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Impact of the mother's voice on sedation need and stress during cardiologic examination of children (SMUSS study): a prospective, interventional, randomised, controlled, monocentric study

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Abstract

Introduction: Cardiac catheterisation is crucial for diagnosing and treating paediatric heart diseases, but it is poorly tolerated by small children, infants, and newborns without sedation. This study investigated whether maternal voice during sedation could lower stress and pain in children undergoing cardiac catheterisation and also assessed mothers' stress levels before and after the procedure. *Methods:* This was a prospective, monocentric, randomised, controlled interventional study at the University Hospital Bonn. Children aged 4 years or younger scheduled for elective cardiac catheterisation under procedural sedation and American Society of Anaesthesiologists class between 1 and 3 were eligible. *Results:* At the end of cardiac catheterisation, the intervention group showed a higher Newborn Infant Parasympathetic Evaluation index with an adjusted mean difference of 9.5 (± 4.2) ($p = 0.026$) and a lower median Children's and Infants Postoperative Pain Scale score of 2.0 (IQR: 0.0–5.0) versus 4.5 (IQR: 3.0–6.0) than the control group ($p = 0.027$). No difference in the children's cortisol level was found ($p = 0.424$). The mothers in the intervention group had a lower cortisol level than those in the control group before cardiac catheterisation (adjusted mean difference: −4.5 nmol/l (± 1.8 nmol/l), $p = 0.011$). *Conclusion:* Listening to the maternal voice during cardiac catheterisation could lead to less postoperative pain and significantly lower stress and discomfort level in children. Less pain could reduce the incidence of postoperative delirium.

Additionally, mothers perceived involvement as positive. A reduced stress level of mothers can positively influence children and possibly reduce pain and anxiety.

Introduction

Cardiac catheterisation represents an important diagnostic and therapeutic procedure in individuals, both children and adults, with heart diseases. In complex cardiac catheterisations and in young children, either general anaesthesia including airway management or more often procedural sedation is usually necessary to achieve appropriate conditions during the cardiologic intervention.

To our knowledge, guidelines regarding the choice of general anaesthesia or sedation for paediatric cardiac catheterisations are not yet available. However, in many paediatric cardiology departments, sedation is preferred over general anaesthesia in clinical practice.[1]

Even in a sedated state, patients can notice auditory stimuli that can positively or negatively impact their well-being.[2]

The extent and consequences of perioperative pain, anxiety, and stress in children are often insufficiently considered due to the lack of objectivity,[3] and intraoperative stress significantly influences postoperative recovery.[4]

Procedural pain and stress are primarily treated pharmacologically. In addition to conventional methods such as anaesthesia or deep sedation, non-invasive and non-pharmacological approaches to reduce anxiety and stress in young children are playing an increasingly significant role. The method of auditory stimulation to reduce perioperative stress and anxiety has been studied for several years.[5,6] Azarmnejad et al. (2015) demonstrated that the maternal voice leads to a less painful arterial blood draw in children[7] and that the maternal voice can be a significant stimulus for infants. Several studies are indicating that listening to

recordings of the maternal voice in the paediatric setting can contribute to the reduction of anxiety, stress, and postoperative pain.[8–11]

This study examined if listening to the pre-recorded maternal voice during a cardiac catheterisation would result in a measurable reduction of stress parameters measured via cortisol and alpha-amylase levels in the children (primary endpoints). Additionally, it tried to evaluate the impact of the intervention on the postoperative necessity for analgesic medication and CHIPPS (Children's and Infants Postoperative Pain Scale). A secondary endpoint was to assess whether the involvement of parents in the medical procedure of their children leads to a measurable reduction in stress among the parents again assessed via cortisol and alpha-amylase levels.

Materials and methods

Study design

The prospective, monocentric, randomised, controlled interventional study was registered in the German Clinical Trials Register (DRKS) under the study number DRKS00023774 and conducted at the University Hospital in Bonn, Germany. Children aged 4 years or younger scheduled for elective cardiac catheterisation in the morning under procedural sedation and with an American Society of Anaesthesiologists class <4 were eligible. Patients were included after informed consent was provided by both parents and the mother agreed to voice recording. Emergency patients and children requiring intensive care or mechanical ventilation were excluded. Other exclusion criteria were hearing impairment of the child, absence of the mother, and cardiac catheterisation under general anaesthesia.

