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Bispectral index-guided sedation in transfemoral transcatheter aortic valve implantation: a retrospective control study

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Abstract: Objective: Transcatheter aortic valve implantation (TAVI) is a minimally invasive therapy for elderly patients with severe aortic valve stenosis who were refused surgical aortic valve replacement because of the high perioperative risk. Traditionally, this procedure has been done under general anesthesia, but more recently local anesthesia and sedation have become popular. This research assessed the effectiveness of transfemoral TAVI under bispectral index (BIS)-guided sedation. Methods: In this single-center retrospective control analysis, clinical data, including demographic characteristics, echocardiography, periprocedural data, and main complications, were collected and assessed in 113 patients undergoing TAVI through the femoral artery under general anesthesia (GA group, n=36) and under BIS-guided sedation (SED group, n=77). Results: The demographic characteristics and echocardiographic parameters between the two groups were similar (P>0.05). Two (2.6%) of patients were moved from BIS-guided sedation to general anesthesia for surgical reasons. Procedures were significantly shorter in the SED group than in the GA group ((127.10±44.43) min vs. (165.90±71.62) min, P=0.004). Patients in the SED group lost less blood and received significantly fewer red blood cells and catecholamines than those in the GA group (5.19% vs. 22.22%, P=0.017 and 67.53% vs. 97.22%, P<0.001). The length of hospital stay was significantly shorter and there were fewer pulmonary complications in the SED group than in the GA group. Thirty-day mortality was similar between the two groups. Conclusions: BIS-guided sedation is a feasible and safe approach for transfemoral TAVI. The anesthesiologist should choose the best anesthetic method according to the team's experience.

Key words: Transcatheter aortic valve implantation; Sedation; Bispectral index
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1 Introduction

Transcatheter aortic valve implantation (TAVI) is a rapidly developing procedure for patients with severe aortic stenosis. Those patients with high perioperative risk, who refuse surgical aortic valve replacement, might choose this minimally invasive procedure (Liu *et al*., 2015; Malaisrie *et al*., 2016). With emerging valve technologies and improving operator experience, TAVI is likely to become an alternative option for patients at intermediate risk in the near future (Arsalan and Walther, 2016).

Traditionally, TAVI is performed under general anesthesia provided by a qualified anesthetist experienced in managing conventional cardiac surgery (Guinot *et al.*, 2010). Growing experience, expansion of the indication to "intermediate-risk" patients, and economic considerations have led to an increasing interest and discussion about performing transfemoral TAVI under sedation (Mayr *et al.*, 2015). Compared with general anesthesia, sedation and local anesthesia have many advantages, such as shorter procedure duration, quicker recovery, and shorter length of hospital stay (Fröhlich *et al.*, 2014). Procedural sedation

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and analgesia is the most commonly used method. In previous studies, some researchers used superficial sedation with Ramsay score 2 to 3 to allow for continuous neurological monitoring (Yamamoto *et al*., 2013). However, other anesthetists prefer deep sedation because it prevents the patient from moving (Mayr *et al.*, 2016).

We hypothesized that different sedation depths would be needed during TAVI depending on the operative stimulation and the importance of the procedures. We used the bispectral index (BIS), one of several systems used to measure the patient's level of sedation, to guide our sedation. The objective of this study is to evaluate the effectiveness of BIS-guided sedation in a group of Chinese patients.

2 Materials and methods

Clinical data from patients undergoing transfemoral TAVI at the Cardiac Center of the Second Affiliated Hospital of Zhejiang University (SAHZU) between March 2013 and February 2016 were collected retrospectively from medical records and the anesthesia collecting and recording system. The study design and informed consent were approved by the Ethics Committee of SAHZU. Before each patient received TAVI, he or she signed a consent form allowing us to collect his or her clinical data.

2.1 Anesthesia management

Anesthesia for all patients was provided by the same two qualified cardiothoracic anesthesiologists. All procedures were conducted under standard monitoring, including electrocardiogram (EKG), pulse oxygen saturation (SpO_2), temperature, and end-tidal carbon dioxide ($ETCO_2$). In addition, an arterial line (right radial), central vein catheter (right internal jugular vein), and BIS (Aspect BIS VISTA, USA) were placed before the beginning of general anesthesia (GA group) or sedation (SED group).

