Research Square

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Intranasal dexmedetomidine versus intranasal dexmedetomidine combined with rectal chloral hydrate for sedation of young children undergoing transthoracic echocardiography: a prospective observational cohort study

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Research Article

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Abstract

Background

To evaluate the safety and efficacy of intranasal dexmedetomidine (DEX) alone versus intranasal low-dose DEX combined with rectal chloral hydrate (CH) for sedation of young children during transthoracic echocardiography (TTE) examination.

Methods

We conducted a 16-month prospective observational cohort study of children aged 1–36 months who underwent sedation for TTE examination. Participants received either 2 μg/kg intranasal DEX (Group DEX) or 1 μg/kg intranasal DEX combined with 20 mg/kg rectal CH (Group DEX-CH). The primary outcome was efficacy, defined as the initial sedation success rate. Secondary outcomes included the sedation onset time, the recovery time, the duration of sedation, and adverse events. Multivariable logistic regression and propensity score matching were used to adjust for confounding factors.

Results

A total of 2,776 children were enrolled, of whom 1,437 (51.8%) received DEX sedation and 1,339 (48.2%) received DEX-CH sedation. After 1:1 propensity score matching, 1,253 children remained in each group. DEX-CH sedation was independently associated with a higher initial success rate (Group DEX 93.2% vs. Group DEX-CH 98.2%; relative risk [RR] 0.26; 95% confidence interval [CI] 0.16–0.41; $P < 0.001$). Group DEX-CH had a longer duration of sedation [36 (27, 50) min vs. 44 (34, 55) min; $P < 0.001$] and recovery time [13 (3, 25) min vs. 20 (10, 32) min; $P < 0.001$]. Group DEX had fewer adverse events (5.3% vs. 8.4%; RR 0.61; 95% CI 0.44–0.84; $P = 0.002$). Sedation onset time did not differ between the groups.

Conclusions

In real-world hospital settings, 1 μg/kg intranasal DEX combined with 20 mg/kg rectal CH for sedation of young children undergoing TTE examination was associated with a higher initial sedation success rate and a longer duration of sedation, whereas 2 μg/kg intranasal DEX was associated with fewer adverse events.

Background

Transthoracic echocardiography (TTE) is an important tool for the diagnosis of heart disease. The examination requires the patient to remain still and at rest so that accurate data can be acquired. Children are often unable to cooperate because of anxiety and fear, especially those younger than 3

years of age. Drug-induced sedation before the examination is therefore required for children who cannot cooperate.

Dexmedetomidine (DEX) is a highly selective central α_2-adrenoceptor agonist that produces a state resembling natural sleep and causes only mild respiratory depression [1]. It has been shown to be a suitable sedative for pediatric patients and is used in clinical practice. DEX can be administered intranasally, a route that is non-invasive, simple, and readily accepted by children and their parents or guardians. Intranasal DEX at 1–4 μg/kg is the recommended dose for preoperative or non-painful procedural sedation in children [2]. High doses may cause bradycardia or hypotension [3].

Chloral hydrate (CH) has been used as a sedative for more than 100 years and remains widely used for pediatric sedation in China. It can be administered orally or rectally and has a favorable safety profile. The recommended dose is 40–70 mg/kg, but the initial dose is associated with a high rate of sedation failure [4, 5]. Repeated administration of sedatives may therefore be required, which increases the clinical workload and the incidence of adverse events such as excessive irritability, vomiting, and prolonged sedation. DEX has been used successfully as a rescue sedative in children in whom CH sedation failed for magnetic resonance imaging (MRI) [6]. Combining DEX with CH may therefore increase the sedation success rate. To our knowledge, no previous study has reported the efficacy of low-dose DEX combined with CH for sedation of young children undergoing TTE examination.

This prospective observational cohort study aimed to compare the efficacy and safety of intranasal DEX alone with those of low-dose intranasal DEX combined with rectal CH for sedation of children undergoing TTE examination.

Methods

Study design

This prospective observational cohort study was conducted at the Children's Hospital of Soochow University to evaluate sedation outcomes in TTE examinations performed between January 2025 and April 2026, and it is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. The study began after the sedation center had started to use DEX alone or DEX combined with CH for sedation during TTE examinations. The study protocol was approved by the Institutional Review Board of Soochow University (No. 2026CS071, Soochow, Jiangsu Province, China). Written informed consent was obtained from the legal guardians of all children before sedation. The legal guardians also permitted the use and publication of the participants' data. Participant privacy and data security were strictly maintained throughout the study. All personal information was securely stored and was accessible only to authorized members of the research team.

