuif, France). The study protocol and the statistical analysis were approved by the Kremlin-Bicêtre ethical committee CCPRB (project number: SC15-016) le Kremlin-Bicêtre France.

2.2. Patients

Patients were enrolled between January 2016 and April 2016 at Gustave-Roussy Institute. They received oral information during the preoperative anaesthesia consultation and gave their written consent at hospital admission.

All consecutive patients scheduled for a subcutaneous central venous access port implantation were screened for study enrolment using the following eligibility criteria: patients over 18 years old admitted in ambulatory care settings, able to fill in a self-report questionnaire and presenting no contraindication to local anaesthesia.

Non-inclusion criteria were:

- an emergency context;
- patients hospitalised in a medical or surgical ward before and/or after the procedure;
- patients with cognitive impairment, medical history of drug abuse, coagulopathy;
- patients under guardianship, or curatorship;
- patients not speaking French fluently and procedures necessitating general anaesthesia or sedation.

2.3. Study design

The hypnosis session was recorded using an audio-holophonic 3D technique. The script was written by a hypnosis specialised physician and read by a trained psychologist. The holophonic 3D technique allowed a virtual spatial movement of the vocal source increasing patient immersion.

It contained a set of non-specific and permissive suggestions including information on the goal of the procedure, focus on breathing, corporal sensations and projection to a pleasant and secured place followed by dissociation, hypnotic suggestion and return. The session was calibrated to last for 26 minutes, according to a preliminary study that determined the mean venous access port implantation duration of performed by a senior staff anaesthesiologist in our department. The procedure was performed under local anaesthesia without any pharmacological sedation in all patients.

The hypnosis session was started before the procedure and the headset was removed at the end of it, even if the hypnosis session was not terminated.

2.4. Treatment protocol and data collection

All patients received written information on the study protocol during the preoperative anaesthesia consultation, at least 48 hours before the venous access port implantation. This ensured a sufficient time for the patients to understand the study protocol prior to give their consent to participate in the study. All participants provided written informed consent the day before surgery.

Patients were randomly assigned the day of hospital admission to receive the audio-recorded hypnosis session or the standard care without sedation. All procedures were scheduled in an ambulatory care setting.

A visual analogic scale (VAS) for anxiety was reported by the patient before being transferred to the operating room and the heart rate was reported by a nurse.

Subcutaneous venous access port implantation was performed by a staff anaesthesiologist using ultra-sonographic and fluoroscopic guidance for all patients [8].

After patient installation and cutaneous disinfection, the recorded hypnosis session was played through noise cancelling headphones (Bose® helmet) and the local anaesthesia was performed. The length of the procedure was reported. Physician comfort about procedure conditions was assessed using a numerical scale ranging from 0, least possible comfort, to 3, best possible comfort.

After the procedure, patients were monitored in post anaesthesia care unit for at least one hour according to the French care recommendations and then patients could rest in the ambulatory care setting. The EVAN-LR Questionnaire was self-reported, four hours after the end of the procedure. An anxiety VAS was reported at the same time as well as a numerical satisfaction scale ranging from 0, worst satisfaction, to 10, better possible satisfaction.

2.5. Study outcomes

The primary outcome was the EVAN-LR (*Evaluation du Vécu de l'Anesthésie Loco-Régionale*) patient satisfaction global index evaluated four hours after the procedure. The EVAN-LR is a multidimensional self-reported questionnaire, validated to evaluate the patient experience and satisfaction after a procedure performed under local or regional anaesthesia without conscious loss [9]. The EVAN-LR is a 19 items scale based on expectation theory, structured in a global index and five dimensions of perioperative experience: comfort pain attention, information, and waiting time. This score ranges from 0 (worst possible experience), to 100 (best possible experience). A score was obtained for each dimension by computing the mean of the item scores for the dimension.

Secondary outcomes were patient anxiety, heart rate before and after procedure, procedure duration and physician comfort.

2.6. Statistical analysis

A preliminary study was performed to calculate the number of patients to enrol in the study. We determined that 148 patients were necessary for a minimal clinically significant difference of 5 points on the global EVAN-LR score with a power at 80% and a bilateral risk alpha at 5% as previously described [10].

