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Reproductive Outcomes for Women With Vasculitis

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ABSTRACT. ***Objective.*** There are limited data on the reproductive health of women with vasculitis. This study used a prospective, international vasculitis pregnancy registry to survey women during and after pregnancy.

Methods. The Vasculitis Pregnancy Registry (VPREG) is imbedded within the Vasculitis Patient-Powered Research Network, an international online research infrastructure. Any pregnant woman with a diagnosis of vasculitis can self-enroll. After enrollment, women are invited to complete online surveys at study entry, once per trimester, and postpartum. Descriptive statistics are reported here.

Results. Between 2015 and 2022, 147 women with 149 pregnancies enrolled in VPREG from 16 countries. Data on 78 pregnancies with known outcomes were included in this analysis. During pregnancy, women on average experienced low levels of pain related to vasculitis (scale 0-10, median 2 [IQR 1-5]) and preserved feelings of wellness (scale 0-10, median 3 [IQR 1-5]). Thirty-six percent of women reported their vasculitis was active during pregnancy. Of the 14 women requiring hospitalization during pregnancy outside of delivery, 4 cited active vasculitis as the indication. Most women (54/73, 74%) were prescribed medications for vasculitis during pregnancy. Seventy-six (97%) pregnancies resulted in live births, with 64% delivering vaginally and 21% experiencing a preterm delivery.

Conclusion. These results demonstrate that most women with vasculitis can experience pregnancies that result in live births delivered at term. During pregnancy, a minority of women reported flares of vasculitis or the need for hospitalization due to vasculitis. These data are useful to rheumatologists and patients to inform and facilitate discussions about reproductive health and vasculitis.

Key Indexing Terms: pregnancy, reproductive healthcare, vasculitis, women's health

Vasculitides are rare diseases; therefore, there is limited information to guide decisions regarding reproductive healthcare for women.[1] Certain types of vasculitis more commonly affect reproductive health as disease-specific peak age of onset falls within reproductive years; these include Takayasu arteritis (TA), Behçet disease, and polyarteritis nodosa.[2] In contrast, giant cell arteritis and Kawasaki disease are less likely to occur in this demographic, although the long-term consequences of Kawasaki disease may affect pregnancy. Vasculitis can affect women of reproductive age, leading to the need for more comprehensive data collection and analysis to evaluate pregnancy complications and outcomes in these women than has been provided by prior case reports and retrospective studies.

Between 2017 and 2022, multiple expert committees provided guidelines for reproductive health care in patients with rheumatic diseases, including the American College of Rheumatology (ACR),[3] American College of Obstetrics and Gynecology, European Board and College of Obstetrics

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and Gynecology, and European Alliance of Associations for Rheumatology.[4-6] However, none of these recommendations offer specific guidance for patients with vasculitis. Similarly, the 2021 ACR/Vasculitis Foundation vasculitis treatment guidelines do not address reproductive health.[7-9] In the absence of reliable data, women with vasculitis interested in pregnancy are faced with making difficult decisions regarding pregnancy and family planning.

Prior studies reported widely varying data regarding pregnancy complications and outcomes without establishing well-defined, clinically meaningful patterns useful to medical providers for anticipatory guidance. Between 2011 and 2021, studies evaluating pregnancy outcomes in antineutrophil cytoplasmic antibody–associated vasculitis (4 publications), Behçet disease (6 publications), and TA (8 publications) reported wide ranges of outcomes, including preeclampsia (0-43.8%), preterm delivery (0-50%), cesarean delivery (27.8-56.3%), and pregnancy loss (0-26.3%).[10-22] The clinical utility of these studies and how the data should affect medical management is unclear. The Vasculitis Pregnancy Registry (VPREG), a prospective, international, patient-reported online database, was created to address these concerns. This study assessed pregnancy outcomes, medication use, and vasculitis activity in an international cohort of women.

METHODS

Recruitment. VPREG is a prospective, patient-driven, international database created to address gaps in clinical research, recruit a diverse patient population, and provide opportunities for patient and provider empowerment. Patients are only permitted to enroll in VPREG while they are currently pregnant. Patients are requested to complete surveys before, during, and after pregnancy that address pregnancy outcomes and complications, vasculitis disease activity, and medication use. Patients self-enroll in VPREG without the need for provider input or information. Patients are recruited through several methods, including engagement of medical providers, internationally available educational resources, and advertisement at national and international conferences. This study was approved by the Duke Institutional Review Board (Pro00061688).