Participants

Children aged 1–36 months who underwent sedation for TTE examination were categorized into two groups according to the sedation method used: 2 μg/kg intranasal DEX (Group DEX) or 1 μg/kg intranasal DEX combined with 20 mg/kg rectal CH (Group DEX-CH).

The exclusion criteria were sedation by any other method; American Society of Anesthesiologists (ASA) physical status III or higher; a history of bradycardia or advanced (second- or third-degree) heart block; allergy to DEX or CH; neurological or neuromuscular disease; hypoxemia; clinically relevant hepatic or renal dysfunction; and nasal masses or a history of epistaxis.

Sedation techniques and procedures

Chloral hydrate solution (50 mg/mL; Jiajia; Tefeng Medicine Co., Ltd., China) was injected into the rectum using a specially designed syringe. Dexmedetomidine solution (100 μg/mL; Aibeining; Jiangsu Hengrui Medicine Co., Ltd., China) was instilled into the nasal cavity in several aliquots using a 1 mL syringe, with the child in the supine position; the alae nasi were then gently massaged to facilitate absorption. Before nasal administration, the nurse cleaned the child's nasal passages with a disposable cotton swab.

The sedation method was chosen on the basis of the anesthesiologist's experience. The depth of sedation was assessed using the Ramsay Sedation Scale (Table 1) at 5-minute intervals. The child's respiratory status, including respiratory rhythm and the color of the lips and mucocutaneous tissues, was also closely monitored. TTE was started when the Ramsay score reached 5. The child was then taken to the echocardiography examination room. If the initial sedation plan failed, the anesthesiologist selected a rescue measure on the basis of personal experience, administering either inhaled sevoflurane or 1 μg/kg DEX.

Table 1
Ramsay Sedation Scale.

Score	Response
1	Awake, anxious, agitated, restless
2	Awake, cooperative, tranquil
3	Responds to commands
4	Asleep, brisk response to stimulus
5	Asleep, sluggish response to stimulus
6	Asleep, no response to stimulus

After completion of the examination, children returned to the recovery room to await awakening. The nurse assessed each child's sedation status every 5 minutes. Children were allowed to leave when the Ramsay Sedation Scale score was ≤ 2.

The vital signs of all sedated children were monitored by a nurse during sedation and recovery. Blood pressure (BP), heart rate (HR), and oxygen saturation (SpO_2) were measured before drug administration. HR and SpO_2 were measured again by the nurse before the examination and on entry to the recovery room. BP was not measured after administration of the sedative drugs to avoid any effect of blood pressure measurement on the sedation procedure. A nurse conducted a telephone follow-up on the day after the examination.

Outcomes

The primary outcome was the initial sedation success rate. Successful sedation was defined as achievement of a Ramsay score of 5 within 40 minutes, with the child completing the examination. Failed sedation was defined as a Ramsay score of ≤ 4 within 40 minutes or the child waking during the examination.

The secondary outcomes assessed in this study included the sedation onset time, the duration of sedation, and the recovery time. The sedation onset time was defined as the time from drug administration to a Ramsay score of 5. The duration of sedation was defined as the time from successful sedation induction to awakening. The recovery time was defined as the time from completion of the examination to awakening. A recovery time exceeding 2 hours was defined as delayed awakening.

The adverse events assessed in this study included bradycardia, hypoxemia, delayed awakening, and gastrointestinal reactions. Bradycardia was defined as a reduction in HR of more than 20% from baseline. Hypoxemia was defined as an SpO_2 of less than 90%. Gastrointestinal reactions included nausea and vomiting, abdominal pain and diarrhea, or abdominal distension.

Statistical analysis

Data are presented as numbers with percentages or as the median and interquartile range (IQR), according to the data distribution. The sample size was determined by the number of cases managed at the sedation center during the study period.

