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Posted Date: 8 March 2024

doi: 10.20944/preprints202403.0507.v1

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Article

Parents' Participation in Care during Neonatal Intensive Care Unit Stay in COVID-19 Era: A Quantitative Observational Study

Emanuele Buccione ^{1,2,*†}, Davide Scarponcini Fornaro ^{2†}, Damiana Pieragostino ^{3,4}, Luca Natale ^{3,4}, Adelaide D'Errico ⁵, Valentina Chiavaroli ⁶, Laura Rasero ⁷, Stefano Bambi ⁸, Carlo Della Pelle ⁹ and Susanna Di Valerio ¹⁰

¹ Doctoral student, Department of Biomedicine and Prevention, University of Rome Tor Vergata, Rome, Italy;

² MSN, RN, Neonatal Intensive Care Unit, Health Local Authority 3 Pescara, Pescara, Italy;

³ Department of Innovative Technologies and Medicine & Odontoiatry, University G. D'Annunzio, ChietiPescara, Italy;

⁴ Analytical Biochemistry and Proteomics Laboratory, Center for Advanced Studies and Technology (CAST), "G. d'Annunzio" University of Chieti-Pescara, Chieti, Italy;

⁵ MSN, RN, Neonatal Intensive Care Unit, Santobono-Pausilipon Children's Hospital, Naples, Italy;

⁶ PhD, MD, Neonatal Intensive Care Unit, Health Local Authority 3 Pescara, Pescara, Italy;

⁷ MSN, RN Department of Health Sciences, University of Florence, 50134 Florence, Italy;

⁸ PhD, MSN, CCN, RN Department of Health Sciences, University of Florence, 50134 Florence, Italy;

⁹ PhD, RN, Medical Department, Health Local Authority 2 Chieti, Chieti, Italy;

¹⁰ MD, Neonatal Intensive Care Unit, Health Local Authority 3 Pescara, Pescara, Italy;

* Correspondence: emanuele.buccione@students.uniroma2.eu; Tel.: +39-349-8098954

† These authors have contributed equally to this work and share first authorship.

Abstract: Background: During the stay in the neonatal intensive care unit, parents play a crucial role in the care of their infants. Recent studies reported a decrease in parental participation due to Coronavirus Disease (COVID-19) pandemic that determined restricted access policies in hospitals. The aim of this study is to describe the barriers to a good parents' participation during the stay in the neonatal intensive care unit in the COVID-19 era. Methods: A quantitative observational study was carried out. Results: 270 parents participated in this study. Mothers' participation in care seems to be higher as compared to fathers ($p = 0.017$). Parents who lived the birth of their first child reported a better level of participation in care when compared to those who lived the birth of their second born ($p = 0.005$). Parents of extremely preterm neonates reported a lower interaction with their infant if compared to parents of term newborns ($p < 0.001$). Conclusions: Some more disadvantaged categories have reported lower scores: cultural and linguistic minorities, parents of multiple children and fathers. COVID-19 pandemic made several Family Centred Care activities not possible with a higher impact on those who benefited the most of these facilities. This study was prospectively registered by the IRB-CRRM of the University "G. d'Annunzio" Chieti-Pescara on the 23/01/2024 with registration number CRRM;2023_12_07_01.

Keywords: neonatal intensive care unit; parenthood; newborns; preterm; nurses

1. Introduction

The length of stay for preterm and ill newborns in the neonatal intensive care unit (NICU) can be considerably extended [1]. This period often causes a separation between parents and their offspring, limiting emotional and physical closeness [2]. Furthermore, the period after birth is critical in the bonding process between parents and newborns [3]. Previous studies have shown that alterations in their role are the greatest source of stress for parents [4–6].

During the stay in the NICU, parents can play a crucial role in the care of their infants [7]. Models such as Family-Centred Care (FCC) and Family Integrated Care (FICare) promote parental participation [8]. These programmes allow parents to become confident, knowledgeable, and independent primary caregivers. FCC and FICare can shorten the time to use the nasogastric tube, reduce hospital length of stay, increase the rate of exclusive breastfeeding, improve the overall prognosis of preterm infants, also exerting also positive effects on parents [9].

