INTRODUCTION

Pregnancies in polycythemia vera (PV) are rare, partly because the disease is usually diagnosed after childbearing age and more often in men. An incidence of only 0.3 per 100,000 has been calculated for women under the age of 40. To date, the course of about 175 PV pregnancies has been reported in retrospective cohort studies or case series. Most of these pregnancies (159 out of three PV studies)
were included in the meta-analysis of Maze et al. The overall live birth rate was only 66.7%, lower than that of the 815 ET pregnancies collected in the same meta-analysis, which was 71.1%. In comparison, the live birth rate for normal pregnancies is reported to be 85%. The advantage of PV-specific therapy, the live birth rate for normal pregnancies is reported to be 85%.4

In one of the largest single-center study published to date, Robinson et al. retrospectively examined 18 pregnancies in eight PV women and compared seven pregnancies treated with standard antenatal care with 11 cases managed according to a formal treatment protocol including phlebotomy, acetylsalicylic acid (ASA), low molecular weight heparin (LMWH) and/or interferon-alpha (IFN). In the group receiving this PV-specific therapy, the live birth rate was 81.8% (nine live births in 11 pregnancies) compared to only 14.3% (one live birth in seven pregnancies) in the other group. In another report, Harrison et al. added 20 other historical PV pregnancies to the 18 cases of Robinson et al. The advantage of PV-specific therapy could be confirmed.

Bertozzi et al. recently published the results of a study including 24 PV pregnancies from two Italian centers. Again, the rate of miscarriages was lower in pregnancies with PV-specific therapy (ASA and/or LMWH) than in those without the corresponding treatment (10.5% vs 40.0%).

With regard to the postpartum course of the disease, Randi et al. observed an association between pregnancy complications and an increased risk of subsequent essential thrombocythemia (ET)-related thrombotic events in the women with miscarriages in 228 ET pregnancies. To the best of our knowledge, this association has not been studied in PV pregnancies.

To investigate the impact of antenatal applied PV-specific therapy on live birth rates, we conducted a retrospective, non-interventional analysis of 41 pregnancies in 20 women with PV. Furthermore, we investigated the association between pregnancy outcome and the postpartum course of PV.

2 | PATIENTS AND METHODS

Clinical data of all MPN patients, who regularly presented to our university clinic, were collected from June 2007 to April 2020 (time of last data cut off April 1, 2020). The patients gave their consent for data collection, and the institutional review board of our center approved the study.

In total, data from 782 MPN patients were screened. The inclusion criteria for this retrospective non-interventional study were women with a diagnosis of PV and at least one pregnancy 2 years before PV diagnosis and/or at any time thereafter. According to these criteria, 20 PV patients with a total number of 41 PV-associated pregnancies were included. The diagnosis of PV was made between 1988 and 2017 and the corresponding pregnancies occurred between 1993 and 2018. All PV patients were JAK2 V617F mutated and were diagnosed according to the WHO 2016 criteria. The data were compiled retrospectively from medical records. Further information was requested from the patients and/or from the other treating physicians.

Pregnancy outcome was defined as spontaneous abortion (pregnancy loss before or in 20th week), stillbirth (intrauterine death after 20 weeks without signs of life at birth), preterm delivery (live birth with a birth weight below 2.5 kg or birth between weeks 24 and 37), or full-term normal delivery (live birth after 37 weeks, including overdue deliveries). The total follow-up time was calculated by summing up the periods from the beginning of each pregnancy until the last contact with our center. Maternal pregnancy complications were defined as any adverse event occurring during pregnancy or within 6 weeks after delivery.

During the observation period from 1993 to 2018, the 41 PV pregnancies were managed according to different treatment recommendations valid at the time of each pregnancy. From 2006 onwards, PV pregnancies at our center were predominantly treated according to the recommendations of Harrison et al. Since 2018, we have been treating pregnant PV patients in line with our recommendations summarized in Table 1.

The major objective of this retrospective analysis was to obtain information on the outcome and impact of PV-specific therapy used during pregnancy on the live birth rate. In addition, information should be provided on potential risk factors affecting pregnancy outcome and risks of obstetrical complications.

Hemorrhagic complications were defined according to Schulman et al.12 If one of these criteria were applicable, for example, heavy bleeding with hemoglobin drop >2 g/dL, transfusion requirement of two or more erythrocyte concentrates or bleeding in vital organs, the bleeding complication was considered a major hemorrhagic complication.

