

ORIGINAL ARTICLE

Pediatric anesthesia practice in Italy: a multicenter national prospective observational study derived from the APRICOT Trial

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ABSTRACT

BACKGROUND: Pediatric anesthesia nowadays requires specific knowledge and expertise. The Anesthesia PRactice In Children Observational Trial (APRICOT) was a European multicenter study designed for the identification of perioperative severe critical events and management. We aimed at analyzing the Italian database in an attempt to determine the practice of anesthesia and the incidence of severe critical events in Italy.

METHODS: Secondary analyses of the database consisted in extracting the raw data from the 25 Italian centers that participated to APRICOT. Descriptive statistics and comparison with the reference data were made for all the variables collected.

RESULTS: The study analyzed 2087 children. The Italian cohort represents 6.7% of the overall study population. Most of the children were ASA 1-2 (90.6%) and underwent a surgical procedure (62.8%). In more than 84% of the cases, anesthesia management was performed by an expert with main or frequent activity in pediatric anesthesia with on an average 15 years of experience. The overall incidence of severe critical events was 3% (95% CI: 2.2-3.8). The most frequently reported severe critical incidents were of respiratory (2%; CI: 1.4-2.6) and cardiovascular origin (0.7%; CI: 0.3-1), while drug error, anaphylaxis and bronchial aspiration were very rare. There were no reports of perioperative cardiac arrest or patients with neurological damage.

CONCLUSIONS: This secondary analysis demonstrates that the incidence of severe critical incidence was lower in Italy in comparison to that reported for Europe. This low rate of critical events may be related to the high expertise and experience of the anesthesiologists in charge of the children in the Italian centres that participated to APRICOT.

(Cite this article as: Wolfler A, De Silvestri A, Camporesi A, Ivani G, Vittori A, Zadra N, *et al.*; Italian Society of Neonatal and Pediatric Anesthesia and Intensive Care (SARNePI). Pediatric anesthesia practice in Italy: a multicenter national prospective observational study derived from the APRICOT Trial. *Minerva Anestesiologica* 2020;86:295-303. DOI: 10.23736/S0375-9393.19.14126-0)

KEY WORDS: Anesthesia; Child; Adverse effects; Airway management.

Pediatric anesthesia is a subspecialty of anesthesia that requires specific knowledge and experience.

Since 1990, guidelines have been established in the USA to promote the safety and well-being of infants and children by reducing perioperative risks.¹ They stated that pediatric anesthesia should be provided or supervised by anesthesiologist with advanced training and clinical competence in pediatric anesthesia. Moreover, both the hospital and anesthesiologists are required to have a minimum annual case volume to maintain clinical competence.² In Europe, during the last decade, a few national guidelines and specific training program for pediatric anesthesia management have been developed and little is known about which critical events are more frequent in the perioperative period in children and their morbidity and mortality.³ The Anesthesia Practice In Children Observational Trial (APRICOT) was a European multicenter, prospective, observational audit of practice conducted in 33 European countries with the aim to identify the rate, management and outcome of perioperative complications during anesthesia and up to 60 minutes after awakening. Results from this study were published in 2015³ and showed a high rate of severe critical events (SCEs) (5.8%) besides a large variability of practice across Europe. Recently, the UK data were published and showed a lower overall incidence of SCEs (3.3% vs. 5.8%, $P < 0.001$) than in the non-UK cohort.⁴ Twenty-five centers participated in Italy to this large study. There are no published data on how pediatric anesthesia is conducted in Italy, neither on the incidence of severe critical events and their outcomes. We therefore decided to perform a secondary analysis of the Italian data from the APRICOT database. Primary aim of this study is to estimate the rate of severe critical events and their outcome and secondary to describe the characteristics of pediatric anesthesia management in Italy.

