VIA MEDICA

PRACE ORYGINALNE I KLINICZNE

Anestezjologia Intensywna Terapia
2017, tom 49, numer 1, 44–50
ISSN 0209–1712
www.ait.viamedica.pl

Local anaesthesia with analgosedation in patients qualified for transcatheter aortic valve implantation (TAVI): first institute's results and experiments

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Abstract

Background: The authors present their own experience of the treatment of patients qualified for transcatheter aortic valve implantation (TAVI) carried out in a modern hybrid operating room. The objective of the present study was to demonstrate the initial results of conducting anaesthesia in high-risk patients qualified for the TAVI procedure (transcatheter aortic valve implantation). In addition, the authors' aim was also to point out to the special challenges of an anaesthesiologist conducting local anaesthesia in such a type of procedures and to evaluate the safety and efficacy of the TAVI procedure conducted under remifentanil analgosedation.

Methods: A retrospective analysis included patients treated during the period from September 2015, when local anaesthesia for the transcatheter aortic valve implantation was used for the first time at our centre, up to February 2016. The studied population consisted of 11 patients treated for severe aortic valve stenosis. The mean age of patients was 80 ± 7 years. Three patients were men (27%) and eight were women (73%). The study included all subsequent patients (n = 11), treated in our centre, for whom it was decided to perform TAVI under local anaesthesia.

Results: The total hospital mortality rate was 0%. All procedures were performed in a hybrid operating room. Despite the complications observed in the described group, the hospital mortality rate during TAVI was 0%. All patients, after 12 ± 5 days of treatment, left the hospital in a good neurological condition, which was assessed based on the CPC-1 (Cerebra Performance Categories Scale) and GCS-15 (Glasgow Coma Scale) scales. With an ejection fraction of the left ventricle of 53 ± 11%, the transcatheter aortic valve was successfully implanted.

Conclusions: Percutaneous aortic valve implantation can be successfully conducted under remifentanil analgosedation. TAVI procedures should be performed in the conditions of a modern, well-equipped hybrid room. The aim of the anaesthesiologist should consist of conducting the least invasive anaesthesia/analgesia, bearing in mind the safety and comfort of the patient.

Anaesthesiology Intensive Therapy 2017, vol. 49, no 1, 44–50

Key words: percutaneous cardiac surgery, aortic stenosis, aortic valve replacement, local anaesthesia

Transcatheter aortic valve implantation (TAVI) has provided a therapeutic alternative for symptomatic patients with severe aortic stenosis [1]. Severe aortic valve stenosis is defined in an integrated manner

Należy cytować wersję: Musiał R, Lipińska-Strasik M, Piątkiewicz A, Stoliński J, Drwiła R. Local anaesthesia with analgosedation in patients qualified for transcatheter aortic valve implantation (TAVI): first institute's results and experiments. Anaesthesiol Intensive Ther. 2017, vol. 49, no 1, 40–46. doi: 10.5603/AIT.a2017.0002.

taking into consideration the aortic valve exit surface area (< 1.0 cm^2 or < 0,6 $cm^{2*}m^{-2}$ BSA except for obese patients) and flow-dependent indices (maximum flow velocity of 4 m s^{-1} through the valve and mean aortic gradient ≥ 40 mm Hg). Severe aortic valve stenosis is a well-known mortality risk factor [2]. Currently, surgical aortic valve replacement (AvR) is the treatment of choice for a large majority of patients with severe aortic valve stenosis [3]. However, nearly 30% of older patients with numerous coexisting diseases are considered not to be eligible for surgical treatment due to perioperative mortality [4]. Transcatheter aortic valve implantation (TAVI), a new method of severe aortic valve stenosis which has been introduced recently, has dynamically developed and minimised surgical trauma related to cardiac arrest, sternotomy, or the use of extracorporeal circulation in high-risk patients [5–8]. The experience of centres that have conducted transcatheter aortic valve implantation is still growing. Many of these centres have abandoned general anaesthesia and transesophageal sonography and are performing procedures with local anaesthetization or sedation [9–11]. The first TAVI in Poland was conducted at our centre in 2008. Since then, a considerable technological advancement has taken place in terms of implanted valves, while the way of treating patients during periprocedureal period is being continuously improved.

The objective of this study was to evaluate the safety and efficacy of the TAVI procedure conducted with remifentanil analgosedation.