Finally, the postpartum course of PV was analyzed. A postpartum course of disease was defined as “complicated” if thrombosis or severe hemorrhage occurred 6 weeks after delivery or thereafter. For this analysis, the postpartum follow-up period was defined as time from 6 weeks after delivery date until the beginning of the respective patient’s next pregnancy, or until the first thrombosis or

| TABLE 1 Treatment recommendations and important issues concerning management of PV pregnancies |
|---------------------------------------------|
| Planning pregnancy and preconception phase |
| - Stop potential teratogenic drugs before conception. |
| - Organize joint care between consultant obstetrician together with hematologist experienced in MPN |
| Pregnancy |
| - Low-dose ASA (75-100 mg/d) in all pregnancies |
| - Tight control of hematocrit (<45%) by phlebotomy |
| - Add IFN and/or LMWH in “high-risk” situations. |
| - Stop ASA two weeks before planned delivery and change to LMWH |
| Delivery |
| - Stop LMWH once the patient goes into labor |
| - For elective cesarean section omit LMWH at least 12 h before delivery |
| Postpartum |
| - LMWH for 6 weeks of postpartum in prophylactic dose |

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clinically relevant bleeding, or until the last contact with the research group—whichever came first.

2.1 | Statistical methods

For continuous variables, the median and range are given. Differences in the proportions were estimated using Fisher’s exact test, Chi-square test, Mann-Whitney-U Test (statistical significance threshold set at \( P < .05 \)), or two-sided log-rank test (Mantel-Haenszel Test).

3 | RESULTS

3.1 | Basic clinical data

The median age of the 20 patients at PV diagnosis was 28.9 years (range 17.8-35.9) and 34.7 years at delivery (range 25.8-42.6). Five out of 41 pregnancies (12.2%) ended before PV diagnosis with a median time between delivery and PV diagnosis of five months (range 3-8). 36 pregnancies occurred after PV diagnosis with a median time between diagnosis and delivery of 4.1 years (range 0.1-18.9). Twelve out of 41 pregnancies (29.3%) were terminated by cesarean section. The median week of gestation at delivery was the 32nd (range 4th-42nd). One twin pregnancy was counted as a single pregnancy. The median number of pregnancies per patient was two (range 1-5). The median follow-up time for the 41 PV-associated pregnancies was 7.9 years (range 0.8-23.0).

The live birth rate in our cohort was 51.2% (21/41), while the rate of miscarriages was 48.8% (20/41). Specifically, 43.9% of pregnancies (n = 18) resulted in spontaneous abortion, 4.9% (n = 2) in stillbirth, 12.2% (n = 5) in preterm delivery, and 39.0% (n = 16) in full-term normal delivery. All newborns remained without abnormalities.

In five pregnancies with delivery before PV diagnosis, live birth rate was only 20.0% (1/5). Among 36 pregnancies with delivery after PV diagnosis, live birth rate was 55.6% (20/36). This difference in live birth rates was not statistically significant (\( P = .184 \)).

Table 2 provides an overview of the basic characteristics and outcome of the 41 pregnancies and a comparison between pregnancies with live births (n = 21) and pregnancies with miscarriages (n = 20). Any statistically significant difference between these two groups could not be observed.

3.2 | PV-specific therapy during pregnancy

PV-specific therapy, which included low-dose acetylsalicylic acid (ASA), low molecular weight heparin (LMWH) and interferon-alpha (IFN), was used in 70.7% of pregnancies (29/41). 69.0% of these ended in live births (20/29). In contrast, live birth rate was only 8.3% in the 12 pregnancies that did not receive any PV-specific therapy during pregnancy (1/12). This difference was statistically significant (Figure 1; \( P < .001 \)).

Acetylsalicylic acid was the most commonly used PV-specific therapy, administered in 56.1% of pregnancies (23/41). ASA was used at a dose of 100 mg per day (88.2%) or 50 mg per day (11.8%). Live birth rate in pregnancies with ASA was 69.6% (16/23 pregnancies) compared to 27.8% without ASA (5/18 pregnancies). This difference was statistically significant (\( P < .01 \)).

