Quality improvement of perioperative outcome in cardiac interventions for children

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List of abbreviations

CVC	Central venous catheter
DET	Delayed extubation
DGAI	The German Society of Anaesthesiology and Intensive Care Medicine
DG Telemed	German Society of Telemedicine
ESAIC	European Society of Anaesthesiology and Intensive Care
ERAS	Enhanced Recovery After Surgery
MRI	Magnetic Resonance Imaging
OTE	On-table extubation
PrAC	Pre-anesthesia consultation

1. Abstract

Introduction:

Congenital heart defects are one of the most common congenital malformations. Although optimized surgical techniques and improved intensive care management have resulted in approximately 90 % of children reaching adulthood, pediatric cardiac surgery is associated with high complication rates. The aim of this dissertation was to improve the quality of the perioperative outcome in cardiac surgery in children.

Methods: A total of four studies were conducted as part of this dissertation. The studies cover from a survey design, a retrospective, a prospective observational to a randomized controlled trial. All of them refer to the quality improvement of perioperative outcome parameters in cardiac surgery in children.

Results: It could be shown in our survey study, that the overall approach of pre-anesthesia consultation in Europe is extremely varied, not at least because of varying legislation in the individual countries. Many anesthesiologists are uncertain about the legal situation; specifically for pediatric anesthesia, 67.3 % stated that purely digital information without face-to-face contact is not legal. Only 22.9 % considered online or telephone information to be legal, while 9.8 % could not assess the current legal situation. In the randomized trial, anesthesiologists and parents were significantly more satisfied with the quality of remote than with on-site pre-anesthesia consultation. The complications in our patient cohort occurred even less frequently in the remote group.

Within our retrospective study, on-table extubation was shown to be safe and associated with a favorable postoperative course, including fewer catecholamine requirements and shorter duration of intensive care unit therapy. Furthermore, in our prospective observatory study, the use of ultrasound-guided central venous catheter insertion and tip positioning in children was shown to be a fast and reliable technique, preventing unnecessary x-ray exposure that may be considered for future policies.

Conclusion: In various study designs, it could be shown, that the use of standardization such as digital informed consent and the use of new technologies in both the pre- and postoperative settings may improve the quality of perioperative outcome parameters in pediatric cardiac procedures.

2. Introduction and aims with references

The prevalence of congenital heart defects is about 1 % of all live births, which makes it one of the most common congenital malformations (Lindinger et al., 2010). A study on the prevalence of congenital heart defects in newborns in Germany (PAN Study), conducted from 2006 to 2009, showed that 12 % of the defects detected were classified as severe heart defects and 61 % as mild heart defects. By far the most common defect was the ventricular septal defect, which accounted for about 48 % (Schwedler et al., 2011).

Congenital heart defects are still associated with a high morbidity and mortality rate. Even though optimized surgical techniques and improved intensive care treatment have led to about 90 % of children reach adulthood (Khalil et al., 2019). Although children are similar to adults except for smaller anatomical sizes, they differ in terms of physiological, biochemical processes and finally, psychology (Larsen et al., 2016). The risk of serious perioperative complications in children is 5.2 % according to data from the APRICOT study (Habre et al., 2017). The surgical and anesthesiological procedures for pediatric patients undergoing surgery for congenital heart defects are complex and require profound knowledge and clinical experience (Larsen et al., 2016).

Because of the unique characteristics of children and in particular, the cohort of children with congenital heart disease, it is essential to assess the actual status and, more importantly, to conduct studies to improve the perioperative outcomes.

2.1 Preoperative online information to increase satisfaction and quality

The pre-anesthesia consultation (PrAC) is composed of different parts. An essential part is the information of the patient about the planned anesthesia and obtaining its informed consent. Especially in the field of pediatric anesthesia, preparation is different, because not only the children, but especially the parents as representatives of their children, make decisions and sign the anesthesia consent (Gentry et al., 2017; Strassberger-Nerschbach et al., 2023). The risk of nosocomial infection during hospitalization is particularly high in critically ill children. Telemedicine, which has become more and more in focus, especially in times of social distancing and the reduction of personal contacts, could, even outside the pandemic, reduce the burden for chronically ill chil-

dren (Sarkies et al., 2020). Telemedicine is defined as "the provision of concrete medical services to overcome spatial distances with the help of modern information and communication technologies" (Marx et al., 2017). It is also described as safe, practical and cost-effective. The use of telemedicine in PrAC could reduce the stress of long travel and waiting times, minimize the risk from hospital-acquired infections, especially in vulnerable groups such as children after cardiac surgery (Harting et al., 2018; Wood et al., 2016). Furthermore, a position paper of the German Society for Anaesthesiology and Intensive Care Medicine (DGAI) and the German Society for Telemedicine (DG Telemed) from 2019 also called for using digital media to improve patient care and actively shape telemedicine in the field of anaesthesiology in Germany (Marx et al., 2019).

Given the safety of remote education and informed consent, it is plausible that both the risk and potential anxiety and discomfort for the child caused by a hospital visit are vastly reduced.

2.2 Postoperative use of new techniques to improve outcomes

Optimal perioperative care is particularly relevant to outcomes in the field of pediatric cardiac surgery and includes not only pre- and intraoperative, but also postoperative care of patients. Enhanced Recovery After Surgery (ERAS) protocols were introduced in adult colorectal surgery more than two decades ago and have been shown to improve postoperative outcomes and shorten length of hospital stay (Kehlet and Mogensen, 2003). At the same time, the ERAS concept was also introduced in adult cardiac surgery. Since then, this concept has been widely adopted to improve postoperative outcomes (Engelman et al., 1994; Ljungqvist et al., 2017). Reasons for commonly performed delayed extubation (DET) after transfer to intensive care unit are various including caution of early postoperative bleeding or concern about difficult to assess and manage combined respiratory and circulatory insufficiency (Baehner et al., 2022).

Recently, there has been discussion about whether early extubation is also beneficial in pediatric patients and may improve clinical outcomes, including a 30 to 50 % reduction in length of stay, leading not only to a reduction in health care costs but more importantly to a reduction in postoperative morbidity (Engelman et al., 1994). Currently,

on-table extubation (OTE) after pediatric cardiac surgery is not the standard procedure and only regularly performed at some centers (Baehner et al., 2020).

Furthermore, point-of-care verification of central venous catheter (CVC) positioning is also not standardized in pediatric patients and correct positioning is usually verified postoperatively by radiographs (Katheria et al., 2013). Medical radiation is the largest source of radiation exposure, with a mean effective dose (ED) of 3.0 mSv/year per person from diagnostic and therapeutic procedures. Although the annual ED is relatively low in pediatric patients, it accumulates over a lifetime and can reach high levels (>100 mSv) in selected cohorts of chronic pediatric patients (Johnson et al., 2014). Prompt verification with ultrasound of position during or immediately after insertion could prevent not only radiation exposure but also potential complications due to suboptimal positioning (Lloreda-García et al., 2016; Sharma et al., 2019). Although the majority of pediatric cardiac centers already perform central venepuncture by ultrasound, this procedure is not yet established in clinical routine, especially in children with pathological cardiac dimensions or abnormal anatomy.

Standardization and the use of new technologies could lead to improved postoperative outcomes, particularly for the cohort of children undergoing cardiac surgery.

2.3 Aim of the study analyses

Optimal treatment of children with congenital heart defects includes not only optimal intraoperative but also pre- and postoperative care. Preoperative anesthesiological information to parents by means of the telephone and online videos could improve the quality of information as well as the satisfaction of anesthesiologist and parents and avoid stressful travel with often long waiting times in the hospital. Our prospective randomized study entitles “Quality comparison of remote anesthetic consultation versus on-site consultation in children with sedation for a magnetic resonance imaging examination (EASE)” aimed to determine whether remote pre-anesthesia consultation and information supported by an online video for parents whose children receive magnetic resonance imaging examinations (MRI) under sedation can replace the usually provided on-site PrAC, without compromising its quality (Strassberger-Nerschbach et al., 2023).

Furthermore, an exploratory survey (Digital Online Anaesthesia Patient Informed Consent before Elective Diagnostic Procedures or Surgery: Recent Practice in Children—An Exploratory ESAIC Survey) was conducted, to investigate the current capabilities in clinical practice and the state of use of telemedicine for obtaining consent in anesthesia in Europe (Neumann et al., 2022).

Standardizations adapted to the needs of the cardiac surgery children group could improve postoperative outcome. The aim of an additional study, ”Effects of On-Table Extubation after Pediatric Cardiac Surgery”, was to assess the effects of OTE after pediatric cardiac surgery compared to the standard approach of delayed extubation (DET) during intensive care treatment (Baehner et al., 2022).

Also, the standardized use of new technologies could contribute to a reduction in intra- and postoperative complications. To investigate these aspects, the study “Point-of-Care Ultrasound-Guided Protocol to Confirm Central Venous Catheter Placement in Pediatric Patients Undergoing Cardiothoracic Surgery: A Prospective Feasibility Study” was conducted. We hypothesized that correct positioning of a CVC in pediatric patients can be performed quickly and safely using point-of-care ultrasound (Baehner et al., 2021).

To summarize, the four studies briefly presented in this dissertation aim to evaluate and improve perioperative management to improve outcomes in pediatric cardiac surgery.

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3. Publications

3.1 Publication 1: Quality comparison of remote anesthetic consultation versus on-site consultation in children with sedation for a magnetic resonance imaging examination **-** A randomized controlled trial

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RESEARCH REPORT

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Quality comparison of remote anesthetic consultation versus on-site consultation in children with sedation for a magnetic resonance imaging examination—A randomized controlled trial

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Abstract

Background: In the course of the corona pandemic, digital media has increasingly been used in many areas of medical practice to reduce personal contact. As it is of interest whether this can be practiced in the context of anesthesia consultations without loss of quality, we interviewed parents whose children received a cardiac or neuro magnetic resonance imaging (MRI) under sedation. Parents either received an on-site or a remote consultation conducted by an anesthesiologist. Both parents and anesthesiologist were asked to indicate their satisfaction with the respective consultation procedure in a questionnaire.

Aim: The aim of this study was to investigate if remote pre-anesthesia consultation, supported by an online video, for parents whose children are receiving MRI examinations under sedation can replace the commonly performed on-site consultation, without decreasing its quality.

Methods: In this randomized trial, a total of 200 patients were included, one half received pre-anesthesia consultation on-site and the other half was given a link to a video and pre-anesthesia consultation was conducted by phone. As a primary analysis, we compared the level of satisfaction for the general procedure, the quality of the pre-anesthesia consultation and the contact to the anesthesiologists (or parents). We further investigated the frequency of complications and the preference for a possible next informed consent.

Results: Both groups showed high levels of satisfaction. Some anesthesiologists and parents were less satisfied with the quality of on-site pre-anesthesia consultation than with the remote. In our patient cohort, there was no evidence for higher risk of complications when information was provided by telephone. Further, parents as well as anesthesiologists clearly favored the combined form of telephone information and

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online video. Overall, 61.2% of parents and 64% of anesthesiologists would choose this form of pre-anesthesia consultation for repeat anesthesia.

Conclusions: We did not observe that combined telephone and video decreased the quality of pre-anesthesia consultation. A remote version seems feasible for simple procedures such as sedation for MRI. Further research on this topic in other areas of anesthesia would be beneficial.

KEYWORDS
digital health, digitalization, pediatric anesthesia, remote consultation

1 | INTRODUCTION

The pre-anesthesia consultation (PrAC) has different aims. These include: (A) gaining information about the patients' health status, optimally by means of a physical examination, to assess the perioperative risk, (B) information of the patient about the planned anesthesia and possible adverse events, (C) decision on the choice of anesthesia, if possible, (D) getting legally informed consent and (E) giving advice to the patient, how to improve his behavior to have a better outcome.[1,2] The achievement of these goals is combined in one PrAC, where the anesthesiologists usually meets the patient for the first time and has a very narrow time window due to a high number of patients to be seen.

The results of the APRICOT study revealed that children especially under the age of three are prone to anesthesia related complications.[3] Thus, parents play a crucial role in the field of pediatrics and pediatric anesthesia and have to make decisions for their child. Especially for children with a serious underlying illness and possibly many previous hospital stays, a visit to the hospital with often long waiting times can be stressful for everyone involved. In addition, the risk of hospital infection increases with each additional inhospital contact.[4,5]

The COVID-19 pandemic was a worldwide exceptional situation and it called for extraordinary measures to keep personal contacts to an absolute minimum. We considered the question if remote PrAC for parents whose children are receiving magnetic resonance imaging (MRI) examinations under sedation, can replace the commonly performed on-site PrAC.

An alternative, which is coming more and more into focus in other medical fields, could be to perform the PrAC in an online format. Some studies have already shown that this kind of patient education is safe, practical and cost-effective.[6,7] It was not yet shown how pronounced the satisfaction of parents and anesthesiologists is concerning the fulfillment of the aims for a PrAC, described above, in a group of children with severe preexisting illness.

To our knowledge, this is the first prospective, randomized trial to investigate if remote PrAC and information supported by an online video, for parents whose children are receiving MRI examinations under sedation can replace the commonly performed on-site PrAC, without decreasing its quality.

What is already known about the topic

To our knowledge, this is the first prospective randomized trial combining telephone and video pre-anesthesia consultation for children with a correspondingly large number of study participants.

What new information this study adds

In this randomized trial, we demonstrated that combined telephone and video pre-anesthesia consultation for parents whose children are undergoing MRI examinations under sedation can replace the commonly performed on-site pre-anesthesia consultation without compromising its quality.

2 | METHODS

2.1 | Study design

The PrAC (online/by phone versus on-site) for children undergoing an MRI Examination under sedation (EASE) trial, is a prospective, randomized controlled mono-center observational study to evaluate the quality of PrAC in children undergoing MRI scan under sedation. The study was registered in the German Registry for Clinical Studies (DRKS00023785).

2.2 | Participants and recruitment

We included neurological as well as neurosurgical patients in the study. This group includes diagnosis or follow-up of tumors and hydrocephalus as well as neurologic diseases and is defined as “neuro”. The group of children with congenital heart defects were those who came for routine follow-up diagnosis or for pre-operative evaluation as part of the routine pre-operative examination, noted as “cardiac”. Eligible participants were children between 0 and 14 years of age who underwent a cardiac or neuro MRI under sedation. Parental consent to participate in the study and willingness to complete questionnaires

was also required. Children who required an emergency procedure or those whose ASA was >4 could not be included in the study. Also, children whose parents lacked German language skills or had no internet and/or telephone access, were excluded from the study. Furthermore, children who, according to the anesthesiologist, could not be informed by telephone due to the severity of their illness or children who required intensive care or ventilation were excluded. The study data was collected at the Department for Anesthesiology and Operative Intensive Care Medicine of the University Hospital Bonn.

2.3 | Interventions

Upon confirmation of the eligibility criteria parents received documents concerning the MRI examination, an invitation to participate in the EASE study and corresponding study documents via email. The trial investigator contacted the parents via telephone and after agreement to partake in the study, the parents were randomized to the (1) on-site or (2) remote group. Parents who were randomized into the remote group.

obtained a link to an information video regarding the anesthesia procedure (https://www.ukbonn.de/anaesthesiologie/forschung-lehre/klinische-studien/klinische-forschungsprojekte/laufend-oder-in-auswertung/). It can be accessed under EASE, which is the German short title. After previewing the video, the parents were asked to make an appointment for an anesthesiologist consultation by telephone.

If the parents were randomized to the on-site group, they were asked to arrange an appointment with the anesthesiologist at the pre-operative evaluation clinic of the hospital. In this dedicated group, the PrAC and the informed consent with signature were obtained, as usual at the University Hospital in Bonn.

On the day of the MRI scan, patients in both groups were thoroughly examined by the anesthesiologist in charge prior to the scheduled intervention. At this point, any outstanding questions could be clarified, and the informed consent was signed from the remote study group, as required by law. During the MRI examination of the child, the parents of both groups were asked to fill in a questionnaire on which they documented, apart from other parameters according to the study protocol, their satisfaction with the general procedure, the quality of PrAC and with the contact to the doctor (Table S1). Likewise, the anesthesiologist performing the anesthesiological consultation documented questions regarding satisfaction with the general procedure and the quality of the PrAC and the contact to the parents from his or her point of view (Table S2).

Furthermore, parents and anesthesiologists should make a statement about which type of PrAC they would prefer in the future–remote or on-site. Information about anesthetic procedure, any anesthesiological complications and fasting were documented as part of the routine recording in the anesthesia protocol. Study participation had no influence on the anesthesiological intervention. Sedation was carried out strictly according to the hospital's standard operating procedures.

2.4 | Study outcomes

2.4.1 | Primary outcome

The primary outcome was the quality of the remote and the on-site PrAC measured by parent's and anesthesiologist's satisfaction.

2.4.2 | Secondary outcomes

As secondary outcomes, we investigated the frequency of complications in both groups.

We investigated the association between the distance to residence and the preference for a possible next PrAC. Further, we assessed factors influencing the parent's preference in choosing the next PrAC to be remote.

2.5 | Randomization and blinding

After obtaining written informed consent, patients were assigned to one of the two groups in a 1:1 ratio using a randomization list: (1) On-site anesthesiological information, (2) anesthesiological information remote. An identification code was ascribed to each enrolled child. Thus, personal data could no longer be attributed to a specific study patient. Due to the study design, neither the parents nor the doctors were blinded.

2.6 | Statistical analysis

All calculations were performed using the R language and environment for statistical computing (version 4.1.0).

Continuous variables were expressed as mean (SD) or median (interquartile IQR) for skewed data, categorical variables were expressed as absolute and relative frequencies. Statistical significance was defined as $p < .05$. All performed tests were two tailed. All analyses were conducted to be exploratory, thus, p-values were not adjusted for multiple testing and results need to be confirmed on independent data.

In order to analyze the primary endpoint, we set up overall satisfaction scores based on the answers given by parents and anesthesiologists. In total, we considered three different overall satisfaction scores for both parents and anesthesiologists, one for each question category (procedure, contact with physician/patient, and quality of PrAC). The respondents were asked to rate the satisfaction with the informed consent with different questions for each category using a four-point scale for each single question (0 = very dissatisfied, 1 = rather dissatisfied, 2 = rather satisfied, 3 = very satisfied). Within a question category, answers were added up to the overall satisfaction score resulting in three satisfaction score, one for each question category. A higher score is associated with a higher level of satisfaction. Satisfaction scores were compared for each question category

among the two groups (remote vs. on-site) using Wilcoxon–Mann–Whitney *U*-test.

In a further review, the files of all 175 patients within the hospital information system of the hospital and especially the anesthesia protocols of the patients were manually screened and any occurring complications in the introduction, during or shortly after the MRI were noted and compared to the definition of complication within the study. We defined complications as the occurrence of at least one of the following events. Respiratory function (Once the patient has respiratory dysfunction EtCO2 exceeds 60 mmHg or SpO_2 <20% from baseline), severe hypotension (noninvasively measured blood pressure <25% from baseline), difficult venous access (more than two puncture attempts), postoperative nausea and vomiting, unplanned admission to the hospital, change of anesthetic procedure (e.g., intubation or laryngeal mask with ventilation), adverse drug reactions (includes reaction to propofol or contrast medium means stop of administration immediately and treat symptomatically).

The frequency of complications in both groups was compared using Fisher's exact test and odds ratios (OR) with 95% confidence intervals. Further, we examined the impact of covariates measured on patient and demographic level on the preference of the parents for the next PrAC being remote (yes/no) by applying a logistic regression model.

3 | RESULTS

As the flowchart in Figure 1 shows, between March 2021 and December 2021, a total of 377 patients were identified through database screening as potential study participants. Of these, 78 were excluded from the study as they did not meet the inclusion criteria. Overall, 299 patients met the inclusion criteria and were asked about their interest in participating in the trial. In total, 99 patients did not want to participate in the trial.

Finally, 200 patients were randomized and assigned in a 1:1 ratio to one of the two groups: (1) On-site anesthesiological consultation, (2) Remote anesthesiological consultation. In the on-site group, four patients were excluded from the study because of canceled and postponed appointments and four patients were excluded for not completing the questionnaire. Furthermore, one patient was excluded from the study because the parents were no longer interested.

