Stress and discomfort in the care of preterm infants: A study of the Comfort Scale and the Newborn Individualized Developmental Care and Assessment Program (NIDCAP®) in a Dutch level III NICU

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Discussion
The core of this thesis was to gain insight in the extent of stress and measurement of stress and discomfort in preterm infants and to explore new ways to reduce stress factors for preterm infants in the Neonatal Intensive Care Unit (NICU) by Newborn Individualized Developmental Care and Assessment Program (NIDCAP) implementation. Furthermore we evaluated the results of NIDCAP implementation on clinical, developmental and growth outcome. We also evaluated the satisfaction of parents and the nursing staff following NIDCAP implementation.

The purpose of this final chapter is to discuss the results from the separate study objectives, as mentioned in chapter 1, to discuss methodological issues, integrate the results and give suggestions for further research and clinical practice.

OBJECTIVES

The first objective was to evaluate whether the Comfort scale can be validated to assess stress and discomfort in preterm infants.

We found (chapter 2) that the Comfort scale is a valid and reliable instrument for use in ventilated preterm infants. The Comfort scale is also able to discriminate between the presence and absence of stress. The cut off point of 20 points with high sensitivity and fair specificity is chosen to prevent a false negative test result, meaning an infant mistakenly classified as not suffering from stress. Stress appeared to still be a real problem in our unit, 27% of the ventilated preterm infants had to deal with stress despite the fact they received routine morphine. This underscores the necessity of proper evaluation of stress in preterm infants. We prefer to use the Comfort scale for the evaluation of stress above clinical judgement because the Comfort scale is a more explicit formulation of the clinical judgement. It is obvious that clinical judgement is never free from subjectivity.

The Comfort scale being a non-intrusive objective observation, fits very well in the stress-preventing policies of todays care of preterm infants in the NICU. The use of the Comfort scale takes little time, 2 minutes for the observation and 1 minute filling in the score, three to six times a day. This can be easily integrated in the daily caregiving of preterm infants.

The second objective of study concerned the applicability of the Comfort scale in studying different modes of mechanical ventilation in relation to stress.

We found (chapter 3) high percentages of scores ≥ 20 points (34.5%) during the first three days of mechanical ventilation although we found no indication that this was influenced by the choice of ventilation mode (high frequency or conventional ventilation).

The study took the edge off the impression among nurses that the impressive vibrations of the tiny bodies were an additional source of stress for the infants. The
Comfort scale showed that our clinical observation, concerning stress, was not accurate. The current use of analgesics and sedatives seemed insufficient to prevent high stress scores. A recently published Cochrane review found insufficient evidence to support a recommendation for the routine use of opioids during mechanical ventilation. It has been suggested that opioids should be used selectively, based on clinical judgement and evaluation of pain indicators. When pain relief is required, morphine is recommended over midazolam because of fewer adverse effects. However there is a need to investigate this issue, specifically in preterm infants. For now we recommend assessment of stress, by means of the Comfort scale on a routine basis during mechanical ventilation.

The Comfort scale has been adapted by adding an item on crying for non ventilated 0 to 3-year-old infants. This adapted version, the Comfort behaviour scale, has been tested (the item of respiratory response and blood pressure excluded) recently for its use on heel puncture in preterm infants with a gestational age between 28 and 37 weeks. Good interrater reliability was found for most items (weighted kappa ranged from 0.62 to 0.84), except on facial tension (weighted kappa 0.45) and muscle tone (weighted kappa 0.53). The intraclass correlation coefficient for the total score was 0.93 (95% CI: 0.89 – 0.96). These results are comparable with our results in ventilated infants. The cut off of 17 points was chosen for this 7 item version of the adapted Comfort scale based on an area under the curve of 0.97 (sensitivity 93.0% and specificity 80.0%).

The Comfort scale measures the amount of actual stress. However to be able to use the observed infants’ behaviour in the prevention of stress or to help the infant to cope with stress is a step further. Communication concerning infant stress (pain), recognizing behaviour as an expression of stress or discomfort, as well as the lag of assessment skills of professionals are described in literature as hampering factors in the care of very preterm infants. Due to the inability of the very preterm infant to communicate verbally an extensive tool, based on behavioural items, is needed to be able to assess stress and consequently prevent it. The ability to identify behaviour, to interpret the meaning of that behaviour and to understand relationships between these behaviours, may help NICU caregivers to become more aware and sensitive of signs of stress in the infant. Caregivers who can accurately assess stress signals are more proficient at interaction with the infants and they are able to prevent moments of stress for the preterm infants.

