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Research paper

Extremely premature infants: How does death in the delivery room influence mortality rates in two level 3 centers in France?

O. Forner^{a,*}, A. Schiby^b, A. Ridley^c, G. Thiriez^b, I. Mugabo^a, V. Morel^b, B. Mulin^d, J.-C. Filiatre^d, D. Riethmuller^e, G. Levy^f, D. Semama^g, D. Martin^g, C. Chantegret^g, S. Bert^h, F. Godoy^g, P. Sagotⁱ, T. Rousseauⁱ, A. Burguet^g

^aService maternité-obstétrique, hôpital Jean-Minjoz, 3, boulevard Alexandre-Fleming, 25000 Besançon, France

^bService réanimation néonatale et pédiatrique, hôpital Jean-Minjoz, 3, boulevard Alexandre-Fleming, 25000 Besançon, France

^cService médecine pédiatrique, hôpital Jean-Minjoz, 3, boulevard Alexandre-Fleming, 25000 Besançon, France

^dRéseau périnatalité de Franche-Comté, hôpital Jean-Minjoz, 3, boulevard Alexandre-Fleming, 25000 Besançon, France

^eService gynécologie obstétrique, hôpital Jean-Minjoz, 3, boulevard Alexandre-Fleming, 25000 Besançon, France

^fService gynécologie obstétrique, hôpital Nord Franche-Comté, 100, route de Moval, 90400 Trevenans, France

^gService réanimation néonatale et pédiatrique, hôpital d'enfants, 14, rue Paul-Gaffarel, 21000 Dijon, France

^hService maternité obstétrique, hôpital d'enfants, 14, rue Paul-Gaffarel, 21000 Dijon, France

ⁱService gynécologie obstétrique, CHU de Dijon, 14, rue Paul-Gaffarel, 21000 Dijon, France

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ABSTRACT

Objectives: Mortality rates of very preterm infants may vary considerably between healthcare facilities depending on the neonates' place of inclusion in the cohort study. The objective of this study was to compare the mortality rates of live-born extremely preterm neonates observed in two French tertiary referral hospitals, taking into account the occurrence of neonatal death both in the delivery room and in the neonatal intensive care unit (NICU).

Methods: Retrospective observational study including all pregnancy terminations, stillbirths and live-born infants within a 22- to 26-week^{0/6} gestational age range was registered by two French level 3 university centers between 2009 and 2013. The mortality rates were compared between the two centers according to two places of inclusion: either the delivery room or the NICU.

Results: A total of 344 infants were born at center A and 160 infants were born at center B. Among the live-born neonates, the rates of neonatal death were similar in center A (54/125, 43.2%) and center B (33/69, 47.8%; $P = 0.54$). However, neonatal death occurred significantly more often in the delivery room at center A (31/54, 57.4%) than at center B (6/33, 18.2%; $P < 0.001$). Finally, the neonatal death rate of live-born very preterm neonates admitted to the NICU was significantly lower in center A (25/94, 26.6%) than in center B (27/63, 42.9%; $P = 0.03$).

Conclusions: This study points out how the inclusion of deaths in the delivery room when comparing neonatal death rates can lead to a substantial bias in benchmarking studies. Center A and center B each endorsed one of the two models of preferential place of neonatal death (delivery room or NICU) detailed in European studies. The reasons behind the two different models and their impact on how parents perceive supporting their neonate need further investigation.

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1. Introduction

Prematurity is one of the leading causes of perinatal morbidity-mortality identified by the World Health Organization (WHO)

[1]. Both ethical and methodological reasons may contribute to a large variability in cohort studies of the outcome of the most immature among these extremely preterm neonates. The guidelines and rationale on active resuscitation of extremely premature infants are largely developed based on epidemiological data relating to short-, medium-, and long-term outcome of very premature infants [2–4]. Moreover, these guidelines are shaped by each country's unique cultural values [5,6] and may vary not only

* Corresponding author.

E-mail address: O.Forner^agoonies86@hotmail.fr (O. Forner).

between countries, but also on a regional scale for any given country [7].

Comparing international mortality rates is therefore exceedingly complex [8]. The management of extremely preterm infants born prior to 26 weeks of gestational age (WG) has been widely debated in France over the past decade by the Perinatal Ethical Reflection Group [9]. Following these debates, comfort care is generally recommended from 22 or 23 weeks of gestation, whereas active resuscitation is performed beginning at 26 WG. The EPIPAGE 2 study outlines a situational analysis of the management of extremely premature infants (23, 24 and 25 WG) by French obstetricians and pediatricians, highlighting a particular heterogeneity in care among the 24-WG age group [10,11]. The study also identifies the unique characteristics of preterm neonate care in France in relation to other European countries, North America, and Japan [5,12].

Moreover, preterm infant mortality rates are influenced by multiple factors such as historical and cultural conditioning and advances in perinatal medical technology [13,14]. In addition to these, methodological reasoning susceptible to modifying regional or national preterm mortality rates should not be overlooked [15,16].

