14. Pregnancy and Transplant

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14.1 Immune Suppression/Therapeutic Drug Monitoring


- Review article integrating National Transplantation Pregnancy Registry data with available literature from the time to outline safety concerns with outcome data. Corticosteroids, azathioprine, cyclosporine, tacrolimus and mycophenolate are reviewed in detail and recommendations for immune suppression management in pregnancy with each agent is offered.


- Review article in which the authors discuss pharmacokinetic and pharmacodynamic changes in pregnancy and the implications on use of immunosuppression agents. Literature outlining outcome data and treatment trends are also reviewed. The authors conclude with a suggested approach to immune suppression management in the pregnant transplant recipient.

- This review article looks at tacrolimus pharmacokinetic changes during pregnancy. Discusses factors that influence interpretation of trough concentrations as well as the effect of tacrolimus on the fetus.


- Systematic review evaluating exposure to synthetic glucocorticoids during gestation and associations with birth size. The authors concluded the limited data available suggests a trend in decreased birth weight, head circumference and birth length among infants exposed to glucocorticoids during gestation compared to those who were not.


- Single center retrospective cohort evaluating the effect of pregnancy on renal function in kidney transplant recipients (n=75) and changes in calcineurin inhibitors drug concentrations and dose requirements during gestation. Generally serum creatinine returned to pre-pregnancy baseline following delivery. The authors observed a decrease in both tacrolimus and cyclosporine levels during pregnancy requiring dose increases of 20-25% for each agent to maintain levels within the defined therapeutic range.


- Systematic review of literature evaluating cyclosporine use in pregnancy. The review explores cyclosporine pharmacokinetic and pharmacodynamic changes in pregnancy. The authors also examine cyclosporine use in pregnancy for different solid organ transplant populations among other indications for cyclosporine.


- Review of the use of immunosuppressive agents in pregnancy. While the focus of the review is on autoimmune conditions, the summaries include corticosteroids, azathioprine, mycophenolate, and cyclosporine. For each agent, the authors
highlight maternal and fetal concerns, placental transfer and excretion into breast milk.

- Pharmacokinetic study with pregnant women (n=10) drawing tacrolimus levels during early (10-14 weeks gestation), mid (22-26 weeks gestation) and late pregnancy (34-38 weeks gestation). Patients included five kidney, one kidney/pancreas, three liver and one heart transplant recipients. CYP3A5 genotyping verified all subjects were non-expressers. Tacrolimus clearance and whole blood concentrations were compared during pregnancy using postpartum as a reference group. Mean oral clearance of tacrolimus was 39% higher during mid and late pregnancy. Free fraction of tacrolimus increased by 91% in plasma and by 100% in whole blood during pregnancy, inversely associated with albumin, α1-acid glycoprotein, hematocrit and red blood cell concentrations. The authors demonstrated that adjusting tacrolimus dose during pregnancy to maintain the same whole blood concentration results in increased unbound (active) tacrolimus levels and area under the curve during pregnancy (112% and 173%, respectively). The authors identified a need to reduce goal tacrolimus trough levels during mid-late pregnancy in order to avoid supratherapeutic exposure.

14.2 Lactation


- The aim of the study was to assess neonatal exposure to tacrolimus from breast milk, through evaluation of maternal trough levels (n=14), infant blood samples (n=15), and breast milk concentrations. Of the infants included, twelve were breastfed and 3 were bottle-fed. Serial blood measurements for each infant were gathered as able. Blood from umbilical cord post delivery was collected in 6 cases. Average maternal blood tacrolimus concentration at delivery was 6.6 mcg/L (range 4.6-11.2 mcg/L). Average umbilical cord blood tacrolimus concentration at delivery was 4.6 mcg/L (range 1-9 mcg/L). Breastfed infant blood tacrolimus concentration average (24 samples) was 1.3 mcg/L (range 0-4 mcg/L) compared with bottle fed infant blood tacrolimus concentration average (6 samples) of 1 mcg/L (range 0-2.3 mcg/L). Average breast milk tacrolimus concentration was 0.8 mcg/L (range 0.1-1.6 mcg/L). Infants with serial blood
samples showed a rapidly decreasing concentration with each day post delivery leading the authors to conclude the tacrolimus exposure is due to gestation rather than delivery through breast milk. Based on the highest documented breast milk tacrolimus concentration, the authors estimated the infants tacrolimus dose from breast milk is 0.56 mcg per day (assuming 0.15 L/kg/day breast milk ingestion, infant weight of 2.4 kg).


