

Impact of hypnosis during coronarography

Impact de l'hypnose au cours de la coronarographie

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ABSTRACT

Introduction: Bien que la coronarographie soit un examen fréquent et à faible risque, beaucoup de patients peuvent présenter de l'anxiété par rapport la procédure ainsi que les résultats possibles de cet examen . L'hypnose est une technique alternative qui suscite de plus en plus d'intérêt pour prévenir l'anxiété au cours de cette procédure. L'objectif de cette étude est de mieux comprendre l'efficacité de l'hypnose dans la réduction de l'anxiété et de l'inconfort chez les patients subissant une coronarographie.

Méthodes : Un total de 60 patients ayant une indication non urgente pour une coronarographie ont été divisés au hasard en deux groupes: un groupe expérimental de patients ayant subi une coronarographie sous hypnose (HYP) et un groupe contrôle (CTRL).

Résultats : Les résultats de notre étude suggèrent que l'hypnose réduit significativement l'anxiété. Le score moyen de l'échelle visuelle analogique (EVA) était significativement plus bas dans le groupe HYP ($0,7 \pm 0,47$ vs $1,66 \pm 0,9$ dans le groupe CTRL, ($P=0,037$)). Le score moyen de l'échelle d'évaluation verbale (VRS) était également significativement plus faible dans le groupe HYP ($0,23 \pm 0,13$ vs $0,83 \pm 0,6$ dans le groupe CTRL ; ($P=0,03$)). La nécessité d'une perfusion de chlorhydrate de morphine était significativement plus faible dans le groupe HYP que dans le groupe CTRL (6,7 % contre 30 % ; $p = 0,02$)). Il n'y a pas eu de différence dans la survenue d'événements indésirables entre les deux groupes. Pour l'opérateur, la qualité de l'intervention était similaire dans les deux groupes ($P= 0,59$), bien que la ponction radiale droite était plus réussie dans le groupe HYP (un seul échec de ponction radiale droite (3,3 %) contre 6 (20 %) dans le groupe CTRL ($p=0,044$)).

Conclusion : Nos résultats ont démontré une réduction significative de la douleur perçue, de l'anxiété et de l'utilisation de médicaments analgésiques chez les patients ayant répondu à l'hypnose. L'hypnose pourrait être une méthode alternative ou complémentaire pour améliorer significativement le confort du patient lors d'une coronarographie.

Mots clés : Hypnose ; Coronarographie ; Anxiété, Douleur, Spasme

RÉSUMÉ

Background: Although coronarography is common and relatively with low risk, patients may experience anxiety about the procedure and about the implications that some diagnosis may have. Hypnosis is an alternative technique with rising interest to prevent anxiety during this procedure.

Aim: The aim of this study is to better understand the effectiveness of hypnosis in reducing anxiety and discomfort in patients undergoing coronarography.

Methods : A total of 60 patients with nonemergency indication for coronarography were randomly divided into two groups: one control group (CTRL), and one experimental group of patients who underwent coronarography under hypnosis (HYP).

Results : Results of our study suggest that hypnosis reduces significantly anxiety. Average Visual analogue scale (VAS) score was significantly lower in HYP group (0.7 ± 0.47 vs 1.66 ± 0.9 in CTRL group, ($P=0.037$)). Average Verbal rating scale (VRS) score was also significantly lower in HYP group (0.23 ± 0.13 vs 0.83 ± 0.6 in CTRL group; ($P=0.03$)). Need for morphine hydrochloride infusion was significantly lower in HYP group compared to CTRL group (6.7% vs 30% $p= 0.02$). There was no difference in the occurrence of adverse events between the two groups. For the physician performing the coronarography, procedure quality was similar in both groups ($P= 0.59$), although right radial puncture was more successful in HYP group (one failure of right radial puncture (3.3%) versus 6 (20%) in the CTRL group ($p = 0.044$)).

Conclusion : Our results demonstrated a significant reduction of perceived pain, anxiety, and use of analgesic drugs in hypnosis responder patients. Hypnosis could be an alternative or complementary method to improve patient comfort significantly, during coronarography.

