

High-Flow Nasal Oxygen Vs. Standard Oxygen Therapy for Patients Undergoing Transcatheter Aortic Valve Replacement With Conscious Sedation: A Randomised Controlled Trial

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Abstract

Background

Minimally invasive surgery is becoming more common and transfemoral transcatheter aortic valve replacement is offered to older patients with multiple comorbidities. Sternotomy is not required but patients must lie flat and still for up to 2 – 3 hours. This procedure is increasingly being performed under conscious sedation with supplementary oxygen, but hypoxia and agitation are commonly observed.

Methods

In this randomised controlled trial, we hypothesised that high-flow nasal oxygen would provide superior oxygenation as compared with our standard practice, 2 l.min⁻¹ oxygen by dry nasal specs. The primary endpoint was the change in arterial partial pressure of oxygen (PaO₂) during the procedure. Secondary outcomes included the incidence of oxygen desaturation and patient movements.

Results

A total of 72 patients were recruited. There was no difference in change in PaO₂ from baseline using high-flow compared with standard oxygen therapy: median [IQR] increase from 12.1 (10.0- 15.3 [7.2- 29.8]) to 13.7 (10.8- 18.7 [8.5- 32.3]) kPa vs. decrease from 15.5 (12.4- 19.4 [9.2- 22.8]) to 14.2 (11.9- 19.3 [9.7- 22.8]) kPa, respectively (p= 0.087). There was a lower incidence of oxygen desaturation in the high-flow group (p= 0.037). Patients in the high-flow group moved less frequently (p= 0.006) and assigned a significantly higher comfort score to their treatment (p= < 0.001).

Conclusion

This study has demonstrated that high-flow, compared with standard oxygen therapy, does not improve arterial oxygenation over the course of the procedure. There are suggestions that it may improve the secondary outcomes studied.

Trial registration

International Standard Randomised Controlled Trial Number (ISRCTN) 13804861. Registered 15/4/2019. <https://doi.org/10.1186/ISRCTN13804861>

Background

Transfemoral transcatheter aortic valve replacement (TAVR) has become an established therapy for high-risk patients with severe aortic stenosis [1]. General anaesthesia was the preferred anesthetic technique in the early days of TAVR, but it has largely been replaced by local anaesthesia and conscious sedation [2]. Patients undergoing TAVR often have multiple cardiorespiratory risk factors that put them at an increased risk of hypoxia with complications, such as confusion or an exacerbation of pulmonary hypertension [3],

especially as they are required to lie flat and still for an extended period of time [4]. Lying flat may be difficult for patients with impaired cardiac function as cardiac failure causes pulmonary edema and dyspnea. Also, patients with respiratory disease or patients who are obese may not be able to lie flat and may become hypoxic. In addition, the deployment of the new aortic valve may require rapid cardiac pacing and standstill with no cardiac output which may impair oxygen delivery to the body and make the patient restless [5].

Various sedation techniques have been described, with most supplying oxygen via either nasal cannulae or face mask [4]. High-flow nasal oxygen (HFNT) allows the delivery of heated and humidified oxygen at an inspiratory fraction of oxygen (FiO_2) of between 0.21 to 1.0, in a flow rate of up to $60 \text{ l}\cdot\text{min}^{-1}$ [6]. Emerging evidence shows that HFNT is effective in various clinical settings such as in the treatment of acute heart failure [7-9], after cardiac surgery [10, 11] and during procedural sedation [12-17]. Besides providing a higher degree of patient comfort by supplying warmed and humidified gas to maintain mucociliary functions [18], it increases pharyngeal pressure by $3 \text{ cmH}_2\text{O}$ and generates an effect similar to continuous airway positive pressure (CPAP) [19].

We designed this randomised controlled study to evaluate clinical outcomes using HFNT in patients undergoing transfemoral TAVR under conscious sedation. The primary hypothesis was that HFNT would improve oxygenation in this group of patients, as measured by arterial partial pressure of oxygen (PaO_2) during the procedure. Secondary outcomes included the number of episodes of desaturation, the type of airway interventions by the anaesthetist, comfort levels of patients as determined by movement during the procedure, cerebral oxygen saturations, peri-operative oxygen therapy duration, hospital length of stay, and patient satisfaction scores.

Methods

The study protocol was approved by the East of England Cambridge East Ethics Committee and all patients provided written informed consent. This was a single center, prospective randomised controlled trial conducted at the Royal Papworth Hospital, Cambridge, UK, a specialist cardiothoracic hospital. Patients with nasal septal defects, those who were participating in another randomised controlled trial, and those who were unable to speak English or had special communication needs were not included. Patients undergoing elective TAVR under sedation were randomly allocated in a 1:1 ratio using Sealed Envelope® (<https://www.sealedenvelope.com/>) online randomisation (unrestricted) to standard oxygen therapy or HFNT. Allocation of treatment arm was done by an investigator before the commencement of the procedure. The transcatheter aortic valve procedure was performed in the cardiac catheter laboratory using a transfemoral approach and percutaneous access via the femoral artery with retrograde valve placement.

