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Granulocyte Colony-Stimulating Factor Use in Pregnant Women with Cancer Requiring Chemotherapy

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Abstract

Background

Cancer complicates approximately 1 in 1,000 pregnancies. Chemotherapy can be safely administered after the first trimester; however, limited safety data on in utero exposure to granulocyte-colony stimulating factors (G-CSF) may influence chemotherapy regimens offered during pregnancy. This study evaluates neonatal and maternal outcomes following G-CSF exposure during pregnancy and examines the incidence of maternal neutropenia among women receiving chemotherapy.

Methods

We conducted a prospective cohort study using data from the Cancer and Pregnancy Registry (1997–2023). Outcomes were compared between pregnant women receiving chemotherapy with G-CSF and those receiving chemotherapy alone. Primary neonatal outcomes included birthweight, fetal growth restriction (FGR), neutropenia or leukopenia at birth, congenital anomalies, and pediatric medical conditions. Maternal outcomes included neutropenia and pregnancy complications.

Results

Among 367 pregnant women receiving chemotherapy, 85 received G-CSF. Mean maternal age at diagnosis was 32.7 years, and mean gestational age at diagnosis was 14 weeks. Breast cancer was the most common diagnosis, and patients with breast cancer were more likely to receive G-CSF than those with other malignancies ($p = 0.04$). No significant differences were observed between exposed and unexposed groups in birthweight (2,610 g vs 2,720 g; $p = 0.13$), FGR (29% vs 20%; $p = 0.06$), neonatal complications (16% vs 18%; $p = 0.73$), congenital anomalies (13% vs 8%; $p = 0.15$), neonatal leukopenia (2% vs 2%; $p = 1.00$), neutropenia (6% vs 5%; $p = 0.73$), or pediatric medical conditions (31% vs 27%; $p = 0.47$). Maternal neutropenia occurred in 7.7% of women overall, with no significant difference between those receiving G-CSF and those who did not ($p = 0.59$).

Conclusion

Exposure to G-CSF during chemotherapy in pregnancy was not associated with adverse maternal, neonatal, or pediatric outcomes.

Trial Registration

ClinicalTrials.gov (NCT02749474), registered April 21, 2016. Retrospectively registered.

Background

Approximately 1 in 1,000 pregnancies are complicated by cancer. Oncologists and obstetricians face the challenge of providing maternal treatment while minimizing fetal risks [1]. In many cases, delaying chemotherapy until after childbirth is not optimal for the mother's health, and instead choosing an elective premature birth can pose additional health risks to the newborn [1]. Fortunately, long-term follow up of children exposed in utero to chemotherapy for maternal cancer have been reassuring [2–5]. Whenever possible, treatment should mimic regimens offered to non-pregnant patients [6, 7]. Granulocyte-colony stimulating factors (G-CSF), such as Neupogen (Filgrastim) or Neulasta (Pegfilgrastim), are commonly prescribed to non-pregnant patients receiving chemotherapy to enhance immunity, lower the risk of infection, or for prophylaxis against febrile neutropenia [8, 9]. When chemotherapy is given during pregnancy, G-CSF may be important for the treatment or prevention of neutropenic fever and susceptibility to infections, which can potentially affect the fetus in utero [10]. Concerns about using G-CSF mobilizers during pregnancy may affect chemotherapy regimen choice or treatment intervals offered during pregnancy. The findings herein will better support clinical decision-making for obstetricians, oncologists and patients when discussing chemotherapy choices for a particular cancer during pregnancy. This is especially helpful for physicians who would otherwise offer dose-dense regimens to patients with breast cancer. The use of dose dense chemotherapy to treat breast cancer in pregnancy has been reported in small numbers without maternal or fetal complications [10], but if more safety data were published regarding the use of G-CSF in pregnancy we believe this option could be offered to more women in pregnancy if clinically indicated.