In the GA group, patients were treated according to a fast-track heart surgery anesthesia protocol with minor modification. Briefly, bolus doses of midazolam (0.03–0.05 mg/kg), etomidate (2–3 mg/kg), sufentanil (0.5–1.0 μg/kg), and cisatricunium (0.2–0.3 mg/kg) were administrated to induce anesthesia. All patients were then intubated with an endotracheal tube. Continuous infusions of propofol, sufentanil, and cisatricunium were used to maintain anesthesia. The BIS was kept in a range of 40–60. In the SED group, all elderly patients were given oxygen via a face mask as soon as they arrived in the operating room. Dexmetomidine (0.1–0.5 μg/(kg·h)), propofol (2–6 mg/(kg·h)), and remifentanil (2–4 μg/(kg·h)) were continuously infused to reach the BIS range of 60–70. Bolus doses of fentanyl (30–50 μg) and propofol (30–50 mg) were used to decrease BIS to 40–60 during the period of skin incision, pacing, balloon expansion, and valve release when necessary. Local anesthesia was performed with 1% (0.01 g/ml) lidocaine and 0.2% (2 g/L) ropivacaine before skin incision. An oropharyngeal airway was used when necessary to keep the airway unobstructed.

External defibrillator pads were placed on each patient (Medtronic, USA). Red blood cells were given if the hematocrit was lower than 25% or hemoglobin (Hb) less than 7 g/L. Mean arterial pressure was maintained above 65 mmHg (1 mmHg=133.3 Pa) during the entire procedure. Intravenous crystalloid or colloid infusion and boluses of catecholamines (norepinephrine or epinephrine) were used to treat hypotension according to trans-esophageal echocardiography (TEE) results. When the procedures were completed, all patients were transferred to the intensive care unit (ICU).

2.2 TAVI technique

All TAVI procedures were performed by the same group of cardiologists. The CoreValve device (Medtronic, USA) was implanted in all patients. The size of valve chosen by the cardiologists depended on the results of TEE and dual-source computed tomography (DSCT). Before the implantation, a balloon was used to dilate the native diseased valve under rapid ventricular pacing. The new valve was then implanted under fluoroscopic guidance. Aortic root angiography and TEE were used to confirm the valve position and function. The incision site of the femoral artery was finally closed percutaneously with an arterial closure device (Abbott Vascular, USA).

2.3 Statistics

Statistical analyses were performed with GraphPad Prism 6.0.2 (GraphPad Software Inc., USA). Categorical data are presented as a number and

percent and were analyzed with χ^2 test. The Fisher's exact test or Yates' continuity-corrected χ^2 test was used when more than 20% of the expected observations were less than 5 or any expected observation was less than 2. Continuous data are presented as mean±standard deviation (SD) and were compared with the Student's *t*-test for unpaired samples when a normal deviation was assumed. The Wilcoxon-Mann-Whitney (WMW) test was used when the data did not deviate normally. A *P*-value of less than 0.05 was considered to be statistically significant.

3 Results

Four of the 117 patients who underwent TAVI in the SAHZU Cardiac Center between March 2013 and February 2016 were excluded from our study as their data were incomplete. Thirty-six (32%) of procedures were performed under general anesthesia, whereas 77 (68%) were conducted under BIS-guided sedation and local anesthesia.

A shift in the proportion of patients from general anesthesia to BIS-guided sedation was observed over time (Fig. 1). From March 2013 to February 2014, general anesthesia was mainly used. From March 2014 to February 2016, most patients underwent TAVI under BIS-guided sedation. Sedation failure occurred in no patients. Two (2.6%) patients in the SED group were converted to GA due to procedural complications, one because of a change in surgery access and the other because of major cardiovascular complications.

3.1 Baseline characteristics

The baseline patient characteristics are shown in Table 1. All demographic variables between the two groups are similar (*P*-value are presented in Table 1). Patients were mostly classified as New York Heart Association (NYHA) III/IV with a history of hypertension and chronic heart failure (85.8%). Ischemic heart disease, peripheral artery disease, and pulmonary hypertension existed in nearly half of the patients. Nearly 20% had diabetes mellitus, atrial fibrillation, chronic obstructive pulmonary disease (COPD), renal failure, or pleural effusion and one-tenth suffered a pulmonary infection. There were no significant differences between the groups in ejection fraction.