Key words : Hypnosis; Coronary angiography; Anxiety, Pain; spasm

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INTRODUCTION

Coronarography is an invasive procedure consisting in selective angiography of the coronary arteries. It represents the gold standard for the anatomical exploration of the coronary arteries and establishes the first step for the indication of possible percutaneous or surgical revascularization (1).

The initial step is to determine the vascular approach for percutaneous arterial puncture. A local anesthesia with lidocaine 2%, or procaine in case of allergy, is systematically performed.

This is particularly interesting in the case of radial approach, since this artery is particularly sensitive to stress due to its pronounced vasomotricity (1). Moreover, mounting catheters on tortuous, heavily calcified arteries or during arterial dilation, can be a source of pain for patients. The discomfort on catheterization table and immobilization are also to be taken into account.

To fight anxiety, sedation before or during this procedure is sometimes necessary.

In recent years, hypnosis has emerged as an effective strategy for acute and chronic pain control.

Hypnosis is widely used in pain management and has been shown to be a valuable alternative or complement to traditional anaesthesia, with the advantage of allowing a reduction in dose of anesthesia (2).

In a hypnotic state, a patient's sensitivity to a stimulus and his emotional interpretation of this stimulus are dissociated (3), and subjective feelings of discomfort can be dramatically reduced; the painful stimulus then becomes acceptable to the patient.

Few data is available about hypnosis use in cardiovascular patients: few reports have been published regarding percutaneous coronary intervention and transesophageal echocardiography under hypnosis (4,5). Even in the context of coronary angiography, its use remains underexplored.

The aim of this study is to better understand the use of non-pharmacological approaches to reduce anxiety among patients undergoing coronarography.

METHODS

Population study

This study had a prospective randomised design, between May 2021 and July 2021 in the cardiology departement of the university hospital of rabta and was a single-centre trial with two arms, including one experimental and one control group.

The study sample included adult patients undergoing coronarography.

Informed consent was obtained before inclusion of patients.

There were 60 patients included in the study (30 patients per condition).

The age of the patients varied from 18 to 90 years.

Patients had to be conscious, awake and able to understand and answer in fluent Arabic.

Patients with psychiatric diseases like dementia, claustrophobia, severe hearing problems, visual impairment or a state of confusion were not included.

The patients were prospectively assigned to HYP Group (n =30 patients) and CTRL Group (n = 30 patients); HYP group: patients underwent coronarography with hypnotic communication as an adjuvant approach for periprocedural analgesia.

CTRL group patients underwent coronarography without analgesic approach and were assigned as control group.

None of our patients received specific premedication for anxiolytic purposes.

All patients had their blood pressure and heart rate measured.

In HYP group patients time required to reach the hypnotic status was recorded.

Coronarography procedure

Right radial access was privileged. During a radial puncture, a mixture of HEPARINE and RISORDAN is injected into the arterial sheath to prevent spasticity or thrombosis. Two specific probes, one for the left coronary artery and one for the right coronary artery, are mounted against the flow of blood under monitoring, and directed with a guide called "J guide". The coronary images are obtained by injection of centiliters of iodinated contrast product under fluoroscopy.

Several incidences are performed to best determine a coronary lesion. These techniques are performed with continuous measurement of heart rate, an electrocardiogram with peripheral leads.

A non-invasive blood pressure measurement is systematically performed before any procedure and then the blood pressure figures are permanently given in an invasive way.

The procedure time, the scan time and the total dose area product (DAP) are recorded.

This study was conducted by trained operators.

Pain control protocol

Local anesthesia with Lidocaine 2% 5 ml was administered to manage radial access.

Hypnosis approach:

Hypnosis: is defined as a "state of modified consciousness involving focused attention and reduced peripheral awareness, characterized by an enhanced capacity for response to suggestions" (6).

