ORIGINAL ARTICLE

Transcutaneous aortic valve replacement with the Edwards SAPIEN XT and Medtronic CoreValve prosthesis under fluoroscopic guidance and local anaesthesia only

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ABSTRACT

Objective To assess the feasibility of transcatheter aortic valve implantation (TAVI; Medtronic CoreValve and Edwards SAPIEN XT) under local anaesthesia with only mild analgesic medication and fluoroscopic guidance.

Methods 461 patients underwent TAVI under local anaesthesia with lidocaine. The procedure was performed successfully in 459 of the cases. All patients were also treated with piritramide, metoclopramide hydrochloride and 62 mg dimenhydrinate. Monitoring consisted of a six-electrode, virtual 12-lead ECG, pulse oximetry, and invasive arterial pressure measurement. There was no continuous surveillance by an anaesthesiologist.

Results There was no need for conversion to general anaesthesia except in four patients who required cardiopulmonary resuscitation. Conscious sedation with intravenous administration of midazolam for agitation or inotropic medication for prolonged hypotension was necessary in only seven of the 461 patients. The combined safety end point according to the Valve Academic Research Consortium consensus document was reached in 12.6%.

Conclusions Our results show that TAVI performed under local anaesthesia with only mild analgesic medication and under fluoroscopic guidance is feasible, with good outcome comparable to published data.

INTRODUCTION

Over the last few years, transcatheter aortic valve implantation (TAVI) has emerged as a reliable treatment strategy for older patients with high-grade aortic stenosis and increased surgical risk.[1] The PARTNER trial[2] demonstrated comparable results to surgical aortic valve replacement. TAVI is typically performed under general anaesthesia, with the consequent need for mechanical ventilation or at least surveillance of the patient by an anaesthesiologist. General anaesthesia is normally performed successfully; however, it may be associated with an increased risk of cardiac and pulmonary morbidity, particularly in this group of older patients.

Under these circumstances, local anaesthesia only combined with mild analgesic medication is an attractive alternative to general anaesthesia to avoid these complications. Furthermore, this approach offers the possibility of a more accurate clinical assessment of the patient during implantation and a significant decrease in implantation time, staff effort, and cost.

A small recent series of studies[3–5] reported the feasibility and outcome of TAVI under local anaesthesia plus mild sedation.

In our centre, transfemoral TAVI is exclusively performed under local anaesthesia with mild analgesic medication under fluoroscopic guidance. We report the feasibility and outcome in a large group of patients undergoing TAVI, including Edwards SAPIEN XT and Medtronic CoreValve prostheses, performed only under local anaesthesia with mild analgesic medication.

METHODS

Patients

From the start of our TAVI programme in November 2007 until September 2012, 461 consecutive patients (202 men; mean age 81±9, range 53–99) underwent TAVI for high-grade aortic stenosis in our institution; 302 were treated with a Medtronic CoreValve device and 159 with an Edwards SAPIEN XT valve. Fifteen of the 461 interventions were valve-in-valve procedures (13 because of high-grade stenosis, two because of high-grade insufficiency). Patient screening routinely included transthoracic echocardiography, dual-source CT and coronary angiography. Before TAVI was performed, all cases were discussed by our multidisciplinary aortic board, consisting of at least one cardiac surgeon, one radiologist, and two interventional cardiologists. Dual-source CT scans (Definition Flash; Siemens Medical Solutions, Forchheim, Germany) were performed routinely before TAVI. The collected data were used to determine the aortic annulus diameter as well as the calcification pattern of the aortic valve leaflets and the distance of the coronary arteries from the aortic annulus. Accessibility via the femoral and iliac arteries was also assessed during the same diagnostic procedure.

Patient preparation

Patients were preloaded with aspirin (100 mg) and clopidogrel (600 mg). Those receiving an Edwards SAPIEN XT valve continued to take clopidogrel

for 1 month, and those receiving a Medtronic CoreValve for 3 months. Aspirin was continued indefinitely. Patients who were already anticoagulated with phenprocoumon (eg, because of atrial fibrillation) were treated with anticoagulation alone. Weight-adjusted heparin or bivalirudin was administered after placement of the arterial sheath.

Device description and implantation procedure

Detailed technical aspects of Medtronic CoreValve implantation and the Edwards SAPIEN procedure have been reported previously.[6–8]

Vascular access was obtained and a commercially available closure device was placed (Prostar XL structure device; Abbott Vascular, Abbott Park, Illinois, USA). Device success and 30-day combined safety data were evaluated according to the Valve Academic Research Consortium consensus document (VARC).[9]

Procedure monitoring consisted of a six-electrode, virtual 12-lead ECG, pulse oximetry, and invasive arterial pressure measurement from the sheath.