Materials and methods

The APRICOT was a prospective, multicenter, observational audit of practice which collected perioperative data to describe anesthesia man-

agement on children admitted during two consecutive weeks period previously determined by each participating center. Specific of the methods were previously describe elsewhere.³ The primary outcome was the occurrence of perioperative severe critical events during anesthesia and up to 60 minutes after. They included episodes of: laryngospasm, bronchospasm, pulmonary aspiration, drug error, anaphylaxis, cardiovascular instability, neurological damage, perioperative cardiac arrest, and the occurrence of new onset stridor at emergence from anesthesia or in the postanesthesia care unit. Each severe critical event was clearly defined and was defined as an event requiring immediate intervention that led, or could have led, to major disabilities or death. Secondary outcome measures were the potential consequences of those severe critical events (*i.e.*, no harm, minor sequelae, major sequelae, in-hospital mortality) at discharge from the hospital or at 30 days postanesthesia or sedation.

The Ethical Committee of each center approved the prospective European study and in some centers a parental written informed consent was needed before enrolling the children in the APRICOT trial. After publication of European data,³ we requested the steering committee of APRICOT to export the all Italian data set. All the variables were analyzed (demographic, pre-operative, intraoperative and postoperative), as for the APRICOT trial. Descriptive statistics was made on continuous and discrete variables. Critical events were described and their incidence was reported with 95% confidence interval (95% CI). A logistic regression was made to determine if any of the following variables was correlated to critical events: interface used (face mask vs. supra glottic airway device vs. endotracheal tube), type of procedure (sedation vs. general anesthesia), anesthesia team experience (years), degree of urgency (elective, urgent emergency), type of induction (inhalation vs. intramuscular). Due to the low number of SCEs we could test only one variable per time.

Results

The Italian cohort for the APRICOT Study was represented by the 2087 children (range of

children enrolled in each hospital: 19-320), enrolled in the 25 participating centers during the two-weeks inclusion period, with a data capture of 84%. This represents approximately 2.74% of children anesthetized over one year in Italy (N.=76,206; supplemental material APRICOT Study).³ When compared to the APRICOT cohort, the Italian database accounted for 6.7% of the overall study recruited population (N.=31,119), and 9.6% of the APRICOT centers (N.=261). Twelve children underwent two procedures, and three more than two each, for an overall number of 2102 procedures. Among the 25 hospitals that took part in the study, eight were pediatric hospitals while the others were general hospitals with a dedicated and structured department of pediatric surgery with daily activity.

Demographic characteristics are reported in Table I. Of note, the median age of included children was five years (IQR 2.3-9.4). The overall number of perioperative complications in Italy was 63 (3.0%; 95% CI: 2.2-3.8), 57 (3.6%; 95% CI: 3.1-4.1) under GA and 6 (1.1%; 95% CI: 1.21-10.8) under sedation (P=0.011). Two procedures had two SCEs and one had three. Their frequencies and characteristics are reported in Table II, III. Respiratory events (bronchospasm, laryngospasm, pulmonary aspiration and post-anesthesia stridor) represented the majority of all complications occurred (72.9%). The overall incidence of complications was lower in Italy when compared with the whole APRICOT database (3.0% vs. 5.3%), and respiratory and cardiovascular complications (the categories with the highest incidence of SCEs) were less frequent as well. In the Italian cohort no case of neurological damage or cardiac arrest was reported. At 30 days 1893 (90.7%) children were discharged alive from the hospital, four (0.2%) were transferred to another hospital, 27 (1.3%) were discharged to a convalescent home, 55 (2.6%) were still in hospital and three children (0.14%) were deceased. We compared pediatric *versus* general hospital but we did not find any difference in SCEs rate (P=0.165).

The most senior anesthesiologist in charge was mainly a specialist in anesthesia with long working experience (median 15 years, IQR 8-22), and in 87.7% of cases with a frequent or mainly pe-

diatric practice (Table IV). The medical history before the procedure is shown in Table III. Most of the children (>90%) were investigated for the presence of possible risk factors for airway complications except familiar smoking, asked in 80.6%. The most frequent surgical procedures were urologic 31% (N.=408), abdominal 18.7% (N.=246), and ENT 16.3% (N.=215). Among non-surgical procedures, diagnostic imaging (MRI and CT scan) (256, 36.0%), lumbar puncture (132, 19.0%) and gastrointestinal exams (125, 17.9%) were the most reported.

