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Study protocol: hypnosis versus standard care for shoulder dislocation reduction in the emergency department – a multicentre, randomised, controlled study protocol

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ABSTRACT

Introduction Anterior shoulder dislocation is a common reason for consultation at the emergency department (ED). Hypnosis could be a safe and effective alternative therapy for pain relief during shoulder dislocation reduction but nowadays, evidence is not sufficient. The main objective of this study is to show that reduction under hypnosis is associated with a decrease in the use of analgesic compared with usual care.

Methods and analysis We will conduct an interventional, controlled, multicentre, randomised study. A total of 44 patients with shoulder dislocation will be randomised in two groups: the hypnosis group (N=22) and the usual care group (N=22). The primary endpoint will be the comparison of morphine equivalent analgesic consumption during a shoulder dislocation reduction manoeuvre. Secondary endpoints will include haemodynamic parameters monitoring, patient and practitioner satisfaction using a Likert scale, use of coanalgesic or sedative drugs, number of reduction attempts and time spent at ED. Adverse events will be recorded. Statistical analysis will include parametric tests, multivariate linear regression and descriptive statistics.

Ethics and dissemination This study has received ethics approval from the Comité de Protection des Personnes of Sud-Est IV on 03/11/2021 (ANSM informed on 19 November 2021). The results will be published in scientific articles and communicated in national and international conferences.

Trial registration number ClinicalTrial.gov: NCT04992598; National Clinical trial no ID RCB : 2021-A01382-39

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ To our knowledge, this is the first multicentric prospective and randomised study to evaluate the effectiveness of hypnosis in the emergency department.
⇒ The method is rigorous and well detailed. The protocol is written by a multidisciplinary team.
⇒ This study is suitable for clinical practice.
⇒ Blinding is not suitable because of the characteristics of hypnosis and the fact that the session must be performed during the reduction.
⇒ A possible bias may be due to different levels of experience between the people that will perform hypnosis but a standardisation session is offered.

BACKGROUND

Anterior shoulder dislocation, also known as anterior glenohumeral dislocation, is a common reason for the consultation at the emergency department (ED), with an estimated annual incidence of 17–24 per 100 000 patients. That represents 45% of all dislocations.[1 2] Most of the time, this is reduced in ED. This is diagnosed thanks to a questioning, a clinical and radiological examination.

Any dislocated shoulder must be reduced quickly to avoid reflex contraction of the muscles and to relieve the patient as fast as possible. Indeed, this is a very painful disease for which there is no specific recommendation for both the reduction manoeuvre and the sedation and analgesia procedure we must use.[3] The result is a development of disparate practices. Concerning the reduction technique, there are more than 50 different techniques but none is validated as a gold standard despite several comparative studies.[4 5] Different levels of analgesia or sedation may be required, depending on the type of dislocation, the associated lesions including fractures and nerve compression, the reduction technique, the operator and the patient (history, pain intensity). The necessary means

for the successful reduction of a limb dislocation are most often part of a procedural sedation-analgesia (PSA).[6] PSA consists in analgesia and moderate to deep brief sedation used during painful procedures.[7] Many molecules are available for PSA such as midazolam, propofol, fentanyl, ketamine or etomidate.[8] Several studies have been conducted to assess a reference among these molecules in the shoulder dislocation reduction but none has been able to prove superiority. PSA requires continuous and close monitoring of the patient, as the molecules used can lead to haemodynamic, respiratory or neurological adverse events.[9] Hypnosis could be a safe alternative to drugs. The American Psychological Association defines the hypnotic state as 'a state of consciousness involving focused attention and decreased sensitivity to the environment, characterised by an increased capacity to respond to suggestion'.[10] The term hypnosis is used to define the hypnotic process that induces this state. More and more neuroscience studies try to understand the mechanisms of hypnosis.[11–13] This modified state of consciousness is safe for the patient because it is above all a physiological state. The effectiveness of hypnosis in pain management was assessed in several medical specialties such as obstetrics, surgery, dentistry.[14–18] Several meta-analyses assessed that medical hypnosis is a safe and effective complementary technique for pain management. In the ED, there is only a few low-level evidence for the use of hypnosis.[19 20] In addition, pain is still insufficiently managed in the ED, especially in case of acute trauma.[21 22] Hypnosis could have a real interest for pain treatment in the ED, alone or in association with other medications. Our primary hypothesis is that a hypnosis session during a shoulder dislocation reduction manoeuvre could reduce the frequency of the consumption of three or more morphine equivalent for 25%–5% of the patients. Our secondary hypothesis is that it would improve haemodynamic parameters (difference of 2%), patient and practitioner satisfaction (Likert scale with 1 point difference), decrease the number of reduction attempts,[1] and decrease the amount of sedation used and time spent in the ED.

