Original Article

To Compare Efficacy of Hypnosis and Intravenous Sedation in Controlling of Important Variables of Vital Signs and Evaluate the Patient Anxiety Before and after Topical Anesthesia in Ophthalmic Surgery

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Abstract

Background: Stress is one of the most important problems among preoperative patients. In order to reduce these signs and symptoms, some medications are used for patients. The aim of this study was to compare the efficacy of hypnosis to intravenous sedation on controlling the important variables of vital signs and to evaluate the patient anxiety before and after regional or topical anesthesia in ophthalmic surgery.

Materials and Methods: This study was designed as a double-blind stratified randomized clinical trial. Hypnotism was administered to hypnotism group, and midazolam, fentanyl, and propofol were given intravenously to the IV sedation group. The patients were monitored and the baseline variables consisted of mean arterial pressure, pulse rate, respiratory rate, and O2 saturation were registered every 15 minutes during surgery. Patient anxiety was measured via Spielbeger`s State Anxiety Index (STAI) score before and after surgery.

Results: 90 patients were participated in the study, with 50% (n=45) assigned to hypnosis group and 50% (N=45) assigned to IV sedation group. Patients characteristics, including age, gender, and body mass index (BMI) duration of surgery were similar among the groups (P>0.05). Spielbeger`s State Anxiety Index (STAI) score before and after surgery were not significantly different in both groups (P>0.05). Heart rate, respiratory rate, mean arterial pressure were lower among hypnosis group as well as this group had higher O_2 saturation during surgery (P<0.05).

Conclusion: Hypnosis can be an effective means of controlling vital signs at different intervals of starting the ophthalmic surgery compared to intravenous sedation. In the hypnosis group anxiety was similar to IV sedation group, but O_2 saturation was more desirable.

Keywords: Hypnosis, Intravenous sedation, Vital signs, O_2 saturation, Anxiety

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Introduction

Stress is one of the most important problems among preoperative patients[1,2]. It manifests with some physical signs and symptoms indicating hyperactivity of autonomic nervous system as well as the feeling of

fear[3]. In order to reduce these signs and symptoms some medications are used for patients upon entering the operating room, during anesthesia, or in the recovery phase[4,6]. Benzodiazepines, alpha adrenergic receptors blockers (e.g., clonidin), butorphanol, phenothiazines (e.g., chlropromazin and promethazin), anitcholinergics (scopolamine), and serotonin antagonists (ondansetron) are usually used to decrease stress and to sedate patients[7]. Each of these medications decreases stress, nausea, and vomiting but causes somnolence and amnesia in preoperative patients[7]. On the other hand, side effects of these medications are considerable, particularly administering them near the time of surgery which may interfere with anesthesiology medications[7]. For this reason, using non-medication methods to decrease patient stress prior surgery seems interesting and has been studied.

Hypnotism has an old history, but, nowadays there are newer methods to induce it[8]. Known effects of hypnotism consist of more stability of vital signs, pain reduction, high patient satisfaction, reduction of getting analgesic medication, making short the time of hospitalization, and improving stress and anxiety[8,9]. Another advantage is that there is not considerable side effect relevant to hypnosis[4,6]. Therefore, its application for medical and dental procedures as an alternative to medication has been reviewed and recommended[10-15]. For example, Faymonville et al. reported that hypnosis during operation, as a sedation and local anesthesia, reduced anxiety, pain, and the need for analgesic[16].

There has been no study to compare the vital signs, respiratory parameters such as O_2 saturation, and patient anxiety among patients who undergo hypnosis and those who receive customary intravenous (IV) medications for sedation during regional or topical anesthesia in ophthalmic surgery. This could introduce us a better method of sedation by which the adverse effects of medication will be decreased and the control of vital signs will be achieved more effectively. On the other hand, patients with some comorbidities such as high blood pressure who may not respond appropriately to antihypertensive medications will benefit from hypnosis more than others. Therefore, the aim of this study was to compare the efficacy of hypnosis to intravenous sedation on controlling the important variables of vital signs and to evaluate the patient anxiety before and after regional or topical anesthesia in ophthalmic surgery.

Methods

This study was designed as a double-blind, stratified (50 to 75 year olds) randomized controlled that was conducted from September 2010 to September 2012 in Labafinejad hospital in Tehran, Iran. The research protocol was approved by the Ethics Committee of Research Center for Anesthesiology, Shahid Beheshti Medical University.

