Cardiology in the Young

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Dexmedetomidine administration is associated with small haemodynamic changes in children undergoing cardiac procedures: a systematic review and meta-analysis

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Original Article

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Abstract

Introduction: Dexmedetomidine is frequently used in paediatric anaesthesia. This includes use in patients with CHD, but detailed analysis of haemodynamics after administration in these patients has not yet been published. We performed a systematic review and meta-analyses examining haemodynamic changes immediately after dexmedetomidine administration in patients with CHD. *Methods:* We conducted a systematic review of PubMed, Embase, and Medline from inception until May 31, 2024. Inclusion criteria were studies that contained children with CHD who received dexmedetomidine for a cardiac procedure and reported at least one haemodynamic variable before and after administration of dexmedetomidine. Exclusion criteria were studies of noncardiac procedures. We performed a meta-analysis on each haemodynamic variable that was reported by at least four studies. *Results:* We screened 5383 abstracts. We included 85 studies for review, and 16 studies were accepted for four meta-analyses (heart rate, 16 studies, $n = 408$; systolic blood pressure, 11 studies, $n = 280$; diastolic blood pressure, 10 studies, $n = 276$; mean arterial pressure, 5 studies, $n = 130$). Analysis of heart rate, systolic blood pressure, and diastolic blood pressure showed a statistically significant reduction ($p < 0.001$), while there was no significant change in mean arterial pressure. The clinical difference was minimal with a decrease in heart rate of 11.3 beats per minute, and a decrease in systolic blood pressure/diastolic blood pressure of 5.9 and 6.2 mmHg, respectively. Heterogeneity was high in all analyses. *Discussion:* Dexmedetomidine is associated with small changes in heart rate, systolic blood pressure, and diastolic blood pressure in children with CHD. Further study is warranted.

Introduction

Dexmedetomidine is an alpha-2 agonist with sedative and analgesic properties that preserves respiratory drive. It has several documented off-label uses, including the prevention of emergence agitation,[1] intraoperative analgesia,[2] and as a supplement to a balanced anaesthetic regimen.[3] However, despite increasing use in a variety of paediatric settings,[4] high-quality safety data are limited, and safety data in specific populations have not been well described.

CHD remains the most common congenital defect worldwide. Approximately 40,000 children undergo congenital heart surgery in the United States every year,[5] and many more operations are performed worldwide. However, the use of dexmedetomidine in paediatric cardiac surgery has shown varying effects on perioperative haemodynamic variables such as heart rate and blood pressure.[6,7] Given the delicate nature of these procedures and often strict haemodynamic requirements, high-quality, placebo-controlled, randomised clinical trials would be ideal for assessing the safety of dexmedetomidine administration to patients with CHD. While those trials remain forthcoming, a large volume of observational studies have been published documenting the haemodynamic effects of dexmedetomidine in paediatric cardiac surgery and cardiac catheterisation procedures.

We aimed to assess the haemodynamic changes associated with dexmedetomidine administration to children with CHD undergoing open heart surgery and cardiac catheterisation procedures with a systematic review and meta-analysis of both observational studies and randomised clinical trials that reported haemodynamic variables both before and immediately after the administration of dexmedetomidine. We hypothesised that dexmedetomidine administration would cause a decrease in at least some of the following parameters: heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, central venous pressure, and pulmonary artery pressure.

Materials and methods

Search strategy

This meta-analysis followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement and Checklist .[8] IRB approval was not required as we used previously published deidentified data. We constructed a search term with the goal of screening as much of the published literature as was reasonable to perform. We utilised the following as our final search term:

(dexmedetomidine OR precedex OR hospira) AND (pedi OR infan* OR prem* OR neonate* OR ICU) AND (adverse OR hypo* OR decr* OR event OR sequelae OR crit*)*

We searched PubMed, EMBASE, and Medline databases from inception to May 31, 2024.

Inclusion and exclusion criteria

We included randomised clinical trials and observational studies that contained a measure of haemodynamic variables in children aged 0-18 with CHD who received either an open heart or a cardiac catheterisation procedure. These studies needed to report at least one measurement of the variable prior to administration of dexmedetomidine, and the same variable must have been recorded after the administration of dexmedetomidine. If multiple time points after the administration of dexmedetomidine were reported, then we used the earliest measurement after dexmedetomidine administration. We excluded case reports or case series that included less than 10 participants per group, studies that included participants over the age of 18, and children with previously diagnosed neurologic, renal, or genetic abnormalities. We also excluded studies that included participants undergoing noncardiac surgical procedures.

