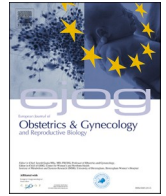


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Full length article

Maternal and perinatal outcomes following code red cesarean delivery performed among hospitals with different level of care

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ABSTRACT

Introduction: Code red cesarean delivery (CD) is performed in the presence of an impending danger to maternal or fetal life. The indications, times, and procedures in this setting remain ambiguous. The aim of this study was to evaluate in a cohort of code red CD the impact of the level of care of Obstetric Units, indications, and decision to delivery interval CD on maternal and perinatal outcomes.

Methods: This was a multicenter retrospective study conducted at four maternal units (two level-2 University Hospitals and two level-1 Community Hospitals) on a cohort of women who underwent code red CD between 2018 and 2021. An independent team of experts performed retrospective audits to assess the appropriateness of indications.

Results: A cohort of 168 code red CDs were included. The most frequent indications were severely abnormal fetal heart rate patterns (41.7 %) and sentinel events (38.1 %). Decision to delivery interval (DDI) was similar between different level of care (20.7 vs 21.4 min, $p = 0.66$) and didn't affect adverse perinatal outcome. Rates of appropriate indications were higher in the level-2 than level-1 hospitals (80.2 % vs 65 %, $p = 0.036$), with worse adverse perinatal outcome in the former than the latter (43.4 % vs 21.1 %, $p = 0.002$). At multivariate analysis, worse perinatal outcomes were independently associated with indications for code red CD ($P = 0.01$) and level-2 units ($P = 0.005$).

Conclusions: Level-1 hospitals guarantee a promptness of response comparable to that of level-2 centers in dealing with emergency in CD, however with lower rates of appropriate indications. Indications for code red CD but not DDI are associated with worse perinatal outcomes.

Introduction

Emergent cesarean delivery (CD) is required whenever prompt delivery is indicated due to risk for imminent fetal or maternal danger [1]. In 2000 a new four-category classification of CD was proposed based on the degree of urgency, from category 1 (emergency) to category 4 (elective) [2], later optimized by the introduction of a color-coded communication tool, with a code red CD indicating an emergent CD [3]. The adoption of a color-based classification facilitates the

communication on of the degree of urgency among the multidisciplinary team. However, the optimal indications and timing for code red CD remain unclear [4].

The time interval commonly utilized to compare perinatal and maternal outcomes is the decision-to-delivery interval (DDI). Several studies have demonstrated that in cases of abnormal fetal heart rate (FHR) patterns, delivery within a short interval results in improved neonatal conditions [5]. However, its effects on maternal and fetal outcomes in case of obstetric emergencies are conflicting [6–9]. While

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the American College of Obstetrics and Gynecology (ACOG) does not recommend any specific time limit for obstetric emergencies [10], in France the time limit is 15 min [11] differently by the National Institute for Health and Care Excellence (NICE) [12] and the Italian guidelines [13] recommend an interval of less than 30 min in case of emergent delivery. However, the adoption of the “30-minute rule” is frequently challenging [14]. Lowering the DDI might be attained by establishing communication tools and specific protocols of care for code red CD [7,15].

Most studies on the subject were conducted in tertiary Obstetrics Units, with anesthesiologists physically present at all times; data is lacking on the effects of Obstetrics Units organization (such as level of care and coverage) on the outcomes [11,16]. Moreover, no previous study has compared the outcomes of code red CD using uniform definitions of indications.

In accordance with the Italian Health Ministry recommendations, specific protocols regarding a standardized 4-tier classification of code red CD have been in place since 2013. The primary aim of this study was to evaluate in a cohort of code red CD the impact of the level of care of Obstetric Units, indications, on maternal and perinatal outcomes. The secondary aim was to evaluate the impact of the indications to CD and decision to delivery interval on maternal and perinatal outcomes.