Patients, physicians and nurses caring for patients were not blinded to the study interventions as blinding would not have been possible due to the nature of the intervention. The researcher collecting data including blood gas measurements (primary outcome) and interviewing patients was blinded. In addition,

the following steps were taken to minimise bias. Patients were not aware of their airway device and the investigators carrying out the follow-up survey and data collection were blinded to the patients' study intervention.

Physiological monitoring according to Association of Anaesthetists standards were applied to all patients [20]. Cerebral oximetry was measured using the Masimo O3 regional oximetry (Masimo, Irvine, CA, USA). A peripheral intravenous cannula was sited and an ultrasound guided ilio-inguinal and fascia iliaca block was performed on the side of the procedure using $2\text{mg}\cdot\text{kg}^{-1}$ of levobupivacaine by the anaesthetist.

Conscious sedation/analgesia is defined as "*a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation*" [21]. In our conscious sedation protocol, a low-dose remifentanyl infusion was commenced at $0.05\text{mcg}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$ and titrated to achieve a Ramsey sedation scale of 2 to 3 [22]. No other premedication or sedative was given to patients. Oxygen therapy was started after commencement of sedation therapy.

Participants in the HFNT group were given warm and humidified oxygen using the Optiflow THRIVE Nasal High Flow delivery system (Fisher and Paykel, Auckland, New Zealand). Oxygen was administered starting at an FiO_2 of 0.3 and flow rate of $50\text{ l}\cdot\text{min}^{-1}$. Continuous capnography monitoring was also used throughout the procedure according to Association of Anaesthetists standards using an attachment to the nasal cannulae provided by the manufacturer.

Participants in the standard oxygen group received $2\text{ l}\cdot\text{min}^{-1}$ oxygen therapy via standard nasal cannulae (not heated or humidified) and capnography and FiO_2 was measured using the gas in-line monitoring system of the anaesthetic machine. The FiO_2 using this protocol was 0.3 (the same as the HFNT group). At any stage during the study, the anaesthetist could manage the patient's airway in any way they deemed to be appropriate in the best interest of the patient. This included changing to an alternative oxygen delivery strategy.

The cardiologist secured further access with a standard arterial sheath in the femoral artery and a venous sheath in the femoral vein. A 14-16 Fr sheath for valve insertion was placed in the contralateral femoral artery. All procedures utilized Edwards SAPIEN 3 (Edwards Lifesciences, Irvine, CA, USA) or Medtronic CoreValve Evolut PRO (Medtronic, Minneapolis, MN, USA) heart valve system. Transvenous rapid ventricular pacing using a balloon-tipped pacing catheter inserted via the femoral vein was used to facilitate rapid pacing for valve deployment. Transthoracic echocardiography was used to assess valve function before and after the intervention.

The primary outcome was the change in arterial oxygenation, as measured by PaO_2 , between the first and second arterial blood gas measurements from the femoral arterial sheath. The first arterial blood gas was obtained as soon the cardiologist obtained access in the femoral artery and the second was obtained 30 minutes later. This was the only arterial access in these patients. Both measurements were taken with the patient receiving HFNT or standard oxygen as per group allocation and at the same FiO_2 . Secondary

outcomes include the number of episodes of desaturation, as defined as an SpO₂ of <93% for > 10 seconds or a decrease of > 5% from the baseline for > 10 seconds; the type of airway interventions by the anaesthetist including changing FiO₂; the number of times the patient moved during the procedure; cerebral desaturation during valve deployment, as defined as regional SO₂ <50% or decrease in baseline > 20% [23]; peri-operative oxygen therapy duration; hospital length of stay; and patient satisfaction scores. Blood gas analysis, oxygen device settings, vital signs, cerebral oximetry and sedation score of patients were collected at 30 minute-intervals after arterial access was obtained.

After the procedure, patients were transferred to the post anaesthesia recovery unit (PACU) until ready for discharge to the ward. The criteria used for patient discharge was a post-anesthetic discharge scoring system (PADS) score of >9. Patients were interviewed within 24 hours after the procedure and asked to rate the comfort level of the oxygen device.