In a previous study by the senior author in 2012, the use of G-CSF agents was reported in 34 of 176 patients receiving chemotherapy during pregnancy [11]. There were no significant differences in neonatal outcomes or anomalies in newborns born to pregnant patients receiving G-CSF with chemotherapy versus chemotherapy alone. In 2020 we surveyed 273 oncologists treating pregnant women with chemotherapy in the Cancer and Pregnancy Registry about their views on prescribing G-CSF during pregnancy. We learned that 20% of oncologists withheld G-CSF due to pregnancy alone. Given the increasing use of dose-dense chemotherapy for breast cancer in non-pregnant women, we aim to publish safety data on the use of G-CSF in pregnancy so that pregnant women with breast cancer could also be offered this option if clinically indicated. We have accumulated more than double the number of mother/infant pairs exposed to G-CSF from our prior study.

Methods

Data and Study Design

The Cancer and Pregnancy Registry was created in 1997 to collect multicenter information about the diagnosis and treatment of cancer during pregnancy, the survival of women diagnosed with cancer while pregnant, and the long-term neurodevelopment and medical health of their newborns. The Cancer and Pregnancy Registry is a Clinical Trials.gov study (NCT 02749474 || 2016-04-13). A unique factor about

the Cancer and Pregnancy Registry is the prospective nature of the data collection from multiple centers. Additionally, pregnant women enroll at the time of a cancer diagnosis, before the outcome of the pregnancy is known, reducing bias that only optimal or only suboptimal pregnancy and neonatal outcomes are reported. The researchers maintain annual communication with the pediatricians for each child's follow-up. As of June 2023, 583 patients consented to be enrolled in the Registry from four different world continents. This created a prospective cohort beginning in 1997 and this current study includes data through June 2023.

Study Variables

Researchers identified patients treated with chemotherapy during pregnancy and classified patients into two groups: those receiving granulocyte colony-stimulating factors (G-CSF) with at least one of their chemotherapy courses (exposed). Primary outcomes of this study include newborn health in the neonatal period and early childhood. Specifically, variables include neutropenia or leukopenia at birth, birthweight percentile and incidence of fetal growth restriction or anomalies at birth, and a diagnosis of asthma, eczema, allergies, or other medical conditions and any behavioral conditions identified during childhood follow up. Neutropenia was defined as an absolute neutrophil count (ANC) of < 1000 per microliter from a complete blood count (CBC) obtained at the time of delivery or on day one of life. Leukopenia was defined as WBC < 5,000 cells/L. Birth percentile was determined using *gestation.net* centile calculator which accounts for the infant’s sex, gestational age at birth, maternal parity, height and weight at first prenatal visit, and ethnicity. Intrauterine growth restriction is defined as birth percentile < 10% for gestational age. Reportable Congenital Anomalies were determined by the Metropolitan Atlanta Congenital Defects Program. Pediatricians were contacted annually to inquire about any medical conditions, or behavioral issues (attention deficit disorder, attention deficit hyperactivity disorder, anxiety, Asperger’s or autism spectrum disorder, obsessive compulsive disorder, oppositional defiant disorder, tic disorder or social skill impairment).

Secondary outcomes concern the mothers’ complications during pregnancy. As only two patients in the database to date have received Udenyca (Pegfilgrastim-cbqv) and Zarxio (Filgrastim-sndz), we limited this current report to only those who received either Filgrastim or Pegfilgrastim during pregnancy. Oncologic and obstetric variables collected for the mothers include the type of cancer, gestational age at first chemotherapy treatment and at delivery; the incidence of any pregnancy complications, and the presence of maternal neutropenia during treatment. Researchers noted whether G-CSF were used prophylactically or as treatment after the development of maternal neutropenia.

Statistical Analysis

All the above-mentioned variables were summarized as count (%) and mean (SD) and compared between the exposed and unexposed groups using two sample t-test or Wilcoxon rank sum test for continuous variables and chi-square test or Fisher exact test for categorical variables. All analyses were

done using SAS 9.4 (SAS Institute, Inc., Cary, NC). A two-sided p value < 0.05 was considered statistically significant.