One-thousand-five-hundreds-eighty-one children (75.2%) underwent GA and 513 (24.4%) sedation. During GA, 1,117 (70.9%) received standard monitoring and 392 (24.9%) standard minus (one of the equipment missing), while under sedation 252 and 253 received respectively standard and standard minus monitoring (50% each).

Propofol was the most used anesthetic agent for sedation (368, 71.7%) and in 194 (37.8%) children opiates were added. Induction drugs used for GA were mainly propofol and sevoflurane and neuromuscular blockade was used in 584 children (36.9%), mainly rocuronium (402, 68.8%). Sevoflurane (N.=1285, 81.6%) and propofol (N.=244, 15.4%) were the most used hypnotic agents for GA maintenance while among opiates, administered in 909 (57.5%) children, fentanyl (N.=329, 66.6%) and remifentanyl (N.=137, 27.7%) were the most commonly used. Nitrous oxide was associated with oxygen as carrier gas in 252 (16.0%) GA, while air in 1293 (82.1%). Airway was managed in 806 (51.7%) children with an endotracheal tube and in 373 (23.9%) with a supraglottic airway (SGA) device. The incidence of SCEs was significantly more frequent when using an ETT (N.=44, 5.4%) than with a SGA and face mask (N.=7, 1.8%) (P<0.000, CI 0.34-0.38).

Regional anesthesia (RA) was associated to GA and to intravenous sedation in 507 (32.2%) and 122 procedures respectively. The three types of surgical procedures with the highest rate of RA were urologic (69.1%), orthopedic (44.2%), and abdominal (43.0%). The vast majority of RA (552, 87.7%) were conducted with the landmarks technique, while only 76 (12.2%) with

TABLE I.—*Descriptive variables of the entire cohort (N.=2087).*

Demographic	Italian cohort		APRICOT Trial
Gender M/F	1358/729 (65.1/34.9)		19559/12427 (61.1/38.9)
Age, years, median (IQR)	5.0 (2.3-9.4)		
Height, cm median (IQR) N.=794	116 (95-140)		
Weight, kg median (IQR) N.=2061	22 (15-37)		
Ethnicity, white	1843 (88.4)		
Anamnestic-physical condition	Not asked/ not pertinent	Positive anamnesis	
Medication	17 (0.8)	418 (19.9)	23.2
Snoring	60 (2.8)	277 (13.2)	14.2
Fever	16 (0.8)	62 (2.9)	2.9
Prematurity	58 (2.8)	148 (7.3)	7.6
Handicap	23 (1.1)	296 (14.3)	13.1
Environmental sensitivity			
Allergy	10 (0.5)	238 (11.3)	12.3
Atopy	39 (1.9)	136 (6.5)	7.5
Airway sensitivity			
Flu	45 (2.1)	272 (12.9)	13.5
Familiar smoking	407 (19.4)	263 (12.5)	30.9-10.9
Wheezing	59 (2.8)	124 (5.9)	6.3
Asthma	28 (1.3)	66 (3.2)	6.1
Anesthesia plan			
Surgical procedure	1320 (62.8)		71.5
Non-surgical procedure	781 (37.2)		28.5
Elective	1859 (88.4)		81.1
Inpatient	1494 (71.1)		60.0
Opening time OR	1963 (93.4)		90.0
Consultation >24 h	1523 (72.4)		59.5
Experience, years median (IQR)	15 (8 – 22)		13.85
Premedication	848 (40.3)		49.0
Anesthesia management			
Anesthesia type			
General	1581 (75.2)		93.4
Sedation	513 (24.4)		6.6
GA drug induction			
Inhalation	875 (55.3)		48.5
Intravenous	702 (44.4)		44.7
Intramuscular	4 (0.2)		6.8
NMBA	584 (36.9)		26.9
Regional anesthesia	631 (30.0)		
Sedation drugs			
Propofol	368 (71.7)		
Others	145 (28.3)		
GA Opiate	909 (57.5)		
Maintenance GA, drug			
Sevorane	1285 (81.6)		
Propofol	244 (15.4)		
Maintenance, opiate			
Fentanyl	330 (36.3)		
Remifentanyl	137 (15.1)		
Reversal NMBA	258 (44.2)		
Airway management			
Face mask	388 (18.5)		19.1
SGAW	373 (17.7)		35.1
SGAW removal			
Deep	273 (73.2)		42.1
Awake	100 (26.8)		57.9
ETT	811 (38.6)		43.9
Cuffed	665 (82.0)		71.9
ETT removal			
Deep	340 (41.9)		26.1
Awake	429 (52.9)		73.9

