Developmental care and very preterm infants : neonatal, neurological, growth and developmental outcomes

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CHAPTER 1

Introduction

Incidence of preterm birth

The incidence of preterm birth is increasing in The Netherlands as well as in the United States. In 2004, 12.5% of all live births in the United States was a preterm birth, which is an increase of 18% since 1990. Although multiple births have contributed to this recent rise, preterm rates for singletons have also increased, up 11% since 1990[1]. The preterm birth rate continued to rise in 2005 (to 12.7% in 2005) as did the rate for LBW births (8.2%)[2].

In 2001 there were approximately 16,000 infants born preterm (less than 37 weeks pregnancy) in the Netherlands, which is 8% of all live births. There were 2,200 very preterm births (born less that 32 weeks pregnancy). The incidence of very preterm births has increased between 1983 and 1999 from 1,068 to 2,170 infants, which is a relative increase from 6.8 per 1000 to 10.8 per 1000 live births[3].

As some of the risk factors for a premature birth are also increasing, i.e. older average age that a woman has her first child as well as a higher maternal age in general, infertility treatments, multiple births, better prenatal care and improved diagnosis and treatment, it is expected that the rise in infants born prematurely will continue[4].

Risks associated with prematurity

Advanced technology in the treatment of preterm infants has resulted in decreasing mortality rates. However all preterm infants are at heightened risk of morbidity and mortality compared with infants born at higher gestational ages[2]. Some of the complications that may occur as the result of being born preterm are respiratory distress syndrome (RDS), intraventricular hemorrhage (IVH), periventricular leukomalacia (PVL), patent ductus arteriousus (PDA), necrotizing enterocolitis (NEC), infections, bronchopulmonary dysplasia (BPD), and retinopathy of prematurity (ROP)[5]. Higher survival rates of very preterm infants have not necessarily led to lower morbidity rates, and has been associated with a higher incidence of intraventricular hemorrhage and BPD[6-8].

Follow-up outcomes of preterm infants

Follow-up studies show that preterm infants have an increased risk of developmental disorders[6,9-11]. Neuromotor abnormalities are the most frequent of the "hidden disabilities" among ex-preterm children and are frequently associated with poorer cognitive ability and attention deficit disorder[12]. A meta-analysis showed increased risk of cognitive deficits and behavioral problems in preterm infants, with cognitive deficits greater and in direct proportion to the infant's gestational age and birthweight[13]. Studies report a higher risk of later disabilities or handicaps at school age as well as learning and behavioral disorders in preterm infants [14,15]. In addition, VLBW children have an increased risk of developing attention deficit hyperactivity disorders (ADHD), have generalized anxiety and more symptoms of depression[16].

The NICU environment

Research on the sensory development of the preterm infant have shown that many of the environmental factors and care practices in the NICU have a significant impact on infant sensory development. In addition, problems of sleep deprivation are related to care practices and NICU organization[17,18]. Current evidence suggests that the NICU environment has strong influences on physiological functioning (hypoxemia, apneas, etc.) and in turn influences the long-term development of the weak and vulnerable central nervous system[19,20]. Because premature infants cannot regulate incoming stimuli, they become easily overstimulated and stressed. Als and colleagues propose that there is a sensory mismatch of the premature infant's developing nervous system's expectations for environmental inputs and the actual sensory overload that is experienced in the neonatal intensive care. This in turn can lead to a greater chance for later developmental problems[21,22].

Parents of premature infants

In addition, many factors in the NICU environment may adversely affect parent-infant attachment and parent involvement essential for long-term development[23]. Family bonding in the NICU is often a very difficult process, due to the separation of parents and child at birth and the continued physical restraints of the complex critical care environment. Cronin et al report that parents of very low birth weight infants (< 1500 grams) continue to manifest stress even up to 5 years after the birth of the child[24]. Involving parents in the care of their infant and instructing them in premature behavior may facilitate bonding, increase parents' confidence in care-giving and possibly decrease the chance of later disturbances in the parent-child relationship.

