Perioperative Outcomes of Adjunctive Hypnotherapy Compared with Conscious Sedation Alone for Patients Undergoing Transfemoral Transcatheter Aortic Valve Implantation

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Summary

Transcatheter aortic valve implantation (TAVI) using a transfemoral approach under local anesthesia with conscious sedation (LACS) is becoming an increasingly common TAVI strategy. However, patients who are awake during the TAVI procedure can experience stress, anxiety, and pain, even when LACS is used. Clinical hypnotherapy is an anxiolytic intervention that can be beneficial for patients undergoing invasive surgery. This study aimed to assess the perioperative outcomes of adjunctive hypnotherapy undergoing transfemoral TAVI with LACS.

Consecutive patients (n = 143) with symptomatic severe aortic stenosis who underwent transfemoral TAVI with LACS only (n = 107) or with LACS and hypnotherapy (n = 36) between January 2015 and April 2016 were retrospectively included in the study. The clinical outcomes were compared between the two groups. The LACS with hypnotherapy group had a significantly shorter length of stay in the intensive care unit (ICU; LACS only versus LACS with hypnotherapy: 4.0 (4.0-5.5) days versus 3.0 (3.0-5.0) days, \( P < 0.01 \)). Moreover, the use of anesthetics (propofol and remifentanil) and norepinephrine was significantly lower in the LACS with hypnotherapy group (e.g., for propofol, LACS only versus LACS with hypnotherapy: 96.4 ± 104.7 mg versus 15.0 ± 31.8 mg, \( P < 0.001 \)). The multiple regression analysis showed that being male, hypnotherapy, and the composite complication score were independently associated with the length of stay in the ICU.

The adjunctive hypnotherapy on LACS among transfemoral TAVI patients may facilitate perioperative management. However, a prospective randomized study is necessary to confirm the efficacy of hypnotherapy among TAVI patients.

Key words: Less invasive, Hypnosis, Psychological relief
was to assess the short-term feasibility and efficacy of adjunctive hypnotherapy for transfemoral TAVI patients.

Methods

Study design: This study retrospectively enrolled consecutive patients who had undergone TAVI at Henri Mondor University Hospital (in Créteil, France) from January 2015 to April 2016. Informed consent was obtained from each participant or the participant’s legally authorized representative. The study protocol, which adhered to the principles of the Declaration of Helsinki, was approved by the Institutional Review Board of Henri Mondor University Hospital.

Patients were considered for inclusion in the study if they had undergone TAVI under LACS (with or without hypnotherapy) after being diagnosed with severe symptomatic aortic stenosis and high surgical risk. High surgical risk was defined as a logistic EuroSCORE 1 > 20%, a Society of Thoracic Surgeons (STS) Predicted Risk of Mortality (PROM) score > 10%, or ineligibility for open-heart surgery, as determined by two independent cardiac surgeons. Patients were excluded if they had severe peripheral vascular disease, had a life expectancy < 1 year due to major comorbidities, or received general anesthesia during the TAVI procedure.

TAVI procedures and LACS with hypnotherapy: All of the patients underwent TAVI using a transfemoral approach, which has previously been described in detail. The TAVI procedures were performed using commercially available self-expandable or balloon-expandable systems, that is, the Medtronic CoreValve (Medtronic Inc., Minneapolis, MN, USA) or Edwards SAPIEN valve (Edwards Lifesciences Corp., Irvine, CA, USA), respectively. Regardless of the local anesthesia, 1% lidocaine was applied subcutaneously at the femoral access site. LACS was maintained using a target-controlled infusion of anesthetics (propofol and/or remifentanil) adjusted according to the patient’s response (based on Ramsay Sedation Scale scores of 2 or 3). The decision of using these drugs was made by the anesthesiologist according to the patient’s pain expression regardless of the anesthetized status. To avoid hemodynamic instability, norepinephrine was administered intravenously at the discretion of the anesthesiologist.

