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Subsequent pregnancies in peripartum cardiomyopathy: Patient-level differences and decision-making

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ABSTRACT

Study objective: To evaluate patient-level differences and decision making surrounding subsequent pregnancies (SSP) after peripartum cardiomyopathy (PPCM).
Design: Mixed methods approach to evaluate quantitative demographic and clinical differences between patients with and without a SSP and to qualitatively describe the decision-making regarding a SSP with a survey component.
Setting/participants: 220 PPCM cases within the University of Pennsylvania Health System.
Main outcome measures: Demographic, clinical and obstetrical outcomes.
Results: 73 patients (33 %) had a SSP, 37 with a live birth. Those with a SSP were more likely to self-identify as Black (70 % vs. 52 %; $p = 0.04$), be nulliparous in index pregnancy (68 % vs. 45 %, $p = 0.02$), were younger at diagnosis (24.3 vs. 30.5 years; $p < 0.01$), and a higher left ventricular ejection fraction (LVEF) at diagnosis (35 % vs. 27.5 %; $p = 0.03$) compared to patients without a SSP. There was no difference in recovery rates of LVEF (62 % vs. 50 %, $p = 0.17$), or need for LVAD, transplant, or death. 22 patients completed the survey (representing 44 SSPs): 41 % of SSPs ($n = 18$) resulted in termination, 18 % ($n = 8$) in a first/s trimester loss, and 41 % (n = 18) in a live-born delivery. All patients who elected termination indicated risk of recurrence/worsening heart failure to be a motivating factor.
Conclusions: Less than 20 % of patients in this single-center, multi-racial cohort had a SSP and delivery after PPCM with fear of recurrence as a large driver in this decision. Patients with a SSP were younger with a higher EF at diagnosis but ultimately had similar cardiac outcomes as patients without a SSP.

1. Introduction

Peripartum cardiomyopathy or PPCM is an uncommon condition in which idiopathic left ventricular systolic dysfunction develops towards the end of pregnancy or in the months following delivery and is associated with significant maternal morbidity and mortality [1–4]. Some of the proposed mechanisms in which PPCM occurs include genetic, hormonal and/or vascular etiologies [5–8]. Recovery, traditionally defined as reaching an EF $\geq$ 50 %, has been described in anywhere from 20 to 70 % of cases depending on the cohort or case series [5–10].

Historically, patients with a history of PPCM contemplating a subsequent pregnancy (SSP) are counseled utilizing the results of a survey of the American College of Cardiology, which surveyed cardiologists across the United States regarding their clinical experience with subsequent pregnancies in PPCM. In this study, they included a total of 60 patients that had a subsequent pregnancy and compared clinical outcomes between patients who did and did not recover their cardiac function prior to a pregnancy. [9] They reported a risk of recurrence or worsened EF

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with a subsequent pregnancy to be approximately 20 % among those who recovered versus 50 % among those with persistent dysfunction. Furthermore, they reported a mortality rate of approximately 19 % among those with persistent dysfunction. There have been additional case series published that have further contributed to our understanding of the risks of a subsequent pregnancy in patients with a history of PPCM, but these studies are limited by small numbers and their generalizability given lack of diversity within the studied populations [9,11–17]. There is also little information on the demographic and clinical differences between patients that do versus do not go on to have a subsequent pregnancy after PPCM. Furthermore, no studies have reported on the patient perspective regarding their decisions to have a subsequent pregnancy, how they perceive their risks, and their thoughts and feelings regarding this life-changing decision of having a subsequent pregnancy.

Therefore, the objective of this study was to evaluate differences in demographics, clinical characteristics, and cardiac outcomes between patients who did and did not have a subsequent pregnancy and to use a mixed-methods approach to quantitatively and qualitatively describe pregnancy, family planning, and emotional outcomes for patients who pursue a subsequent pregnancy after PPCM.

2. Materials and methods

A prior study performed within the University of Pennsylvania Health System identified 220 individuals who were diagnosed with PPCM between 1986 and 2016. The results evaluating clinical outcomes by race and timing of diagnosis have previously been published [18,19]. This current study utilizes this established cohort. Institutional Review Board approval was obtained (IRB #822548) prior to initiation of this study.