Setting

The study was conducted from 20 April 2021 to 5 August 2022 in the cardiac catheterisation laboratory at the University Hospital Bonn, Germany. Parents were informed about the possibility to participate in the study by an anaesthetist during the preoperative evaluation on the day before the planned intervention. Patient recruitment was done consecutively. The children and their mothers were randomised into two groups by lottery procedure (via randomisation list provided by randomizer.org). In the intervention group, the mother read a fairy tale validated for the age range of her child for 15 min. This was recorded on a tablet computer and pseudomised with a code specific for her child. The children of the intervention group heard their mother's reading via headset from induction of anaesthesia until the end of cardiac catheterisation nonstop. Recording equipment was fitted to reproduce voices with a nearly natural spectrum. All recordings were uncompressed. Volume was adjusted to the child's age. Apart from the study intervention, all children were treated according to standard of care. Sedation medication and haemodynamic data such as blood pressure, heart rate, and Newborn Infant Parasympathetic Evaluation (NIPE) were documented and analysed.

Children followed the perioperative fasting guidelines outlined in the European Society of Anaesthesiology and Intensive Care guideline of 2022.[12] All children older than 6 months received 0.5 mg/kg midazolam orally preoperatively.

At the operating room entrance, the child's preoperative anxiety was assessed by a third person via the modified Yale Preoperative Anxiety Scale. Here the children were still accompanied by their parents. The modified Yale Preoperative Anxiety Scale is a validated observation scale that assesses the preoperative anxiety in children. It consists of five items: activity, vocalisation, emotional expressivity, state of apparent arousal, use of apparent arousal, and use of parents.[13] The assessment took place at four different time points (see Table 1). The item "use of parents" was not assessed as parents were absent at the aforementioned time points. In the calculation, each item value was divided by the highest possible achievable value. Subsequently, the values of all four items were added, divided by 4, and multiplied by 100. This resulted in the modified Yale Preoperative Anxiety Scale score, a dimensionless number between 22.92 and 100, a higher value indicating more stress and increased anxiety.[14]

Additionally, a saliva sample was collected from the mother using a SalivaBio Oral Swab (Salimetrics, Carlsbad, USA) to assess the stress level by measuring cortisol and alpha-amylase (Table 1). The cortisol level was analysed using the Expanded Range High Sensitivity Salivary Cortisol Enzyme Immunoassay Kit (Salimetrics, Carlsbad, USA). The alpha-amylase concentration was examined using the Salivary Alpha-Amylase Kinetic Assay Kit (Salimetrics, Carlsbad, USA).

Upon arrival in the operation room, a saliva sample was taken from the children using a SalivaBio Children's (Salimetrics, Carlsbad, USA). No stimulants were applied before or during saliva collection.

Children were connected to standard monitoring and the NIPE device. Additionally, the level of sedation was controlled and recorded via electroencephalogram monitoring (Narcotrend-Compact M device, MT MonitorTechnik GmbH & Co. KG, Bad Bramstedt, Germany). The depth of anaesthesia was evaluated at various study time points to ensure an adequate depth of sedation (Table 1).

Both groups received headphones during anaesthesia induction (Amiron Home headphones, Beyerdynamic, Heilbronn, Germany, specialised for playing human voices). The position of the headphones did not interfere with the cardiologists or anaesthesiologists. In the intervention group, the maternal voice was played in a loop.

All cardiac catheterisations were performed under sedation with spontaneous breathing. Inhalation induction was carried out with sevoflurane. Sedation was maintained continuously with intravenous propofol at a rate of 5–10 mg/kg/h. The last measurement of the children's stress parameters in saliva was performed as soon as sevoflurane was no longer detectable on expiration. Headphones were removed, and the patients were transferred to the recovery room (Table 1) where the vital parameters of the subjects were recorded again. Mothers provided a second saliva sample. Before transfer to the regular ward, the Paediatric Anaesthesia Emergence Delirium scale and the Children's and Infants Postoperative Pain Scale were applied to screen for emergence delirium and to measure postoperative pain (Table 1).