An anesthesiologist determined whether they would undergo hypnosis based on whether a hypnotist was available to take part in the TAVI procedure. The hypnotist started to perform the hypnotherapy in a waiting room from the pre-procedural period to the procedure. Using eye fixation and muscle relaxation, the hypnotherapy patients were induced into a state of ‘mental focalization on a pleasant life experience or daydream’ in order to provide psychological relief. During hypnotherapy, the patients were provided with suggestions that were intended to treat specific physical symptoms or anxiety. The details of the induction technique and the exact words used were selected depending on the hypnotist’s observations of the patient’s behavior and judgments regarding the patient’s needs.

Baseline characteristics, follow-up, and endpoints: Baseline demographics and clinical characteristics were compared between the LACS only and LACS plus hypnotherapy groups. Although no clear criteria for ICU discharge exist, the ICU patients were discharged based on the attending physician’s decision regarding whether they did not have any severe conditions that would necessitate the use of an adrenergic agent, mechanical circulatory support, mechanical ventilation, or non-invasive positive-pressure ventilation. However, the general ward of our hospital cannot monitor the electrocardiogram for 24 hours, so the length of ICU stay was relatively long in this study.

The endpoints comprised the length of stay in the ICU, 30-day mortality, and complications during the ICU stay based on the Valve Academic Research Consortium-2 criteria (i.e., the need for pacemaker implantation, bleeding, stroke, acute myocardial infarction, acute kidney disease, pericardial effusion, and vascular complications). Statistical analyses: The continuous variables are presented as means ± standard deviations or median with interquartile range. The between-group differences were compared using unpaired Student’s t-tests or Mann-Whitney U tests when the data were not normally distributed. The categorical variables are presented as frequencies, and the between-group differences were compared using Pearson’s χ²-tests or Fisher’s exact tests when Pearson’s chi-square tests were not applicable owing to the sample size.

Univariate analyses of variables that were potentially associated with the length of stay in the ICU were performed. Variables with P < 0.10 in the univariate analyses were used in the multiple regression analysis. When multicollinearity between the selected variables was suspected, the collinear variable with the highest variance inflation factor was excluded.

The statistical tests were two-tailed, and P < 0.05 was considered statistically significant. The analyses were performed using Statistical Package for Social Sciences (SPSS) version 22 (IBM Corp., Armonk, NY).

Results

Patient enrolment and baseline characteristics: Of the 194 patients referred to our center for TAVI during the study period, 24 were excluded because non-femoral arteries were used as the access site, and, subsequently, 27 were excluded because they were treated with a general anesthetic (the total number of general anesthesia patients was 49). Thus, the vast majority of patients who were referred to our center underwent transfemoral TAVI (87.6%), and most of the transfemoral TAVI patients underwent LACS (84.1%). Consequently, 143 patients were included in the study (Figure), 107 (74.8%) of whom underwent LACS only and 36 (25.2%) of whom underwent LACS with hypnotherapy.

The baseline demographics and clinical characteristics of the patients overall, and in each group, are shown in Table I. There were no significant between-group differences in the baseline clinical characteristics. It appears that patients with low-risks did not tend to be selected in the hypnotherapy group.
Outcomes in this study: The procedural characteristics and outcomes are shown in Table II. Our center mainly uses the self-expandable device because it is one of the major Medtronic device training centers in France. Although there were no significant between-group differences in distributions of the valve types and sizes, fluoroscopy duration, the quantity of contrast medium used, and total procedure time, the patients in the adjunctive hypnotherapy group received significantly less propofol, remifentanil, and norepinephrine compared with those in the LACS only group.

There were two deaths associated with the TAVI procedures, which occurred as a result of annulus rupture in the hypnotherapy group and cardiac tamponade in the LACS only group (due to perforation of the left ventricle with the guidewire). In addition, two patients in the LACS only group died owing to heart failure 17 days after the TAVI procedure and sepsis, respectively. There were no
significant between-group differences in the 30-day mortality rate and complication rates (individually and when all the complications were combined to produce composite scores). However, the adjunctive hypnotherapy group had a significantly shorter length of stay in the ICU compared with the LACS only group.

Univariate analysis of the length of stay in the ICU indicated that the associated variables were as follows (P < 0.10, Table III): hypnotherapy, age, previous history of heart failure, STS PROM score, logistic EuroSCORE 1, and combined complication, nevertheless no correlation was observed with anesthetics drugs.