Although NIDCAP is not designed specifically to assess stress, a study on 24 of the movement items, has shown that a subset of eight movement behaviours are statistically significantly associated with pain. Other studies showed that behavioural signs according to NIDCAP were associated with acute pain in preterm infants. The conclusion of these studies was that the NIDCAP tool did not only assess stress, but also pain.

NIDCAP and developmental care interventions also decreased pain scores significantly during interventions. NIDCAP can be used as a tool to gain insight into pain and stress behaviour of the individual preterm infant as well as to help all caregivers including parents to become more sensitive and responsive to the infants cues, thus enhancing...
mutual interaction. Caregivers become more attuned to the needs of the infant and can thereby provide adequate (i.e. neither too much nor too little) stimulation and prevent stress. Accordingly NIDCAP can be described as belonging to the new generation of interventions, which focuses on the interaction between the infant and caregiver.

A survey was performed to gain insight into care according to NIDCAP, being the new way of caring for preterm infants in Dutch speaking NICU’s.

We found (chapter 4) a continuum of developmental care in Dutch speaking NICU’s in the Netherlands and Flanders. At one side of this continuum some of the principles of developmental care based on initiatives of individual professionals were applied. No policy was formulated. A second group was formed by the majority of NICU’s where the concept of developmental care was accepted. In these NICU’s, developmental care existed from a set of resources and developmental care was part of the unit policy. This meant availability of facilities and support by the organization. The third group had committed themselves to apply developmental care according to NIDCAP and tried to establish individualized care based on behavioural observations. This group had a high level of expertise present.

The study showed there is consensus in the Dutch definition of the concept of developmental care as described in chapter 4. It is desirable to use the definition with the implementation process of developmental care in NICU’s.

The study clarified that developmental care in whatever way, does not only have far-reaching consequences for the view and policy on care in preterm infants but also influences all the people individually taking part in this process i.e. nurses, doctors, paramedics with their expertise and parents. Developmental care leads to permanent changes in the way that NICU’s are traditionally designed and organized.

The study showed developmental care and particularly NIDCAP apparently to be the new way of care for (very) preterm infants in the NICU’s. A recent study came to the same conclusion. That study reported developmental care (not specifically NIDCAP) to be perceived by neonatal nurses as the vital component to care provided in the NICU’s. A new dimension has been added to the expertise of the nursing discipline.

Until now there is limited evidence of the effect of NIDCAP on short term medical, neurodevelopmental and family outcome.

The Cochrane review concluded that the effect of NIDCAP on neurodevelopmental outcome (measured in four out of the five trials included) was conflicting; in some trials a significant improvement on scores at 9, 12 and 24 months of age was found. In others no improvement on neurodevelopment could be demonstrated. Family outcome was measured in only one trial, in which a significant group difference in family stress and perception of the child was found. There was a number of overall design limitations of the trials included in this review. Because of the nature of the intervention, blinding was not possible and several studies reported on contamination of the control group with
developmental care practices. Meta-analysis was also limited due to the large variation in outcome or methods of measurement.\textsuperscript{12}

Another meta-analysis, including 5 randomized controlled trials, as well as 3 phase-lag cohort studies concluded that there was inconclusive evidence to support the NIDCAP as a framework in which to provide developmental care.\textsuperscript{20,13-16,21-24} Only a statistically significant improvement in days of requirement for supplemental oxygen was found. Also an improvement at 9 or 12 months was seen in neurodevelopment but not at 2 years. However, it should be noticed that three of the included studies were performed before the introduction of surfactant.\textsuperscript{13,14,23}

The third objective in this thesis was to show that care according to NIDCAP improves the clinical outcome of the NICU stay of very preterm infants.