Materials and methods

This multicenter, retrospective cohort study was conducted at four Obstetrics Units (two level-2 referral university hospitals: San Gerardo Hospital, Monza and Parma Hospital, Parma; and two level-1 community hospitals: Desio and Carate-Brianza Hospitals), which implemented a predefined protocol of care for code red CD between 2018 and 2021. Fig. 1 describes Protocol for managing code red cesarean delivery in level-1 and level-2 hospitals. Women were enrolled using the color code listed in the operative note, in accordance with the Italian guidelines [13]. According to the protocols, level-1 hospitals had a 24 h attendance of one or more midwives, a medical assistant specialized in obstetrics and gynecology, an assistant specialized in anesthesiology (though not dedicated to Labor and Delivery), and an assistant specialized in pediatrician, with one obstetrician available on call. Whereas, in Level-2 hospitals, two specialized obstetricians, a dedicated anesthesiologist, and a neonatologist were always present on-site. The key distinction between the two levels lies in the staffing availability: in level-1 hospitals, only one obstetrician is available on-site at all times, while the second obstetrician is on call, whereas in level-2 hospitals, the entire obstetric and neonatal team is present and actively engaged, with an anesthesiologist dedicated to the Labor and Delivery unit. An operating room was always available for obstetric emergencies both settings. The hospital level was determined according to the organizational, structural, and technical standards defined at national level. Since these

maternity levels are specific to the Italian healthcare system, a supplementary table (Table S1) has been provided to clarify the differences between them and offer a brief description of their corresponding definitions.

Detailed information was collected into a single database, including demographic characteristics medical, surgical and obstetric history; mode of conception, pregnancy complications; labor and delivery data (fetal presentation, induction of labor, analgesia, CD indications, FHR tracing before CD if available); as well as maternal and neonatal outcomes.

The indications for code red CD were classified as: sentinel events (uterine rupture, cord prolapse, placental abruption, and maternal cardiovascular collapse); severe abnormal FHR patterns according to local protocols; failure of vacuum extraction and other indications i.e. massive or uncontrolled hemorrhage. The time intervals recorded were: decision-to-incision interval (DII), decision-to-delivery interval (DDI), and interval between the initiation of anesthesia and the incision. The type of anesthesia used (general, epidural or spinal) and the number of obstetricians involved during the surgery were documented.

The following neonatal outcomes were recorded: umbilical artery blood gas analysis (pH, Base Excess (BE) and lactates); Apgar score at 5 min; birth weight and centile (based on Italian curves) [15]; need for resuscitation and/or intubation; length of stay in NICU; and need for neonatal cooling. A composite adverse perinatal outcome was created based on umbilical arterial pH ≤ 7 , base excess (BE) ≥ 12 mmol/L, Lactate ≥ 10 mmol/L, Apgar score at 5 min < 7 , and need for neonatal intubation [16–18]. The following maternal variables were recorded: duration of hospital stay after CD, blood transfusion, puerperal infections, reintervention, and anesthesiologic complications.

The appropriateness of indications for code red CD was assessed in consensus by a group of four expert obstetricians (defined as lead of labor and delivery units with more than 15 years of experience) from the 4 Obstetrics Units who had access to the full patients data including prevailing clinical scenario. All data were anonymized, and perinatal outcomes were not known during the discussion through video-call meetings. Each case was analyzed considering the ante-partum and intra-partum events, including evaluation of the last 60 min of FHR tracings. For cases in which the FHR tracing was missing, the appropriateness of the decision to perform a code red CD was based on the clinical records. In the event of a discrepancy in the assessment of the appropriateness, the opinion of at least two experts excluding the expert of the unit involved in the case was accepted as final.

Statistical analysis included Chi-square, ANOVA and logistic regression to correct for confounders such as appropriate indications and DDI (SPSS Statistics Software version 28.0.1.1). The outcomes of interest were adverse perinatal outcomes. Associations between indicators and outcomes with a P value less than 0.05 were considered statistically significant.

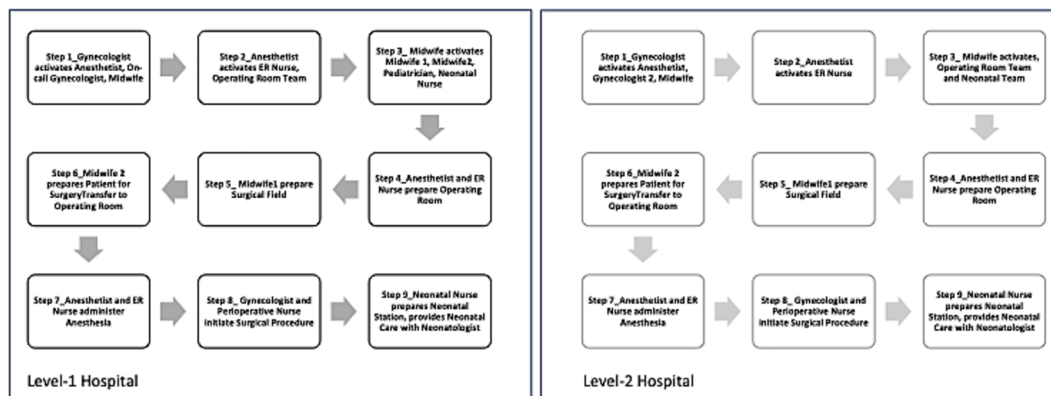


Fig. 1. Protocol for managing code red cesarean delivery in level-1 and Level-2 Hospitals.