We reviewed data in TAVR patients who received sedation with remifentanyl from an audit from 2018 and the mean (SD) arterial PaO₂ was 10.0 (5.2) kPa using standard oxygen therapy. We hypothesised that HFNT would lead to a clinically significant improvement of 35% during the procedure. Following these assumptions, a sample size of 34 patients in each arm would be sufficient to detect a difference between study groups at 80% power and a significance level of 0.05. Assuming a dropout rate of 5%, the final sample size was set at 36 patients per group. Data analysis was performed using an intention-to-treat approach. Categorical variables were compared using Fisher's exact test. Normality was checked using Shapiro-Wilk test and by assessment of skewness and its standard error. Comparison between groups were analysed using Student's t-test where assumptions were met, and Wilcoxon rank sum test if the data was not normally distributed. Repeated measurements were analysed with Wilcoxon signed rank test. All tests were two-tailed and statistical significance was accepted at $p < 0.05$. Statistical analysis was performed using R version 4.0.1 (R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 72 patients who underwent transfemoral TAVR between June 2019 and October 2020 were enrolled into the study. None of the participants crossed over to the other treatment arm. Three patients did not complete the procedure: the valve was not deployed in two patients and one patient passed away as a result of a complication of the procedure. Three patients required conversion to general anaesthesia: one patient in the standard oxygen group developed unstable supraventricular tachycardia and required synchronised DC cardioversion; another in the standard oxygen group had difficulties with valve deployment and required multiple rapid pacing episodes; and one patient in the HFNT group required transesophageal echocardiography. These three patients were excluded from data analysis. (Figure 1). The dose of remifentanyl used for sedation during the procedure was similar in both groups, median (IQR [range]) in HFNT group 0.32 (0.24- 0.43 [0.14- 0.85]) mg vs. standard oxygen 0.37 (0.26- 0.44 [0.10- 0.66]) mg, $p = 0.428$. Procedure time was also similar in both groups, HFNT 116.0 (101.8- 128.8 [74.0 - 151.0]) min vs. standard oxygen 110.5 (101.0- 134.5 [73.0 - 218.0]) min, $p = 0.883$.

The two groups had similar baseline characteristics (Table 1) except that twice as many patients had undergone previous cardiac surgery in the HFNT group compared with the standard oxygen group (40% vs. 20%, respectively). None of the patients required continuous positive airway pressure therapy and one patient in the HFNT group required home oxygen therapy.

Table 2, and Figures 2 and 3 illustrate the blood gas analysis results. All patients had their first arterial gas analysis after insertion of the femoral arterial line. This was mean (SD) 51 (16) minutes after the pre-surgery checklist had been completed. PaO₂ at baseline was lower in the HFNT compared with the standard oxygen group, median [IQR (range)] 12.1 (10.0- 15.3 (7.2- 29.8]) vs. 15.5 (12.4- 19.4 (9.2- 22.8]) kPa. As described before, the FiO₂ was 0.3 in both groups and there was no difference in the change in PaO₂ between the groups after 30 minutes (p= 0.082), Table 1.

Other study secondary outcomes are shown in Table 3. There was a reduced incidence of significant oxygen desaturation in the HFNT group (p= 0.027). Furthermore, five patients in the standard oxygen group required escalation of airway device from nasal cannula to a face mask, versus none in the HFNT group. Four patients in the HFNT group demonstrated cerebral desaturation during valve deployment (12%) compared with eight in the SOT group (24%), p= 0.340. Furthermore, three patients in the SOT group experienced syncope compared with none in the HFNT group. Two patients in the standard group were observed to be restless and agitated, as compared with one in the HFNT group.

Patients described HFNT as being more comfortable, with patients reaching for the airway device fewer times (p= 0.006) and giving it a significantly higher comfort score when interviewed after the procedure (p= < 0.001). There was difference between the two groups in oxygen requirements in PACU (p= 0.209) or duration of hospital stay (p= 0.912). There were no postoperative complications related to the use of both oxygen devices. No patient died in either group during the first 30 days after TAVR.

Discussion

We have shown no difference in change in arterial oxygenation over the course of the TAVR procedure in patients who received HFNT or standard oxygen while sedated. Regarding secondary outcomes, fewer patients who received HFNT desaturated or required airway manipulation during the procedure and patients who received HFNT reported feeling more comfortable.

The treatment for aortic stenosis is aortic valve replacement, which has traditionally required sternotomy and cardiopulmonary bypass. Minimally invasive TAVR without sternotomy has become the standard of care for patients with aortic stenosis at increased surgical risk [24]. Nevertheless, TAVR remains a high-risk procedure when applied to patients who are poor surgical candidates. Around 3250 TAVR cases were performed across centres in the UK in the year 2016 [25] and this is increasing yearly. Transfemoral TAVR is increasingly being done while patients receive conscious sedation [4], with observational study data showing benefits such as an improvement in hemodynamic stability and shorter hospital and ICU stay [26]. Hence, it is important to review our anaesthetic practice.