- Concentrations of cyclosporine in whole blood and breast milk were measured in seven kidney transplant and two kidney-pancreas patients and their breast-fed infants. Mother trough cyclosporine concentrations ranged from 55 to 130 ng/mL. Breast milk cyclosporine concentrations ranged from 64 to 227 ng/mL, samples were collected at random intervals. In all of the infants tested, none had whole blood cyclosporine levels that exceeded the lower limit of detection (30 mcg/mL). Serial cyclosporine measurements in breastmilk obtained for two patients illustrated concentration variation throughout the day.

- This is a case report about a renal transplant recipient who continued breastfeeding while on cyclosporine. Drug levels were measured in blood samples from the mother and baby as well as in breast milk in order to justify safety of continuation of breastfeeding while on cyclosporine.


- Observational case series including 10 mother-baby pairs to examine the effects of breastfeeding while taking less than 2 mg/kg/day of azathioprine. Infants were taken regularly to be examined by a pediatrician, complete blood counts were collected to detect bone marrow suppression, mothers were instructed to report any illness their child experienced and completed questionnaires regularly to assess frequency of breastfeeding. The authors did not appreciate any major difference in blood counts or infectious complication in the infants studied compared to the general population. Of note, none of the mothers studied were transplant recipients.


- Review of available literature outlining safety of breastfeeding after transplant. The authors address the physiology of breast milk production, summarize literature for each immunosuppressive agent and reference National Transplantation Pregnancy Registry data to support immune suppression lactation recommendations for clinicians.

- Pharmacokinetic study in eight solid organ transplant recipients (4 kidney, 1 kidney/pancreas, 1 kidney/heart, and 2 liver) to measure infant tacrolimus exposure during gestation through maternal tacrolimus blood concentrations and umbilical cord concentrations. Average umbilical cord blood tacrolimus concentration was 6.6 ± 1.8 ng/mL while average maternal blood tacrolimus concentration was 9 ± 3.4 ng/mL at the time of delivery. Most tacrolimus levels were collected within 6 hours of taking the dose. Unbound tacrolimus concentration in the umbilical cord were one-fifth of maternal concentrations.

14.3 Outcomes


- Retrospective review of 141 transplant patients experiencing 197 pregnancies who were immunosuppressed with cyclosporine before and during pregnancy. Common complications included premature birth (54% delivered at less than 37 weeks), low birth weights (50% less than 2.5 kg), maternal hypertension (56%), preeclampsia (29%), infections (22%) and rejection (11%).


- Single center retrospective study of all cardiac transplant patients who conceived from 1986 to 2014 (22 pregnancies in 17 women). Average time from transplant to conceive was 98 ± 62.4 months. Rejection occurred in one pregnancy which was attributed to noncompliance with immune suppression, LV function was unchanged in all other cases. Complications included hypertension (13.6%), preeclampsia (13.6%), and cholestasis (4.5%). Twenty pregnancies, 11 of which were caesarean section, resulted in live births, and 4 infants required special neonatal cares. Since pregnancy, four women have died, one from postpartum hemorrhage, two from non-compliance and one of graft coronary disease.

- This retrospective study investigated the effects of pregnancy on long-term renal function as well as the prognosis of pregnancy and delivery among renal transplant recipients. The study highlights significant differences between creatinine, bicarbonate, albumin, triglycerides and proteinuria levels according to preconception, gestational, and postpartum sampling.


- Case report on two renal transplant recipients who remained on belatacept during their pregnancy. Discusses lab variations and long-term outcomes of both women peri- and post-partum.


- Literature review and evaluation of National Transplantation Pregnancy Registry data relating to immunosuppressive agents used in pregnancy.


- National Transplantation Pregnancy Registry report on outcomes from 2,000 pregnancies post transplantation.


- This review highlights studies of pregnancy-related outcomes in kidney transplant recipients. Fifty articles were included in this analysis, representing 4706 pregnancies in 3570 kidney transplant recipients. Hypertension, elevated serum creatinine and proteinuria are described in association with adverse pregnancy outcomes.