METHODS

Aims, design and study setting

Primary objective

The main objective of this study is to compare the consumption of morphine equivalent analgesics during a shoulder dislocation reduction maneuver with and without hypnosis.

Study settings

This study is conducted in seven French ED which are: the Fleyriat Hospital in Bourg-en-Bresse, the Metz-Thionville Regional Hospital (CHR Metz-Thionville), the Sarreguemines Hospital, the Saint Joseph Saint Luc Hospital in Lyon, the South Lyon University Hospital, the Vienne Hospital and the North-Western Hospital in Villefranche.

Patient and public involvement

No patient involved.

Study design

This study is an interventional, randomised, multicentre, usual care study. It will run from February 2022 to July 2022. Patient prescreening is done by the Intake Nurse Organiser (IOA). The patient is given a brief, clear and fair oral information about the study and the caregiver collects his oral consent. If the patient's condition permits it, the patient receives written information at the same time as the oral information (information not available in online supplemental appendix). If not, the investigator gives the information note to the patient after the reduction procedure. Inclusion in this research is only possible if a hypnosis qualified caregiver (nurse or physician, no specific level required) is available at the time of inclusion. The collection of oral consent is recorded in the medical file by the investigating physician. Randomisation is carried out by opening numbered envelopes provided by the coordinating centre. The study design is summarised in figure 1.

Inclusion criteria

Patients going to an ED involved in the study who meet all of the following criteria will be included :

- Patient 18 years and over.
- Checked in the ED for an anterior shoulder dislocation, confirmed thanks to X-ray.
- Have given oral consent to participate in the study.
- Is affiliated or is a recipient of a social security plan.
- An hypnosis qualified staff member (nurse, nurse's aide or physician) is available at the patient admission time.

Non-inclusion criteria

The criteria for non-inclusion are:

- Patients with a shoulder fracture on X-ray.
- Patients with a shoulder prosthesis.
- Patients with recurrent dislocations.
- Patients who does not speak or understand the French language.
- Patients with cognitive dysfunction.
- Patients with a psychiatric history of psychosis.
- Patients who are deaf or hard of hearing.
- Patients under legal protection (guardianship, curatorship).
- Pregnant women.
- Patients who already had a prehospital reduction.

Randomisation

The randomisation list is established by the methodology of the Plateforme d'Appui à la Recherche Clinique (PARC) of the CHR Metz Thionville before the beginning of the research. It will be kept in a protected computer file at the PARC of CHR Metz-Thionville. The two groups' numbers (hypnosis or control) are balanced with a ratio of 1:1. The sealed randomisation envelopes will be available for the emergency physicians and under the responsibility of the