Study sample: After obtaining written informed consent from the patients, 108 patients who were scheduled for elective cataract operations under local anesthesia were selected. The method of cataract surgery used in this study was phacoemulsification. Two patients were excluded due to psychological disorder and six patients due to using sedative and tranquilizer medications the sample consisted of 47 (52.2%) males and 43 (47.7%) females. Ethnic/racial backgrounds were 100% white and Persian.

Patients who refused to participate, who had a psychiatric disorder, which used sedatives or tranquilizers were excluded from this study. On the other hand, the patients should have a positive hypnotism test to be included. For this purpose, the hypnotizability of patients was tested by different ideomotor suggestion. In this method, the patient was asked to look at the middle of the forehead of examiner who was a psychiatrist and if there is any deviation in the eyes, the test will be positive. In our study 10 patients were excluded since they did not have the positive hypnotism test.

Thus, our final sample was consisted of 90 patients. Participants were randomized into 2 study groups, with 50% (n=45) assigned to hypnosis group (H group) who received saline 0.9% intravenously (IV) and 50% (n=45) assigned to the sedation group (S group) who received IV sedation which included midazolam (0.5-1 mg) and fentanyl (50-100 microgram) followed by propofol with starting dose of 10mg stat IV and repeated frequently as needed until the patient had Ramsay Sedation Score (RSS) 3 or more. At this time (time 0) the surgeon starts surgery the ramsay sedation score will test every 5 minutes

during surgery by an anesthesiologist and if the patient had RSS less than 2, propofol had been injected intra venously every 1-2 minutes in order to keep RSS 3 or more.

Groups were homogenous; mean age, gender, mean BMI, duration of surgery, and previous surgery ratios were not statistically different in the two groups. All of the cataract surgeries were performed in the morning between 8 AM and 12 P.M by an ophthalmologist who had more than 5 years experiences. The treatment drugs were diluted to a volume of 4 ml and presented as coded syringes with a white cover by an anesthesiologist who was blinded to the group allocation. In this regard, for hypnotize group we used saline 0.9% as a placebo. In both groups, pre-op dilatation was done with Tropicamide 1%, Phenylephrine 5-10% and NSAID drops. Patients were instructed on the operating table to look at the microscope light and not to move the eye. Microscope light was initially adjusted to a lower intensity and then gradually increased. Two to three drops of proparacaine 0.5% were put on the cornea and conjunctival sac followed by a clear cornea section. HPMC (Hydro propyl methylecellulo) was the viscoelastic used in all cases.

Measures collected were State and Trait Anxiety Index (STAI) before and after operation, anxiety measured with numeric scale before and after operation. In this study, only STAI before and after surgery were presented.

The day of surgery, just before and after the procedure, the psychologist evaluated patients` anxiety using the STAI form (Bergeron, Landry, 7 Belanger, 1976)[17]. Psychometric properties of STAI were reported by McDowell (2006) and the author concluded that STAI is probably the most widely used self-reported measure of anxiety and one of the best measures of anxiety available. STAI contains two 20-item indexes measuring trait anxiety and state anxiety. We kept only the results of state anxiety. The results of STAI vary from 20-80:>65 anxiety is very high, it is from 56-65, moderate is from 55-46, light from 36-45, and very high is<35. The psychologist was blinded as to group assignment.

Hypnosis technique: Hypnosis was typically administered to patients in the form of a relaxing induction phase followed by suggestions for control of side effect profiles (e.g., pain, nausea, and distress). The technique was started in the operating room few minutes before starting the surgery.

In order to obtain muscular relaxation, we asked the patients to breathe slowly with long exhalation and to focus on each muscle group. Patients were told that muscle relaxation resulted from extended exhalation. This was repeated until the patient reported that they were relaxed from head to toe.

In hypnosis group, they were invited to a quiet environment and progressive relaxation technique was used. In this technique, we fixed their attention on a color changing egg-morphing light and to concentrate on the edge of the egg, and on its colors provided. We reinforced the relaxation using a stair metaphor: we told the patients they were on a small staircase with three steps. At each step they would be twice as relaxed until they reached the floor at the bottom of the stairs. At this point (time 0) we consider the patient in a hypnotic trance and topical anesthesia was administered and surgery was started. We did not test for the depth of the trance because it could modify the attitude of the patient, and because the patient can create change at any level of trance.