- Systematic review and meta-analysis of literature reporting pregnancy outcomes in liver transplant recipients from 2000-2011. Of the 578 studies identified, 50 pregnancies are reported in 306 liver transplant recipients. The authors report a live birth rate of 76% (95%CI 72.7-80.7%), miscarriage rate of 15.6% (95%CI 12.3-19.2%), preeclampsia rate of 21.9% (95%CI 17.7-26.4%), cesarean section rate of 44.6% (95%CI 39.2-50.1%), and preterm delivery rate of 39.4% (95%CI 33.1-46%).


- Retrospective cohort studying pregnancy in transplant data from five German transplant centers. Transplant recipients who conceived (n=81) were matched to a control group. Pregnant transplant recipients receiving azathioprine and prednisone were compared to those receiving cyclosporine and the matched control group. Outcomes of interest include graft survival, patient survival, and long term graft function with the authors observing no difference between the groups for any outcome studied.


- Observational study of 16,195 female kidney transplant recipients from 1990 to 2003, age 15-45 years, using United States Renal Data System data. Pregnancy rate within 3 years of transplant was 33 per 1,000 females based on Medicare claims data. Live birth rate was 19 per 1,000 females. Pregnancies resulting in fetal loss remained constant at 45.6%. The authors compare the results reported to the National Transplantation Pregnancy Registry and UK Transplant Pregnancy Registry which use voluntary registries and report much higher live birth rates.

- Letter to the editor outlining a case report of a successful pregnancy of a renal transplant recipient while immunosuppressed with sirolimus, cyclosporine and prednisone.


- Single center retrospective study from 1969-2011 including 46 female solid organ transplant recipients and 61 pregnancies, 89% of which were planned and 93% resulted in live births. Complications during pregnancy included preeclampsia (26%), gestational diabetes (21%), infection (23%), threat of premature delivery (16%), intrauterine growth retardation (15%), haemorrhage at delivery (7%). Gestational diabetes occurred more frequently in patients receiving tacrolimus compared to cyclosporine (35% vs 7.7%, p=0.02). Renal function was stable during pregnancy and post delivery. Neonates with low birth weights occurred in 15% of cases and three malformations were diagnosed. Immunologic profiles were assessed before and after pregnancy. *De novo* donor specific antibodies were detected in three transplant recipients (5.9%). The authors note that in 2 of the 3 cases of donor specific antibody development the child’s father shared HLA subtype with the deceased organ donor.


- Review of recent literature and single center experience of pregnancy following liver transplantation. The authors provide management recommendations for each phase of the liver transplant recipients pregnancy journey, from pregnancy prevention to breast feeding.


- Observational cohort of 152 solid organ transplant recipients who fathered 205 pregnancies while taking mycophenolate. Data was gathered from the National Transplantation Registry. Of the 194 live births reports, only 6 resulted in fetal malformations (3.1%), similar to the general population.

- Retrospective analysis from 1992 to 1998 where case reports of tacrolimus use during pregnancy from clinical studies, reports from health care professionals and surveys of transplant registries were evaluated (100 pregnancies, 84 mothers). One patient included was taking tacrolimus for an autoimmune disorder, the remaining were solid organ transplant recipients. Of the 100 pregnancies studied, 71 progressed to delivery. Complications during pregnancy following transplantation include rejection (n=9), preeclampsia (n=8), renal impairment (n=7), and infection (n=6). All cases of rejection were treated with bolus steroids, no reports of graft loss. Four fetal malformations were reported.

Kim HW. et al. (2008). The experience of pregnancy after renal transplantation: pregnancies even within postoperative 1 year may be tolerable. *Transplantation, 85* (10), 1412-9. Retrieved from: [https://www.ncbi.nlm.nih.gov/pubmed/?term=Pregnancies+even+within+postoperative+1+year+may+be+tolerable](https://www.ncbi.nlm.nih.gov/pubmed/?term=Pregnancies+even+within+postoperative+1+year+may+be+tolerable)

- This is a retrospective analysis looking at graft, fetal, and maternal outcomes of pregnancy in renal transplant recipients.