Recent studies reported a decrease in parental presence and participation during NICU stay due to Coronavirus Disease (COVID-19) pandemic that determined restricted access policies in hospitals [10–12]. Restricted visit policies resulted in a negative experience of parenthood and a negative impact on breastfeeding [11]. The pandemic has impacted parental well-being directly through stress due to COVID-19, but also indirectly due to the health policies and visiting restrictions, which significantly altered the experience of parenthood. The ability to cope with this challenging situation depended on individual features as well as the physical and social environmental factors of the NICU [10,13].

The impact of COVID-19 restrictions on the access to NICU by parents was qualitatively described in several published studies [10–12], but none quantitatively reported the limits related to decreased participation in care.

In the Italian healthcare care context, no instruments were available to quantitatively evaluate the participation in the NICU activities. Recently, Scarponcini Fornaro and colleagues validated the Italian version of the scale ‘Parental Participation in Care: Neonatal Intensive Care Unit (PPCS: NICU)’ which allows to evaluate the parents’ participation in care of their neonates [14,15].

2. Materials and Methods

The aim of this study is to describe the barriers to a good parents’ participation during the stay in the NICU using PPCS: NICU in the COVID-19 era. A monocentric retrospective cohort study based on a prospectively collected data was designed following the statement ‘Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)’ [16].

2.1. Sample and Setting

The study was carried out in 22 beds mixed NICU (medical and surgical) of a generic hospital. The study participants included parents whose babies were admitted to the NICU and agreed to participate using a written informed consent form. During data collection, one parent at a time was allowed to enter the NICU twice a day, for a maximum of two hours, due to visiting restrictions related to COVID-19. Only for twins both parents were allowed to enter the NICU simultaneously.

2.2. Data Collection

Parents’ sociodemographic data were retrospectively collected (age, gender, race, occupational status, experience of previous abortion or deaths). Newborns retrospectively recorded variables were gestational age, body weight at admission, type of childbirth, twin-birth, and all medical devices used to support the newborn. During COVID-19 pandemic NICU nurses performed evaluations of parental participation in care, in order to highlight parents with a low participation. Two evaluations for each parent were performed. The first observation was recorded in the first three days. The second observation was provided between the seventh and tenth days of hospitalization. The instrument used was the Italian PPCS:NICU [15]. It consists of one dimension composed by 16 items, which is similar to the original scale [14]. The items used a 3-point Likert Scale (3 = always, 2 = sometimes, 1 = never). The highest score that can be obtained is 48, the lowest is 16. A score of 16 points indicates that the parent does not participate in the care of her/ his infant. Higher scores indicate higher participation levels. No cut-off points were specified by the instrument [14]. The first three items are focused on communication between parent and health professionals. From fourth to fifteenth items the tool covers the interaction between parent and newborn (physical contact, breastfeeding, hygienic care, and support during painful procedures). The last item is focused on parents’ expression of

emotions and fears. In the validation study the tool in Italian language showed an overall Content Validity Index (CVI) of 0.976 and a good reliability (Cronbach α = 0.926) [15] (supplementary material).

2.3. Statistical Analysis

Excel software was used to store the data. Summary statistics are presented as absolute frequencies and percentages and as medians and interquartile ranges [IQR] for continuous non-normally distributed data (according to the Shapiro-Wilk test). Nonparametric tests were performed to compare median values reported by each categorical variable using the Kruskal-Wallis test and the U Mann-Whitney test. Bonferroni adjusted p-values were calculated for multiple comparisons. A subgroup analysis by periods was performed to assess whether parental participation differed according to the duration of hospitalisation of their neonates. Pearson's correlation was performed to estimate the association between continuous variables and tool scores. To balance the effects of any confounders, a multiple logistic regression was used. Statistical significance was established at a P value less than .05. Statistical analysis was performed using IBM SPSS version 22.0. While for the statistical power analysis, G * Power 3.1 [17].

3. Results

Data collected refers to the period between April and December 2022. Two-hundred and seventy parents were included in this study. 136 participants were female (50.4%). The 21.9% (n=59) of the sample experienced previous abortions, while 2.6% (n=7) experienced previous offspring deaths. For 55.2% (n=149) it was the birth of their first child, and most couples (47.4%, n= 128) experienced a natural childbirth. Most of the cases are Caucasian (88.1%, n=238). The median [IQR] age was 34 [9] years. All parents' features are detailed in Table 1.