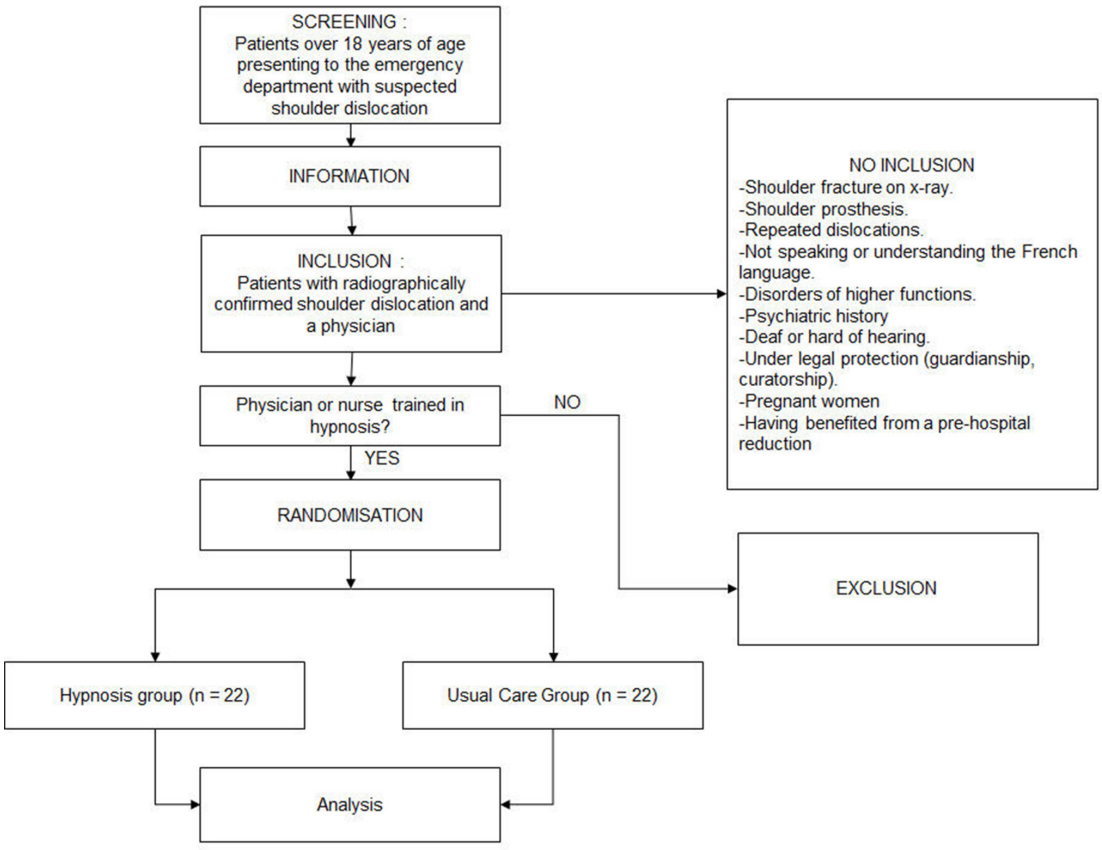

Figure 1 Flow chart of study.

main investigator of each centre. Randomisation will be performed in the ED, on arrival of an eligible patient, if a qualified caregiver is available, by chronological drawing of numbered sealed envelopes after oral consent of the patient. Blinding is not applicable for this study because there is no 'placebo hypnosis'.

Hypnosis intervention

The hypnosis intervention is delivered by a doctor or a nurse qualified. Given the limited number of caregivers trained to perform hypnosis in the ED and in order to maximise the number of patients included in the hypnosis group, there will not be any level of training or year of practice required. To overcome this bias, a preliminary training session will be conducted by videoconference to formalise and align the practices during the implementation of the study. In addition, an outline session will be provided and the hypnotherapist will be allowed to adapt it during the session according to the patient's needs. The hypnosis session is standardised and includes suggestions for analgesia and muscle relaxation. The hypnotic state is described to the patient as 'a state of mental focus on a pleasant life experience that provides a distraction during the manoeuvre'. The word 'hypnosis' will be used intentionally in the hypnosis arm to potentiate the effect of this therapy. In the hypnosis with the usual care group (HYP group), the patient is asked to choose a very pleasant life experience to be relieved during the manoeuvre. An hypnotic state is then induced. The hypnosis session will precede any drug therapy. If analgesia sedation is not sufficient under hypnosis, the physician will add analgesic and/or sedative medications as well as in the usual care group. Once patients are considered to be at an adequate level of trance (±10 min), the reduction manoeuvre is initiated by the physician while continuing the hypnosis session. Termination will end the hypnosis session and bring the patient out of the trance state.