Screening and assessment of studies

Screening was conducted using Covidence systematic review software (Veritas Health Innovation, Melbourne, AUS). Duplicates were automatically removed by the software and checked manually to ensure accuracy. The initial screen of titles and abstracts was performed by two authors independently (WMJ, NDR). Studies selected for full-text review were read by two authors independently (WMJ, NDR) to determine whether they met all inclusion and exclusion criteria. Disagreements were resolved by a third author (MAH).

Data extraction

Data were extracted independently by two authors (WMJ, NDR). Data sheets were then compared to ensure the accuracy of data extraction. The following information was extracted from included studies: first author, year of publication, title of the manuscript, study design, sample size in the control and intervention groups, type of surgery (open heart/catheterisation), the route of dexmedetomidine administration (bolus/infusion/intranasal), the dose of dexmedetomidine administered in mcg/kg, the haemodynamic outcomes measured, and the centrality (mean/median) and variance (standard deviation/interquartile range/range) measures reported for each haemodynamic variable.

We chose to collect, as for the control group, the haemodynamic measurement taken immediately prior to dexmedetomidine administration, and, as for the intervention group, the first measurement taken after the administration of dexmedetomidine. We excluded all subsequent measurements in order to minimise confounding due to surgical factors and elimination of the drug after administration.

When numbers for means and standard deviations were not reported in the text, we visually estimated the mean and standard deviation of haemodynamic variables using graphs provided in the manuscripts.

Risk of bias

Bias assessment of all included studies was performed by two authors independently (WMJ, NDR). Randomised clinical trials were analysed using a revised tool to assess risk of bias in randomised trials (RoB 2).[9] Observational studies were analysed using the Risk of Bias in Non-randomised Studies—of Exposures (ROBINS-E) [10]. Discrepancies in the individual domains and overall risk of bias assessments were adjudicated by a third author (MAH).

Data analysis

Data analysis was performed using Cochrane RevMan (Cochrane, London, UK). A random effects model was chosen *a priori* for analysis due to the likely substantial between-study heterogeneity introduced by the differences in assessment type, age, and diagnosis among the included studies. We aimed to analyse the pooled effect size in the following domains: heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, central venous pressure, and pulmonary artery pressure. Between-study heterogeneity was assessed using the I^2 statistic calculated for each pooled analysis.

We chose an I^2 of greater than 50% as an indication to explore sources of heterogeneity. We planned to analyse the following covariates via meta-regression in order to examine sources of between-study heterogeneity where necessary: age, type of surgery, route of administration, and risk of bias.

Results

Study characteristics

A total of 5383 abstracts were identified for screening after removal of duplicates. Upon review, 4686 studies were excluded due to lack of relevance. A total of 234 studies were removed due to too few participants in each group, 122 studies were review articles, and 256 studies did not include any haemodynamic variables. A total of 85 studies were included for full-text article review.

An additional 65 studies were excluded after full-text review for lacking a measure of haemodynamic variables, and four studies contained participants undergoing noncardiac procedures. A total of 16 studies were included in our analysis (Figure 1, Table S1). Of the 16 included studies, 16 studies were analysed for differences in heart rate, 11 studies were analysed for differences in systolic blood pressure, 10 studies were analysed for differences in diastolic blood pressure, and 5 studies were analysed for differences in mean arterial pressure. The number of studies was insufficient to conduct analyses on central venous pressure and pulmonary artery pressure.

Assessment of risk of bias

After assessment of included studies, there was at least a moderate-to-high risk of bias in every study included in the analysis (Supplemental Information, Table S2 and Table S3).