GA: general anesthesia; NMBA: neuromuscular blockade agent; SGAW: supraglottic airway; ETT: endotracheal tube; OR: operating room. Data are expressed as n (%) or otherwise indicated. When available, data were compared with the APRICOT Trial.

TABLE II.—Rate and description of complications, (N.=63).

Complications Time of occurrence	N. (%)	Treatment	Consequences
Bronchospasm	24 (1.1)	17 bronchodilator	6 hypoxemia
Induction	6 (25.0)	6 IV steroids	1 intubation
Maintenance	4 (16.7)	2 epinephrine	17 uneventful
Awakening	14 (58.3)	2 intubation	
Hemodynamic instability	14 (0.7)	7 hypotension	All uneventful
Induction	6 (42.8)	4 bradycardia	
Maintenance	8 (57.1)	3 bleeding	
Laryngospasm	11 (0.5)	3 IV propofol	All uneventful
Induction	9 (81.8)	3 intubation	
Awakening	2 (18.2)	3 IV steroids, 1 succinilcoline	
Stridor	7 (0.3)	3 with CPAP	All uneventful
Awakening	6 (85.7)	3 with oxygen	
PACU	1 (14.3)	1 IV steroid	
Pulmonary aspiration	4 (0.2)	3 with broncho tracheal suction	All uneventful
Induction	2 (50.0)	1 intubation, 1 with bronchodilator	
Awakening	2 (50.0)		
Drug error	2 (0.1)	Both wrong dosage	Both uneventful
Induction	2 (100)		
Anaphylaxis	1 (0.05)	IV steroids	Uneventful
PACU	1 (100)		

PACU: Postanesthesia Care Unit.

TABLE III.—Incidence of critical events. Data from the Italian cohort compared with the APRICOT trial.

	N. Italy	Incidence (95% CI) Italy	Incidence (95% CI) APRICOT trial
Laryngospasm	11	0.5% (0.2-0.8)	1.2% (1.1-1.3)
Bronchospasm	24	1.1% (0.7-1.6)	1.2% (1.1-1.3)
Bronchial aspiration	4	0.19% (0.00-0.38)	0.1% (0.06-0.13)
Postanesthetic Stridor	7	0.3% (0.1-0.6)	1.1% (0.9-1.3)
Anaphylaxis	1	0.05% (-0.05 to 0.14)	0.01% (0.002-0.025)
Cardiovascular instability	14	0.7% (0.3-1)	1.9% (1.7-2.0)
Cardiac arrest	-	-	0.03% (0.01-0.05)
Neurological damage	-	-	0.02% (0.002-0.03)
Drug error	2	0.10% (-0.04 to 0.23)	0.2% (0.1-0.2)
Overall (any of them)	63	3.0% (2.2-3.8)	5.3% (5.0-5.5)

ultrasound use. One hundred sixty-six (26.4%) children received a central block, mainly caudal (N.=116, 69.9%), 236 (37.5%) peripheral block, mainly ileoinguinal and TAP (N.=93; 39.4%) while 176 (27.9%) received wound infiltration. One-thousand-twenty (48.5%) children were anesthetized with spontaneous breathing, 997 (47.4) were mechanically ventilated, mainly in the volume controlled (N.=598, 60.0%). Intra-operatively, 1804 (85.8%) children received IV fluids, 428 (23.7%) of them received glucose containing fluids, mainly at a concentration of 1% (N.=132) and 5% (N.=215). The median duration of anesthesia was 47 minutes (IQR 30-75). Logistic regression showed a significative higher

risk of SCEs during a surgical vs. non-surgical procedure (P=0.004) and during GA vs. sedation (P=0.016).