Standard care

In the usual care group, each physician will perform the reduction as they usually do.

Procedure

In both groups, the patient will be monitored continuously (blood pressure (BP), heart rate (HR), respiratory rate (RR) and saturation) for a shoulder dislocation reduction manoeuvre. Pain management will be performed according to the pain assessment with the objective of EN<4, according to current recommendations. In the hypnosis group, hypnosis will be the first treatment introduced; it can be completed by the analgesics and/or sedatives medications afterwards if needed. In both groups, the type of shoulder dislocation reduction manoeuvre will be reported.

At the end of the manoeuvre, the patient's arm is immobilised elbow to body in both groups. The success of the manoeuvre will be checked by a clinical and radiographic examination. The instructions for further management

are given to the patient without modification of the practices. Continuous, monitored surveillance will continue after the procedure if the patient received drugs that require it.

Primary outcome measure

The amount of analgesics administered from the moment the patient arrives in the ED until the end of the reduction manoeuvre will be collected in milligrams by the nurse in charge of the patient as the injections will be necessary. The names of the drugs used will be recorded on the case report form (CRF). In order to compare the dose of morphine with each other, we will convert them into equipotent doses.[23] We consider that 2 mg of morphine for patients who weigh less than 60 kg or 3 mg of morphine for patients who weigh more than 60 kg corresponds to one dose. Patients will be classified into three groups: patients who required one dose or less; those who required two doses and those who required more than three doses.

Secondary outcome measure

The patient's pain will be assessed by self-report using a numerical scale pain graduate from 0 to 10 cm (0 cm=no pain; 10 cm=worst pain) before the procedure, every 3 min during the procedure (the worst numeric pain scale will be retained) and 5 min after the end of the procedure. In addition, the nurse will perform a hetero-evaluation pain scale during the procedure (numeric pain scale 0=no pain; numeric pain scale 10=worst pain). We expect an improvement of three points.[13]

HR, BP, oxygen saturation (Sat) and RR will be recorded every 3 min from the time the patient enters the continuous monitoring room until discharge. We expect a global difference of 2.5%.[18]

The use of sedatives, the name of the drugs and the amount used during the manoeuvre will be reported by the nurse on the CRF. We expect a 25% reduction in overall sedative use, based on clinical relevance.

The number of reduction attempts will be recorded in the CRF. If the physician needs more than two reduction attempts, the patient will be managed according to the recommendations for the management of shoulder dislocation (surgical opinion).

Once the manoeuvre is completed, the physician in charge of the patient will take care to report in the CRF his comfort during the procedure using a self-assessment and the patient's satisfaction using a Likert scale of five items. We expect a difference of 1 point on the Likert scale for the hypnosis group.

The time spent in the ED will be collected in the CRF in minutes afterwards, once the patient will leave the department. We expect a difference of 1 hour between the two groups.

Confounding factors

We identified several confounding factors that will be collected in CRF, such as:

- Patient characteristics.
- Sedatives used.
- Type of manoeuvre (Milch, Kocher, Matsen, Hippocrate, Chair method or other).
- Patient under beta-blocker or antihypertensive treatments (interaction on haemodynamic parameters).
- Experience of the caregiver providing the hypnosis session (declarative).

Safety evaluation

Possible adverse events related to the study or to the management will be investigated from the beginning of the drug administration until the patient's discharge. They will be reported in the CRF. These events may be the persistence of a residual hypnotic state at the end of the treatment, abreaction (emotional discharge where an effect previously repressed because of its painful nature occurs in the field of consciousness of the patient) (59,60), nausea and vomiting, haemodynamic adverse effects, respiratory adverse effects, neurological adverse effects, allergic reaction, anaphylaxis.