Within the remote group, a total of 16 patients were excluded, 12 of whom due to a noncompleted questionnaire and four due to a canceled or postponed examination appointment. Finally, 91 patients were analyzed in the on-site group and 84 in the remote group.

Patient characteristics are shown in Table 1. Of the 175 patients included, 98 (56.0%) were male and 77 (44.0%) female. The ratio of neuro to cardiac patients was 97 (55.4%)–78 (44.6%). The mean distance from home to the clinic site was 77.18 ± 89.87 km, whereby the remote group lived slightly further away (84.06 ± 86.95 km) than the on-site group (70.82 ± 92.5 km). Of the total 175 children included, 9.1% belonged to ASA 1, 36.6% to ASA 2, 46.3% were classified as ASA 3, and finally 8.0% belonged to ASA class 4. Further patient characteristics can be found in Table 1.

The graphs in Figure 2 show the distribution of overall satisfaction scores for each category partitioned by way of PrAC separately for parents (A) and anesthesiologist (B). Overall, Figure 2 shows that parents and anesthesiologists were in general satisfied with the PrAC in both groups as the maximal possible satisfaction score was frequently reached and lower satisfaction values were rarely observed (Table 2 for possible range of satisfaction scores). Some parents that underwent on-site PrAC showed a lower satisfaction level for the quality of the PrAC as the remote group ($p = .012$). The same effect was observed for the anesthesiologist ($p = .024$). Further, overall, anesthesiologists showed a higher level of satisfaction for the general procedure of remote PrAC ($p = .002$). Results for all questions used to set up the overall satisfaction score are shown in Table S3.

A total of 13 (7.4%) complications were observed, of which 11 (12.1%) were in the on-site group and only 2 (2.4%) in the remote group (Fisher's Exact test, $p = .019$, OR = 0.18, 95% CI [0.019, 0.858]). In detail, the following events were identified: One child with apnoea which requires Esmarch's maneuver, four children with coughing, one with bronchospasm and the need of deeper sedation, four oxygen saturation drops <94% which requiring less sedation and three difficult venous accesses, of which two needed the use of ultrasound. Thus, it can be stated that in our patient cohort there was no evidence for higher risk of complications when PrAC was provided by telephone.

The avullium chart in Figure 3A shows the preference for a possible next PrAC based on the randomized group as stated by the parents and the anesthesiologist in the survey. The randomized PrAC is, as induced by the randomization, equally distributed in the two groups, while after conducting the study, the majority of parents and anesthesiologist would prefer a remote PrAC for a possible next MRI examination (61.2% for parents [35/87 from the on-site group and 69/83 from the remote group], 64% for anesthesiologists [44/91 from the on-site group and 68/84 from the remote group]). Further, the majority of parents and anesthesiologists whose children or patient was randomized to the remote group would favor a next possible PrAC to be remote. This emphasizes the high levels of satisfaction in the remote group as parents and anesthesiologists would choose the remote option.

The distance from residence to the hospital might influence the decision for the next PrAC stated by the parents as the parents might want to avoid long traveling distances. To explore the association between the distance to the residence and the request for the next PrAC as stated in the questionnaire, distances were categorized into four groups using the 25%, 50%, and 75% percentile of the distance in km. With larger distances to residence, there is a slightly increasing interest of the parents in the request for the next PrAC to be remote (65.12%, Figure 3B). But also, parents who live quite close to the clinic location, would be more likely to operation for remote PrAC (62.5%). Additionally, Figure 3B shows that more cardiac patients than neuro patients live further than 105 km away from the clinic site (76.74%–23.25%) reflecting the large catchment area of the UKB.

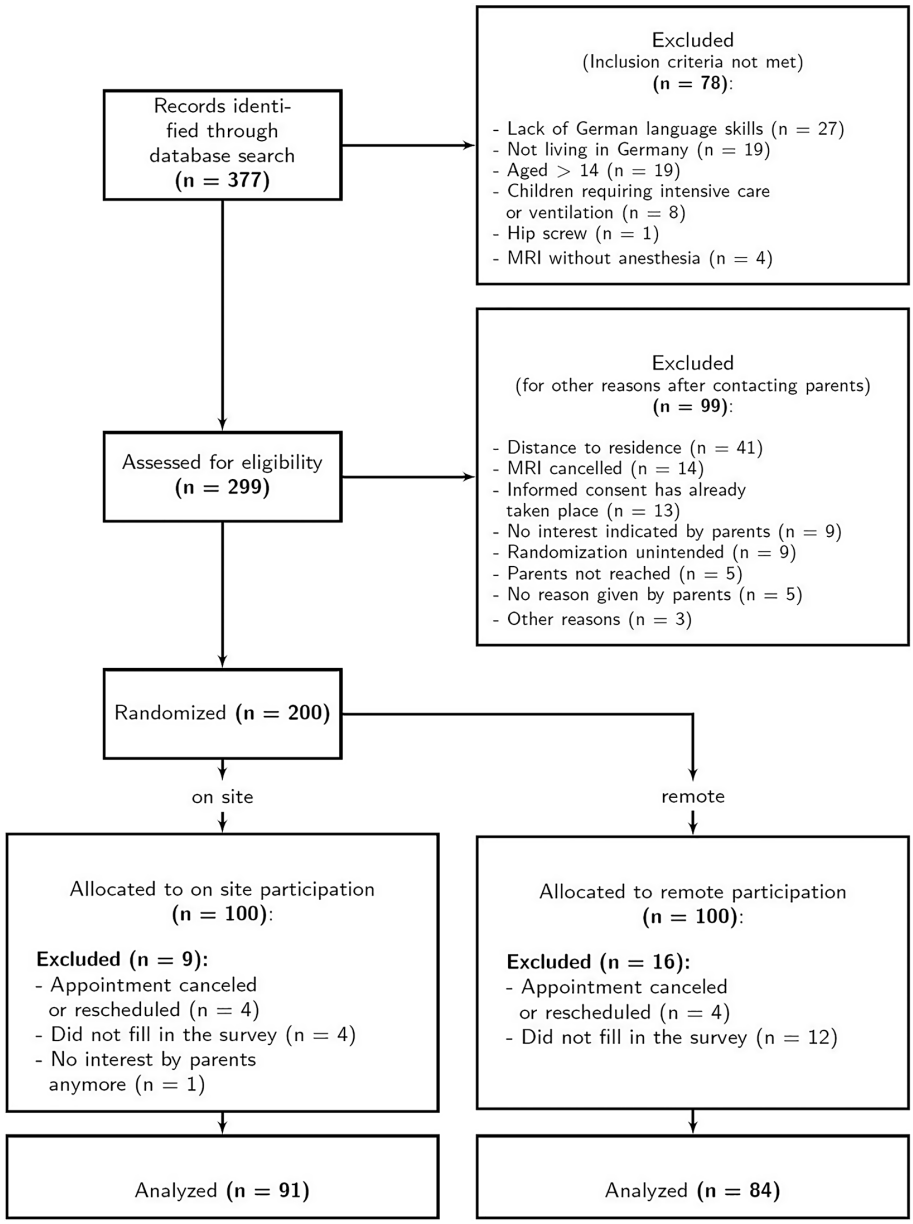

FIGURE 1 Flowchart demonstrating the number of all patients at each step of the study.

A logistic model (see Table 3) was applied to investigate the impact of different factors on the decision to carry out the next PrAC by telephone (binary outcome, 0 = next PrAC not via telephone [*n* = 58], 1 = PrAC via telephone [n = 90]). Solely the randomized group seems to have a very large effect on the decision of the choice of next PrAC (OR = 15.79, 95% CI [5.93–48.33]). Thus, parents that received PrAC via telephone by randomization strongly tend the next PrAC to be remote as stated in the questionnaire. This supports the result of the parents being, in general, satisfied with the remote PrAC. All other variables do not have a statistically significant impact.

4 | DISCUSSION

In this randomized trial involving children ≤14 years undergoing cardiac and neuro MRI examination under sedation, we can conclude that combined telephone and video PrAC for parents could replace the commonly performed on-site PrAC without decreasing its quality. With an overall complication rate of 7.4%, complications in our patient cohort occurred even less frequently in the remote group ($p = .019$).

The first reported use of telemedicine in anesthesia dates back to 2004 and refers to a case series in which a telemedical prehospital

TABLE 1 Patient characteristics. Continuous variables were expressed as mean (SD) or median (interquartile IQR) for skewed data, categorical variables were expressed as absolute and relative frequencies. The educational level of the parents refers to the German education system.

Characteristic	Level	Overall ($n=175$)	remote ($n=84$)	on-site ($n=91$)
Sex (%)	Male	98 (56.0)	48 (57.1)	50 (54.9)
	Female	77 (44.0)	36 (42.9)	41 (45.1)
Primary disease (%)	Cardiac	78 (44.6)	45 (53.6)	33 (36.3)
	Neuro	97 (55.4)	39 (46.4)	58 (63.7)
Distance to residence (mean (SD))		77.18 (89.87)	84.06 (86.95)	70.82 (92.50)
ASA (%)	1	16 (9.1)	5 (6.0)	11 (12.1)
	2	64 (36.6)	24 (28.6)	40 (44.0)
	3	81 (46.3)	45 (53.6)	36 (39.6)
	4	14 (8.0)	10 (11.9)	4 (4.4)
Parent's age (%)	18–25	7 (4.0)	3 (3.6)	4 (4.4)
	26–30	18 (10.3)	11 (13.1)	7 (7.7)
	30–35	53 (30.3)	18 (21.4)	35 (38.5)
	>35	91 (52.0)	50 (59.5)	41 (45.1)
	Missing	6 (3.4)	2 (2.4)	4 (4.4)
Children's age (%)	0–6 months	8 (4.6)	1 (1.2)	7 (7.7)
	6 months–2 years	21 (12.0)	9 (10.7)	12 (13.2)
	2–6 years	99 (56.6)	50 (59.5)	49 (53.8)
	>6 years	44 (25.1)	23 (27.4)	21 (23.1)
	Missing	3 (1.7)	1 (1.2)	2 (2.2)
Number of anesthesia (%)	first time	27 (15.4)	11 (13.1)	16 (17.6)
	second time	24 (13.7)	11 (13.1)	13 (14.3)
	3–5 times	49 (28.0)	22 (26.2)	27 (29.7)
	>5 times	69 (39.4)	38 (45.2)	31 (34.1)
	Missing	6 (3.4)	2 (2.4)	4 (4.4)
Type of insurance (%)	Statutory health insurance	142 (81.1)	74 (88.1)	68 (74.7)
	private	27 (15.4)	9 (10.7)	18 (19.8)
	Missing	6 (3.4)	1 (1.2)	5 (5.5)
Educational level (parents) (%)	Lower educated	10 (5.7)	5 (6.0)	5 (5.5)
	Middle educated	61 (34.9)	29 (34.5)	32 (35.2)
	Higher educated	44 (25.1)	24 (28.6)	20 (22.0)
	Academic	51 (29.1)	23 (27.4)	28 (30.8)
	Missing	9 (5.1)	3 (3.6)	6 (6.6)
Request for next consultation (%)	remote	104 (59.4)	69 (82.1)	35 (38.5)
	on-site	66 (37.7)	14 (16.7)	52 (57.1)
	Missing	5 (2.9)	1 (1.2)	4 (4.4)
Complications	Yes	13 (7.4)	2 (2.4)	11 (12.1)
	No	162 (92.6)	82 (97.6)	80 (87.9)

anesthesia consultation was performed in 10 patients by means of a camera installed on a screen. Already at that time, patients as well as physicians rated the consultation as very satisfying.[8]

The overall satisfaction score in the present study shows that both anesthesiologists and parents were in the majority satisfied with the PrAC in both groups. With regard to the score, the categories quality, general process and contact were taken into account. Both anesthesiologists and parents were more satisfied with the quality of remote than with on-site PrAC (parents: $p=.024$, anesthesiologists: $p=.012$). In particular, the general process of remote PrAC represented a higher level of satisfaction among anesthesiologists compared to the on-site group ($p=.002$). In conclusion, there is no indication in our data that parents and anesthesiologists are more satisfied in the on-site group than in the remote group.

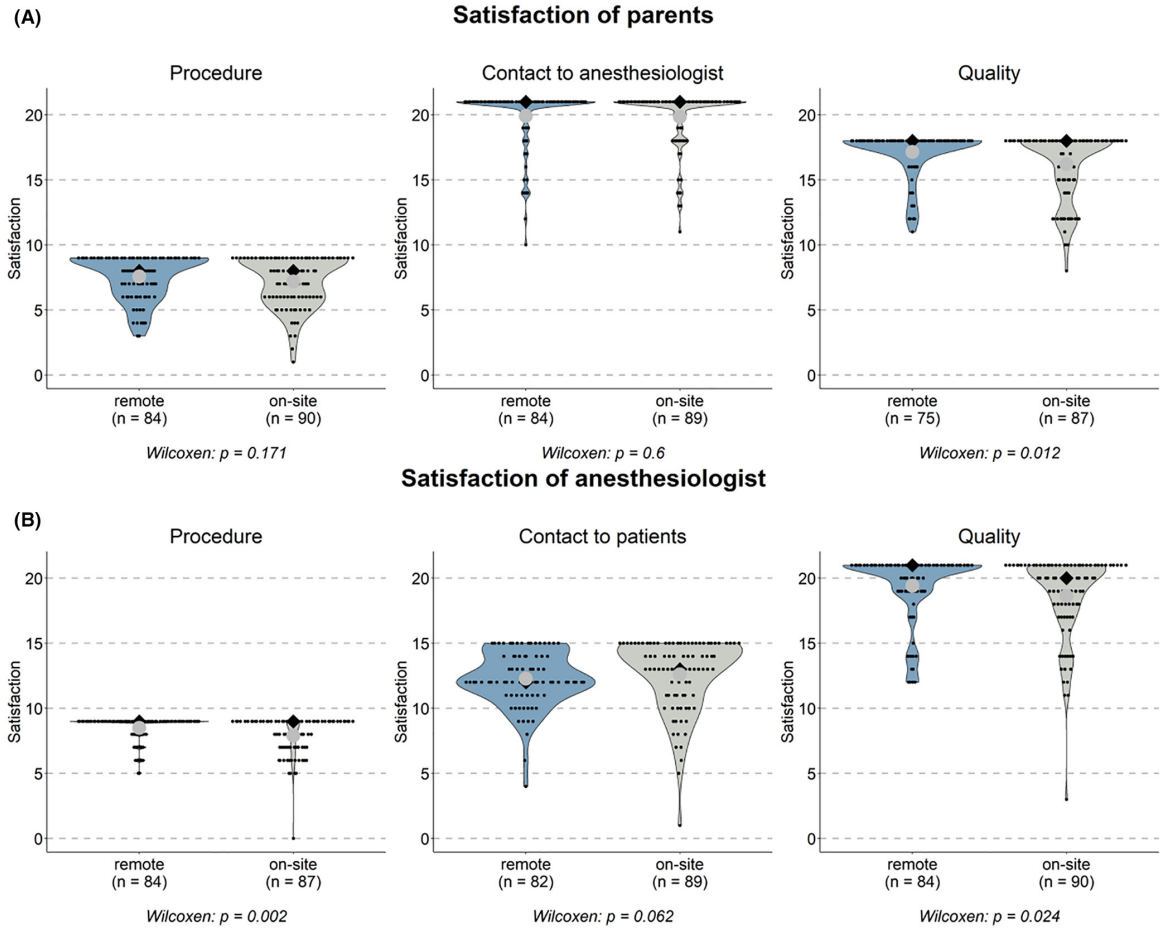

FIGURE 2 The distribution of overall satisfaction scores with pre-anesthesia consultation (PrAC) for each category and method of PrAC separately for parents (A) and anesthesiologists (B). The black diamond represents the median of the satisfaction scores, the gray dot represents the mean of the satisfaction scores. Note that the IQR of possible satisfaction scores is different for each set of questions (see Table 2).

TABLE 2 Satisfaction scores for parents and anesthesiologists. The scale for the singles questions was 0 = completely dissatisfied, 1 = rather dissatisfied, 2 = rather satisfied, 3 = completely satisfied. Questionnaires can be found in the supplementary material.

Satisfaction Score	Category	Overall ($n = 175$)	remote ($n = 84$)	on-site ($n = 91$)	Number of questions	Possible score IQR	p
Parents	Procedure (median [IQR])	8.00 [6.00, 9.00]	8.00 [6.00, 9.00]	8.00 [6.00, 9.00]	3	[0,9]	0.171
	Contact to Anesthesiologist (median [IQR])	21.00 [20.00, 21.00]	21.00 [20.00, 21.00]	21.00 [20.00, 21.00]	7	[0,21]	0.6
	Quality (median [IQR])	18.00 [16.00, 18.00]	18.00 [18.00, 18.00]	18.00 [15.00, 18.00]	6	[0,15]	0.012
Anesthesiologist	Procedure (median [IQR])	9.00 [8.00, 9.00]	9.00 [8.75, 9.00]	9.00 [7.00, 9.00]	3	[0,9]	0.002
	Contact to Patient (median [IQR])	13.00 [11.00, 15.00]	12.00 [11.00, 14.00]	13.00 [11.00, 15.00]	5	[0,15]	0.062
	Quality (median [IQR])	20.00 [18.00, 21.00]	21.00 [19.00, 21.00]	20.00 [18.00, 21.00]	7	[0,21]	0.024

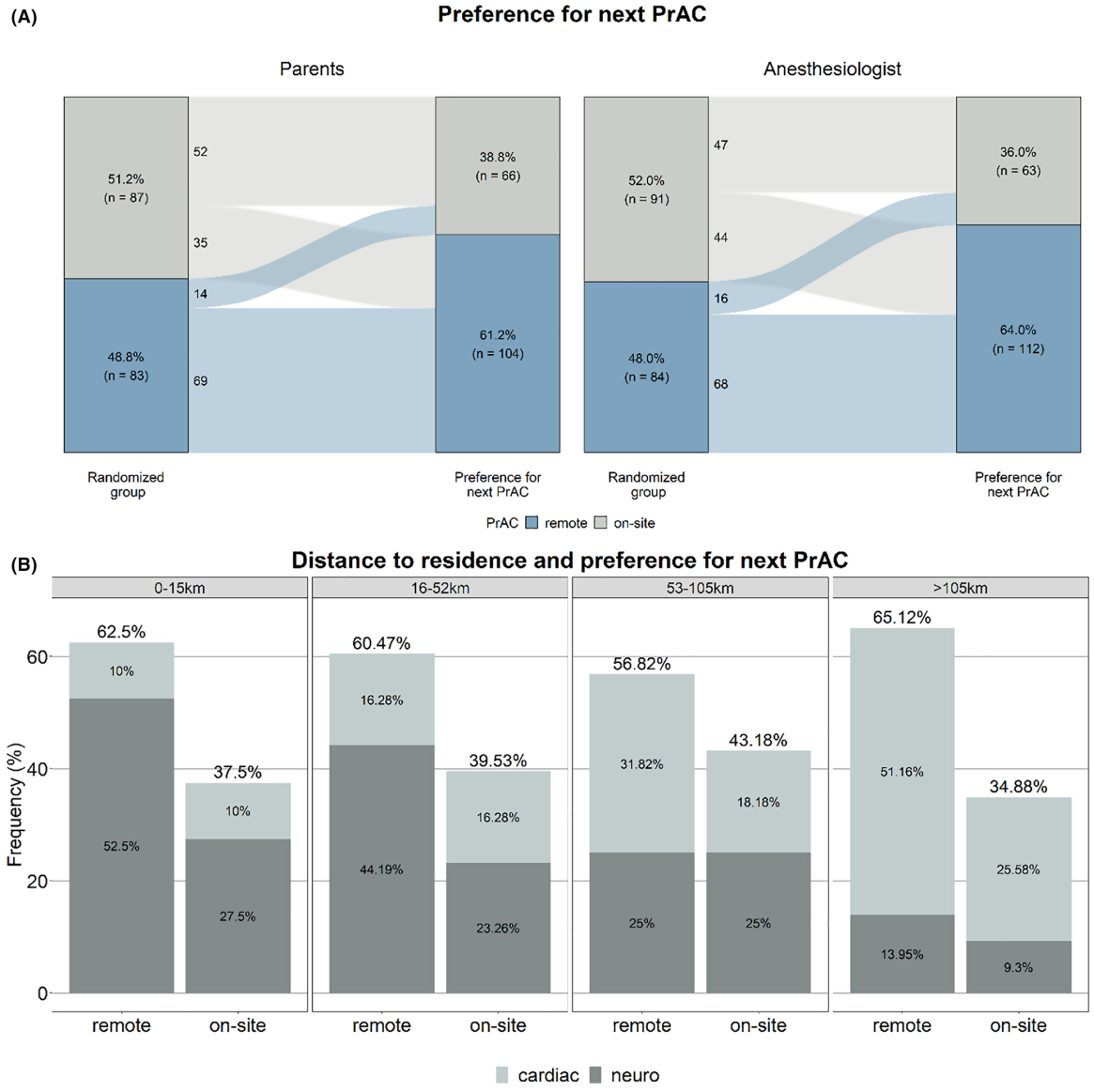

FIGURE 3 (A) Preference for the next pre-anesthesia consultation (PrAC) depending on the randomized group. (B) Distance to residence and request for next PrAC stated by the parents for pediatric cardiac (light brown) and pediatric neuro (brown).