We then used the same metaphor of a long awaited visiting friend used by Levitas et al. (2006)[18] andCatoire et al. (2012) in their study[19]: we asked patients to imagine that they were waiting for a very good friend for a long time. One day, this long awaited friend knocks at their home door. They open the door and ask him to come in. They take good care of their friend so that he stays with them for a very long time. Then, during the surgery, the hypnotist suggested a visit to a previously chosen place, and described the place using all senses. Finally, he gave post-hypnotic suggestions of relaxation and calm. In order to minimize the effects of interpersonal style, the same practitioner induced both hypnosis and muscle relaxation. This procedure lasted 30 to 50 minutes in the two groups.

In the IV sedation group, we induced muscle relaxation (hypnosis placebo). We started the relaxation 10 minutes before surgery and continued it during surgery. In IV sedation group, just after intravenous injection of sedative drugs, while patients had Ramsay Sedation Score 3 or more the topical anesthesia was performed and the surgery was started.

The interventions were conducted by two psychologists, who had PhD of clinical psychology with advanced training in using hypnosis in a medical setting. The interventionists did not participate in the

collection of data, each of them worked with an equal number of hypnosis and patients with intravenous sedation. In order to measure STAI, patients and the observer did not aware to the IV drugs used for the patients.

Data collection: Patients with inclusion criteria to take part in the study completed an epidemiologic form, including age, body mass index (BMI), racial type, and previous operation. In both groups after entering the operating room and getting intravenous line, the patients were monitored and the baseline variables were documented. These variables consisted of blood pressure, pulse rate, respiratory rate, and O_2 saturation. The pulse rate, respiratory rate, and blood pressure were measured and checked every 15 minutes during the surgery by an anesthesiologist and a nurse who were as blinded to group assignment. O_2 saturations were measured by a single pulse oximeter during the study.

Statistical analyses: Data were analyzed by SPSS software for Windows (version 13.0). Continuous variables, including: hemodynamic data, respiratory rate, and O_2 saturation values over time within the groups, were analyzed using repeated measures analysis of variance (ANOVA) followed by Bonferroni`s post hoc testing. Statistical comparisons among the groups were performed using two-way ANOVA, followed by unpaired t-test with Bonferroni`s correction. Nominal or categorical data, including the overall incidence of shivering between the four groups were analyzed and compared using the $\chi 2$ test. Values are given as mean (SD) or median (range). $p<0.05$ was considered statistically significant.

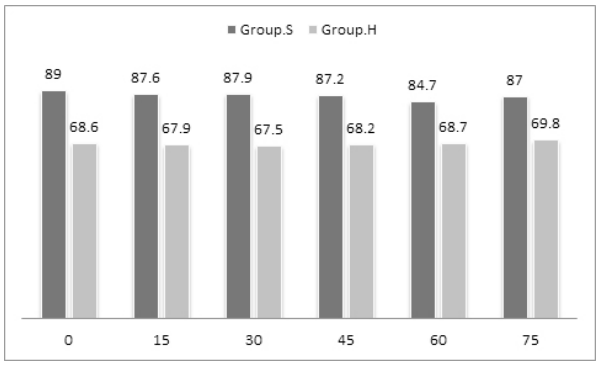

Figure 1. Change in heat rate with time. Data are presented as mean (SD). There was significant difference between the groups by using repeated measures ANOVA followed by Bonferroni`s post hoc testing ($p<0.05$). Heart rate was significantly higher in IV sedation (S) group than hypnosis (H) group.
Group S: IV sedation group
Group H: Hypnosis group
Vertical column is hear rate (number)
Horizontal column is the time (minutes).

