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Original Article

Early neonatal outcomes in infants of mothers with organ transplantation under immunosuppressive treatment

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ABSTRACT

Background. This study aimed to examine early clinical and laboratory findings in infants born to mothers who had organ transplants and received immunosuppressive treatment.

Methods. Between 2016 and 2023, the study examined infants of mothers who underwent organ transplantation and were receiving immunosuppressive treatment, and followed at the Department of Neonatology at Akdeniz University. Demographic, clinical, and laboratory characteristics of mothers and infants were recorded. On the first day of life, complete blood count values were examined, as well as potassium levels on the first, third, and seventh days, and creatinine levels on the third and seventh days. The tacrolimus blood level was calculated by taking the average of the tacrolimus blood values of the mother measured during the pregnancy. The infants were evaluated for any potential morbidities caused by intrauterine immunosuppressive drug exposure.

Results. The study included 21 mothers (some with multiple pregnancies) and 27 infants. According to the findings of this study, 74% of these infants were born premature, 67% had low birth weight, and all were delivered via cesarean section. Prematurity was associated with the morbidities found in the infants. In the early period, lymphopenia was detected in 37%, neutropenia in 25.9%, thrombocytopenia in 11.1%, hyperkalemia in 18.5%, and creatinine elevation in 7.4%, all of which returned to normal within a few days. There was no significant relationship between maternal tacrolimus blood levels and infant potassium and creatinine levels.

Conclusion. Apart from an increased risk of prematurity, low birth weight, and cesarean delivery, no effects were observed in these infants during the early period. However, long-term follow-up is necessary to monitor for any potential morbidities.

Key words: organ transplantation, pregnancy, immunosuppressive treatment, prematurity.

With the increasing success of organ transplantation, the number of pregnancies among women who regularly take immunosuppressive drugs after transplantation is increasing. Immunosuppressive treatments, such as calcineurin inhibitors (tacrolimus and cyclosporine), azathioprine, mTOR inhibitors, mycophenolate, and corticosteroids, help to prevent organ rejection. However, some of these medications may pose risks to a developing fetus. Female transplant recipients have successful pregnancies using these medicines.[1,2] With the use of such medications, there are potential risks associated with pregnancy in transplant patients, including an increased risk of premature birth, low-birth weight, nephrotoxicity, immune dysfunction, and birth abnormalities.[2-4]

Previous studies have found that maternal tacrolimus has more favorable results than cyclosporine in pregnant women receiving immunosuppressive drugs after organ transplantation. However, it has been linked to several adverse effects, including preterm birth, intrauterine growth restriction, reversible hyperkalemia, and renal effects.[5,6]

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Azathioprine, another often used agent, has been reported to cause myelosuppression. Effects on the neutrophil, platelet, and erythrocytic series, notably the lymphocyte series, have been observed.[2,7] Although early intrauterine azathioprine exposure has been shown to cause congenital anomalies, these are not more common than in the general population.[2,8]

This study aimed to evaluate the early clinical and laboratory findings in infants born to mothers who received organ transplantation and immunosuppressive treatment at our hospital.

Materials and Methods

This retrospective cohort study was conducted in a tertiary neonatal intensive care unit (NICU) after receiving approval from the Akdeniz University Ethics Committee (2023/269). The study included infants delivered at Akdeniz University Hospital between 2016 and 2023 to mothers who had organ transplants and were receiving immunosuppressive treatment during pregnancy. The medical records of mothers and infants were reviewed. Demographic, clinical, and laboratory characteristics were recorded. Infants with a gestational age of less than 37 weeks were classified as premature infants, and those with a birth weight less than 2,500 g were classified as low-birth weight infants. Urine output in the first 3 days of life (mL/kg/h), time to reach birth weight, and breastfeeding rates were also recorded in infants admitted to the NICU. A complete blood count was performed within the first 24 h to evaluate white blood cell and platelet counts, creatinine levels were measured on the third and seventh postnatal days, and potassium levels were measured on the first, third, and seventh postnatal days to evaluate renal effects. Leukocytosis was defined as a white blood cell count > 30,000/mm^3, whereas leukopenia was described as a white blood cell count < 6,000/mm^3. The lower limit of neutropenia was determined using gestational age reference curves.[9] Lymphopenia was defined as a lymphocyte count below the five percentiles for the week of gestation, thrombocytopenia as a platelet count below the five percentiles for the week of gestation, and eosinophilia as an eosinophil count > 1,100/mm^3.[10] Reference curves were used to evaluate neonatal blood creatinine levels.[11,12] While potassium levels between 3.5 and 6 mmol/L were considered normal, levels > 6 mmol/L were considered hyperkalemia. We calculated the average maternal tacrolimus blood level by dividing the total blood level by the number of measurements obtained to determine tacrolimus exposure during pregnancy.