Low molecular weight heparin was used in 21 PV pregnancies (51.2%). In seven of the 21 cases, therapy with LMWH began in the third trimester and replaced the previously given ASA therapy. In 14 pregnancies, LMWH treatment started in the first trimester. All patients who received LMWH continued this treatment until 6-week postpartum, but only if there was a live birth. More live births

| TABLE 2 | Basic clinical data and outcome of 41 pregnancies in 20 PV patients and a comparison between the 21 live births and the 20 miscarriages |
|---------------------------------|---------------------------------|---------------------------------|----------------|
|                                | All pregnancies (n=41)          | Pregnancies with live births (n=21) | Pregnancies with miscarriages (n=20) | \( P^* \) |
| Median follow-up time in years (range) | 7.9 (0.8-23.0) | 5.8 (0.8-19.8) | 13.9 (1.4-23.0) | .114 |
| Pregnancies with delivery before/ after PV diagnosis – N (%) | 5/36 (12.2/87.8) | 1/20 (4.8/95.2) | 4/16 (20.0/80.0) | .136 |
| Median maternal age at PV diagnosis in years (range) | 28.9 (17.8-35.9) | 27.2 (17.8-35.9) | 29.1 (19.0-35.7) | .487 |
| Median maternal age at delivery in years (range) | 34.7 (25.8-42.6) | 35.3 (27.1-42.6) | 34.5 (25.8-39.0) | .481 |
| Hematocrit at PV diagnosis - % (range) | 47.0 (41.4 – 55.0) | 47.0 (41.4-52.0) | 47.0 (43.0-55.0) | .500 |
| Median hematocrit values during pregnancy - % (range) | 40.0a (39.0-47.0) | 39.8b (39.0-45.3) | 40.4c (34.8-47.0) | .904 |

*Available in n = 31 pregnancies.

bAvailable in n = 19 pregnancies.

cAvailable in n = 12 pregnancies.

*Statistical comparison between life births and miscarriages.
were observed with LMWH than without: 81.0% (17/21) vs. 20.0% (4/20). This difference in live birth rate was statistically significant (P < .001). The different LMWH compounds used were Enoxaparin in 11 of 21 pregnancies (52.4%), Dalteparin in eight (38.1%), and tinzaparin in two pregnancies (9.5%).

Interferon-alpha therapy was used in six pregnancies (14.6%). Pegylated IFN was administered in three and conventional IFN in the other three cases.

Live birth rate for pregnancies with IFN was 83.3% (5/6 pregnancies). This live birth rate was not significantly increased (P = .885) compared to pregnancies without: IFN (45.7%, 16/35). IFN as monotherapy was used only in one pregnancy (outcome: live birth).

Regarding treatment combinations, ASA and LMWH (without IFN) were combined in 13 pregnancies. Eleven of these 13 pregnancies resulted in live births (84.6%). Three other pregnancies were treated with a triple combination of ASA, LMWH, and IFN. Live birth rate was 100% (3/3). In eight of the 16 cases mentioned, ASA and LMWH were used simultaneously throughout the pregnancies. Table 3 summarizes the PV-specific pharmacotherapies together with associated pregnancy outcomes.

All patients received phlebotomies according to the treatment guidelines valid at the time of pregnancy. Thus, phlebotomy was performed in 19.5% of pregnancies (8/41). The median hematocrit in pregnancies with phlebotomies was 43.0% and 42.0% in those without. Live birth rate was higher in pregnancies with phlebotomies than in those without: 62.5% live births (5/8) vs. 48.5% live births (16/33). This difference in live birth rates was not statistically significant (P = .506).

3.3 Maternal pregnancy complications

We observed 18 maternal pregnancy complications during 18 pregnancies in 17 patients: six bleedings during pregnancy, four bleedings at delivery, one pre eclampsia, one deep leg vein thrombosis during pregnancy, and six placenta pathologies. All complications occurred during pregnancy or at delivery and none during the postpartum period of 6 weeks. All maternal complications were observed in pregnancies with delivery after PV diagnosis.

All six bleeding complications that occurred during six pregnancies were vaginal bleedings and were classified as minor. 5/6 (83.3%) occurred with ASA alone (n = 1) or with combination of ASA and LWMH (n = 4). The remaining vaginal bleeding occurred during a pregnancy with IFN alone. The overall rate of minor hemorrhagic complications during pregnancy was 14.6% (6/41). The live birth rate in these six pregnancies was 83.3% (5/6). The only miscarriage in this group occurred in a pregnancy with ASA but without LMWH application.

Bleeding at delivery was reported in four out of 41 pregnancies (9.8%). Three were classified as minor and one as major bleeding. The major bleeding was a vaginal bleeding after a twin birth. This patient received ASA + LMWH + IFN during pregnancy. In two out of three pregnancies with minor bleedings at delivery, LWMH, and ASA were combined and LMWH alone was used in the remaining cases.
pregnancy. All four pregnancies with bleedings at delivery resulted in live births.

Preeclampsia was observed in one pregnancy (1/41, 2.4%) and resulted in a premature delivery in 36th week. In this pregnancy, PV-specific therapy with ASA, LMWH, and IFN was used.