The validated Paediatric Anaesthesia Emergence Delirium scale was developed by Sikich and Lerman for children aged 0–6 years.[15] The Paediatric Anaesthesia Emergence Delirium score was calculated according to the S2e21 Guidelines: Prevention and Treatment of Paediatric Emergence Delirium.[16] However, the Paediatric Anaesthesia Emergence Delirium score can also be increased by pain-related agitation. Distinction between postoperative pain and delirium is not

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Table 1. Assessment points for questionnaires and laboratory parameters

Child								
Time points	Explanation of measurement values	Day before surgery	T1 Transfer OR	T2 Induction of sedation	T3 Cannulation by cardiologist	T4 + 30 min after cannulation	T5 End of cardiac catheterisation	T6 Recovery room
Randomisation		x						
Intervention group: voice and sedation				x	x	x		
Control group: only sedation				x	x	x		
mYPAS	Higher values indicate more preoperative anxiety		x					
Narcotrend	Depth of anaesthesia recorded via EEG monitoring (lower values reflect deeper sedation)		x	x	x	x	x	
Haemodynamic	Includes systolic and diastolic blood pressure and heart rate		x	x	x	x	x	x
NIPE	Measurement of pain state (lower indices reflect more pain)		x	x	x	x	x	
Saliva: cortisol	Higher values indicate more stress		x				x	
Saliva: alpha-amylase	Higher values indicate more stress		x				x	
CHIPPS	Value >4: pain could not be ruled out							x
PAED	ED I score >9 indicates Emergence delirium							x

Mother						
Time points		T1 Transfer OR	T2 Induction of sedation	T3 Cannulation by cardiologist	T4 + 30 min after cannulation	T5 End of cardiac catheterisation
Informed consent	x					
Voice recording	x					
Cortisol		x				x

mYPAS = modified Yale Preoperative Anxiety Scale; NIPE = Newborn Infant Parasympathetic Evaluation; CHIPPS = Children's and Infants Postoperative Pain Scale; PAED = Paediatric Anaesthesia Emergence Delirium; T1 = transfer OR; T2 = induction of sedation; T3 = cannulation by cardiologists; T4 = +30 min after cannulation by the cardiologists; T5 = end of cardiac catheterisation.

always easy.[16] Locatelli et al. (2013) recommend assessing only the first three items of the Paediatric Anaesthesia Emergence Delirium scale (ED I score). Delirium can be assumed for values of ≥9.[17] The collection of a pain scale can be useful to differentiate between postoperative agitation due to pain and delirium. Therefore, the Paediatric Anaesthesia Emergence Delirium scale was used in combination with the Children's and Infants Postoperative Pain Scale.

Statistics

Analyses were performed using the statistical software R (Version 4.0.3). Linear mixed regression models were used to analyse the primary endpoints cortisol and alpha-amylase. The measurement time point, group assignment (with or without the mother's voice), and interaction terms between time and group assignment were included as fixed effects. Time was modelled as a categorical variable. To adjust for the dependence of observations due to repeated measurements, random effects in the form of patient-specific intercepts were included in the model. Effect estimates were determined using the restricted maximum likelihood method. As a sensitivity analysis, an additional model adjusted for the applied surgical procedure was fitted, and a subgroup analysis including only the children who underwent diagnostic procedures was performed.

Secondary endpoints with repeated measurements were analysed analogously to the primary endpoints using linear mixed regression models. For the comparison of CHIPPS and Paediatric Anaesthesia Emergence Delirium (PAED) scores between the two groups, the Mann–Whitney *U* Test was used.