Hypoxia is likely to be more common in patients undergoing transfemoral TAVR due to both patient- and procedure-related factors. Patients are often elderly and have multiple comorbidities [27]. Up to a third of them have chronic lung disease [28]. Furthermore, the procedure takes up to two hours and patients are required to lie still in the supine position on a reasonably hard and narrow table. The reduction in functional residual capacity further predisposes them to hypoxia [29], which is often worsened by the need for procedural sedation. As a result of oxygen desaturation, patients regularly become restless and agitated. Therefore, we decided to study whether HFNT would increase arterial pO_2 and reduce the incidence of intra-operative adverse events.

One of the mechanisms by which HFNT improves oxygenation is by alveolar recruitment [6]. This results from the generation of positive airway pressure, although the magnitude of this effect is dependent on the patient having their mouth closed [30]. We did not notice the expected improvements in blood gases despite high oxygen flows. This may be because patients did not have their mouths closed or this is not seen in sedated patients for another reason. In procedures such as bronchoscopy [12, 13], gastroscopy [14, 15], endoscopic retrograde cholangiopancreatography [16] in which an improvement in oxygenation with the use of HFNT have been shown, the presence of an endoscope may have produced the same effect as having the mouth closed.

High-flow nasal therapy did not have a significant effect on carbon dioxide partial pressure in our study, with $PaCO_2$ levels increasing similarly over time in both the HFNT and SOT groups. Achieving a sufficiently high flow rate is critical to reduce the anatomic dead space in order to maximize CO_2 clearance [31]. Douglas et al. noted that increasing the HFNT flow rate from 40 to 60 $l \cdot min^{-1}$ brought the $PaCO_2$ down to within the normal range [32], suggesting that a higher O_2 flow rate than that used in our study (50 $l \cdot min^{-1}$) may have a greater effect on CO_2 clearance.

In contrast to the lower rates of desaturation in our HFNT patient group, this was not proven in morbidly obese patients undergoing colonoscopy [33]. However, there is increasing evidence that the high concentration oxygen therapy used in this study may be detrimental by causing hypoventilation and, hence, hypercapnia [34]. This suggests that hypoventilation may be the cause of hypoxia in morbidly obese patients receiving HFNT. In contrast, our patient cohort has a much lower BMI of 27.6 (5.2) $kg \cdot m^{-2}$ (mean (SD)), suggesting that HFNT may be less useful in morbidly obese patients.

Patient comfort level and satisfaction score in many of these studies produced mixed results [35, 36], with many suggesting no added benefit of HFNT [12, 13, 37]. This is in contrast to our study which suggests that HFNT has an added advantage of improving the comfort level in patients.

High-flow nasal therapy has been shown to have beneficial effects in cardiac patients both in the setting of the treatment of acute heart failure [7-9] and in the treatment of postoperative hypoxemia after cardiac surgery. In a recent case report, it was used to treat desaturation in a patient undergoing percutaneous balloon aortic valvuloplasty under sedation [38]. In addition to respiratory benefits, it also resulted in

hemodynamic improvements in patients with heart failure [9] This is a potential added benefit for patients undergoing transfemoral TAVR, many of whom have heart failure due to severe aortic stenosis.

Limitations

We have shown no difference in arterial oxygenation in patients who received HFNT or standard oxygen therapy during sedation for TAVR. This may have been because we did not recruit enough patients to see a true difference as the difference was smaller than that used in our power calculation (35%). The study was not powered for the secondary outcomes so these are exploratory and must be interpreted with caution, and future studies should look to confirm their findings. Also, our groups differed with respect to baseline PaO₂; we are not sure of the reason for this but it is likely to be a random finding. The PaO₂ tended to decrease slightly 30 mins later in the SOT group and increase in the HFNT but this was not statistically significant when comparing the two groups – this could also be due to type-2 error.

Secondly, arterial blood gases were only able to pick up pO₂ and pCO₂ values at certain time-points and we only managed to capture data at two time-points in most patients. The first arterial gas analysis was obtained at a mean (SD) of 51 (16) minutes after the patient had been checked in, allowing for only one more arterial gas analysis before the end of the procedure. Continuous measurement of pO₂ and pCO₂ with the use of transcutaneous carbon dioxide monitoring could have been more reflective of the benefits that HFNT can provide.

Also, this study investigated HFNT using a single delivery device at a FiO₂ of 0.3 and flow rate of 50 l.min⁻¹. Differences might be seen with alternative HFNT delivery devices or different FiO₂ and flow rates, as shown in studies demonstrating the beneficial effects of a higher flow rate on CO₂ clearance³⁹.

Conclusions

We have shown that HFNT, compared with SOT, did not improve arterial oxygenation in patients undergoing transfemoral TAVR under sedation over the course of the procedure. There are suggestions that it may improve the secondary outcomes studied, which are hypothesis generating for future studies.