A multivariable logistic regression model was used to calculate a propensity score (PS) for each participant to address baseline imbalances. The model incorporated a comprehensive set of covariates known to influence the choice of sedation method: age, weight, sex, diagnosis of heart disease, and examination time. Propensity score matching (PSM) was then applied to eliminate significant baseline differences between the two groups. Patients in the two groups were matched 1:1 without replacement using a nearest-neighbor algorithm within a caliper width equal to 0.2 of the standard deviation of the logit of the calculated propensity score. Matching quality was assessed by comparing the standardized mean difference (SMD); an SMD exceeding 0.1 is widely regarded as an indicator of imbalance.

The relative risk (RR) and confidence interval (CI) for successful sedation and for adverse events were calculated using log-binomial regression analysis. The normality of the data distribution and the homogeneity of variances were assessed using the Shapiro–Wilk and Levene tests, respectively. The Mann–Whitney U test was used to compare the sedation onset time, recovery time, and duration of sedation between the two groups. The chi-square test was used to compare the initial sedation success or failure rate and the incidence of adverse events between the two groups. All analyses were performed using Python 3.8 and SPSS 23.0. Statistical significance was defined as a *P* value < 0.05.

Results

Demographic characteristics

Figure 1 shows the STROBE flow diagram of the patients included in this study. A total of 6,233 children underwent sedation at the sedation center, of whom 3,457 were excluded. Consequently, 2,776 children were enrolled: 1,437 (51.8%) received intranasal DEX sedation and 1,339 (48.2%) received DEX-CH sedation. The demographic characteristics of the two groups are presented in Table 2. Before matching, Group DEX was younger and had a lower body weight than Group DEX-CH (SMD > 0.1). After PSM, 1,253 children remained in each group, these baseline imbalances were eliminated, and the two groups were comparable (SMD ≤ 0.1).

Table 2
Baseline demographic characteristics of the study population.

Demographic feature	Unweighted Sample			Propensity 1:1 Matching		
	DEX	DEX-CH	SMD	DEX	DEX-CH	SMD
Number of patients	1437	1339	-	1253	1253	-
Age (month) [median (IQR)]	11 (6, 17)	12 (7, 18)	0.14	12 (6, 18)	12 (6,18)	0.03
Male/Female (n)	769/668	699/640	0.03	662/591	653/600	0.01
Weight (kg) [median (IQR)]	9.5 (7.5, 11)	10 (8, 11.5)	0.19	10 (8, 11.5)	10 (8, 11)	0.04
Diagnosis						
Congenital Heart Disease	496 (34.5%)	494 (36.9%)	0.10	438 (35.0%)	457 (36.5%)	0.10
Postoperative Period of Congenital Heart Disease Surgery	246 (17.1%)	211 (15.8%)		216 (17.2%)	196 (15.6%)	
Kawasaki disease	191 (13.3%)	172 (12.8%)		161 (12.8%)	161 (12.8%)	
Arrhythmia	2 (0.1%)	7 (0.5%)		2 (0.2%)	7 (0.6%)	
Myocardial lesions	15 (1.1%)	21 (1.6%)		12 (1.0%)	21 (1.7%)	
Examination for definitive diagnosis	487 (33.9%)	434 (32.4%)		424 (33.8%)	411 (32.8%)	
The examination time (min) [median (IQR)]	23 (17, 28)	22 (17,27)	0.09	22 (17, 27)	23 (18, 28)	0.09

DEX, dexmedetomidine; DEX-CH, dexmedetomidine combined with chloral hydrate; IQR, interquartile range; SMD, standardized mean difference.

The primary outcome, the initial sedation success rate, is presented in Table 3. The initial sedation success rate was higher in Group DEX-CH than in Group DEX: 1,168 (93.2%) in Group DEX versus 1,230 (98.2%) in Group DEX-CH (RR 0.26; 95% CI 0.16–0.41; $P < 0.001$). The reasons for initial sedation failure were failure of sedation induction and examination failure. In total, 85 (6.8%) children in Group DEX had initial sedation failure, comprising 45 (3.6%) with induction failure and 40 (3.2%) with examination failure. In Group DEX-CH, 23 (1.8%) children had initial sedation failure, comprising 16 (1.3%) with induction failure and 7 (0.6%) with examination failure. Group DEX had a higher induction failure rate (RR 2.88; 95% CI 1.62–5.12; $P < 0.001$) and a higher examination failure rate (RR 5.87; 95% CI 2.62–13.15; $P < 0.001$) than Group DEX-CH.

Table 3
Comparison of the initial sedation success and failure rates between Group DEX and Group DEX-CH after Propensity 1:1 Matching.