The study was approved by the Territorial Ethical committee of the Lombardy region (ID: 3909_S.M). All women provide a written consent to the use of their clinical anonymized and deidentified data upon admission.

Results

Among the 25,065 deliveries during the study period, 4,783 were CD (19.1 %). Overall rates of CD in levels 1 vs level 2 hospitals were 16.5 % in level 1 hospitals and 20.5 % in level 2 hospitals. Of them, 174 (3.5 %) were classified as code red CDs. Due to incomplete data, six cases were excluded, leaving 168 available for the analysis (Fig. 2).

Pregnancies were conceived via assisted reproductive technology in 6 cases (3.6 %); 23 (13.7 %) were complicated by gestational diabetes mellitus (GDM) and 12 (7.1 %) by hypertensive disorders. Fetal growth restriction (FGR) and oligohydramnios were recorded in 5.3 % and 7.7 %. Gestational age at delivery was 38.4 ± 3.5 weeks; 20.2 % of deliveries (34/168) were preterm. In 43.5 % of patients (73/168) labor was induced.

Socio-demographic characteristics, medical obstetric history and intrapartum care of the participants according to the hospital level are described in Table 1. A history of previous uterine surgery was more commonly in level-2 than level-1 hospitals (20.5 % vs 8.2 %, $p = 0.03$) while Level-1 had higher rates of non-Caucasian ethnicity.

Table 2 displays the indications and logistics of code red CDs. The most frequent indications were severely abnormal FHR patterns (70/168; 41.7 %) and sentinel events (64/168; 38.1 %). A single case of maternal cardiovascular collapse occurred in a level-2 hospital due to the rupture of a splenic artery aneurysm, leading to the patient’s death. Sentinel events (48.2 % vs 28.2 %; $p = 0.01$) were more frequent in level-2 than level-1 hospitals, whereas abnormal FHR was reported more frequently in level-1 than level-2 hospital settings (49.4 % vs 33.7 %, p

$= 0.04$). Mean DII was 16.7 min and mean DDI was 21.0 min. In 17.2 % of cases (29/168) the DDI exceeded 30 min. Interestingly, DII (16.2 vs 17.3 min, $P = 0.49$) and DDI (20.7 min vs 21.4 min, $p = 0.66$) were similar between the two groups (Fig. 3).

Table 3 shows the maternal and neonatal outcomes. Mean blood loss during code red CD was 575.9 mL, with 2 % of patients (4/168) requiring intraoperative blood transfusion and 5 % (9/168) requiring postoperative blood transfusion. Twenty-nine women (17.3 %) experienced postpartum uterine atony and 17.3 % (29/168) fever or endometritis. Two patients (1.2 %) developed hematoma of the broad ligament, requiring reintervention in one case. Four of the 168 patients (2.4 %) experienced complications of anesthesia.

No differences were found in terms of adverse maternal outcomes between hospital settings. In level-2 hospitals, birth weight was lower (2846 vs 3125 g, $p = 0.01$), need for neonatal resuscitation was higher (39.8 % vs 22.3 %, $p = 0.02$), and umbilical artery pH ≤ 7 was more frequent (pH 21.7 % vs 4.7 %; $p < 0.00$) than in level-1 hospitals. Need for intubation (26.5 % vs 2.3 %; $p < 0.00$) and NICU admission (33.7 % vs 2.3 %; $p < 0.00$) were also significantly higher in level-2 hospitals. The overall incidence of adverse composite perinatal outcome was higher in level-2 than level-1 settings (43.4 % vs 21.2 %; $p = 0.00$).