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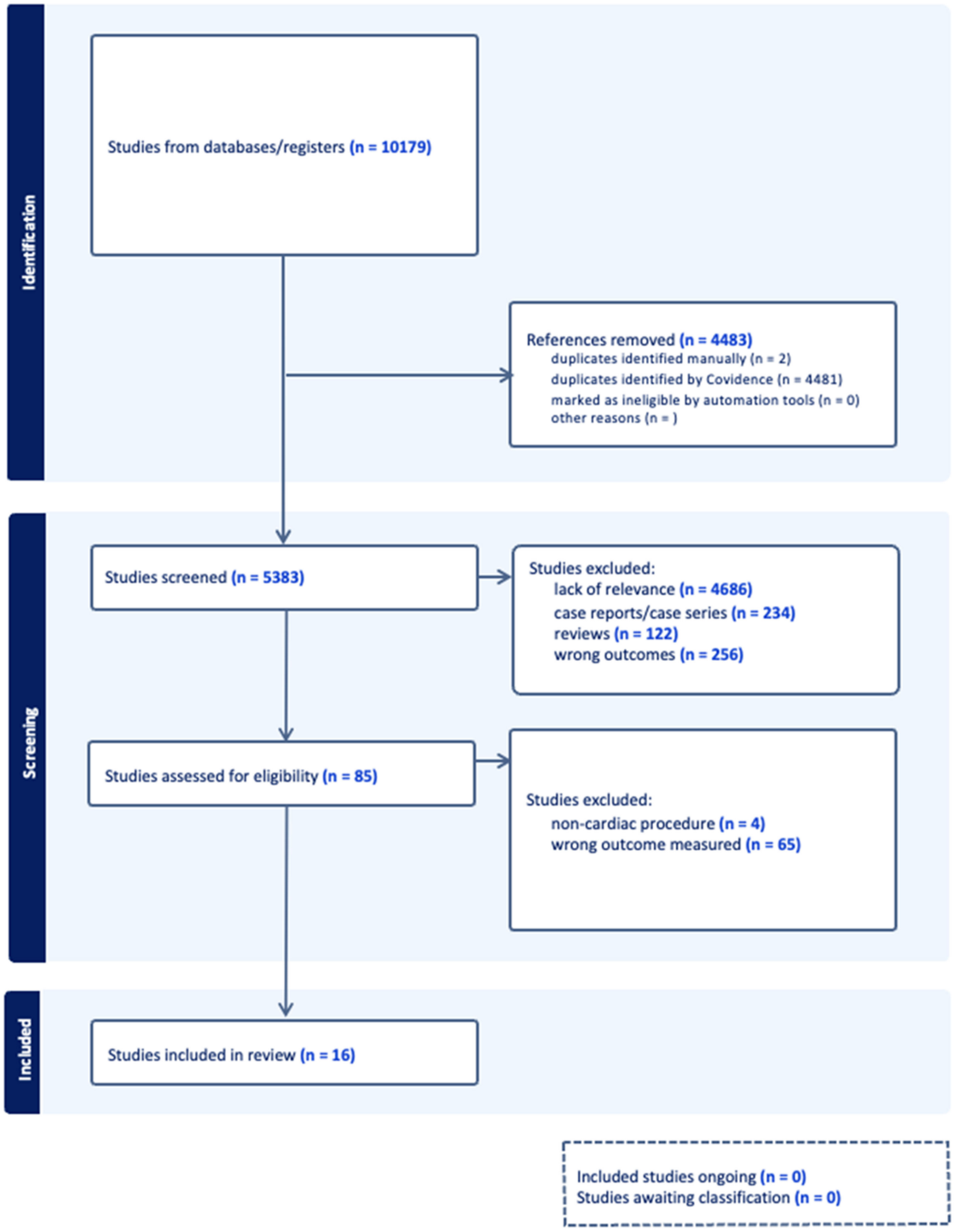

Figure 1. PRISMA diagram displaying our search strategy and method for including and excluding studies published on the haemodynamic effects of dexmedetomidine on children with congenital heart disease.

Heart rate

Sixteen studies reported a measurement of heart rate in patients receiving dexmedetomidine.[11–26] A total of 408 measurements were included. A meta-analysis demonstrated a mean difference of −11.25 beats per minute (95% confidence interval (CI) −15.24, −7.30, $p < 0.00001$) before and after administration of dexmedetomidine. I^2 was 90% (Figure 2).

Systolic blood pressure

Eleven studies reported a measurement of systolic blood pressure in patients receiving dexmedetomidine.[12–25] A total of 280 measurements were included. Meta-analysis demonstrated a mean difference of −5.91 mmHg (95% confidence interval (CI) −7.14, −4.83, $p < 0.0001$) pre- and post-administration of dexmedetomidine. I^2 was 76% (Figure 3).