All interventions were performed under local anaesthesia with only mild analgesic and antiemetic medication without surveillance by an anaesthesiologist. The team was composed of two interventional cardiologists and two nurses. Implantation was performed under fluoroscopic guidance alone. Paravalvular leak and grade of aortic regurgitation were evaluated angiographically using the method described by Sellers *et al*.[10] In cases where aortic regurgitation was judged to be more than trace, haemodynamic measurements were used to further evaluate aortic regurgitation.

Lidocaine 1% (15–30 mL) was used for local anaesthesia and applied subcutaneously. Piritramide (a synthetic opioid; 7.5–15 mg according to the patient's weight) was used as analgesic medication. All patients were also treated intravenously with 10 mg metoclopramide hydrochloride and 62 mg dimenhydrinate to prevent nausea.

All sheath sizes were able to be inserted with this combination of local and systemic analgesic medication. Because of the sedative potential of the applied medications, most patients were asleep during implantation, but could be addressed at any stage of the procedure. Consequently, continuous surveillance by an anaesthesiologist was not necessary.

Generally, in our institution, no guidelines are in place to identify patients who require general anaesthesia during the TAVI procedure. Possible indications for use of general anaesthesia or deep conscious sedation are emergency procedures or disoriented and/or agitated patients.

Statistical analysis

Statistical analyses were performed using the SPSS software package (V.18.0). Continuous variables are expressed as mean ±SD and compared using Student's t test. Categorical date are expressed as numbers and percentages and compared by Fisher's exact test or the χ^2 test as appropriate. $p<0.05$ was considered significant. All values are given as mean±SD.

RESULTS

A total of 461 patients underwent TAVI. The mean logistic euroSCORE was 16.27±14.2. Further baseline clinical characteristics are given in table 1. Procedural outcomes are shown in table 2. TAVI was performed successfully in 459 of the 461 cases. One valve embolisation occurred, and the patient was referred for cardiac surgery during which the embolised valve was recovered and successful surgical valve replacement was performed. In the second patient, valve positioning was not possible and only balloon valvuloplasty could be performed. Four patients died in the catheter laboratory: two cases of acute cardiac failure in patients with highly reduced left ventricular function, one patient with rupture of the iliac artery during sheath removal, and another with rupture of the aortic annulus.

Table 1 Baseline characteristics

Characteristic	Overall (n=461)	CoreValve (n=302)	Edwards (n=159)	p Value
Age (years)	81.09±6.82	81.14±6.56	80.99±7.29	0.822
Female	258 (55.97)	158 (52.32)	100 (62.89)	0.334
Height (cm)	165.81±8.96	166.36±8.71	164.79±9.35	0.073
Weight (kg)	72.70±15.25	72.85±14.98	72.44±15.77	0.784
pAOD	47 (10.2)	30 (9.93)	17 (10.69)	0.871
Hypertension	356 (77.22)	243 (80.46)	113 (71.07)	0.020
Diabetes	129 (27.98)	89 (29.47)	40 (25.16)	0.383
Dyslipidaemia	189 (41)	137 (45.36)	52 (32.7)	0.009
Former smoker	54 (11.71)	42 (13.91)	12 (7.55)	0.047
Previous MI	45 (9.76)	30 (9.93)	15 (9.43)	0.907
Previous PCI	224 (48.59)	173 (57.28)	51 (32.08)	<0.001
Previous CABG	51 (11.06)	35 (11.59)	16 (10.06)	0.755
Atrial fibrillation	147 (31.89)	98 (32.45)	49 (30.82)	0.753
Pacemaker	48 (10.41)	30 (9.93)	18 (11.32)	0.634
Previous BAV	21 (4.56)	18 (5.96)	3 (1.89)	0.058
Previous stroke	48 (10.41)	31 (10.26)	17 (10.69)	0.874
Creatinine max	1.95±1.70	1.98±1.67	1.90±1.77	0.632
COPD	54 (11.71)	38 (12.58)	16 (10.06)	0.451
LVEF <40%	58 (12.58)	45 (14.9)	13 (8.18)	0.039
Neoplasia	99 (21.48)	64 (21.19)	35 (22.01)	0.905
Logistic euroSCORE	16.27±14.18	22.76±11.65	18.46±9.63	<0.001
β Blocker	289 (62.69)	181 (59.93)	108 (67.92)	0.105
Statin	270 (58.57)	188 (62.25)	82 (51.57)	0.028
ACE inhibitors or ARB	345 (74.84)	236 (78.15)	109 (68.55)	0.031
Aspirin	389 (84.38)	267 (88.4)	122 (76.73)	0.002
Clopidogrel	359 (77.87)	266 (88.08)	93 (58.49)	<0.001

Values are mean±SD or number (%). Units for creatinine: mg/dl.
ARB, angiotensin receptor blocker; BAV, balloon aortic valvuloplasty; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; pAOD, peripheral artery occlusive disease; PCI, percutaneous coronary intervention.