The COVID-19 pandemic has led to a veritable telemedicine and digital health evolution and a rapid increase in the expansion and use of telemedicine services.[9] As this trend is expected to continue after the pandemic, this randomized study showed that remote PrAC is safe and effective. A considerable advantage is also that long waiting times can be avoided, which will ultimately result in great economic benefits. In turn, less capacity and staff would be bound up in the hospital, which could lead to cost efficiencies. With remote PrAC, parents could avoid long, stressful journeys[10,11] and also reduce traffic and environmental pollution. In particular, the pediatric patients with preexisting conditions could benefit from further expansion of telemedicine to reduce the risk of infection with each additional contact.[12]

The literature repeatedly describes the fear of physicians that remote education may have a negative effect on the contact and trust relationship with the patients.[13,14] A crucial point for this could be the lack of framework and special guidelines.[14] Creating such frame conditions, such as a fixed telephone appointment and the conducting of the meeting in a quiet atmosphere, would provide relief.[9,14] In our study, the median satisfaction score for patient contact in the remote group is slightly lower than in the on-site group (remote: 12.00 [11.00, 14.00], on-site: 13.00 [11.00, 15.00]) but the difference in distributions did not reach statistical significance ($p = .062$).

A previous study by Neumann et al. showed that 60.2% of anesthesiologists asked would consider remote anesthesia consultation instead of on-site consultation.[14] With regard to the future

TABLE 3 Results of the logistic model. The outcome is defined as the next possible consultation to be remote (yes [$n=90$] /no [$n=58$]).

Predictors	Levels	Odds ratios	Confidence intervals	*p*
(Intercept)		251.42	0.65–163333.59	.077
Randomized consultation	Remote	15.79	5.93–48.33	<.001
Sex	Female	0.54	0.20–1.41	.215
Field	Neuro	1.88	0.60–6.22	.288
Distance to residence		1.00	1.00–1.01	.430
Age parents	26–30 years	0.17	0.01–2.47	.228
	30–35 years	0.07	0.00–0.89	.057
	> 35 years	0.24	0.01–2.70	.283
Age children	6 months – 2 years	0.25	0.02–2.39	.240
	2–6 years	0.39	0.04–3.13	.389
	> 6 years	0.16	0.01–1.72	.144
Number of anesthesia	second time	0.58	0.11–2.91	.504
	3–5 times	0.97	0.20–4.61	.970
	> 5 times	1.82	0.37–9.23	.461
Graduation levels parents	Middle educated	1.65	0.28–9.30	.572
	Higher educated	1.62	0.24–10.29	.612
	Academic	1.93	0.30–12.00	.478
ASA score	2	1.04	0.20–5.33	.958
	3	1.04	0.17–6.46	.963
	4	1.17	0.09–16.55	.904
Satisfaction	Procedure	0.97	0.71–1.30	.819
Satisfaction	Contact to doctor	0.90	0.65–1.22	.496
Satisfaction	Quality of consultation	0.90	0.69–1.17	.438
Observations		148		
R^2 Tjur		0.344		

preference, we observe similar results with 64% of the anesthesiologists preferring the next PrAC to be remote. Likewise, 61.2% of parents questioned would like the next PrAC to be remote.

The possible influence of the distance from home to hospital was also considered in this study. In this regard, we observed in our study that the further the parents live from the clinic location, the more often remote PrAC is preferred (65.12%). This does not seem surprising in view of rising benzine prices and the increasing awareness of climate protection. However, when looking at the study participants who live very close, it is also noticeable that most of them would prefer remote PrAC (62.5%). The impact of the distance to residence on the decision for the next PrAC is also not statistically significant in the logistic regression model.

We also observe in Figure 3 that parents tend to favor remote PrAC after participating in the study, but we were also interested in the question of which other factors might influence this decision. We looked at the field of investigation (cardiac or neuro), the distance to residence (km), the age of parents (categorized, as retrieved in the survey), the number of previously performed MRIs with anesthesia, the graduation level of the parents, the ASA score and the randomized group (on-site or remote). Solely the randomized group seems to have a very large effect on the decision of the choice of next PrAC (OR = 15.79, 95% CI [5.93–48.33]). Thus, parents that received PrAC via telephone strongly tended to receive a possible next PrAC via telephone. All other variables do not have a significant impact on the decision.

4.1 | Strength and limitations

Of course, this study has some limitations. Two different fields of medical specialization (neuro and cardiac) may have introduced bias. The cardiac children receive multiple MRI examinations over a longer period of time to monitor the course of their underlying diseases. Therefore, parents may be more familiar with the anesthesiological procedure.

Although the questionnaire was designed with the greatest possible care by experienced clinical and research anesthesiologists, response bias may have occurred. Questionnaires were not anonymized, there were potentially socially desirable answers that did not–or only partially–correspond to the actual attitude of the respondents. In addition, the questionnaire was not tested in advance

and was not developed with the help of a psychologist, this possibly led to unclear formulations or suggestive questions.

A strength of the study is the randomized study design. Not only an observational questionnaire was collected, but primarily two groups of patients with two different types of PrAC were compared.

5 | CONCLUSION

Remote PrAC seems feasible and safe for simple procedures such as sedation for an MRI. Both parents and anesthesiologists appear to show a high satisfaction rate when PrAC is performed remotely. However, to expand this area even more, specific guidelines for example, within the framework of Europe-wide harmonization are desirable to provide both parents and anesthesiologists with a safe implementation for remote PrAC. All results gathered from this study are the object of an exploratory analysis. To confirm results, further studies with potentially improved and approved questionnaires need to be conducted.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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3.2 Publication 2: Digital Online Anaesthesia Patient Informed Consent before Elective Diagnostic Procedures or Surgery: Recent Practice in Children—An Exploratory ESAIC Survey (2021)

Journal of
Clinical Medicine

MDPI

Article

Digital Online Anaesthesia Patient Informed Consent before Elective Diagnostic Procedures or Surgery: Recent Practice in Children—An Exploratory ESAIC Survey (2021)

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Abstract: Background: One undisputed benefit of digital support is the possibility of contact reduction, which has become particularly important in the context of the COVID-19 pandemic. However, to the best of our knowledge, there is currently no study assessing the Europe-wide use of digital online pre-operative patient information or evaluation in the health sector. The aim of this study was to give an overview of the current status in Europe. Methods: A web-based questionnaire covering the informed consent process was sent to members of the European Society of Anaesthesia and Intensive Care Medicine (ESAIC) in 47 European countries (42,433 recipients/930 responses). Six questions related specifically to the practice in paediatrics. Results: A total of 70.2% of the respondents indicated that it was not possible to obtain informed consent via the Internet in a routine setting, and 67.3% expressed that they did not know whether it is in line with the legal regulations. In paediatric anaesthesia, the informed consent of only one parent was reported to be sufficient by 77.6% of the respondents for simple interventions and by 63.8% for complex interventions. Just over 50% of the respondents judged that proof of identity of the parents was necessary, but only 29.9% stated that they ask for it in clinical routine. In the current situation, 77.9% would favour informed consent in person, whereas 60.2% could imagine using online or telephone interviews as an alternative to a face-to-face meeting if regulations were changed. Only 18.7% participants reported a change in the regulations due to the current pandemic situation. Conclusion: Whether informed consent is obtained either online or on the telephone in the paediatric population varies widely across Europe and is not currently implemented as standard practice. For high-risk patients, such as the specific cohort of children with congenital heart defects, wider use of telemedicine might provide a benefit in the future in terms of reduced contact and reduced exposure to health risks through additional hospital stays.

Keywords: telemedicine; digital informed consent; children; European practice

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1. Introduction

Particularly for seriously ill children, the risk of contracting nosocomial infections during a hospital stay is high. Children after cardiac surgery showed an overall nosocomial infection rate of 10.8% [1].

Even beyond the current pandemic situation, avoiding hospitalisation reduces the burden on seriously or chronically ill children. For example, an Australian study in 2019

showed that at-home antibiotic therapy for children with moderate to severe cellulitis had the same efficacy but fewer adverse effects compared to standard treatment in hospital [2].

Telemedicine is described as "the provision of concrete medical services overcoming spatial distances with the aid of modern information and communication technologies" [3]. This aid may provide many advantages, especially in severely ill children, who show a significant risk from hospital waiting-times and visits, particularly given the current need to limit social contacts during the pandemic. Numerous studies show that telemedicine care for patients is safe, effective, and cost-efficient [4]. The first publication regarding informed consent for anaesthesia using telemedicine dates back to 2004 and shows a high level of satisfaction among both anaesthetists and patients [5]. A study by Wool in 2016 evaluated the efficiency and reliability of telemedicine consultations for preoperative assessment of patients undergoing oral and maxillofacial surgery, including a six-year follow up period. Among other things, the authors concluded that in 98% of the cases, "Most patients received adequate medical and physical examination and were able to undergo surgery with anaesthesia as planned at the clinic appointment immediately after the telemedicine consultation" [6]. In 2018, Vogel et al. pointed out that video-assisted patient education can significantly improve patients' level of knowledge and lead to increased patient satisfaction [7]. Furthermore, a position paper of the German Society for Anaesthesiology and Intensive Care Medicine (DGAI) and the German Society for Telemedicine (DG Telemed) from 2019 also called for using digital media to improve patient care and actively shape telemedicine in the field of anaesthesiology in Germany [3]. Given the safety of remote education and informed consent, it is plausible that both the risk and potential anxiety and discomfort for the child caused by a hospital visit are vastly reduced. However, the use of technology in this context was highly restricted prior to the COVID-19 pandemic [8,9].

One way to reduce the number and length of hospital stays, especially for children who have to undergo repeated procedures and examinations under anaesthesia, is patient informed consent using telemedicine. Benefits, such as cost savings, reduced waiting times, and increased patient safety, may be realized, especially for the vulnerable paediatric patient population. While the technology for digital support in patient informed consent has been possible for years, it remains unclear how widespread these opportunities actually are in clinical practice.

We therefore aimed to examine the current state of telemedicine's use to obtain informed consent in anaesthesia in Europe. In particular, we aimed to investigate how anaesthetists judge the legal situation with regard to purely telemedical patient informed consent, the necessity of informing both parents in paediatric anaesthesia, and the necessity of parental/caretaker identity verification. In addition, the study examined whether there are different ways of obtaining informed consent depending on the severity of the procedure or surgery and whether the technical requirements are fulfilled to do so.

2. Materials and Methods

2.1. Study Protocol

To evaluate the recent practice of the informed consent process, a Europe-wide survey was created by the Department of Anaesthesiology at the University Hospital Bonn and conducted by ESAIC. The survey was sent to anaesthetists who consented to receive ESAIC informational emails in 47 European countries.

The survey focused on the use of digital support in the context of anaesthesia in general with a total of 27 questions, with a special focus on the peculiarities of patient information in paediatric anaesthesia. This was examined in six specific questions with three answer options each (for a detailed description see the Supplementary Materials, Table S2).

In addition to the collection of demographic data, such as gender or level of education, the anaesthetists were asked to express their opinions regarding the advantages and disadvantages of telemedicine-supported informed consent and whether telemedicine is

at all possible in terms of the anaesthetist's technical equipment. We included all survey answers (as opposed to only those that referred to paediatric anaesthesia) to illustrate the general use of digital media and their assessment as well as the potential for future use following the pandemic.

We used "LimeSurvey CE", Hamburg, Germany (Version 5.1, https://community.limesurvey.org/downloads/, accessed on 29 November 2021) for the online questionnaire, hosted on a secured Linux Debian (Version 10.11) server. The survey was conducted over a three-week period (July to August 2021) and was supported by the ESAIC. An email containing a link to the survey was distributed to 42,433 active members by the ESAIC communication committee (https://kai-survey.de/limesurvey/733779/, accessed on 29 November 2021). According to the applicable medical professional regulations, an ethical approval was not necessary for this anonymous survey.

2.2. Questionnaire

Following previous projects [10–13], our working group developed an online questionnaire to analyse the use of telemedical support in healthcare and also specifically in paediatric anaesthesia in Europe. The questionnaire consisted of 27 mainly multiple-choice questions. Respondents were allowed to omit questions. The questionnaire could be completed in 7–10 min. Questions were asked concerning general anaesthesia issues, and a special part of the questionnaire was designed to consider paediatric anaesthesia. The general questions dealt with whether online informed consent is implementable in daily routine and whether anaesthesiologists know whether it is legal to obtain informed consent online depending on the country. Six questions were included in the special paediatric part of the questionnaire. The content of these questions was whether consent had to be obtained from both parents or only from one parent. A distinction was made here between simple procedures and high-risk procedures. In the next question, it was assessed whether the anaesthesiologist knew the legal regulations in his or her country for online informed consent. We asked whether the identity of the parents should be checked and if it is actually checked in routine practice. Furthermore, we asked the anaesthesiologists about the risks and benefits of online informed consent in paediatric anaesthesia.

We also investigated the general sentiment among participants of how informed consent should be obtained in the future and if ensuring certain guidelines might help to facilitate remote interviews in both adult and paediatric populations. Our survey thus assessed whether special regulations favouring informed consent online or per telephone in the general patient population were implemented during the pandemic situation.

2.3. Statistical Analysis

Data were summarized using descriptive statistics. For each question, the absolute number and the percentage of responses was calculated and used to interpret the opinion distribution. A chi-square test of independence was used for categorical variables. All analyses were performed using the programming language R (R Core Team, Vienna, Austria, Version 3.6.2). The threshold for statistical significance was set to $p \leq 0.05$. To facilitate reproducible research, we programmed an interactive web application to investigate the data (https://kai-survey.shinyapps.io/ESAIC-KAI-survey-2021/, accessed on 29 November 2021). The code to perform descriptive statistical analysis and visualisation was stored at GitHub and can be viewed online (https://github.com/GrigorijSchleifer/ESAIC-informed-consent-survey/, accessed on 29 November 2021).

3. Results

Population

The study population was defined as practicing ESAIC members. Respondents who did not provide their residency or submitted entries with missing values were excluded, leaving 930 eligible responses. Overall, responses were provided by medical doctors (99%, n = 920), nurses (0.2%, n = 2), physician assistants (0.6%, n = 6), and other undisclosed

professions (0.1%, *n* = 1). Fifty-six percent (*n* = 521) of participants were male, 43.6% (*n* = 406) female, and 0.3% (*n* = 3) diverse. Respondents were predominantly consultants (78.6%, *n* = 731) or residents (15.3%, *n* = 143) (Table 1) from 47 countries (Table S1). The highest number of responses came from Germany (*n* = 132), Spain (*n* = 73), and Switzerland (*n* = 65) (Figure 1).

Table 1. Distribution among medical professions and level of expertise of the study population stratified by gender.

	Stratified by Gender			
	Diverse	**Female**	**Male**	***p***
n (%)	3 (0.3)	406 (43.6)	521 (56)	
Profession (%)				<0.001
Medical doctor	2 (66.7)	402 (99.0)	516 (99.2)	
Nurse	1 (33.3)	0 (0.0)	1 (0.2)	
Physician assistant	0 (0.0)	4 (1.0)	2 (0.4)	
Other	0 (0.0)	0 (0.0)	1 (0.2)	
Expertise (%)				0.33
Anaesthesia technician	0 (0.0)	4 (1.0)	6 (1.2)	
Consultant	2 (66.7)	303 (74.8)	426 (81.8)	
Resident	1 (33.3)	75 (18.5)	67 (12.9)	
Special trained nurse	0 (0.0)	0 (0.0)	1 (0.2)	
Other	0 (0.0)	23 (5.7)	21 (4.0)	

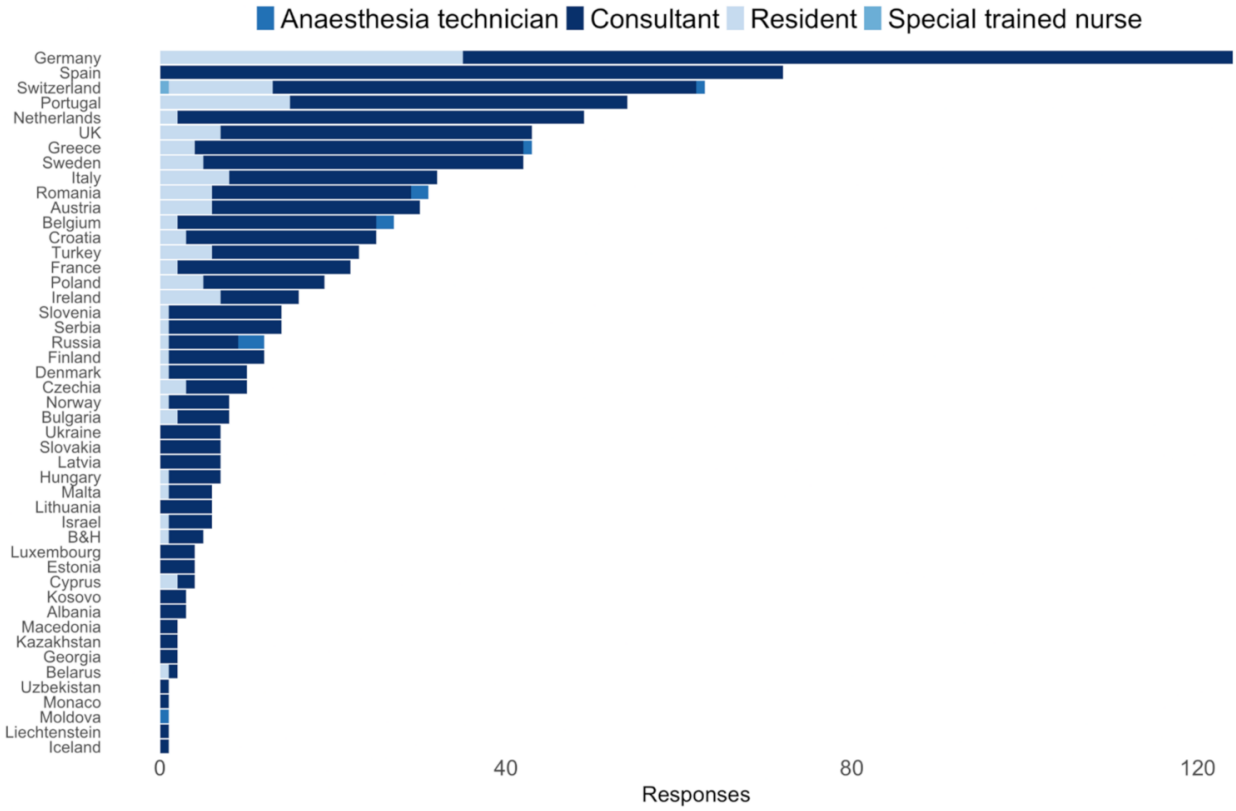

Figure 1. Responders' level of expertise separated by the country.