Table 1. – Median scores according to characteristics of parents and newborns.

Factors	Categories	N (%)	Median [IQR] I assessment	p-value	Median [IQR] II assessment	p-value
Gestational Age	Extremely Preterm	8 (3.0%)	31 [9]	<0.001	39.5 [9]	0.033+
	Very Preterm	32 (11.9%)	35 [12]		42 [10]	
	Moderate/Late preterm	60 (22.2%)	42.5 [7]		46 [3]	
	Term	170 (63.0%)	42 [9]		45 [7]	
Parents' Gender	Female	136 (50.4%)	42 [8]	0.017	46 [6]	0.003
	Male	134 (49.6%)	39 [11]		44 [9]	
First Child	No	121 (44.8%)	38 [12]	0.005	44 [10]	0.015
	Yes	149 (55.2%)	42 [8]		46 [6]	
Previous Abortions	No	211 (78.1%)	41 [9]	0.325	45 [8]	0.294
	Yes	59 (21.9%)	39 [12]		47 [7]	
Previous Deceased Children	No	263 (97.4%)	41 [10]	0.070	46 [7]	0.093
	Yes	7 (2.6%)	35 [6]		40 [6]	
Type of Delivery	Natural Birth	128 (47.4%)	43 [8]	<0.001	46 [6]	0.006
	Elective Cesarean Section	76 (28.1%)	40.5 [10]		44 [8]	

	Emergency Cesarean Section	66 (24.4%)	38 [12]		46 [9]	
Parents' Ethnicity	Caucasian	238 (88.1%)	42 [8]	<0.001	46 [7]	<0.001
	African	18 (6.7%)	30.5 [15]		38 [9]	
	Hispanic/Latino Americans	10 (3.7%)	45 [8]		47.5 [4]	
	Asian*	4 (1.5%)	16 [0]		16 [0]	
Job	Unemployed	60 (22.2%)	42 [10]	0.119	44 [8]	0.126
	Employee	200 (74.1%)	41 [10]		46 [7]	
	Student	10 (3.7%)	32 [24]		42 [21]	
Twins	No	237 (87.8%)	41 [11]	0.981	45 [8]	0.029
	Yes	33 (12.2%)	40 [7]		47 [1]	

Table 1 - Bold values: statistically significant; * = excluded due to low number; IQR: Interquartile range; †= not statistically significant after bonferroni correction.

One hundred and fifty-two newborns were included in the study, of which 11.2% (n = 17) were twins. Fifty newborns (37.1%) were preterm. The median body weight at admission [IQR] was 2790 [1140] grams. The median gestational age was 37 [5] weeks.

The overall participation in care, at admission, reported a median score of 41 [10]. After approximately seven days of hospitalization, a significant overall improvement was observed with a median score of 46 [8] and $p < 0.001$ was observed.

3.1. Barriers Related to Parental Background

Mothers' participation in care levels appears to be significantly higher compared to fathers (median score of 42 [8] and 39 [11], respectively; $p = 0.017$). This result is also confirmed by the second observations, when mothers reported a median score of 46 [6] versus 44 [9] reported by fathers ($p = 0.003$). Parents who lived the birth of their first child reported a better median level of participation in care compared to those who lived the birth of their second child (42 [8] vs 38 [12]); $p = 0.005$. Furthermore, this difference appears to remain unchanged over time with a higher score in parents of only children (46 [6] vs 44 [10]); $p = 0.015$). African parents reported significantly lower participation in care with a median score of 30.5 [15] vs 42 [8] reported by Caucasian people and 45 [8] by Hispanics ($p < 0.001$), this difference remains significant also in the second observation. Lastly, parents who experienced natural birth showed higher participation in care with a median score of 43 [8] compared an parents who underwent to emergency cesarean section (median score 38 [12]) with a $p < 0.001$, also in this case, the difference still significative over time.