A single valve was implanted in 454 cases; the other seven patients needed a second valve to achieve a good result. There was no need for conversion to general anaesthesia except in the four patients described above. Conscious sedation, with intravenous administration of midazolam for agitation or inotropic medication for prolonged hypotension, was necessary in only seven of the 461 patients. Mean overall procedure time was 131 ±40.9 min (128±42.3 min in the Medtronic CoreValve group and 135±37.8 min in the Edwards SAPIEN XT group). Mean overall contrast volume was 171.2±101 mL (175.3±119 mL in the Medtronic CoreValve group and 163.8±53 mL in the Edwards SAPIEN XT group).

Table 3 shows 30-day procedural outcomes related to VARC. Death from any cause occurred in 23 patients; four were procedure-related, and eight further patients died from cardiac causes. Overall, cerebral complications (including major and minor stroke and transient ischaemic attack) rates were low (2.1%). Major vascular complications occurred in 20 patients (4.3%), and life-threatening haemorrhage in 22 patients (4.8%). Overall, 59 permanent pacemakers (12.8%) had to be implanted. The combined safety end point according to VARC

Table 2 Procedural outcome and device success

Procedural outcome	Overall population (n=461)	CoreValve (n=302)	Edwards (n=159)	p Value
Device success	459 (99.57)	300 (99.67)	159 (100)	0.547
Successful vascular access	460 (99.78)	301 (99.67)	159 (100)	1.000
Successful implantation	459 (99.57)	300 (99.67)	159 (100)	0.547
Correct position	459 (99.57)	301 (99.67)	158 (99.37)	1.000
AR grade ≥3	15 (3.25)	14 (4.64)	1 (0.63)	0.024
Only 1 valve implanted	454 (98.48)	296 (98.01)	158 (99.37)	0.430
Procedure duration (min)	131.03±40.89	128.73±42.3	135.37±37.85	0.092
X-ray duration (min)	17.28±10.93	18.3±12.58	15.39±6.51	0.006
Contrast volume (mL)	171.28±101.29	175.27±119.08	163.81±53.58	0.249
Adverse events				
Groin problems	33 (7.16)	29 (9.6)	4 (2.52)	0.004
Intraprocedural death	4 (0.87)	2 (0.66)	2 (1.26)	0.611
ICU stay (days)	2.83±2.84	2.91±3.12	2.64±1.92	0.320
In-hospital stay (days)	16.21±8.52	16.91±9.07	14.85±7.2	0.010
Postprocedural stay (days)	10.13±6.22	10.71±6.76	8.62±4.21	<0.001

Values are mean±SD or number (%).
AR, aortic regurgitation; ICU, intensive care unit.

was reached in 12.6% in the overall group (14% in the Medtronic CoreValve group and 9% in the Edwards SAPIEN XT group).

DISCUSSION

Despite the fact that TAVI performed under general anaesthesia or conscious sedation shows remarkable results even in octogenarians, these patients in particular would benefit from less invasive strategies. TAVI itself, compared with open-heart surgery, especially when performed via transfemoral access, is a significant step in a less invasive direction. TAVI performed under only local anaesthesia with mild analgesic medication without the need of endotracheal intubation is a further step in this direction.

Additional postulated advantages of local anaesthesia include a reduced need for inotropic medication because of more stable haemodynamics, shorter procedure duration, earlier mobilisation of the patient, and subsequent reduced in-hospital stay.