METHODS

PATIENTS

The study was conducted following the Declaration of Helsinki. The preparation of this manuscript was approved by the management of the local hospital. The study included all subsequent patients treated at the Anaesthetics and Intensive Care Unit of the Clinical Department of Cardiovascular Surgery and Transplantation of the Jagiellonian University in Krakow, who were qualified for the TAVI procedure under local anaesthesia. The analysis included a group of 11 patients treated during the period from September 2015, when the first TAVI in local anaesthesia was conducted in our clinic, up to February 2016. The retrospective analysis included demographical data, coexisting disease, valve sonogram prior and after TAVI, procedure time, fluoroscopy, valve type, ejection fraction of the left ventricle after acceptance to the hospital, troponin profile, time of hospital stay, intensive care time, as well as complications occurring during treatment.

METHODS

Transcatheter aortic valve implantation procedures were carried out in a hybrid operating room which is an operating theatre with an integrated angiogram, where endovascular or intracardiac procedures are carried out. Our centre has the Artiz Zeego (Siemens, Germany) angiogram at its disposal. The hybrid operating room constitutes a combination of a conventional operating theatre and a room for percutaneous procedures and haemodynamic study. The room is fitted with high-end technology equipment. The X-ray machine, installed on a c-arm, pivots 360 degrees, enabling precise imaging, and thus allowing angiographic, subtractional and tomographic examinations. The hybrid room is equipped with an anaesthetization station that fully monitors vital functions, enabling the safe performance of analgesia, analgosedation, as well as general anesthetization. The procedures were carried out by interventional cardiologist, with the active participation of a cardiac surgeon, radiology technician and perfusionist. The course of analgosedation was supervised by an anaesthesiologist, along with an anaesthesiological nurse. The retrospective analysis included patients treated during the period from September 2015, when local anaesthesia for transcatheter aortic valve implantation was used for the first time at our centre, up to February 2016. The studied population consisted of 11 patients treated for severe aortic valve stenosis. The study included all subsequent patients (n = 11), treated at our centre, for whom it was decided to perform TAVI under local anaesthesia. The routine monitoring included a five-point electrocardiogram with an automatic analysis of the ST segment, pulse oxymetry, direct blood pressure measurement via a cannula inserted in the radial artery (usually right), transthoracic echocardiography and hourly diuresis via a Foley catheter inserted in the urinary bladder. Prior to the procedure, patients were inserted with two peripheral cannulas. One of these was intended for propofol (Fresenius Kabi, Deutschland) and remifentanil (Ultiva, Glaxo, Anglia) infusion, whereas the other one was for liquid infusion. In ten patients, an endocardial lead was inserted into the right ventricle, while in two patients, it was decided to insert the central injection for the measurement of the central venous pressure (CVP). All patients were supplied with passive oxygen therapy via face mask with an oxygen flow of 4–5 L min^{-1}. Analgesia was conducted by continuous infusion of an ultra-short-acting remifentanil opioid in doses 0.05–0.08 mg kg^{-1} min^{-1}; a few patients were continuously infused with propofol (Fresenius Kabi,

Table 1. General characteristics of patients

Patients	1	2	3	4	5	6	7	8	9	10	11	Median	Interqartile range
Age (years)	80	87	77	79	82	87	82	85	80	63	75	80	8
Sex	F	F	F	F	F	F	F	F	M	M	M	3 (M)	–
IM	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	9	–
PCI	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	8	–
CABG	No	No	Yes	No	No	No	No	No	No	Yes	No	2	–
Stroke	No	No	Yes	No	No	No	No	No	No	No	No	1	–
Diabetes	No	Yes	No	Yes	No	No	Yes	No	Yes	No	No	4	–
Weight (kg)	73	62	78	66	73	68	63	75	76	74	106	73	10
Height	158	168	161	157	153	152	149	163	167	169	160	160	14
BMI (kg cm^{-2})	29.2	22.0	30.1	26.8	31.2	29.4	28.4	28.2	27.3	25.9	41.4	28.4	3.30
Other	Foramen ovale	St. after thyroid removal, asthma, HA FA, colon diverticula	MIC, HA, FA, COPD, St. after hysterectomy, umbilical hernia	HA, FA	St. after haemorrhage from UGIT, HA, ulcer disease, CRI st III, anaemia	St. after haemorrhage from UGIT, HA, ulcer disease, FA, colon diverticula	Hyperthyroidism, St. after meningiomaradiotherapy, COPD	CRI, paroxysmal FA,	CRI, paroxysmal FA, CRI st III, HA, ulcer disease, St. after impl. DDD	St. p. TAVI Medtronic Corevalve Valve in valve	St. after thoracotomy, orcelain aorta, COPD	–	–