Successful sedation	**DEX**	**DEX-CH**	**RR (95% CI)**	**P value**
	n (%)	**n (%)**		
	1168(93.2%)	**1230 (98.2%)**	**0.26 (0.16–0.41)**	**< 0.001**
Failure sedation				
Total	85 (6.8%)	23 (1.8%)	-	-
Failure induction	45 (3.6%)	16 (1.3%)	2.88 (1.62–5.12)	< 0.001
Failure examination	40 (3.2%)	7 (0.6%)	5.87 (2.62–13.15)	< 0.001

Table 4 shows the differences in sedation onset time, recovery time, and duration of sedation between the two groups. There was no significant difference in sedation onset time between the groups [18 (14, 23) vs. 18 (15, 23) min; $P = 0.67$]. Group DEX-CH had a longer recovery time [13 (3, 25) vs. 20 (10, 32) min; $P < 0.001$] and a longer duration of sedation [36 (27, 50) vs. 44 (34, 55) min; $P < 0.001$] than Group DEX.

Table 4
Comparison of sedation onset time, recovery time, and sedation duration between Group DEX and Group DEX-CH after Propensity 1:1 Matching.

The sedation onset time (min) [median (IQR)]	**DEX**	**DEX-CH**	***P* value**
	18 (14, 23)	**18 (15, 23)**	**0.67**
The recovery time(min) [median (IQR)]	13 (3, 25)	20 (10, 32)	< 0.001
The duration of sedation (min) [median (IQR)]	36 (27, 50)	44 (34, 55)	< 0.001

Table 5 shows the adverse events. The incidence of adverse events was lower with DEX sedation than with DEX-CH sedation [66 (5.3%) vs. 105 (8.4%); RR 0.61; 95% CI 0.44–0.84; $P = 0.002$]. DEX sedation was associated with more bradycardia [65 (5.2%) vs. 28 (2.2%); RR 2.39; 95% CI 1.53–3.76; $P < 0.001$] and fewer gastrointestinal reactions [0 vs. 81 (6.5%); RR and 95% CI not estimable; $P < 0.001$]. The incidence of delayed awakening did not differ significantly between the two groups [2 (0.2%) vs. 3 (0.2%); RR 0.67; 95% CI 0.11–3.99; $P = 0.65$]. Hypoxemia did not occur in either group.

Table 5
Comparison of adverse events between Group DEX and Group DEX-CH after Propensity 1:1 Matching.

Total	**DEX**	**DEX-CH**	**RR (95% CI)**	***P* value**
	n (%)	**n (%)**		
	66 (5.3%)	**105 (8.4%)**	**0.61 (0.44–0.84)**	**0.002**
Bradycardia	65 (5.2%)	28 (2.2%)	2.39 (1.53–3.76)	< 0.001
Hypoxemia	0	0	-	-
Awakening delay	2 (0.2%)	3 (0.2%)	0.67 (0.11–3.99)	0.65
Gastrointestinal reaction	0	81 (6.5%)	not estimable	< 0.001

Discussion

In this study, children who received low-dose DEX combined with CH had a higher sedation success rate, a longer recovery time, and a longer duration of sedation than those who received DEX alone. The incidence of adverse events was higher with DEX-CH sedation than with DEX sedation. Sedation onset time did not differ significantly between the two groups.

The initial sedation success rate was significantly higher with DEX-CH sedation than with DEX sedation. DEX is an α_2-adrenoceptor agonist that induces a state resembling natural sleep, and it can be used alone or in combination with other sedatives. Intranasal DEX at 2 μg/kg has been reported to be the optimal dose for young children, as higher doses do not necessarily increase the sedation success rate but may cause severe bradycardia [7]. DEX has also been reported to reduce the requirement for other anesthetics, such as sevoflurane, propofol, and fentanyl [8]. Wang et al. reported a sedation success rate of 97.6% with oral CH (30 mg/kg) combined with intranasal DEX (2 μg/kg) for electroencephalography in children up to 18 years of age, which was substantially higher than the rates reported for CH alone in other studies [9, 10]. The initial sedation success rate in the present study was similar to that reported by Wang et al., although lower doses of CH and DEX were used in children aged 1–36 months. Cui et al. demonstrated that children up to 3 years of age have a lower rate of sedation failure with a single dose of CH [11]. It therefore appears necessary to use lower doses of DEX and CH in children up to 3 years of age, who have a lower body weight and a lower plasma clearance rate [12].