Abbreviations

CPAP: continuous airway positive pressure

FiO₂: inspiratory fraction of oxygen

HFNT: high-flow nasal oxygen

PACU: post anaesthesia recovery unit

PADS: post-anesthetic discharge scoring system

PaO₂: arterial partial pressure of oxygen

TAVR: transfemoral transcatheter aortic valve replacement

Declarations

Ethics approval and consent to participate

The study protocol was approved by the East of England Cambridge East Ethics Committee and all patients provided written informed consent. The study was registered before recruitment started (International Standard Randomised Controlled Trial Number (ISRCTN) 13804861).

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

AK and SS have received educational grant funding or honoraria from Fisher and Paykel, Auckland, New Zealand. AK or his institution have received educational grant funding, honoraria or travel funding from Pharmacosmos, Nordic Pharma, Hemonetics and Masimo. AK is the Editor-in-Chief of *Anaesthesia*. FF or his institution have received educational funding from Werfen and grant funding and honoraria from Abbott Point of Care. No other conflicting interests declared.

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Authors' contributions

A.A. Klein was responsible for study design, protocol writing, ethical approval, patient recruitment, trial conduct, sample collection, data analysis, interpretation and manuscript writing.

S. Scheuermann was responsible for study design, protocol writing, ethical approval, patient recruitment, trial conduct, sample collection, data analysis, interpretation and manuscript writing.

A. Tan was responsible for patient recruitment, sample collection, trail conduct, data analysis, interpretation and manuscript writing.

P. Govender was responsible for patient recruitment, trial conduct, sample collection, data analysis, interpretation and manuscript writing.

S. George was responsible for study design, trial conduct, sample collection, data analysis, interpretation and manuscript writing.

F. Falter was responsible for trial conduct, sample collection, data analysis, interpretation and manuscript writing.

G. Martinez was responsible for trial conduct, sample collection, data analysis, interpretation and manuscript writing.

M. McKie was responsible for data analysis, interpretation and manuscript writing

J. Pack was responsible for trial conduct, data analysis, interpretation and manuscript writing.

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Tables

Table 1. Baseline characteristics in patients randomly allocate to high-flow nasal oxygen therapy (HFNT) or standard oxygen therapy during sedation for transcatheter aortic valve replacement. Values are mean (SD), number (proportion) or median (IQR [range]).

Variable	High-flow nasal oxygen therapy n = 35	Standard oxygen therapy n = 34
Age; y	83.3 (5.8)	81.4 (6.6)
Sex		
Male	23 (66%)	21 (62%)
Female	12 (34%)	13 (38%)
Body mass index; kg.m ⁻²	26.2 (4.0)	29.0 (6.0)
Body surface area; m ²	1.8 (0.2)	1.9 (0.2)
Euro-SCORE 2	2.9 (1.9- 4.7 [0.72- 30.82])	3.1 (1.9- 4.8[1.01- 31.35])
ASA physical status		
2	4 (11%)	3 (9%)
3	18 (51%)	19 (56%)
4	13 (37%)	12 (35%)
Smoking status		
Current smoker	2 (6%)	2 (6%)
Never smoker	21 (60%)	16 (47%)
Previous smoker	12 (34%)	16 (47%)
Asthma		
	3 (9%)	2 (6%)
COPD		
	3 (9%)	3 (9%)
Inhaler therapy		
	6 (17%)	4 (12%)
Previous cardiac surgery	14 (40%)	7 (21%)
Oxygen saturation on room air, %	96.6 (2.4)	96.9 (2.5)
Baseline NIRS, L, %	63.5 (5.6)	63.6 (8.8)
Baseline NIRS, R, %	63.3 (7.1)	64.2 (7.0)

ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease; NIRS, near infra-red spectroscopy.

Table 2. Intra-operative blood gas analysis in patients randomly allocate to high-flow nasal oxygen therapy (HFNT) or standard oxygen therapy during sedation for transcatheter aortic valve replacement. Values are median (IQR [range])

Variable	Oxygen therapy	Baseline	30 minutes	p value
pO ₂ ; kPa	Standard oxygen therapy	15.5 (12.4- 19.4 [9.2- 22.8])	14.2 (11.9- 19.3 [9.7- 22.8])	0.420
	High-flow nasal oxygen therapy	12.1 (10.0- 15.3 [7.2- 29.8])	13.7 (10.8- 18.7 [8.5- 32.3])	
pCO ₂ ; kPa	Standard oxygen therapy	6.2 (5.7- 7.0 [2.0- 8.7])	6.5 (5.7- 7.2 [4.8- 9.3])	0.005
	High-flow nasal oxygen therapy	5.9 (5.2- 6.3 [3.4- 7.3])	5.9 (5.3- 6.6 [4.1- 10.2])	
FiO ₂	Standard oxygen therapy	0.3 (0.3- 0.3 [0.28- 0.5])	0.3 (0.3- 0.3 [0.29- 0.6])	0.388
	High-flow nasal oxygen therapy	0.3 (0.3- 0.3 [0.3- 0.4])	0.3 (0.3- 0.4 [0.3- 0.5])	
				0.296

Table 3. Secondary outcomes in patients randomly allocate to high-flow nasal oxygen therapy (HFNT) or standard oxygen therapy during sedation for transcatheter aortic valve replacement. Values are number (proportion) or median (IQR [range]).

