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The Impact Of Medical Home Model On Neurological And Developmental Outcomes Of Preterm Infant

Bütüncül İzlem Modelinin Preterm Bebeklerin Nörolojik Ve Gelişimsel Sonuçları Üzerine Etkisi

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ÖZ

Aim: The medical home also known as the patient-centered medical care, is a team based health care delivery model led by a physician that provides comprehensive and continuous medical care to patients with the goal of obtaining maximized health outcomes. The aim of the study is to compare the 2-year neurodevelopmental outcomes of very preterm infants who received health care in a medical home at a big maternity hospital in Turkey with the historical controls who delivered standard care.

Material and Methods: Inborn infants who were ≤32 week's gestation and discharged between September 2007 and December 2011 were enrolled to the study. Intervention group were prospectively followed within the concept of medical home (between September 2009 and December 2011) and the control group were followed with standard health care (between September 2007 and September 2009). At 18-24 months' of corrected age, the neurological examinations and the developmental assessments using the Bayley Scales of Infant Development-II were performed.

Results: The cerebral palsy rates in the intervention and control group were 10.6% (n=17) and 17.4% (n=27) respectively and the difference was not statistically significant (p=0.107). Whereas the rate of neurodevelopmental impairment in the intervention group was significantly lower than the control group (25% and 38.7%; p=0.011).

Conclusion: Our data suggest that beginning a good follow-up process within the context of medical home, with efficient developmental support and guidance provided a reduction on neurodevelopmental impairment rate at 2 years of age.

Keywords: Prematurity, neurodevelopment, medical home, primary health care

ABSTRACT

Giriş: Çalışmanın amacı Türkiye'de büyük bir doğum hastanesinde taburculuk sonrası yapılan bütüncül izlem modeli ile izlenen preterm bebekler ile birinci basamakta sağlık hizmeti alan preterm bebeklerin 2 yaştaki nörolojik ve gelişimsel sonuçlarını karşılaştırmaktı.

Gereç ve Yöntemler: Çalışmaya 32 gestasyon haftası ve altında doğan, Ekim 2007 ile Aralık 2011 arasında taburcu olan bebekler alındı. Girişim grubu bütüncül izlem modeli kapsamında prospektif olarak izlendi (Ekim 2009-Aralık 2011) ve kontrol grubu birinci basamakta standart sağlık hizmeti aldı (Ekim 2007-Aralık 2009). Diizeltilmis 18-24 aylarmda bebeklerin nörolojik muayeneleri ve "Bayley Bebekler için Gelişimi Değerlendirme Ölceği II" ile gelişimsel değerlendirmeleri yapıldı.

Bulgular: Girişim grubunun %10.6 (n=17) ve kontrol grubunun %17.4 (n=27)'ünde serebral palsi saptandı ve gruplar arasındaki fark anlamlı değildi (p=0.107). Ancak gelişimsel sorun oranının girişim grubunda kontrol grubuna göre anlamlı düzeyde düşük olduğu saptandı (%25 ve %38.7; p=0.011).

Sonuç: Bulgularımız, bütüncül izlem modeli kapsamında yapılan iyi bir izlem, yeterli gelişimsel destek ve sorunların erken farkedilip yönlendirme yapılmasının 2 yaştaki nörolojik ve gelişimsel sorunların görülme oranında azalma sağlayabileceğini göstermiştir.

Anahtar Kelimeler: Prematürite, nörolojik ve gelişimsel sonuç, bütüncül izlem modeli, birinci basamak sağlık izlemi.

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Introduction

In the recent 30 years, the survival rates of the very preterm (≤32 weeks gestation) infants has increased due to the improvements in antenatal and neonatal intensive care(1), however, these infants are more likely to have higher rates of neurodevelopmental impairment (NDI), including cognitive impairment, cerebral palsy, hearing or visual impairments, behavioral problems and lower academic performance at school age compared to infants with term infants (2-4).