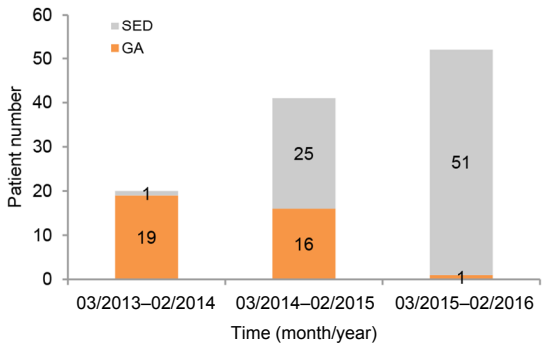

Fig. 1 Shift from general anesthesia (GA) to BIS-guided sedation (SED)

Table 1 Baseline patient characteristics

Characteristics	Overall (*n*=113)	GA (*n*=36)	SED (*n*=77)	*P*-value
Age (year)	74.68±6.22	75.94±5.63	74.09±6.40	0.141
Male	74 (65.48%)	21 (58.33%)	53 (68.83%)	0.274
BMI (kg/m^2)	23.18±3.28	22.97±3.17	23.27±3.20	0.675
LVEF (%)	52.34±13.13	51.44±12.23	52.75±13.62	0.694
NYHA III/IV	84 (74.34%)	30 (83.33%)	54 (70.13%)	0.168
Heart failure history	97 (85.84%)	32 (88.89%)	65 (84.42%)	0.525
Hypertension	59 (52.21%)	17 (47.22%)	42 (54.55%)	0.468
Peripheral artery disease	55 (48.67%)	16 (44.44%)	39 (50.65%)	0.539
Ischemic heart disease	53 (46.90%)	17 (47.22%)	36 (46.75%)	0.963
Atrial fibrillation	18 (15.93%)	5 (13.89%)	13 (16.88%)	0.685
COPD	18 (15.93%)	7 (19.44%)	17 (22.08%)	0.750
Pulmonary hypertension	52 (46.01%)	17 (46.22%)	35 (45.45%)	0.861
Diabetes mellitus	20 (17.70%)	7 (19.44%)	13 (16.88%)	0.740
Renal failure	17 (15.04%)	5 (13.89%)	12 (15.58%)	0.814
Pulmonary infection	8 (7.08%)	5 (13.89%)	3 (3.90%)	0.108
Pleural effusion	22 (19.47%)	10 (27.78%)	12 (15.58%)	0.136

Data are expressed as mean±SD or number (percent). BMI: body mass index; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; COPD: chronic obstructive pulmonary disease

3.2 Periprocedural variables and complications

Periprocedural variables and complications data are shown in Table 2. The average procedural time was (139.50±57.19) min. Total procedure time in the SED group was significantly shorter than that in the GA group ((127.10±44.43) min vs. (165.90±71.62) min, P=0.004). Patients in the SED group lost significantly less blood ((105.30±11.61) ml vs. (186.90±39.65) ml, P=0.014) and were significantly less likely to receive red blood cells and catecholamines (5.19% vs. 22.22% and 67.53% vs. 97.22%, P<0.05) than those in the GA group. The rates of periprocedural complications (ventricular fibrillation and cardiac tamponade) were the same in both groups.

3.3 Postprocedural variables and complications

Postprocedural variables and complication data are presented in Table 3. Four patients eventually died, three in the GA group and one in the SED group. The thirty-day mortality was similar in the two groups (8.33% in GA group vs. 1.30% in SED group, P=0.181). The length of hospital stay was significantly longer in the GA group than in the SED group ((17±7) d vs. (14±6) d, P=0.006).

There was no difference between the groups in the occurrence of cardiovascular complications, such as stroke, major vascular complication, surgery for vascular complication, or pacemaker implantation. For some general complications with anesthesia, such as post-operative cognitive dysfunction (POCD) and post-operative nausea and vomiting (PONV), the rates of occurrence were similar. There was a trend that less PONV occurred in the SED group than in the GA group (1.30% vs. 8.33%, P=0.095). The reintubation rate after the procedure in the SED group was 1.30% compared to 5.56% in the GA group, but no statistical difference was found (P=0.494). There was a higher occurrence of pulmonary infection (47.22% vs. 12.99%, P<0.001) and pleural effusion (47.22% vs. 22.08%, P=0.009) in the GA group than in the SED group.

