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ORIGINAL ARTICLE

Advantage of bedside versus conventional operating room surgery in the management of term and preterm newborn infants: a single center retrospective observational study

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Abstract

Purpose To compare postoperative outcomes of bedside surgery (BS) with those of surgery performed in the operating room (ORS) in preterm and full-term neonates.

Methods Data from neonates undergoing major surgical interventions were retrospectively evaluated. Primary outcome was the incidence of postoperative hypothermia. Secondary outcomes were the mortality rate within 30 days of surgery and the occurrence of post-operative infection within 48 h of surgery.

Results 374 interventions performed on 222 neonates were analysed: 55 interventions on 47 neonates in the BS group and 319 interventions on 175 neonates in the ORS group. Compared to the ORS group, infants in the BS group had lower gestational age (GA) and birthweight, higher incidence of morbidity and mortality at discharge. No difference was found in the incidence of postoperative hypothermia and infections within 48 h of surgery, while mortality within 30 days of surgery was higher in the BS group. To multivariable logistic regression analysis, weight at the time of surgery [OR (IC 95%) 0.711 (0.542–0.931); *p 0.013*] and emergency/urgency modality [OR (IC 95%) 1.934 (1.221–3.063); *p 0.005*] were identified as variables associated with the risk of hypothermia, while GA [OR (IC 95%) 0.830 (0.749–0.920); *p 0.000*] and need for presurgery inotropes [OR (IC 95%) 8.221 (2.128–31.760); *p 0.002*] were associated with mortality within 30 days of surgery.

Conclusions BS resulted safe and effective in not increasing the risk of postoperative adverse events despite being performed in worse clinical conditions than ORS.

Keywords Bedside surgery · Operating room · Preterm infants · Neonatal surgery · Critically ill neonates · Neonatal intensive care · Postoperative outcomes

Introduction

Medical advances have led to significant improvements in the survival of preterm infants and, at the same time, to an increase in the incidence of comorbidities related to prematurity, some of which require surgery [1]. Moreover, congenital anomalies represent approximately 9% of surgical pathologies worldwide, and two-thirds of these anomalies can be corrected surgically [2]. Abdominal surgical emergencies and oncological diseases contribute to the burden of surgical pathology for patients of all ages [3]. It is estimated that one-third of all infant deaths are attributable to a surgical condition; it is, therefore, mandatory to identify strategies that allow us to reduce the preventable deaths of newborn infants and children under the age of five, as planned

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by the United Nations Organization among the objectives to be achieved by 2030 [4].

The management of term and preterm newborn infants with surgical conditions is demanding, requiring the involvement of a multidisciplinary team in which the neonatologist should be the reference professional figure. Preterm infants, specially, are susceptible to rapid perioperative hemodynamic deterioration due to their low body weight, organ immaturity and intrinsic physiological fragility [5]. Mortality rates can exceed 60% among surgical newborn infants in resource-limited countries [6].

One of the main risk factors for unfavourable outcomes in critically ill surgical patients is transportation to and from the operating room (OR) [7, 8]. It has been observed that several incidents can occur during the intra-hospital transfer of critically ill newborn infants, including hypothermia, dislodgement of endotracheal tube and intravenous lines [9, 10].

To avoid these problems, the bedside surgery approach (Bedside Surgery—BS) is spreading in neonatal intensive care units (NICUs) throughout the world. However, high-level scientific evidence would be needed to establish the effectiveness of BS compared to conventional OR surgery (ORS) in reducing adverse outcomes related to perioperative management of term and preterm infants.

Due to the methodological difficulties in controlling confounding variables—such as the setting preference by the surgeon and the anaesthesiologist, the distance variability between the NICU and the OR, the planning modality of the surgery (elective or urgent/emergency surgery), the clinical stability of the patient—these studies are lacking and are difficult to carry out [5].