IM — myocardial infarction; PCI — percutaneous coronary intervention; CABG — coronary artery bypass graft; BMI — body mass index; CRI — chronic renal insufficiency; DDD — atrioventricular stimulation inhibited by the appropriate rhythm of the atria and/or ventricles; MIC — morbus ishemicus cordis; HA — hypertonia arterialis; FA — flagelatio atriorum; COPD — chronic obstructive pulmonary disease; UGIT — upper gastrointestinal tract

Germany) in doses 4–12 mg kg^{-1} h^{-1}. During the procedure, a standard liquid infusion was used (12–15 mL kg^{-1} h^{-1}) in order to maintain haemodynamic stability. Two external defibrillator electrodes were installed on the chest of each patients. Moreover, each patient had two units of packed red blood cells crossed and reserved for the periprocedureal period.

Heparin was administered during the procedure in order to obtain an activated coagulation time (ACT) of 250 seconds. In our study, prostheses of the following valves were implanted: Lotus Valve System (Boston Scientific), Sapien 3 (Edwards) and Core Valve Evolut R (Medtronic).

Prior to uncovering the artery, local anaesthesia with 1% lidocaine – was infused in the area of the right and left groins. The femoral artery was surgically uncovered and then injected undera visual supervision. The injection site was secured by a purse-string closure. After the procedure, all patients were transferred to the intensive care unit for further monitoring.

STATISTICAL ANALYSIS

Statistical analysis was conducted using STATISTICA 10 PL software. The median and interquartile ranges were calculated for quantitative variables. Relative values were provided for the analysis of qualitative variables.

RESULTS

The authors report their first experiences in conducting transcatheter aortic valve implantation under analgosedation at their centre. Table 1 presents demographic data and general characteristics of the studied groups with coexisting diseases. The studied population consisted of 11 patients treated for severe aortic valve stenosis. The mean patient age was 80. Three patients were men and eight were women. The study included all subsequent patients (n = 11), treated at our centre, for whom it was decided to perform TAVI under local anaesthesia. The total hospital mortality rate was 0%.

Table 2. Patient characteristics in the immediate preoperative period

Patients	1	2	3	4	5	6	7	8	9	10	11	Median	Interqartile range
Angina class — 1 CCS										X		1	–
Angina class — 2 CCS			X	X	X	X	X	X			X	7	–
Angina class — 3 CCS	X	X							X			3	–
NYHA class II					X							1	–
NYHA class III	X	X	X	X		X	X		X	X	X	9	–
NYHA class IV								X				1	–
LVEF (%)	35	50	60	65	60	40	60	68	30	35	35	50.000	25.000
Peak gradient	79	100	75	80	107	70	80	85	72	24	63	79.000	15.000
Average gradient	48	60	50	50	71	43	47	48	42	14	37	48.000	8.000
Surface area (cm^{-2})	0.7	0.7	0.6	0.9	0.5	0.6	0.9	0.7	0.9	1.3	0.8	0.700	0.300
Logistic EuroScore	42%	27%	45%	12%	15%	27%	15%	15%	15%	14%	16%	–	–

CCS — Canadian Cardiovascular Society; NYHA — New York Heart Association; LVEF — left ventricular ejection fraction

Patient characteristics in the immediate preoperative period are shown in Table 2. The majority of patients (n = 9) were classified under class NYHA III (New York Heart Association). One patient was in class NYHA II and one in NYHA IV. The mean left ventricle ejection fraction was 50. Except for one patient, all patients exhibited severe aortic valve stenosis with an exit surface area of below 1 cm^2. In a patient with a valve surface area of 1.8 cm^2, a transfemoral aortic valve implantation with Medtronic Corevalve 31 mm had been performed three years earlier. Due to severe aortic regurgitation, the cardiology team decided to implant a new type of valve, namely "valve-in-valve".

On the day before the procedure, the consulting anaesthesiologist classified all patients under group IV based on the ASA scale (American Society of Anesthesiologists), which means that these patients suffered from severe systemic diseases that were life-threatening. The precise time of each procedure and intraoperative variables are presented in Table 3. Three patients in the direct postoperative period were administered with catecholamines. In only one patient were vasodilators used. The mean time of intensive care was 24 hours. However, at this point it should be emphasised that nine patients were admitted to the intensive care unit due to the necessity of monitoring the basic vital functions and prophylactic action against possible TAVI complications. Although the state of the patients while admitted to the intensive care unit was stable, one patient (a woman) was admitted in shock, and in whom symptoms of atrioventricular block were observed during the procedure. Despite the insertion of a prophylactic endocavitary probe, cardiac arrest may occur. In such cases, an indirect heart massage and conversion from analgosedation to general anaesthesia should be performed immediately. In our study, one patient required a 48-hour stay at the intensive care unit, in whom conversion from analgosedation to general anaesthesia was performed due to a lack of coprocedure. The postoperative characteristics of the reported group are presented in Table 4.