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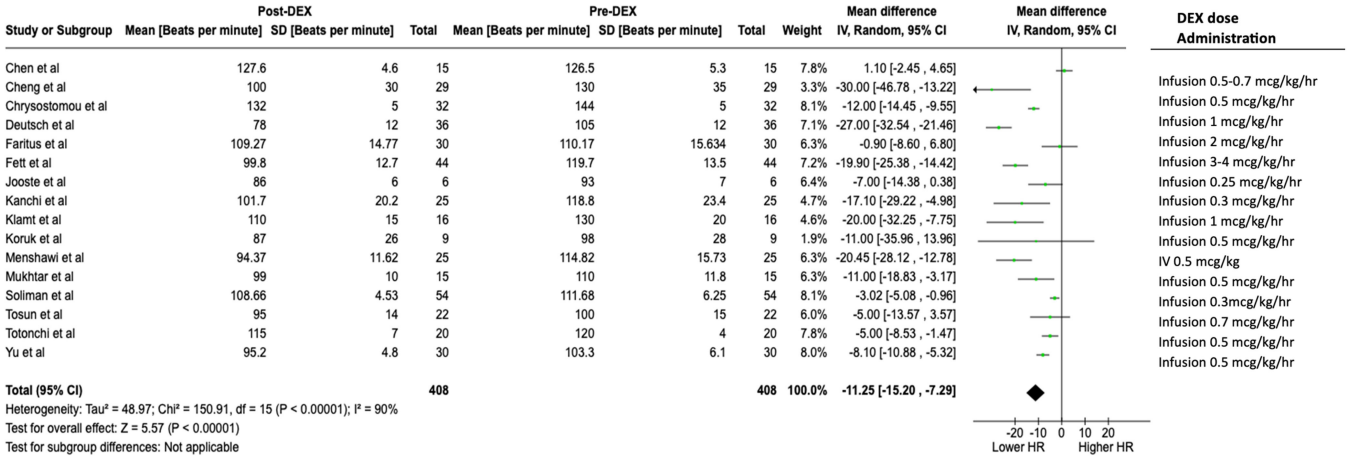

Figure 2. Meta-analysis of measures of heart rate (HR) before and after the administration of dexmedetomidine in children with congenital heart disease. Lower heart rate indicates a measured decrease in heart rate after the administration of dexmedetomidine. Higher heart rate indicates a measured increase in heart rate after the administration of dexmedetomidine. Data represented as mean beats per minute with standard deviation (SD) measured in beats per minute.

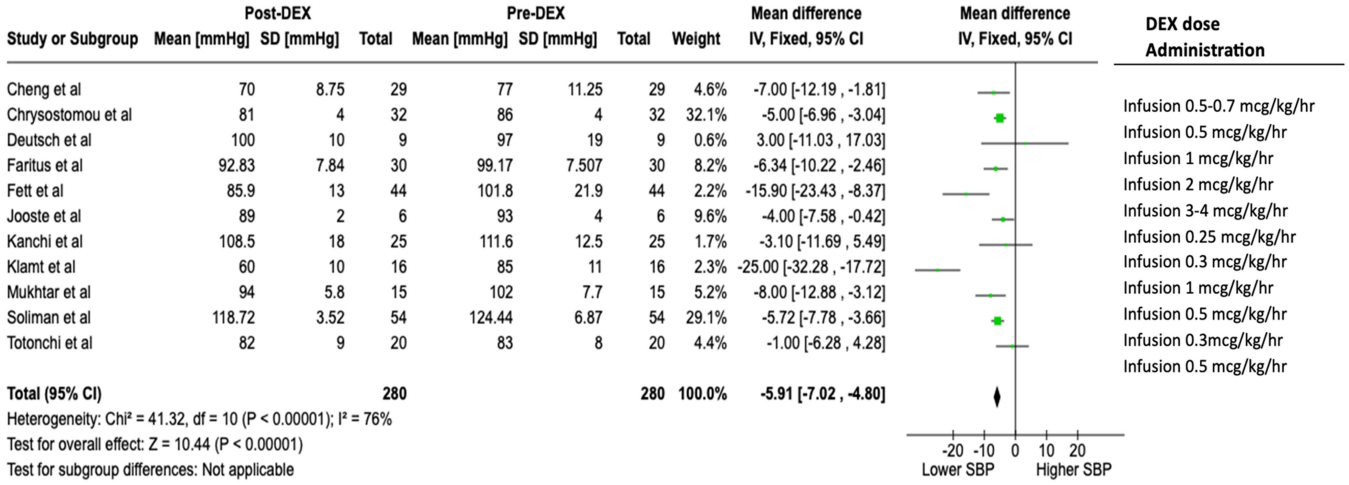

Figure 3. Meta-analysis of measures of systolic blood pressure (SBP) before and after the administration of dexmedetomidine in children with congenital heart disease. Lower SBP indicates a measured decrease in systolic blood pressure after the administration of dexmedetomidine. Higher SBP indicates a measured increase in systolic blood pressure after the administration of dexmedetomidine. Data represented as mean mmHg with standard deviation (SD) measured in mmHg.