Although sedation onset time was similar in the two groups, Group DEX-CH had a longer recovery time and a longer duration of sedation. This may reflect the pharmacokinetic characteristics of CH and DEX. Li et al. described the pharmacokinetics of intranasal DEX in a large cohort of Chinese children aged 3 months to 3 years and reported that the time for 2 μg/kg DEX to reach the target plasma concentration was 20 minutes and that the maximum blood concentration (C_{max}) was attained at 61 minutes; this dose achieved a preset therapeutic threshold for mild-to-moderate sedation that was maintained for up to 2 hours [2]. CH reaches an effective blood concentration within 30 minutes after rectal administration, and

its C_{max} is attained at 1 hour, with an effect lasting 4–8 hours [13]. The duration of action of CH is therefore considerably longer than that of DEX, which is consistent with our results. The sedation method should provide a duration and depth of sedation adequate for the length of the examination. Although Group DEX had a faster recovery, it also had a higher examination failure rate, which may increase the need for rescue medication.

In this study, the main adverse reaction in Group DEX-CH was gastrointestinal: 81 (6.5%) children defecated because of rectal irritation, without nausea or vomiting. This was related to the rectal route of administration, and no child required additional treatment. Nevertheless, rectal administration is easier to perform and better accepted by toddlers than oral administration, which carries a higher risk of vomiting, crying or resistance, and coughing, probably because of the bitter and irritating nature of the drug [14]. The main adverse reactions to DEX are bradycardia and a biphasic arterial blood pressure response, both of which are related to the infusion rate and the dose administered. High peak plasma levels are responsible for the complex hemodynamic effects of DEX. Intranasal administration of DEX avoids high peak plasma levels but still achieves adequate plasma levels after absorption [15]. In our cohort, Group DEX had a higher incidence of bradycardia. Because of technical limitations at our hospital, the anesthesiologists did not measure non-invasive blood pressure in the children after drug administration. However, these bradycardic episodes were self-limiting and did not require medical intervention [16]. Mason et al. found no detectable change in blood pressure when the heart rate decreased during intranasal DEX administration [17]. Neither hemodynamic collapse nor a need for pharmacologic intervention was observed in either group. Delayed awakening occurred in 3 (0.2%) children who received DEX-CH sedation and in 2 (0.2%) children who received DEX sedation. A prolonged duration of sedation is inappropriate for short examinations. In the present study, the probability of delayed awakening was relatively low in both groups. Hypoxemia was not observed in either group.

Limitations

This study has several limitations. First, we analyzed the sedative effects only in children aged 1–36 months; the effects in children older than 3 years were not assessed. Second, blood pressure and heart rate were not monitored continuously throughout the examination because of equipment limitations. Some children may therefore have experienced adverse effects such as hypertension, hypotension, or bradycardia that were not detected. Third, although physiology and drug metabolism differ across the age range of 1–36 months, we did not perform further subgroup analyses.

Conclusions

This study describes two safe and effective sedation protocols for young children undergoing TTE examination. Our observations suggest that 1 μg/kg intranasal DEX combined with 20 mg/kg rectal CH was associated with a higher initial sedation success rate and a longer duration of sedation, whereas 2 μg/kg intranasal DEX was associated with a shorter recovery time and fewer adverse events.

Abbreviations

DEX Dexmedetomidine

CH Chloral hydrate

TTE Transthoracic echocardiography

MRI Magnetic resonance imaging

STROBE Strengthening the Reporting of Observational Studies in Epidemiology

ASA American Society of Anesthesiologists

BP Blood pressure

HR Heart rate

SpO_2 Oxygen saturation

IQR Interquartile range

PS Propensity score

PSM Propensity score matching

SMD Standardized mean difference

RR Relative risk

CI Confidence interval

Declarations

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of Soochow University (Approval No. 2026CS071) and was conducted in accordance with the ethical standards set out in the Declaration of Helsinki (2013 revision). Written informed consent was obtained from the legal guardians of all children before inclusion in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Author Contribution