The study to evaluate differences in demographics, clinical characteristics and cardiac outcomes between patients who did and did not have a SSP was a retrospective cohort study. Data collection began with a DataStore query for ICD-9 codes for PPCM and was followed by an extensive chart review. The study population was patients with PPCM and the standard clinical definition was used here: heart failure characterized by an EF of <45 % or fractional shortening of <30 % diagnosed in the third trimester of pregnancy or within several months of delivery. Our exposed group were patients with a subsequent pregnancy and delivery - we chose this as the definition assuming that continuation of a pregnancy and the delivery process would be most likely to impact cardiac outcomes. Our unexposed group were patients with either no subsequent pregnancy or no delivery (e.g. spontaneous miscarriage <20 weeks or termination). We compared demographic and clinical differences between those that had a subsequent pregnancy with a delivery and those that did not. Clinical variables evaluated included EF at time of PPCM diagnosis, the presence of a pregnancy-associated hypertension diagnosis in the pregnancy with PPCM diagnosis, and whether they had LVEF recovery (defined as reaching EF $\geq$ 50 %). We also evaluated the final cardiac endpoint for all patients in the cohort which included the above outcomes along with persistent dysfunction (EF <50 %), need for LVAD or transplant, or death from any cause.

The second part of the study utilized a mixed-methods approach, expanding upon the initial retrospective cohort study and adding structured surveys administered during individual patient interviews. Patients identified as having had a SSP on initial chart review were contacted via phone call, the electronic medical record patient portal, or text message and were invited to complete a 15–30 min phone interview to further discuss their PPCM diagnosis and any subsequent pregnancies. The portion of the study focused on patients with a diagnosis of PPCM with any subsequent pregnancy, including those with miscarriages, terminations, and deliveries. During the interview, a survey comprised of nominal, multiple choice, and open-ended questions was administered. The outcomes reviewed in the survey included pregnancy outcomes, family planning outcomes, and emotional experience of the patient.

We had a fixed sample size of $n = 220$ based on the original cohort. Categorical variables were compared with chi-square and Fisher's exact test, where appropriate. Continuous variables were assessed for normality and compared with means or medians, as statistically appropriate with either *t*-test or Wilcoxon rank sum test. A *p*-value of 0.05 or lower was considered significant. Stata version 12.0 was used for analyses.

3. Results

There were 220 patients with PPCM in the original cohort (Fig. 1). Of those, 73 had at least one subsequent pregnancy (SSP) and 147 had no SSP. Of the 73 patients with a SSP, 37 patients had a pregnancy with a delivery whereas 36 had a pregnancy without a delivery (first trimester loss, termination, second trimester losses). Differences in patient characteristics between patients with subsequent pregnancy and delivery ($n = 37$) and patients without SSP or SSP without delivery ($n = 183$) are presented in Table 1.

Average age at index PPCM diagnosis for our overall population was 29.4 years, 55 % self-identified as Black or African American and approximately half (49 %) were multiparous (Table 1). Those with a subsequent pregnancy and delivery were younger at the time of initial diagnosis, more likely to be Black or African American, and more likely to be nulliparous at the time of PPCM diagnosis compared to those without a subsequent pregnancy and delivery. Additionally, patients with a subsequent pregnancy and delivery had a higher EF at diagnosis (35 % vs. 27.5 %, $p = 0.03$) and a higher rate of achieving recovery although this did not reach statistical significance (78 % vs. 63 %, $p = 0.08$). There were no differences in ultimate cardiac outcome between those with and without a subsequent pregnancy and delivery with 52 % of the cohort demonstrating recovery overall and 33 % having persistent dysfunction (Table 2). A sensitivity analysis was performed excluding patients with a subsequent pregnancy and no delivery and results were overall unchanged.

Of the 73 PPCM patients who had a subsequent pregnancy, four were deceased which left 69 eligible for the qualitative survey portion of the study. A total of 34 patients were reached: two declined to participate and 10 were lost to follow-up. Ultimately, 22 patients participated in the survey accounting for a total of 44 subsequent pregnancies (Fig. 2). There were no demographic or clinical differences between those that did and did not participate in the survey portion of the study (Supplemental Table 1).