We assessed the availability of technological solutions for the informed consent process across Europe. In 70.2% (*n* = 486) of the responses, we observed that it was not possible to obtain informed consent via the Internet in a routine setting. While 6.6% (*n* = 46) of those surveyed mentioned varying technical standards from day to day, 23.1% (*n* = 160) confirmed that it was possible to obtain consent via the Internet (Figure 2). Major differences could be

observed for the technical distribution of tools supporting remote education across Europe (Figure 3).

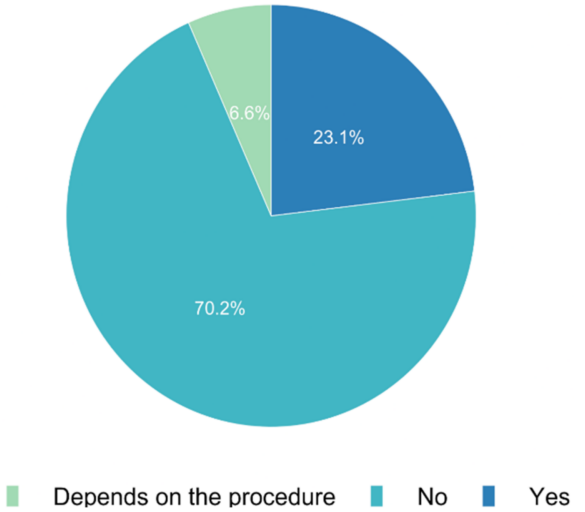

Figure 2. Is it possible to obtain informed consent online via the Internet in your routine setting?

Figure 3. Is it possible to obtain informed consent online via the Internet in your routine setting? Only countries with at least 15 responses were colour coded.

The survey also investigated whether a remote consent process for paediatric patients in Europe was presumed to be legal. In paediatric practice, 67.3% (n = 432) of responses stated that online/telephone-based consent did not comply with legal regulations. Approx-

imately a fifth (22.9%, n = 147) of respondents answered that online consent was legal for paediatric patients (Figure 4). Interestingly, there were major differences across European countries in perceived legal requirements for remote informed consent (Figure 5).

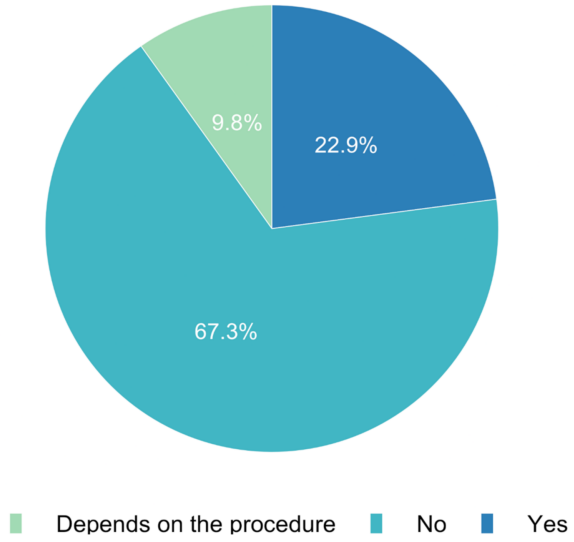

Figure 4. Do you know if it is legal to obtain informed consent from the parent/caregiver via the Internet or telephone?

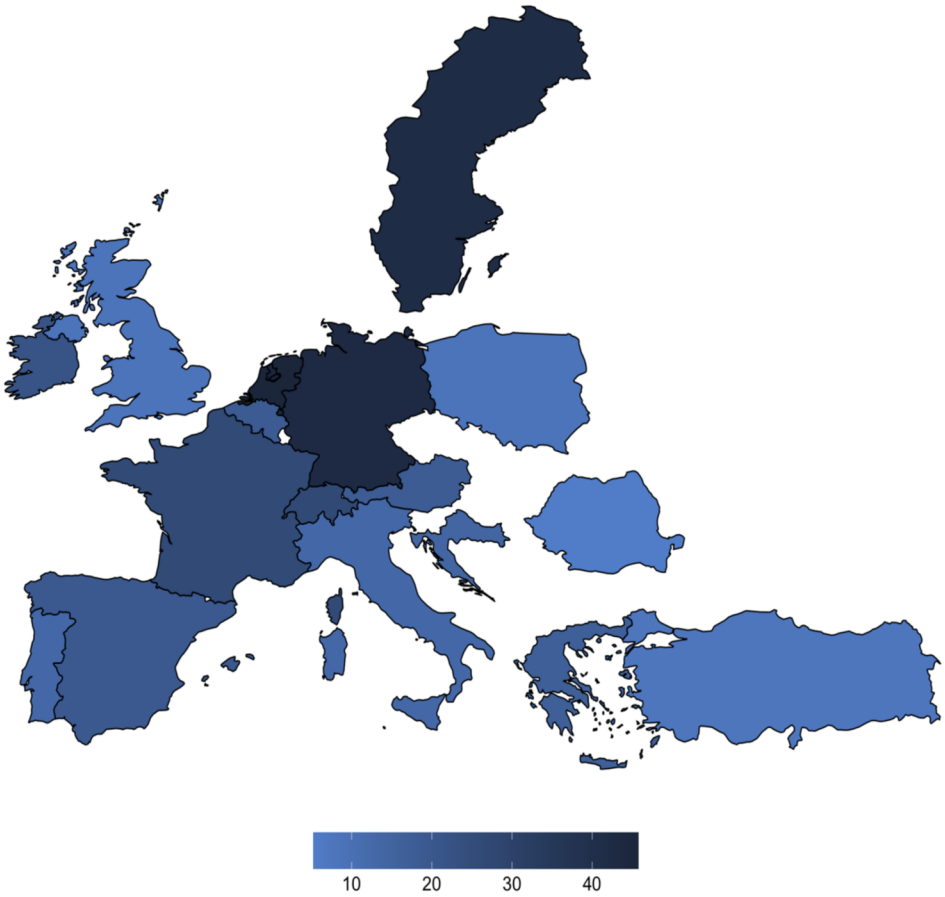

Figure 5. Do you know if it is legal to obtain informed consent from the parent via the Internet or telephone? Only countries with at least 15 responses were colour coded.

The answers to the question of whether written informed consent is required from both parents for elective surgery varied. For simple procedures, 14.2% (n = 92) of participants wished to obtain consent from both parents. In comparison, 25.7% (n = 167) of the responses stated that consent had to be obtained from both parents for complex procedures. For 77.6% (n = 502) of colleagues surveyed, informed consent for simple surgery could be given with only one parent present versus 63.8% (n = 415) for complex interventions (Figure 6).

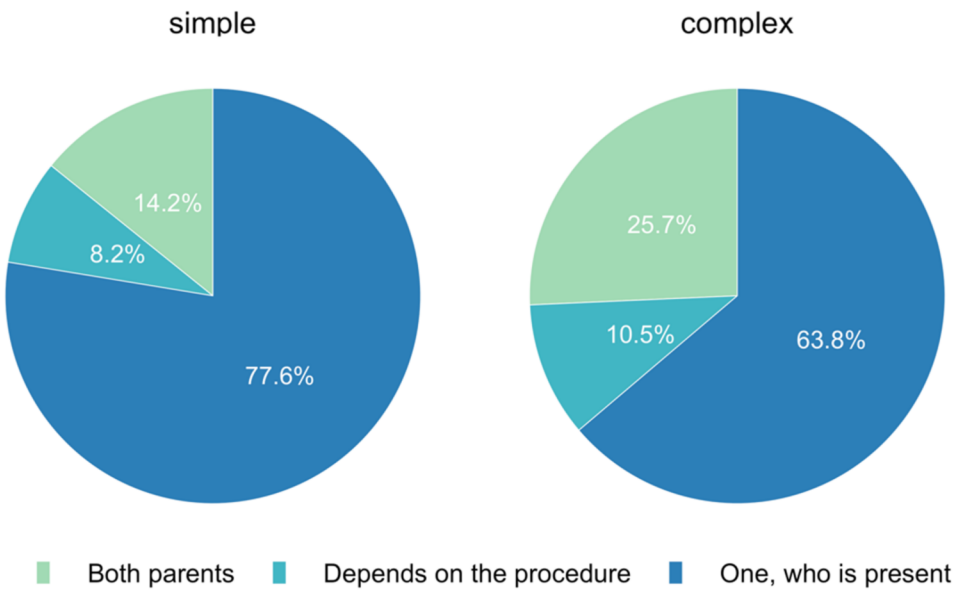

Figure 6. Is written informed consent for elective surgery required from both parents or just from one?

We evaluated how identity of the legal representatives was confirmed. Overall, 56.1% (n = 362) of survey participants reported that it was necessary to see parents' ID cards to confirm parental identity. However, only 29.9% (n = 193) of those surveyed actually verified identity by routinely checking ID when parents were present. There is an obvious discrepancy between the expectation of identification of legal representatives for paediatric patients and the routine practice (Figure 7).

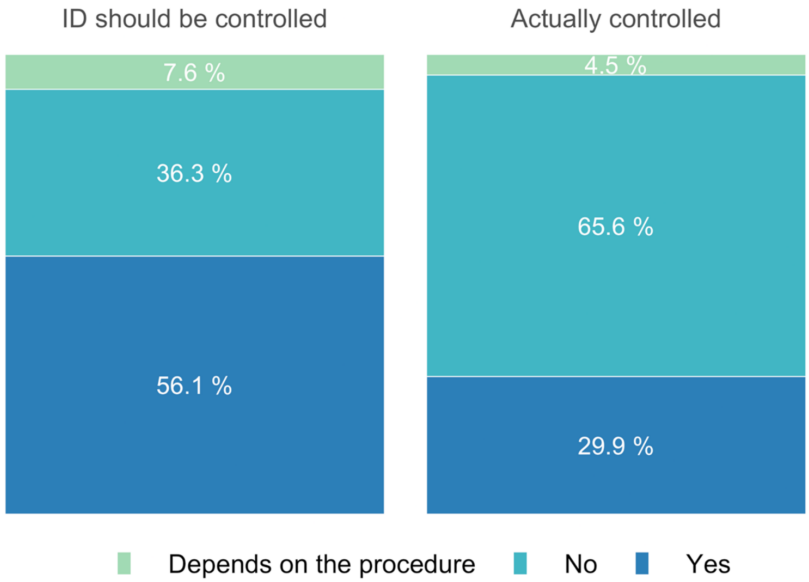

Figure 7. Do you think it is necessary to verify the identity of the parent/guardian (i.e., to check their ID card)?

Within our survey, we additionally asked the participants what concerns they had regarding telephone or online interviews. We found that major concerns were the lack of interaction, personal observation of the patient, and doctor–patient relationship. Overall, 26.8% (n = 632) said they were concerned about the lack of contact, 21.4% (n = 504) worried about missing out on personal observation of the patient, and 16.8% (n = 264) about a missing doctor–patient relationship. Legal uncertainty was also mentioned as a concern (Table S2). We also assessed the general sentiment of the survey population toward the implementation of online/telephone interviews. Overall, 35.3% (n = 470) of respondents confirmed that a remote consent procedure could limit time spent waiting for the interview and could be more efficient than a face-to-face interaction (24.6%, n = 327). Furthermore, 23.1% (n = 308) of the study participants replied that remotely informed consent could be less stressful. From an organisational perspective, the use of standardized questionnaires was seen as an advantage by 16.8% (n = 224) of colleagues surveyed (Table S2).

We also investigated the general sentiment among participants of how informed consent should be obtained in the future in both adult and paediatric populations. Overall, the majority (77.9% n = 589) of participants would prefer to do anaesthesiological preoperative evaluations in person. Only 7.5% (n = 57) could imagine obtaining consent online via a patient's self-assessment or in a videoconference (11.6%, n = 88). Three percent (n = 22) favoured obtaining informed consent via telephone (Figure 8A). Interestingly, 60.2% (n = 414) confirmed that an online interview would be an alternative to personal face-to-face meeting if certain conditions were met.

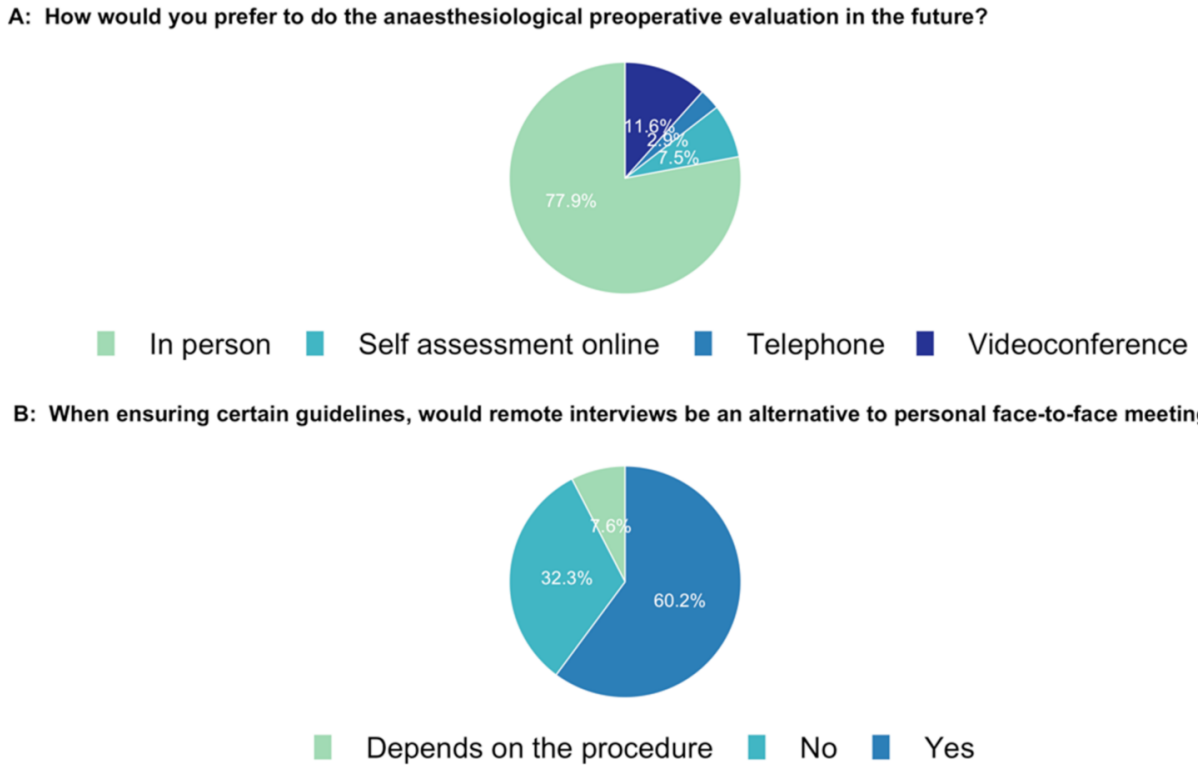

Figure 8. How would you prefer to conduct anaesthesia preoperative evaluations in the future?

Our survey assessed whether special regulations favouring informed consent online or per telephone in the general patient population were implemented during the pandemic. While 25.2% (n = 202) of participants did not know of any regulations, 56.1% (n = 450) of responses denied any regulatory adjustments favouring online consent. Only 18.7% (n = 150) reported that regulations favouring informed consent either online or per telephone were implemented in their countries (Figure 9).

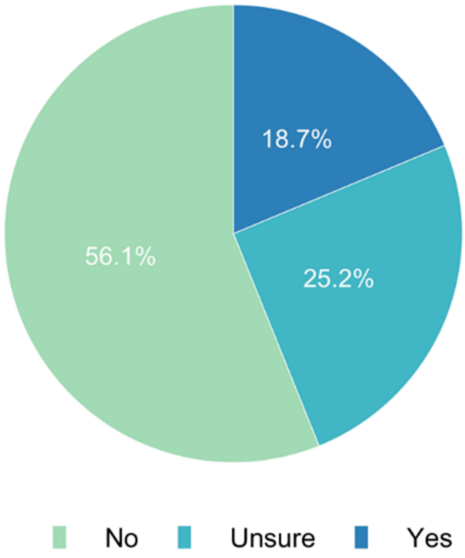

Figure 9. Do special regulations exist in your country during the current pandemic situation favouring online or telephone-based informed consent?

4. Discussion

Our survey showed, for one, that the implementation of telemedicine in daily practice has been very limited across Europe and, for another, that perceived legal bases are very different among the individual countries.

In our questionnaire, 70.2% of responders stated that in their hospitals, it would not be possible to provide patient education via the Internet or telephone in a routine setting. In the United States, a collective of healthcare academics, researchers, providers, and industry representatives has called for healthcare reform coupled with telemedicine and information technology for many years [14]. Closing the gaps between technical feasibility and usability in everyday clinical practice remains a challenge.

In addition to the technical and practical problems, there is also the legal aspect of anaesthesiological information. Specifically relating to paediatric anaesthesia, 67.3% of respondents stated that purely digital education without any in-person interaction is not legal. Only 22.9% considered online or telephone-based education to be legal, while 9.8% were unable to assess the current legal situation. This was also extremely different among the participating European countries and underpins the fact that there is still no uniform regulation in this regard (Figure 5) and that even within a country, there is still great uncertainty concerning legality. The legal basis is quite different throughout Europe; in some countries, online or telephone education of patients is legal, whereas in others, only face-to-face education is [15,16].

European legislation considers telemedicine to be a health service on the one hand and an information service on the other and therefore is subject to different legislation [8]. Specific legal regulations for the use and handling of telemedicine are lacking in many countries, and harmonization across the EU is often described as unfeasible, for one, because of data protection problems [8].

The European Society of Anaesthesiology and Intensive Care (ESAIC) has published a guideline on preoperative anaesthesiological information [17], with recommendations for preoperative evaluation and the benefits of digital media, both of which are defined in this manuscript.

Considering the aspect of parental presence, it became apparent that most anaesthesiologists considered consent from only one parent sufficient. However, this also differed with regard to the complexity of the intervention (77.6% versus 63.8% for simple versus complex procedures, respectively). On the other hand, 14.2% of anaesthesiologists (for simple procedures) and 25.7% (for complex procedures) stated that consent of both par-

ents was required. This may imply that both parents have to take time off work for the consultation, which can of course have economic or financial consequences and is not necessarily perceived as comfortable. Added to this are the sometimes not inconsiderable waiting times in the preoperative outpatient departments. This could mean an advantage for parents using online or telephone-based education.

A special question was designed to address the verification of parental identity. Although 56.1% of anaesthetists found it necessary, for example, to be shown a parent's ID card, only 29.9% of the respondents said they actually practised this. Here, too, telemedicine could standardise the procedure: a QR code could be used to send a scan of the ID card to the doctor, for example, and many countries already have electronic ID cards that can be scanned online.

Especially during the COVID-19 pandemic, minimising personal contacts is an essential preventive factor to avoid further spread of the virus [17,18]. Children in particular are vulnerable and must be protected. This raises the question of whether the use of telemedicine can replace the personal patient presentation and whether there are adverse effects for patients to be feared as a result.

As an outlook for the future, it remains to be noted that in the overall group of respondents, only 22% would favour patient education online or via telephone. However, by differentiating between adult and paediatric anaesthesia, we found that 60.2% see digital education as an alternative to the face-to-face educational interview given optimal organisation of the process. This includes ensuring a specific guideline, which may include, e.g., a specific appointment time for the interview, a secure data-protected online service, a relaxed environment without distractions, and explicit parental consent for an online or telephone interview.

Limitations

Although the questionnaire was sent to 42,433 active members of the ESAIC, only 930 anaesthetists took up the offer to participate in the survey. This corresponds to 2.19% of the respondents, and therefore, the data presented are limited in their representativity.

Nevertheless, an interesting picture emerges of how different the use of digital media in medicine is among European countries.