Identified risk factors for adverse long-term outcomes for these high risk infants include; male gender, brain injuries (intraventricular hemorrhage (IVH) or periventricular leukomalacia (PVL)), neonatal infections, bronchopulmonary dysplasia (BPD), and retinopathy of prematurity (ROP) (5-8).Previous studies have demonstrated that high risk infants for developmental delays and disabilities should receive more comprehensive health care when compared with infants who had nosuch risks (9, 10).

The medical home (MH) provides a preventive and curative health care service which required to follow and support the physical and developmental health status of the children and to perform the appropriate treatments by a single staff in a single health facility (11). American Academy of Pediatrics (AAP) describes MH as a model of delivering care that is accessible, continuous, comprehensive, family centered, coordinated, compassionate, and culturally effective (12). Studies on MH have demonstrated multiple benefits, including increased parent and physician satisfaction, improved health outcomes, decreased hospitalization and emergency department visits and decreased health care costs(12-14).

There was no data about the effects of MH on the long-term outcome of very preterm infants

who are at great risk for health and developmental problems from the early infancy to adulthood.Since infants are screened early and continuously for special health care needs and receive the early intervention services that they require in medical home, we hypothesized that infants receiving care through a medical home would have better outcomes.

The aim of this prospective cohort study with a historical comparison group was to determine whether assessment in a medical home would improve neurodevelopmental outcomes at 18-24 months' corrected age in very preterm infants born in a level III neonatal intensive care unit in Turkey.

Material and Methods

Study Population

This study was approved by the local ethical committee and written consent was obtained from the parents before participating.

Intervention Group

The cohort consisted of inborn infants with gestational age ≤32 weeks and who were discharged between September 2009 and December 2011 to receive health care in a MH. The infants who were born > 32 weeks gestational age, hospitalized less than 10 days, died before discharge and born with major malformations were excluded from the study. The families of the infants were invited to participate in a programmed regular follow-up every 3 months after discharge up to 2 years of age.

The follow-up process with respect to physical health and development was performed by the same health care staff within the context of MH. The follow-up team consisted of a neonatologist, an audiologist, an ophthalmologist, a physical therapy and rehabilitation specialist, a physiotherapist, a child developmental specialist, a developmental behavioral pediatrician and a pediatric neurologist.

The developmental follow-up, support and treatment of the determined problems were planned in collaboration with the family. Families were guided in ways to support infants' development.

Control Group

The historical control group consisted of infants who have similar demographic characteristics with the intervention group and discharged before September 2009 to receive standard health care. Standard health care was defined as follows; the infants received care for continuing problems from multiple providers, often in multiple settings and not necessarily by the same physician or health care team. Same exclusion criteria were used for both groups.

Measures

Data about perinatal and neonatal characteristics were collected from the NICU database. Respiratory distress syndrome (RDS), patent ductus arteriosus (PDA) confirmed by echocardiography, sepsis defined as clinical signs of infection with/without a positive blood culture (15), stage > 2 necrotizing enterocolitis (NEC) according to the Modified Bell Staging Criteria (16), IVH grade > 3 according to the classification of Papile(17) , BPD defined by supplemental oxygen requirement at 36 weeks' postmenstruel age (18), ROP stage > 3 according to international committee(19) were recorded from the database and their effects on outcomes were analyzed.

At 18-24 months' CA, a comprehensive examination was done in all infants. A pediatric neurologist performed the neurological evaluation. Cerebral palsy (CP) was defined as a nonprogressive motor disorder with abnormal muscle tone, persistent or exaggerated primitive reflexes or a positive Babinski sign associated with delayed motor development (20).

At 18-24 months' CA, a detailed neurological examination and Bayley Scales of Infant Development-II (BSID-II) (21) were performed for theneurodevelopmental assessment by the same investigators. The Mental Developmental Index (MDI) and Psychomotor Developmental Index (PDI) were determined. The mean BSID-II score is 100 for the Mental Developmental Index (MDI) and the Psychomotor Developmental Index (PDI), with a standard deviation (SD) of 15. MDIand PDI scores were deemed to be 49 when the child couldnot be tested because of severe developmental delay. The scores were classified as normal (MDI/PDI ≥ 85), borderline (MDI/PDI 70-84) and abnormal (MDI/PDI < 70). NDI was defined as the presence of one or more of the following events: 1) cerebral palsy (CP) with functional deficits, 2) bilateral hearing loss and/or blindness, and 3) MDI or PDI of <70 on the Bayley Scales of Infant Development II. CP was defined as a non-progressive motor disorder with abnormal muscle tone, persistent or exaggerated primitive reflexes, or a positive Babinski sign associated with delayed motor development.