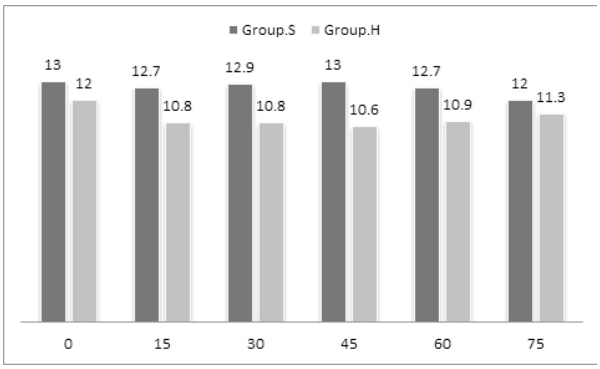

Figure 2. Change in respiratory rate with time. Data are presented as mean (SD). There was significant difference between the groups by using repeated measures ANOVA followed by Bonferroni`s post hoc testing ($p<0.05$). Respiratory rate was significantly higher in IV sedation (S) group than hypnosis (H) group.
Group S: IV sedation group
Group H: Hypnosis group
Vertical column is respiratory rate (number)
Horizontal column is the time (minutes).

Results

Ninety eight patients were approached for the study. Two patients were excluded due to psychological disorders, six patients due to using sedative and tranquilizer medications and ten patients had negative hypnotism test. Our final study group consisted of 90 patients (45 hypnosis and 45 IV sedation). Patients characteristics, including age, gender, body mass index (BMI), duration of their surgeries, history of any previous surgery, and other parameters such as heart rate, blood pressure, respiratory rate, and O_2 saturation just prior to administration of intravenous sedation and hypnosis were similar among the groups (Figure 1). Spielbeger`s State Anxiety Index Score (STAI) were also similar among the groups (Figure 2). As hypotension and apnea are the most common side effects of IV sedation, the incidences of them were compared between groups (Figure 3). In Figure 1 to 4 the mean of heart rate (HR), respiratory rate (RR), blood pressure (BP), and O_2 saturation are shown every 15 minutes over the surgery for both groups ($P<0.05$). At time 0 the surgery was started by surgeon for both groups and Ramsay sedation score for IV sedation group (S group) was 3 or more (Figure 1-4).

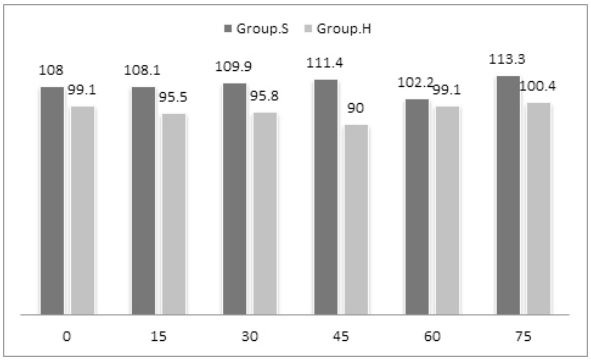

Figure 3. Change in mean arterial pressure (MAP) with time. Data are presented as mean (SD). There was significant difference between the groups by using repeated measures ANOVA followed by Bonferroni`s post hoc testing (p<0.05). Mean arterial pressure was significantly higher in IV sedation (S) group than hypnosis (H) group.
Group S: IV sedation group
Group H: Hypnosis group
Vertical column is mean arterial pressure (mmHg)
Horizontal column is the time (minutes).

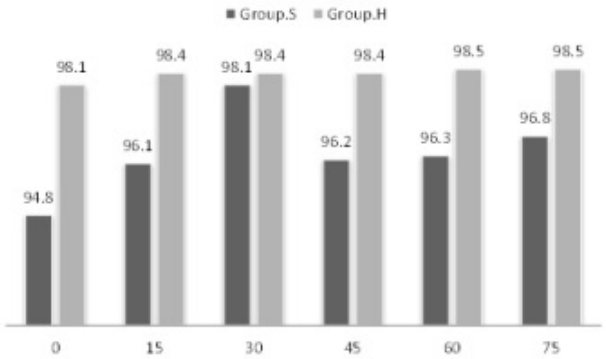

Figure 4.Change in Spo2(o2 saturation via pulse oximeter) with time .Data are presented as mean(SD).There was significant difference between the groups by using repeated measures ANOVA followed by Bonferroni`s post hoc testing(P<0.05).Spo2 was significantly lower in IV sedation (S) group than hypnosis(H) group .
Group S: IV sedation group
Group H: Hypnosis group
Vertical column is o2 saturation by measured pulse oximeter (percent)
Horizontal column is the time (minutes)

The mean of heart rate, respiratory rate, and the mean of blood pressure (mean arterial pressure) during surgery were lower among hypnosis group compare to IV sedation group (Figure1, 2, and 3). It is also of note that the mean of O_2 saturation measured by pulse oximeter was higher among hypnosis group in comparison with IV sedation group (Figure 4).