Moreover, the first multiple regression analysis (which involved variables associated with P < 0.10 in the univariate analyses) showed that being male, hypnotherapy, and the composite complication score were independently associated with the length of stay in the ICU (Table IV). The second model excluded logistic EuroSCORE due to collinearity with the STS PROM score. The second model showed that the STS PROM score, hypnotherapy, and the composite complication score were independently associated with the length of stay in the ICU (Supplemental Table). These findings indicate that adjunctive hypnotherapy conferred an advantage and no increased risk of complications.

**Discussion**

When TAVI patients, who are often frail, develop severe complications, they often have to stay in ICUs for a long time. Our analysis not only showed that the composite complication score was strongly correlated with the length of stay in the ICU but also demonstrated that adjunctive hypnotherapy was independently associated with reduced lengths of ICU stay and reduced anesthetics use during LACS. Early mobilization is important for patients in the ICU to prevent disuse syndrome, reduce the risk of developing dementia, and avoid exacerbating any comorbidities. Thus, our results suggested adjunctive hypnotherapy is feasible and effective in post-operative ICU management for patients undergoing TAVI with LACS. However, the 30-day mortality and complications rate did not differ between the groups. A potential reason is that the clinical factors of TAVI may influence survival to a greater extent than the anesthetic strategy. Moreover, fluoroscopy time and total procedure time also did not differ between both groups (conversely, the adjunctive hypnotherapy group tended to be longer) because the procedure of the hypnotherapy itself might require a slightly longer examination time.

Although it is difficult to obtain objective evidence of hypnosis, one objective aspect is the quantity of anesthetics required for LACS. That is, a hypnotized patient requires a lower dose of anesthetics because hypnosis suppresses the stress related to pain and anxiety. In addition, the myocardial depressant effects of anesthetics can lead to hemodynamic instability necessitating inotropic support. Although we did not analyze data on hemodynamic collapse, the LACS only group required a greater quantity of anesthetics and also more norepinephrine. This indicates that the patients with LACS only group had more hemodynamic instability than those in the adjunctive hypnotherapy group.

Previous research has shown that hypnosis, combined with LACS, provided better relief of pain and anxiety compared with conventional LACS. Although the reduction in the anesthetic use among patients who underwent either structured attention or hypnosis was similar, only the hypnosis group had fewer episodes of hemodynamic instability. In our data, quantities of anesthetics had no correlations with the length of ICU stay even though hypnotherapy was significantly associated with shorter length of ICU stay. These indicate that the beneficial effects of hypnotherapy are not solely explained by reductions in

**Table II. Transfemoral TAVI Procedural Characteristics and Outcomes**

| Variables                        | All patients | Hypnotherapy + | Hypnotherapy - | P value |
|----------------------------------|--------------|----------------|----------------|---------|
| Self-expandable valve            | 126 (88.1)   | 33 (91.7)      | 93 (86.9)      | 0.45    |
| Balloon-expandable valve         | 17 (11.9)    | 3 (8.3)        | 14 (13.1)      |         |
| Valve size, mm                   | 27.9 ± 2.1   | 27.4 ± 2.1     | 28.0 ± 2.1     | 0.15    |
| Contrast medium, mL              | 149.7 ± 44.4 | 159.9 ± 48.0   | 147.1 ± 43.1   | 0.28    |
| Fluoroscopy time, minutes        | 17.2 ± 8.4   | 19.1 ± 9.4     | 16.7 ± 8.0     | 0.27    |
| Total Procedure time, minutes    | 81.3 ± 25.1  | 86.7 ± 27.7    | 78.6 ± 23.3    | 0.17    |
| Propofol, mg                     | 71.4 ± 95.2  | 15.0 ± 31.8    | 96.4 ± 104.7   | <0.001  |
| Remifentanil, μg                 | 129.2 ± 150.6| 56.6 ± 76.5    | 163.8 ± 164.5  | <0.001  |
| Norepinephrine, μg               | 0.58 ± 0.11  | 0.11 ± 0.28    | 0.78 ± 1.33    | <0.01   |
| Length of ICU stay, days         | 4.0 (3.0-5.0)| 3.0 (3.0-3.5)  | 4.0 (4.0-5.0)  | <0.01   |
| 30-day mortality                 | 4 (5.3)      | 1 (5.6)        | 3 (5.2)        | 0.95    |
| AKI                              | 6 (4.2)      | 1 (2.8)        | 5 (4.7)        | 0.62    |
| PM implantation                  | 18 (12.6)    | 4 (11.1)       | 14 (13.1)      | 0.75    |
| Vascular complication            | 13 (9.1)     | 5 (13.9)       | 8 (7.5)        | 0.32    |
| Bleeding                         | 14 (9.9)     | 4 (11.1)       | 10 (9.5)       | 0.79    |
| Stroke                           | 5 (3.5)      | 2 (5.6)        | 3 (2.8)        | 0.37    |
| Tapenade                         | 5 (3.5)      | 1 (2.8)        | 4 (3.8)        | 0.77    |
| Combined complication            | 48 (33.6)    | 12 (33.3)      | 36 (33.6)      | 0.97    |