There was no correlation between age and their parenthood ($r = -0.80$; $p = 0.18$ at admission and $r = -0.87$; $p = 0.15$ after about 7 days). Other factors such as previous abortions; previous deaths and occupational status did not affect the level of parenthood during the stay in the NICU. All scores are detailed in Table 1.

3.2. Barriers Related to Neonates Features

Parents of extremely premature newborns reported a significantly lower interaction with their infant with a median score of 31 [9] compared to parents of term newborns (median score 42 [9]; $p < 0.001$). However, after approximately seven days of hospitalisation, there was not a significant difference between the parental participation scores of preterm and term neonates. Parents of twins showed significantly higher participation only in the second evaluation with a median value of 45 [8] vs 47 [1] reported by parents of the only newborns ($p = 0.029$). According to the Mann-Whitney U

test, the fathers reported a higher participation than those of the only neonates in care with a median value of 44 [8] vs a median value of 42 [13] ($p = 0.025$) respectively.

Lastly, all devices related to critically ill conditions were associated with significantly lower interaction between parents and neonates. The only devices not associated with a minor interaction are: peripheral venous catheter, high flow nasal cannula, monitoring of brain functions (Table 2).

Table 2. – Median scores according to the presence of medical device used to support newborns.

Factor	Categories	N (%) ; Median (IQR) I assessment	p-value	N (%) ; Median (IQR) II assessment	p-value
Peripheral venous catheter	No	119 (44.1%); 39 (11)	0.062	89 (33.0%); 46 (9)	0.663
	Yes	151 (55.9%); 42 (9)		181 (67.0%); 46 (6)	
Central venous catheter	No	238 (88.1%); 41.5 (9)	0.011	212 (78.5%); 46 (7)	<0.001
	Yes	32 (11.9%); 38 (17)		58 (21.5%); 42 (9)	
Umbilical venous catheter	No	180 (66.7%); 42 (9)	0.462	270 (100%); 46 (8)	-
	Yes	90 (33.3%); 39 (10)		-	
Continuous infusions	No	92 (34.1%); 38.5 (11)	0.203	132 (48.9%); 46 (8)	0.015
	Yes	178 (65.9%); 42 (10)		138 (51.1%); 45 (7)	
Arterial catheter	No	260 (96.3%); 41 (10)	0.032	270 (100%); 46 (8)	-
	Yes	10 (3.7%); 34 (10)		-	
High-flow nasal cannula	No	226 (83.7%); 41 (11)	0.679	226 (83.7%); 46 (8)	0.713
	Yes	44 (16.3%); 41 (10)		44 (16.3%); 46 (5)	
Non-invasive ventilation	No	258 (95.6%); 41 (10)	0.802	261 (96.7%); 46 (7)	0.049
	Yes	12 (4.4%); 41 (7)		9 (3.3%); 40 (6)	
Endotracheal tube	No	224 (86.0%); 42 (8)	0.001	243 (90.0%); 46 (7)	0.001
	Yes	46 (17.0%); 35 (13)		27 (10.0%); 41 (9)	

High-frequency oscillatory ventilation	No	258 (95.9%); 41.5 (9)	0.005	266 (98.5%); 46 (8)	0.140
	Yes	12 (4.4%); 34 (10)		4 (1.5%); 40 (10)	
Gastric tube	No	168 (62.2%); 42.5 (10)	0.006	170 (63.0%); 46 (7)	0.031
	Yes	102 (37.8%); 39 (11)		100 (37.0%); 44 (8)	
Cerebral function monitoring	No	252 (93.3%); 42 (10)	0.100	264 (97.8%); 46 (8)	0.074
	Yes	18 (6.7%); 39.5 (9)		6 (2.2%); 42 (9)	
Bladder catheter	No	250 (92.6%); 42 (9)	<0.001	252 (93.3%); 46 (7)	<0.001
	Yes	20 (7.4%); 34 (17)		18 (6.7%); 39 (11)	
Stoma	No	266 (98.5%); 41 (10)	-	264 (97.8%); 46 (7)	0.005
	Yes*	4 (1.5%); 16 (0)		6 (2.2%); 22 (26)	
Skin temperature probe	No	183 (67.8%); 43 (9)	<0.001	208 (77.0%); 46 (7)	0.010
	Yes	87 (32.2%); 39 (11)		62 (23.0%); 44 (8)	
Phototherapy	No	242 (89.6%); 42 (9)	0.006	263 (97.4%); 46 (8)	0.040
	Yes	28 (10.4%); 36 (12)		7 (2.6%); 41 (5)	
Pulseoximeter sensor	Yes	270 (100%); 41 (10)	-	270 (100%); 46 (8)	-
Carbon-dioxide Sensor	No	228 (84.4%); 42 (8)	< 0.001	251 (93.0%); 46 (7)	0.001
	Yes	42 (15.6%); 35 (11)		19 (7.0%); 41 (9)	
PPS:NICU total score	Overall	41 (10)		46 (8)	<0.001