Quality control

Data process will be carried out under the responsibility of the PARC of the CHR Metz-Thionville. The data will be entered and proofread in a Cleanweb data entry mask. The data validation and freezing processes will be carried out according to the current procedures at the PARC of the CHR Metz-Thionville.

Sample size calculation

We expect that 25% of the patients will need three or more equipotent doses of analgesics in the control group, and 5% in the hypnosis group.[23] Under these conditions and with an alpha risk set at 5%, it is necessary to include 35 patients per group, or 70 patients in total, to achieve a power of 80%.

Statistical analysis

The comparability of the groups will be assessed using Fisher's exact tests (qualitative factors) or Student's t-tests (quantitative factors). The frequency of three or more equipotent analgesic doses consumption will be compared between the two groups (hypnosis and no hypnosis) using a Fisher's exact test and then multivariate logistic regression to account for possible confounding factors. Qualitative secondary endpoints will be compared between groups using the same strategy, quantitative endpoints will be compared using Wilcoxon tests and then multivariate linear regressions. The analyses will be performed on an intention-to-treat basis. The significance level will be set at 5%.

ETHICS AND DISSEMINATION

The sponsor and the investigators undertake that this research will be carried out in compliance with the Public Health Code, as well as in accordance with Good Clinical Practice (I.C.H. version 4 of 1 May 1996 and decision of

24 November 2006) and the Declaration of Helsinki. This research has received an ID-RCB number 2021-A01382-39 on the ANSM website. This research has received a favourable opinion from the People Protection Committee of Sud-Est IV on 03/11/2021 (ANSM informed on 19/11/2021). This research is registered on ClinicalTrials.gov under the no NCT04992598. An opinion from the ethics committee has not yet been requested. The results will be published in scientific articles and communicated in national and international conferences.

DISCUSSION

To our knowledge, this is the first clinical multicentric and randomised study with a high level of evidence focused on hypnosis in the ED. This study relies on a prior training of the different caregivers to homogenise the practices. Hypnosis is clearly defined, as recommended in the literature, and a session outline is proposed, although the hypnotherapist is free to modify the session as needed according to the patient's reaction.[24] The script includes direct suggestions for analgesia as the literature shows that hypnotic interventions are most effective when they do that.[25] In a meta-analysis, Patterso*n et al* show that several studies succinctly describe their experimental intervention, but only Lang *et al* describe a carefully detailed procedure.[18 26]

Although hypnosis had shown to be effective in the management of chronic and acute pain, the various studies about hypnosis had lacked a high level of evidence.[24 26 27] In order to provide reliable evidence of the effects of hypnosis during a shoulder reduction procedure, we carefully designed this study and included full details of the implementation plan. Randomisation generated by chronological envelope drawing will be adopted to minimise selection bias, and blocked randomisation will be applied to ensure prognostic balance between groups. Our primary endpoint is robust and objective, based on drug quantity. We purposely did not use pain assessment by scales as the primary endpoint; these scales, although validated, are complex to use in clinical research and could induce bias depending on how the request is formulated and on the expected answer. However, it seems interesting to have these pain scales as a secondary criterion, so that we have complementary pain index : one of the patient's perception, one of physician behaviour and a biological one.

If hypnosis leads to reduced consumption of analgesic during a shoulder dislocation reduction procedure, the use of hypnosis would be recognised and considered as a reasonable complementary and alternative therapy in patients with shoulder dislocation. If our results are consistent with the literature, our study should show a significant difference in the amount of analgesics used during a shoulder dislocation reduction procedure.[28 29] Under strict quality control, we expect the results of this study to provide high-quality evidence to determine whether hypnosis would reduce the amount of pain medication used during a shoulder dislocation reduction manoeuvre in the ED. More broadly, our study could improve ED pain management with hypnosis, decrease analgesic-related adverse effects, and reduce ED time by reducing postreduction monitoring time. In addition, our study could change the different beliefs around hypnosis from the hospital community and lead more emergency physicians to train in hypnosis to improve their practice. It will then be interesting to extend our study to other painful procedures performed in the ED, or even in the prehospital setting.

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