Infants were classified as normal when they had normal neurological examinations, MDI and PDI scores ≥ 85 on Bayley Scales of Infant

Development II, no hearing and visual problems. NDI and CP were defined as primary outcomes. An MDI score lower than 70, a PDI score lower than 70, and survival free of NDI were defined as secondary outcomes.

The ophthalmological examinations were performed during hospitalization first and continued after discharge periodically. Audiological evaluations of infants were performed by “Otoacoustic Emission” and “Brainstem Auditory Evoked Response (BAER)” tests.

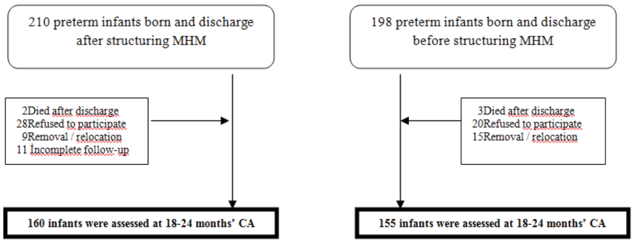
Statistical Analysis

The statistical evaluation of the data was performed using the software “Statistical Package for Social Sciences (SPSS), Version-16,0”. Descriptive statistics were calculated and reported as means and medians.Independency between categorical variables was tested with the X^2 test or Fisher’s exact test. Intervention and control groups were compared with the 2-sample Wilcoxon-Mann-Whitney test, the X^2 test, and Student’s t test. We performed multinominal logistic regression analysis to assess the perinatal variables. P value <0.05 was accepted as statistically significant and only significant risk factors are reported with 95% confidence intervals (CIs).

Results

One hundred sixty of 210 infants in the intervention and 155 of 198 infants in the control group were analyzed. The participation rates were 76 % and 78 % respectively. The trial profile was demonstrated in Figure 1.

Figure 1: Trial Profile



Perinatal and Neonatal Characteristics

Table 1 shows the perinatal and neonatal characteristics of both groups. The mean birth weight, gestational age, gender and multiple gestations did not differ between the groups (p> 0.05). The rates of RDS, sepsis (proven or suspicious) and ROP Stage ≥3 were significantly higher in the intervention group when compared with the control group (p=0.024, p=0.001 and p=0.002 respectively).

Table 1: Baseline Characteristics of the groups

	Intervention Group	Control Group	p
Birth weight, mean, g	1205 ± 340	1220 ± 260	0.664
Gestational age, mean, wk	28.9 ± 2,3	29.6 ± 2.1	0.06
Male gender, n %	82 (51.2)	67(43.2)	0.176
Multiple births, n %	68(35.8)	57 (36.7)	0.178
RDS, n %	87 (54.4)	64(41.3)	**0.024**
PDA, n %	54 (33.)	39(25.2)	0.109
NEC Stage ≥2, n %	4(2.5)	3 (1.9)	1.000
Sepsis (proven or suspected),n %	97 (60.6)	62 (40)	**0.001**
Grade 3-4 IVH, n %	9(5.6)	7 (4.5)	0.46
BPD, n %	19 (11.9)	13(8.4)	0.353
ROP Stage ≥3, n %	21 (13.1)	5 (3.2)	**0.002**

RDS: Respiratory Distress Syndrome
NEC: Necrotizing Enterocolitis
IVH: Intraventricular Hemorrhage
BPD: Bronchopulmonary Dysplasia
ROP: Retinopathy of Prematurity

Outcomes at 18-24 Months’ CA

One hundred and sixty (76.2%) infants in the intervention group were assessed at a mean age of 22 ± 2.4 months. In the control group, 155 (78.3%) were assessed at a mean age of 20 ± 2.3 months. The mean evaluation time of the infants were similar in both groups (p>0.05).