The aim of this study was to compare the post-operative outcomes of surgery performed at the patient's bedside with those of surgery performed in the conventional OR in preterm and full-term newborn infants.

Methods

Study design and setting

This was a retrospective observational cohort study, carried out at the NICU of the Fondazione Policlinico Universitario A. Gemelli, IRCCS in Rome—Italy, between March, 1 2018 and April, 30 2024.

Population and inclusion and exclusion criteria

We included all surgical interventions performed in preterm and full-term newborn infants admitted to the NICU who required, during their hospitalization, one or more major elective or urgent/emergency surgical interventions.

We excluded surgeries performed on infants with complex malformations associated with genetic syndromes undergoing palliative surgery and those for which data relevant to the study were missing. Furthermore, surgical procedures performed on infants for which the parents had not provided written informed consent for participation in the study were also excluded.

Major surgical interventions were considered to be those performed for the following conditions: congenital malformations, such as diaphragmatic hernia, oesophageal atresia, intestinal atresia, lymphatic malformations, and acquired surgical conditions, such as necrotizing enterocolitis, spontaneous intestinal perforation, intestinal volvulus, intestinal recanalization after abdominal surgery, intracranial haemorrhage.

The study was carried out in compliance with the Declaration of Helsinki and does not contain any personal information that could lead to the identification of the patient; all data analysed were collected as part of routine diagnosis and treatment; and patient medical care was not set up for research purposes but was part of standard clinical procedure. The study was approved by institutional review boards (Study ID 6601) and parents gave written consent to the processing of personal data.

Primary and secondary outcomes

Primary outcome of the study was the incidence of postoperative hypothermia, defined as a rectal temperature below 36.5 °C [11]. Secondary outcomes were the mortality rate within 30 days of surgery and the occurrence of post-operative infection within 48 h of surgery.

Data collection

The following data were collected: gestational age (GA), determined by the best obstetric estimate based on the first day of the last menstrual period, prenatal ultrasound and postnatal physical examination; birth weight (BW); gender; post-menstrual age (PMA) and day of life (DOL) at the time of surgery; anatomical compartment where the major surgery was performed; planning modality of the surgery (elective or urgent/emergency surgery); duration of surgery. Before and after surgery we recorded body temperature and weight, blood pH, need for inotrope therapy (in the 48 h before and in the 48 h after surgery). The extent of body weight, body temperature and blood pH variation (Δ-weight, Δ-body temperature and Δ-pH) before and after surgery was calculated.

Duration of parenteral nutrition, duration of invasive and non-invasive ventilation, length of hospital stay, occurrence of systemic infection (defined as positive blood or cerebrospinal fluid culture within 48 h after surgery), grade 3–4 intraventricular haemorrhage (IVH) [12], periventricular leukomalacia (PVL) > grade 2 [13], moderate and severe forms of bronchopulmonary dysplasia (BPD) [14], and occurrence of death within 30 days of surgery were also registered.

All data were collected from electronic clinical records.

Bedside and operating room surgery protocols

Our NICU is an open space with 16 beds. One bed is reserved for bedside surgical procedures. This bed is located in a 16 square meters, negative pressure (−6 Pascal) room adjacent to the open space. The room is equipped with a central air flow system and with an area for hand washing and disinfection. In the room, there are an open infant warmer incubator (Giraffe Incubator Carestation, GE Healthcare), one ventilator (Dräger Babylog VN500), one docking stations for the syringe pumps, two monitors with alarming equipment software, one mobile surgical lamp. The average room temperature during procedures is set at 26 °C. The BS team consists of two surgeons, an anaesthesiologist, a neonatologist, a scrubbed nurse, and an OR technician. The neonatologist intubates the neonate and attends the surgery for adjustment of the ventilator. Intravenous anaesthesia is given throughout the procedure.