Discussion

Mortality during modern anesthesia is a rare event⁵ and has been estimated an incidence of 0.36 case per 10,000 anesthetics.⁶ This is mainly due to the improved safety profile of anesthetic drugs, technological advancement and implementation of guidelines and standards for minimum monitoring requirements during anesthesia and sedation⁷ combined with a better knowledge and training of the anesthesiologists. Beside

TABLE IV.—Distribution for ASA status. Data from the Italian cohort compared with the APRICOT Trial.

	APRICOT Trial	Age, years, mean (SD); 95% CI	Team 1	APRICOT Trial	Team 2	APRICOT Trial	Team 3	APRICOT Trial	Team 4	APRICOT Trial
ASA 1 (N.=1079, 51.7%)	60.7%	6.27 (4.31); 6.0-6.5	704 (65.2%)	53.9%	211 (19.5%)	15.2%	148 (13.7%)	22.4%	16 (1.5%)	8.5%
ASA 2 (N.=813, 38.9%)	28.1%	5.86 (4.43); 5.6-6.2	611 (75.1%)	64.4%	127 (15.6%)	12.9%	68 (8.4%)	15.7%	7 (0.9%)	7.0%
ASA 3 (N.=165, 7.9%)	9.6%	5.65 (4.79); 4.9-6.4	137 (83.0%)	72.0%	15 (9.1%)	10.6%	13 (7.9%)	10.6%	0	6.8%
ASA 4 (N.=28, 1.3%)	1.6%	3.61 (3.88); 2.1-5.1	19 (67.9%)	78.9%	6 (21.4%)	9.6%	3 (10.7%)	8.8%	0	2.6%
ASA 5 (N.=2, 0.1%)	0.04%	0.03 (0.03); -.35 to 0.4	2 (100%)	91.7%	0	8.3%	0	0.0%	0	0.0%
Overall (N.=2087)		6.0 (4.40); 5.8-6.2	1473 (70.6%)	59.0%	359 (17.2%)	14.0%	232 (11.1%)	19.2%	23 (1.1%)	7.8%
APRICOT Trial		6.3 (4.5); 6.3-6.4								

Team 1: specialist anesthesiologist with mainly (>80%) pediatric cases; team 2: specialist anesthesiologist with frequent (50-80%) pediatric cases; team 3: specialist anesthesiologist with occasional (<50%) pediatric cases; team 4: anesthesiologist in training. ASA: American Society of Anesthesiology; ASA I: normal healthy patient; ASA II: mild systemic distress; ASA III: severe systemic distress; ASA IV: severe systemic distress that is a constant threat to life; ASA V: moribund patient who is not expected to survive without surgical intervention. Data are expressed as N. (%) or otherwise indicated.

this catastrophic complication, there are multiple life-threatening events, which may lead to increase perioperative morbidity with bad outcomes. There are few published data showing the rate of critical events during and after anesthesia in children in Italy.⁸ This secondary analysis provides an insight of pediatric anesthesia practice in the country. Two aspects might be highlighted from these data. The first is the incidence of severe critical events in the participating centers in Italy compared to other countries in Europe, and the second, is how pediatric anesthesia is conducted in those centers.