In our high-volume centre, right from the start of our TAVI programme, the procedure was performed under local anaesthesia with only mild analgesic medication. Valve positioning was performed with only fluoroscopic guidance from the very

Table 3 Clinical outcome according to VARC

Clinical outcome	Overall (n=461) 30 days	CoreValve (n=302) 30 days	Edwards (n=159) 30 days	p Value
Death				
From any cause	23 (5.0)	18 (5.9)	5 (3.1)	0.260
Procedure-related	4 (0.9)	2 (0.7)	2 (1.2)	0.611
From cardiac cause	8 (1.7)	7 (2.3)	1 (0.6)	0.272
Cerebral complications				
Transient ischaemic attack	2 (0.4)	1 (0.3)	1 (0.6)	1.000
Major stroke	6 (1.3)	5 (1.6)	1 (0.6)	0.669
Minor stroke	2 (0.4)	1 (0.3)	1 (0.6)	1.000
Vascular complications				
Any	33 (7.1)	29 (9.6)	4 (2.5)	0.004
Major	20 (4.3)	16 (5.3)	4 (2.5)	0.229
Minor	13 (2.8)	13 (4.3)	0	0.006
Bleeding complications				
Life threatening	22 (4.8)	16 (5.3)	6 (3.7)	0.646
Minor	33 (7.1)	20 (6.6)	13 (8.1)	0.571
Transfusions	57 (12.3)	39 (13)	18 (11.3)	0.658
Acute kidney injury				
Creatinine >3 mg/dL	3 (0.9)	2 (0.7)	1 (0.6)	1.000
Renal replacement therapy	1 (0.2)	1 (0.3)	0	1.000
Pacemaker implantation	59 (12.8)	54 (17.8)	5 (3.1)	<0.001
Periprocedural MI	2 (0.4)	1 (0.3)	1 (0.6)	1.000
Repeat procedure	3 (0.9)	3 (1)	0	0.554

Values are number (%).
MI, myocardial infarction; VARC, Valve Academic Research Consortium consensus document.

beginning, without transoesophageal echocardiography (TEE). Not using TEE guidance during the procedure might limit the capability to grade postprocedural paravalvular regurgitation (PVR). Therefore angiographic quantification of aortic regurgitation should be combined with haemodynamic parameters to adequately assess the degree of PVR.

Not using TEE means that conscious sedation and even general anaesthesia can be avoided. In our experience, the use of piritramide as analgesic, in combination with metoclopramide hydrochloride and dimenhydrinate with their sedative potential, results in most patients being asleep during the procedure but capable of being addressed at any time. This is a unique advantage over general anaesthesia or conscious sedation for several reasons. First, patients can at any time indicate discomfort, and the operator is able to react immediately. Second, the operator is at any time able to interact with the patient and is therefore in a position to diagnose and react to possible complications (eg, transient ischaemic attack, perforations) faster than would be possible with a patient under conscious sedation or general anaesthesia. Third, as the patient is responsive, there is no need for continuous surveillance by an anaesthesiologist. This leads to a significant decrease in staff requirements, procedure duration and costs, as described by Motloch *et al*.[5]

Better procedural tolerance, greater patient compliance, and the possibility for immediate cardiac support are arguments for general anaesthesia or conscious sedation. In our experience, and similar to the reports of Durand *et al*,[3] Motloch *et al*[5] and Yamamoto *et al*,[4] lack of pain, patients' compliance and tolerance of rapid pacing were mostly unproblematic.

Only seven of 461 patients required conscious sedation—with intravenous midazolam for agitation in three and inotropic medication for prolonged hypotension in four. Two of the latter group needed endotracheal intubation because of major complications with subsequent cardiopulmonary resuscitation (one iliac rupture, one acute heart failure). All patients who required surgery (20 for vascular complications, one because of dislocation of the Edwards SAPIEN XT in the ventricle) were able to be transferred to the operating room without the need for general anaesthesia.

Our patient cohort is similar to other cohorts described in the literature, consisting of older patients (mean age 81±6.8; range 53–99) with high-grade aortic stenosis or degenerated aortic bioprostheses and an increased logistic euroSCORE (16.27 ±14.2). Our results are comparable to those from other studies, which were mostly performed using general anaesthesia and TEE assistance. Thirty-day mortality, incidence of stroke, periprocedural myocardial infarction, major vascular complications and haemorrhagic complications in our study were similar to other published studies (table 4). Also, on comparison of the combined safety end point at 30 days according to VARC, our results are similar to previous published studies in which TAVI was performed either under local anesthesia[3] or mostly under general anesthesia.[11]

Our study reports the largest patient cohort so far in which TAVI was performed under local anaesthesia only and the only cohort to include Medtronic CoreValve prostheses and Edwards SAPIEN XT prostheses in comparable quantities. The comparison of outcomes between the two models shows favourable results for the Edwards SAPIEN XT valve when the 30-day safety end points according to VARC are looked at. Some of the differences (eg, pacemaker implantation incidence, aortic regurgitations) are known and are caused by the different design of the two models. Other differences in our cohort, such as vascular complications, cerebral ischaemia and overall death, can be explained, at least in part, by the fact that we started our TAVI programme with the Medtronic CoreValve prosthesis. Only after over 200 CoreValve implantations and the associated learning curve did we start our Edwards SAPIEN XT programme; a significant part of the differences in outcomes between the two models can be explained by this fact.