Fifty percent of survey participants had only one SSP, the remainder had $\geq$2 SSPs. The pregnancy outcomes for patients with any SSP are noted in Table 3. There were 12 (27.3 %) that resulted in a full-term delivery and 6 (13.6 %) in a preterm delivery, 18 % resulted in a miscarriage (first or early second trimester) and 41 % ended in

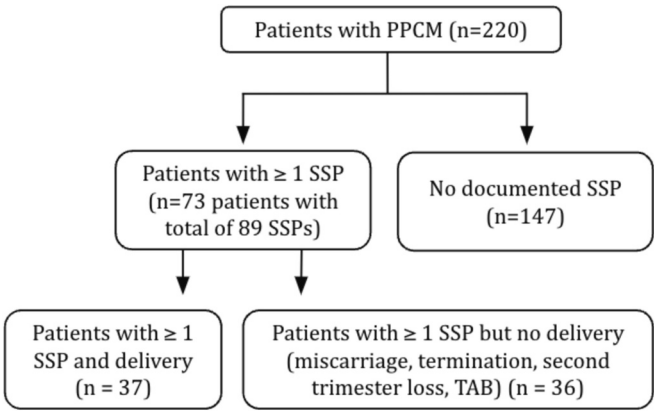

Fig. 1. Inclusion of participants into initial review.

Table 1
Demographic and clinical data for patients with a subsequent pregnancy with delivery versus those without.

	Overall (n = 220)	Subsequent pregnancy and delivery (n = 37)	No subsequent pregnancy with delivery (n = 183)	p value
Age at diagnosis (years)[a]	29.4 ± 6.6	24.3 ± 5.3	30.5 ± 6.3	<0.01
Black or African American	121 (55)	26 (70)	95 (52)	0.04
Number of children at time of diagnosis				
0	104 (49)	25 (68)	79 (45)	0.02
1	82 (38)	7 (19)	75 (43)	
2+	27 (13)	5 (14)	22 (12)	
Delivery by cesarean	111 (53)	16 (44)	95 (55)	0.25
EF at diagnosis (%)[b]	30 [17.5–40.0]	35.0 [30–42.5]	27.5 [15–40]	0.03
Pregnancy-associated hypertension during pregnancy with PPCM diagnosis	80 (44)	14 (42)	66 (45)	0.80
Ever recovered	145 (66)	29 (78)	116 (63)	0.08

EF, ejection fraction; PPCM, peripartum cardiomyopathy.
Data are n (%) unless otherwise specified.
[a] Mean years ± standard deviation.
[b] Mean EF [95th% CI].

Table 2
Ultimate cardiac outcome data for patients with a subsequent pregnancy with delivery versus those without.

	Overall (n = 220)	Subsequent pregnancy & delivery (n = 37)	All others (n = 183)	P value
Recovery	114 (52)	23 (62)	91 (50)	0.17
Persistent dysfunction	72 (33)	12 (32)	60 (33)	0.97
Transplant	10 (5)	0 (0)	10 (5)	0.22
LVAD	3 (1)	0 (0)	3 (2)	1.00
Death	17 (8)	2 (5)	15 (8)	0.74

LVAD, left ventricular assist device.

pregnancy termination (n = 18). There were 11 survey participants who accounted for the 18 terminations. All of the participants who underwent a termination indicated a concern for risk of recurrence or worsening heart failure to be their primary motivator for termination. There were 9 participants (81 %) who indicated a concern for risk of death as another powerful motivator and 3 participants indicated other reasons for termination including "not the right timing" and feeling "sick all the time".

In order to better capture patient perspectives on subsequent pregnancies after a diagnosis of PPCM, all survey participants were asked, "After your diagnosis of PPCM, how did you feel about getting pregnant again" and whether they had thoughts or recommendations for healthcare providers. Some of their responses are presented in Table 4. Many of the survey participants indicated they were not aware of their risk until they conceived.

4. Conclusions

Within this single-center cohort of diverse patients with peripartum cardiomyopathy, only 17 % of patients had a subsequent pregnancy and delivery. Those with a subsequent pregnancy and delivery were younger at the time of their diagnosis, and more likely to be diagnosed with their first pregnancy. The qualitative part of our study revealed that fear of recurrence was a frequent driver in the decision not to continue a SSP.

Patients with a subsequent pregnancy tended to be younger and

Table 3
Pregnancy outcomes among survey participants with a subsequent pregnancy.