Results

Study participants

Of 583 women enrolled in the Cancer and Pregnancy Registry, 367 pregnant patients with singleton gestations received chemotherapy during pregnancy and were included in this analysis. Most were diagnosed with a primary cancer during pregnancy, most commonly breast cancer; 11 were diagnosed with recurrent disease.Eighty-five women, including the original 34 reported previously, received Filgrastim or Pegfilgrastim (G-CSF) during pregnancy. Demographic characteristics are summarized in Table 1. Mean maternal age, race, and country of origin did not differ significantly between exposed and unexposed groups, with the exception of the “other” race category, which was less frequent in the unexposed group (p = 0.02). For the overall cohort, mean (± SD) maternal age at cancer diagnosis was 32.7 ± 10.9 years, and mean gestational age at diagnosis was 14.0 ± 8.1 weeks.

Table 1: Demographic characteristics of pregnant women receiving chemotherapy with or without G-CSF

Characteristic	Overall (n=367)	Exposed (G-CSF n=85)	Unexposed (n=282)	p value
Age at diagnosis, Mean ± SD	34 ± 7.4	34 ± 5.0	34 ± 5.0	0.69
Race/Ethnicity, n (%)				
White	279 (76)	58 (68)	216 (77)	0.12
African American	22 (6)	5 (6)	16 (6)	0.94
Asian	23 (6)	2 (2)	20 (7)	0.11
Other	30 (8)	12 (14)	17 (6)	0.02
Unknown	13 (4)	8 (9)	13 (5)	0.96
Country				
United States	348 (95)	77 (91)	264 (94)	0.34
Canada	13 (4)	1 (1)	11 (4)	0.22
Other (Eng, Aus, Thai)*	5 (1)	0	4 (1)	0.27
Unknown	1 (0.2)	7 (8)	3 (1)	0.07

*Eng = England, Aus = Australia, Thai = Thailand

G-CSF– granulocyte colony-stimulating factors

SD – standard deviation

Table 2 summarizes cancer types and G-CSF use. Breast cancer was the most common diagnosis, including 47 women treated with dose-dense chemotherapy. Patients with breast cancer were more likely to receive G-CSF compared with patients with other cancer types (80% vs 20%, p = 0.04). Other malignancies included Hodgkin and non-Hodgkin lymphoma, acute leukemia, choriocarcinoma, and cancers of the cervix, bladder, bone, colon, gallbladder, nasopharynx, rectum, lung, ovary, and pancreas.

Table 2
Cancer types and G-CSF use among pregnant women receiving chemotherapy

Cancer Diagnosis	#Patients receiving Chemotherapy (n = 367)	#Patients receiving Filgrastim/Pegfilgrastim (85)
Breast (premenopausal)	261	68 (42 F, 22 P, 4 Both)
Dose-dense	47	30 (9F, 19P, 2 Both)
● Prophylactic	214	25
● Therapeutic		5
Conventional		38 (13F, 23P, 2 Both)
● Prophylactic		20
● Therapeutic		16
● Unclear		2
Hodgkin's Lymphoma	31	4 (2F, 2P)
● Prophylactic		3
● Therapeutic		1
Non-Hodgkin's Lymphoma	20	8 (4F, 4P)
● Prophylactic		2
● Therapeutic		5
● Unclear		1
Ovarian	13	0
Cervical	11	0
Acute Leukemia	4	3 (2F, 1P)
● Prophylactic		2
● Therapeutic		1
Lung	3	1 (1P)
● Prophylactic		1
● Therapeutic		0
Miscellaneous	24	1 (P – Bone cancer)
● Unclear		

F = Filgrastim, P = Pegfilgrastim, Both = combination of Filgrastim and Pegfilgrastim

Cancer Diagnosis	#Patients receiving Chemotherapy (n = 367)	#Patients receiving Filgrastim/Pegfilgrastim (85)
Total:	367	85 (34F, 45P, 4 Both)
F = Filgrastim, P = Pegfilgrastim, Both = combination of Filgrastim and Pegfilgrastim		

Maternal outcomes

Pregnancy outcomes and maternal complications are presented in Table 3. Overall, 70/367 (19%) pregnancies resulted in spontaneous preterm delivery or preterm premature rupture of membranes (PPROM), with no significant difference between groups (20% exposed vs 19% unexposed, p = 0.80). Elective iatrogenic preterm births were excluded from this comparison.Gestational diabetes mellitus and preeclampsia were the most common maternal complications. Less frequent complications included placenta previa, placental abruption, pyelonephritis, chorioamnionitis, oligohydramnios, and thromboembolism. The overall incidence of maternal complications did not differ between exposed and unexposed groups (31% vs 28%, p = 0.69).