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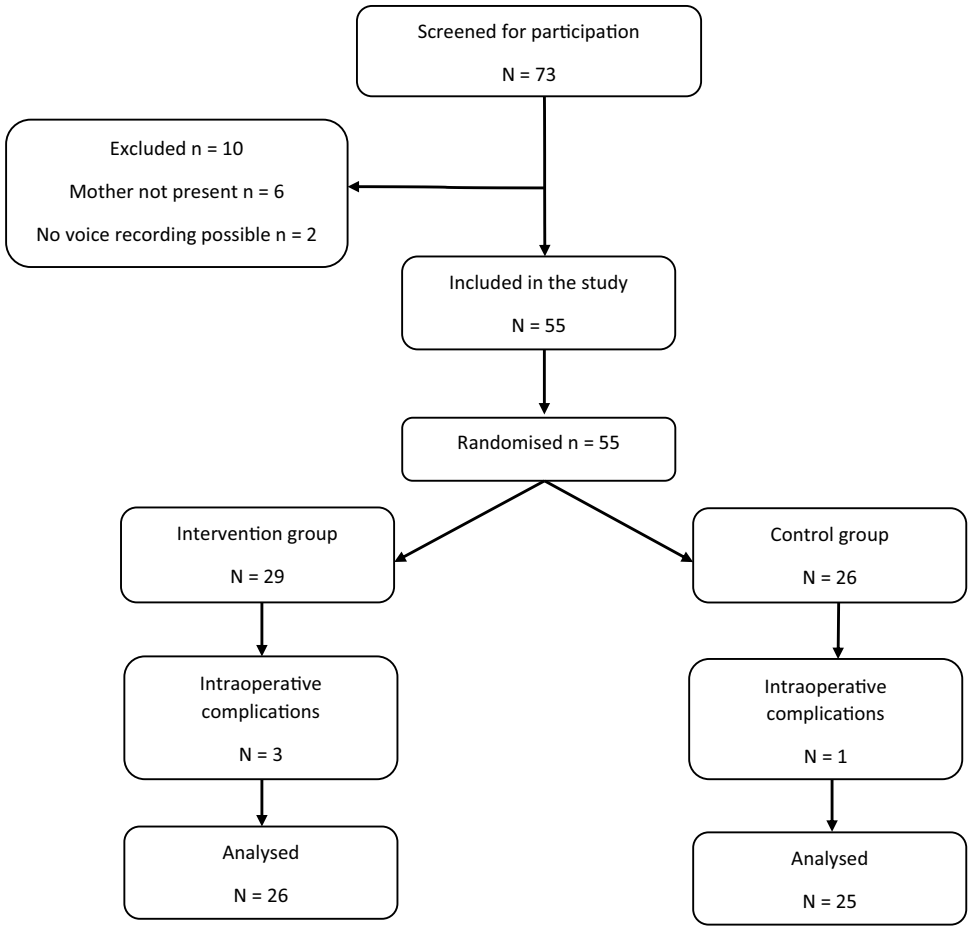

Figure 1 Patient sample.

Results

After screening 73 patients, 55 patients were randomised. Four patients had to be excluded due to intraoperative complications. A total of 51 children with a mean age of 19.5 (±14.3) months were analysed, with 26 children in the intervention group and 25 in the control group (Figure 1). Children in the intervention group were younger and lighter than children in the control group. While more than half of the intervention group—children had to undergo vascular dilatation, most children in the control group received diagnostic cardiac catheterisation. Both groups were similar regarding gender distribution, duration of anaesthesia, length of procedure, and American Society of Anaesthesiologist classification (Table 2).

Perioperative haemodynamic parameters as well as Narcotrend and NIPE values were similar throughout the study period.

Results of the children study group

The results of the secondary endpoint analyses are exploratory rather than confirmatory and may be interesting points to further investigate in future studies.

Cortisol level

The results of the mixed model indicate a 3.5 (±4.2) nmol/l increased cortisol level in the intervention group compared to the control group at the end of cardiac catheterisation (T5) adjusted for the levels before surgery (T1). The difference between the two groups was not statistically significant ($p = 0.424$; Supplemental Material, Table 1). Additionally adjusting for the procedure yielded similar results (adjusted mean difference: 5.8 [± 4.4] nmol/l, $p = 0.204$). The subgroup analysis including only children who underwent diagnostic procedures resulted in a slightly lower adjusted mean difference cortisol (2.3 [±5.8] nmol/l, $p = 0.699$).

Alpha-amylase level

The adjusted mean difference in alpha-amylase level between the two groups at the end of cardiac catheterisation was estimated as 26.0 (± 60.7) U/l indicating a higher level in the intervention group. However, the result was not statistically significant ($p = 0.670$; Supplemental Material, Table 1). Results of the sensitivity analysis with adjusting for procedure were similar (adjusted mean difference: 20.3 [± 60.1] U/l, $p = 0.745$). A slightly lower adjusted mean difference was found in the subgroup analysis of the children who underwent diagnostic procedures (17.0 [± 95.6] U/l, $p = 0.861$).

