Effectiveness of Hypnosis for the Prevention of Anxiety During Coronary Angiography (HYPCOR Study): a prospective randomized study

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Research Article

Keywords:

Posted Date: February 2nd, 2022

DOI: <https://doi.org/10.21203/rs.3.rs-1180062/v1>

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Abstract

Background – Coronary angiography is the gold standard for the diagnosis of coronary artery disease. This procedure is nevertheless a source of anxiety given the inconvenience caused by its invasiveness but also due to the consequences linked to the discovery of potential diseases.

Aim - The aim of this study was to determine the effectiveness of hypnosis on reducing patient anxiety prior to coronary angiography.

Methods – A total of 169 patients with non-urgent indications of coronary angiography and no history of prior coronary angiography were randomized to a hypnosis or control group. Patients in the hypnosis group underwent a hypnosis session with posthypnotic suggestions in self hypnosis, while those in the control group had a conversational interview with the hypnotherapist. The primary endpoint was the level of anxiety prior to the exam assessed by the Spielberger State-Trait Anxiety Inventory (STAI-Y A).

Results - Performing a hypnosis session did not translate into a significant decrease in anxiety prior to the procedure. Age, trait anxiety, state anxiety the day before and belief that hypnosis works in general were associated with anxiety prior to the procedure. There was no adverse effect secondary to hypnosis. There was no statistically significant difference between the 2 groups for the occurrence of complications due to the procedure.

Conclusion - In the present study, performing a hypnosis session upstream of a coronary angiography, did not reduce the state anxiety measured immediately before the intervention. In all cases, the hypnotic experience seems to be positive for the patient, which encourages further research efforts.

Trial registration - The research protocol was registered on the ClinicalTrials.gov registry (NCT02818101; 29/06/2016) and with the ANSM (IDRCB 2016-A00205-46; 02/02/2016).

Background

Coronary angiography, medical imaging technique used in cardiology to visualize the coronary arteries in case of suspected coronary disease, has experienced spectacular growth over the last thirty years (1), particularly with the advent of radial puncture as opposed to the use of femoral puncture. This interventional procedure has increasingly replaced reference surgical treatments. Percutaneous endoluminal revascularization techniques have furthermore emerged as a major treatment for acute and chronic coronary insufficiency (2, 3).

Coronary angiography is most often performed under local anesthesia (4). Indeed, it is important to know during the procedure if the patient feels chest pain (which can lead to a coronary lesion). However, the absence of general anesthesia can represent a source of anxiety for patients, which in itself may be the cause of adverse events (5, 6). In addition, in principle painless, the procedure can become painful at various steps during the test: at the time of the puncture, during the progression of the probes along

tortuous, spastic or highly calcified arteries, or at the time of balloon. In general, and whether performed in emergency conditions or as a scheduled procedure, there is preoperative anxiety (7). This psychological state can moreover condition the success of the procedure (8). The diagnostic stakes as well as their consequences can also represent a source of anxiety for patients requiring coronary angiography (9). Preoperative anxiety is also known as the most important prognostic factor in patients over 70 years of age during cardiac surgery (10).

Several management approaches have previously been evaluated in reducing anxiety in patients before and during coronary angiography, including massage, music therapy, and aromatherapy (11–18). A 2004 study on coronary angioplasty alone also compared hypnosis with drug sedation without significant results (19). STAI-Y A is commonly used to assess anxiety prior to cardiac catheterization combined with management techniques aiming to reduce perioperative and pre-interventional anxiety. Music therapy is the most frequently assessed method and shows a significant decrease in STAI-Y A (13). However, no study has been undertaken to assess the effectiveness of hypnosis in reducing pre-procedural anxiety.

Hypnosis is a state of consciousness involving focused attention and reduced peripheral awareness characterized by an enhanced capacity for response to suggestion (20). Just as this process can have a protective effect on pain, called hypnoanalgesia, it also allows reducing anxiety during therapeutic or diagnostic medical procedures (21–26). A recent review of the literature concluded that «the use of hypnosis during a surgical intervention or during a medical or interventional radiology procedure allows reducing the consumption of sedatives and/or analgesics intraoperatively (27). While such results appear to constitute a solid foundation, new studies would be welcome».

The objective of the present study was to determine the effectiveness of hypnosis on pre-interventional anxiety during the performing of a coronary angiography.