The conventional ORs are located 3 or 4 floors below our NICU. The newborn infants are transferred to the OR with a neonatal transport incubator (Baby Shuttle, Ginevri). In the OR, infants are warmed using a blanket connected to a forced air system (Calima™ Temperature Management Unit, Ajalvir, Madrid). The temperature of the OR is set at approximately 27 °C before the start of surgery and decreased to 23 °C to 25 °C after the patient is covered by surgical drapes. During ORS, a conventional anaesthesia ventilator (AISYS CS2, GE Healthcare, Fairfield, CT, USA) is used to perform volume-controlled ventilation, maintaining the same parameter previously set during ventilation in the NICU.

The ORS team consists of two surgeons, an anaesthesiologist, a scrubbed nurse, and an OR technician. Both inhalation and intravenous anaesthesia are administered in OR.

The body temperature is measured continuously during both BS and ORS.

Sample size and statistical analysis

The sample size calculation was based on the observation that the incidence of hypothermia following ORS in our neonatal population is 50%. To detect a reduction of up to 25% in this incidence, it was necessary to enroll in each study group (BS-Group and ORS-Group) at least 55 surgical interventions, for a total sample size of at least 110 surgical interventions, considering a power of the study of 80% and an alpha error of 0.05 [15].

The demographic, clinical and laboratory characteristics of the sample were summarized using the main descriptive statistic.

Continuous variables were expressed as mean and standard deviation (SD) if distributed as a normal, otherwise as median and interquartile range (IQR); categorical variables were expressed as absolute and relative frequency (percentage).

Continuous variables, distributed as a normal, were compared using the independent samples t-test otherwise with the Mann–Whitney test. The normality in the distribution of the quantitative variables was verified using the Shapiro-Wilks test. Categorical variables were compared using the Chi-square test and/or Fisher's exact test.

To identify the odds ratio of the different risk factors, a multivariable logistic regression analysis was performed using 30-day mortality and hypothermia as dependent variables. A p value < 0.05 was considered statistically significant.

Data were analysed using SPSS (statistical package for the social sciences) version 25.0 (SPSS, Inc, Chicago, IL, USA).

Results

During the study period, 419 surgical interventions were performed on 267 newborn infants. Forty-five surgeries, performed on 45 infants, were excluded: 5 because they were performed on infants with complex malformation syndromes for which the surgery had palliative purposes and 40 because they lacked data relevant to the study. Three hundred and seventy-four surgeries, performed on 222 infants, were then included and analysed: 55 surgeries on 47 infants were included in the BS group and 319 surgeries on 175 infants were included in the ORS group (Fig. 1). This disparity in the number of surgical interventions in the two study groups was due to the fact that although BS has been practiced in our NICU since March 2018, the progressive confidence in the patient's bedside procedure has led to its implementation from 2021.

Baseline and clinical characteristics of infants undergoing bedside or operating room surgery are shown in Table 1. Infants in BS-Group had significantly lower GA and BW than infants in the ORS Group. As a consequence, they had a higher incidence of moderate/severe forms of BPD, longer duration of invasive and non-invasive mechanical ventilation and parenteral nutrition and higher mortality rate at discharge.

The abdominal and thoracic anatomical compartments were those most frequently involved in bedside surgical interventions, while the neurological compartment was the