One pregnancy-associated maternal thrombosis was documented (deep leg vein thrombosis during pregnancy) and resulted in a stillbirth in 24th week. No PV-specific therapy was used during this pregnancy. Maternal pregnancy complications (with exception of placental abnormalities, for which information was not available for every pregnancy) occurred in 37.9% of pregnancies with PV-specific therapy (11/29). In contrast, only one maternal complication occurred in 12 pregnancies without PV-specific therapy (8.3%). This difference was not statistically significant (P = .058).

All bleedings during pregnancy and/or delivery (10/29, 34.5%) occurred under PV therapy (10/29). No bleeding complications were reported in 12 pregnancies without PV-specific therapy. Thus, maternal bleeding complications during pregnancy or at delivery were significantly more frequent when PV-specific therapy was used (P = .021).

Common complications associated with PV pregnancies include placenta pathologies. Information regarding placenta was available in 23 out of 41 pregnancies (56.1%). Placenta abnormalities were reported in six pregnancies (6/23, 30.4%). Three ended in premature delivery. One case was a premature placental abruption, one placenta showed signs of placental calcification, and one placental insufficiency was diagnosed, respectively. The remaining three pregnancies with placenta abnormalities ended in miscarriages: two cases with placental necrosis, and one placenta insufficiency with thrombosis. Live births in all six pregnancies with placenta abnormalities was 50.0%. In pregnancies with normal placenta, the live birth rate was 88.2% (15 of 17 pregnancies, P = .051).

**TABLE 4** Characteristics, absolute, and relative frequencies of 18 maternal pregnancy complications occurring in 41 PV pregnancies

| Maternal pregnancy complications | Total number (n = 18) | Per pregnancy (n = 41) | Per pregnancy with PV-specific pharmacotherapy (n = 29) | Per pregnancy without PV-specific pharmacotherapy (n = 12) | Complications |
|----------------------------------|-----------------------|------------------------|--------------------------------------------------------|----------------------------------------------------------|---------------|
| Vascular thromboses/embolism, N (%) | 1 (5.6)               | 1 (2.4)                | 0                                                      | 1 (8.3)                                                  | • deep leg vein thrombosis (during a pregnancy without PV-specific therapy) |
| Major hemorrhagic complications a, N (%) | 1 (5.6)               | 1 (2.4)                | 1 (3.4)                                                | 0                                                       | Major vaginal bleeding after twin birth. This patient was on ASA+LMWH+IFN b |
| Minor hemorrhagic complications, N (%) | 9 (50.0)              | 9 (22.0)               | 9’ (31.0)                                              | 0’                                                      | • Vaginal bleeding with ASA + LMWH (n=4) |
|                                      |                       |                        |                                                        |                                                          | • Vaginal bleeding with ASA alone (n=1) |
|                                      |                       |                        |                                                        |                                                          | • Vaginal bleeding with IFN b alone (n=1) |
|                                      |                       |                        |                                                        |                                                          | • Bleeding at delivery with ASA + LMWH (n=2) |
|                                      |                       |                        |                                                        |                                                          | • Bleeding at delivery with LMWH alone (n=1) |
| Other complications, N (%)           | 1 (5.6)               | 1 (2.4)                | 1 (3.4)                                                | 0                                                       | • Preeclampsia (n=1) |
| Placenta abnormalities, N (%)        | 6 (33.3)              | 6 (14.6)               | 4 (13.8)                                               | 2 (16.7)                                                 | • Premature placenta abruption with ASA alone |
|                                   |                       |                        |                                                        |                                                          | • Placental calcification with ASA + LMWH |
|                                   |                       |                        |                                                        |                                                          | • Placental insufficiency with LMWH alone |
|                                   |                       |                        |                                                        |                                                          | • Placenta necrosis with ASA alone |
|                                   |                       |                        |                                                        |                                                          | • Placenta necrosis with LMWH alone |
|                                   |                       |                        |                                                        |                                                          | • Placenta insufficiency with thrombosis during pregnancy without PV-specific therapy |

Abbreviations: ASA, acetylsalicylic acid; LMWH, low-molecular weight heparin.

aAccording to the “Definition of major bleeding in clinical investigations of antihemostatic medical products in surgical patients.”
bInterferon-alpha.

*Difference in number of maternal pregnancy complications is statistically significant (P = .021).
Table 4 summarizes all 18 maternal pregnancy complications in 17 PV patients.

3.4 | Postpartum disease course of PV

The median postpartum follow-up time in all 41 pregnancies was 1.2 years (range 0.1-13.7). An uncomplicated postpartum course of PV was observed after 36 pregnancies and a complicated course after five pregnancies. A complicated postpartum course of disease was observed in only one out of 21 live birth pregnancies (4.8%). This patient suffered a portal vein thrombosis 10.3 years after delivery at the age of 48 years.