Variable	High-flow nasal oxygen therapy n = 35	Standard oxygen therapy n = 34	p value
Number of desaturations			0.037
0	31 (86%)	23 (68%)	
1	4 (11%)	3 (9%)	
>1	1 (3%)	8 (24%)	
Cerebral desaturation,			0.340
Yes	4 (12%)	8 (24%)	
No	29 (88%)	26 (77%)	
Remifentanil dose; mg	0.32 (0.24- 0.43 [0.14-0.85])	0.37 (0.26- 0.44 [0.10-0.66])	0.428
Number of times patient reaches for airway device,			0.006
0	33 (94%)	23 (68%)	
≥1	2 (6%)	11 (32%)	
Comfort level			< 0.001
Excellent	16 (47%)	3 (9%)	
Good	13 (38%)	10 (29%)	
Fair	5 (15%)	19 (56%)	
Poor	0	2 (6%)	
Throat dryness			0.715
Severe	1 (3%)	1 (3%)	
Moderate	10 (29%)	15 (41%)	
Slight	7 (21%)	8 (24%)	
Not at all	16 (47%)	11 (32%)	
Abdominal bloating			0.360
Severe	0	0	
Moderate	0	2 (6%)	
Slight	3 (9%)	1 (3%)	

Not at all	31 (91%)	31 (91%)	
PACU oxygen therapy			0.145
Yes	13 (38%)	20 (59%)	
Discharge from PACU with oxygen therapy;			0.765
Yes	6 (18%)	8 (24%)	
PACU stay; min	54.0 (37.0- 79.0 [8.0-210.0])	48.5 (38.5- 81.5 [15.0-196.0])	0.935
Duration of oxygen therapy; min	121.5 (102.8- 172.8 [0-2237.0])	143.0 (110.0- 241.0 [78.0 - 4397.0])	0.209
Hospital stay; days	3.1 (2.2- 5.9 [1.33-18.2])	3.1 (2.2- 5.3 [1.05-18.4])	0.912
Duration of procedure; min	116.0 (101.8- 128.8 [74.0- 151.0])	110.5 (101.0- 134.5 [73.0- 218.0])	0.883

IQR, interquartile range; PACU, post anaesthesia recovery unit.