The incidence of SCEs in the Italian centers that participated to APRICOT was lower than that in the whole APRICOT cohort (3.0% vs. 5.3%, respectively) and comparable to that reported by observed in the British cohort (3.3%).⁴ This is a reassuring result which can be used as reference for future trials or for institutional quality improvement projects. This data could be interpreted in various ways. First of all, most of the pediatric anesthesia practice in Italy is performed by experienced pediatric anesthesiologists. Looking at the data reported in the Italian cohort, pediatric anesthesia is conducted by a specialist anesthesiologist with mainly or frequent activity with children and with a long

experience. The analysis performed in the APRICOT paper³ clearly showed a significant correlation between the seniority of the team involved and less respiratory SCEs. Similarly, the frequency of pediatric anesthesiology activity plays a role in preventing critical events: the longer the time spent in pediatric anesthesia the lower the rate of adverse events.^{4, 9} Both the British and the Scandinavian cohort studies as well as this study demonstrate that the experience of the anesthetic team is the most relevant in reducing the incidence of severe critical events in children with preoperative medical conditions with high ASA-PS Score.^{4, 9} One main difference between Italy and other European countries is there are no anesthetic nurses or pediatric anesthesia technicians in Italy. Moreover, anesthesiologist in training are always supervised directly by a specialist. Indeed, only 1.1% of procedures were managed by trainees alone, while about 10% of anesthesia were managed by an anesthesiologist in training supervised by a specialist, which is clearly a small percentage when compared with the European data (19%). On the other hand, it is also possible that, due to the voluntary basis of participating centers, we collected data from those hospital with the higher expertise and larger pediatric caseload, and missed-hospitals

where pediatric activity is sporadic and performed by anesthesiologists with occasional pediatric activity. Moreover, two differences in case mix of the Italian vs. European cohorts should be considered. Children included in Italy underwent mainly urologic surgery, while ENT is the most represented surgery for Europe. Recently, a paper published by the APRICOT group reported a sub-analysis on the children underwent ENT surgery.¹⁰ They demonstrated that ENT has a significantly higher incidence of respiratory SCEs than other surgeries (3.93% vs. 2.61% respectively, RR 1.51). Secondly, the Italian cohort has a higher rate of sedation than the rest of the Apricot study and due to the absence of airway manipulation under sedation, the incidence of respiratory and cardiovascular critical events is less frequent under sedation.³ Therefore, these peculiarities of the Italian cohort introduce a clear bias and provide a possible explanation of the lower incidence of respiratory SCEs which consequently affected the overall number of complications.

Respiratory and cardiovascular were the most frequent SCEs in both populations compared to neurological damage, anaphylaxis, drug errors which were reported rarely or for nothing. The low rate of drug errors reported should be considered cautiously since the study design was not focused on this specific aspect. The overall respiratory events (bronchospasm, laryngospasm, pulmonary aspiration and postanesthesia stridor) represented the vast majority of all complications occurred (72.9%), if compared with the cardiovascular critical events (33.5%). This data is in line with the European ones. Induction and awakening represent the two most critical periods during anesthesia. In both there is an airway manipulation either because a device is positioned or removed. This information reinforces the need for an adequate training in airway management and treatment of respiratory events.¹¹ Finally, none of the children died and no major sequelae derived by the SCEs were reported which means that the events were of minor severity and or adequately managed.

About the preoperative assessment, in Italy “passive familiar smoking” is not investigated in almost one out of five children although

the recent paper published by Habre *et al.* on risk factors for respiratory events underlined the importance of this aspect as a trigger for bronchospasm.¹² This information is missing in about one third of children in the European data, too. It is possible that this message has not been interiorized yet by the anesthesiologists and is undervalued as risk factor in the context of the whole anamnestic investigation. We suggest specific questionnaire should be implemented and used during the preoperative visit to define which aspects are important to be explored to identify children at risk of developing a critical respiratory event during perioperative period.

Two interesting data were reported in this study. One was parental presence at induction. It was allowed in almost half of the cases with the highest rate for preschool children (59% and 77.5% in GA and sedation respectively). The majority of children with no parental presence were those who received an inhalational induction inside the OR. This is probably due to the difficult logistic of introducing parents/caregivers in the OR. We believe that it is important to allow parents remaining near their children during anesthesia induction, as well as during the whole hospital stay. Of course, the environment and the logistic should always be adapted to avoid parental separation at any time of pediatric hospitalization.