The indications for code red CD were deemed appropriate in 72.6 % (119/164) of cases. Rates of appropriate indications were significantly higher in level-2 than level-1 hospitals (78.3 % vs 63.5 %; $p = 0.04$) (Table 4). In 4 cases the medical records did not contain adequate documentation to allow a decision, and the remainder were deemed to have inappropriate indications. CD classified as appropriate compared with inappropriate code red CD had significantly lower DII (15.4 vs 20.4 min, $p = 0.01$) and DDI (19.4 vs 25.7 min, $p = 0.00$). Appropriate code red CD also had greater blood loss at delivery (636.3 mL vs 418.9 mL, $p = 0.02$) and showed a trend for greater need for blood transfusion (7 % vs 0 %, $p = 0.06$). Composite adverse neonatal outcomes were more

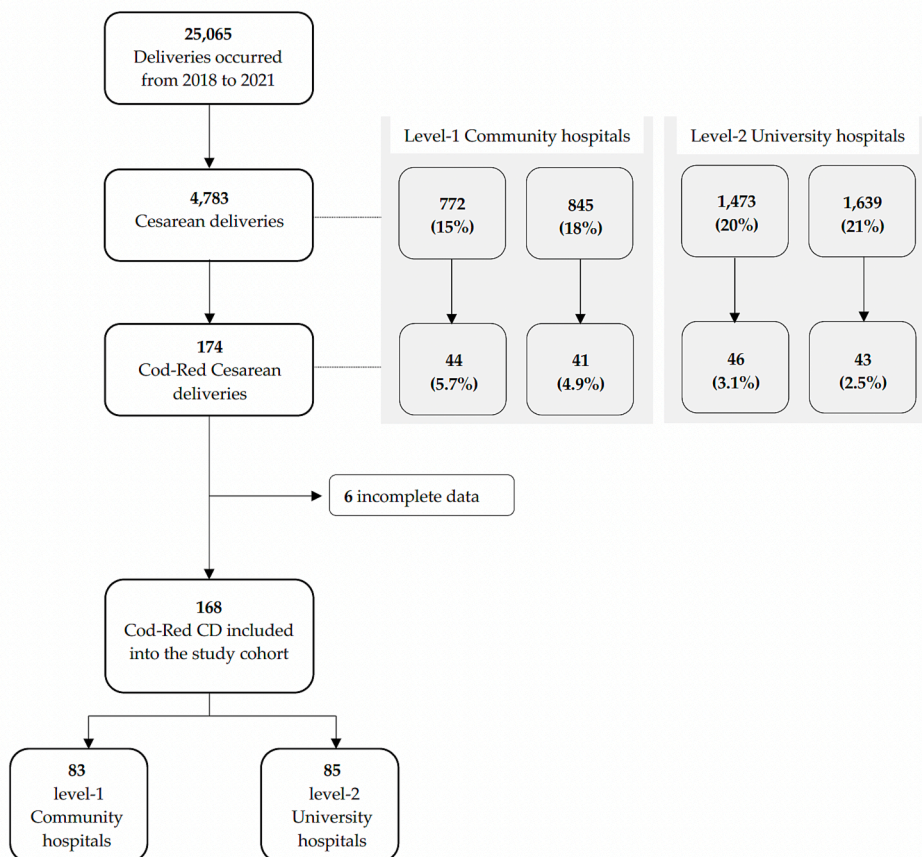


Fig. 2. Box plot Decision-to-Delivery Intervals (quartiles) within Level-I and Level-II Hospitals.

Table 1
Description of the study sample [mean ± SD or Number (%)].

		Overall (n = 168)		Level-1 Community hospitals (n = 85)		Level-2 University hospitals (n = 83)		p-value
		mean	SD	mean	SD	mean	SD	
Socio demographic variables	Maternal age (years)	32.9	5.7	32.9	5.6	33.0	5.9	0.916
	BMI pre-conception	23.8	4.5	23.6	3.7	24.0	5.2	0.526
	BMI at term	28.4	4.7	28.3	4.3	28.6	5.1	0.697
Obstetrical History	n		%	n	%	n	%	
	Ethnicity (Not Caucasian)	29	17.3	20	23.5	9	10.8	0.04
	Multiparous	23	13.7	13	15.3	10	12	0.665
	Previous Cesarean delivery	24	14.3	7	8.2	17	20.5	0.028
	Comorbidity (preconception)	36	21.4	22	25.9	14	16.9	0.189
	Pregnancy complications ^a	86	51.2	46	54.1	40	48.2	0.054
	Fetal pathology ^b	29	17.3	15	17.6	14	16.9	0.583
	Gestational age < 37 weeks	34	20.2	15	17.6	19	22.9	0.446
Intrapartum care	Cephalic presentation	148	88.1	78	91.8	70	84.3	0.265
	Induction of labor	73	43.4	41	48.2	32	38.5	0.217
	Epidural analgesia	46	27.4	18	21.2	28	33.7	0.083

^a Hypertension/Pre-eclampsia; Gestational diabetes/Pre-conception diabetes mellitus; Autoimmune diseases; Cholestasis; Haemoglobinopathies; Thyroid diseases.
^b Fetal Growth Restriction/Small for gestational age; Fetal malformations; Poly-/Oligohydramnios.