Statistical analysis

Patient data were analyzed using the Statistical Package for the Social Sciences for Windows 23.0 (IBM Corp., Armonk, New York) package program. Frequency (*n*), percentage (%), mean, standard deviation (SD), and median (Interquartile range-IQR) values are reported for descriptive statistics. The normality assumption was tested using the Shapiro–Wilk test, which examined the histogram, q–q plot, skewness, and kurtosis values. Pearson and Spearman correlation analyses were used to evaluate the relationships between quantitative variables. When the p value was <0.05, the results were considered statistically significant.

Results

The study included 21 mothers and 27 infants (with multiple pregnancies). The maternal and neonatal characteristics of the infants are shown in Table I. Twenty two of the infants were born to mothers who underwent kidney transplant and 5 of the infants were born to mothers who underwent liver transplant. When the medications used by the mothers were evaluated, it was shown that a combination regimen was often used, with tacrolimus being the most frequently used agent (Fig. 1). There was a mean of 6.4±2.8 yr between transplantation and first live birth. During pregnancy, the tacrolimus blood levels of all mothers were monitored. However, the blood levels of the

Table I. Characteristics of the study participants (N=27).

Maternal characteristics	
Age at delivery (years)	30 ± 4.4
Age at transplantation (years)	23.8 ± 4.5
Interval from transplantation to first live birth (years)	6.4 ± 2.8
Assisted reproductive techniques	2 (7.4%)
Number of pregnancies after transplantation	1 (1-2)
Immunosuppressive drugs during pregnancy	
Tacrolimus	25 (92.5%)
Azathioprine	18 (66.6%)
Corticosteroids	21 (77.7%)
Antihypertensive medication	10 (37%)
Characteristics of newborn	
Gestational week (GW)	32 ± 3.9
≥ 37	7 (25.9%)
32- 37	8 (29.6%)
28- 32	5 (18.6%)
≤ 28	7 (25.9%)
Birth weight (grams)	1940 (880-2760)
Low birth weight	18 (66.6%)
Male gender	15 (55.5%)
Small gestational age	5 (18.6%)
Type of delivery	
Emergency caesarean section	11 (40.7%)
Elective caesarean section	16 (59.3%)
Antenatal corticosteroids	13 (48.1%)
APGAR score (5th minute)	8 ± 1.3
Indication for caesarean section	
Preterm labor	7 (25.9%)
Preeclampsia/Eclampsia	11 (40.7%)
Premature rupture of the membranes	2 (7.4%)
Intrauterine growth restriction	2 (7.4%)
Miscellaneous	5 (18.6%)

Data are presented as n (%), mean ± standard deviation, or median (Q1-Q3).

other agents were not monitored (Table I). All infants were delivered via cesarean section, with 40.7% (n = 11) requiring an emergency cesarean section. The preterm birth rate was 74% (n = 20), and the low-birth weight rate was 66.6% (n = 18). Preterm birth occurred in 81.8% of infants born to renal transplant mothers and 40% of infants born to liver transplant mothers. The proportion of patients that required NICU monitoring was 81.4% (n = 22). The patients did not have early-onset sepsis. Culture-proven,

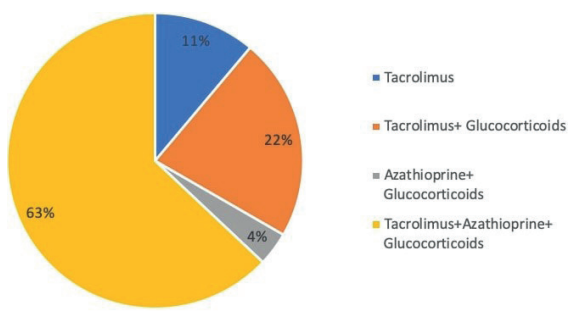


Fig. 1. Immunosuppressive regimens during pregnancy.

Table II. Clinical characteristics of patients.

Resuscitation in the delivery room	10 (37%)
Hospitalization	22 (81.4%)
Culture-proven sepsis	4 (14.8%)
Asphyxia	-
Transient tachypnea of newborn	8 (29.6%)
Respiratory distress syndrome	12 (44.4%)
Bronchopulmonary dysplasia	5 (18.5%)
Retinopathy of prematurity	3 (11.1%)
Necrotizing enterocolitis	1 (3.7%)
Intraventricular hemorrhage	-
Periventricular leukomalacia	1 (3.7%)
Patent ductus arteriosus	5 (18.5%)
Congenital malformation	1 (3.7%)
Type of nutrition	
Breastfeeding	14 (51.8%)
Breastfeeding + formula feeding	5 (18.5%)
Formula feeding	8 (29.6%)
Respiratory support	21 (77.7%)
Invasive respiratory support	9 (33.3%)
Noninvasive respiratory support	21 (77.7%)
Respiratory support (day)	4 (1-34)
Day of reached birth weight	11 ± 4.2
Urine output on first day (ml/kg/h) (n=17)	3.4 (2-4.2)
Urine output on third day (ml/kg/h) (n=17)	3.7 ± 1.0
Length of hospital stay	21 (6-75)