In countries with limited resources, it may be more difficult to implement the use of online tools, as patients may not have access to computers or the internet. Thus, at least in the near future, a widespread use of telemedicine to support health care in all European countries is probably not possible although it is desirable. One further limitation of the survey is the possibility of a response bias. Because the survey was anonymous and performed online without any human interaction, socially desirable responses and interviewer bias should not be of concern. Even though our questionnaire was designed with maximum care, a pre-test to evaluate a possible bias effect of primer questions could not be included because the survey was distributed by the ESAIC only once. This could potentially induce question-order effects that would limit the external validity of our findings.

5. Conclusions

According to international studies, digital patient education has proven to be feasible, safe, efficient, and cost-effective and has been increasingly recommended and used during the COVID-19 pandemic [6,8]. This paper highlights the current standard in Europe and filters out concerns anaesthetists have about a telemedicine approach while pointing out the potential benefits. Overall, the approach in Europe is extremely varied, not least because of varying legislation in the individual countries.

It would be desirable to create a uniform legal basis, especially for digital online anaesthesiological patient informed consent, to minimise unnecessary personal contacts while maintaining the same standard of information—even beyond a pandemic situation. Consequently, there would be greater opportunity to protect the health of particularly vulnerable and severely ill groups, such as those of children with congenital heart defects.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/jcm11030502/s1, Table S1: Number of responses; Table S2: Questionnaire items.

Author Contributions: Conceptualization, E.S. and M.W.; Data curation, G.S. and M.W.; Formal analysis, C.N. and G.S.; Investigation, N.S.-N. and D.C.; Methodology, C.N., M.V. and M.W.; Software, G.S. and D.C.; Supervision, M.W.; Visualization, N.S.-N. and G.M.; Writing—original draft, C.N., N.S.-N. and J.K.; Writing—review & editing, G.M., A.G.-P., M.V., M.C., E.S. and M.W. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: According to the applicable medical professional regulations, an ethical approval was not necessary for this anonymous survey.

Informed Consent Statement: Not applicable.

Data Availability Statement: Complete dataset is available on https://kai-survey.shinyapps.io/ESAIC-KAI-survey-2021/ (accessed on 29 November 2021). The code to perform descriptive statistical analysis and visualisation was stored at GitHub and can be viewed online https://github.com/GrigorijSchleifer/ESAIC-informed-consent-survey/ (accessed on 29 November 2021).

Conflicts of Interest: The authors declare no conflict of interest.

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3.3 Publication 3: Effects of On-Table Extubation after Pediatric Cardiac Surgery

Journal of
Clinical Medicine

MDPI

Article

Effects of On-Table Extubation after Pediatric Cardiac Surgery

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Abstract: Background: Enhanced recovery after surgery (ERAS) protocols are utilizing a multidisciplinary approach, reassessing physiology to improve clinical outcomes, reducing length of hospital stay (LOS) stay, resulting in cost reduction. Since its introduction in colorectal surgery. the concept has been utilized in various fields and benefits have been recognized also in adult cardiac surgery. However, ERAS concepts in pediatric cardiac surgery are not yet widely established. Therefore, the aim of the present study was to assess the effects of on-table extubation (OTE) after pediatric cardiac surgery compared to the standard approach of delayed extubation (DET) during intensive care treatment. Study Design and Methods: We performed a retrospective analysis of all pediatric cardiac surgery cases performed in children below the age of two years using cardiopulmonary bypass at our institution in 2021. Exclusion criteria were emergency and off pump surgeries as well as children already ventilated preoperatively. Results: OTE children were older (267.3 days vs. 126.7 days, $p < 0.001$), had a higher body weight (7.0 ± 1.6 kg vs. 4.9 ± 1.9 kg, $p < 0.001$), showed significantly reduced duration of ICU treatment (75.9 ± 56.8 h vs. 217.2 ± 211.4 h, $p < 0.001$) and LOS (11.1 ± 10.2 days vs. 20.1 ± 23.4 days; $p = 0.001$) compared to DET group. Furthermore, OTE children had significantly fewer catecholamine dependencies at 12-, 24-, 48-, and 72-h post-surgery, while DET children showed a significantly increased intrafluid shift relative to body weight (109.1 ± 82.0 mL/kg body weight vs. 63.0 ± 63.0 mL/kg body weight, $p < 0.001$). After propensity score matching considering age, weight, bypass duration, Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery Mortality (STATS)-Score, and the outcome variables, including duration of ICU treatment, catecholamine dependencies, and hospital LOS, findings significantly favored the OTE group. Conclusion: Our results suggest that on-table extubation after pediatric cardiac surgery is feasible and in our cohort was associated with a favorable postoperative course.

Keywords: enhanced recovery after surgery (ERAS); on table extubation; pediatric cardiac anesthesia

Citation: Baehner, T.; Pruemm, P.; Vergnat, M.; Asfour, B.; Straßberger-Nerschbach, N.; Kirfel, A.; Hamann, M.; Mayr, A.; Schindler, E.; Velten, M.; et al. Effects of On-Table Extubation after Pediatric Cardiac Surgery. *J. Clin. Med.* **2022**, *11*, 5186. https://doi.org/10.3390/jcm11175186

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1. Introduction

Individualized, high-quality, and resource aware peri-operative care is outcome relevant in the modern area of pediatric cardiac surgery [1,2]. Enhanced recovery after surgery (ERAS) protocols have been introduced beginning in colorectal surgery more that 2 decades ago and have shown to improve postoperative outcome while reducing length of hospital stay (LOS) [3]. Since then, this concept has widely been accepted to improve postoperative outcomes especially regarding the prevention of postoperative cognitive dysfunction and reduction of cardiac and pulmonary complications, as well as nausea and vomiting [4].

At the same time, the first ERAS protocols were published in adult cardiac surgery [5]. In addition to these obvious advantages, when children are undergoing surgery, reduced exposure to anesthetics, especially in the neonatal period, has additional significant benefits. The neurotoxic effects of anesthetics in the developing brain have been acknowledged for a long time [6–8]. In this context, any extended anesthesia duration and accumulation of anesthetics should be prevented [9]. In particular, within the first two years of extrauterine brain development, when most surgical procedures for congenital cardiac defects are performed, the administration of various anesthetics has been shown to impair neurological development and accelerate cerebral apoptosis [6,10,11]. Although, a single exposure to anesthetics within the first 36 months of life has not been shown to cause long-term cognitive impairment in otherwise healthy children, experimental animal studies suggest that protracted exposures may adversely affect cerebral development [12–14]. In addition to the neurotoxicity aspect noted previously, rapid termination of anesthesia after surgery, and thus reduction of controlled ventilation duration, in children with passive pulmonary perfusion has substantial hemodynamic benefits [15]. The shift from controlled to a spontaneous or even assisted ventilation mode in children with univentricular cardiac physiology leads to a major improvement of pulmonary blood flow and oxygenation [15,16]. During controlled ventilation, the pulmonary preload needs to be kept at a high level to ensure passive pulmonary blood flow, accepting significant amounts of volume intake with all the associated negative consequences of fluid overload. These facts have been previously acknowledged. However, on-table extubation (OTE) after pediatric cardiac surgery is not the standard procedure and regularly performed at some centers only [17]. Reasons for commonly performed delayed extubation (DET) after transfer to intensive care unit are various including caution of early postoperative bleeding or concern about difficult to assess and manage combined respiratory and circulatory insufficiency [18,19].

Recently, there has been a discussion regarding whether early extubation may also be beneficial in pediatric patients, potentially improving clinical outcomes, including a 30%–50% reduction in LOS resulting not only in decreased health care expenses, but most notably a reduction of postoperative morbidity [4]. However, standards differ between centers and OTE is performed at a few institutions only [17]. At our center for pediatric cardiac surgery, early OTE has been established. However, both OTE and DET after admission to ICU are still performed. In each case the team makes a joint decision of OTE or DET on a patient-individualized basis including the course of the surgical procedure and hemodynamic situation. The aim of the present retrospective single center analysis was to assess the efficacy and safety of OTE in pediatric cardiac surgical patients. Therefore, we retrospectively analyzed the records of 152 pediatric cardiac surgery cases.

2. Materials and Methods

In accordance to the Declaration of Helsinki and §15 of the Medical Association Nordrheins' professional code of conduct, we performed a retrospective analysis of all pediatric cardiac surgery cases on patients less than or equal to 24 months of age and using cardiopulmonary bypass at the University Medical Center Bonn, Germany, between 1 January 2021 and 31 December 2021. Data analysis was based on medical records and electronic patient file including electronic patient data management system. Inclusion criteria were: age less than or equal to 24 months, elective surgery, and use of cardiopulmonary bypass. Exclusion criteria were: re-surgery, insufficient or missing of relevant data, emergency surgery, and prior to surgery already ventilated children. Hence, 152 patients were included in the study. A total of 7 patients had to be excluded. In 5 patients, the exact time of extubation could not be determined. In one case, the child was already admitted to our center on mechanical ventilation. In one case, despite initial planning of a cardiopulmonary bypass, the surgery was performed without the usage of cardiopulmonary bypass. Finally, 145 cases were included for further analysis. Total ventilation time for DET was defined as intraoperative ventilation and postoperative mechanical ventilation duration in the intensive care unit until extubation. Early extubation was defined as OTE in the operating theatre after surgery.

Cumulative fluid balance and catecholamine dosage related to body weight at the end of surgery and on postoperative days 1–3, as well as duration of intensive care treatment and length of hospital stay (LOS) were evaluated. The vasoactive-inotropic score (VIS) was used to assess and evaluate cumulative catecholamine therapy [20]. The duration of catecholamine therapy was defined as the time from the start of surgery to the end of any inotropes or vasopressors in the OR or ICU. Postoperative fluid balance was related to preoperative body weight in kilograms and expressed in ml/kg. There are three models for stratification of complexity used with similar discriminatory capacity [21]. The present study used the Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery (STAT)-score to assess case complexity and risk for mortality associated with congenital heart surgery.

2.1. Anesthesia and Sedation Protocol

General anesthesia was induced by inhalational of sevoflurane or intravenous injection of propofol and rocuronium (0.3 mg/kg for intubation). After endotracheal intubation, using an age adjusted micro-cuff tube, balanced anesthesia was maintained according to a standardized protocol using sevoflurane (minimum alveolar concentration 0.5%) and remifentanil (10–20 mcg/kg/h). Standard monitoring was used, including electrocardiogram (ECG), non-invasive blood pressure, O2 saturation, temperature, invasive blood pressure, near-infrared spectroscopy (NIRS), and bi-spectral index (BIS). In the OTE group, patients received piritramide (0.2 mg/kg) before propofol and remifentanil infusions were terminated at the end of the surgery. Subsequent analgesia was performed using piritramide (0.05 mg/kg every 4 h) and paracetamol (10 mg/kg every 6 h). Medications were given oral beginning on postoperative day 2. For the DET group, at the end of the surgery, patients were sedated during transfer and admission on ICU using remifentanil (10–20 mcg/kg/h) and propofol (5–10 mg/kg/h). Piritramide (0.05 mg/kg every 4 h) and paracetamol (10 mg/kg every 6 h) were started before extubation and termination of remifentanil and propofol infusions. Sufentanil (1–3 mcg/kg/h), midazolam 0.1–0.3 mg/kg/h), and ketamin (1 mg/kg) were given patients requiring prolonged sedation. Additional analgesics were given if patients showed signs of pain or stress.

2.2. Statistical Analyses

Statistical analyses were performed using SPSS 28 (SPSS Inc., Chicago, IL, USA) and the statistical programming environment R version 4.1.2 (Foundation for Statistical Computing, Vienna, Austria). Descriptive statistics are presented as mean ± standard deviation (SD) for symmetric continuous variables or median with inter-quartile range (IQR) for skewed variables. In the exploratory data analysis, differences between treatment groups (OTE vs. DET) were determined using two-sample *t*-test or non-parametric rank-based Mann-Whitney tests for skewed data. To account for potential confounders affecting the treatment decision and potential outcomes, propensity score-matching was performed based on logistic regression with the variables age, weight, complexity of performed procedure using STAT-Sore as well as duration of cardiopulmonary bypass. Based on nearest neighbor matching, for every OTE patient one control (DET) patient was selected via the corresponding propensity score leading to an equal number of controls and cases [22]. Performance of the matching procedure was assessed graphically via group differences in the matching variables before and after the approach was performed. After matching, differences between treatment groups were assessed using Wilcoxon signed rank test for paired differences. As our approach represents an exploratory analysis of observational data, we refrained from adjusting the typical two-sided significance level of 0.05 for multiple testing [23].

3. Results

A total of 43 of the 145 patients (29.6%) were OTE in the OR while 102 (70.3%) were DET during intensive care treatment. Ventilation duration was significant shorter in patients

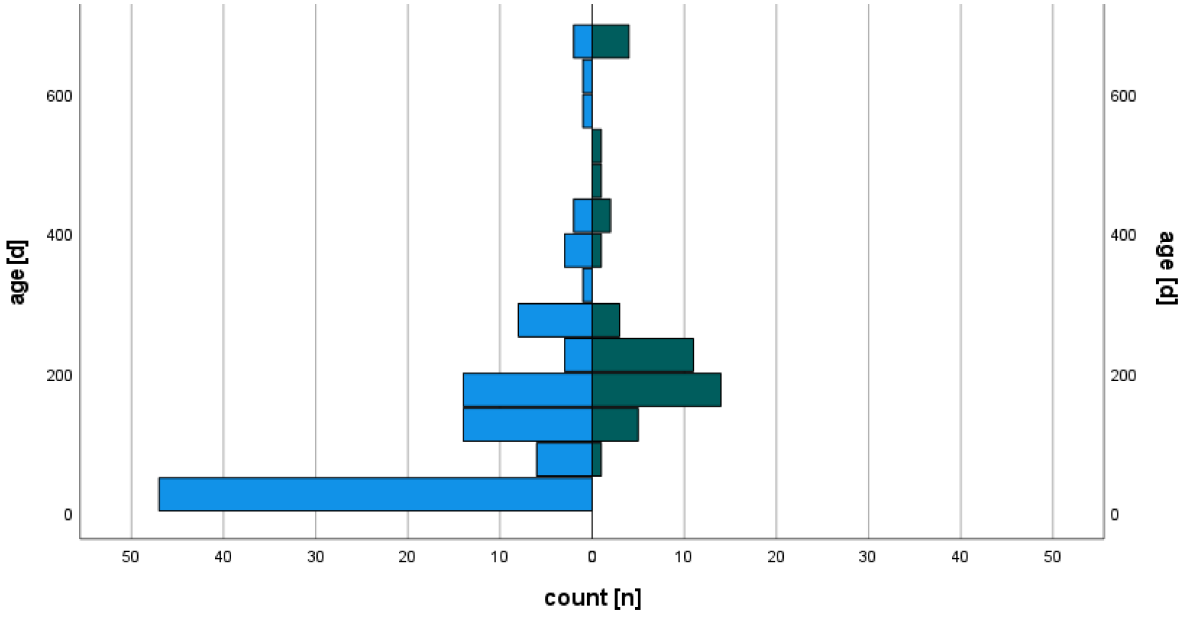
that were OTE compared to DET patients (5.7 ± 1.5 OTE vs. 103.3 ± 97.1 DET hours mean ± SD, $p < 0.0001$). Furthermore, reintubation during the course of postoperative intensive care treatment occurred in one OTE patient due to re-surgery for bleeding complication and 10 DET patients all due to respiratory complications.

Demographics and intraoperative characteristics differed significantly between OTE and DET group. On table extubated children were significantly older (267 ± 163 OTE vs. 127 ± 148 DET days mean ± SD, $p < 0.0001$), had a higher body weight (7.0 ± 1.6 OTE vs. 4.9 ± 1.9 DET kg mean ± SD, $p < 0.0001$), and were larger (68 ± 8 OTE vs. 59 ± 8 DET cm mean ± SD, $p < 0.0001$) compared to children that were DET during intensive care treatment (Figure 1a–c).

Furthermore, the duration of surgery was significantly shorter in the OTE group compared to DET group (237 ± 61 OTE vs. 323 ± 81 DET min mean ± SD, $p < 0.0001$). Similarly, cardiopulmonary bypass duration was significantly shorter in the OTE group compared to DET group (119 ± 54 OTE vs. 162 ± 62 DET min mean ± SD, $p < 0.0001$).

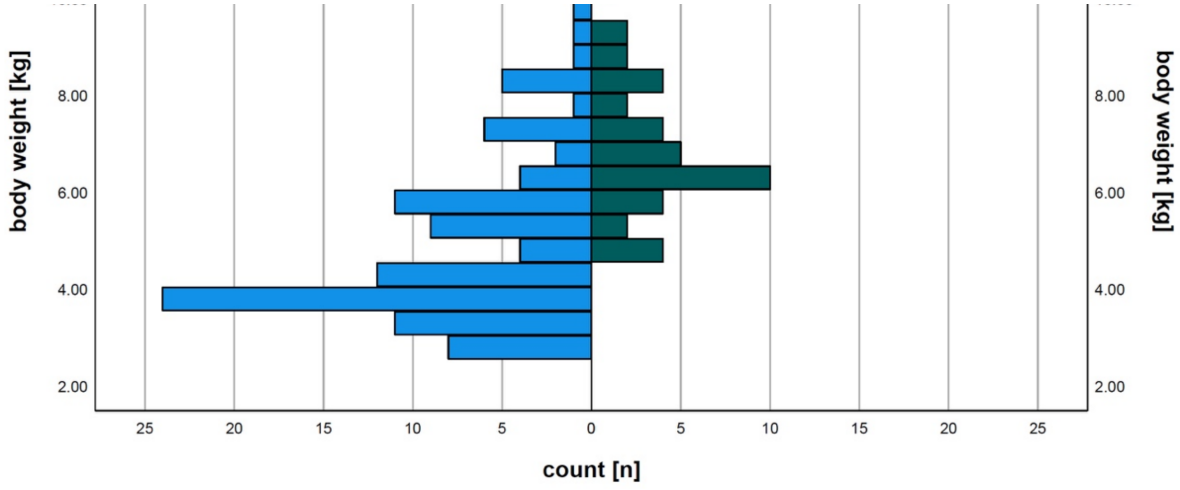
Patients in the OTE group received significantly fewer RBC transfusions (35 ± 16 OTE vs. 75 ± 39 DET ml/kg, mean ± SD, $p < 0.0001$) and fewer crystalloid fluids substitutions (63 ± 563 OTE vs. 109 ± 82 DET ml/kg, mean ± SD, $p < 0.0001$) compared to DET group relative to absolute body weight. After the intraoperative fluid loading, patients in the DET group showed greater negative fluid balances during the postoperative course (Figure 2).

Catecholamine dosages were not different between groups prior to surgery (1.5 ± 2.7 OTE vs. 3.1 ± 4.8 DET VIS score, mean ± SD, $p = 0.106$). However, catecholamine dosages represented by the VIS score were significantly lower in OTE compared to DET patients during the postoperative period (Figure 3). Furthermore, weaning from catecholamine therapy was much faster in OTE patients compared to DET patients (48.6 ± 52.9 OTE vs. 155.6 ± 147.7 DET h, mean ± SD, $p < 0.0001$). Length of hospital stay (LOS) (11 ± 10 OTE vs. 20 ± 23 DET d, mean ± SD, $p = 0.001$) and duration of intensive care treatment (76 ± 57 OTE vs. 217 ± 211 DET h, mean ± SD, $p < 0.0001$) were significantly shorter in OTE patients compared to DET patients (Figure 4).