Analysis was performed on an intention-to-treat approach. The R studio software Version 0.99.489 was used for the statistical analysis.

Randomisation was performed online by the Tenalea® software.

Stratification was done according to the gender and the cancer type (lungs, breast, gastrointestinal, gynaecological and other).

A *t*-student parametric test has been used to compare the means of global index, the different dimensions' scores, the duration of the procedure, the heart rates, the VAS of anxiety and the VAS of satisfaction. The anaesthesiologist's comfort numerical scale (NS) has been analysed by a Fisher exact test.

A 2-sided *P*-value of less than .05 was considered significant.

3. Results

3.1. Patient population

Thirty-one out of 190 informed patients declined enrolment in the study. Most of these patients were afraid of hypnosis ($n = 24$, 77%) (Fig. 1).

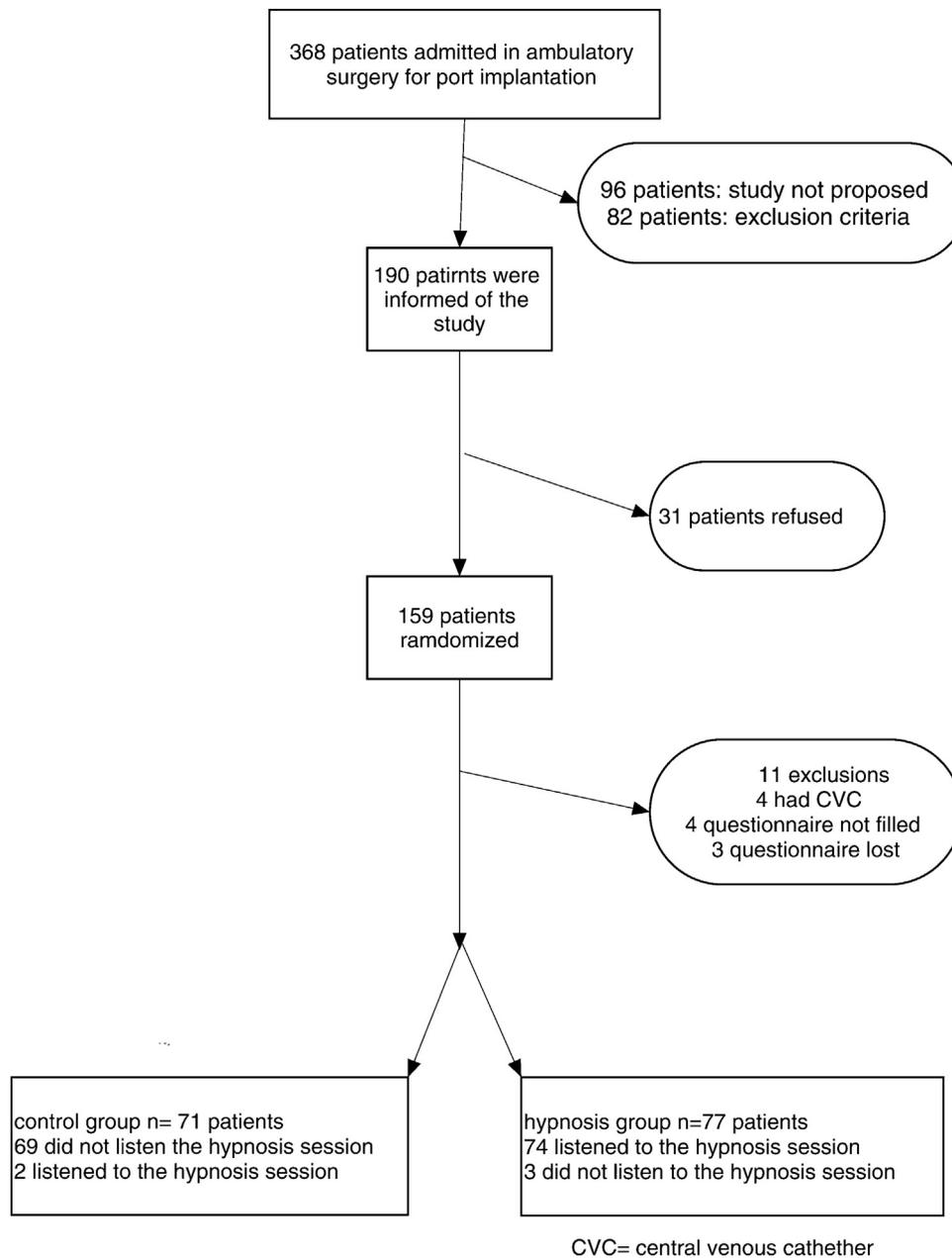


Fig. 1. Flowchart.

A total of 159 patients were randomized in the HYPNOPAC study between January 2016 and April 2016 at Gustave-Roussy Institute (Fig. 1). The baseline patients' characteristics are shown in Table 1.

3.2. Primary outcome

The EVAN-LR mean global index was significantly higher in the hypnosis session group (78 ± 14) than in the standard care group (71 ± 17) ($P = 0.006$).

Scores obtained for the comfort and the pain dimensions of the EVAN-LR scale were significantly higher in the hypnosis group than in the standard care group (respectively 83 ± 19.7 vs. 78 ± 20 ; $P < 0.05$ and 82 ± 23 vs. 74 ± 25 ; $P < 0.05$).

3.3. Secondary outcomes

The statistical analysis found no significant difference in the other dimensions (information, attention, waiting time). There was no difference in procedure duration, anaesthesiologist's comfort, heart rate variation, VAS of anxiety after the procedure and NS of global satisfaction. (Table 2 and 3).

4. Discussion

Perioperative experience is an important outcome for patient undergoing surgery or invasive medical procedure [3,11] When these procedures are performed without loss of consciousness,