In our phase-lag cohort study (chapter 5) the effect of individualized developmental care (NIDCAP) and conventional care on short term clinical outcomes of preterm infants, admitted to a tertiary neonatal intensive care unit was compared. Interestingly, NIDCAP infants had a lower incidence of cerebral damage during the NICU period as compared to infants in the conventional care group. This effect could neither be explained by differences between both groups in the presence of cerebral haemorrhage at inclusion, nor by other differences in neonatal background characteristics, nor by a secular trend of lower cerebral damage incidence in our NICU. The fact that NIDCAP is aimed at a reduction of stress and a better match between environment and brain development might be an explanation. The fact that NIDCAP may have resulted in less severe cerebral damage, should be interpreted with precaution, since the number of patients included in our study was rather small. But in this respect and in line with others\textsuperscript{25,26}, we conclude that NIDCAP deserves further exploration.

Recently, preliminary short term outcome data from a large NIDCAP randomized controlled trial on very preterm infants was presented.\textsuperscript{27} This study confirms the finding of significantly less mechanical ventilation, lower incidence of chronic lung disease and shorter hospitalization.

Care according to NIDCAP during the NICU period improves growth and developmental outcome during the first two years of life of preterm infants, was the fourth objective to be studied. We found (chapter 6) no effect of NIDCAP on the mental or psychomotor developmental outcome at the corrected age of 24 months compared to conventional care as measured with the Bayley Scales of Infant Development-II. At term age, NIDCAP group infants were still motor and autonomic (Neurobehavioral Assessment Scale [NBAS]) less stable compared to conventional care infants. No differences were seen in the neurological status (Touwen) or growth parameters during the first 24 months of age. Growth did not differ between the groups. Our study provided no evidence for a beneficial effect of NIDCAP on developmental outcome or growth. However, taking the
fragile status (NBAS scores) of NIDCAP infants into account, their equal developmental outcome at 24 months is remarkable.

The fifth objective was to evaluate if NIDCAP increases satisfaction rates of the parents of preterm infants. From the quality of care perspective improving satisfaction was an important issue. In our study (chapter 7) we showed parents to be statistically significant more satisfied (NICU- Parent Satisfaction Form [NICU-PSF]) with caregiving according to NIDCAP than the conventional care for their infants. No difference was seen in the amount of perceived support by nurses (Nurse Parent Support Tool [NPST]) of parents in both care groups.

In the literature a cut off point was given, neither for the NICU-PSF nor for the NPST. The principle of, the higher the score the more satisfied, was applied. However, with conventional care scoring as high as it was, it seemed almost impossible to expect a significant increase in satisfaction after implementing NIDCAP. Considering the fact that we have only just started with NIDCAP, we are content with the extent of the improvement so far.

A recently published study concluded in line with our results that mothers in the NIDCAP group, tended to rate the staffs’ ability to support them in their role as a mother somewhat higher, compared to the control group mothers. Another study reported on parents having noticed, the positive experience and effects of wellbeing of their infant cared for by NIDCAP. However, that did not result in differences in parental stress between parents with infants cared for by NIDCAP or control care.

The sixth objective of study, was the improvement of job satisfaction of the nursing staff caring for preterm infants with NIDCAP. We (chapter 8) showed that despite major changes in nursing care practice by means of NIDCAP did not affect overall satisfaction (measured with Index of Work Satisfaction [IWS]). It was of clinical relevance that IWS index scores suggested that nurses in our setting were consistently satisfied with their job.

NIDCAP also introduced a shared autonomy among nurses. NIDCAP trained professionals took over a part of the autonomy to make decisions for their infants based on their own knowledge and experience and by providing the nurse with recommendations for care and support of development. This shared autonomy did not influence the satisfaction score, autonomy was scored the most important and most satisfying component before as well as after introduction of NIDCAP.

Interaction was ranked as the second most important component. Within primary nursing interaction among and between nurses and medical doctors was already an important issue. NIDCAP introduction added the dimension of interaction between nurses and NIDCAP trained nurses, resulting in increased satisfaction scores on this component.
Nurses were satisfied with their professional status, which was reflected in the satisfaction score being one of the highest. However professional status was not ranked as an important component.

Nurses were a little less satisfied about their tasks requirements after the introduction of NIDCAP than before. NIDCAP introduction brought a major shift in the tasks and activities of nurses, from routine care based, to care based on the signs and signals of the infant and more important from task based to relation based care. It is possible that the scores reflect the process of change rather than how satisfied nurses were with their new job responsibilities and activities.

The organizational policies were scored as the least important component. However, it was the only component with a statistically significant increase after the NIDCAP introduction. This was mainly caused by the fact that there was statistically significant more disagreement on the statement of “not enough opportunities for advancement”. New educational possibilities such as NIDCAP training for the nurses are likely to be the cause of this change.