(**a**)

Figure 1. *Cont.*



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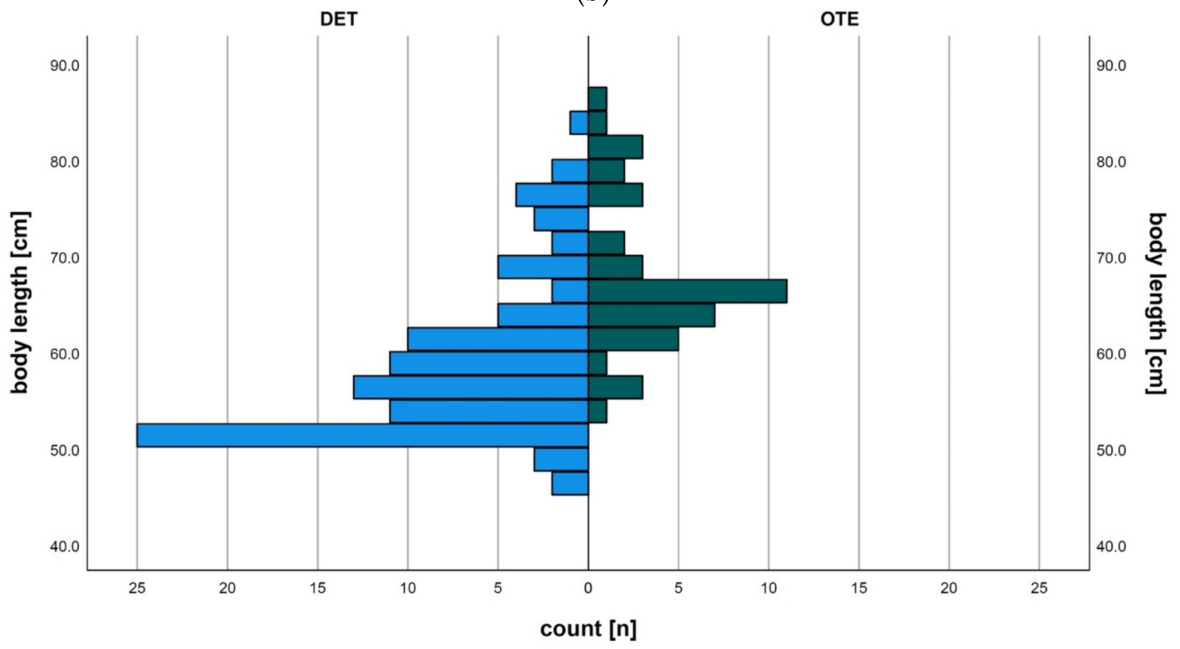

(**c**)

Figure 1. Population pyramid illustrates the distribution of patients in relation to (**a**) age (days of life); (**b**) body weight (kg); (**c**) height (cm). Blue bars represent delayed extubation group (DET) versus on-table extubation (OTE) green bars.

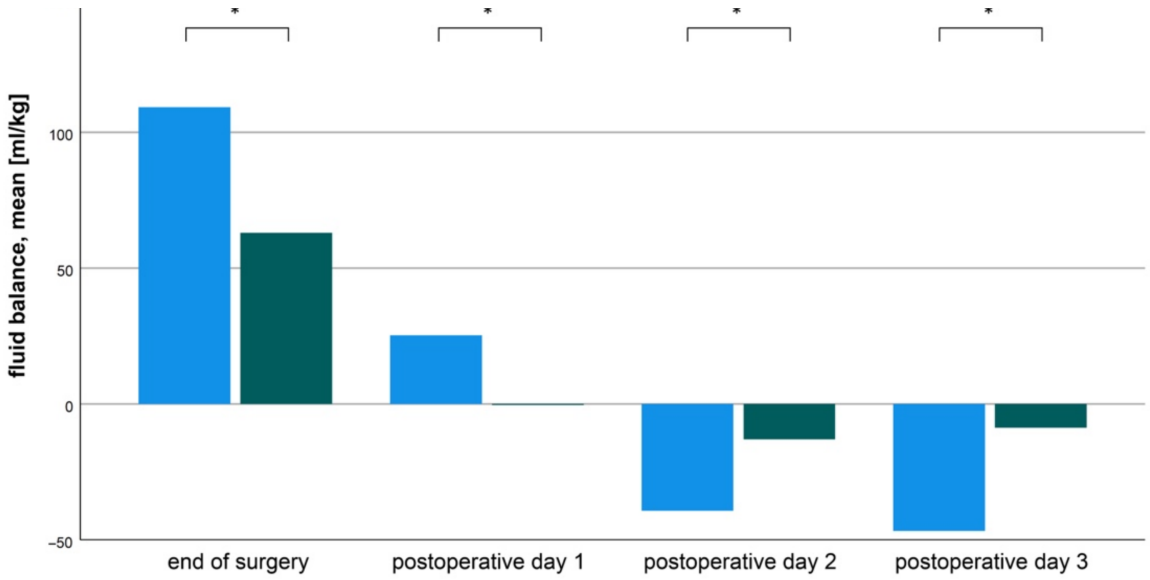

Figure 2. Perioperative fluid balance analysis revealed that the patients in the delayed extubation DET) group had significantly higher fluid shifts than the patients in the on-table extubation (OTE) group. In the diagram the mean fluid balance is shown. The columns represent the mean fluid balance at the time of end of surgery, 1st 2nd and 3rd postoperative day. Blue columns represent the DET group, green columns represent the OTE group. All differ significantly * $p < 0.0001$.

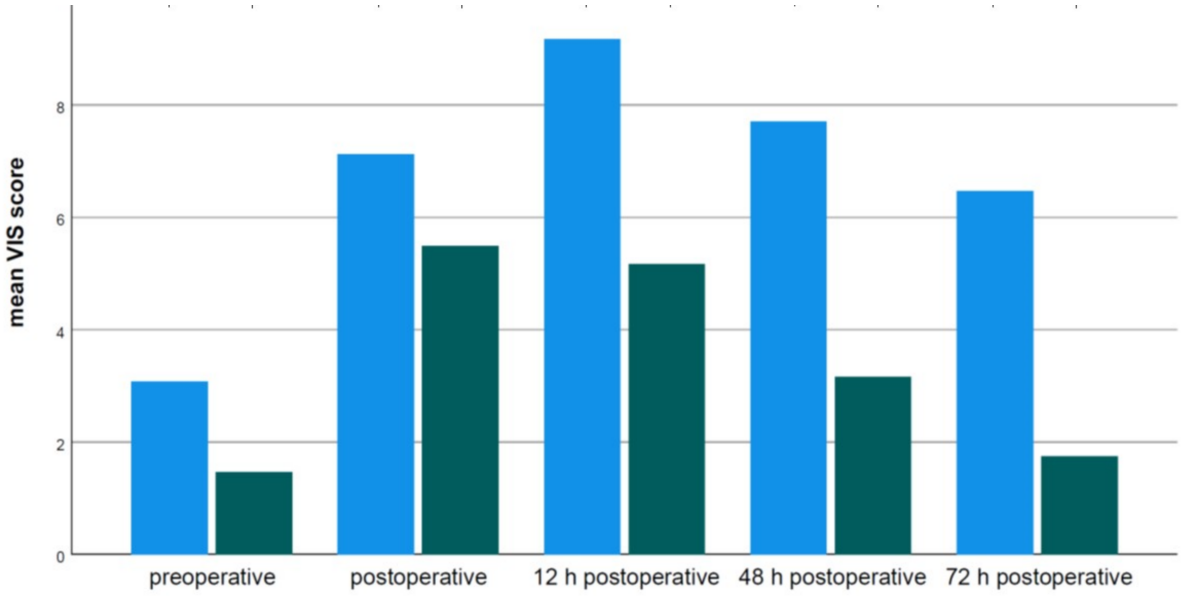

Figure 3. Mean vasoactive-inotropic score (VIS) in delayed extubation (DET) group (blue bars) and on-table extubation (OTE) group (green bars) preoperative, postoperative, 12 h postoperative, 48 h postoperative, 72 h postoperative. n.s. not significant, * $p < 0.05$, ** $p < 0.001$.

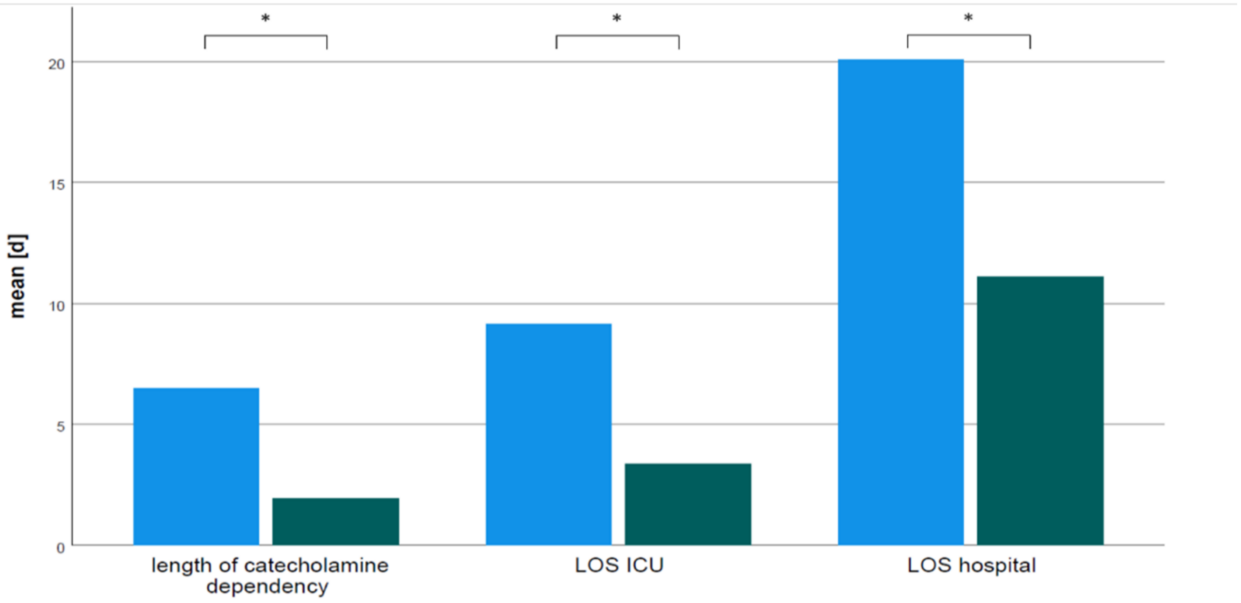

Figure 4. Mean duration of catecholamine dependency, intensive care therapy LOS ICU), and length of hospital stay (LOS hospital) in delayed extubation (DET) group (blue bars) and on-table extubation (OTE) group (green bars). All differ significantly * $p < 0.0001$.

Perioperative inflammatory markers were assessed beginning prior to surgery and daily until day three. Leucocytes and CRP (C-reactive protein) were not different between groups prior to surgery. Leucocytes and CRP increased in both groups after surgery. However, there was no difference observed between DET or OTE during the consecutive postoperative course until day three (Table 1).

Table 1. Perioperative markers of inflammation.

Variable	Total		DET		OTE			
	Mean	SD	Mean	SD	Mean	SD	*p*-Value	Missing
Leukocytes preOP [g/L]	10.5	3.5	10.7	3.5	10.1	3.3	0.341	6
Leukocytes postOP [g/L]	12.1	4.4	12.5	4.8	11.4	3.1	0.365	0
Leukocytes postOP day 1 [g/L]	12.1	4.4	12.5	4.8	11.3	3.1	0.261	3
Leukocytes postOP day 2 [g/L]	13.6	9.3	13.0	4.2	14.9	15.8	0.627	2
Leukocytes postOP day 3 [g/L]	10.2	3.7	10.2	3.7	10.3	3.7	0.710	4
CRP preOP [mg/dL]	3.5	11.7	4.3	13.9	1.7	2.7	0.277	8
CRP postOP day 1 [mg/dL]	24.5	25.2	24.4	28.3	24.9	16.4	0.313	14
CRP postOP day 2 [mg/dL]	59.9	48.5	63.4	51.1	52.2	41.6	0.212	8
CRP postOP day 3 [mg/dL]	64.6	60.3	69.6	62.1	53.2	54.8	0.082	13

DET delayed extubation time, OTE on-table extubation, preOP preoperative, postOP postoperative, C-reactive protein (CRP).

Pathologies differed significantly between OTE and DET groups with some procedures only extubated after admission to ICU (Supplemental 1). The impact of the type of surgical procedure and/or the degree of complexity of the surgical intervention on the decision of OTE or DET was evaluated on the basis of the STATS-score. Children exhibiting a higher STATS-score were significantly more likely to be DET during intensive care treatment (Figure 5).

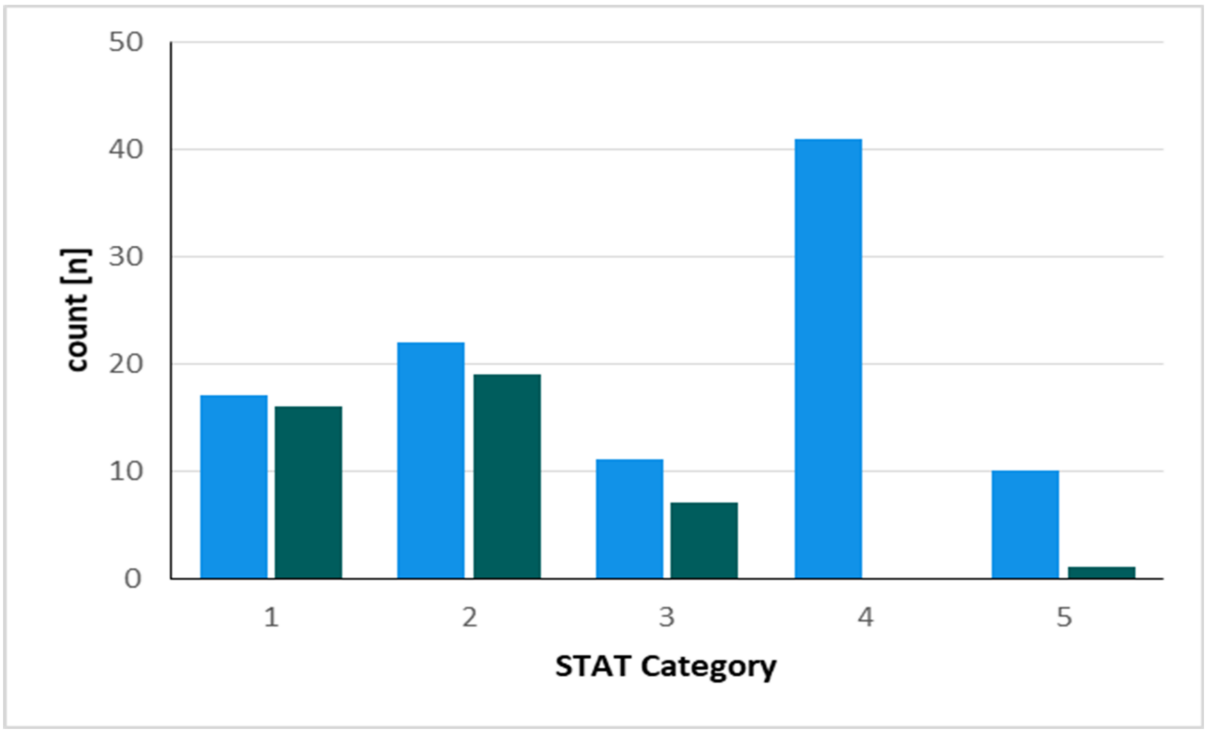

Figure 5. The distribution of cases according to the Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery Mortality (STAT) category is shown. Blue columns represent the absolute number of cases in the DET group, the green columns represent the cases in the OTE group.

To evaluate the impact of potential confounders on the postoperative outcome we performed propensity score matching followed by "nearest neighbor" procedures for similar cases. We matched general demographics such as age and weight, and indicators of surgery such as complexity of performed procedure using STAT-Score as well as duration of cardiopulmonary bypass. Duration of intensive care treatment and catecholamine therapy remained significantly shorter in OTE patients compared to DET patients after propensity score matching (Figure 6), while the difference regarding general LOS no longer reached statistical significance ($p = 0.095$).

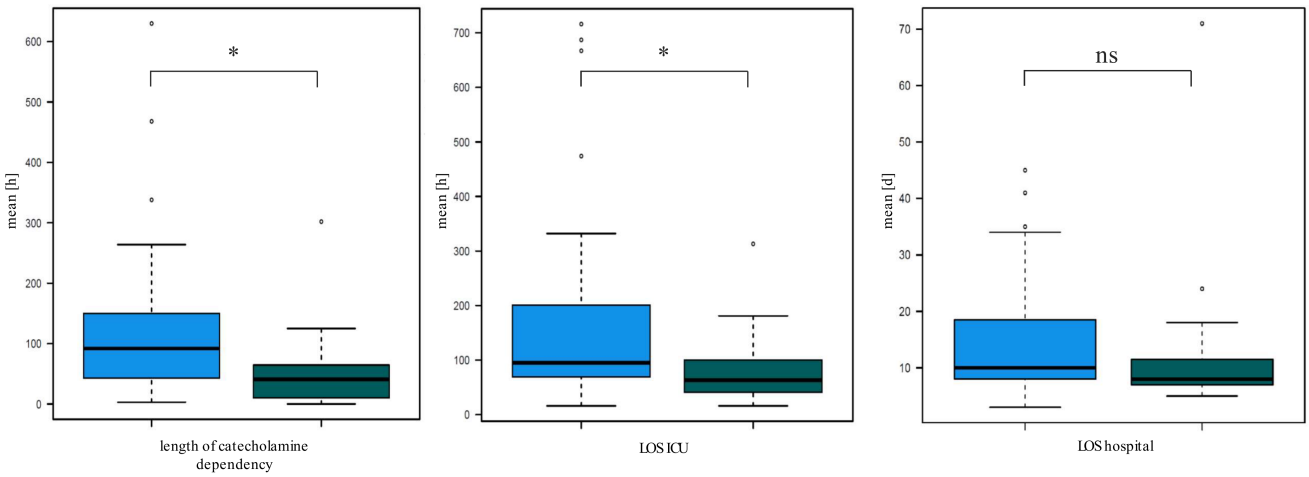

Figure 6. Duration of catecholamine dependency ($p < 0.001$), duration of intensive care therapy ($p < 0.001$), and length of hospital stay ($p = 0.095$) in delayed extubation DET group (blue bars) and on-table extubation OTE group (green bars) after propensity score matching, n.s. not significant, * $p < 0.05$.

4. Discussion

On-table extubation is nowadays an established part of enhanced recovery protocols after pediatric cardiac surgery [17], but the frequency of performing OTE significantly differs between pediatric cardiac surgery centers even with comparable patient collectives and cases [24]. On-table extubation has been performed with an increasing frequency at our institution in recent years. However, which patients benefit most from early extubation, and in which patients an early extubation strategy leads to increased risk for perioperative complications has not been objectively evaluated [18,19]. Therefore, the aim of this study was to assess, whether on table extubation is a safe procedure and to evaluate potential benefit from early extubation.

To evaluate the safety and potential benefits of OTE, we retrospectively reviewed infants up to 24 months of age that received pediatric cardiac surgery using cardiopulmonary bypass. Using these inclusion criteria, we have already selected a higher-risk collective, especially due to early age and usage of extracorporeal circulation. Our data indicate that successful early extubation was predominantly performed in infants with an advanced age, body weight, and height as well as lower cardiopulmonary bypass durations. This observation is conclusive because the youngest and smallest children that receive the most complex procedures with extended surgical duration are exposed to longest cardio pulmonary bypass duration and represent the highest risk population. These results are is in line with the work of Winch et al., who analyzed 416 children that underwent congenital cardiac surgery within the first year of life to assess predisposing factors for a successful early extubation [25]. Early extubation in the operating room could successfully be performed in 56% of the children, whereas 10% required reintubation, most frequently within the first 24 h. Although the infants were younger than the patients in our study, Winch et al. reported a higher extubation rate compared to our data. However, this was associated with an increased re-intubation rate that was also in contrast to our results. Our reported OTE rate is comparable to Varghese et al., who reported an OTE rate of 30.4% in a group of 148 patients after cardiac surgery with a mean age of seven days [26]. Also consistent with our data, this study demonstrated that children who were extubated early had a significantly shorter duration of ICU treatment.

Furthermore, children in the OTE group had significantly less volume shifts intraoperatively as well as during the postoperative course. Interestingly, despite the clinically more favorable course in the OTE group, no difference was observed in perioperative markers of inflammation. We can only speculate that the main impact of the surgical procedure was on the expression of systemic inflammatory markers and that the benefit of shorter duration of ventilation and reduced catecholamine therapy is secondary in this regard.