XH: study conception and design, statistical analysis, interpretation of the results, and drafting of the manuscript.WZ: patient enrollment, data acquisition, and contribution to the interpretation of the results.QY: formatting of the tables and figures, reference management, and assistance with manuscript editing. QW: supervision of the study protocol, coordination of ethical approval, and final approval of the manuscript. All authors reviewed and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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Data Availability

The data associated with this study have not been deposited in a publicly available repository. However, all data relevant to the study are included in the article. The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

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Figures

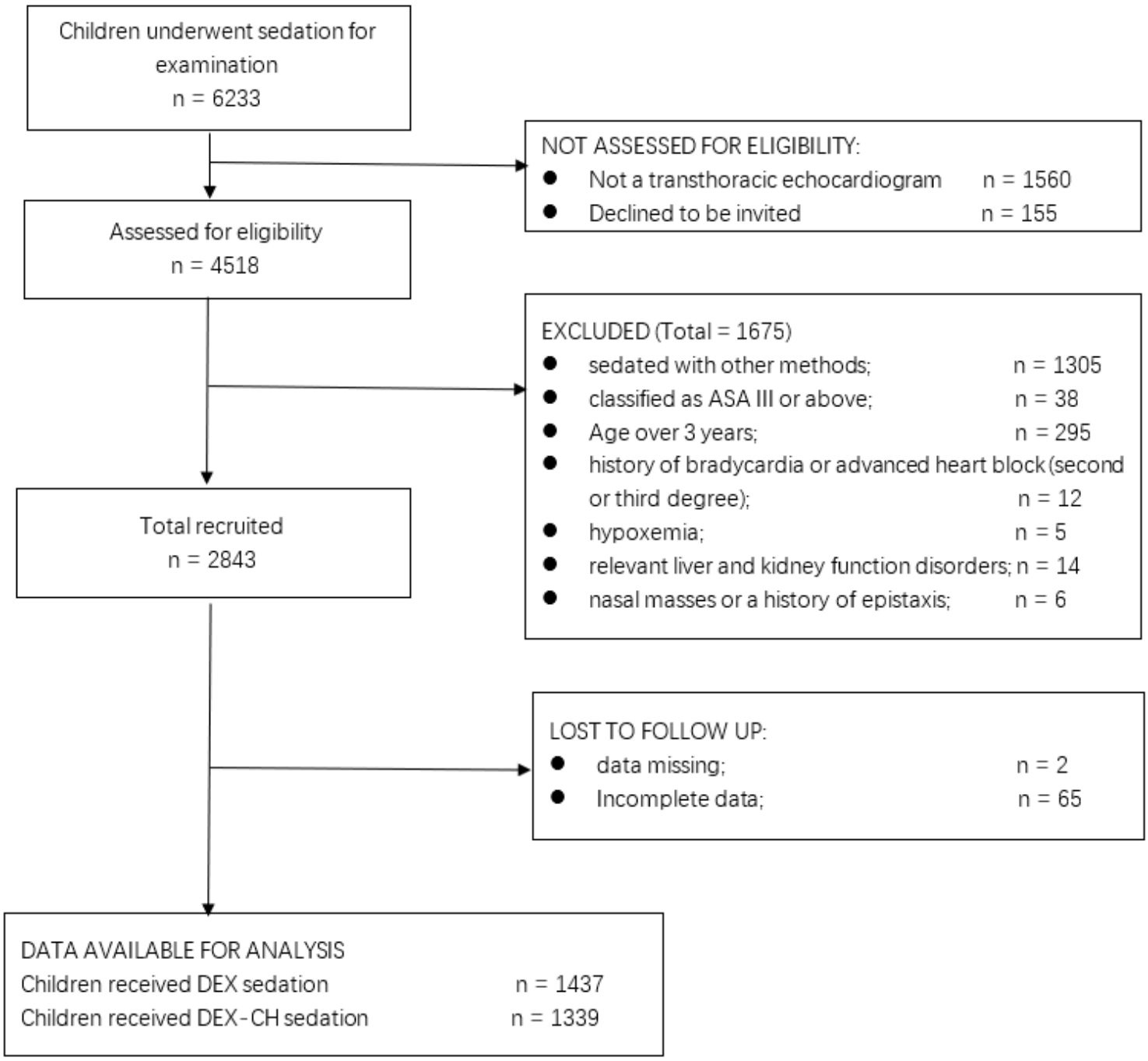


Figure 1

STROBE flow diagram of study participant selection