Hypnosis has three main components: absorption, dissociation and suggestibility. Absorption is the tendency to become fully involved in a perceptual, imaginative or ideational experience; dissociation is the mental separation from the environment; and suggestibility is the responsiveness to social cues, leading to an enhanced tendency to comply with instructions and a relative suspension of critical judgment (7).

Hypnotic conditions:

The hypnotic workflow may be divided into the following

steps:

- A. Assessment of the patient's state of anxiety using Spielberger STAI-Y scale.
- B. Focusing patient's attention in order to be dissociated from the surrounding, subjects have to be alert and sitting in a comfortable armchair in a quiet room.
- C. Suggestions: Subjects are invited to imagine pleasant life experiences
- D. Validation of hypnotic status: Subjects were considered hypnotized when relaxing facial muscles were observed.
- E. Reinforcement and consolidation
- F. Discussion (physician-patient comparison) using Likert scale.

Psychological outcomes

Patients' feelings :

Anxiety:

The anxiety scale chosen in our work is the Spielberger STAI-Y (State-Trait-Anxiety Inventory) (8) .

It is a test designed to assess momentary and habitual anxiety.

The STAI-Y consists of 2 scales of 20 items each:

- The Anxiety State Scale; assesses the feelings of apprehension, tension, nervousness, and anxiety that the subject is experiencing at the time of the consultation. It is an indicator of transient changes in anxiety caused by therapeutic or aversive situations.
- The Anxiety Trait Scale assesses the feelings of apprehension, tension, nervousness, and anxiety that the subject usually experiences. Each item has a score ranging from 1 to 4 (4 being the highest anxiety score). It ranges from 20 to 80.
- The norms: - Very high: > to 65 - High: 56 to 65 - Average: 46 to 55 - Low: 36 to 45 - Very low: < or =35

Pain:

Pain scales chosen in our study are the Visual Analogue Scale (VAS) and the Verbal Rating Scale (VRS).

The visual analogue scale is presented in the form of a ruler with 2 sides oriented from left to right on which a cursor moves. One side or front side is for the patient. The reverse side is used by the nurse to measure the intensity of the pain. Its left end is marked "no pain". It is connected by a blue line to the right end marked "maximum imaginable pain".

The nurse asks the patient to move the cursor from left to right on the blue line according to their perception of the intensity of their pain.

The nurse then turns the ruler over onto its reverse side which is graduated from 0 to 10 from right to left. She can then visualize the VAS score located by the red line of the cursor that the patient has positioned (9).

Verbal pain intensity scale (verbal rating scale VRS): These pain scales give people a simple way to rate their pain intensity using a verbal or visual descriptor of their pain (10). Some examples would be the words : -1 :mild 2: discomforting 3 :distressing 4 :horrible, 5 :excruciating.

Operators' feeling:

At the end of the procedure, the operator assesses its progress by using LIKERT scale.

The typical Likert scale is a 5- or 7-point ordinal scale used by respondents to rate the degree to which they agree or disagree with a statement (11).

Operators assess also its progress by recording procedure time, fluoroscopy time, right radial puncture (Success/switch) and angiographic spasm (evaluated by difficulty in moving the catheter through the radial artery, onset of sudden pain or narrowed artery in fluoroscopy)

Hemodynamic outcomes:

Heart rate and blood pressure are permanently measured per procedure.

Endpoints

Primary endpoint was to evaluate hypnosis as an adjunctive technique to perform a painless procedure

Secondary endpoints were hemodynamic parameters, the use of anxiolytic or analgesic treatments, pain evaluation, operator comfort and patient satisfaction with the management.

Statistical analysis

The data was evaluated using the Statistical Package for the Social Sciences (SPSS) 20.0 program (IBM Corp. Armonk, New York United States) for Windows and by analyzing descriptive statistics (frequency, mean, and standard deviation).

Demographic comparisons of the two groups were conducted using a Chi-square analysis for categorical variables and independent t-tests for continuous variables. The Anova test is used to examine effect of hypnosis on hemodynamic parameters. P values < 0.05 were considered as statistically significant for all analysis.