As a surrogate for morbidity, we selected the duration of intensive care therapy and the hospital length of stay. ICU treatment and length of hospital stay were both significantly reduced in OTE patients compared to DET children which is in line with Varghese et al. [26]. For a more detailed consideration of intensive therapy, we focused on the amount and duration of cathecholamine therapy using the VIS score [20]. Patients in the OTE group showed significantly lower VIS scores as well as a shorter duration of catecholamine therapy, indicative of a more stable cardiovascular situation.

Significant demographic and procedural differences between the OTE and DET group need to be acknowledged and raised the question to what extent the favorable postoperative courses were a result of older age, higher somatometric parameters, lower exposition of cardiac surgical stress factors such as surgery and/or CPB time or a result of the early extubation itself. Therefore, we performed propensity score matching for the variables age, weight, complexity of performed procedure using STAT-Sore as well as duration of cardiopulmonary bypass to exclude demographical and procedural differences between groups. After correction for these variables, the outcome parameters duration of intensive care treatment and catecholamine therapy remained statistically significantly reduced in favor of the OTE group, while length of hospital stay did not reach statistical significance.

In one collective of patients, the benefit of early extubation strategy is obvious, based on pathophysiologic considerations. It is well known that positive pressure ventilation has a harmful impact on pulmonary blood flow in patients with Fontan physiology. Therefore, there is strong evidence that in these patients rapid transition to spontaneous breathing improves pulmonary blood flow and thus hemodynamics [15]. It is likely that this might also be the case in patients undergoing Glenn procedure. However, even in these congenital heart defects, where the benefits of early extubation are obvious, the degree to which early extubation is currently performed varies considerably between centers due to preferences or traditions [24]. Our collective included 11 children with Glenn procedure. However, children scheduled for Fontan completion were not included, because this procedure is frequently performed in children over 24 months of age. Of the 12 children who underwent Glenn surgery, 58.33% were extubated in the operating room. Considering the current state of knowledge, it is not clear whether good initial conditions make early extubation possible and subsequently lead to positive outcome, or if early extubation itself has positive impact on clinical course. It could be assumed that especially the infants with low individual and operative risk factors are suitable for early extubation and therefore may have a favorable perioperative course. In our study, we found that OTE was very uncommon in newborns and younger infants with an elevated STATS-score. We speculate that these children in particular represent a special risk collective. However, there were also infants in our study with increased age, increased weight and short bypass times who did not undergo on-table extubation. The question arises why these children were not assigned to an OTE. Another reason for delayed extubation might be a higher STATS-score. Complex cardiac defects or surgical procedures of high complexity were significantly less likely to be extubated on-table. For example, in our study, no infant who underwent a Norwood procedure was extubated on the table. According to a survey of our group in Germany, no on-table extubations are performed after Norwood procedures [17].

Risk classifications such as the STATS-score have been developed to assess this perioperative risk [21]. Early extubations were predominantly performed in STATS-score 1–3, with almost no OTE performed in groups 4 and 5. This reflects the higher level of complexity of the operations in these categories as well as the higher disease burden of the patients. Some physicians do not recommend early extubation in neonates due to the relatively horizontal alignment of the ribs, weak intercostal muscles, narrow subglottic portion, and post-anesthetic apnea [27,28]. In order to consider the influence of possible confounding variables, we performed a propensity score matching, which adjusted for the variables age, weight, complexity of performed procedure using STAT-Sore, as well as duration of cardiopulmonary bypass and considered the nearest neighbor. After matching, both groups were comparable. Outcomes regarding catecholamine therapy, and ICU LOS remained significantly in favor of the OTE group. However, especially in pediatric cardiac surgery, it is difficult to assess the perioperative risk exclusively due to the surgical procedure performed or the underlying heart defect. Within a single diagnosis of a congenital heart defect, such as a ventricular septal defect, there might be a wide range of possible conditions with very different complications and courses. We intended to address this by considering confounding variables, but we are aware that this will remain incomplete in this complex patient population. Nevertheless, our study showed that OTE is associated with a favorable perioperative course. Although in this study, we do not address the adverse effects of prolonged sedation and mechanical ventilation in a particularly vulnerable patient population, the adverse effects of prolonged sedation and prolonged mechanical ventilation in infants are obvious and should therefore be prevented whenever possible.

5. Conclusions

Our study indicates that, in pediatric cardiac surgery, OTE is safe and associated with a favorable postoperative course, including fewer catecholamine requirements and shorter duration of ICU therapy.

Author Contributions: Conceptualization, T.B. and M.V. (Markus Velten); data curation, T.B., P.P., E.S., M.H., M.V. (Mathieu Vergnat) and B.A.; formal analysis, A.K. and A.M.; investigation E.S. and M.W.; project administration, M.V. (Mathieu Vergnat), M.W. and N.S.-N.; supervision, M.V. (Markus Velten) and M.W.; visualization, T.B.; writing—original draft, T.B.; writing—review & editing, M.V. (Markus Velten). All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review of the Rheinische Friedrich-Wilhelms-University Bonn (protocol code 383/19, day of approval 13 December 2019).

Informed Consent Statement: Patient consent was waived due to the retrospective nature of the investigation.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

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3.4 Publication 4: Point-of-Care Ultrasound-Guided Protocol to Confirm Central Venous Catheter Placement in Pediatric Patients Undergoing Cardiothoracic Surgery: A Prospective Feasibility Study

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Article

Point-of-Care Ultrasound-Guided Protocol to Confirm Central Venous Catheter Placement in Pediatric Patients Undergoing Cardiothoracic Surgery: A Prospective Feasibility Study

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Abstract: Background: Central venous catheters (CVC) are commonly required for pediatric congenital cardiac surgeries. The current standard for verification of CVC positioning following perioperative insertion is postsurgical radiography. However, incorrect positioning may induce serious complications, including pleural and pericardial effusion, arrhythmias, valvular damage, or incorrect drug release, and point of care diagnostic may prevent these serious consequences. Furthermore, pediatric patients with congenital heart disease receive various radiological procedures. Although relatively low, radiation exposure accumulates over the lifetime, potentially reaching high carcinogenic values in pediatric patients with chronic disease, and therefore needs to be limited. We hypothesized that correct CVC positioning in pediatric patients can be performed quickly and safely by point-of-care ultrasound diagnostic. Methods: We evaluated a point-of-care ultrasound protocol, consistent with the combination of parasternal craniocaudal, parasternal transversal, suprasternal notch, and subcostal probe positions, to verify tip positioning in any of the evaluated views at initial CVC placement in pediatric patients undergoing cardiothoracic surgery for congenital heart disease. Results: Using the combination of the four views, the CVC tip could be identified and positioned in 25 of 27 examinations (92.6%). Correct positioning was confirmed via chest X-ray after the surgery in all cases. Conclusions: In pediatric cardiac patients, point-of-care ultrasound diagnostic may be effective to confirm CVC positioning following initial placement and to reduce radiation exposure.

Keywords: central venous catheter 1; point-of-care ultrasound 2; pediatric cardiac anesthesia 3

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1. Introduction

Central venous catheters (CVC) are commonly required in neonatology and pediatric intensive care patients, and ultrathin single-lumen catheters are preferably used. However, during high-risk procedures, such as congenital cardiac or major pediatric surgeries, multilumen CVC with larger diameters, analogous to those used in adult perioperative medicine, are required to perform differentiated drug therapies and perfuse higher volumes. While various central veins are feasible to access, the most common puncture site for CVC in pediatric anesthesia for congenital heart surgery in Germany is the internal jugular vein [1]. Point-of-care verification of CVC positioning is not standardized in pediatric patients and correct positioning is usually verified postoperatively by X-ray [2]. However, incorrect positioning of the catheter may induce serious complications, such as extravasation, pleural and pericardial effusion, arrhythmias, valvular damage, or incorrect drug release before correct CVC positioning is verified post-surgery [3,4]. Therefore, timely point of care

diagnostics, preferably without exposing the patient to radiation, and position verification immediately after introduction or during insertion may have enormous advantages and would be desirable for correct positioning of the catheter tip, preventing potential deleterious consequences.

Ultrasound-guided techniques of correct CVC tip positioning, e.g., a method of direct ultrasound tip position of CVC using a microconvex probe, have been described in adult perioperative patients and are already established in the clinical routine [5].

Central venous puncture is nowadays ultrasound guided at the majority of pediatric heart centers [1]. However, existing formulas calculating depth of insertion based on body dimensions are unreliable, especially in children with pathologic heart dimensions or abnormal anatomy [6]. For example, in cases of extreme cardiomegaly, the CVC may be inserted too deep after only a few centimeters.

At our center, puncture of the central vessel is also performed under continuous ultrasound guidance. Our research group has found that ultrasound can also be used to monitor the intrathoracic position of the CVC tip, especially in young children. Jugular, parasternal, and subcostal ultrasound windows have proven to be favorable.

The relatively large glandular tissue of the thymus provides a very good acoustic window for the central intrathoracic vessels, especially in young children who have not undergone previous thoracic surgery. It is also favorable that the large thymic tissue in young children displaces the lung parasternal and therefore provides a good view of the central vessels. Another favorable circumstance is that the thorax in the infant is largely cartilaginous, and thus no sound cancellation by bone complicates ultrasound diagnosis.

Therefore, the aim of the present study was to test the hypothesis that CVC placement and tip confirmation can safely be performed via point-of-care ultrasound visualization, reducing radiation exposure in pediatric patients undergoing cardiothoracic surgery.

2. Materials and Methods

To evaluate the safety and feasibility of ultrasound-guided CVC placement and tip positioning in pediatric patients undergoing cardiothoracic surgery, the following examination protocol has been developed based on our daily routine. The ideal position of the CVC tip is the junction of the superior vena cava (SVC) and the right atrium (RA). Consecutively, from the two parasternal, the suprasternal notch, and the subcostal view, the SVC, the CVC tip itself, and the right pulmonary artery (RPA) have been attempted to be identified. If the junction of the superior vena cava into the right atrium could not be identified, the RPA was used as an accessory structure. The RPA is in direct anatomic relation to the junction of the superior vena cava with the right atrium [7].

The present prospective study was conducted at the pediatric cardiac surgery suite and pediatric cardiac ICU at the University Hospital Bonn, Germany. The study was performed in accordance with the principles expressed in the Declaration of Helsinki and after approval by the institutional revenue board (IRB) at the Rheinische Friedrich-Wilhelms-University Bonn (protocol No. 159/14). Nineteen children, ranging from 3 days old to 4 years of age and weighing between 2.55 and 16 kilograms in body weight, that underwent pediatric cardiac surgery for congenital heart disease, were included. The sample size was calculated based on previous studies' evaluations on CVC tip positioning in adult patients [5].

Children requiring a CVC for cardiac surgery were included and evaluations were performed by anesthesiologists highly experienced in both pediatric cardiac anesthesia and vascular ultrasound. A total of 28 examinations were performed on 19 children. Ten children were examined by one examiner, and nine children were examined by two examiners and were assessed separately.

After induction of general anesthesia, the children received a CVC according to the standard in-hospital procedure using ultrasound-guided puncture of the right jugular venae. The primary depth of insertion of the CVC was calculated based on the child's height using the following formula: primary insertion depth (cm) = body length (cm)/10.

Subsequently, using a standard examination procedure with the above-mentioned 4 ultrasound views, an attempt was made to identify the following structures: superior vena cava, right pulmonary artery, and the CVC tip (Figure 1).

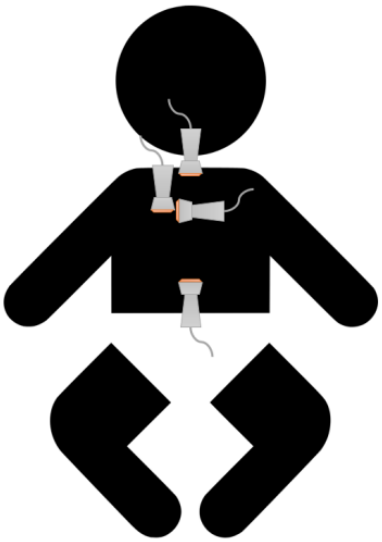

Figure 1. Schematic view of the four probe positions.

The examiner had to rate the visualization of the identified structures and duration of the assessment on a five-point scale. This five-point scale was defined as follows:

Class 1	Structures can be reliably identified, sharp and complete contour, prompt display
Class 2	Structures can be delineated, not reliably complete, no prompt display
Class 3	Structures incompletely identified, only after image optimization, delayed visualization
Class 4	Structures insufficiently identified after image optimization, strongly delayed visualization
Class 5	Structures not visualized

After distinct visualization of the CVC tip in the SVC, the catheter was corrected for position.

Echo views: here, we describe the 4 probe positions and subsequent views that were evaluated in the present manuscript for CVC placement and tip confirmation (Figure 1).

- First view: parasternal craniocaudal view

A linear transducer, or hockey stick, was used for the assessment of the parasternal view. The transducer was positioned in the 3rd intercostal space right parasternal with the transducer index mark parallel to the sternum. The superior vena cava (SVC) is present in the longitudinal section; the junction of the SVC with the right atrium is depicted and the CVC is visible in the SVC (Figure 2).

- Second view: parasternal transversal view

A linear transducer, or hockey stick, was used. From the previous position, the probe was rotated 90 degrees. The SVC was visualized in the cross-section, with the brachiocephalic trunk (BCT) and the right carotid artery. The right pulmonary artery (RPA) can be seen longitudinally (Figure 3).

- Third view: suprasternal notch view

A cardiac sector transducer was primarily used. The use of a linear transducer/hockey stick is also possible in young children. The limiting factor is the penetration depth of the linear transducer or hockey stick. The connection from the right internal jugular vein to the innominate vein (Innom V) can be seen. Ideally, the junction into the right atrium and the distal ascending aorta in the cross-section are also visualized (Figure 4).

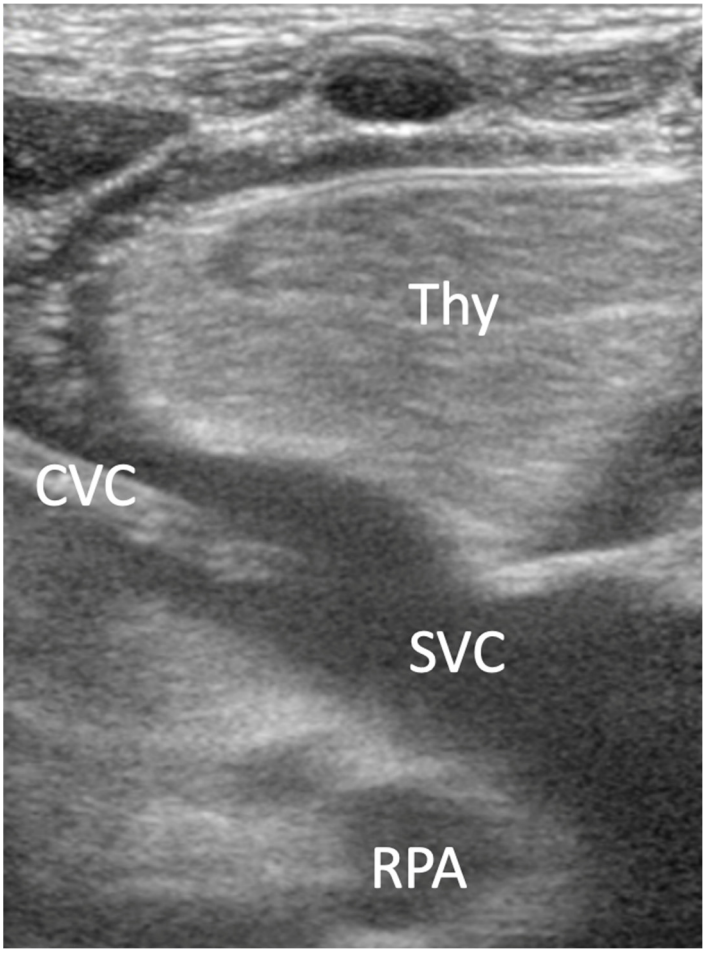

Figure 2. Parasternal craniocaudal view: thymus (Thy), central venous catheter (CVC), superior venae cava (SVC), right pulmonary artery (RPA).

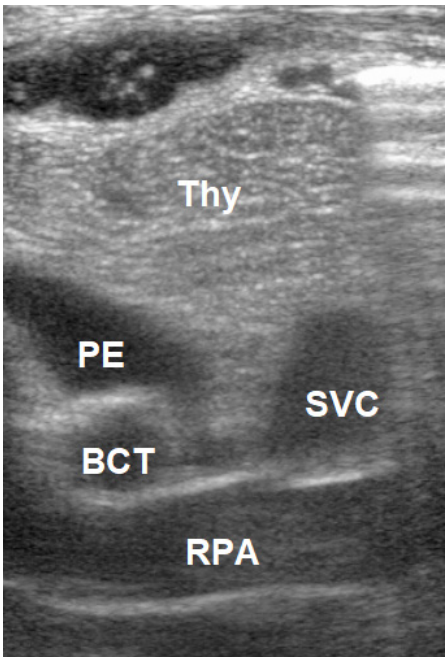

Figure 3. Parasternal transversal view: superior venae cava (SVC), brachiocephalic trunk (BCT), right pulmonary artery (RPA), pericardial effusion (PE).

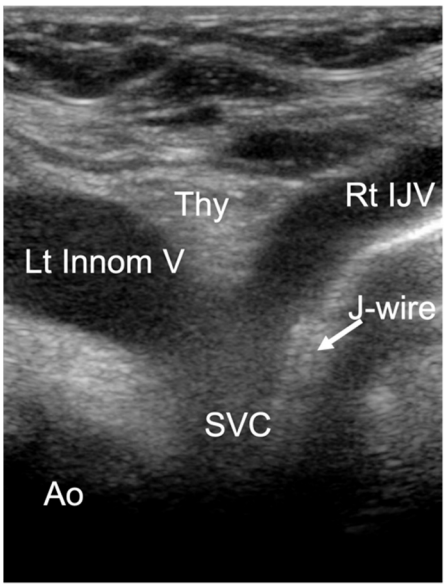

Figure 4. Suprasternal notch view: superior vena cava (SVC), right internal jugular vein (Rt IJV), left innominate vein (Lt Innom V), aorta (Ao), thymus (Thy).

- Fourth: subcostal view

A cardiac sector transducer was primarily used. The use of a linear transducer/hockey stick might also be possible in young children. The limiting factor is the penetration depth of the linear transducer or hockey stick.

View from subcostal, a four-chamber view can be seen. By tilting the transducer, the superior vena cava is displayed in a longitudinal section, and the entry of the superior vena cava into the right atrium is clearly visible (Figure 5). A PW Doppler signal can be placed in the confluence of the superior vena cava to the atrium and a vena cava flow signal can be detected.

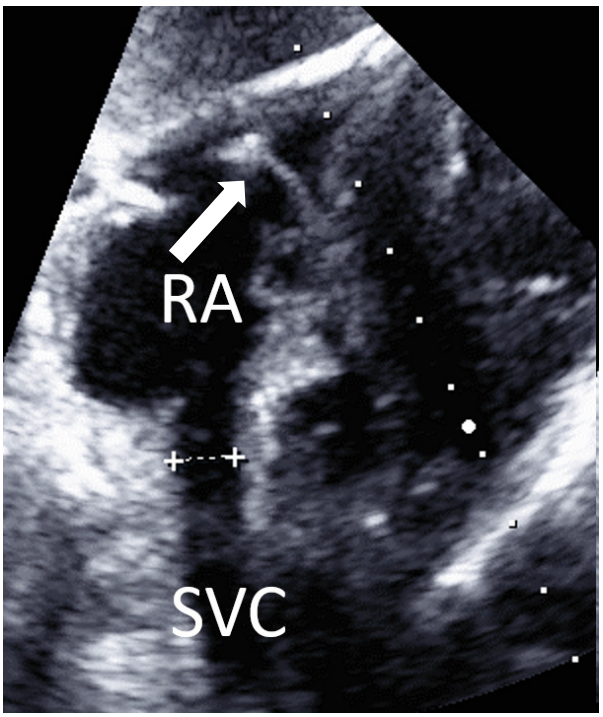

Figure 5. Subcostal view: superior vena cava (SVC) and right atrium (RA). Arrow: J-wire in RA. Caliper indicates SVC diameter.