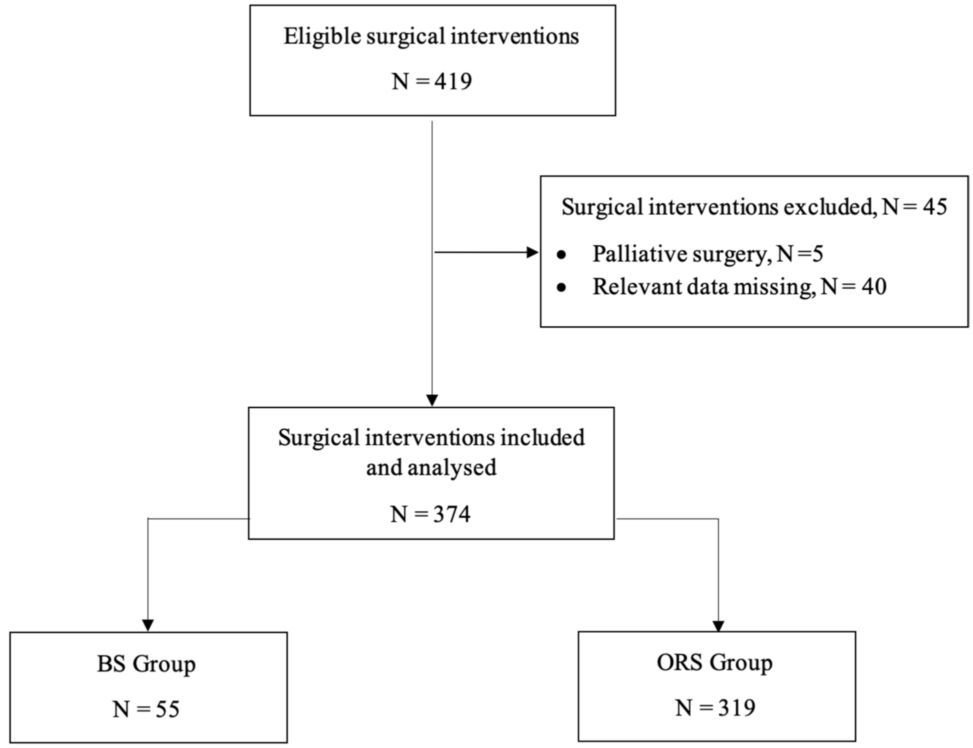

Fig. 1 Consort flow diagram of the study

Table 1 Characteristics of newborn infants in the two study groups undergoing surgery

	BS group infants *N* 47	ORS group infants *N* 175	*p*
Gestational age, weeks	29.6 ± 4.9	32.9 ± 5.3	< 0.001
Birth weight, grams	1332 ± 1005	2019 ± 1089	< 0.001
Gender, *n*	30 (63.8)	101 (57.7)	0.506
IVH > 2, *n*	14 (33.3)	49 (29.2)	0.598
PVL > 2, *n*	3 (6.3)	16 (10.1)	0.770
Moderate/Severe BPD, *n*	13 (40.6)	19 (11.7)	< 0.001
Invasive MV duration, days	14 (7–36)	2 (0–10)	< 0.001
NIV duration, days	11 (0–65)	2 (0–25)	0.009
PN duration, days	53 (15–100)	17 (3–40)	< 0.001
Length of hospital stay, days	79 (21–169)	54 (26–109)	0.271
Survival at discharge, *n*	32 (72.7)	162 (92.6)	< 0.001

Data are shown as mean (SD), median (IQR) or number (percentage)

IVH intraventricular hemorrhage; PVL periventricular leukomalacia, MV mechanical ventilation, NIV non-invasive ventilation, PN parenteral nutrition

one most represented among the surgical interventions performed in the OR (Table 2).

BS was performed earlier, as demonstrated by the significantly lower postnatal day and postmenstrual age of the BS Group infants compared to those of the ORS Group (Table 2). Urgent/emergency surgery was the significantly more frequent modality among the BS procedures compared to those performed in OR, and the need for inotropes before surgery is significantly higher in the BS Group than in the ORS Group. The median duration of the surgical procedures was higher among the BS Group infants compared to the ORS Group infants (Table 2).

Surgical indications for each anatomical compartment are detailed in Table 3.