International collaboration. The VPREG website, surveys, and educational handouts and videos are undergoing translation into multiple languages through international collaborations that also play a key role in patient recruitment, improved access to patient resources, and streamlined feedback to improve patient experience with the VPREG interface. Multiple international collaborative meetings were held virtually between 2020 and 2023 to maintain international engagement, facilitate communication, and expand international recruitment.

Enrollment and survey completion. The enrollment process requests information about patient demographics, data on diagnostic criteria, manifestations of vasculitis, treatments used for vasculitis, contraception use, prior pregnancies, and need for assisted reproductive technology. After enrollment, patients were requested to complete online surveys once per trimester and once in the postpartum period to assess vasculitis activity, medication use, pregnancy complications and outcomes, and need for hospitalization. To explore the effect of vasculitis during pregnancy on patient perceptions of pain and wellness, women were asked to rate these variables on a scale of 0 to 10 (0 = no pain and 10 = pain as bad as it could be; 0 = very well and 10 = very poorly). Participants were asked to report on the health of their child following delivery. Mothers were given flexibility on how they perceived their child's health and defined "healthy" and "not healthy."

In July 2022, women with incomplete survey data since the inception of VPREG in 2015 were contacted via secure email, text, and/or phone to request survey completion. Survey responses were matched with variables in the original surveys and recorded in REDCap.

Statistical analysis. Descriptive statistics were used to report patient characteristics, vasculitis disease activity during pregnancy, and pregnancy and neonatal outcomes. All analyses were conducted in SAS 9.4 (SAS Institute).

RESULTS

Patient population and demographics. Between 2015 and 2022, 147 women who conceived 149 pregnancies enrolled in VPREG, with 9 women experiencing ongoing pregnancies at the time of data analysis. These 9 patients were excluded, along with an additional 62 women who were lost to follow-up (Figure). Women were labeled as lost to follow-up if they had no known pregnancy outcomes. Patients excluded from analysis had similar distribution of age and types of vasculitis (data not shown). Seventy-six women with 78 pregnancies were included in the final analysis (Table 1). Women from 11 countries were represented in this patient sample, with most women living in North America (n = 62). The average age at enrollment was 32.6 (SD 4.8) years.

Characteristics of vasculitis and medication utilization during pregnancy. Nine types of vasculitis were represented, with the most common category being small-vessel vasculitis (57%) (Table 1). Granulomatosis with polyangiitis (40%) and TA (21%) were the most frequently reported diagnoses.

The majority of women (74%) received vasculitis-specific medication during pregnancy. Nearly half (49%) of all participants reported glucocorticoid use during pregnancy. Azathioprine (27%) and tumor necrosis factor inhibitors (10%) were the most commonly reported medications for vasculitis taken during pregnancy. Four women were treated with rituximab during pregnancy.

Vasculitis disease activity, pain, wellness, and functionality during pregnancy. The median scores for pain and wellness in pregnancy were 2 (IQR 1-5) and 3 (IQR 1-5), respectively. Twenty women (20/56, 36%) reported experiencing vasculitis disease activity during pregnancy (Table 2). Fourteen women (14/74, 19%) were hospitalized during pregnancy other than for delivery. Of those hospitalizations, 6 were for pregnancy-related complications and 4 were vasculitis-related complications. Additionally, 2 women had a second hospitalization following postpartum discharge, including 1 woman with a vertebral artery dissection.

Pregnancy outcomes. Throughout their pregnancy management, some women reported undergoing ultrasound imaging (n = 49; Table 3). Seventy-six percent (37/49) of women reported no ultrasound abnormalities. Of the 49 women who reported the results of their ultrasound, abnormalities included subchorionic hemorrhage (n = 3) and placental abnormalities (n = 2). A twin demise at 14 weeks' gestation was the only ultrasound observation that had affected the outcome of the pregnancy (singleton vs twin delivery); this patient continued to carry a singleton pregnancy, which resulted in a live birth.

The majority of pregnancies resulted in vaginally delivered (49/77, 64%) live births (76/78, 97%) at full term (median 38 [IQR 37-39] weeks). The 2 nonlive births were a therapeutic abortion at 5 weeks' gestation and fetal demise at 22 weeks' gesta-