Developmental Outcome

MDI and PDI scores of both groups were summarized in Table 2. Although the difference was not statistically significant, in the intervention group, the percentage of infants with a MDI<70 (22.5%) was lower compared to the controlgroup (32.2%) (p=0.058). Furthermore the number of infants with a PDI<70 were significantly lower in the intervention group compared to the control group (p=0.027).

Table 2: Comparison of Mental and Psychomotor Development at 2 years Age between groups

	Intervention Group(n=160) Mean (SD or %)	Control Group (n=155) Mean (SD or %)	p
MDI, mean (SD), range	82 ± 18.5	82 ± 20	0.827
PDI, mean (SD), range	89.8 ± 19.4	87.25 ± 21	0.271
MDI classification score			
MDI ≥85, n %	80 (50.0)	77 (49.7)	0.077
MDI 70-84, n %	44 (27.5)	28 (18.1)	0.077
MDI <70, n %	36 (22.5)	50 (32.2)	0.058
PDI classification score			
PDI ≥85, n %	112 (70)	100 (64.5)	0.053
PDI 70-84, n %	23 (14.4)	15 (9.7)	0.053
PDI <70, n %	25 (15.6)	40 (25.8)	**0.027**

Neurological Outcome

Seventeen (10.6%) of160 infants in the intervention and 27 (17.4%) of 155 infants in the control group were diagnosed as CP, the difference was not statistically significant (p=0.104;Table 3).

Table 3: Neurological and Neurodevelopmental Outcomes

	Intervention Group (n=160) **N** **%**	**Control Group (n=155)** **N** **%**	**p**
Cerebral Palsy	17 10.6	27 17.4	0.104
MDI and/or PDI < 70	40 25.0	60 38.7	**0.011**
Deafness	1 0.62	1 0.64	0.371
Blindness	1 0.62	0	1
NDI	40 25.0	60 38.7	**0.011**
Normal	73 45.6	68 43.9	0.821

Outcomes of Sensorial System

One infant (0.6%) in the intervention group and 1 (0.6%) infants in the control group had hearing loss and required a hearing aid (p=0.371). In the intervention group there was only one infant who was totally blind; on the other hand no infant had serious vision impairment in the control group (Table 3).

Overall Neurodevelopmental Outcome

NDI was significantly lower in the intervention group compared to the control group (25% and 38.7%; p=0.011; Table 3). Multinominal logistic regression models were performed to investigate the association of neonatal variables with cerebral palsy, MDI <70, PDI <70 and NDI (Table 4). Only ROPstage ≥3 was found to be an independent risk factor for PDI <70 at 18-24 months' CA (OR: 3, 69; 95% CI: 1.04-13.17; p=0.44).

Table 4: Neonatal Risk Factors for Adverse Outcome at Age 2

Outcome	Risk Factors	P value	OR	95%CI
Neurodevelopmental Impairment	RDS	0.82	1.1	0.474-2.56
	PDA	0.25	0.58	0.23-1.46
	NEC Stage ≥2	0.85	0.8	0.07-8.6
	IVH Grade 3-4	0.51	1.8	0.28-12.2
	ROP Stage ≥3	0.89	2.6	0.86-8.24
	BPD	0.25	1.9	0.61-6.2
	Sepsis	0.34	1.74	0.55-5.48
Cerebral Palsy	RDS	0.52	1.54	0.42-5.77
	PDA	0.38	1.76	0.49-6.26
	NEC Stage ≥2	0.98	-	0.00- (-)
	IVH Grade 3-4	0.43	2.6	0.24-28.45
	ROP Stage ≥3	0.71	3.8	0.89-16.19
	BPD	0.21	0.23	0.22-2.27
	Sepsis	0.36	1.94	0.47-7.99

Discussion

In this study we assessed the impact of medical home on neurodevelopmental outcomes of very preterm infants and our data suggest that a MH created for the follow-up of very preterm infants can provide a better neurodevelopmental outcome probably due to family integration to health care, early detection and treatment of long term morbidities.