Methods

Study population

Patients were recruited between March 20, 2016 and July 26, 2017 at the Metz-Thionville Regional Hospital Center. Their hospitalization in cardiology was scheduled for the conduct of a coronary angiography without emergency indication. Patients did not receive any systematic premedication for anxiolytic purposes. Patients who had undergone a previous coronary angiography were not included, since past experiences may change the emotional level. Included patients consisted of adults (≥ 18 years of age) and having undergone coronary angiography with or without stenting during the procedure. Exclusion criteria were: non-french-speaking patients with cognitive disorders, deaf or hearing impairments, under legal protection, or a psychiatric history of psychosis.

Procedures

On the day before the examination, a pre-inclusion visit was conducted by a cardiologist. An information document and a non-opposition form were given to the patient. Included patients were randomized by random draw into two arms: the hypnosis group and the control group. Only the hypnotherapist was aware of the random draw. The personnel of the cardiology department and of the angiography technical platform were not informed of the patient's group.

On the morning of the procedure, patients in the hypnosis group underwent a hypnosis session with posthypnotic suggestions in self-hypnosis to be performed during the coronary angiography. The purpose of the post-hypnotic suggestions was to facilitate self-hypnosis in the coronary angiography room so that the patient could manage their anxiety and pain if any. This session was performed in the patient's room, before leaving for the coronary angiography unit. Hypnotherapists participating in the study consisted of 4 emergency physicians, a child health nurse and a nurse anesthetist. All were trained in an institute recognized by the Francophone Confederation of Hypnosis and Brief Therapies and had at least 2 years of clinical experience. Patients in the control Group had a conversational meeting with a hypnotherapist.

State anxiety and trait anxiety were measured in both groups on the day prior to the procedure while state anxiety was again measured immediately before performing the coronary angiography. Hemodynamic parameters (Blood Pressure and Heart Rate) were measured (1) the day before the procedure, (2) on the morning of the procedure in the patient's room, (3) immediately before the coronary angiography, (4) immediately after the coronary angiography and (5) the next day. Pain was assessed using a Visual Analog Scale (VAS) the day before the procedure, on arrival in the intervention room, upon exiting the intervention room and the day after the procedure. Depending on the clinical situation, the operator could introduce an anxiolytic (midazolam) and/or analgesic (paracetamol, morphine) treatment, hence the reason for the recording of the treatments as well as the occurrence of adverse events. At the end of the examination, the operator's comfort was measured by a Lickert scale. The operator was also asked his/her opinion as to whether the patient belonged to the hypnosis or control group.

Patients were contacted at 1 month post-procedure to assess their overall satisfaction using a Lickert scale ranging from 1 to 5, as well as their opinions on the effectiveness of hypnosis on themselves as well as on the population in general. A simple numerical rating scale is more sensitive to the changes in anxiety induced by the intervention.

Endpoints

The primary endpoint was the patient's level of anxiety prior to the performing of the coronary angiography using SPIELBERGER's inventory (STAI-Y A). The secondary endpoints were hemodynamic parameters, the use of anti-anxiety or analgesic treatment and their respective dosages, pain assessment, operator comfort and patient satisfaction in their care management.

Supervision of the study

This randomized, single-blind, single-center study was designed by the principal investigator (N.G.) and the methodologist (C.G.). The research protocol was registered on the ClinicalTrials.gov registry

(NCT02818101; 29/06/2016) and with the ANSM (IDRCB 2016-A00205-46; 02/02/2016). The Metz-Thionville Regional Hospital Center sponsored and funded the trial. The research protocol was approved by the East-III Protection of Persons Committee. The data were processed at the Clinical Research Support Platform of hospital. The methodologist (C.G.) verified the completeness and quality of the data, and performed the statistical analyses.

Statistical analysis

The size of the sample (85 patients per group) needed to achieve 90% power with a 5% alpha risk, was calculated from the literature which allowed estimating an expected score of 50 on STAI-Y A (standard deviation 10) for the control group and a clinically relevant difference of 5 points between the two groups^{26,27}.

The results are presented as medians and ranges or numbers and percentages. Hypnosis (experimental) and control groups were defined under the intention-to-treat principle. Comparison between the two groups was performed using Wilcoxon tests for quantitative variables and Fisher's exact tests for qualitative variables. A multivariate generalized linear model was used to identify factors that may influence STAI Y A score prior to coronary angiography (age, sex, group, trait anxiety, state anxiety the day before, belief in hypnosis effectiveness in general and belief in hypnosis effectiveness for itself). Wilcoxon tests were also used to compare the following secondary endpoints: pain (VAS), hemodynamic parameters, and Fischer's exact tests for the use of treatments and the occurrence of complications between the two groups. The threshold of significance was set at 5%.; Bonferroni corrections were applied for multiple testing when appropriate. All analyses were performed with SAS / STAT software version 9.4 (SAS Inst., Cary, NC).