Diastolic blood pressure

Ten studies reported a sample mean of measured diastolic blood pressure in measured (pre-administration) and control (post-administration) groups using dexmedetomidine.[12,14,15–19,22,23,25] A total of 276 measurements were included. A meta-analysis demonstrated a mean difference of −4.58 mmHg (95% confidence interval (CI) of −5.72, −3.45, $p < 0.00001$) before and after dexmedetomidine administration. I^2 was 95% (Figure 4).

Mean arterial pressure

Five studies reported a sample mean of measured mean arterial pressure in measured (pre-administration) and control (post-administration) groups using dexmedetomidine.[11,12,14,21,26] A total of 130 measurements were included. Meta-analysis demonstrated a mean difference of 0.13 mmHg (95% CI: −0.98, 1.32, $p = 0.77$) between measured and control groups. I^2 was 86% (Figure 5).

Sources of heterogeneity

Due to the design and characteristics of the studies included, we were unable to generate sufficient group sizes for meta-regression to search for sources of heterogeneity. The studies we included did not sufficiently stratify participants by our variables of interest, so exploration of heterogeneity was not performed.

Discussion

Our results demonstrate a slight decrease in heart rate, systolic blood pressure, and diastolic blood pressure after administration of dexmedetomidine to paediatric patients with CHD. We found no change in mean arterial pressure. There was substantial between-study heterogeneity in each of the analyses, which we were not able to attribute to any specific demographic or clinical factor. We did consider the significant variations in dosage as well as the route of administration of dexmedetomidine as potential causes. The bioavailability of dexmedetomidine given intranasally, orally, and intravenously may have attributed to this heterogeneity seen in our

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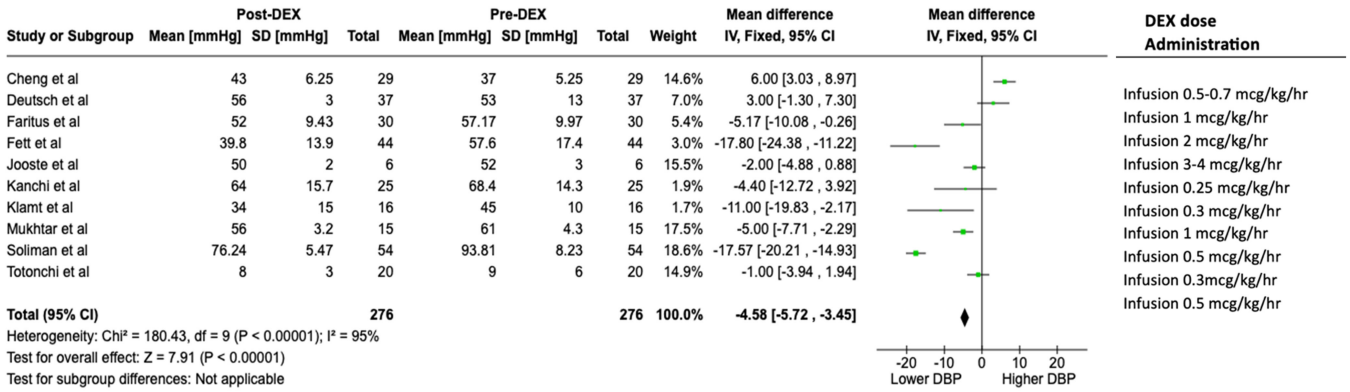

Figure 4. Meta-analysis of measures of diastolic blood pressure (DBP) before and after the administration of dexmedetomidine in children with congenital heart disease. Lower DBP indicates a measured decrease in diastolic blood pressure after the administration of dexmedetomidine. Higher DBP indicates a measured increase in diastolic blood pressure after the administration of dexmedetomidine. Data represented as mean mmHg with standard deviation (SD) measured in mmHg.