Despite the differences in outcome between the two models, our overall results are comparable to big randomised and observational studies and therefore it is reasonable to assume, taking into account our patient number, that TAVI performed under local anaesthesia with only mild analgesic medication and fluoroscopic guidance can produce comparable results to the standard approach and has many potential advantages, especially for this older patient cohort.

Limitations

The major limitation of our study is the lack of a control group, as, in our centre, TAVI was performed under local anaesthesia only right from the beginning. Therefore we cannot finally compare our results with patients treated under general anaesthesia. However, as shown in table 4, our results are comparable to published data from the PARTNER A and B cohorts,[1 2] the GARY Registry[12] and the France 2 Registry,[1 3] studies that were mainly performed under general anaesthesia. To definitively

Table 4 Comparison of results with other studies

Variable	PARTNER A[1] (n=244)	PARTNER B[2] (n=179)	GARY Registry[12] (n=2694)	France 2 Registry[13] (n=2361)	Present study (n=461)
30-day death	8 (3.3)	9 (5.0)	138 (5.1)	190 (8.5)	23 (5.0)
Major stroke	7 (2.9)	9 (5.0)	43 (1.7)	51 (2.2)	6 (1.3)
Major bleeding	23 (9.5)	30 (16.8)	NA	36 (1.5)	22 (4.8)
Transfusion	NA	NA	305 (11.5)	NA	57 (12.4)
Stage 3 AKI or renal replacement therapy	6 (2.5)	2 (1.1)	75 (2.9)	NA	4 (0.9)
Major vascular complications	34 (14.0)	29 (16.2)	NA	129 (5.5)	20 (4.3)
Periprocedural MI	0	0	NA	20 (0.8)	2 (0.4)
Repeat procedure	3 (3.8)	3 (1.7)	25 (0.9)	47 (2.0)	3 (0.6)
30-day AR ≥3	38 (13.1)	23 (15.0)	9 (0.3)	13 (0.9)	15 (3.3)
Pacemaker	5 (6.4)	6 (3.4)	390 (23.7)	359 (15.2)	59 (12.8)

Values are number (%).
AKI, acute kidney injury; AR, aortic regurgitation; MI, myocardial infarction; NA, not available.

determine the benefits of local or general anaesthesia, a randomised study would be needed, analysing clinical outcome, catecholamine use, length of hospital stay, and bleeding complications, all potentially related to the anaesthesia regimen of choice. However, from our experience, a less invasive strategy for TAVI performed under mild analgosedation at least seems warranted.

Key messages

What is already known on this subject?
TAVI has emerged as a reliable treatment strategy for older patients with high-grade aortic stenosis and increased surgical risk. TAVI is typically performed under general anaesthesia with the need for mechanical ventilation or at least the need for surveillance. Only small series have reported the feasibility and outcome of TAVI under local anaesthesia with mild sedation.

What this study adds?
In this study we report the largest experience so far of TAVI under local anaesthesia using either the Medtronic CoreValve or the Edwards SAPIEN XT valve.

How might this impact on clinical practice?
TAVI compared with open-heart surgery, especially when performed via transfemoral access, is a significant step in the less invasive direction. TAVI performed only under local anaesthesia with mild analgesic medication without the need for endotracheal intubation is a further step in this direction. Octogenarians in particular could benefit from this less invasive approach. Furthermore, it may also result in a significant decrease in staff, costs and length of in-hospital stay.

CONCLUSION

This study shows that TAVI performed under local anaesthesia with only mild analgesic medication and fluoroscopic guidance without TEE assistance can produce good results. This approach not only offers many potential advantages for the patient, but may also result in a significant decrease in staffing levels, costs and length of in-hospital stay. However, to confirm these potential benefits, a randomised study is needed.

Contributors MG: valve implantation, data analysis, manuscript writing, patient follow-up; PL: patient follow-up, data analysis; MN: valve implantation; FS: CT image analysis; CB: CT image analysis; CS: manuscript review; TP: patient follow-up, valve implantation; MDA: manuscript review, language correction; PB: valve implantation; SM: manuscript review; CK: valve implantation, manuscript writing and review.

Competing interests None.

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Heart

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