The continuous variables are presented as means ± standard deviations or median (interquartile range), and the categorical variables are presented as frequencies (with percentages). TAVI indicates transcatheter aortic valve implantation; LACS, local anesthesia with conscious sedation; ICU, intensive care unit; AKI, acute kidney injury; and PM, pacemaker.
Table III. Univariate Analysis for Length of Stay in the ICU

| Variables                      | Correlation coefficient R | 95% CI           | P value |
|--------------------------------|---------------------------|------------------|---------|
| Hypnotherapy                   | −0.21                     | −0.36 to −0.04   | 0.01    |
| Age                            | −0.19                     | −0.35 to −0.03   | 0.02    |
| Male                           | −0.12                     | −0.28 to 0.05    | 0.17    |
| Body mass index                | −0.08                     | −0.24 to 0.09    | 0.36    |
| NYHA class, III/IV             | 0.10                      | −0.07 to 0.26    | 0.26    |
| Hypertension                   | 0.02                      | −0.15 to 0.18    | 0.86    |
| Diabetes Mellitus              | 0.09                      | −0.07 to 0.25    | 0.28    |
| Dyslipidemia                   | 0.11                      | −0.06 to 0.27    | 0.20    |
| Smoker                         | −0.08                     | −0.24 to 0.09    | 0.36    |
| Previous MI                    | −0.08                     | −0.24 to 0.09    | 0.55    |
| Previous PCI                   | −0.03                     | −0.19 to 0.14    | 0.75    |
| Previous CABG                  | −0.05                     | −0.21 to 0.12    | 0.57    |
| Previous heart failure         | 0.15                      | −0.01 to 0.31    | 0.07    |
| COPD                           | 0.09                      | −0.08 to 0.25    | 0.29    |
| Atrial fibrillation            | −0.09                     | −0.25 to 0.08    | 0.31    |
| eGFR                           | −0.13                     | −0.29 to 0.04    | 0.14    |
| STS PROM score                 | 0.23                      | 0.07 to 0.38     | < 0.01  |
| Logistic EuroSCORE1            | 0.16                      | −0.001 to 0.32   | 0.05    |
| LVEF, %                        | 0.06                      | −0.22 to 0.10    | 0.45    |
| Indexed AVA                    | 0.03                      | −0.15 to 0.21    | 0.78    |
| mean AVPG                      | 0.01                      | −0.16 to 0.19    | 0.88    |
| PAG                            | −0.001                    | −0.21 to 0.21    | 0.99    |
| Self-expandable valve use      | 0.02                      | −0.15 to 0.18    | 0.83    |
| Valve size                     | −0.11                     | −0.27 to 0.06    | 0.21    |
| Contrast medium                | −0.1                      | −0.27 to 0.08    | 0.27    |
| Fluoroscopy time               | −0.06                     | −0.23 to 0.12    | 0.53    |
| Propofol use                   | 0.12                      | −0.11 to 0.34    | 0.32    |
| Remifentanil use               | 0.16                      | −0.07 to 0.37    | 0.17    |
| Norepinephrine use             | 0.08                      | −0.15 to 0.30    | 0.48    |
| Combined complication          | 0.33                      | 0.18 to 0.47     | < 0.001 |

Abbreviations are shown in Tables I and II. CI indicates confidence interval.