Regarding the primary and secondary outcomes, no difference was observed in the incidence of postoperative hypothermia between the two study groups (Table 4). Pre- and postoperative body temperature was comparable in the two groups, while in the BS Group a significantly smaller negative variation in body temperature was

Table 2 Data relating to surgical interventions

	BS group surgical interventions *N* 55	ORS group surgical interventions *N* 319	*p*
Anatomical compartment, *n*			
Abdominal	35 (63.6)	124 (38.9)	< 0.001
Inguinal	1 (1.8)	0	0.147
Thoracic	9 (16.4)	10 (3.1)	< 0.001
Neurological	10 (18.2)	184 (57.7)	< 0.001
Neck	0	1 (0.3)	1
PMA at the time of surgery	32.7 (29.0–38.4)	38.7 (34.9–41.7)	< 0.001
Body weight at the time of surgery	1330 (870–2740)	2535 (1803–3228)	< 0.001
DOL at the time of surgery	13 (5–43)	35 (10–87)	0.001
Emergency/urgent surgery, n	49 (89.1)	113 (35.4)	< 0.001
Inotropic drugs before surgery	20 (36.4)	19 (5.9)	< 0.001
Surgery duration, minutes	90 (63–120)	66 (40–120)	0.073

Data are shown as mean (SD), median (IQR) or number (percentage)

PMA Postmenstrual age; DOL day of life

Table 3 Surgical indications for each anatomical compartment

	BS group surgical interventions *N* 55	ORS group surgical interventions *N* 319
Abdominal	35	124
Peritoneal drainage catheter placement	3	0
Omphalocele repair	1	0
Volvolus derotation	1	1
Intestinal stoma formation	30	79
Percutaneous endoscopic gastrostomy	0	11
Gastroraphy	0	4
Ladd's band resection	0	1
Intestinal recanalization	0	28
Inguinal	1	0
Orchiectomy/Orchidopexy	1	0
Thoracic	9	10
Congenital diaphragmatic hernia repair	4	1
Esophageal atresia with fistula repair	5	7
Tracheostomy	0	1
Pneumectomy	0	1
Neurological	10	184
Ventriculo-subgaleal shunt placement	5	75
Externalization of the ventricular shunt	5	9
Ventriculoperitoneal shunt	0	50
Ventriculoatrial shunt	0	4
Brain washing	0	8
Ventricular shunt revision	0	35
Arteriovenous malformation resection	0	3
Neck	0	1
Lymphangioma resection	0	1

Table 4 Primary and secondary outcomes

	BS group surgical interventions *N* 55	ORS group surgical interventions *N* 319	*p*
Hypothermia, *n*	26 (47.3)	173 (54.2)	0.316
Body temperature before surgery, °C	36.6 (36.3–36.8)	36.6 (36.5–36.8)	0.548
Body temperature after surgery, °C	36.5 (35.8–36.8)	36.3 (35.4–36.7)	0.086
Δ-Body temperature, °C	− 0.2 (− 0.7–0.4)	− 0.3 (− 1.2–0.2)	0.038
Blood pH before surgery	7.36 (7.27–7.40)	7.40 (7.35–7.44)	< 0.001
Blood pH after surgery	7.28 (7.19–7.36)	7.37 (7.32–7.42)	< 0.001
Δ-pH	− 0.07 (− 0.15–0.00)	0 (− 0.04–0.13)	< 0.001
De novo inotropic drugs after surgery	5 (9.1)	6 (1.9)	0.013
Weight before surgery, grams	1330 (870–2740)	2535 (1803–3228)	< 0.001
Weight after surgery, grams	1370 (890–2700)	2590 (1800–3280)	< 0.001
Δ-weight, grams	10 (− 10–60)	20 (− 10–70)	0.180
Infection within 48 h of surgery	7 (12.7)	38 (11.9)	1
Mortality rate within 30 days of surgery	10 (18.2)	5 (1.6)	< 0.001

Data are shown as median (IQR) or number (percentage)

observed compared to that observed in the infants of the ORS Group (Table 4).

The BS Group infants had a lower blood pH both before and after the surgical procedure compared to the infants of the ORS Group, as well as the pre- and postoperative negative variation of the blood pH was significantly greater among BS Group infants. The need for inotropes started de novo after surgery was also significantly higher in the BS Group compared to the ORS Group.