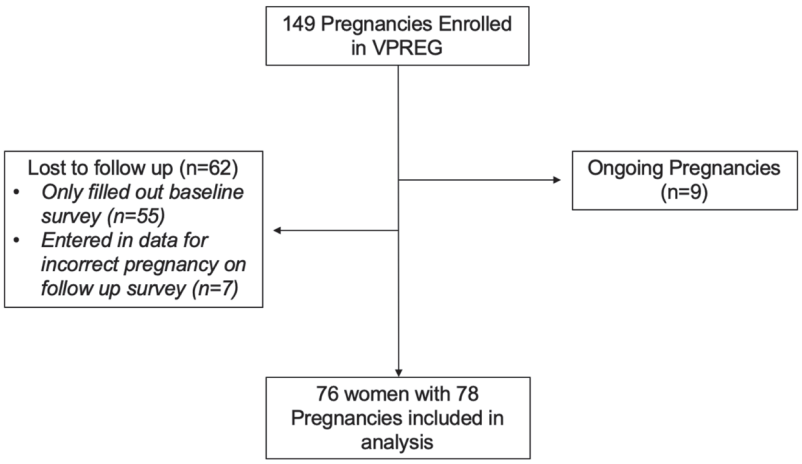

Figure. Participants in the VPREG Registry. VPREG: Vasculitis Pregnancy Registry.

tion. Pregnancy complications in live births included preterm delivery (16/75, 21%), preeclampsia (14/56, 25%), gestational hypertension (12/56, 21%), and gestational diabetes (5/56, 9%; Table 1).

Offspring outcomes. Sixty-three mothers (63/70, 90%) reported their children as "healthy." Two of 14 (14%) children born preterm (< 37 weeks) were reported as "not healthy" compared to 5 (9%) of children born at term. The explanations provided by mothers for why their child was not healthy were widely ranging, from birthing complications to congenital hypothyroidism (Table 3). The majority of women (30/35, 86%) attempted breastfeeding.

DISCUSSION

To our knowledge, these are the first reported results from an international, prospective pregnancy database for women with vasculitis. This diverse population included women from 5 continents and 11 countries, with more than 10 types of vasculitis. Most women experienced preserved well-being, retained functionality, and reported low pain scores, with a minority requiring hospitalization for vasculitis during pregnancy. The majority of women (74%) were prescribed vasculitis-specific medications during pregnancy and experienced live births (97%) at full term.

A 2023 nationwide French cohort study including women with any type of systemic vasculitis reported fewer women (40.7%) receiving immunosuppression, including glucocorticoids (GCs), compared to the VPREG cohort during pregnancy.[23] In concordance with the current findings, azathioprine was the most frequently reported medication used for vasculitis during pregnancy. Use of GCs was stable throughout trimesters and ranged from 23.7% to 27.9%, which was lower than in the VPREG cohort (49%). A 2015 study from the French Takayasu's Network reported 40.4% of women were exposed to GCs during pregnancy, which is more consistent with the current findings.[21] Differences between these reports may be accounted for by the prospective, multicontinental nature of the VPREG database compared to retrospective studies within a single country. The high utilization of GCs during pregnancy is notable, as prior research demonstrated GC exposure increases risk for poor pregnancy outcomes, including preterm birth, gestational hypertension, gestational diabetes, premature rupture of membranes, and preeclampsia. Additionally, the amount and length of exposure of GCs may affect outcomes, since higher doses and longer exposures are associated with worse outcomes.[24] Of note, 22% of women reported taking aspirin during pregnancy (Table 1). The reasons for low utilization of aspirin during pregnancy are likely multifactorial, including (1) differences in regional practices; (2) access to providers, both rheumatologists and obstetricians, with knowledge of appropriate management of higher-risk pregnancies; and (3) the patient's comfort level with taking additional medications during pregnancy, even if recommended by their medical team. Despite the recommendations from the ACR, which are derived from data in women with systemic lupus erythematosus and antiphospholipid syndrome, there are no vasculitis-specific guidelines that recommend prophylactic aspirin or low molecular weight heparin during pregnancy.[3]

Approximately a third of women in this study experienced vasculitis disease activity (36%) during pregnancy, with 5% hospitalized for vasculitis. This rate of activity is consistent with prior data that documents between 20% and 40% of women with systemic vasculitides experience disease flares during pregnancy.[25] Disease activity can vary depending on the type of vasculitis and level of activity leading up to conception.[13,26] Given the lack of formal guidelines from expert panels on vasculitis and reproductive health, these outcomes inform reproductive conversations with patients and reinforce the importance of planned pregnancies in women with well-controlled disease on pregnancy-compatible medications. Most women did not experience pain related to vasculitis that limited their functionality or significantly affected their wellness during pregnancy. De Man et al used this same functionality assessment, derived from the Health Assessment Questionnaire, in healthy pregnant women.[27] Women with vasculitis had similar functionality scores compared to healthy women during pregnancy.[27] This finding is significant as it demonstrates most women with vasculitis can achieve their reproductive goals while preserving their prepregnancy schedule and lifestyle.