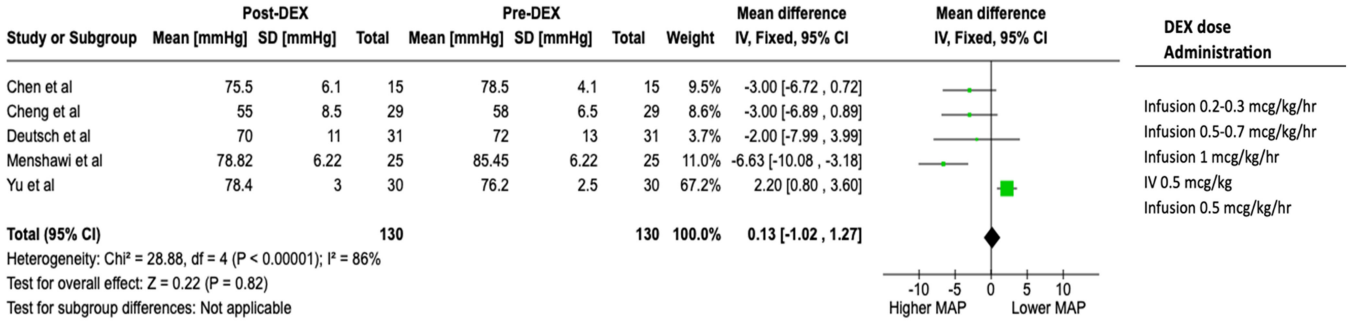

Figure 5. Meta-analysis of measures of mean arterial pressure (MAP) before and after the administration of dexmedetomidine in children with congenital heart disease. Lower MAP indicates a measured decrease in mean arterial blood pressure after the administration of dexmedetomidine. Higher MAP indicates a measured increase in mean arterial pressure after the administration of dexmedetomidine. Data represented as mean mmHg with standard deviation (SD) measured in mmHg.

analysis, but it requires further evaluation. Overall, our findings support the existing literature that dexmedetomidine can potentially be used safely in this population of paediatric patients.

Our study results add further evidence that dexmedetomidine has a good safety profile in children with cardiac disease. A previous meta-analysis found that dexmedetomidine use was associated with stability in a variety of haemodynamic markers.[27] Our analysis adds to this by the inclusion of additional studies and by quantifying the effect of dexmedetomidine administration on haemodynamic variables. We also limited our analysis to the earliest haemodynamic measurement after dexmedetomidine administration as a comparison, which implies a low risk of early adverse haemodynamic consequences upon initiation of dexmedetomidine. These results comport with the findings of Qiu et al, who found that the administration of dexmedetomidine was safe as a premedication to patients with CHD and a left-to-right shunt.[28] Chrysostomou et al also found a decreased incidence of ventricular and supraventricular tachyarrhythmias and minimal changes in electrocardiology measurements without significant adverse effects when dexmedetomidine was administered after cardiac surgery.[13] This collectively suggests that dexmedetomidine can be used safely in children with CHD during the perioperative period.

Strengths of our study include a wider collection of studies than previously reported in other meta-analyses [30]. We were also able to quantify the change in heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure, which allows the clinician to better assess the effect of dexmedetomidine on these complex patients. Finally, we limited our analysis to the earliest time point after administration of the drug when haemodynamic changes are likely to occur.

Limitations of our study included a moderate-to-high risk of bias amongst our selected studies. The inclusion of observational studies in addition to randomised clinical trials may have impacted this bias. The limited amount of randomised clinical trials and the differing primary outcomes of published studies included probably contributed to this bias. Due to the limited number of studies and variability in the demographic and clinical characteristics of the included participants, we were unable to identify specific risk factors for larger haemodynamic changes due to dexmedetomidine administration through meta-regression. An additional limitation includes the wide variations in dosing of dexmedetomidine that create a challenge in assessing the validity of our work. Dosage plays a significant role in the haemodynamic effects of dexmedetomidine administration and should be taken into consideration. Future studies should examine this factor as a potential cause for the between-study heterogeneity seen in our analysis. Finally, we chose to include children undergoing both open-heart surgery and catheterisation procedures in order to assess the effect of anatomy as opposed to surgical factors. These children may, in fact, respond differently to dexmedetomidine administration, but due to the limited number of included participants, we were unable to perform a subgroup analysis.

Our findings are important for the future consideration of sedative and anaesthetic protocols in children undergoing cardiac

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surgery. Ensuring the safe and effective use of anaesthetic agents is critical, particularly when dealing with a high-risk cohort of paediatric patients. As the number of procedures for CHD continues to rise, physicians may now consider the use of dexmedetomidine with greater confidence and understanding of its haemodynamic impact.

While dexmedetomidine has not yet obtained FDA approval, it remains widely used among cardiac paediatric patients. Our study provides further evidence for minimal quantitative changes in the paediatric haemodynamic profile with the use of dexmedetomidine. We show that this drug may potentially be safe for use in children with CHD undergoing cardiac surgery.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S1047951125101613.

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