- Retrospective cohort study evaluating graft outcomes among kidney transplant recipients who became pregnant while on mycophenolate using The National Transplantation Pregnancy Registry data (n=382). Outcomes evaluated included miscarriages, birth defects and 2 and 5-year postpartum graft loss. The authors report no difference comparing those who discontinued mycophenolate >6 week prior to pregnancy and those who did not. Discontinuing mycophenolate during the second trimester or later increased risk of miscarriages (OR 9.35, 95%CI 4.31-20, p<0.001) and birth defects (OR 6.06, 95%CI 1.96-18.87, p = 0.002). Discontinuing mycophenolate <6 weeks prior to pregnancy increased risk of graft loss at 5 years compared to those who discontinued mycophenolate >6 weeks prior to pregnancy (OR 5.56, 95%CI 1.38-22.22, p=0.016).

King et al.’s response to the critique of their study. Importantly they acknowledge the risk of mycophenolate exposure in the first trimester is understated. They assert the original conclusion supporting FDA guidance to stop mycophenolate >6 weeks prior to conception is the best practice supported by their evidence.


- Review of outcomes at liver transplant centers in Finland which resulted in good perinatal outcome with healthy, mostly full-term, normally grown offspring; however, serious maternal complications related to underlying liver pathology, transplant surgery and immunosuppressive medication occur frequently.


- Review article outlining the risk of pregnancy post transplantation on the mother and fetus. The authors used volunteer patient registries and available literature to describe the frequency of complications in post transplant pregnancies including hypertension, preeclampsia, graft loss and rejection. The authors also review fetal exposure to immunosuppressive medications during gestation and then through breastmilk.


- Retrospective study assessing graft outcomes from pregnancies occurring in a single center from 1976-2015. A total of 56 pregnancies in 35 women were reported. Live birth rate was 78.9%. Complications included hypertension (76%) and preeclampsia (30%). A third of the patients experienced graft function deterioration during pregnancy, of whom 63.2% did not recover to baseline.

National population-based retrospective cohort study including male transplant recipients from 1967-2009. Data retrieved from the Medical Birth Registry of Norway. A total of 474 babies were identified as having fathers who were transplant recipients and 4614 babies who were fathered by males before undergoing transplantation. Compared to the general population, paternal solid organ transplant deliveries did not differ in rates of major malformations or preterm delivery. An observed increased risk in preeclampsia and small-for-gestational-age was found (50% and 30%, respectively) in the paternal solid organ transplant deliveries compared to the general population, not statistically significant. Rates of preeclampsia were increased in the paternal solid organ transplant deliveries compared to the general population (adjusted odds ratio 1.5, 95%CI 1.0-2.3). This increased rate in preeclampsia held true comparing pregnancies fathered prior to transplantation and after (adjusted odds ratio 7.4, 95%CI 1.1-51.4), though this difference was not statistically significant once patients identified as having a child with more than one partner were excluded.


Investigators of the National Transplantation Pregnancy Registry letter to the editor responding to King et al.’s article above. The authors argue taking mycophenolate during the first semester of pregnancy increases risk of miscarriage and phenotypic birth defects. They identify their differing conclusion is a result of inappropriate patient and outcome grouping in the analysis.


This article begins with a case report on a successful living kidney donation amongst identical twins. It chronicles the restoration of fertility and pregnancy of the recipient. Both individuals went on to deliver normal infants post donation and transplantation, respectively.

Single center retrospective study evaluating pregnancies occurring post transplantation from 1995-2009 in 23 patients. Of 29 pregnancies, 26 resulted in live births. Immunosuppressive medications included cyclosporine (n=11), tacrolimus (n=9), mycophenolate (n=1), and azathioprine (n=12). One infant suffered a cleft palate malformation; the mother was immunosuppressed with mycophenolate. No significant change in maternal renal function was observed from before pregnancy to post delivery.


Retrospective cohort study using data from the National Transplantation Pregnancy Registry to evaluate pregnancy outcomes in lung transplant recipients. Twenty-one lung female transplant recipients were included, reporting 30 pregnancies. Lung transplant patients had a higher rate of premature birth compared to other transplant populations but the author did not concluded there was any difference in long term outcomes between the children.


Outcomes reported from 193 kidney transplant recipients in the United Kingdom Transplant Pregnancy Registry. Notably 50% of pregnancies in renal transplant patients resulted in live births. The analysis suggested an association between hypertension during pregnancy and worse post pregnancy graft survival. Serum creatinine greater than 150 mol/L prior to pregnancy was associated with worse renal function after pregnancy.