Table 2 - Bold values: statistically significant; IQR: Interquartile range; * = excluded due to low number.

3.3. Multiple Linear Regression

Multiple linear regression analyses were performed to limit the influence of possible confounders (Tables 3 and 4).

Table 3. – Multiple linear regression according to the characteristics of the parents.

Factors	Beta	95% Confidence Interval		P value
		Lower Limit	Upper Limit	
Parents' age	-0.022	-0.130	0.077	0.617
Parents' gender	-0.176	-0.482	-0.161	<0.001
First child	0.079	-0.125	3.046	0.071
Previous abortion	0.061	-0.471	3.193	0.145
Previous deceased child	-0.009	-5.128	4.146	0.835
Type of delivery	-0.178	-2.942	-1.041	<0.001
Parents' ethnicity	-0.256	-5.558	-2.802	<0.001
Parents' job	-0.046	-2.625	0.850	0.316
Twins	0.124	1.126	5.775	0.004

Table 3 – Dependent variable: Parental Participation in Care Neonatal Intensive Care Unit Score; Bold values: statistically significant.

Table 4. – Multiple linear regression according to the characteristics of the newborns and the medical device.

Factors	Beta	95% Confidence Interval		P value
		Lower Limit	Upper Limit	
Gestational age	0.040	-1.388	2.283	0.632
Peripheral venous access	0.054	-0.890	2.931	0.295
Central venous access	-0.037	-3.686	1.863	0.519
Umbilical venous access	-0.057	-4.505	1.703	0.376
Continuous infusions	0.148	0.630	4.867	0.011
Arterial access	-0.040	-10.611	5.165	0.498
High-flow nasal cannula	-0.063	-3.726	0.589	0.154
Non-invasive ventilation	0.005	-4.005	4.432	0.921
Endotracheal tube	-0.021	-5.047	3.916	0.804
High-frequency oscillatory ventilation	0.011	-5.455	6.615	0.850
Gastric tube	0.028	-1.393	2.453	0.588
Cerebral function monitoring	-0.063	-6.656	1.052	0.154
Bladder catheter	-0.154	-9.904	-1.100	0.014
Stoma	-0.226	-21.315	-9.347	<0.001
Skin temperature probe	0.073	-1.188	4.185	0.274
Phototherapy	-0.093	-6.936	0.044	0.053
Carbon-dioxide Sensor	0.026	-3.821	5.309	0.749

Table 4 – DEPENDENT VARIABLE: PARENTAL PARTICIPATION IN CARE NEONATALE INTENSIVE CARE UNIT SCORE; BOLD VALUES: STATISTICALLY SIGNIFICANT.

It was confirmed that participation in care is negatively affected by parents' gender ($\beta = -0.176$; 95% CI -0.482 to -0.161; $p < 0.001$), type of delivery ($\beta = -0.178$; 95% CI (-2.942 to -1.041); $p < 0.001$) and parents' ethnicity ($\beta = -0.256$; 95% CI: -5.558 to -2.802; $p < 0.001$). Furthermore, some clinical device or

condition could negatively affect the interaction between parents and their newborns: catheter placement in the bladder catheter ($\beta = -0.154$; 95% CI: -9.904 to -1.100; $p = 0.014$) or presence of stoma ($\beta = -0.226$; 95% CI: -21.315 to -9.347; $p < 0.001$).