The variation in body weight following surgery was comparable in the two study groups.

No significant difference was observed in the occurrence of infections within 48 h of surgery, while the mortality rate within 30 days of surgery was significantly higher in the BS Group than in the ORS Group (Table 4).

Multivariable logistic regression analysis found that the variables independently associated with mortality within 30 days of surgery were gestational age [OR (IC 95%) 0.830 (0.749–0.920), *p* 0.000] and the need for inotropic drugs before surgery [OR (IC 95%) 8.221 (2.128–31.760), *p* 0.002]. Gestational age was inversely associated with mortality within 30 days of surgery, increasing the risk by 17% with its reduction, while the need for inotropic therapy before surgery was associated with an eightfold increased risk of mortality within 30 days of surgery. BS did not appear to be associated with an increased risk of mortality within 30 days of surgery, nor did it appear to be associated with the risk of hypothermia (Table 5). Variables significantly associated with the risk of hypothermia were the weight at the time of surgery [OR (IC 95%) 0.711 (0.542–0.931), *p* 0.013]. and the emergency/urgent modality of surgery [OR (IC 95%) 1.934 (1.221–3.063), *p* 0.005]. Weight at the time of surgery was inversely associated with postoperative hypothermia, increasing the risk by 29% with its reduction, while the emergency/urgent surgical procedure was associated with an almost twofold increased risk of postoperative hypothermia (Table 5).

Table 5 Multivariable logistic regression analysis

	OR (IC 95%)	*p*
Hypothermia		
Bedside surgery	0.885 (0.474–1.653)	0.702
PMA at the time of surgery	1.016 (0.995–1.037)	0.132
Body weight at the time of surgery	0.711 (0.542–0.931)	0.013
Emergency/urgent surgery	1.934 (1.221–3.063)	0.005
Mortality within 30 days of surgery		
Bedside surgery	3.610 (0.985–13.234)	0.053
Gestational age	0.830 (0.749–0.920)	0.000
Birth weight	0.768 (0.222–2.653)	0.676
Emergency/urgent surgery	6.210 (0.771–50.015)	0.086
DOL at the time of surgery	1.001 (0.987–1.016)	0.864
Inotropic drugs before surgery	8.221 (2.128–31.760)	0.002

DOL day of life; PMA postmenstrual age

Discussion

The findings of our study showed that the occurrence of both postoperative hypothermia and infection within 48 h of surgery were not increased for bedside surgical interventions compared to those performed in the OR, despite BS was performed on more fragile neonates, who were more immature, with a lower body weight and in more critical clinical conditions. Indeed, it is worth noting that among infants who underwent surgery at bedside there was a significantly lower negative variation in the pre- and postoperative body temperature than that observed among infants who underwent surgery in the OR.

Our findings are difficult to compare with the data currently available in the literature for several reasons. The first reason is that many studies on BS in newborn infants are mainly aimed at the feasibility and safety assessment, and do not often have a control group of infants undergoing conventional surgery in the OR [16–24]. The second reason is the heterogeneity of the studied populations, the indications for surgical interventions, and the clinical outcomes assessed in the studies comparing BS and ORS.

Postoperative hypothermia in children occurs in approximately 50% of cases [25], reaching 85% in premature infants undergoing laparotomies for necrotizing enterocolitis [26, 27]. Neonatal hypothermia in newborns is associated with increased mortality and morbidity [28], and preventive actions are needed [29, 30].

Surgical procedures performed in the NICU at the patient's bedside have been reported to have lower rates of intra- and postoperative hypothermia compared to surgeries performed in the conventional OR [9, 31]. In our study, we failed to find a difference in the incidence of hypothermia between neonates operated at the bedside and in the OR. This result could be justified by the fact that in our institution much attention is paid to prewarming conventional ORs before surgery on neonates. Risk factors associated with hypothermia were instead the weight at the time of surgery and the emergency/urgent modality of surgery; this last variable probably because it compromises the setting of an adequate perioperative thermoregulation protocol. Furthermore, the fact that the negative variation in the pre- and postoperative body temperature was significantly lower in infants operated at the bedside, despite the significantly lower PMA and body weight at the time of surgery, represents an important success in terms of safety for neonates undergoing BS approach.