4 Discussion

4.1 BIS-guided sedation is feasible in TAVI

It is difficult to provide sedation safely in elderly patients with severe complications (Lambert and Anwar, 2016). According to our results, BIS monitoring

Table 2 Periprocedural variables and complications

Variables/complication	Overall (n=113)	GA (n=36)	SED (n=77)	P-value
Operation time (min)	139.50±57.19	165.90±71.62	127.10±44.43	0.004
Blood lost (ml)	131.30±15.22	186.90±39.65	105.30±11.61	0.014
Catecholamines	87 (76.99%)	35 (97.22%)	52 (67.53%)	<0.001
Epinephrine	87 (76.99%)	35 (97.22%)	52 (67.53%)	<0.001
Norepinephrine	79 (69.91%)	33 (91.67%)	46 (59.74%)	<0.001
RBC transfusion	12 (10.62%)	8 (22.22%)	4 (5.19%)	0.017
Ventricular fibrillation	2 (1.77%)	1 (2.78%)	1 (1.30%)	0.834
Cardiac tamponade	1 (0.88%)	0 (0%)	1 (1.30%)	0.696
LVEF post procedure (%)	55.55±10.36	55.03±8.80	55.78±11.04	0.727

Data are expressed as mean±SD or number (percent). RBC: red blood cell; LVEF: left ventricular ejection fraction

Table 3 Postprocedural variables and complications

Variables/complication	Overall (n=113)	GA (n=36)	SED (n=77)	P-value
Length of hospital stay (d)	15±6	17±7	14±6	0.006
Thirty-day mortality	4 (4.54%)	3 (8.33%)	1 (1.30%)	0.181
Acute kidney injury	1 (0.88%)	0 (0%)	1 (1.30%)	0.696
Stroke	2 (1.77 %)	0 (0%)	2 (2.60%)	0.834
Major vascular complication	2 (1.77%)	1 (2.78%)	1 (1.30%)	0.834
Surgery for vascular complication	2 (1.77%)	1 (2.78%)	1 (1.30%)	0.834
Pacemaker implantation	18 (15.93%)	7 (19.44%)	11 (14.29%)	0.583
Reintubation	3 (2.65%)	2 (5.56%)	1 (1.30%)	0.494
POCD	5 (4.42%)	3 (8.33%)	2 (2.60%)	0.373
PONV	4 (3.54%)	3 (8.33%)	1 (1.30%)	0.095
Pulmonary infection	27 (23.89%)	17 (47.22%)	10 (12.99%)	<0.001
Pleural effusion	34 (30.09%)	17 (47.22%)	17 (22.08%)	0.009

Data are expressed as mean±SD or number (percent). POCD: post-operative cognitive dysfunction; PONV: post-operative nausea and vomiting

can effectively guide the depth of sedation during TAVI.

When compared with procedural sedation, BIS monitoring has several advantages. It is an objective method of monitoring sedation that has been widely used in various surgical and endoscopic procedures: a BIS value of about 70 provides effective sedation for procedures like gastrointestinal endoscopy inspection and endoscopic submucosal dissection (Yu *et al*., 2013). BIS can also provide continuous monitoring of sedation depth, enabling the anesthesiologist to alter the depth of sedation in pace with the procedures.

In TAVI, the most important issue is control of sedation depth. Patients undergoing TAVI always have unstable hemodynamic states which are worsened by commonly used anesthetics. This always leads to unsatisfactory sedation depth. Patients have to stay stable and no movement is permitted during the procedure. However, prolonged deep sedation could result in severe complications, especially in these kinds of patients, such as hypotonia of the hypopharyngeal muscles in elderly patients, intraprocedural hypercarbia, and increased aspiration risk (Mayr *et al*., 2015). Continuous BIS monitoring can provide satisfactory sedation depth, prevent body movement during key procedures, and reduce the risk of prolonged deep sedation.

According to our experience, deep sedation is needed (BIS less than 50) during skin incision, ventricular pacing, balloon expansion, and valve releasing, because the stimulation is big and patient may move during these crucial periods. At other stages of the procedure, the value of BIS could be maintained at around 70.

Some anesthetists chose general anesthesia because of the need to use TEE to evaluate valve function. In our center, we do TEE evaluation under deep sedation (BIS value around 40) while keeping the patient breathing spontaneously. Some measures need to be undertaken to prevent possible complications. These include strict fasting, keeping the airway unobstructed and suction after probe extraction.

4.2 BIS-guided sedation vs. general anesthesia

Even though TAVI has become the treatment of choice for patients who are considered inoperable or at very high risk for a surgical procedure, the best method of anesthesia for this procedure is still under debate.