Figures

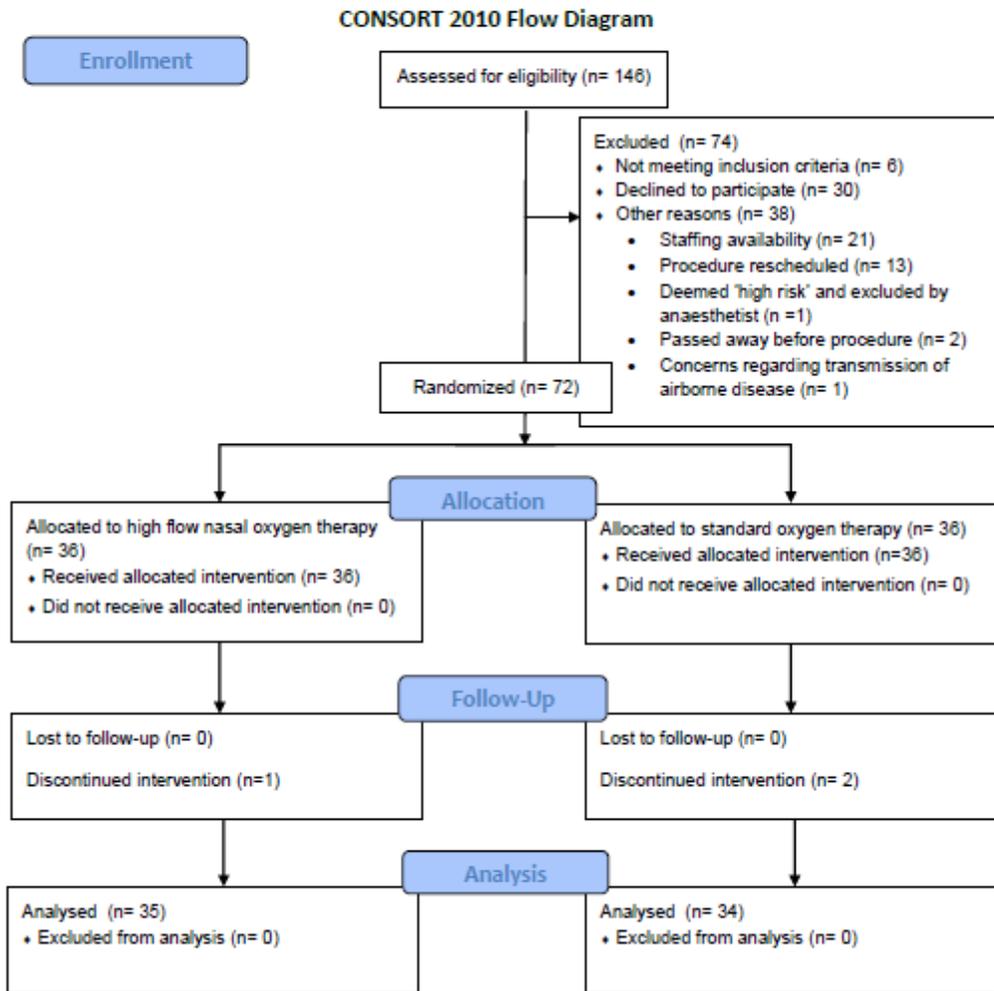


Figure 1

Study flow diagram

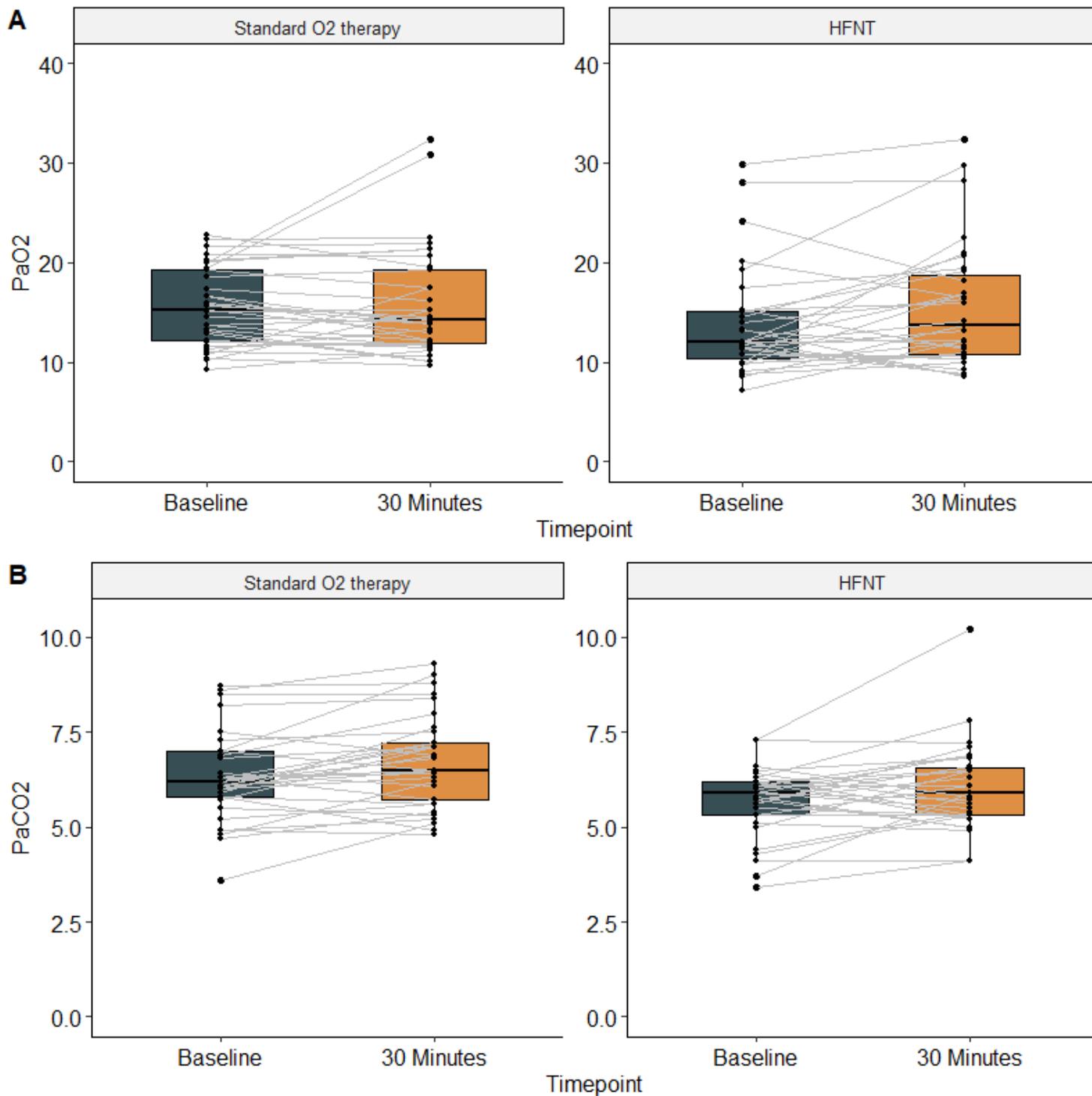


Figure 2

Change in arterial partial pressure of oxygen (PaO₂) and arterial partial pressure of carbon dioxide (PaCO₂) from 0 minutes to 30 minutes during transfemoral transcatheter aortic valve implantation (TAVR) in patients randomly allocated to high-flow nasal oxygen therapy (HFNT) or standard oxygen.