The primary objective of this study was therefore to evaluate to what extent the inclusion of infant deaths in the delivery room can potentially influence the mortality rate of cohorts including extreme preterm infants born alive and transferred to the NICU (neonatal intensive care unit). The secondary objective is to draw neonatologists' attention to the variability of place of death among extreme preterms, whether it be the delivery room or the NICU. This is a topic that is little discussed in the non-European literature.

2. Material and methods

We conducted a retrospective benchmarking study. All premature babies born between 22^{0/6} and 26^{6/6} WG in two French level 3 university maternity centers were included over a period of 5 years, from 1 January 2009 to 31 December 2013. Both centers A and B are referral NICUs for their region providing care for extremely premature infants. The centers are located in adjacent districts (Burgundy and Franche-Comté) and have 31,000 births per year. The delivery room was architecturally separate from the NICU in both centers. For this reason, maternity ward neonatologists intervened in preterm infant resuscitation in collaboration with intensive care neonatologists.

Neonates were registered with the combination of three sources of information. The first source was the French Medical Information System registry (Programme de médicalisation des systèmes d'information [PMSI]), a national database of patient hospital discharge summaries, using the codes Z38, P964, P95, P072, and linked to a gestational age between 22 and 26 weeks of gestation. A second source was the manual registry of all births that occurred in the delivery room of the two centers. The registry recorded maternal and neonatal identity, date and hour of birth, gestational age, birth weight, gender, vital status at birth, APGAR score, and outcome of the neonate. A third source of information was the review of every maternal and neonatal computerized hospitalization record of birth between 22 and 26 WG.

Gestational age was determined by ultrasonography in over 95% of the cases in both centers. Otherwise, gestational age was determined using the date of the last menstrual period.

The vital status of very preterm neonates was defined as: (1) stillborn after medical termination of pregnancy (MTP) for a severe congenital malformation after a collegial decision by the Multidisciplinary Center for Prenatal Diagnosis (Centre pluridisciplinaire de diagnostic prénatal), (2) stillborn due to

intrauterine fetal death either previously diagnosed or observed upon delivery, and (3) live-born neonates according to WHO criteria. Fetal viability at birth was assessed using the WHO criteria: an infant is declared live-born if it manifests signs of life (respiratory movements, heartbeat, etc.) and if it is viable (at least 22 WG and/or birth weight of 500 g) [8]. If the previously listed criteria are absent, the infant is declared stillborn in accordance with the 19th of June 2009 interministerial decree, and live-born according to WHO criteria. In France, we have defined "gray zones" corresponding to minimal gestational age at which survival is uncertain and therefore resuscitation at birth is performed on a case-by-case basis. The WHO did not define infant viability but rather set minimal age/weight criteria for birth registration.

The outcome of live-born infants was further classified into three categories: live birth but death in the delivery room whether or not there was active reanimation or palliative care, infant transferred to the NICU but death during resuscitation, and infant transferred to the NICU and discharged from the hospital alive.

A small number of infants' initial vital status according to the PMSI server was later modified after review of the medical records. At hospital A, two infants recorded as intrauterine fetal demise in fact died as a result of MTP and were classified as such for our analysis. In France, MTP is commonly prescribed for fetal morphological abnormalities and severe intrauterine growth retardation. The procedure is carried out by optional feticide followed by induced labor after ethical discussion in accordance with French legislation. The two centers in our study are both referral centers for prenatal diagnostics, but organize their MTPs differently. Nearly all MTPs at center A first perform a feticide. However, at center B not all MTPs are carried out at the referral center since level IIB centers in the district are also authorized to perform MTP. In these centers, a feticide is not systematically performed depending on the clinical situation and the parents' wishes.

At center A, all medical terminations of pregnancy for fetal indications were carried out after feticide. Only two terminations for maternal reasons occurred without prior feticide and the infants presented no signs of life at birth. At center B, feticide was performed in 61% of cases (35/52). For the 20 infants born after MTP without feticide, no signs of life at birth were observed in this group.

Three different mortality rates of live-born neonates were compared between the two centers:

- the death rate in the delivery room, corresponding to the number of infants deceased in the delivery room over the total number of live-born infants between 22^{0/6} and 26^{6/6} WG;
- the death rate among live-born infants, corresponding to the number of infants deceased in the delivery room or in the NICU over the total number of live-born infants;
- the death rate in the NICU, corresponding to the number of infants deceased in the NICU over the total number of live-born infants admitted to the NICU.

We then compared mortality rates between the two centers according to birth weight strata (less than 500 g, 500–749 g, and 750 g and more), or gestational age (22–23, 24 and 25–26 WG).

Analysis of variance was used to compare neonatal gestational age and birth weight between the two centers. The Pearson chi² test and the Fisher test were used to compare mortality rates. No multivariate analysis was performed due to a limited number included in the cohort and a lack of discrimination between the two centers with regard to gestational age and birth weight. The statistical tests were completed using the Stata 9 software (College Station, TX, USA).

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