The nature of the relationships that families develop with health care providers in the NICU may have a profound influence on how individuals and families respond to the experience of having a preterm infant[25].

Developmental Care

The challenge confronting healthcare professionals who care for preterm infants and their families is not only to assure the infants' survival, but to optimize their developmental course and outcome[26].

In order to address these problems, researchers have concentrated on ways to improve the care and environment of the NICU for infants and parents through the use of developmental care programs. In the last 15-20 years, interest has increased and programs have been implemented in various neonatal nurseries. The philosophy behind developmental care is to reduce stress and support development of premature infants as well as their parents. The NIDCAP (Newborn Individualized Developmental Care and Assessment Program) is a comprehensive program used as a framework for the implementation of individualized developmental care in the NICU[26].

NIDCAP

The NIDCAP program is an approach in which the infant's behavior provides the best information from which to design care[27]. Repeated, systematic behavioral observations of the infant are carried out and recommendations for caregiving are made based on these observations. These behavioral observations are based on the Synactive Theory of Development which states that there is a continuous interaction of five subsystems within the developing infant: the autonomic system, the motor system, the state organizational system, the attentional-interactive system, and the self-regulatory system [27,28]. The infant is in constant interaction with the environment and the infant's level of functioning can be observed via these subsystems.

The autonomic system's functioning is observable in the infant's breathing patterns, color fluctuations and visceral stability or instability such as bowel movements, gagging and hiccoughing. The motor system functioning is observable in the infant's body tone, postural repertoire and movement patterns, as reflected in facial and trunkal tone, tone of the extremities and in the extensor and flexor postures and movements of face, trunk and limbs. State organization is observable in the infant's range of available states (from sleeping, to alert, to aroused), their robustness and modulation and the patterns of transitions from state to state. Some infants show the full continuum of states, from deep sleep to light sleep, then to drowsy and quiet alert and to active awake and aroused and then to upset and crying[29]. Other infants during interactions move from sleep to aroused states and immediately back to sleep again, skipping the alert state. Thus state stability and the smooth transition from state to state would reflect intact state organization whereas the opposite would reflect disorganization[21]. The attention and interaction system is seen in the infant's ability to come to an alert, attentive state and to use this state to take in information from the environment and in turn, elicit and modify these inputs from the world around him. The self-regulatory system is seen in the strategies the infant uses to maintain a balanced, relatively stable state of subsystem integration or to return to a more balanced and relaxed state[28] (Table 1).

The five subsystems are interdependent and interrelated. For example, physiological stability lays the foundation for motor and state system control. State organization, the management of sleep–wake cycles, creates a component of self-regulatory competence. The loss of integrity in one system influences the other systems, as they manage environmental demands [30].

The behavior of the infant and how the infant is coping with the environmental inputs can be observed via the subsystems and the balance of avoidance, stress behaviors and approaching, self-regulatory behaviors[21,27]. The infant uses these strategies and mechanisms to move away from and avoid inappropriate environmental demands or to seek out and move towards inputs currently appropri-

Table 1. Behavioral systems and channels of communication

Subsystems	Channels of communication
Autonomic/physiologic	- respiration pattern - color changes - heart rate - visceral stability
Motor	- posture - tone - movements
State[29] - Deep sleep - Light sleep - Drowsy - Quiet alert - Active awake, aroused - Upset, crying	- range of states - state transition patterns - robustness of states
Attention-Interaction	- ability of the infant to come to an alert, attentive state, take in input and interact with the environment
Self-regulatory	- strategies used to return to a calm balanced state - behaviors the infant uses to bring and keep the subsystems in balance

Based on the Synactive Theory of Development from Als[27] ate for the infant's intake capacities. Avoidance behaviors are believed to reflect stress. Approach and self-regulatory behaviors are seen when the input does not exceed the capabilities of the infant. For example, extension behaviors primarily are thought to reflect stress and disorganization and flexion behaviors are thought to reflect self-regulatory competence. Diffuse behaviors are thought to reflect stress and well-defined robust behaviors reflect self-regulatory balance [21].