Study examining outcomes of pregnancies with exposure to mycophenolate or sirolimus using data from the National Transplantation Pregnancy Registry. Of the pregnancies exposed to mycophenolate (n=26) there were 15 live births and 11 spontaneous abortions. Of the live births exposed to mycophenolate, 4 children had structural malformations (26.7%). Seven transplant recipients
became pregnant while taking sirolimus resulting in 4 live births one of which had a structural abnormality. The authors noted the structural abnormality observed in the sirolimus group was from a mother who was switched from mycophenolate late during pregnancy.


- Review of management of the pregnancy in liver transplant recipients and available literature.


- Case report of a 30 year old female with a history of acute rejection, immune suppressed with everolimus, cyclosporine and prednisone, who presented 12 weeks pregnant. She continued on the same immune suppression for the remainder of the pregnancy. The patient delivered by cesarean section during week 30, after the mother presented with worsening renal function and proteinuria and severe hypertension. The child was born without malformation and the mother’s renal function improved by the 6 months postpartum follow visit.


- This study reviewed 692 pregnancies to 447 kidney transplant recipients between 1971 and 2010. The data highlights that the overall outcomes for babies of women with transplants have improved over the past 40 years, contrary to past research which has shown that babies born to transplant recipients are more likely to be born preterm. This analysis demonstrated that the only factor impacting gestational age that remains is the length of time between transplantation and pregnancy.
14.4 Living Donor Outcomes

- Retrospective cohort of 85 living kidney donor outcomes after 131 pregnancies following kidney donation. Study subjects were matched with non-donors from the general population. Gestational hypertension was more common in kidney donors (odds ratio 2.4, 95%CI 1.2-5; p=0.01). Preeclampsia was also more common among kidney donors.

- This survey of previous living donors evaluated fetal and maternal outcomes as well as pregnancy outcomes after kidney donation and found similar outcomes to those reported in the general population, but inferior to pre-donation pregnancy outcomes.

- Review of literature regarding pregnancy outcomes in women post kidney donation. Outcomes of gestational hypertension, preeclampsia, premature birth and low birth weights were collected for the general population and in women post kidney donation for comparison. Though individual studies report slight increases incidence of gestational hypertension and preeclampsia, after reviewing the literature available, the authors conclude that kidney donation does not pose great harm to pregnancy, rather the donor should be monitored more closely during pregnancy.

- Case report describing the pregnancy of a living liver donor within 6 months of donation. The pregnancy proceeded to deliver without complication.
14.5 Contraception


- Survey of 183 women post transplantation from a single center to investigate fertility awareness and quality of contraceptive counseling following transplant. Of the women surveyed, 44% did not know women could conceive following transplantation and only 36% reported a healthcare provider discussed the potential for pregnancy after transplantation. The authors also report the frequency and types of contraceptive use post transplantation.


- Single center study in which 197 women kidney transplant recipients of reproductive age were interviewed. Following transplant 50.2% of recipients reported menstrual irregularity compared to 70.6% prior; 79.7% of recipients were sexually active compared to 91.9% prior; 48.7% were advised to use contraception compared to 74.1% prior; and 72.1% were using a contraception method compared to 86.3% prior. Among those interviewed there were 14 pregnancies after transplant, 92.9% of which were unplanned.


- Since restoration of fertility can return as soon as one month after transplantation, the Centers for Disease Control and Prevention (CDC) issued formal recommendations to guide contraceptive use in solid organ transplant recipients. This article reviews those recommendations including the benefits of long-acting reversible contraception specifically in the transplantation population.


- Systematic literature review using PubMed through 2009 to assess the contraceptive use among women having undergone solid organ transplantation. Eight articles from seven studies were included. The authors conclude that the data available indicated combined oral contraceptives and transdermal
contraceptive patch effectively prevented pregnancy without significant variation in biochemical measures from the general population. Evidence to assess the other forms of contraception were not available.


- This survey of abdominal transplant female patients discusses transplant-specific outcomes in both mother and fetus. It also illustrates survey responses regarding how patients were counseled about pregnancy after transplantation.