Table 1. Patient demographics, characteristics of vasculitis, and treatment during pregnancy.

	Values
Age at enrollment, yrs, mean (SD) (n = 76)	32.6 (4.8)
Country of origin, n (n = 78)	
North America	
USA	53
Canada	9
South America	
Argentina	1
Europe	
UK	3
Ireland	2
Sweden	2
Finland	1
Greece	1
Australia	
Australia	3
Asia	
Turkey	2
UAE	1
Type of vasculitis (n = 78)	
Small-vessel vasculitis	45 (57)
GPA	31 (40)
EGPA	3 (4)
ANCA vasculitis not otherwise specified	1 (1)
Microscopic polyangiitis	2 (3)
Urticarial vasculitis	5 (6)
IgA vasculitis	2 (3)
Leukocytoclastic vasculitis	1 (1)
Medium-vessel vasculitis	
Polyarteritis nodosa	1 (1)
Large-vessel vasculitis	
Takayasu arteritis	16 (21)
Variable-vessel vasculitis	
Behçet disease	7 (9)
Single-organ vasculitis	
CNS vasculitis	4 (5)
Relapsing polychondritis	1 (1)
Other	4 (5)
Medications for vasculitis used during pregnancy (n = 73)	
None	19 (26)
Glucocorticoids	36 (49)
Immunosuppressants	
Azathioprine	20 (27)
TNFi	7 (10)
Hydroxychloroquine	4 (5)
Rituximab	4 (5)
Colchicine	3 (4)
Calcineurin inhibitor	2 (3)
Methotrexate[a]	1 (1)
Antiplatelet/anticoagulant	
Aspirin	16 (22)
Low molecular weight heparin	5 (7)
Smoking during pregnancy (n = 49)	1 (2)

Values are expressed as n (%) unless indicated otherwise. [a] Accidental exposure during first trimester, then discontinued. ANCA: antineutrophil cytoplasmic antibody; CNS: central nervous system; EGPA: eosinophilic granulomatosis with polyangiitis; GPA: granulomatosis with polyangiitis; TNFi: tumor necrosis factor inhibitor.

Table 2. Vasculitis disease activity during pregnancy.

	Values
Vasculitis activity during pregnancy (n = 56)	20 (36)
Hospitalized during pregnancy other than for delivery, n (n = 74)	14 (19)
Pregnancy	6
Vasculitis	4
Unknown	4
Pain during pregnancy (n = 78)	2 (1-5)
Wellness during pregnancy (n = 78)	3 (1-5)
Functionality during pregnancy[a] (n = 48)	
Walking 2 mi	28 (58)
Getting out of bed	14 (29)
Walking outside	13 (27)
Dressing	12 (25)
Bathing	10 (21)

Values are expressed as n (%) or median (IQR) unless indicated otherwise. [a] Values denote those having difficulty with the activities.

The majority of prenatal care in our study was uneventful as most ultrasound and imaging results were reportedly normal. The rate of live births in this study was higher (97%) than a multicentered Italian study and single-center United Kingdom study, which reported 86.9% and 74.5% live births including all systemic vasculitides, respectively.[12,28] The live birth rate in VPREG is likely higher because women who experienced miscarriages either did not enroll or were lost to follow-up. The patient who experienced a fetal demise at 22 weeks had an unplanned pregnancy due to failure of contraception with possible methotrexate exposure. This reinforces the importance of highly effective contraception with use of teratogenic medications; methotrexate causes pregnancy loss in 40% and birth defects in 7% of exposed pregnancies.[29] Such exposure creates additional physical, emotional, and psychological stress on the patient. Additional management with maternal fetal medicine and close monitoring is recommended during pregnancies when the mother and fetus are exposed to teratogenic agents.[2,26]

Most pregnancies were delivered vaginally at term. However, 21% delivered preterm and 36% required a cesarean delivery. A systematic review of pregnancies in small-vessel vasculitides reported a preterm delivery and cesarean delivery rates of 16-44% and 11-43%, respectively, depending on the type of vasculitis.[11] In 45 case reports of TA between the years 1987 and 2010, 31 (69%) required cesarean delivery.[11] The difference between these rates could possibly be attributed not only to the unique pathophysiology of each type of vasculitis but also to country-specific obstetric practices, advancements in obstetric care, pregnancy-safe immunosuppressive options, and the increased comfort with pregnancy in patients with rheumatic disease.