Heartbeat and blood pressure

The control group consistently showed slightly higher heartbeat rates than the intervention group and the mean systolic (adjusted mean difference: 13.3 [± 3.4] mmHg, $p < 0.001$) and diastolic blood pressure values (adjusted mean difference: 6.0 [± 2.7] mmHg, $p = 0.027$) were higher in the intervention group at the end of cardiac catheterisation, but this was not clinically relevant (see Supplemental Material, Table 2).

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Table 2. Patient characteristics

	Mother's voice group (MM) $n = 26$	Control group (MO) $n = 25$	All patients $n = 51$	p-values
Age in months				0.761
Mean (±SD)	18.9 (± 14.6)	22.2 (±14.3)	19.5 (±14.3)	
Age under 6 months (n)	8 (30.7%)	7 (28%)	15 (29.4%)	1.000
Gender				
Female	14 (53.8%)	14 (56.0%)	28 (54.9%)	
Male	12 (46.2%)	11 (44.0%)	23 (45.1%)	
Height in cm				0.641
Mean (±SD)	75.3 (±15.3)	77.4 (±15.3)	76.3 (±15.2)	
Weight in kg				0.947
Mean (±SD)	8.99 (±3.67)	9.17 (±3.17)	9.08 (±3.40)	
ASA status				1.000
1	1 (3.8%)	0 (0.0%)	1 (2.0%)	
2	1 (3.8%)	1 (4.0%)	2 (4.0%)	
3	24 (92.4%)	24 (94.0%)	48 (94.0%)	
Diagnosis				0.471
Pulmonary atresia	6 (23.2%)	3 (12.0%)	9 (17.6%)	
Pulmonary stenosis	2(7.7%)	2 (8.0%)	4 (7.8%)	
HLHS	5 (19.2%)	7 (28.0%)	12 (23.5%)	
Common truncus	1 (3.8%)	2 (8.0%)	3 (5.9%)	
Double inlet left ventricle	3 (11.5%)	0 (0%)	3 (5.9%)	
other	9 (34.6%)	11 (44.0%)	20 (39.2%)	
Procedure				0.515
PDA occlusion	1 (3.8%)	1 (4.0%)	2 (3.9%)	
MAPCA occlusion	2 (7.7%)	1 (4.0%)	3 (5.9%)	
Diagnostic cardiac catheterisation	8 (30.8%)	13 (52.0%)	21 (41.2%)	
Vascular dilatation	14 (53.8%)	8 (32.0%)	22 (43.1%)	
Creation of ASD	1 (3.8%)	1 (4.0%)	2 (3.9%)	
Implantation of stents	0 (0%)	1 (4.0%)	1 (2.0%)	
Time of anaesthesia (min)				0.111
Median [Q1, Q3]	128 [100, 153]	105 [95, 120]	113 [95, 146]	

p-values are based on Fisher's exact tests (for the categorical variables), independent samples t tests (for age, height, and weight), and Mann–Whitney U test (for time of anaesthesia).
ASA status = American Society of Anaesthesiologists physical status; HLHS = hypoplastic left heart syndrome; MAPCA = main aortopulmonary collateral artery; PDA = patent ductus arteriosus; ASD = atrial septal defect; n = number of patients; SD = standard deviation.

Narcotrend index

The important adequate sedation of both groups is similar at vascular cannulation by the cardiologist with slightly higher values in the intervention group (adjusted mean difference: 4.9 [± 6.0], $p = 0.412$) (see Supplemental Material, Table 2).

Newborn Infant Parasympathetic Evaluation index

The NIPE index shows similar values for both groups at the first measurements. At the end of cardiac catheterisation, the intervention group presented with a higher index (58.8 ± 7.36) than the control group (57.1 ± 8.5) ($p = 0.026$). The mean difference at T5 adjusted for the scores at T1 was 9.5 (± 4.2, $p = 0.026$) (Supplemental Material, Figure 1).

Paediatric Anaesthesia Emergence Delirium (PAED)

While the Children's and Infants Postoperative Pain Scale of the intervention group shows a median score of 2.0 (IQR: 0.0–5.0), the control group had a median score of 4.5 (IQR: 3.0–6.0). The Mann–Whitney U test yields $p = 0.027$ (Supplemental Material, Table 3). Median PAED score was 2.0 (IQR:1.0–5.0) in the intervention group and 3.0 (IQR: 2.3–5.8) in the control group ($p = 0.272$; Supplemental Material, Table 3).