Table 1
Demographic and Baseline patients characteristics.

	Control Group (n = 71)	Hypnosis Group (n = 77)	All (n = 148)
Age			
Mean ± SD	57.3 ± 14.1	61 ± 13	59.4 ± 13.7
Sex Female n (%)	44 (62)	49 (63)	93 (63)
Cancer			
Gastroenterology or gynaecological n (%)	24 (34)	23 (29)	47 (32)
Lung n (%)	9 (13)	9 (12)	18 (12)
Breast n (%)	8 (11)	9 (12)	17 (11)
Other n (%)	30 (42)	36 (47)	66 (45)
VAS ANX before			
Mean ± SD	4 ± 3	4 ± 2	4 ± 3
HR before			
Mean ± SD	82 ± 16	80 ± 15	81 ± 16

VAS ANX: visual analogue scale of anxiety, HR: heart rate.

Table 2
Results of the different EVAN-LR Scale dimensions.

Dimension, mean ± SD	Control group (n=71)	Hypnosis group (n = 77)	All (n = 148)	P
Comfort	78 ± 20	88 ± 17	83 ± 19	0.002
Pain	74 ± 25	89 ± 17	82 ± 23	< 0.001
Attention	78 ± 24	79 ± 20	79 ± 22	0.84
Information	65 ± 22	68 ± 20	66 ± 21	0.34
Waiting	59 ± 28	66 ± 31	63 ± 30	0.12

Table 3
Secondary outcomes analyses.

	Control Group (n = 71)	Hypnosis Group (n = 77)	All (n = 148)	P
Procedure duration (minutes)				
Mean ± SD	25.4 ± 11.4	24.3 ± 10.3	24.9 ± 10.9	0.55
Anesthesiologist's comfort				0.61
NS 1 n (%)	53 (75%)	60 (78%)	113 (76%)	
NS 2 n (%)	15 (21%)	16 (21%)	31 (21%)	
NS 3 n (%)	3 (4%)	1 (1%)	4 (3%)	
HR difference (before-after the procedure)				0.46
median (Q1,Q3)	5 (−0.2, 5)	2 (−3, 5)	3 (−1, 7)	
VAS anxiety difference (before-after the procedure)/10				0.35
Mean ± SD	2 ± 2.7	2.3 ± 2.8	2.5 ± 2.8	
NS satisfaction/10				0.64
Mean ± SD	8.5 ± 1.6	8.4 ± 1.8	8.4 ± 1.7	

NS: numeric scale. 1 = good. Patient calm, motionless. 2 = a little agitated. 3 = very uncomfortable, patient agitated; HR: heart rate; VAS: visual analogic scale; Q: quartile.

patient conditioning and comfort become a cornerstone of the process [12]. An anxious, restless, or simply uncomfortable patient can make general anaesthesia or monitored sedation necessary and might leads to side effects in an ambulatory setting [13]. Hypnosis has already showed promising results but a validated scale [3,6] has never assessed its benefit.