Women with vasculitis have inherently higher risks associated with pregnancy. Rates of preeclampsia and gestational hypertension are higher in this group of diseases compared to the general population (5-7%).[30] The currently reported observed rates of preeclampsia (25%) and gestational hypertension (21%) are consistent with prior reports.[12-14,21] Hypertensive

Table 3. Pregnancy and neonatal outcomes.

	Results
Pregnancy	
Ultrasound (n = 49)	
No abnormalities	37 (76)
Subchorionic hemorrhage	3 (6)
Placental abnormalities	2 (4)[a]
Twin demise at 14 weeks' gestation	1 (2)
Fetal demise at 22 weeks' gestation	1 (2)
Polyhydramnios	1 (2)
Hydronephrosis	1 (2)
Hypoechoic focus on fetal intestine	1 (2)[b]
Unspecified	2 (4)
Birth outcome (n = 78)	
Live births	76 (97)
Nonlive births	2 (3)[c]
Weeks of gestation at delivery, median (IQR) (n = 68)	38 (37-39)
Type of delivery (n = 77)	
Vaginal	49 (64)
Cesarean	28 (36)
Unknown	1
Preterm delivery (n = 75)	16 (21)
Preeclampsia (n = 56)	14 (25)
Gestational hypertension (n = 56)	12 (21)
Gestational diabetes (n = 56)	5 (9)
Rehospitalization postpartum (n = 29)	2 (7)[d]
Neonatal characteristics and care	
Child's health (n = 70)	
Healthy	63 (90)
Not healthy[e]	7 (10)[f]
Breastfeeding (n = 35)	
Yes	30 (86)[g]
No	5 (14)

Values are expressed as n (%) unless indicated otherwise. [a] Calcification (1), low-lying placenta, vasa previa, velamentous insertion (1). [b] Resolved spontaneously. [c] Fetal demise at 22 weeks' gestation, and elective termination of pregnancy at 5 weeks' gestation. [d] Vertebral artery dissection (1), no explanation (1). [e] Children could have > 1 condition. [f] Neonate complications: hyperbilirubinemia hypoglycemia (3), asthma (2), allergies (2), heart murmur (1), congenital hypothyroidism (1). [g] Duration: ongoing (1), 2-5 months (2), 6-12 months (5), > 12 months (9), no answer (13).

disorders in pregnancy are major contributors to maternal, fetal, and newborn morbidity and mortality.[31] Preeclampsia requires urgent medical attention and treatment to prevent progression to eclampsia. These complications are significant as changes in clinical management should be considered, including aspirin as a preeclampsia prophylaxis, initiation of pregnancy-compatible antihypertensives, and frequent blood pressure monitoring.[3]

This study has some notable strengths, including that data were collected prospectively and specifically to address the study questions. Additionally, VPREG results are highly generalizable given the worldwide recruitment efforts that expand beyond academic centers, thereby capturing participant experiences in multiple countries, demographics, and clinical settings.

However, this study also has limitations to consider, including lack of access to medical records and physician-reported data, high rate of participants loss to follow-up, low response rates to specific survey questions, and reliance on patient recollection. It is possible women who join research initiatives such as VPREG have different experiences, perceptions, and outcomes than women not interested or unable to participate. There is a unique benefit of allowing patients to voice their perceived narrative of the reproductive experience. The number of women lost to follow-up could be attributed to several causes, including multiple failed attempts to contact patients, obstacles in the VPREG workflow to contact patients, limited time in the postpartum period, pregnancy loss, and pregnancy complications. To improve patient retention and survey completion rates, patients received regularly scheduled reminder emails and phone calls.

The VPREG Registry has kindled a community of women and medical professionals that advocate for the future of medical management and guidance within this population. At the time of completion of this study, VPREG has collaborated with medical providers, translators, and patient advocates in 16 countries, and VPREG resources have been translated into 5 languages. VPREG is actively recruiting participants internationally. We will continue to work with our international collaborators to discuss feedback and recommendations to improve recruitment and retention of patients worldwide. A large, diverse cohort of women will improve the power and generalizability of results and contribute to evidence-based medical practice and reproductive guidance for women with vasculitis. VPREG also serves as a centralized organization positioned to improve the reproductive experience for patients and providers through community and innovation.

In conclusion, the results from this global, patient-reported, online database demonstrated mostly positive pregnancy outcomes (full term, live birth, healthy neonate) for women with vasculitis. However, pregnancy complications were present and demonstrate the importance of collaborative, multidisciplinary care in this population at high risk of poor outcomes from pregnancy.

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