Table 2
Organizational aspects [Number (%)].

INDICATIONS for code red CD	Overall (n = 168)		Level-1 Community hospital (n = 85)		Level-2 University hospitals (n = 83)		p value
	n	%	n	%	n	%	
Severely abnormal FHR patterns	70	41.7	42	49.4	28	33.7	0.043
Operative vaginal delivery failure	19	11.3	13	15.3	6	7.2	0.143
Sentinel events	64	38.1	24	28.2	40	48.2	0.011
Uterine rupture	7	4.2	0	0	7	8.4	0.006
Umbilical cord prolapse	22	13.1	6	7.0	16	19.3	0.022
Abruptio placentae	34	20.2	18	21.2	16	19.3	0.848
Maternal indication	5	3.0	3	3.5	2	2.4	1.000
Other indications	15	8.9	6	7.0	9	10.8	0.424
Appropriate indications	119	70.8	54	63.5	65	78.3	0.036
PROCEDURES	n	%	n	%	n	%	
General anesthesia	61	36.3	31	36.5	30	36.1	0.564
Epidural anesthesia	28	16.7	10	11.8	18	21.7	0.10
Spinal anesthesia	79	47.0	44	51.8	35	42.2	3.41
More than one obstetrician involved	135	80.3	53	62.3	82	98.8	<0.001
Shifts (holiday or night)	111	66.1	54	65.5	57	68.7	0.517

FHR: Fetal heart rate; DII: Decision-to-incision interval; DDI: Decision-to-delivery interval.

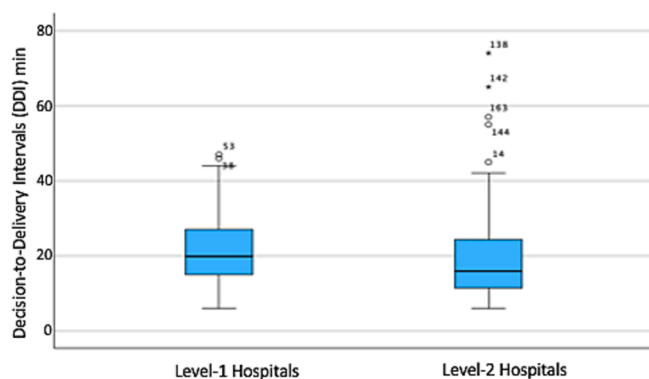


Fig. 3. Box plot Decision-to-Delivery Intervals (quartiles) within Level-I and Level-II Hospitals.

frequent in appropriate code red CD (39.5 % vs 15.5 %; p = 0.01). Maternal adverse outcome was not influenced by code red CD appropriateness.

In a multivariate logistic regression model including level of care and variables differently represented in level-1 and level-2 hospitals, adverse perinatal outcomes were associated with appropriate indications (odds ratio = 3.4, 95 % CI 1.4–8.5; p = 0.01) and delivery at a level-2 care hospital (OR = 2.8, 95 % CI 1.4–5.9; p = 0.01).

Overall, cases with and without composite adverse perinatal outcome had similar DDI (21.9 min SEM 1.1 versus 19.3 min SEM 1.4, p = 0.18). Even in the subgroup of code red CD performed for severe FHR tracing anomalies, adverse composite perinatal outcome was not related to DDI (17.04 min SEM 1.5 versus 20.02 min SEM 1.4, p = 0.20). Similarly, no relationship was found between DDI and composite adverse maternal outcome (19.5 SE 1.3 min vs 21.7 SE 1.1 min, p = 0.25).

Discussion

Our study offers a unique opportunity to assess the impact of code red protocols on maternal and neonatal outcomes thanks to the possibility to combine standardized protocols with a diverse cohort of hospitals. A key strength is the homogeneity of the data collected across different hospital settings, all of which adopted the same protocols for defining and managing code red CDs. This consistency, together with similar rates of premature deliveries and fetal growth-restricted babies, minimizes the impact of potential confounders on perinatal outcomes. Furthermore, the use of unbiased experts to assess the appropriateness of indications ensured objectivity throughout the evaluation.