The incidence of infection within 48 h of surgery was similar between neonates operated at the bedside and in the OR, suggesting adequate conditions of sterility for bedside procedures. Comparable rate of postoperative infection after BS and ORS has also been reported by other authors [9, 32]. Again, the fact that no difference was found in the infection rate within 48 h of surgery between the two groups, despite a significantly lower PMA and body weight at the time of surgery in the BS group, represents another important safety success for neonates undergoing the BS approach.

In our study, neonates operated at the bedside experienced higher mortality rates within 30 days of surgery and worse overall survival compared to patients operated in the OR. However, multivariable logistic analysis did not detect BS as a risk factor associated with increased mortality. Similarly, Herle et al., in their retrospective study comparing 28 neonates operated at the bedside for abdominal surgical conditions with 60 neonates operated in the conventional OR for similar indications, found lower survival in infants operated at the bedside than in infants operated in conventional OR [10]. As in our study, poor survival was associated with higher inotrope requirement. Furthermore, in Herle's study, low weight was associated with poor survival, while in our study, low gestational age was associated with it. All these results highlight that more severe neonatal clinical conditions favour BS, as also emerged from our recent national survey in which the main criteria for BS, among Italian neonatal surgery units, were found to be both extremely low gestational age and birth weight, and critical clinical conditions [33]. These findings are also consistent with reports in the global literature on BS in the NICU, usually intended for neonates considered too ill or clinically unstable to be transported to a conventional OR [9, 10, 19–21, 34, 35].

Similar findings were reported by Niec et al., who compared 48 infants with congenital diaphragmatic hernia operated at the bedside in the NICU with 137 infants operated for the same condition in the OR [35]. The authors observed higher overall mortality among infants operated at bedside, although, in multivariate analysis, repair location was not found to be a significant predictor of survival to discharge; also in Niec's study, as in our study, infants operated at bedside had worse clinical conditions before surgery [35].

The main limitation of this study is its retrospective nature, which led to a patient selection bias; in fact, although only major surgical interventions were included in the study, it emerged that BS was evidently reserved for the most critical neonates. However, despite the worse clinical conditions of neonates operated at the bedside, BS was not found to be a risk factor associated with adverse postoperative outcomes. The strength of our study is that it represents, to our knowledge, the one with the largest population. Furthermore, by including in the study not only elective surgeries but also those performed in emergency/urgent modality, we were able to evaluate this variable, identifying it as a risk factor associated with postoperative hypothermia. Finally, the characteristics of the studied population, which includes preterm and full-term infants, undergoing elective and emergency/urgent surgery, allow the generalizability and external validity of the results.

Conclusion

BS seems to be safe and effective in not increasing the risk of postoperative adverse events despite being performed in worse clinical conditions than conventional ORS.

Future clinical research efforts should be aimed at establishing, through randomized clinical trials, the superiority of

BS over ORS, to identify precise clinical criteria, according to which newborn infants can be assigned to BS or ORS.

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Author contributions Simonetta Costa contributed to the conceptualization of the study and wrote the first draft of the manuscript. Simona Fattore contributed to the data analysis. Cecilia Brughitta, Paola Catalano, Nicola Frattaruolo, and Filomena Valentina Paradiso contributed to the acquisition of the patients' data. Liliana Sollazzi, Marco Rossi, Paola Aceto, Lorenzo Nanni, and Giovanni Vento contributed to reviewing and editing the first draft of the manuscript. All authors gave the final approval of the version to be published.

Data availability No datasets were generated or analysed during the current study.

Declarations

Competing interests The authors declare no competing interests.

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