Discussion

This study provides data on different vital and cardinal variables in patients with hypnosis in comparison to customary IV medications used for sedation in regional or topical anesthesia during ophthalmologic operations. We observed that the control of pulse rate, respiratory rate, blood pressure, and O_2 saturation were significantly better in patients who underwent hypnosis than in those who received IV medications for regional anesthesia as well as the Spielbeger`s State Anxiety Index Score (STAI) were also similar among the groups.

It has been shown that hypnosis could have beneficial effects on blood pressure[20]. Other methods of mental and instinctual such as biofeedback can play an important role in controlling of blood pressure[10,11,19]. According to our findings, it could be suggested that the efficacy of hypnosis in patients whose high blood pressure must be controlled, particularly when control of blood pressure is not possible by medication, hypnosis can be useful.

Hypnotism has been shown to be effective to improve pain sensation and anxiety of patients and decreased the need to use midazolam and alfentanil for patient satisfaction was better than other methods of stress control[21,22]. In a study conducted by Faymonville et al. hypnotism was shown as a complete palliative method for anxiety and pain of patients; it also improved the stress of patients during surgery better than IV sedation methods and reduced the use of midazolam and alfentanil. In another study it was noted that by using hypnosis patient or surgeon satisfaction increased considerably and remarkable improvements in treatming conditions for both patients and surgeons were achieved[11]. Montgomery et al. in their meta-analysis supported the position that hypnosis is an effective adjunctive procedure for a wide variety of surgical patients[22].

In our study, we found that despite reduction in respiratory rate, the percent of O_2 saturation in patients with hypnosis increased. This implies that the reduction in respiratory rate was regulated to improve oxygen saturation. Also, this observation may be due to increase in depth of respiration. In our opinion, further studies are required to investigate spirometer tests in patients with hypnosis and the possibility of using hypnosis in patients with respiratory system problems.

An important strength of this study is derived from this fact that, this is not a clinical based-sample study, but patients were selected and divided randomly into

either hypnotism or IV sedation group. In addition, to our knowledge, it was the first study to assess the effect of hypnosis on vital signs, and O_2 saturation in ophthalmic operation.

We met some limitation in this study. First, it has been suggested that randomized clinical trials underestimate the efficacy of psychological interventions[22]. In clinical practice, no surgical patient is told that he/she may or may not receive treatment based on the flip of a coin. Rather, the clinician and the patient determine the course of treatment together. Therefore, it is possible that randomized trials may somewhat underestimate the impact of hypnosis[22,23]. The second limitation is that all of the patients in the present study had the same race and ethnic, and one may argue that different ethnics and races may have different responses to hypnosis base on their cultures. Third, we could not determine the depth of hypnosis since it may modify the attitude of the patient. This may, in some extend, influences our results because we do not know the exact level of hypnotism over our survey. It is left to the future research to determine whether hypnosis has different efficacy among different cultures and other elements such as additional attention from health care professional or of specific elements associated with hypnosis must be considered.

Conclusion

There was a strong beneficial clinical impact resulted from hypnosis compared to IV sedation in regional or topical anesthesia of ophthalmic surgery. These effects are not limited to patients with specific characteristics and can be obtained easily by hypnosis intervention.

According to these findings, it could be suggested that some parts of hypnosis methods could be implicated in the training courses of certain branches of medicine that perform painful procedures such as surgeons, dentists, and orthopedics without assistance of an anesthesiologist. It was also found that the rates of patient anxiety and hemodynamic variables in hypnosis group were meaningfully better to be controlled more than IV sedation group. Based on the all of the aforementioned statements it could be suggested that in ophthalmic surgery with topical or regional anesthesia, hypnosis could be a better option than IV sedation. In addition to that, anesthesia care options are often made based on surgeon and anesthesiologist skill, as well as the expectation and needs of the patient[24].

In our opinion, more studies are required to formally assess cost-effective of hypnosis interventions and its efficacy for other painful surgeries, to compare the same benefits in other cultures, as well as enhance our understanding of the mechanisms underlying such effects.

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Conflict of Interest

There is no conflict of interest for authors and there is no relationship with organizations that could influence the work.

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Ethical Approval

The study protocol was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences.

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