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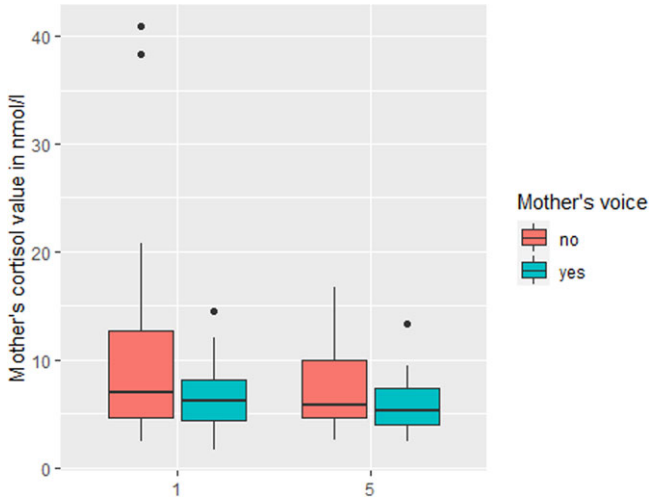

Figure 2 Cortisol levels of the mother at T1 and T5. T1 = transfer OR; T5 = end of cardiac catheterisation.

Results of the modified Yale Preoperative Anxiety Scale questionnaire differed not significantly at all four different time points (Supplemental Material, Table 3).

Results of the mother study group

Before surgery, the intervention group mothers showed a higher cortisol level (6.7 ± 3.6 nmol/l) than the mothers in the control group (11.2 ± 10.7 nmol/l; adjusted mean difference: −4.5 [±1.8] nmol/l, $p = 0.010$). After the intervention, the intervention group mothers had a mean cortisol concentration of 5.8 (±2.7) nmol/l, and the control group mothers had an average value of 7.4 (±4.1) nmol/l (Figure 2).

Discussion

The influence of the mother's voice on children has been studied several times in recent years. Authors such as Kim et al. (2010) and Rajan et al. (2017) demonstrated a positive effect of the mother's voice on children's well-being.[9,10]In this study, stress was measured through selected hormone parameters in the saliva of both children and mothers. Furthermore, post-interventional pain and consciousness were stratified using observation scales.

Our primary hypothesis that the maternal voice would reduce the stress level of their children could not be confirmed. However, we found both reduced post-interventional pain in children and relevant lower preoperative stress levels in the mothers of the intervention group.

With a similar modified Yale Preoperative Anxiety Scale, we assumed that the preoperative anxiety of both groups was alike. In our results, all mean modified Yale Preoperative Anxiety Scale scores were above 30. Yang et al. (2020), who investigated the effect of the maternal voice on children during surgery, also determined preoperative anxiety using the modified Yale Preoperative Anxiety Scale and found values between 42.5 and 45.5.[11]

Unfamiliar environment as well as separation from their parents could contribute significantly to preoperative anxiety. The preoperatively increased anxiety level of the children might have influenced the subsequent measurement of stress levels.

Contrary to our results, Kim et al. (2010) described an influence of the maternal voice on the depth of sedation and the need for sedatives.[9]

In our patients, an increase in cortisol concentration was observed from the baseline point (before the voice was played) to the end of the measurement (after the voice was played) with slightly increased cortisol levels in children who heard the mother's voice during intervention. However, the difference between the two groups was not significant. The results match those of Liu et al. (2019) found no significant minimisation of stress levels in saliva during surgery.[18]

The emotional state of children and very anxious parents have a negative effect on children in the perioperative setting.[19]

The interindividual stress levels of the patients resulted in large differences in cortisol levels. The heterogeneity of the concentrations in saliva has also been described by other authors.[6,20]

In the study by Davis et al. (2009), baseline stress levels for cortisol from 5.5 nmol/l to 8.28 nmol/l were measured in the age group 12–24 months.[21] This is also the average age of our patient collective where average baseline values for cortisol of 11.9 nmol/l were measured. Comparison of the stress levels is only possible to a limited extent, as Davis et al. (2009) studied only mentally and physically healthy children. The slightly higher level of our patients might be linked to their cardiological diseases and pretreatments.