This model is based on the assumption that the infant actively and consistently, through his behavior, communicates his/her thresholds for sensitivity versus competence. The range of infant behaviors becomes evident as the infant matures[30].

If the input is too much for the infant and his own regulatory capacities are exceeded, a further parameter of functioning is seen in the kind and amount of facilitation that is needed to help the infant return to a more balanced subsystem functioning[28]. Sensitivity to these signs of organization or disorganization provides the caregiver with an understanding of each infant's threshold for activity and stimulation[30].

In the healthy full term newborn the five subsystems are mature, integrated, synchronized and managed smoothly. All five systems are managed easily and without stress. The less mature, healthy preterm or sick preterm may be unable or partially able to manage environmental inputs, demonstrating over-reactive responses and poor tolerance from even minimal input. Loss of control and stress responses become frequent unless the environment and caregivers work to read the infant's messages and thresholds for sensitivity and adjust care and handling and the environment based on the infant's behavioral communications[30].

A behavioral observation method is used based on the assumption that the behavior of the infant is the primary route for communicating thresholds to stress or relative functional stability. The observation is carried out for 20 minutes before caregiving or handling in order to have a baseline of the infant's behavior, during the caregiving and for at least 10 minutes after caregiving in order to assess the infant's ability to recover and what interventions may be needed to help facilitate the infant. The observation sheet is divided into 2-minute time segments in which specific behaviors observed can be checked. A narrative descriptive of the infant's behavior before, during and after caregiving is made based on the observation, with interpretation of behavioral signals as stress vs. self-regulatory behaviors. On the basis of this description, an individualized developmental care plan is made with suggestions for the reduction of stress behaviors and the increase of self-regulatory behaviors. These may include interventions in the physical environment of the infant, direct caregiving and discharge planning[28]. The emphasis of NIDCAP is on an individual approach in which the behavior of the infant is used to deliver caregiving.

Various components of a developmental care program may consist of:

a) Reducing environmental sources of stress by lowering noise, light and activity levels and the use of incubator covers. Nurseries should be quiet, soothing places with individual dimmed lighting.
b) Supporting motor development by positioning the infant in comfortable aligned, softly flexed positions during sleep and caregiving interaction and using various materials and buntings to provide soft boundaries.
c) Providing containment by gently swaddling the infant's body, arms and legs with your hands or with a soft blanket to reduce diffuse and jerky movements during caregiving interactions.
d) Reducing the physiological and behavioral destabilization associated with procedural handling by providing support or containment, allowing the infant a "time-out" when thresholds to stress are exceeded, and providing aids for self-regulation, such as pacifiers or objects to grasp.
e) Supporting organization of sleep-wake states through preserving undisturbed rest periods and providing light-dark cues for the development of circadian rhythms.
f) Attention to readiness for and the ability to take oral feedings, providing individual feeding support determined by the infant's individual needs and preferences. Feeding success is not only judged by the infant's intake but also by the infant's overall energy levels and autonomic, motor and state functioning.
g) Involving parents in the care of their infant and guiding parents in recognizing their infants behaviors and ways in which they can support their infant during caregiving interactions [21,31,32].

Developmental care studies carried out up to 2000

Studies evaluating the effect of individual developmental care were published from the mid 1980's. The first study published was a phase-lag study, after that various RCT's were carried out[31,33-37]. Many of the developmental care studies originate from the United States and Sweden where most infants remained in the same neonatal unit until discharged to home (Table 2).