Data are presented as n (%), mean ± standard deviation, or median (Q1-Q3).

late-onset sepsis was found in 14.8% (*n* = 4) of infants requiring NICU support (coagulase-negative staphylococcus in three patients and *Acinetobacter baumannii* in one patient). Only one infant was found to have iris coloboma as a congenital anomaly. Fifty-two infants (*n* = 14) were exclusively breastfed, whereas 29.6% (*n* = 8) were fed solely formula. The clinical characteristics of infants who require hospitalization are shown in Table II.

At birth, 37% (*n* = 10) of the infants had lymphopenia, 25.9% (*n* = 7) had neutropenia, and 11.1% (*n* = 3) had thrombocytopenia. On the third day of life, 7.4% (n = 2) of the infants had high creatinine levels, while on the seventh day, only 3.7% (n = 1) had high levels. Notably, one of the two patients with high creatinine levels on day 3 also had high levels on day 7, but the levels returned to normal by day 10. The mothers of two patients with increased creatinine levels had undergone renal transplantation, and both mothers were receiving tacrolimus, azathioprine, and steroid combination therapy. On the first day of life, hyperkalemia was observed in 18.5% (*n* = 5) of the infants. The infants had no renal failure or mortality (Table III).

The average blood tacrolimus level of the mothers was 4.8 ± 1.1 ng/mL, and the median number of measurements was 12 (9-16). There was no significant relationship between maternal tacrolimus blood levels and infant potassium and creatinine levels.

Table III. Laboratory characteristics of patients

	Mean ± SD / median (IQR)		n (%)
White blood cell (/mm^3)	9,780 (6,255-12,295)	Leukocytosis/Leukopenia	-/5 (18.5%)
Neutrophil (/mm^3)	4,750 (3,340-8,845)	Neutropenia	7 (25.9%)
Lymphocyte (/mm^3)	2,870 (1,135-3,985)	Lymphopenia	10 (37%)
Eosinophil (/mm^3)	150 (30-255)	Eosinophilia	-
Monocyte (/mm^3)	980 (832-1,552)	Monocytosis	-
Basophil (/mm^3)	40 (20-90)	Basophilia	-
Platelet (/mm^3)	228,857 ± 85,127	Thrombocytopenia	3 (11.1%)
3rd day creatinine level (mg/dL)	0.64 ± 0.25	High creatinine (3rd day)	2 (7.4%)
7th day creatinine level (mg/dL)	0.47 ± 0.24	High creatinine (7th day)	1 (3.7%)
1st day potassium level (mmol/L)	5.3 ± 0.79	1st day hyperkalemia	5 (18.5%)
3rd day potassium level (mmol/L)	4.7 ± 0.56	3rd day hyperkalemia	-
7th day potassium level (mmol/L)	4.6 ± 0.79	7th day hyperkalemia	-

Complete blood count parameters were checked for 25 patients. On the first day, potassium level was checked for 23 patients. On the third day, creatinine and potassium levels were checked for 19 patients, and on the seventh day, potassium and creatinine levels were checked for 11 patients.

Discussion

After successful organ transplantation, the number of women taking immunosuppressive drugs and becoming pregnant have increased, along with the number of infants exposed to these drugs. However, data on the short- and long-term effects of immunosuppressives on these infants are limited. According to the findings of this study, 74% of these infants were born early, 67% had low-birth weight, and all were delivered via cesarean section. The morbidities found in these infants were related to prematurity. In the early period, lymphopenia was found in 37%, neutropenia in 25.9%, thrombocytopenia in 11.1%, hyperkalemia in 18.5%, and creatinine elevation in 3.7%, all of which returned to normal within a few days.

According to various studies, the rate of preterm birth after organ transplantation ranges from 29% to 86%.[3,13,14] Preterm birth is more common among infants born to mothers who have had a kidney transplant than in infants born to mothers who have had a liver transplant.[15] The occurrence of morbidities, such as preeclampsia, hypertension, renal failure, rejection, infection, and postpregnancy graft loss, in mothers who have undergone kidney transplantation may be the explanation for this.[3] Another study found that increasing the time between transplantation and conception (>5 yr) increased the probability of preterm birth from 55% to 85% while decreasing the average gestational week from 36 to 34 weeks.[16] In this study, we found that the premature birth rate was 81.8% in infants born to mothers who underwent kidney transplants and 40% in infants born to mothers who underwent liver transplants. The proportion of patients with an interval of more than 5 years between transplantation and first live birth was 59%. The results were similar to those reported in the literature regarding prematurity.