Table IV. Multiple Regression Analyses for Length of Stay in the ICU, in Which the Variables Associated with P < 0.10 in the Univariate Analyses Were Used in the Multiple Regression Analysis

| Variables                      | Univariate analysis | Multiple Regression Analysis |
|--------------------------------|---------------------|------------------------------|
|                                | P value             | Standardized partial regression coefficient | 95% CI | P value | VIF |
| Age                            | 0.02                | −0.13                         | −0.10 to −0.01 | 0.12 | 1.15 |
| Previous Heart Failure         | 0.07                | 0.07                          | −0.46 to 1.20 | 0.38 | 1.18 |
| Hypnotherapy                   | 0.01                | −0.22                         | −1.96 to −0.34 | < 0.01 | 1.03 |
| STS PROM score                 | < 0.01              | 0.17                          | −0.02 to 0.14 | 0.12 | 2.01 |
| Logistic EuroSCORE1            | 0.05                | 0.07                          | −0.03 to 0.05 | 0.53 | 2.11 |
| Composite Complication         | < 0.001             | 0.28                          | 0.62 to 2.14 | < 0.0005 | 1.10 |

ICU indicates intensive care unit; CI, confidence interval; VIF, variance inflation factor; STS, Society of Thoracic Surgeons; and PROM, Predicted Risk of Mortality.

anesthetics use but may be explained by reductions of anxiety and pain.13)

There is evidence that hypnosis can modulate the immune system.21) Several studies have suggested that hypnosis regulates stress-induced disorders of T-lymphocytes and natural killer cells and increases plasma cortisol concentrations.22-24) Another study showed that hypnosis reduced the inflammatory cytokine interleukin-6 in healthy subjects.25) Based on these findings, we speculate that hypnosis-induced relief from stress, which can modulate the immune system, may have mediated the shorter length of stay in the ICU.

Both transfemoral approach and LACS on TAVI are becoming increasingly common. In addition, TAVI patients tend to be elderly and frail; thus, most TAVI patients need a strategy to control their pain and anxiety using the smallest possible quantity of anesthetics. A recent report suggested that using a minimally invasive TAVI procedure with LACS may reduce costs compared with traditional TAVI procedures.26) Furthermore, hypnotherapy
is inexpensive and associated with shorter lengths of ICU stay, which could further reduce the costs of TAVI procedures. Therefore, hypnotherapy has the potential to be a cost-effective intervention for TAVI patients.

We consider that hypnotherapy is not a special treatment but rather necessary clinical communication that can be described as the sharing of a sense of purpose with patients and gaining their confidence. These are clinically important and simple to obtain, though are often neglected. We should not deal with hypnotherapy as an "amazing therapy" and should consider that gaining the trust or sharing the goals with patients improves clinical outcomes.

The study has several limitations. First, because it involved a retrospective single-center analysis which did not involve randomization, selection bias may not be entirely excluded (however, the characteristics in the two groups were similar). Second, the number of subjects was relatively small because of the single-center design, relatively short study period, and stringent inclusion criteria. Hence, a large-scale, multi-center, prospective study is necessary to confirm the results. In addition, as we did not evaluate the patients' pain or anxiety, it is unclear whether hypnosis had a positive effect on these outcomes in TAVI patients. Despite these limitations, our results suggest that adjunctive hypnotherapy has benefits for patients undergoing transfemoral TAVI in terms of the shorter length of ICU stay and the reduction of anesthetics use.

Conclusion

The adjunctive hypnotherapy on LACS among transfemoral TAVI patients may facilitate perioperative management. However, a prospective randomized study is necessary to confirm the efficacy of hypnotherapy among TAVI patients.

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Gauthier Mouillet and Emmanuel Teiger have served as TAVI procedural proctors for Medtronic Inc. The others have no conflicts of interest to declare.

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Supplemental Files
Supplemental Table
Please see supplemental files; https://doi.org/10.1536/ihj.19-296