Very preterm or VLBW infants are under important risk for delays and limitations that may last potentially lifelong in all developmental fields (22). With an increase in the survival rates of VLBW preterm infants, considerable numbers of these infants will develop motor, cognitive and behavioral problems(23). There are many studies investigating interventions that target the following questions: "Which factors correlate best with good or bad long-term outcomes?" "What is the best to support the infant and to minimize the adverse outcome?"(24). After discharge, these infants usually receive care from multiple providers, often in multiple settings. Transitions between providers place patients at risk for a host of adverse events and results in incomplete information for providers and patients alike (25,26).

Therefore VLBW preterm infants and children are particularly vulnerable to adverse consequences resulting from inadequate and inappropriate health and developmental care coverage. A follow-up model that provides accessible, family-centered, continuous, coordinated and comprehensive care with medical home can address these challenges (9).

In the studies demonstrating the usefulness of MH, the researchers emphasized that application of this model increased the satisfaction of physicians, patients and their families, the adaptation of the patients to the treatments; decreased hospitalization and emergency department visits and therefore the health care expenses were reduced(12,15,27). Asthma-focused studies found that patients at intervention sites improved more in asthma process of care and it was strongly associated with adherence to medication use(28). Additionally, investigations have demonstrated that health interventions such that may prevent some of the developmental problems, particularly the complications in the fields of motor and linguistic development of the infants in the early term (23,29-31). Based on these data we followed our high-risk infants regularly within the concept of medical home. First of all, we increased the awareness of the families on the risks of their infants. We became a partner with the families in decision-making at all levels so that they were satisfied with the services they received. The children were screened early and continuously for health and developmental needs. The developmental follow-ups were performed by experienced staff. The families were educated about how to support the infants' development at home. The problems that the follow-ups have revealed were diagnosed and the required health services were early initiated, therefore the physical and developmental potentials of the children were maximized. As a result we provided a quality care that was accessible, continuous, coordinated, comprehensive and family-centered. By this approach, we made a positive impact on the neurodevelopmental outcomes of these high risk infants.

In this present study, CP rate was 10.6% and 17.4% in the intervention and control group respectively and was slightly higher than previously reported by other studies(32). Although the difference was not significant, the number of infants who were diagnosed as CP was higher in the control group. Furthermore the rates of RDS, sepsis and ROP Stage≥3 were higher in the intervention group yet the percentages of infants who have abnormal MDI and PDI scores were lower than the infants in the control group and the NDI rates decreased from 38.7% to 25% which could be attributed to the successful implementation of MH.

One of the limitations of this studyis relatively high ratesof discontinuation to follow-up visits approximately 20% in both groups. We considered if this situation cause bias thus those who do not return for follow-up may be healthier than those who are successfully monitored, making outcomes appear worse than they are. Alternatively, those who do not attend follow-up may be sicker or more impaired than their peers who are monitored, making outcomes appear better than they are(31). From a systemic review, it was emphasized that higher rates of NDI were significantly correlated with greater loss to follow-up (33). Furthermore the investigators were not blinded to the study groups and BSID II was performed relatively at an early age. In view of the fact that, assessing neurodevelopmental outcomes at 2 years of age may lead underestimation of the full spectrum of cognitive and neuromotor outcomes, such as specific learning difficulties or milder motor dysfunctions, assessment at 5 years of age is necessary. Besides radiologic evaluation of central nervous system which would reflect the brain injury was not performed. Since this study is not a randomized controlled study, it is not clear that, whether temporal effects or the intervention itself is the cause of the better outcomes.

Conclusion

Our data suggest positive effects of medical home model on the neurodevelopmental outcomes of VLBW and/or preterm infants constructed at a large maternity hospital with a big neonatal intensive care unit in a developing country in Turkey. Although the overall rates of NDI were higher in our cohort, a good follow-up in the context of medical home and the administration of efficient developmental support decreased NDI rates. This shows that well-designed, timely early intervention can improve the outcome and the quality of life of children at risk of developing disabilities. However, to provide a more complete picture of outcome of this recent cohort of survivors, we plan a long-term follow-up.

Conflict of Interest Statement : None declared.

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