3.4. Sensitivity Power Analysis of Multiple Linear Regression

Sensitivity power analysis (Figure 1) allowed to determine the minimum effect size to which this study was sensitive. For a power of 0.95, based on the sample size recruited (270 participants) and an alpha level of 0.05, this analysis showed sensitivity for an effect size $f^2 = 0.13$, which is defined as medium.

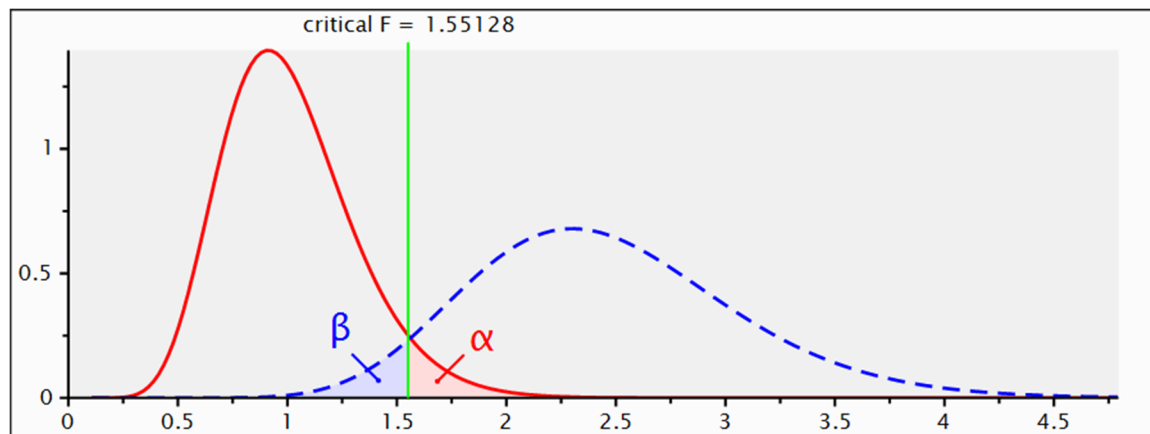


Figure 1. Distribution plot.

4. Discussion

This study described the early barriers to parenthood during the stay in COVID-19 era. No similar published study had a comparable sample size which has been shown to be sensitive to a medium effect size [18]. Furthermore, this is the first study to be performed using the PPS:NICU scale after cross-cultural validation for the Italian population. This scale allows a quantitative assessment of the participation by nurses and health professionals. Before, only the Italian EMpowerment of PArents in the Intensive Care-Neonatology (EMPATHIC-N) questionnaire was available, but this tool provides a self-assessment of the quality of care perceived by parents of neonates admitted to NICU [19]. Another study was carried out using the index parental participation scale (IPP), but no validation study was still carried out to test the Italian version [20].

The sample highlighted fair general participation in care, according to another Italian study that reported no significant differences in participation before and during pandemic [20]. Despite this, our results highlighted an important cultural barrier to parenthood, shown by foreign parents, as described in previous studies. In fact, low awareness about cultural and social factors by healthcare professionals can reduce the effectiveness of communication with families in the NICU, exacerbate family denial, erode trust, and generally have a generally damaging effect on interactions between staff and families [21,22]. The impact of parental primary language on communication in the neonatal intensive care unit was also described as a barrier that contributes to suboptimal healthcare delivery [23]. Probably, the restrictions caused by COVID-19 and the conversations between parents and healthcare professionals often conducted by phone made the impact of these barriers very large.

Parents who have already had other children show a lower participation score, this phenomenon could be due to the lack of baby-sitting as already described by Kerr et al., can be linked to a poor availability of babysitting services for other children [24]. Furthermore, during the pandemic period, the fear of attending the NICU may have arisen to risk contracting the virus and infecting the closest relatives.

Our findings also highlighted a lower interaction between extremely preterm newborns and their parents. A previously published study described that during the stay in the NICU, mothers of

preterm infants experienced disruption of family dynamics, support and bonding; physical and emotional isolation; negative psychological impact compounded by increased concerns, change in maternal role and survival mode mentality [25]. Furthermore, the complex psychosocial needs of parents of extremely preterm infants were challenging for the NICU and its staff already before the COVID-19 pandemic [26]. Communicating parents' needs and informing them about the available support was essential to help them to cope with their infants' hospitalization [26]. However, restrictions during the COVID-19 era often made this not possible. It is already described that, during pandemic period, parents experienced increased stress due to the restricted NICU visitation policies, limited opportunities to care for their infant, lack of support, and inconsistent communication regarding their infant status and COVID-19 protocols [27].