Pregnancy or family planning outcome	N (%)
Pregnancy outcome	
Full-term delivery	12 (27.3)
Preterm delivery	6 (13.6)
Second trimester loss	3 (6.8)
SAB	5 (11.4)
TAB	18 (40.9)
Contraception after SSP	
LARC (subdermal implant or IUD)	10 (45)
Sterilization	10 (45)
Pills	6 (27)
DepoProvera	4 (18)
Condoms	1 (4.5)
Patch, NuvaRing, other	0 (0)
None	8 (36)

SAB, spontaneous abortion; TAB, therapeutic abortion; LARC, long-acting reversible contraception; IUD, intrauterine device.

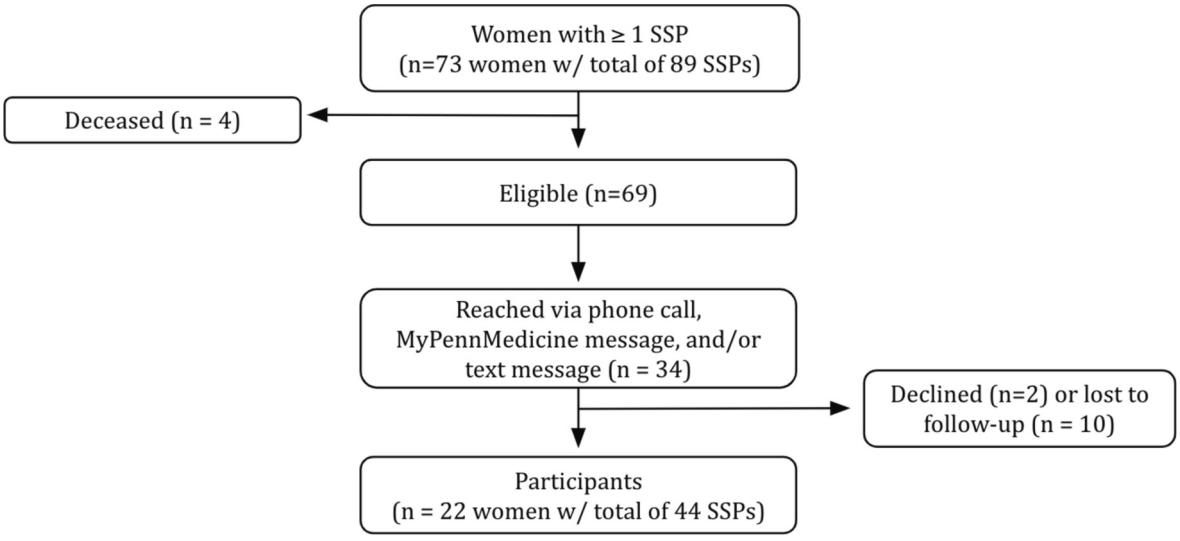

Fig. 2. Inclusion of participants who had a SSP in survey regarding pregnancy, family planning, and emotional outcomes.

Table 4
Participant reflections.

After your diagnosis of PPCM how did you feel about getting pregnant again?	Thoughts and recommendations for healthcare providers?
"I still want children, but I was told I could not have any more children because of my cardiomyopathy. I was told I could die." [ended in termination with LARC]	"When they told me my life expectancy, he was really blunt, and if he hadn't been so blunt and cold it would've been easier."
"[Before my next pregnancy] I wasn't given any information about the risk of a subsequent pregnancy." [ended in termination with permanent contraception]	"It's hard to process because [some people are] very dismissive of what I've been through… Women who get this should get some sort of support system."
"Got a second opinion after strong recommendation of no other pregnancy, and they said I had a 33 % chance of dying, 33 % of recurrence, and 33 % chance of nothing."	"There was a few other people that were going through what I was going through, and we got in touch with each other, and that was helpful. Support groups are very beneficial."
"Super upset because I wanted to have a number of children, and it was very devastating, and it was kinda hard to hear the message. It took a while before I could process it…" [two subsequent full-term deliveries]	"The most important thing that I noticed is that the doctors did a really good job informing me of what was going on, communicating, and checking in on my mental health. They made sure I felt my mental health was just as important as my physical health. I felt safe. Having a plan made such a big difference."
"Scared. I was told I could die with another pregnancy." [1 termination, 2 miscarriages, 2 preterm deliveries]	"[Afterwards] I wanted a tubal but my doctor told me I was too young." [full term delivery and 1 termination]
"I was kinda terrified because the lady who had relayed to me I had [PPCM] told me the mortality is really high so you shouldn't get pregnant. I decided I wasn't going to have any more kids."	