Results

A total of 169 patients were included in the analysis: 85 patients in the hypnosis group and 84 in the control group (figure 1). One patient initially randomized in the control group was excluded before completing the study because not meeting inclusion criteria. Patient characteristics at baseline were comparable between the two groups (Table 1), with the exception of the answer to the question « Do you think that hypnosis works, in general? » for which more patients in the hypnosis group answered « no ».

Table 1. Characteristics of the study patients at inclusion (day before coronary angiography)

Characteristic	Hypnosis group (N=85)	Control group (N=84)	P*
Age (years)	66 (44 ; 91)	68 (38 ; 88)	0.44
Gender (F)	27 (32)	30 (36)	0.63
Believes hypnosis works in general			
Yes	59 (69)	62 (74)	0.03**
No	19 (22)	8 (10)	
No opinion	7 (8)	14 (17)	
Believes hypnosis works on self			
Yes	34 (40)	32 (38)	0.74
No	16 (19)	20 (24)	
No opinion	35 (41)	32 (38)	
Heart rate (bpm)	76 (49 ; 148)	72 (50 ; 177)	0.15
Systolic blood pressure (mmHg)	142 (93 ; 182)	148 (101 ; 192)	0.08
Diastolic blood pressure (mmHg)	77 (39 ; 109)	78 (40 ; 111)	0.79
Pain (visual analog scale)	0 (0 ; 5)	0 (0 ; 2)	1
State anxiety (STAI-Y A)	49 (37 ; 70)	49 (35 ; 73)	0.84
In women	50 (37 ; 65)	49 (35 ; 73)	0.74
In men	49 (39 ; 70)	49 (39 ; 73)	0.61
Trait anxiety (STAI-Y B)	47 (35 ; 64)	48 (27 ; 80)	0.96
In women	43 (36 ; 64)	46 (27 ; 80)	0.93
In men	48 (35 ; 64)	48 (31 ; 68)	0.86

Data are presented as median (min ; max) or number (percentage).

*Wilcoxon or Fischer's exact tests.

** p<0.05

The STAI-Y A immediately before coronary angiography was 45 (range: 35-73) in the hypnosis group and 946 (36-74) in the control group (Table 2), with this difference not being statistically significant. The score distribution in both groups is shown in Figure 2. Midazolam was used in 9 patients (11%) in the hypnosis group versus 14 patients (17%) in the control group, this difference being not significant (Table 2). There

was no significant difference between the 2 groups with regard to the occurrence of adverse events, pain, operator satisfaction, and the opinion of the operator as to whether the patient belonged to the hypnosis group or control group (Table 2).

Table 2. Comparison of the course and consequences of coronary angiography between the Hypnosis and Control groups

Characteristic	Hypnosis group (N=85)	Control group (N=84)	P*
Use of Midazolam	9 (11)	14 (17)	0.27
Use of I-V paracetamol	1 (1)	2 (2)	0.62
Use of morphine	1 (1)	2 (2)	0.62
Operator believes that the patient is under hypnosis			
Yes			0.85
No	54 (64)	50 (60)	
No opinion	22 (26)	25 (30)	
	9 (11)	9 (11)	
Pain before the procedure (visual analog scale)	0 (0 ; 8)*	0 (0 ; 7)*	0.95
VAS $\geq$ 4	5 (6)	7 (8)	0.57
Pain after the procedure	0 (0 ; 6)*	0 (0 ; 7)*	0.50
VAS $\geq$ 4	1 (1)	3 (4)	0.37
Pain the day after the procedure	0 (0 ; 6)*	0 (0 ; 3)*	0.42
VAS $\geq$ 4	3 (4)	1 (1)	0.62
Complications	8 (9)	11 (13)	0.48
Vasovagal episode	4 (5)	4 (5)	0.99
Hematoma	4 (5)	5 (6)	0.75
Cutaneous allergy	1 (1)	1 (1)	0.99
Anaphylactic shock	1 (1)	0 (0)	0.99
Ventricular fibrillation	0 (0)	1 (1)	0.50
State anxiety (STAI-Y A) immediately before the procedure			
In women	45 (35 ; 73)	46 (36 ; 74)	0.23
In men	44 (35 ; 65)	44 (36 ; 69)	0.53
	46 (39 ; 73)	48 (39 ; 74)	0.21
Operator satisfaction			0.99
Yes (greater than 4/5)	58 (68)	59 (70)	

No (less than or equal to 4/5)	18 (21)	17 (20)
No opinion	9 (11)	8 (10)

Data are presented as median (min ; max) or number (percentage) *Wilcoxon or Fischer's exact tests.