Despite the complications that occurred in the described group, the hospital mortality rate of TAVI was 0%. As shown in Table 5, all patients after 9 days of treatment left the hospital in a good neurological condition, which was assessed based on the CPC-1 (Cerebral Performance Categories Scale) and GCS-15 (Glasgow Coma Scale) scales. With an ejection fraction of the left ventricle of (mean) 60%, a transcatheter aortic valve was successfully implanted.

In our study, a pacemaker was implanted in two patients due to third-degree atrioventricular block. In one patient, it was necessary to open the thorax medially and perform a heart tamponade decompression. No complications described in the literature occurred, such as stroke, aortic dissection, aortic perforation, myocardial infarction, coronary vessel damage, haemodynamic instability requiring the introduction of extracorporal circulation or complications related to the peripheral vessels [12–14]. In two cases, it was necessary to convert local anaesthesia to general anaesthesia.

Table 3. Intraoperative variables for each patient

Patients	1	2	3	4	5	6	7	8	9	10	11	Median	Interqartile range
ASA	IV	IV	IV	IV	IV	IV	IV	IV	IV	IV	IV	11	–
GFR	63	57	84	62	28	61	66	33	44	60	79	61.000	22.000
Duration of the surgery	90	250	90	160	75	80	100	80	110	70	80	90.000	30.000
Ultiva	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11	–
Propofol	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	10	–
CVC	Yes	Yes	No	No	No	No	No	No	No	No	No	2	–
Endoscopic electrode sheath	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	10	–
Size of the prosthesis	23	25	23	23	23	27	23	23	27	29	31	–	–
Duration of fluoroscopy	16	22	19	34	13	13	15	17	20	11	17	17.000	7.000
Absorbed dose (mGy)	232	162	826	1842	486	1197	439	1232	957	499	1831	826.000	793.000

ASA — American Society of Anaesthesiology; GFR — glomerular filtration rate; CVC — central venous catheter

Table 4. Postoperative characteristics of the reported group

Patients	1	2	3	4	5	6	7	8	9	10	11	Median	Interqartile range
Presion drugs	No	Adr, DB, Lev	No	DB	No	No	No	No	No	No	DB	3	–
Vasodilators	No	No	No	No	No	No	No	No	Yes	No	No	1	–
Max lactate concentration	0.6	5.5	0.9	1.0	0.7	1.3	1.3	0.8	0.9	0.8	2.6	0.900	0.500
Max. hsTnT	0.08	0.38	0.54	0.39	0.07	0.26	0.12	0.20	0.20	0.03	0.21	0.200	0.300
Max. CK-MB	13	32	55	25	22	37	21	13	18	29	23	23.000	14.000
GFR after the surgery	56	45	84	86	43	74	61	38	65	70	85	65.000	39.000
Stay in the ICU (h)	20	6 days	20	48	24	24	20	24	20	16	24	24.000	4.000
Hospital stay (days)	9	13	9	24	18	9	10	9	8	9	14	9.000	5.000

hs TnT — high-sensitive troponin T; CK-MB — creatine kinase–myocardial band

DISCUSSION

The transcatheter aortic valve implantation (TAVI) is an innovative and rapidly developing technique which has been available at our centre since 2008. It is considered as an alternative to conventional open heart surgery. Patients qualified for the procedure of aortic valve replacement but with high risk of hospital mortality (EuroScore) [15, 16] may be qualified for this minimally invasive procedure. Until 2015, the procedures at our centre were conducted using general anaesthesia and very often on elderly patients with numerous burdens (most commonly ASA IV); such patients constitute a real challenge for the anaesthesiologist. The majority of patients after the transcatheter aortic valve implantation demonstrate a considerable increase in their quality of life [17]. The authors report their first experiences of the treatment of patients qualified for the TAVI procedure under local anaesthesia along with analgosedation. The anaesthetists used analgosedation and successfully led all patients through the perioperative period. It should be emphasised that besides the perfect coprocedure