RESULTS

Patients characteristics at inclusion

A total of 60 patients were included. Thirty patients were randomized to the hypnosis group (HYP group) (mean age 60 ± 11 years, 50% women) and 30 to the control group (mean age 62 ± 11 years, 50% women).

Overall, 34% of the examinations were performed for chronic coronary syndrome, 20% for preoperative assessment, and 10% to investigate left ventricular dysfunction.

There was no significant difference between the two groups in terms of sex, age, existence of comorbidities coronarography indication (table 1).

Table 1. Patients characteristics at inclusion

Characteristics	Hypnosis group N=30	Control group N=30	P
Age (years old)	60 ± 11	62±11	
Gender			
Male	15 (50%)	15(50%)	0.6
Female	15 (50%)	15(50%)	
Weight (kg)	80 ±13	76±14	0.34
Smoker	9 (30%)	11 (37%)	0.9
Coronarography indication :			
Stable angina	10 (34%)	11 (36%)	0.70
Documented ischemia	11(36%)	9(30%)	0.14
Left ventricular dysfunction	3(10%)	5 (17%)	0.40
Preoperative assesement	6(20%)	5 (17%)	0.69
STAI-Y trait			
Low to moderate	14	13	
High	15	17	0.47

Categorical variables are presented as fractions and percentages. Continuous variables are presented as mean ± SD or as median (25th–75th percentile)

Coronarography procedure

Psychological outcomes and pain control :

Hypnosis significantly reduced patient discomfort:

- Average VAS score is 0.7 ± 0.47 in HYP group vs 1.66 ± 0.9 in CTRL group; ($p = 0.037$).

- Average VRS score is 0.23 ± 0.13 in HYP group vs 0.83 ± 0.6 in CTRL group; ($p=0.03$).

Necessity of morphine hydrochloride infusion was found significantly less in HYP group compared to CTRL group (6.7% vs 30% , ($p= 0.02$))

There was a tendency of decreased use of midazolam in HYP group when compared to CTRL group without reaching significant difference (13% vs 27% ; ($p=0.19$)).

Procedural outcomes:

There was no significant difference between the two groups in terms of puncture time ($100 \pm 89s$ vs $85 \pm 60s$; $p=0.76$), fluoroscopy time (6.14 ± 4.7 min VS 8.05 ± 1.21 min; $p=0.17$), the total dose area product (5955 ± 2531 Vs 7066 ± 2489 ; $p=0.27$) and of the amount of contrast product quantity ($78 \pm 19ml$ Vs 84 ± 36 ml ; ($P=0.37$)).

For the physician performing the coronarography, procedure quality was similar in both groups ($P= 0.59$), although right radial puncture was more succesful in HYP group (1 failure of right radial puncture (3.3%) versus 6 (20%) in the CTRL group ($p=0.044$)).

Moreover there were significantly less angiographic spasm in HYP group compared to CTRL group (3.3% vs 27% ; $p=0.011$).

There was no difference in the occurrence of adverse events between the 2 groups.

For cardiologist operators, satisfaction with the course of the procedure was identical in both groups. (Table 2)

Hemodynamic outcomes :

Regarding hemodynamic parameters; Systolic blood pressure had a tendency to decrease per procedure in Hyp groups without reaching significant difference. (average SBP : 136 mmhg before Vs 127 mmhg after $p=0.78$)

Heart rate was identical in both groups.

Table 2. Clinical and procedural data

Characteristics	Hypnosis group N=30	Control group N=30	P
Use of midazolam	4 (13%)	8 (27%)	0.19
Use of morphine	2 (6.7%)	9 (30%)	0.02
Puncture time (s)	100 ± 89	85 ± 60	0.76
Failed right radial puncture	1 (3.3%)	6(20%)	0.044
VAS	0.7	1.66	0.037
VRS	0.23	0.83	0.03
Angiographic spasm	1 (3.3%)	8(27%)	0.011
Scopy time (min)	6.14 ± 4.7	8.05 ± 1.21	0.17
Total Dose Area product (DAP)(Gy.m ²)	5955 ± 2531	7066 ± 2489	0.27
Contrast Product (ml)	78 ± 19	84 ± 36	0.37
Complications			0.3
Vagal discomfort	1(3.3%)	3 (10%)	
Hematoma	0	0	
Skin allergy	0	0	
Anaphylactic shock	0	0	
Fistula	0	0	
Others	0	0	
STAI-Y state			0.02
Low to moderate	27 (90%)	19 (63%)	
High	3(10%)	11(37%)	
Operator's satisfaction (Likert scale)			0.59
Yes (higher than 4/5)	22(73%)	23(76%)	
No (less than 4/5)	8(27%)	7(24)	