Another aspect is the use of regional anesthesia in combination with GA. The rate was higher for urological surgery rather than orthopedical and the land-marks technique was still used in the majority of blocks. It seems that the use of ultrasound in pediatrics is not that diffused as it should be in Italy. A possible explanation might be related to the seniority of anesthesiologists practising (more than ten years) which could be less available to change their practice and to learn new methodologies.

Most of the descriptive data were comparable between the Italian and the Apricot cohorts, with homogenous populations in terms of ASA-PS, age, physical and medical conditions. The main difference was the rate of children with asthma which was double in the Apricot than in the Italian cohort. A possible explanation is that asthma

prevalence is different among European countries and in Italy there is a low prevalence rate, less than 10%.¹³

Limitations of the study

One limitation of this data report is that we cannot exclude an underreporting of SCEs and we do not have information about centers that did not participate to the study. Nevertheless, the similarities with the entire study population lead us to assume that the Italian cohort represents a real and representative sample. In Italy there is no national pediatric anesthesia-incident-reporting system like the one recently implemented in the USA.⁶ We therefore cannot compare these data with others previously collected.

Conclusions

In conclusion, SCEs in pediatric anesthesia are infrequent and mostly without consequences. Respiratory events remain the most common severe critical event, which advocates for careful airway manipulation both at induction and at awakening in order to prevent bronchospasm and laryngospasm. Similarly to other countries, the results of the present secondary analysis highlight the importance of implementing a specific pediatric training pathway and good clinical procedures, while developing appropriate skills for safe management of pediatric anesthesia in children in Italy. In particular, we believe that developing a specific pediatric anesthesia curriculum with an outcome-based evaluation and appraisal should be a fundamental step to define mandatory knowledge and skills across Europe. Scientific societies and regulatory bodies should endorse such initiative with the final goal to improve safety and quality of pediatric anesthesia.

What is known

- Pediatric anesthesia requires dedicated knowledge, skills and expertise.
- Little is known about the incidence of severe critical events during pediatric anesthesia in Italy.

What is new

- Severe critical events in pediatric anesthesia in Italy occur in 3% of cases.
- Respiratory critical events are predominant compared with other events.
- There is urgent need for a dedicated pediatric anesthesia curriculum and an outcome-based certification to improve quality and safety, especially in the most fragile pediatric populations.

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions.—Andrea Wolfer and Nicola Disma analyzed data and wrote the first draft of the paper; Annalisa De Silvestri made the statistical analysis; Bruno Locatelli, Marinella Astuto, Nicola Zadra, Lorena Pasini, Anna Camporesi, Giorgio Ivani, Alessandro Vittori and Anna Camporesi contributed for important intellectual content to the paper. All co-authors approved the paper in the final version.

Comment in: Mondardini M, Caldetini E. Anesthesia in children: the protective role of the expertise and experience. *Minerva Anesthesiol* 2020;86:247-9. DOI: 10.23736/S0375-9393.20.14301-3)

Acknowledgements.—We thank all the Italian centers' coordinators for their effort in enrolling patients, data collection and data entry: M Vason, Ferrara; F Rossetti, G Rizzo, Firenze; RL Pinciroli, Legnano; S Neri, Milano; P Stoa, Milano; C Aurilio, Napoli; A Guddo, Palermo; L Bortone, Parma; S Tesoro, Perugia; B Kuppers, Pisa; N Almenrader, A Vari, M Sammartino, Roma; L Brazzi, L Pistidda, Sassari; E Cerutti, Torino; D Pedrotti, Trento.

History.—Article first published online: December 9, 2019. - Manuscript accepted: November 27, 2019. - Manuscript revised: November 7, 2019. - Manuscript received: September 4, 2019.