Immunosuppressives used during pregnancy have varying placental transfer and fetal effects. Although the pharmacokinetic parameters of corticosteroids differ depending on the agent because the placenta metabolizes 90% of the administered dose (11-beta-hydroxysteroid dehydrogenase), very low doses pass to the fetus, and fetal exposure remains relatively low.[1,2,6] Tacrolimus enters the placenta (at approximately 70% of the maternal concentration), but fetal exposure is reduced by placental expression of glycoprotein P, a transporter that returns the drug to the maternal circulation.[1,5] Tacrolimus has been reported to cause reversible neonatal hyperkalemia, renal impairment, intrauterine growth restriction, and premature delivery

as a result of hypertension, preeclampsia, and premature membrane rupture.[5] Borek-Dzieciol et al. observed that only 10% of the study group (40 infants of mothers who had undergone kidney transplantation and 40 control patients) developed hyperkalemia.[17] Creatinine levels did not increase significantly. Another study compared the infants of mothers who underwent liver transplants with a control group. The results showed no difference in blood urea nitrogen and creatinine levels between the two groups. Additionally, only 5.9% of patients who underwent liver transplantation had increased creatinine levels, which was comparable with the control group.[18] Because of the toxic effects of tacrolimus, it is critical to maintain normal levels in the blood during pregnancy. However, a case of transient acute kidney injury occurred despite the mother's blood tacrolimus level being within the normal range.[19] This study found that 7.4% and 3.7% of infants had increased creatinine levels on the third and seventh days of life, respectively. In 18.5% of infants, hyperkalemia was observed on the first day of life, but these values normalized throughout follow-up. Although the creatinine level was comparable with other studies, the higher incidence of hyperkalemia in this study could be attributed to the higher number of preterm births. During the first days of life, urine output of the patients was normal. There was no relationship between the mother's average blood tacrolimus level during pregnancy and renal parameters.

Azathioprine metabolism is a complex process that produces several metabolites. However, azathioprine and its first metabolite have a low transplacental passage, accounting for only 1–5% and 1–2% of the maternal levels, respectively. In addition, the fetal liver does not synthesize the enzyme necessary for its activation. Only 6-thioguanine nucleotides, known as toxic to the blood, can pass the placental barrier, accounting for 22–91% of the maternal concentration.[1,2,20] Azathioprine and its metabolites are unlikely to increase the prevalence of congenital anomalies, although they may cause anemia, leukopenia, and thrombocytopenia due to myelosuppression.[21,22] Another study found that the number of T and B cells at birth was lower in patients taking azathioprine than in the control group.[23] Previous studies suggest that exposure to immunosuppressive drugs, particularly azathioprine, during pregnancy may increase the incidence of infections during the first year of life.[24] According to the findings of this study, 37% of the patients had lymphopenia, 25.9% had neutropenia, and 11.1% had thrombocytopenia. Furthermore, 14.8% of individuals admitted to the hospital had culture-proven sepsis.

Prematurity increases the risks of neonatal respiratory conditions (e.g., respiratory distress syndrome and bronchopulmonary dysplasia), necrotizing enterocolitis, patent ductus arteriosus, sepsis, and neurological conditions (e.g., periventricular leukomalacia, seizures, intraventricular hemorrhage, and hypoxic-ischemic encephalopathy).[25] In this study, morbidities found in infants were mainly related to premature birth, such as respiratory distress syndrome (44.4%), bronchopulmonary dysplasia (18.5%), necrotizing enterocolitis (3.7%), and retinopathy of prematurity (11.1%).

There are few studies on the long-term effects of intrauterine exposure to immunosuppressive drugs in children. No significant medical or developmental effects were found in these studies, which focused on general developmental factors such as weight and height, immune function, renal and cardiovascular outcomes, and neurocognitive and behavioral development.[14,23,26,27] There are some limitations to the current study, such as the lack of a control group, the small sample size and the lack of long-term follow-up of the patients. Prospective studies with larger sample sizes and long-term follow-up are needed to establish the follow-up parameters and duration for these patients.

It is noteworthy that the rates of prematurity, low-birth weight, and cesarean section in infants born to mothers who underwent organ

transplants were found to be high, which is consistent with previous studies. Transient hematological and renal disorders were also found in the first few days of life. However, we believe that this situation is caused by a combination of many factors, including prematurity, low-birth weight, cesarean section, maternal morbidities, and medications.

Ethical approval

The study was approved by the Akdeniz University Ethics Committee (22.03.2023/269).

Author contribution

The authors confirm contribution to the paper as follows: study conception and design: KC, SA, BA, HO; data collection: KC, ZK, NOZ; analysis and interpretation of results: KC, SA, ZK, BA, HO; draft manuscript preparation: BA, HO, KC. All authors reviewed the results and approved the final version of the manuscript.

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Conflict of interest

The authors declare that there is no conflict of interest.

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