The IWS reflects the level of satisfaction of the individual nurse instead of the nursing staff as a group. Recently the IWS was adapted to focus on the nursing group.

A study on staff opinions, with respect to NIDCAP, reported nurses and doctors to be positive about NIDCAP in regard to the infants’ wellbeing. However, NIDCAP was also thought to be time consuming and might worsen job conditions. Nurses in that study had a more positive attitude and experienced a more positive impact of NIDCAP on the NICU conditions compared to conventional care.

METHODOLOGICAL ISSUES

The studies described in this thesis concerned non-randomized comparisons. It is obvious that evidence-based practice, based on randomized controlled trials is highly preferable. In our opinion a randomization was not applicable for our studies on NIDCAP implementation. Since NIDCAP entails vigorous modification of nursing care that causes irreversible changes to caregivers’ behaviour and environmental modifications, it therefore leads to the inevitable contamination of the control care. Unfortunately, a cluster randomized controlled trial in many NICU’s nationwide was not an alternative option, since implementation of NIDCAP is expensive, labour intensive and time consuming. For this reason many NICU’s were not able or willing to invest such an amount of money and time or had other priorities.

Randomized controlled trials are widely accepted as the most reliable method of determining effectiveness but most trials evaluate the effects of a single intervention. NIDCAP can be seen as a complex of different interventions, which may act both independently and interdependently and requires a different methodology for the
evaluation of its effects. Therefore the evaluation of the NIDCAP intervention is difficult because of the problems of developing, identifying, documenting, and reproducing the NIDCAP intervention. An iterative phased approach to the development and evaluation of the NIDCAP using different but complementary methods from quantitative research (descriptive studies, surveys, case studies) as well as from qualitative research (phenomenological study, benchmarking, ethnographic studies) may be a more suitable approach to be able to come to a better understanding of a multidisciplinary approach of care, such as NIDCAP.

NIDCAP can be seen as part of the environmental neonatology as introduced in the eighties. NIDCAP can be defined as the study on the effects of newborn intensive care facilities and micro environments on the growth, development, behaviour and health conditions of infants. NIDCAP has been thought to constitute an applied discipline in its own right. NIDCAP needs a multidisciplinary approach from the perspective of social as well as medical sciences. Outcomes chosen to measure the effect of this intervention should be much more in line with social sciences such as, satisfaction, comfort and quality of life. With these social science outcomes one is able to look further than the facts of the usefulness of the intervention and value the intervention on its merits. NIDCAP should be placed in a broader perspective, when it is restricted to medical and developmental outcome, there is the risk of losing a very worthwhile intervention in the care of the preterm infants and their parents.

Our studies were hampered by another methodological issue. Groups were not similar with respect to background characteristics, as well as some clinical and socio economical characteristics. Differences were accounted for in multivariate analysis. However, due to the relatively small sample sizes in our studies, the number of variables that could be adjusted for, was limited.

The duration of the intervention period of NIDCAP (during NICU stay only) in this study is a matter of discussion. Comparison of our results with other studies is rather difficult since in the Netherlands infants are transferred to general hospitals as soon as intensive care is no longer required. Consequently NIDCAP care ended at discharge from the NICU because developmental care was not yet introduced in these hospitals at that time. In studies from other countries infants stayed in the NICU and received NIDCAP care until discharge from the hospital or at least until 36 weeks post conceptional age. The ideal length of the intervention is not yet known.

INTEGRATION OF RESULTS

Integrating the results described in this thesis and the methodological issues of studying developmental care, resulted in the following implications for further research and clinical practice.
Research implications

Research on stress should be focused on the measurement of stress and prevention of stress. Consensus in the use of the Comfort scale as the way to measure stress and pain for preterm infants would be a major step forward. Studies on adequate analgesic and sedation are still necessary especially during invasive treatment.

Further research on NIDCAP is needed to prevent developmental care to end up in science and history books just as a trend of the first years of the 21st century. NIDCAP deserves a chance to prove it is the preferred model and deserves a firm footing in the care for very preterm infants and their parents.

Performing a multi-center European (and North American) study combining quantitative and qualitative methodologies and medical, nursing and behavioural science viewpoints would be worthwhile and is highly recommended.