Uniform times of cardiac catheterisation were chosen for this study to account for the circadian release of cortisol. The cortisol awakening response, which leads to an increased cortisol level in the early morning, could have influenced the results. Other factors, such as current medication, sleep rhythm, and age, can also affect the cortisol level.[21]

Furthermore, an adequate measurement of acute stress is potentially distorted by the presence of chronic stress.[22]

According to Chaturvedi et al. (2018), there is a significant increase in alpha-amylase in saliva during medical procedures such as tooth extractions.[23] In our evaluation, alpha-amylase levels were higher in the intervention group than in the control group, and no effect of the maternal voice on alpha-amylase levels could be detected.

The reasons for this could be similar to the analysis of cortisol values.

The maternal cortisol levels decreased between the preoperative and postoperative measurement and the cortisol concentrations of the mothers in the intervention group were lower at both measurement points. This could be due to the fact that the test subjects were randomised after agreeing to study participation. Active involvement might explain why the mothers in the intervention group showed lower stress levels. This was confirmed through the mother's feedback during and after the recording of the audio file.

In a similar setting, Kim et al. (2010) showed that mothers were less stressed if they could do something good for their child.[9]

The NIPE index was between 40 and 60 at all time points indicating no pain.[24]

The mean heart rate between 106 and 119 beats per minute was normal for the respective age groups.[25] The average heart rate of the control group was slightly higher than that of the intervention group. Argstatter et al. (2006) found similar results in their investigations on the effect of music during exercise.[5]Kim et al. (2010), on the other hand, found an increase in heart rate over the course of the cardiac catheterisation, without significant differences between the intervention group and the control group.[9]

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With values of 85 mmHg to 87 mmHg, average systolic blood pressure is within the physiological range for this age group.[26] Analysis showed a slight increase in the mean systolic and diastolic values of the intervention group at the end of the cardiac catheterisation. Similar results were found in other studies on the effect of maternal voice or music.[5,9,10]

We measured lower CHIPPS scores in the intervention group (median: 2.0) than in the control group (median: 4.5).

According to Bächle-Helde (2013), postoperative pain and discomfort can be assumed at a Children's and Infants Postoperative Pain Scale score higher than 4.[27] Our results are consistent with those of Byun et al. (2018), who found less postoperative pain after auditioning the maternal voice.[8]Further studies on auditory stimulation with music have also found reduced postoperative pain.[28]

Our results showed less postoperative delirium in the intervention group. This result could be confirmed by other studies.[4,8,9,11]

As the occurrence of emergence delirium is closely linked to the occurrence of postoperative pain and results of the CHIPPS score indicate less postoperative pain in the intervention group compared to the control group, this could explain the reduced occurrence of postoperative delirium in the intervention group.

Limitations

We assumed that the mother's voice has a positive effect on children. However, it cannot be ruled out that the mother's voice is a negative stimulus for some children and that maternal emotions such as anxiety and stress may be transferred to the children.[9]

The observation scales were collected by the doctoral student or study staff. This could lead to subjective evaluations by the observers. Furthermore, as the study personnel was not blinded, bias cannot be ruled out.

An additional limitation is the sample size, as the main objective of the study was to investigate group differences in the primary endpoints cortisol and alpha-amylase levels. In order to evaluate the secondary outcome parameters more precisely, further studies with an appropriate number of subjects are needed.

Conclusion

Listening to their mother's voice during cardiac catheterisation did not lower cortisol and alpha-amylase levels significantly but showed potential in reducing post-procedure pain and stress in children. This intervention could also decrease the likelihood of postoperative delirium. Its benefits include being non-invasive, easy to implement, and cost-effective, without impacting medical procedures negatively. Mothers involved felt less stressed and valued their participation positively. Further research is necessary to explore these observations.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S1047951124025757.

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Competing interests. The author(s) declare none.

Ethical standard. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki 1964 and its subsequent updates as well as the national guidelines (AMG). Ethics approval was provided by the Ethics Commission of the Medical Faculty of the University Hospital Bonn (lfd. Nr. 343/20) on 4 November 2020.

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