State anxiety was still not associated with groups in multivariate analysis (Table 3). In this analysis, state anxiety prior to coronary angiography was shown to decrease with age($p=0.001$) and with the belief that hypnosis works in general ($p=0.048$). It was shown, to increase with trait anxiety($p=0.03$) and with state anxiety the day before ($p<0.0001$). Gender and belief that hypnosis works on self were not significantly associated with it. An interaction between hypnosis group and beliefs about hypnosis was tested and was not significant ($p=0.10$).

Table 3. Multivariate analysis (generalized linear model) of factors suspected of influencing state anxiety (STAI-Y A) prior to coronary angiography (N = 169, $R^2=0.47$, $p<0.0001$)

Characteristic	Parameter	Standard Deviation	P
Hypnosis	1.48	0.95	0.12
Age (years)	-0.16	0.05	0.001*
Gender (F)	-1.40	1.02	0.17
Trait anxiety (STAI-Y B)	0.13	0.06	0.03*
State anxiety the day before (STAI-Y B)	0.48	0.07	<0.0001*
Believes that hypnosis words on self	-1.75	1.07	0.10
Believes that hypnosis works in general	-2.36	1.19	0.048*

* $p<0.005$

The 1-month telephone follow-up showed no difference in patient satisfaction regarding their care (Table 4). In contrast, more patients in the hypnosis group responded that they believed hypnosis to be effective on them compared to the control group ($p=0.003$).

Table 4. Follow-up on D30 (by telephone)

Characteristic	Hypnosis group (N= 35)	Control group (N= 35)	P*
Overall satisfaction of care management			0.99
Yes (greater than 4/5)	24 (69)	28 (80)	
No (less than or equal to 4/5)	11 (31)	7 (20)	
Believes hypnosis works in general			0.99
Yes	28 (80)	27 (77)	
No	4 (11)	4 (11)	
No opinion	3 (9)	4 (11)	
Believes that hypnosis works on themselves			0.03**
Yes			
No	28 (80)	19 (54)	
No opinion	7 (20)	9 (26)	
	0 (0)	7 (20)	

Data are presented as numbers (percentage)

*Fischer's exact tests with Bonferroni correction for multiple testing.

**p<0.005

For the hemodynamic parameters, heart rate kinetics were identical in both groups (Figure 3A). Systolic blood pressure seemed slightly lower in hypnosis group, but differences were not statistically significant (figure 3B). Diastolic blood pressure showed no differences between groups.

Discussion

To our knowledge, the present is the only study to assess hypnosis using preoperative STAI in coronary angiography. In the present study, performing a hypnosis session with suggestions in self-hypnosis prior to coronary angiography did not translate into a significant drop in the state anxiety score. With scores of 45 in the hypnosis group and 46 in the control group, the state anxiety levels of included patients could be considered as « average » (28). These values are higher than the norms reported for patients in specific situations such as patients hospitalized for various organic diseases, or having to undergo medical tests or surgery (28). However, our results are in agreement with those of Lang et al., with regard to patients hospitalized for a biopsy under hypnosis with a suspicion of breast cancer or to performing a

trans-oesophageal ultrasound (22, 29). The state anxiety score prior to the procedure, with alternative medicine, is average as also observed in our study (13–17).

The lack of effectiveness of hypnosis may be due to the timing of the assessment. Indeed, the technique used during the hypnosis session utilizes posthypnotic suggestions in self-hypnosis. However, the patients were subjected to Spielberger's inventory upon their arrival in the coronary angiography room, hence before initiating a process of self-hypnosis. The assessment performed herein thus probably evaluates the effects of morning management and not the effectiveness of hypnosis during coronary angiography. This is seemingly in keeping with findings reported in several randomized clinical trials using STAI and involving interventional medicine showing a decrease in anxiety during an invasive examination but without any significant difference in pre-interventional or during the first stages of the procedure. *Lang et al.*, which also utilized Spielberger's Inventory, and in which there was no significant difference in state anxiety scores before the procedure as well as during the first 0-15 min time interval (30). A simple numerical rating scale is more sensitive to the changes in anxiety induced by the hypnosis (22, 30, 31). Other scales, such as the Beck Anxiety Inventory or Hamilton Anxiety Scale, also lead to the same conclusion (24). Indeed, while hypnosis is effective against anxiety, its statistical evidence appears to be provided by an assessment during the entire intervention and not in the moments that precede the latter (22, 24, 30, 31). These results hence raise the possible interest of hypnosis during pre-coronary angiography since hypnosis has shown a clear superiority relative to groups receiving other adjunctive measures such as « structured attention » or empathy (22, 31).