- This survey illustrates the need for improved family planning methods in female transplant recipients of reproductive age. It discusses the various contraceptive methods available to women, their specific relevance in the transplant population, as well as their prevalence of use in this population.


- Review of literature in cardiac transplant specific contraception, stratifying by complicated post-operative course and uncomplicated transplant course.

14.6 Pregnancy Planning/Fertility


- Case report of a male kidney transplant recipient immune suppressed with prednisone and sirolimus who had a sperm analysis demonstrating impaired motility and altered structure. Sirolimus was changed to tacrolimus and he continued on prednisone for immunosuppression. After two months his sperm analysis returned to normal.

Review evaluating the effect of mTOR inhibitors on testosterone, follicle stimulating hormone, luteinizing hormone, sexual function, fertility and sperm mobility. The authors conclude mTOR inhibitors decrease testosterone levels, increase luteinizing hormone levels and disrupt spermatogenesis.


- Observational study of male kidney transplant recipients age 20-40 years between 1995-2005 (n=95). Patients were sent a questionnaire and a sperm analysis was performed for consenting participants (n=33). Male transplant recipients immune suppressed with sirolimus had a reduced sperm count compared to those not taking sirolimus (28.6 ± 31.2 * 10^6 and 292.2 ± 271.2 * 10^6, respectively, p=0.006). The proportion of motile spermatozoa was also decreased in transplant recipients taking sirolimus compared to those who were not (22.2 ± 12.3% and 41 ± 14.5%, respectively, p=0.01). Patients taking sirolimus containing immune suppression regimens fathered fewer pregnancies compared to those taking sirolimus-free regimens (5.9 95%CI 0.8-42 pregnancies/1,000 patient years compared to 92.9 95%CI 66.4-130 pregnancies/1,000 patient years, p=0.007).


- This observational study looked at the risk of allograft failure among 729 women who became pregnant within the first 3 posttransplant years. The probability of allograft failure from any cause including death (ACGL) increased with the number of years after pregnancy.


- This article addresses a myriad of reproductive health topics and family planning recommendations following abdominal organ transplantation. Such topics include fertility in the pre- and posttransplant setting, contraception in transplant...
recipients, pregnancy outcomes in transplant recipients, immunosuppression risks with pregnancy, and breastfeeding after transplant.

14.7 Complications


- Case report of a 22 year old kidney transplant recipient who became pregnant 12 months after transplant and subsequently was diagnosed with biopsy confirmed 1b acute cellular rejection and antibody-mediated rejection episode. She decided to treat the rejection and continue with the pregnancy, receiving high-dose steroids, intravenous immunoglobulin and antithymocyte globulin (rabbit). She later gave birth without complication.


- This study assessed infants born to female kidney recipients, who have been prospectively followed during their first year of life, and who were submitted to an immunological investigation at birth and a subsequent assessment at eight months. Children of kidney transplant recipients had lower CD4 positive T cells, NKT and B cell initially, but recovered to the levels of the control group by 8 months. Data from the study indicate children born of transplant recipients have a 4.4 (95%CI 1.026-15.225) times higher risk of hospital admission within the first months of life.


- Review of current literature evaluating preeclampsia risk in kidney transplant recipients and kidney donors. In addition to synthesizing the various preeclampsia rates from available sources, the authors evaluate risk factors for preeclampsia, the usefulness of risk calculators and strategies to minimize preeclampsia occurrence.

- This useful article highlights counseling points for the transplant recipient in every stage of family planning. It discusses immunosuppressive medications used during pregnancy and their effects on the developing fetus. The authors also discuss pregnancy complications and their prevalence in the transplant population.


- This article reviews information to guide providers on counseling the kidney transplant recipient about risks of pregnancy for the mother and the fetus and provides information to help guide treatment of the pregnant transplant recipient.


- Summary of the consensus conference organized by the Women’s Health Committee of the American Society of Transplantation held March 1-2, 2003. The article summarizes available evidence supporting consensus statements on how to determine timing of pregnancy post transplantation, comorbid factors that may influence pregnancy outcomes, preconception counseling, obstetrical management, and treatment of rejection during pregnancy. Importantly, the conference identified key gaps in knowledge to direct research in order to generate enough evidence for the creation of pregnancy in transplantation guidelines.

Review article describing biological mechanisms of alloimmunization during pregnancy and the impact on donor availability later in life.