PPCM: peripartum cardiomyopathy; LARC: long-acting reversible contraception.

more likely to have been nulliparous at time of PPCM diagnosis, suggesting that being earlier in their reproductive life may have contributed to the decision to have an additional pregnancy. Additionally, patients with a subsequent pregnancy and delivery were more likely to have a higher EF at the time of initial diagnosis (35 % compared to 27.5 %) and tended to be more likely to have achieved recovery (defined as ever having an EF $\geq$50 %), suggesting that severity of disease affected the decision to proceed with a subsequent pregnancy. This conclusion is supported by the interviews, which indicated a prominent concern with recurrence of disease.

There was no difference in long-term cardiac outcome between patients with and without a subsequent delivery. This observation may reflect bias, in that patients with less severe disease chose to have a SSP. If so, the finding would suggest that a SSP places lower-risk women at a risk that now is on par with higher-risk women. On the other hand, the finding also suggests that SSPs, when monitored closely and optimally managed, for example, with goal directed medical therapy and specialty care, may bear less risk than initial studies had indicated, as is supported by more recent studies. [12,13,15,17] This finding is important, because as is revealed by the qualitative portion of the interviews, numerous patients were counseled of a very high risk with a SSP, leading to termination. Of the patients that had a subsequent pregnancy, approximately 40 % chose to terminate the pregnancy, and the risk of PPCM recurrence and worsening heart failure was the strongest identified motivator for pregnancy termination, or not to proceed with a subsequent pregnancy in the first place. More nuanced counseling may have led to different decisions.

Significant advances in treatment of heart failure in and around pregnancy as well as in obstetrical care of women with risk factors for or history of peripartum cardiomyopathy likely allow for improved outcomes in subsequent pregnancies in peripartum cardiomyopathy. This includes advances in areas such as goal directed medical therapy, cardio-obstetric teams and multidisciplinary approaches to care planning. Furthermore, the results of this study suggest that younger women and those with a better ejection fraction may have more favorable outcomes with subsequent pregnancies than previously believed.

Overall, the qualitative portion of the interviews highlighted the need for additional preconception counseling to review, in depth, the risks and benefits of a subsequent pregnancy and to aid in obtaining contraception for those interested. Additionally, the interviews highlighted the importance of social, emotional, and behavioral support needs for this high-risk population. Providers could aid with support by referring patients to on-line support networks (e.g. active network on social media), forums or behavioral health services.

Larger longitudinal studies of patients with peripartum cardiomyopathy and subsequent pregnancies are needed to better understand how certain clinical and demographic characteristics may impact clinical outcomes with subsequent pregnancies, as well as how subsequent pregnancies impact less common clinical outcomes such as LVAD, heart transplant, and death,

While the sample size of this study is small, it is one of the largest studies evaluating subsequent pregnancy outcomes after PPCM in both a quantitative and qualitative way.

In conclusion, <20 % of PPCM patients in this multi-racial cohort have a subsequent pregnancy and delivery, with fear of recurrent PPCM and associated morbidity being the driving factor in this decision. Our study highlights the importance of adequate counseling so patients can make an informed decision about a pregnancy prior to conceiving, and the need for emotional support when making these decisions. Lastly, if those that had a subsequent pregnancy were, in fact, lower risk, it begs the question why ultimate cardiac outcomes were no different and highlights the need for continued research regarding the true risk and impact of a subsequent pregnancy on cardiac health in patients with PPCM.

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Presentation

None.

Disclaimer

None.

CRediT authorship contribution statement

Olga Corazón Irizarry: Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Jennifer Lewey:** Writing – review & editing, Writing – original draft, Supervision, Resources, Conceptualization. **Camille McCallister:** Writing – review & editing, Writing – original draft, Data curation. **Nathanael C. Koelper:** Writing – review & editing, Writing – original draft, Formal analysis. **Zoltan Arany:** Writing – review & editing, Writing – original draft, Supervision, Resources, Funding acquisition, Data curation, Conceptualization. **Lisa D. Levine:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Conceptualization.

Ethical statement

All procedures were performed in compliance with relevant laws and

institutional guidelines and have been approved by the appropriate institutional committee(s).

The study was performed under the IRB approval 822548 using expedited review and initially approved in May 2015.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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NA.

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