Besides medical outcome, evaluation should be focused on measurement of psychological and morphological changes in brain function, wellbeing and behaviour of infants and the wellbeing of parents. Standardization of outcome parameters, methods of measurement and consistent timing of assessment is necessary to at least be able to compare separate study results. The influence of NIDCAP on working conditions and job satisfaction of professionals should be a standard item in research on NIDCAP.

For comparison of study results standardization is necessary for the scoring of type or level of developmental care interventions and the care environment, the duration of the intervention as well as the number of observations for each infant before performing further research on developmental care models as NIDCAP.

The cost of the NIDCAP intervention is considerable because of the need for specially trained personnel. The economic impact of the implementation and maintenance of developmental care practices should be evaluated. Economic evaluation which takes into account both the increased costs of the intervention and cost savings, resulting from possible lesser or shorter medical consumption by preterm infants, should be studied. Such an evaluation could be the answer to the question if we should invest our financial limited resources in NIDCAP.

The cultural context and beliefs in relation with developmental care and NIDCAP principles should be a topic in future research, especially in multicultural populations such as the metropolitan areas in the western part of the Netherlands.

Studying the continuity of individualized developmental care during NICU stay as well as during regional hospital stay should give more insight into the desirable length of the intervention. Also the combination of NIDCAP with other developmental intervention programs, in the first period after hospitalization, such as Infant Behavioural Assessment Intervention Program (IBA-IP) should be studied to gain more information on the desirable period of developmental care.

Another aspect to study is the way preterm infants react after being cared for by NIDCAP compared to conventional care when the infant is challenged or triggered. Is the
behaviour of NIDCAP infants more organized, do they show less stress behaviour and is their regulation better compared to conventional care infants? On the other hand it could be questioned if it is really necessary to scientifically prove that the obvious human care, with the evaluation of well-being and the application of structured gentle care to support a fragile preterm infant and its family, is better. Perhaps it would be more appropriate to prove a more active and invasive care is not harmful but required for the preterm infant compared to the more natural developmental care. In case of equal suitability the human care is obviously preferred.

Implications for clinical practice
This thesis describes that clinical practice in the NICU should be integrated in a developmental care environment for infants and their parents, in combination with individualized developmental care, based on regular behavioural observations according to the NIDCAP model of care for the very preterm infants. All potential painful and / or stressful periods and events should be assessed with the Comfort scale and actions to prevent or minimize pain, stress and discomfort should be formulated in an individualized care plan.

In the future the developmental care in the NICU setting should ideally be continued with other age specific developmental care programs (i.e. IBA-IP), after the intensive care period, once the infants are autonomic stable and have moments of alertness, during the remaining hospitalization and first few months at home. A continuum of developmental care is desirable to support the quality of life of (very) preterm infants. It is important that the terminology used should be universal and related to the outline of the developmental care concept, as well as to the description of the level of developmental care and hence its place within the continuum of developmental care.

It is recommended that implementation of developmental care and NIDCAP will be performed by a multidisciplinary team, since it concerns all disciplines involved in the care of preterm infants. Within the actual implementation, the special place of the nursing discipline has to be determined, as the neonatal nurse is the backbone of the NICU. It is the neonatal nurse who works in collaboration with medical decision-making professionals, provides direct medical related care and engages and supports families of premature or critically ill infants. It is essential to understand the neonatal nurses’ perception of barriers to provide quality care (developmental/NIDCAP care) because those at the bedside have a comprehensive appreciation of the infants needs and their perception is important to infant outcome.

It is also recommended to use the available expertise and knowledge of NICU’s who have already implemented developmental care and NIDCAP. A model of site visits could be a way to be able to provide recommendations regarding developmental care policies, practical outline and necessary expertise to implement or to generate developmental care into a higher level, all based on the ambition of the NICU’s being visited.
CONCLUSIONS

Despite questionable methodology issues and limited evidence of medical and developmental outcome, the findings of this thesis are encouraging. NIDCAP has been well received by the parents but also by the nursing staff. It is a very attractive concept from a human perspective. Despite the need of further research, it is reasonable to encourage NICU’s to implement developmental care, preferably including individualized behavioural observations and at least assessment of stress and discomfort to prevent routines and structures which undermine the infants’ health, wellbeing and neurological development as well as wellbeing of parents and to support infants in developing to their full potential.
REFERENCES


Discussion