Other researchers have suggested that TAVI performed under sedation results in better control of hemodynamic status, shorter procedural time, and shorter overall length of stay in hospital when compared with general anesthesia (Dehédin *et al*., 2011). According to our results with elderly Chinese patients, sedation with local anesthesia had several advantages over general anesthesia for transfemoral TAVI. Even though there was no difference in the thirty-day mortality rate between the two methods, sedation with local anesthesia increased hemodynamic stability (less need for norepinephrine and epinephrine support), reduced postprocedural pulmonary complications, and led to shorter hospital stays.

We found fewer pulmonary complications, including pulmonary infection and pulmonary effusion, in the SED group. This advantage was also found by some other researchers (Goren *et al*., 2015). Preexisting pulmonary infection, TEE insertion, long procedure time, and the high incidence of blood transfusion may be the main reasons for the high rate of pulmonary complications in our sample. However, larger sample numbers would be needed to analyze their real relationship.

We compared the incidence of POCD and PONV between the SED and GA groups. The average rate of POCD in TAVI is 4.4% and it was similar between the two groups. Two patients with POCD also had a stroke, delirium being the main symptom. There was a lower incidence of PONV with sedation, possibly because of the much higher dose of opioids and reduced hemodynamic stability seen in general anesthesia.

We also demonstrated that there was no significant difference between the two groups in the occurrence of major postprocedural complications such as stroke, acute kidney injury, and major vascular complications. Other studies have reported the same (Bergmann *et al*., 2011). Just as others reported (Yamamoto *et al*., 2013), the mode of anesthesia in our center shifted with time and increasing experience. The number of procedures under bispectral guide sedation and local anesthesia increased while those under general anesthesia decreased.

4.3 Limitations

Firstly, due to the functioning of the BIS machine, there is a delay of several seconds in determining the

value of BIS, which the user should take into account. Secondly, as the sample was from one center, the research result might not be applicable. Thirdly, in this retrospective observational study, the anesthetic method was not chosen randomly by the anesthesiologists, so that a selection bias could not be avoided. A multicenter randomized controlled prospective study comparing BIS-guided sedation with standard methods of sedation is underway. Lastly, our study was completed during a period of learning for both the anesthesiologists and cardiologists; this may affect the result. For example, we thought that the operation time was shortened in the BIS-guided sedation group because of the benefit of the anesthetic method, but the real situation was that most patients underwent BIS-guided sedation during the later phase when the experience of the anesthesiologists and cardiologists had increased.

5 Conclusions

BIS-guided sedation is safe and feasible for the vast majority of patients who are undergoing transfemoral TAVI. The anesthesiologist should choose the best method of anesthesia, taking into account the team's experience as well as the patient's status.

Compliance with ethics guidelines

Wei HE, Rong-rong HUANG, Qing-yu SHI, Xian-bao LIU, Jian-an WANG, and Min YAN declare that they have no conflict of interest.

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). Informed consent was obtained from all patients for being included in the study.

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中文概要

题　目：脑电双频谱指数导向的镇静在股动脉入路经导管主动脉瓣植入术中的应用

目　的：探讨脑电双频谱指数（BIS）导向的镇静在股动脉入路经导管主动脉瓣植入术（TAVI）中的可行性和有效性。

创新点：由于 TAVI 患者高龄、心功能差、合并症多，加上导管室布局不利于麻醉操作，实施镇静难度很大。我们利用目前常用的镇静监测手段 BIS 来实施导向镇静，有效地实现了深度可控的镇静，减少了并发症。

方　法：回顾了本中心所有经股动脉入路的 113 名 TAVI 患者（图 1）。将患者分为两组，其中 36 名患者进行了全身麻醉，77 名患者施行了 BIS 导向的镇静。两组患者的术前一般情况的差别不显著（表 1）。术中资料显示，BIS 导向的镇静组较全身麻醉组手术时间更短、失血更少、输血制品和血管活性药使用更少（表 2）。术后的资料显示，两组的 30 天死亡率差异不显著，而 BIS 导向的镇静组有更短的住院时间和更少的肺部并发症（表 3）。

结　论：BIS 导向的镇静在股动脉入路 TAVI 是安全可行的。各个临床中心可根据自身经验选择最合适的麻醉方法。

关键词：经导管主动脉瓣植入术；镇静；脑电双频谱指数