However, a limitation of our study is its retrospective design, which restricts our ability to draw definitive conclusions regarding causality.

In conclusion, our study provides valuable insights into the management of code red CDs across different hospital levels. We found that level-1 hospitals, while offering a response comparable to level-2 settings in terms of DDI and maternal complications, have a higher proportion of emergency CDs and a lower rate of appropriate indications. This suggests a lower threshold for calling a code red CD in these hospitals, particularly in cases of suspected intrapartum fetal compromise [17]. Large published series have reported a rate of code red CD ranging from 2.5 % to 9.1 % [1,4,18,19], with different definitions for emergency. Our overall rate of code red CD (3.5 %) is within this range. The rates of code red CD in each maternity units were as follows: 5.1 % and 4.9 % for the two level-1 hospitals, and 3.1 % and 2.5 % for the two level-2 hospitals.

A worse composite perinatal outcome was observed in level-2 hospitals than in level-1 even after correcting for significant variables

Table 3
Maternal and perinatal outcomes.

		Overall (n = 168)		Level-1 Community hospital (n = 85)		Level-2 University hospitals (n = 83)		p value
		n	%	n	%	n	%	
<i>Maternal outcomes</i>	Adverse Maternal outcomes	51	30.4	30	35.3	21	25.3	0.181
	Blood transfusions	9	5.4	3	3.5	6	7.2	0.323
	Post-partum fever	29	17.3	17	0.2	12	14.5	0.417
	Need for re-intervention	1	0.6	1	1.2	0	0	1.00
	Anesthesiologic complications	4	2.4	2	2.4	2	2.4	1.00
	<i>mean SE</i>	<i>mean SE</i>	<i>mean SE</i>	<i>mean SE</i>	<i>mean SE</i>	<i>mean SE</i>		
	Blood loss ml	576	40.7	509	36.4	646	73.7	1.34
		<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	
<i>Neonatal outcomes</i>	UA pH <=7.0	22	13.1	4	4.7	18	21.7	0.001
	UA BE < -12	20	12.0	7	8.2	13	15.7	0.151
	UA Lactate > 10	12		5		7		0.551
	Apgar at 5 min < 7	30	17.9	11	12.9	19	22.9	0.109
	Fetal weight gr	2992	55.6	3125	63.4	2846	92	0.012
	LGA	14	8.3	7	8.2	7	8.4	1.00
	SGA	28	16.6	13	15.3	15	18.1	0.539
	Need for reanimation	52	31.0	19	22.3	33	39.8	0.019
	Neonatal Intubation	24	14.3	2	2.3	22	26.5	<0.001
	Neonatal cooling	7	4.2	1	1.2	6	7.2	0.061
	NICU access	30	17.9	2	2.3	28	33.7	<0.001
	<i>Adverse composite perinatal outcome</i>		54	32.1	18	21.2	36	43.4

Abbreviations. UA: Umbilical artery; BE: Base excess; LGA: Large for gestational age; SGA: Small for gestational age; NICU: Neonatal intensive care unit.

Table 4
Code red cesarean delivery characteristics in relation to appropriateness of indications.

CD INDICATIONS	Overall (n = 164)		Appropriate (n = 119)		Not appropriate (n = 45)		P-value
	n	%	n	%	n	%	
Severely abnormal FHR patterns	68	41.5	44	37.0	24	53.3	0.075
Operative vaginal delivery failure	19	11.6	18	15.1	1	2.2	0.026
Sentinel events	66	40.2	51	42.8	15	33.3	0.27
Uterine rupture	6	3.7	5	4.2	1	2.2	1.00
Umbilical cord prolapse	22	13.4	21	17.7	1	2.2	0.009
Abruptio placentae	33	20.1	22	18.5	11	24.4	0.392
Maternal indication	5	3.0	3	2.5	2	4.4	0.616
Other indications	11	6.7	6	5.0	5	11.1	0.171
PROCEDURES	<i>mean SEM</i>	<i>mean SEM</i>	<i>mean SEM</i>	<i>mean SEM</i>	<i>mean SEM</i>	<i>mean SEM</i>	
Decision-incision-interval (min)	16.8	0.8	15.4	0.9	20.4	1.7	0.006
Decision-delivery-interval (min)	21.1	0.9	19.4	1	25.6	1.8	0.002
General anesthesia	60	36.6	51	42.9	9	20	0.007

FHR: fetal heart rate; CD: cesarean delivery; SEM: standard error of the mean.

among Obstetrics Units. We found a higher rate of appropriate indications for code red CD in level 2 hospitals, which per se are associated with worse perinatal outcomes.