This study is the first to report an encouraging improvement in patients experience and comfort using a recorded hypnosis session by using a validated scale.

Indeed, in this initial context of a cancer disease hypnosis offered a change of perception with increased comfort and control of pain, which is very positive at this specific moment, as was a recent investigation on postoperative pain after breast cancer surgery [14].

Therefore, if this inaugural procedure goes well (Port-A-Cath implantation), it decreases the phenomena of trauma perception and awareness, suggesting that the following procedures may follow smoothly. Cancer is more and more considered as chronic disease in which invasive procedures (diagnostic, curative, palliative, reconstructive, etc.) are expanding, and the patient's

adhesion is a major issue for further management avoiding potential interruption in care [9].

The EVAN-LR Scale is the regional anaesthesia version of the EVAN-G scale. EVAN-LR is a tool assessing five domains of patients' perception of the perioperative period surrounding regional anaesthesia. Discrimination ability of EVAN-LR addresses the whole care process from the preoperative visit to the postoperative period after anaesthesia performed without loss of consciousness. It contains several items suggested to assess the intraoperative period and therefore was retained as the primary outcome of the present study. The global index of EVAN-LR was higher in the hypnosis session group than in the standard care group: 78 ± 14 versus 71.2 ± 17 (*P*: 0.006). An EVAN-LR global index difference of 5 points was considered the minimal clinically important difference [10]. Two of the five dimensions (comfort and pain) of the EVAN-LR scale were also significantly higher in the hypnosis group than in the control group. These results are in accordance with previous studies [5,6].

No difference was found between groups in terms of procedure duration or anaesthesiologist's comfort.

We also acknowledge that the HYPNOPAC study has several limitations. First, it was a mono-centric study. Hypnosis, even if performed through a recorded session needs to be implemented. Due to scarcity of data, hypnosis performed in operative rooms remains limited [5]. In our centre, hypnosis belongs to usual care as most of the anaesthesiologists and nurse anaesthetists can perform it on special demand by the patients. We are aware that the applicability of a 26 min recording could be questioned for anaesthesia residents or seniors not used to the procedure as the duration of the procedure can be prolonged, however a longer version of the recording can easily be adapted for this purpose, which would probably not significantly affect the results.

Second, it was an open study. The treatment group consisted in a visible headset with an mp3 device. A recorded approach was chosen instead of a live hypnosis session to improve reproducibility of the treatment being evaluated. A live approach is time consuming for healthcare provider and is probably less extendable to routine practice [15]. These observations led us to develop an audio record dedicated to the implantation of a subcutaneous venous access port, with a specific content and length. Moreover, the standardisation of the recorded session decreases the risk of a bias related to the variability of the intervention and the suggestions of a therapist during a live session. However, it might be interesting to compare a recorded session to a live approach in the operative room setting.

We did not assess the anxiety nor the pain scores during the procedure because it meant interrupting the hypnotic process to collect these data.

The implantation of a subcutaneous venous port is a key step for patients diagnosed with cancer as it represents the very beginning of a possible long and difficult healthcare process with chemotherapy. The hypnosis script offers a wide range of possibilities and might be adapted to other procedures. However, this tool cannot replace the specific trust relation between the patient and the care provider, which is essential prior the use of these new non-pharmacologic tools.

4.1. Conclusion

An audio-recorded hypnosis session improved perioperative experience of patient diagnosed with cancer after subcutaneous venous port implantation performed under local anaesthesia.

Funding

Internal funds of department of anaesthesia.

Disclosure of interest

The authors declare that they have no competing interest.

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