According to our results, fathers seemed less involved than mothers in the care of their newborns. This is supported by another result that shows how the fathers of the twins, who had the opportunity to visit their children together with their partner, reported a higher value of participation than the fathers of the only children. As previously described, this is reportable to relational suffering (separation from the partner, separation from the newborn) [28]. Furthermore, fathers who experienced minor restrictions reported a greater involvement in caregiving activities [29]. A recent study highlights how early positive perceptions of fatherhood could significantly predict fathers' confidence in neonatal care and to be significantly influenced by psychological satisfaction due to the intimate relationship between fathers and their offspring [30].

Lastly, this study showed a lower involvement of parents who had a planned or unplanned cesarean section. Two previous published studies support these findings. Mothers who experienced cesarean section reported having worse postnatal depression, a lower maternal bonding, and openness emotions [31]. Furthermore, cesarean sections cause maternal feelings such as sadness and disappointment with the unplanned birth process [32].

Before the pandemic, implementing parent-infant closeness in the NICU was a challenge for nurses and healthcare professionals [1]. Optimization in neonatal care, such as zero separation and parent-infant closeness, was reset with the onset of the pandemic. The ideal collaboration between NICU nurses and parents has always been characterized by flexibility and reciprocity, and is based on verbal and action dialogues [7]. Obviously, during the pandemic period, this was very limited with a negative impact on the well-being of parents and newborns.

5. Conclusions

Many studies provided a qualitative analysis of the feelings and emotions experienced by parents of infants admitted to the NICU during the COVID-19 pandemic. This study is one of the few that conducted a quantitative description of the interactions between parents and their newborns. This was possible using the Italian PPCS:NICU Scale that was validated in the Italian context. Despite a general fairly good participation in care, some barriers to parenthood during NICU stay in the COVID-19 era were highlighted. Some more disadvantaged categories have reported lower scores: parents of cultural and linguistic minorities, parents of multiple children, and fathers. The COVID-19 pandemic made several Family-Centred Care activities not possible with a greater impact on those who benefited the most from these facilities (24 hour visit, kangaroo care, cultural mediation service, psychological or educational support).

Supplementary Materials: The following supporting information can be downloaded at the website of this paper posted on Preprints.org. Table S1: Italian version of the scale 'Parental Participation in Care: Neonatal Intensive Care Unit (PPCS: NICU)'

Author Contributions: Conceptualization, E.B. and D.S.F.; methodology, E.B. and S.B.; formal analysis, E.B. and D.S.F.; investigation, D.S.F. and A.D.; data curation, D.S.F. and L.N.; writing—original draft preparation, E.B., D.S.F. and L.N.; writing—review and editing, V.C., S.B. and L.R.; visualization, C.D.P. and D.P.; supervision, S.D.V. All authors read and approved the final manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Parents who participated in this study were not subject to any interventions. Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from patients to publish this article. The research was carried out according to the principles of the original Declaration of Helsinki and its subsequent amendments. Data were stored and managed in accordance with current Italian legislation on data protection. The collected were aggregated and anonymously analyzed. The present study was approved by the Institutional Internal Review Board of the Department of Innovative Technologies in Medicine & Dentistry of the University of Chieti with approval number 'CRRM_2023_12_07_01'.

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

Data Availability Statement: The datasets used during the current study are available from the corresponding author on reasonable request.

Public Involvement Statement: No public involvement in any aspect of this research.

Guidelines and Standards Statement: This study was designed following the statement 'Strengthening the Reporting of Observational Studies in Epidemiology (STROBE). von Elm, E.; Altman, D.G.; Egger, M.; Pocock, S.J.; Gøtzsche, P.C.; Vandenbroucke, J.P. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for Reporting Observational Studies. *Journal of Clinical Epidemiology* 2008, 61, 344–349, doi:10.1016/j.jclinepi.2007.11.008.

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

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