Moreover, patients at higher risk for severe complications, such as multiple previous CDs admitted to trial of labor (risk for uterine rupture), preterm labor (risk for cord prolapse), or emergent transport are typically referred to University Hospitals, likely contributing to higher appropriate indication rates and poorer perinatal outcomes.

Interestingly, no differences in DDI were found between the two settings, contrasting previous reports [20,21]. An Australian audit on emergency CD showed different operating room times between hospital levels [22], unlike our findings. The adoption of specific and shared protocols by our Obstetrics Units, as recommended by the Italian Health Ministry [13], likely reduced DDI in urgency. Our data indicate that a common protocol of care in response to an obstetric emergency plays a more pivotal role than having the entire medical staff onsite [7]. Moreover, our study suggests that a standardized 4-tier classification is

feasible at different unit levels and may be more advantageous than the recommendation to expedite delivery within rigid and arbitrary time intervals [23]. DDI is a challenging issue in obstetrical practice: despite the “30-minutes rule” being considered a benchmark of good intrapartum care, very little data support this recommendation [9]. Homer et al [24] were unable to demonstrate improved perinatal outcomes when delivery was accomplished within 30 min of the decision to intervene. Similarly, in a review of more than 30,000 neonates born with an emergency CD, the rate of low Apgar scores was not different in neonates delivered within or after 30 min [25]. Conversely, several studies have shown worse neonatal acidemia, lower Apgar scores, and greater rates of neonatal intensive care unit admissions in neonates delivered beyond the “safety 30 min threshold” [10,26,27]. Indications for emergency CD represent a major factor to consider when assessing the clinical relevance of the DDI [28–30]. In our study, the appropriateness of indication to the emergency, which may be considered a proxy of the severity of the condition, has a greater impact on the perinatal prognosis compared with the DDI, although it should be noted that only 17.2 % (29/168) of CD could not be performed within 30 min.

From the maternal point of view, emergency CDs are associated with more complications in terms of infections, wound dehiscence, and hemorrhage [18,31]. Moroz et al [32] showed an increased risk of blood loss, need for transfusion, and broad ligament hematoma in a DDI setting < 2 min. As suggested by ACOG and the American Association of Pediatrics, DDI should be based on the timing that best incorporates maternal and fetal risks and benefits [33], limiting the need to establish a “one size fits all” timing for emergency or code red CD.

Conclusions

Level-1 maternal units yield comparable maternal and perinatal outcomes to those of level-2 in dealing with emergency CD, but they have lower rates of appropriate indications. DDI does not appear to have an effect on the perinatal outcomes even when code red CD is performed for severely abnormal FHR tracing. The adoption of a standardized 4-tier color coded classification for expedited delivery seems clinically valuable regardless of the maternity unit organization, such as level of care and coverage.

Author contributions

Substantial contributions to the concept and design or analysis and

interpretation of data (AL, TG, PA, BF, FS, GA, MG, CE, RC, MIM). Drafting the manuscript or revising it critically for important intellectual content (AL, TG, GA, MG, FS). All authors have read and approved the version of the manuscript submitted. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

CRedit authorship contribution statement

Anna Locatelli: Writing – review & editing, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Giuseppe Marino:** Writing – original draft, Formal analysis, Data curation, Conceptualization. **Enrico Corno:** Writing – original draft, Formal analysis, Data curation, Conceptualization. **Francesca Bonati:** Writing – review & editing, Methodology, Data curation, Conceptualization. **Armando Pintucci:** Writing – review & editing, Methodology, Data curation, Conceptualization. **Isabella Marzia Maini:** Writing – review & editing, Methodology, Data curation, Conceptualization. **Stefania Fieni:** Writing – review & editing, Methodology, Data curation, Conceptualization. **Simona Fumagalli:** Writing – original draft, Formal analysis, Data curation, Conceptualization. **Alessandro Ghidini:** Writing – review & editing, Methodology, Conceptualization. **Clara Repposini:** Data curation, Writing – review & editing. **Tullio Ghi:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization.

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Declaration of competing interest

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.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejogrb.2024.11.025>.

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