In contrast, miscarriages were associated with a complicated postpartum course of PV in four out of 20 cases (20.0%). Here, three thrombotic events (one femoral vein thrombosis and two cases of Budd-Chiari syndrome) and one major hemorrhage (a spontaneous intrasplenic bleeding that required splenectomy) occurred after a median time of 5.5 years (range 0.4-10.5) after delivery. The median age at the first complicating event after miscarriage was 38.8 years (range 29.7-49.2).

A Kaplan-Meier analysis of the postpartum course of PV was performed (Figure 2). Event-free postpartum survival distributions differ significantly between the live birth pregnancy group (n = 21) and the miscarriage pregnancy group (n = 20; P = .035).

4 | DISCUSSION

Pregnancies in PV are challenging for both hematologists and obstetricians due to the high risk of maternal pregnancy complications and of miscarriages. To date, the exact pathogenesis of these complications is a matter of debate. It has been suggested that a negative influence of PV on placental development is one of the main reasons for the increased rates of miscarriage, preterm delivery and preeclampsia.3,7,15 There is evidence that PV-specific therapy administered during pregnancy has a positive influence on the development of the placenta5,15 and thus on the live birth rate.

Compared to other published data, the live birth rate for our 41 PV pregnancies was only 51.2%. In the largest study by Harrison et al,7 38 PV pregnancies had a live birth rate of 58.0%, and Bertozzi et al9 even observed a slightly higher live birth rate of 62.5% in their 24 PV pregnancies. From 2006 onwards, PV pregnancies at our center were generally managed according to the recommendations of Harrison et al7 and since 2018 according to our recommendation,9 which are summarized in Table 1. It is noteworthy that the live birth rate of our PV pregnancies since 2006 is an encouraging 72.7%, which may be explained by the increased use of PV-specific therapy. This PV-specific therapy was used in 94% of pregnancies with PV as of 2006. Therefore, similar to the publications by Robinson1 and Harrison,7 we found a significant advantage (P < .001) of PV-specific therapy compared to standard antenatal care with a 69.0% overall live birth rate with PV-specific therapy. It appears that with adequate therapy and management of PV during pregnancy, the results are similar to those of ET-associated pregnancy. In the meta-analysis by Maze et al,5 the live birth rate of 815 ET pregnancies was 71.1%, a comparable result to the pregnancies with PV-specific therapy mentioned above.

In the absence of clear contraindications, Robinson and Harrison16 recommended in their 2020 review of the management of Philadelphia-negative myeloproliferative neoplasms (MPN) in pregnancy the administration of low-dose acetylsalicylic acid (ASA) during MPN pregnancies. In addition, low-molecular weight heparin should be used at least 6-week postpartum, or during pregnancy, if there has been previous thrombosis, an additional thrombosis risk factor, or a previous poor pregnancy outcome.16 Cytoreduction with interferon-alpha (routinely pegylated interferon) is recommended in MPN pregnancy if the woman has an indication for cytoreductive therapy before pregnancy anyway, or if it is necessary to reduce the platelet count (platelets >1500 × 10^9/L) or an increased packed cell volume resistant to phlebotomy.16

In our 41 PV pregnancies, the proportion of women with maternal complications was 29.3%. This is mainly due to the high proportion of predominantly minor bleeding in the group on PV-specific therapy. There was only one major bleeding complication, which occurred during a twin delivery. In the studies by Robinson1 and
Bertozzi, the risk of maternal complications was somewhat lower, at 22.2% and 16.7% respectively.

Similar to what Randi et al. reported for ET pregnancies, we observed a significantly increased number of complicated postpartum courses after miscarriage in PV. To the best of our knowledge, this association has not yet been reported in PV pregnancies. If these results are confirmed by further studies, a prolonged cytoreduction with interferon-alpha or at least a prolonged anti-aggregation with low-dose ASA or even a durable anticoagulation could be discussed for such patients with miscarriages.

In conclusion, the live birth rate of PV pregnancies can be significantly improved by the use of PV-specific therapy without increasing the risk of fetal complications. However, this increased the rate of maternal bleeding, which was mostly minor. In addition, our data indicate that women with PV have an increased risk of disease-related complications after miscarriage.

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CONFLICT OF INTEREST
All authors declare that they have no conflict of interests.

DATA AVAILABILITY STATEMENT
The data that support the findings are available from the corresponding author upon reasonable request.

ORCID
Kai Wille https://orcid.org/0000-0002-7682-8563

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