Table 3
Pregnancy and Delivery Data

Variable	Overall (n = 367)	G-CSF exposed (n = 85)	G-CSF not given (n = 282)	p value
Gestational age at first treatment, Mean ± SD weeks	20.6 ± 5.5	19.6 ± 5.7	20.9 ± 5.4	0.07
Gestational age at delivery, Mean ± SD weeks	36.6 ± 2.3	36.4 ± 2.3	36.7 ± 2.4	0.38
Maternal pregnancy complications, n(%)	106 (29)	26 (31)	80 (28)	0.69
Preterm delivery from spontaneous rupture or PPROM, n(%)	70 (19)	17 (20)	53 (19)	0.80
G-CSF – granulocyte colony-stimulating factors				
SD – standard deviation				
PPROM – preterm premature rupture of membranes				

Fifteen women developed an infection during chemotherapy. Two were receiving G-CSF at the time of infection; only one of these patients was neutropenic when infection was diagnosed. Overall, maternal neutropenia occurred in 28/367 (7.7%) women receiving chemotherapy. Three women receiving prophylactic G-CSF developed neutropenia (3/57, 5%), compared with 25 women who did not receive prophylactic G-CSF (25/310, 8%); this difference was not statistically significant (p = 0.59).

Fetal and neonatal outcomes

Mean gestational age at delivery for the cohort was 36.6 ± 2.3 weeks and did not differ between the exposed (36.4 ± 2.3 weeks) and unexposed groups (36.7 ± 2.4 weeks; p = 0.38). Mean birthweight was also similar between groups (2,610 ± 539 g exposed vs 2,720 ± 588 g unexposed; p = 0.13).Fetal growth restriction occurred in 81/367 (22%) neonates: 25/85 (29%) in the exposed group and 56/282 (20%) in the unexposed group (p = 0.06; Table 4).

Table 4
Newborn and Pediatric Follow-Up Data

Variable	Overall (n = 367)	G-CSF exposed (n = 85)	G-CSF not given (n = 282)	p value
Newborn Data				
Birth weight, Mean ± SD grams	2694 ± 578.4	2610 ± 539.1	2720 ± 588.3	0.13
Fetal Growth restriction n (%)	81 (22)	25 (29)	56 (20)	0.06
Complications at birth, n (%)	65 (18)	14 (16)	51 (18)	0.73
Birth defects, n (%)	33 (9)	11 (13)	22 (8)	0.15
Neonatal Leukopenia, n (%)	4 (2)	1 (2)	3 (2)	1.00
Neonatal Neutropenia, n (%)	10 (6)	3 (6)	7 (5)	0.73
Pediatric Follow-Up				
Total, n (%)	101 (28)	26 (31)	75 (27)	0.47
Behavioral	31 (8)	8 (9)	23 (8)	0.72
Asthma	30 (8)	10 (12)	20 (7)	0.17
Eczema	44 (12)	13 (15)	31 (11)	0.28
Allergic Rhinitis	28 (8)	3 (4)	25 (9)	0.10
G-CSF – granulocyte colony-stimulating factors; SD – standard deviation				

A neonatal complete blood count at birth or on day 1 of life was available for 178 neonates (47 exposed, 131 unexposed). Neutropenia was present in 3/47 (6%) exposed neonates and 7/131 (5%) unexposed neonates (p = 0.73). Leukopenia occurred in 1/47 (2%) exposed and 3/131 (2%) unexposed neonates (p = 1.00). Among the 10 neonates with neutropenia, the mean interval between the final chemotherapy cycle and delivery was 3.9 ± 2.0 weeks, with half born within four weeks of maternal chemotherapy.

Immediate neonatal complications, most commonly hyperbilirubinemia, apnea, hypoglycemia, and respiratory distress, occurred in 14/85 (16%) exposed neonates and 51/282 (18%) unexposed neonates (p = 0.73).