Categorical variables are presented as fractions and percentages. Continuous variables are presented as mean ± SD or as median (25th–75th percentile) ; VAS : visual analogue scale ; VRS : verbal rating scale ; DAP : dose area product

DISCUSSION

As coronarography is an invasive diagnostic procedure, with potential adverse effects and discomfort for the patient, local anesthesia with lidocaine is usually performed. The use of intravenous drugs, such as midazolam, is a well-established complementary technique to improve patient tolerance, however these drugs can induce cardiovascular depression, hypoxia, apnea, even at usual dosage (12).

Hypnosis can be an alternative, safe method to improve patient comfort without negatively affecting the diagnostic success of this procedure.

Hypnosis is an advanced stage of mental focus, with a limited perception of the surrounding environment and an increased capacity to follow commands [2].

When using hypnosis, one person (the subject) is guided by another (the hypnotist) to respond to suggestions for changes in subjective experience, alterations in perception, sensation, emotion, thought or behavior [3].

Anxiety control :

The effects of hypnosis are generating much interest and research. In the present study, we evaluated the possible beneficial role of hypnosis technique, in a prospective, randomized trial. The outcomes were assessed by evaluating the anxiety, pain perception, sedation, and

necessity of anxiolytics.

The result of our study suggests that hypnotherapy has beneficial effects to reduce anxiety and stress and have a positive impact on altering pain perception on patients undergoing coronarography, with no adverse events and without compromising the performance of the procedure. Among the signs of hypnosis effectiveness, we noticed that it significantly reduced patient discomfort: average VAS score was 0.7 in HYP group vs 1.66 in CTRL group, ($p=0.037$), and Average VRS score was 0.23 in HYP group vs 0.83 in CTRL group, ($p=0.03$). Moreover, we noticed that there were significantly less patients with high anxiety score (STAI-Y state) in HYP group when compared to CTRL group (3 (10%) Vs 11 (37%), $P=0.02$).

These findings are similar to those published in several studies, where hypnosis was also effective in reducing the level of discomfort during the procedure ; in a small study, Elkins and al, suggest Six patients scheduled for colonoscopy for colorectal cancer screening, all these patients receiving hypnosis for anxiety and pain management during colonoscopy reported a high level of satisfaction with their medical care (13). Furthermore, results of another study suggest that the hypnosis intervention is helpful for most prostate biopsy patients (14).

Additionally, it seems that hypnosis has shown its effectiveness even in cardiac surgery. In fact, Saadat et al revealed that hypnosis performed before surgery using Ericksonian techniques reduced patients' anxiety levels by 56% from baseline (15).

However, a similar study conducted at the Metz-Thionville Regional Hospital Center in France enrolled 169 patients scheduled for non-emergency coronarography and randomized them into a hypnosis group and a control group. Patients in the hypnosis group received a hypnosis session prior to the procedure. The study concluded that hypnosis did not reduce the level of anxiety measured immediately before the intervention. (16)

Procedure progress :

Mounting catheters in tortuous or heavily calcified arteries can be a source of significant pain for patients. Ensuring that the patient is comfortable and relaxed is mandatory to prevent radial artery spasm (17). Our results indicate that the rate of failed right radial puncture was significantly lower in the HYP group compared to the CTRL group (3.3% vs. 20%, $p = 0.044$), as was the incidence of angiographic spasm (3% vs. 27%, $p = 0.011$). These findings suggest a potential anxiolytic effect of hypnosis. Additionally, the higher rate of failed radial puncture in the CTRL group (20%) may be attributed to several factors, including small-caliber or diseased radial arteries, absence of sedation, or inadequate local anesthesia at the puncture site.