Table 5. Patient characteristics at hospital discharge

Patients	1	2	3	4	5	6	7	8	9	10	11	Median	Interqartile range
LVEF (%)	50	70	60	60	60	50	60	60	35	35	45	60.000	15.000
Peak gradient	26	12	24	22	20	23	24	16	22	11	16	22.000	8.000
Average gradient	14	7	15	12	12	11	12	10	15	8	10	12.000	4.000
IA	No	No	Slight	No	No	Slight	Slight	Slight	No	No	Slight	–	–
CPC	1	1	1	1	1	1	1	1	1	1	1	11	–
GCS	15	15	15	15	15	15	15	15	15	15	15	11	–
Compli-cations	No	SCA I effective resuscitation during implantation Conversion to general anaesthesia Tamponade, median thoracotomy, implantation ICD	No	Conversion to general anaesthesia due to lack of patient's cooperation	No	No	No	No	No	No	Block A–V, Implantation DDD	–	–

LVEF — left ventricular ejection fraction; IA — aortic insufficiency; CPC — Cerebra Performance Categories Scale; GCS — Glasgow Coma Scale; SCA — sudden cardiac arrest; ICD — implantable cardioverter–defibrillator; A-V — atrio-ventricularis

of cardiovascular teams, the success of the treatment significantly depends upon a modern and extensively equipped hybrid procedures room, functioning within the operating theatre. The anaesthesiologist has to have an anesthetization station at his disposal while the perfusionist must be able to allow the connexion of the artificial heart-lung apparatus.

It should be emphasised that the study possesses several significant limitations. First, this is a non-randomised study while the data were obtained from medical documentation. Second, a significant limitation is that only a small number of patients participated in this study, and hence, it appears to be legitimate to continue this study and observe the treatment results for a larger number of patients. Bearing in mind the number of examined patients, certain useful, clinical trends were observed in this study. The authors have demonstrated that patients can be safely led through the TAVI procedure under remifentanil analgosedation. Not all patients qualified for the TAVI procedure have to be subjected to general anaesthesia. This applies only to patients implanted with Core Valve Evolut R (Medtronic), Sapien 3 (Edwards) as well as Lotus Valve System (Boston Scientific) valves. TAVI procedure analgosedation constitutes a great challenge for the anaesthetist, who, in coprocedure with cardiac surgeon, should bear in mind the possible life-threatening complications.

The literature reports available regarding the use of local anaesthesia along with analgosedation in patients qualified for TAVI are non-randomised in nature. The majority of them are observational studies and case series. Opinions of the researchers differ based on the type of anaesthesia used. A literature review demonstrates certain regularity. The centres, where TAVI procedures were performed for the first time, usually conducted them under general anaesthesia. Moreover, local anesthetization has begun to prevail over general in centres that have years of experience with TAVI procedures. Supporters of general anaesthesia mention as a benefit, for example, the possibility of conducting transesophageal ultrasonography and the comfort of the operator which stems from the fact of working with an anesthetised and paralysed patient, and which allows for the precise placement of the valvular prosthesis [18].

Behan *et al.* [19] emphasised that in the majority of cases, TAVI may be conducted under analgosedation. They point to the fact that the use of local anaesthesia needs only a shorter hospital stay and that patients tolerate analgosedation better than general anaesthesia. Mayr *et al.* [20] stated that both local anesthetization and general anaesthesia can be successfully used for TAVI. The type of anesthetization to be used should be decided by the 'Heart Team', and sedation should be conducted by an experienced anaesthetist.

Maas *et al.* [21] carried out a meta-analysis of data from 5,919 patients. They demonstrated that neither mortality nor the incidence of major adverse cardiac and cerebrovascular events after TAVI is affected by the choice of either local anaesthesia or general anaesthesia. The lack of relationship between mortality and the type of anaesthesia selected was also demonstrated by Dall'Ara *et al.* [22].

CONCLUSIONS

According to the authors, percutaneous aortic valve implantation may be successfully conducted under remifentanil analgosedation. TAVI procedures should be performed in a modern, well-equipped hybrid operating room. The aim of the anaesthesiologist should consist of conducting the least invasive anaesthesia/ /analgesia, bearing in mind the safety and comfort of the patient. Conversion to general anaesthesia may be necessary in case of intraoperative complications.

ACKNOWLEDGEMENTS

1. Source of funding — none.
2. Conflict of interest — none.

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Otrzymano: 12.07.2016 r.
Zaakceptowano: 4.01.2017 r.