3. Results

The present study included children aged between 2 days and 54 months. The mean age was 8.9 months, and the mean body weight was 5.8 ± 3.5 kg with a range between 2.5 and 16 kg (Table 1). In all children, the CVC was successfully inserted into the right internal jugular vein. In all cases, the position of the CVC was verified postoperatively by chest X-ray. Additionally, positioning was intraoperatively verified by the surgeon through visual inspection during opening of the cardiac structures, or by palpation of the CVC tip in the SVC. The mean insertion depth was 0.13±0.02cm/cm body height (Table 1).

Table 1. Patients' characteristics.

	Mean	SD	Range
body weight (kg)	5.8	3.46	2.55–16
body height (cm)	65	16	50–109
age (months)	8.9	15	0.007–53.37
insertion depth (cm)/body height (cm)	0.13	0.02	

Ten children had no previous surgical procedures, while the remaining nine children had undergone surgery previously. Due to the procedure or individual reasons, not each of the four views could be obtained in all children. In one child, the parasternal and jugular views were not performed, and in two other children, the suprasternal view was not performed. However, most views have been performed in all patients included in our study. The most successful visualization of the superior vena cava was from subcostal (88%), followed by the suprasternal notch (87%), and the parasternal transversal view in (74%) of the cases (Table 2).

Table 2. Echocardiographic evaluation.

Parasternal Craniocaudal View	*n*	Sufficiently Identifiable		Mean Classification	SD
SVC	27	17	63%	1.94	17
CVC tip	27	11	41%	1.64	11
RPA	27	12	44%	2.25	12
Parasternal transversal view	*n*	sufficiently identifiable		mean classification	SD
SVC	27	20	74%	2.10	20
CVC tip	27	11	41%	1.73	11
RPA	27	13	48%	2.31	13
Suprasternal notch view	*n*	sufficiently identifiable		mean classification	SD
SVC	23	20	87%	1.75	20
CVC tip	23	5	22%	2.60	5
RPA	23	6	26%	2.17	6
Subcostal view	*n*	sufficiently identifiable		mean classification	SD
SVC	24	21	88%	1.38	0.65
CVC tip	24	19	79%	1.53	0.68
RPA	24	18	75%	2.17	0.76

superior vena cava (SVC), central venous catheter (CVC) tip, right pulmonary artery (RPA).

Although visualization of the SVC from the parasternal transversal view and suprasternal notch view was easy to achieve, the tip of the CVC could only be identified in 41% and 22% of the cases, respectively. Similarly, identification of the right pulmonary artery was possible from the suprasternal view in only 26% of the cases.

The most reliable visualization of all structures from one view was achieved from the subcostal view. From the subcostal view, the superior vena cava was visible in 88% of the cases, the CVC tip in 79%, and RPA in 75% of the cases.

Particularly in pre-operated children, the parasternal views were significantly more difficult or even impossible to achieve. The visualization of the structures in these cases was more frequently classified as poor or not possible. Thus, in none of the nine children

with previous sternotomy, neither the CVC tip, nor the right pulmonary artery could be reliably visualized in the parasternal views (Figure 6a,b).

In summary, using the combination of the four views, all structures have clearly been visualized in the majority of the children and the CVC tip could be identified and positioned in 25 of 27 examinations (92.6%). Correct positioning was confirmed via chest X-ray after the surgery in all cases.

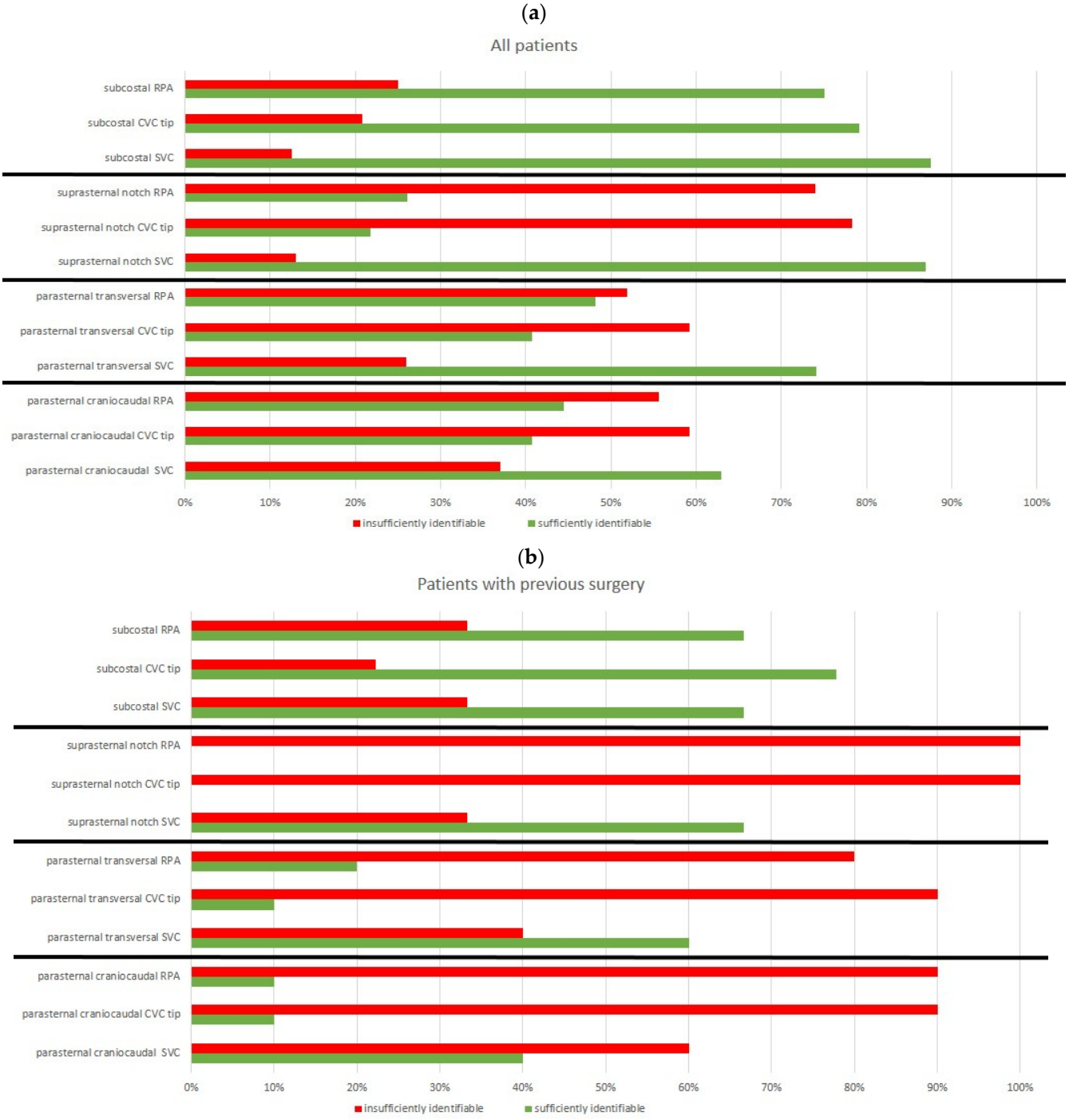

Figure 6. Visualization of CVC tip and anatomical structures in all patients (**a**) and patients with previous surgery (**b**), (% all patients in respective group).

4. Discussion

Ultrasound-guided puncture of central vessels is an accepted standard procedure for the insertion of central venous catheters in adult as well as in pediatric patients, preventing incorrect puncture and damage to proximate structures as well as arterial puncture [8–11].

Formulas calculating the insertion depth are commonly used in pediatric patients but are very imprecise. The reasons for this may be due to the patient, e.g., cardiomegaly due to heart disease, or to the physician performing the procedure, e.g., due to different insertion points [6,12]. Therefore, verification of the correct insertion depth and positioning is still performed by X-ray diagnosis in many areas and subsequent correction of the CVC positioning is frequently required.

Ultrasound-guided positioning of the CVC tip has been described in adults, but studies in children have not been performed so far [5,13,14]. The present feasibility study utilizes four transthoracic views visualizing the tip of the CVC and the related anatomical structures. In children, from the suprasternal notch, the SVC can be visualized very easily.

However, for reliable identification, a pulsed-wave Doppler signal can be derived from the superior vena cava, especially in the case of subcostal sections. This is usually possible and prevents confusion, e.g., with the brachiocephalic trunk (Figure 7).

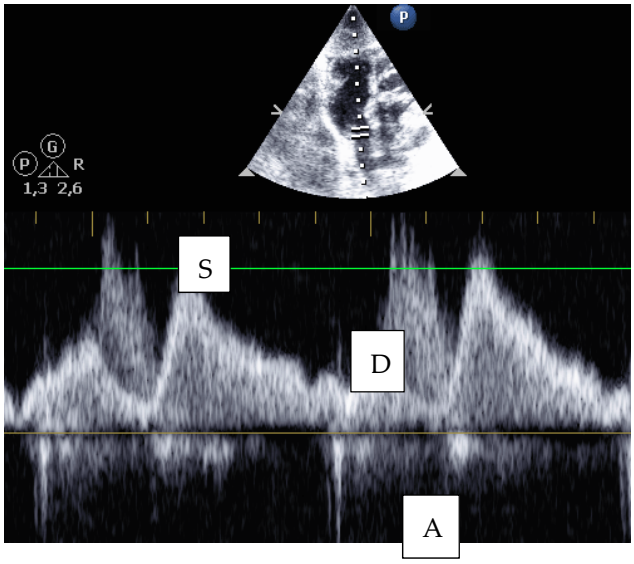

Figure 7. Subcostal view: PW Doppler signal from the superior vena cava with systolic (S), diastolic (D), and atrial (A) waves.

From the subcostal view, the distance between the CVC tip and the junction of the superior vena cava and the right atrium can usually be measured precisely. The CVC can thus be precisely retracted to the level above the right pulmonary artery. This offers significant advantages, especially in procedures where ligation of the superior vena cava is required, such as a Glenn operation. From the subcostal view, the essential structures can be identified in both naive children and children that have undergone previous cardiac surgery. If only one view is intended to be used for positioning of the CVC tip, the subcostal view is most promising in verifying CVC tip position. However, the results of our study indicate that, by combining the four views, a very good orientation and the correct intravascular position as well as the correct insertion depth of the CVC can be achieved during insertion of the central venous catheter.

Difficulties identifying the anatomic structures and CVC tip have been observed in children who have previously undergone cardiac surgery. The thymus provides an ideal parasternal acoustic window in small children. Therefore, these difficulties may be due to the fact that the thymus, and its favorable acoustic conditions, has been removed in the previous surgery and is therefore no longer present. In addition, there is certainly scar tissue which also restricts the view from parasternal views.

The CVC is identified by visualizing a double structure in the vein. The tip of the CVC is particularly echogenic. If the identification of the CVC tip is not clear, a useful tool is continuous flushing of the CVC with saline. Due to the small diameter of the CVC, a turbulent flow is created at the CVC tip, so that a clearly visible jet is created even without the use of agitated saline or ultrasound contrast medium (see Video S1). The jet is easy to identify and provides an indirect indicator of the position of the CVC. In addition, it is often possible to identify the J-wire of the CVC passing over the tip of the CVC (Figure 8).

Most importantly, in all cases when the tip positioning was feasible through echocardiographic evaluation, the correct positioning was confirmed intraoperatively by direct visualization or palpation as well as postoperatively via X-ray verification of the CVC tip at the junction of the SVC and the RA. However, the examinations in our study were performed by colleagues highly experienced in cardiac and vascular ultrasound evaluations and it is unclear how much training is required to gain competence for sonographic CVC evaluation. Therefore, further investigations of the views in a larger group of children and examiners are required, evaluating the safety and precession of ultrasound-guided CVC insertion depth in children, and verifying the results of this feasibility study. Furthermore, chest X-ray diagnostics are performed after cardiac surgery, not only evaluating the lungs and confirming CVC tip positioning, but also evaluating the heart and chest wall. However, during ICU therapy, the CVC often needs to be replaced and our protocol may have the potential to reduce radiation in situations when radiography diagnostics are only performed for tip CVC positioning verification and pneumothorax exclusion.

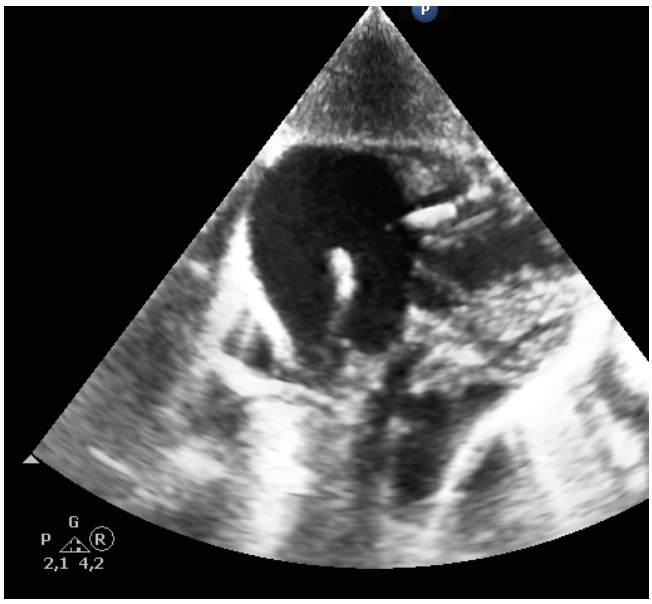

Figure 8. J-wire of the CVC passing over the tip of the CVC.

Medical radiation is the largest source of radiation exposure accounting for a mean effective dose (ED) of 3.0 mSv/y per person originating from diagnostic and therapeutic interventions. The annual ED in pediatric patients with CHD is relatively low (<3 mSv/y); however, yearly exposure accrues over the lifetime, potentially reaching high values (>100 mSv) in selected cohorts of chronic pediatric patients and cancer risk estimation highlights the need to limit medical radiation exposure [11,15].

5. Conclusions

Based on the present observational feasibility study, we were able to demonstrate that ultrasound-guided CVC insertion and tip positioning in children is a fast and reliable technique, preventing unnecessary X-ray exposure that may be considered for future policies.

Supplementary Materials: The following are available online at https://www.mdpi.com/article/10.3390/jcm10245971/s1, Video S1: Turbulent flow is created at the CVC tip.

Author Contributions: Conceptualization, T.B. and S.-C.K.; Data curation, T.B., M.R., E.S. and I.H.; Formal analysis, T.B.; Investigation T.B., E.S. and M.V.; Project administration, M.V., M.W. and N.S.-N.; Supervision, M.V. and E.S.; Visualization, T.B.; Writing—original draft, T.B. and N.S.-N.; Writing—review & editing, M.V. and S.-C.K. All authors have read and agreed to the published version of the manuscript.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

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4. Discussion with references

4.1 **“**Quality improvement of perioperative outcome in cardiac interventions for children” based on four publications

Within this dissertation it could be shown that the use of new technologies and standardization can improve outcomes of cardiac surgery patients in the pre- and the postoperative setting.

Especially before the intervention, the combined use of telephone and video consultation for anesthesia seems to be able to replace the usual on-site consultation without affecting its quality, especially in simple or repetitive cases such as MRI examinations. Both anesthesiologists and parents were more satisfied with the quality of the remote consultation than with the on-site consultation (parents: p= 0.024, anesthesiologists: p= 0.012). Notably, anesthesiologists were more satisfied with the overall process of anesthesia in the remote than in the on-site group (p= 0.002). This statement is comparable to a report based on a 2004 case series, where both patients and physicians rated the online consultation as very satisfying (Wong et al., 2004). Remote PrAC allowed parents to avoid long, stressful trips and also reduced traffic and environmental impact. In particular, pediatric patients with pre-existing conditions could benefit from further expansion of telemedicine to reduce the risk of nosocomial infections with each additional contact (Badawy,and Radovic 2020; Connelly et al., 2022; Dick et al. 1999). Additionally in our patient cohort occured fewer anesthesia related complications in the remote group, namely 7.4 % (p= 0.019). However, we do not account the way of informed consent to be causal for anesthesia related complications. Although the European Society of Anaesthesiology and Intensive Care (ESAIC) has published a guideline through the fields of tele-intensive medicine and tele-emergency medicine, which includes recommendations on preoperative evaluation and the use of digital media, the literature consistently describes physicians' concerns that remote care could compromise patient contact and trust (Hensel and Powell 2022; Marx et al., 2019). Furthermore, our ESAIC survey has shown that many physicians are uncertain about the legal situation. Specific to pediatric anesthesia, 67.3 % indicated that purely digital information without face-to-face contact is not legal. Only 22.9 % considered online or telephone information to be legal, while 9.8 % could not assess the current legal situation. There is also great uncertainty about legality within the EU and even within a single

country (Raposo et al., 2016; Schallner,and Bürkle 2020). However our ESAIC survey showed that 60.2% of anesthesiologists surveyed would consider remote consultations for anesthesia over on-site consultations. Similar results regarding future preference, were found in our EASE study, with 64% of anesthesiologists preferring remote consultations at the next PrAC. Similarly, 61.2% of parents surveyed would like the next PrAC to be performed remotely.

In conclusion these studys show the need for a firm legal framework and guidelines for remote PrAC within Europe.

In the postoperative setting, the use of new approaches and the adoption of fixed standards may also improve outcome parameters. Within one of our studies, OTE in pediatric cardiac surgery was shown to be safe and associated with a favorable postoperative course, including lower catecholamine requirements and shorter duration of intensive care therapy. This finding is also comparable to a study by Varghese et al., in which both the duration of intensive care and the length of hospital stay were significantly reduced in the group of OTE children compared with DET children (Varghese et al., 2016). Although OTE is now an integral part of improved recovery protocols after pediatric cardiac surgery, the frequency with which it is performed varies significantly between pediatric cardiac surgeries centers, even in comparable patient populations.

In particular, the group of children receiving cardiac surgery must undergo many different examinations and procedures during their lifetime, some of which inevitably involve exposure to radiation. Therefore, it is necessary to limit, where possible, medical radiation exposure. In a study conducted as part of the dissertation, it was shown that correct positioning of a CVC in pediatric patients can be performed quickly and safely using point-of-care ultrasound in 25 of 27 examinations (92,6 %), eliminating the need for radiographs otherwise required for postoperative CVC position monitoring. Although ultrasound-based techniques are now considered the gold standard, difficulties in identifying anatomic structures exist, particularly in children with previous cardiac surgery. Despite the existence of various formulas for CVC location, extensive experience is needed to learn sonographic assessment of CVCs (Schindler et al., 2021). Standardized procedures as well as comprehensive studies could help to evaluate the safety and precision of ultrasound-guided CVC insertion depth in children and thus lead to a significant reduction in radiation exposure and improvement in outcome.

4.2 Conclusion and prospects

Children with congenital heart defects represent a particularly vulnerable group within the health care system. Although they are similar to adults except for smaller anatomical sizes, they differ in terms of physiological and biochemical processes. Even though approximately 90 % of children reach adulthood due to improved anesthetic and surgical procedures, the risk of perioperative complications is still 5.2 % (Habre et al. 2017, Khalil et al. 2019; Larsen et al. 2016).

In our studies, we have identified several opportunities to improve patient safety and reduce the burden of these children throughout the perioperative course.

In the preoperative setting, the use of digital patient information appears to improve anesthesiologist and parent satisfaction. Specific guidelines in the context of Europe-wide harmonization are desirable to provide the necessary regulatory framework with this. To further reduce the health burden in these children, ultrasound-guided insertion and positioning of a CVC has proven to be a fast and reliable technique that avoids the need for unnecessary radiographs. To further improve the perioperative course, on table extubation after surgery for the correction of congenital heart defects seems to be a safe attempt to reduce duration of intensive care stay and catecholamine requirements.

In future, further studies on the cohort of children after cardiac surgery are necessary, currently, we are performing a multicentre prospective trial to confirm the results of our monocentric CVC study.

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