There was also, significant less of use of intravenous analgesics, especially morphine chlorhydrate in HYP group (6.7% vs 30 %, $P=0.020$) , and a tendency without reaching a significant decrease of use of hypnotics ; Midazolam used in this case,(13% in HYP group vs 27% , $p=0.19$). These findings confirm the results of smaller scale studies

showing a reduction of drug use when adjunct hypnosis was used during invasive medical procedures (18,19) This is not only found in invasive procedures but also in surgical settings, Greenleaf studied 32 CABG patients to examine the effect of hypnosis on recovery from surgery, and their results indicated that hypnosis decreased the necessity of postoperative remifentanyl and morphine administration (20). However, we should also consider the HYPCOR study results regarding the use of midazolam. In fact, midazolam was used in 9 patients (11%) in the hypnosis group compared to 14 patients (17%) in the control group; this difference was not statistically significant. This may be explained by the timing of the hypnosis intervention, as it was performed before the procedure rather than during it, which may have reduced its effectiveness (16).

Despite these obvious hypnosis effects, there were no significant difference between the two groups in terms of fluoroscopy time, and contrast quantity use. Operators' satisfaction with the procedure course was identical in both groups. This may be explained by the fact that these operators are trained, hence this method would be suitable for young operators in training.

Hemodynamics outcomes:

In terms of blood pressure, before intervention, systolic and diastolic Blood pressure were identical in the 2 groups, however we noticed a trend towards lower blood pressure per procedure in the HYP group without reaching a significant decrease (136mmhg before Vs 127 mmHg after $p=0.78$). This finding is consistent with other studies and the HYPCOR study, which reported a slightly lower systolic blood pressure in the hypnosis group, though the difference was not statistically significant. Diastolic blood pressure also showed no difference between groups (16,21). whereas the study of blood pressure in healthy subjects conducted by Sletvold and al, shows variations of this hemodynamic parameter at different stages of a hypnosis session. It is observed that there was a decrease in the DBP (22). However, as patients with coronary artery disease have a lower level of control of the parasympathetic system, they do not experience significant change of blood pressure, under hypnosis especially diastolic blood pressure, due to an attenuation of the baroreflex, which leads to arteriolar resistance (23). Heart rate evolution is identical in the 2 groups. The absence of difference implies that hypnosis does not allow a modulation at the central level. However, it is possible that there is not enough data to demonstrate this effect. Furthermore, some studies show that the measurement of cardiac variability would have been a more relevant indicator than heart rate (24-25).

Complications:

There was no difference in the occurrence of adverse events between the 2 groups, this lack of difference shows the absence of harmful effects of hypnosis as an adjunctive measure during coronarography. In HYPCOR study also, there was no significant difference between the 2 groups regarding the occurrence of adverse events (16)

There are no clinical trials directly evaluating the adverse effects of hypnosis. The synthesis of the Cochrane reviews is comforting, although it does not exclude the occurrence of serious adverse effects, their incidence, would be low (26).

Limitations of the study:

There are several limitations to this study which need to be highlighted. First, the relatively small sample size and the single-center study design. In fact, we were limited by the hypnotist disponibility. Moreover, hypnosis requires consent and active participation of the patient, so considerable social or educational level may be determinative parameter of limitation in this cohort of patients.

Perspectives:

After identifying the limitations, these conclusions encourage further larger studies. Results of this trial reinforce the idea that hypnosis presents a real interest as an adjunctive care with less iatrogenic risks. It should be considered especially with young operators to prevent angiographic spasm and patients' discomfort.

CONCLUSION

Hypnosis could be an alternative or complementary method to improve patient comfort significantly, during coronarography. The process is safe, and it seems promising in terms of helping to reduce side effects. Further evaluation of the relative values of hypnosis may be warranted.

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