Our study highlighted the fact that patients believed that « hypnosis is generally effective » before coronary angiography significantly influenced pre-interventional anxiety, independently of the group to which the patient belonged. This question raises two important points with, on the one hand, the patient's beliefs and opinions regarding hypnosis and, on the other, the accompaniment aspect intrinsic to the clinical trial under the guise of a « hypnosis » label. Indeed, the general public develops different ideas and expectations from different sources, especially in medical care (32). The sociocognitive model of hypnosis explains that variables such as participant motivation, beliefs, or expectations are key variables for the hypnotizability of subjects (33, 34). The strengthening of these variables moreover allows facilitating hypnotic reactivity according to certain authors (35). On the other hand, Gandhi and Oakley have demonstrated the impact of the « hypnosis » label, whose title alone, according to these authors, plays a non-negligible anxiolytic role (36).

As observed by *Dufresne et al.*, our study shows that one month after management, the patients' opinion was influenced by the hypnotic experience (37). This difference between the two arms of the hypnotic process experience may suggest a resort to self-hypnosis during the procedure. In all cases, the modification in favor of a favorable opinion represents a positive reinforcement for subsequent hypnosis management. However, such hypothesis will require evaluating the effectiveness of hypnosis in patients who have already previously benefited from this approach and in the same setting in order to confirm such effect.

STUDY LIMITATIONS

Our study presents several limitations. First, our study included its single-center nature and consequently its risk of non-representativeness of practices and of the population. However, patient clinical activity within the cardiology department of the Mercy Hospital is substantial, with 2,314 percutaneous coronary angioplasties and 4,500 coronary angiographies performed in 2016. In addition, the study included the intervention of 6 different cardiologists and was also conducted with the intervention of 6 health personnel qualified in hypnosis. Hence, given the number of patients and operators, we believe our results can be extrapolated to other centers.

Secondly, our study could not be performed in double-blind manner because it is impossible to achieve the placebo of hypnosis. In order to avoid any follow-up bias, it would appear appropriate that the intervention in the control group not be limited to simply an interview with the hypnotherapist but also by another unconventional technique. There were no significant differences in reported pain levels in our 2 groups.

Thirdly, the assessment of pain was performed only at peri-procedural times. It is thus possible that such assessment was not adapted since, overall, literature reviews highlight the positive effects of hypnosis on pain during medical or surgical management and more rarely does not find a difference in terms of benefit to the patient, as is the case in the present study.(22, 23, 30, 31, 38–40). Hence, it would have been more suitable to assess pain levels during the procedure per se.

Finally, while none of our patients received specific premedication, the usual treatment of the patients was not defined as an exclusion criterion. Under these conditions, patients on anti-anxiety medication (benzodiazepine, antidepressant, etc.) may have been included, which may induce a relative bias in terms of anxiety level.

Conclusion

In the present study, performing a hypnosis session upstream of a coronary angiography, with posthypnotic suggestions in self-hypnosis to be performed during the procedure, failed to reduce the anxiety state measured immediately before the conducting of the procedure, compared to a simple conversational interview with the hypnotherapist. Factors associated with lower state anxiety before the procedure were age, trait anxiety, and believing that hypnosis is an effective technique in general. In all cases, the hypnotic experience seems to be positive for the patient, which encourages further research efforts

Declarations

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

In accordance with the Declaration of Helsinki, all methods were carried out in accordance with relevant guidelines and regulations. The research protocol was registered on the ClinicalTrials.gov registry (NCT02818101; 29/06/2016) and with the ANSM (IDRCB 2016-A00205-46; 02/02/2016). The research protocol was approved by the East-III Protection of Persons Committee. Authors confirm that informed consent was obtained from all study participants.

CONSENT FOR PUBLICATION

N/A

AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

COMPETING INTERESTS

The authors declare that they have no conflicts of interest.

FUNDING

The Metz-Thionville Regional Hospital Center sponsored and funded the trial.

AUTHORS CONTRIBUTIONS

LAV, CG, CG, NG prepared the first draft of the manuscript. NG, CG, NO wrote the study protocol. SW, NG, MV, JB, KK were investigators. LAV reported the changes made by all authors. All authors validated the final version of the manuscript.

ACKNOWLEDGEMENTS

N/A

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Figures

Figure 1

Patient Inclusion and Follow-up Diagram

Figure 2

Comparison of anxiety score distributions (STAI-Y A) immediately before coronary angiography between the Hypnosis group (N = 85) and the Control group (N = 84)

Figure 3

A and B. Heart rate and blood pressure evolution in the hypnosis (N = 85) and control (N = 84) groups. Error bars represent 95% confidence intervals. No significant differences exist between groups at the different time points.

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