Table 2. NIDCAP studies published before 2000

Author and year	Design	Participant's	N	Intervention	Main outcomes
Als 1986	Phase-lag	Birthweight < 1250 g GA < 28 weeks Ventilated ≥ 24 hours in first 48 hours of life and 60% FiO_2 ≥ 2 hours in first 48 hours	E=8 C=8	Caregiving by NIDCAP trained personnel until discharge	Days ventilation Days O^2 Days before bottle feeding 2 APIB system scores at term age MDI and PDI at 3, 6 and 9 months
Als 1994	RCT	Birthweight < 1250 g GA < 30 weeks Ventilated within first 3 hours and > 24 hours of first 48 hours	E=20 C=18	Caregiving by NIDCAP trained personnel until discharge	Days ventilation (ns) Days O^2 ($p=0.05$) IVH Days before bottle feeding ($p=0.05$) Severity of BPD Days of hospitalization MDI and PDI at 9 months
Buehler 1995	RCT	Birthweight ≤ 2500 GA 30-34 weeks No ventilatory support Also 3rd C group of healthy full-term infants	E=12 C=12 FT=12	Individual developmental care by specially trained personnel until discharge	4 APIB system scores at term age 3 Prechtl summary scores and total Prechtl score at term age Outcomes comparable to full term infants in E group
Fleischer 1995	RCT	Birthweight < 1250 g GA ≤ 30 weeks No ventilation in first 3 hours or for > 24 hours of first 48 hours of life	E=17 C=18	Individual developmental care by specially trained personnel until discharge	Days ventilation and /or CPAP Duration of stay > 42 weeks PCA ($p=0.05$) 4 APIB system scores at term age
Ariagno 1997	RCT	Birthweight < 1250 g GA ≤ 30 weeks No ventilation in first 3 hours or for > 24 hours of first 48 hours of life	E=11 C=12	Follow-up of some of original participants of RCT by Fleischer, 1995	No significant difference in MDI and PDI at 4, 12 months and 24 months

All outcomes are significant in favor of the intervention group unless otherwise indicated
E: experimental group, C: control group, RCT: Randomized Controlled Trial, GA: gestational age, MDI: Mental Development Index, PDI: Psychomotor Development Index, IVH: intraventricular hemorrhage, PCA: postconceptional age

Developmental Care in NICU's in the Netherlands

Developmental care programs were relatively unknown in the Netherlands in 1999. Since then, the interest for developmental care and NIDCAP has increased. Studies that have been published to date are scarce. Before NICU's in the Netherlands implement developmental care programs, research is needed to evaluate the effectiveness of this program in our present neonatal system.

One of the criticisms of developmental care programs has been that it is difficult to ascertain which of the components are responsible for the improved outcomes[36,38-40]. It was suggested that research is needed in which the effectiveness of the various components of the developmental care program can be evaluated in addition to the comprehensive NIDCAP program.

In this thesis we have attempted to answer some of these questions as well as measure the effect of developmental care in a NICU in the Netherlands. The study consisted of a pilot study measuring the effect of a short-term, hospital based intervention with parents in which they were instructed in preterm infant behavior with the goal of increasing their responsiveness to their infant and therefore their confidence in caregiving. This was followed by two consecutive randomized controlled trials.

The phase one RCT evaluated the effect of basic elements of developmental care (standardized incubator covers and nests and positioning aids) designed to reduce stress and improve physiological stability in infants compared to standard care, which at that time consisted of no covers or nesting.

The phase two RCT studied the effect of the comprehensive NIDCAP (Newborn Individualized Developmental Care and Assessment Program), with the use of the behavioral observation and assessment tool with recommendations for caregiving as well as supporting the parents, as compared to the basic elements of developmental care.

Outline of this thesis

This thesis examines the effect of a developmental care program in a tertiary NICU at two locations in the Netherlands on preterm infants born < 32 weeks gestational age.

Chapter 2 describes a pilot study to evaluate the effect of a short-term, hospital based intervention with parents and their premature infants born < 32 weeks gestational age in the neonatal department of the Leiden University Medical Center, in which parents were instructed in understanding preterm infant behavioral cues.

In Chapter 3 we examine the effects of basic developmental care on short-term morbidity, growth and neurodevelopmental outcomes to term age.

Chapter 4 studies the effect of basic developmental care on 1 and 2 year growth and neurodevelopmental outcomes.

Chapter 5 describes the effect of the comprehensive NIDCAP developmental care program on short-term morbidity, growth and neurodevelopmental outcomes to term age.

Chapter 6 examines the effect of NIDCAP on 1 and 2 year growth and neurodevelopmental outcomes.

Chapter 7 contains the General Discussion on the results of this study.

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