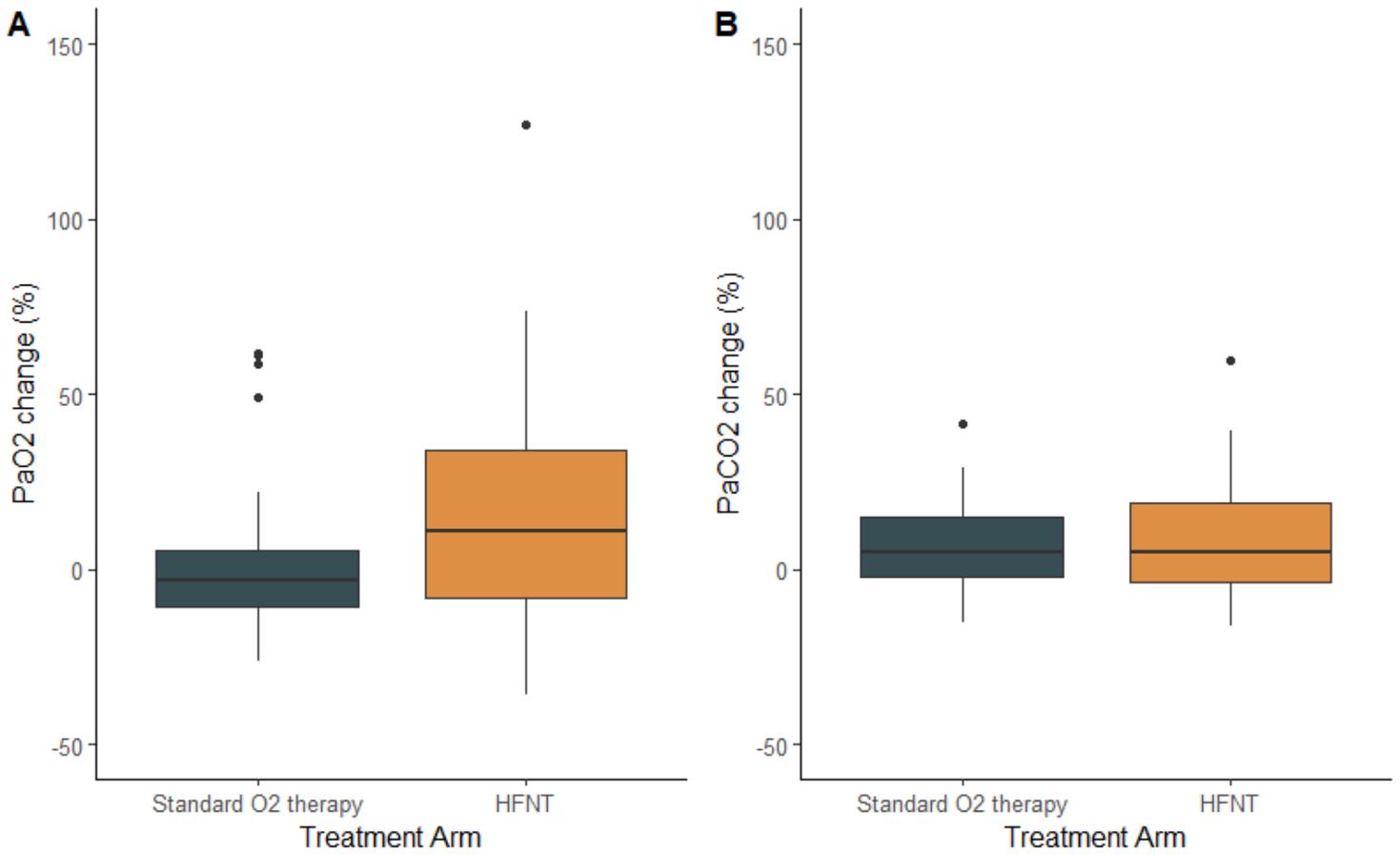


Figure 3

Percentage change in arterial partial pressure of oxygen (PaO2) and arterial partial pressure of carbon dioxide (PaCO2) in both high-flow nasal oxygen (HFNT) and standard oxygen therapy groups from 0 minutes to 30 minutes during transfemoral transcatheter aortic valve implantation (TAVR) in patients randomly allocated to high-flow nasal oxygen therapy (HFNT) or standard oxygen.