Congenital anomalies were identified in 11/85 (13%) exposed and 22/282 (8%) unexposed neonates (p = 0.15). Ureteropelvic junction obstruction was the most common anomaly (four exposed, four unexposed). Multiple hemangiomas were the second most frequent anomaly and occurred only in the unexposed group. No patients received chemotherapy during the first trimester (Supplemental Table 1).

Pediatric follow-up data are summarized in Table 4. Medical conditions, most commonly asthma, eczema, and allergic rhinitis, were reported in 26/85 (31%) exposed children and 75/282 (27%) unexposed children (p = 0.47). Behavioral diagnoses did not differ significantly between groups.

Discussion

When cancer is diagnosed during pregnancy, termination has not been shown to improve maternal survival [12–16]. Studies comparing pregnant women with cancer to age- and stage-matched non-pregnant controls demonstrate similar oncologic outcomes when comparable therapies are administered [6, 7, 17–20]. Long-term follow-up studies of children exposed in utero to chemotherapy administered after the first trimester have been reassuring, with neurodevelopmental outcomes largely influenced by gestational age at delivery rather than chemotherapy exposure itself [2–5].

Despite these data, chemotherapy regimens offered during pregnancy may differ from those used in non-pregnant patients, particularly with respect to dose-dense protocols requiring G-CSF support. Anecdotal reports from patients with breast cancer in our cohort suggest that dose-dense chemotherapy would have been offered outside of pregnancy, highlighting ongoing clinician hesitancy regarding G-CSF use during gestation. Our findings provide additional evidence to inform discussions surrounding chemotherapy optimization during pregnancy.

In this prospective cohort of 85 pregnancies exposed to G-CSF during chemotherapy, no statistically significant differences were observed in maternal, obstetric, neonatal, or pediatric outcomes compared with women treated with chemotherapy alone. Outcomes evaluated included gestational age at delivery, birthweight, fetal growth restriction, preterm delivery, neonatal complications, congenital anomalies, and hematologic abnormalities. Neonatal neutropenia and leukopenia were uncommon and occurred at similar rates in both exposure groups. Consistent with prior literature, neonates with hematologic abnormalities were more frequently delivered within three to four weeks of the final maternal chemotherapy cycle [21].

Maternal complications, including infection and neutropenia, were also comparable between groups. Although neutropenia occurred in a small proportion of women receiving prophylactic G-CSF, the overall incidence did not differ significantly from women who did not receive prophylactic support. These

findings align with prior reports describing the safety of G-CSF use during pregnancy, including smaller retrospective studies and registry-based analyses [10, 22, 23].

Our study expands on existing literature by including a larger number of exposed pregnancies, a prospectively collected control group, and long-term pediatric follow-up. The prospective design of the Cancer and Pregnancy Registry minimizes selection bias and allows for systematic longitudinal assessment of offspring health.

Several limitations warrant consideration. Neonatal complete blood counts were not uniformly obtained across all participating centers, limiting the assessment of neonatal hematologic outcomes. Additionally, the relatively low incidence of many outcomes restricts statistical power to detect small differences. While this study focused on Filgrastim and Pegfilgrastim, continued data collection is ongoing for biosimilar G-CSF.

Abbreviations

ANC
absolute neutrophil count
CBC
complete blood count
FGR
fetal growth restriction
G
CSF-granulocyte colony-stimulating factors
GDM
gestational diabetes mellitus
PPROM
premature rupture of membranes

Declarations

Ethics approval

Creation and maintenance of the Registry was approved by the Office of Research & Sponsored Programs – Division of Research Integrity, Institutional Review Board at Cooper University Healthcare. The IRB approval/reference number is 15-028. All enrolled patients provided informed consent.

Consent for publication

Not Applicable

Data availability

The data supporting the findings of this study are available from the corresponding author, AB, upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Author contributions

EC conceived and designed the study. AB collected the data, and JD and JG performed statistical analysis and interpreted the results. EC and AB drafted the manuscript, and all authors critically revised it for important intellectual content. All authors approved the final version of the manuscript.

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Supplementary Files

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- GCSFSupplementalTable1.docx