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The prevalence of threatened miscarriage in Malta

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ABSTRACT

A retrospective cohort study was conducted in Malta to assess the prevalence of threatened miscarriage. The study focuses on cases managed at a local state hospital over a 12-month period. Currently, data on pregnancies prior to 22 weeks' gestation are not publicly available, which hampers understanding of the frequency and impact of threatened miscarriage. This research provides the basis for a potential prospective study which analysis the epidemiology and outcomes of threatened miscarriage and advocates for early intervention and appropriate patient counselling. The study included females who visited the Accident and Emergency Department in a local state hospital in 2019 with first trimester vaginal bleeding. It excluded patients with incomplete medical records. Data from various hospital departments were collected, anonymised and analysed to track outcomes such as miscarriage, ongoing pregnancy, ectopic or molar pregnancy. The research aimed to create a comprehensive local registry of pregnancy outcomes following threatened miscarriage, reflecting the national situation. In 2019, 711 pregnant women in Malta experienced first-trimester vaginal bleeding. Of these, 241 had successful births beyond 22 weeks' gestation, while 412 experienced miscarriages, with other outcomes including ectopic and molar pregnancies and 58 women had an unknown pregnancy outcome. A significant association was found between maternal age and risk of miscarriage, particularly higher for women aged 35–46 and those under 19. Birthweight data revealed that threatened miscarriage complications likely led to low birthweights in a significant proportion of newborns. This study analysed pregnancy outcomes which were preceded by first trimester vaginal bleeding in pregnant women in Malta. Establishing a local register of pregnancy outcomes following first trimester vaginal bleeding provides clinicians with enhanced insights into the current local context. This resource may improve patient counselling and informed policy decisions and lay the groundwork for future research in the field.

Introduction

The first trimester is a crucial period in pregnancy and concerns such as vaginal bleeding (VB), which affects about 25 % of pregnancies, pelvic pain or other related symptoms may prompt women to seek medical evaluation to ensure the health and well-being of both themselves and their developing fetus [1]. When non-obstetric causes of VB, such as cervical polyps, are ruled out, there are four main causes of bleeding in the first trimester of pregnancy. These include continued pregnancy, pregnancy loss, ectopic and molar pregnancies [2,3]. Trends in quantitative β subunit levels of human chorionic gonadotropin (β-hCG) offer valuable insights for differentiating between normal and abnormal early pregnancies, especially when it is too early to detect an intrauterine pregnancy (IUP) or determine the cause of bleeding through ultrasound [2].

Of all four obstetric causes of VB, threatened miscarriage (TM) is the only cause of bleeding in which a viable IUP is present. It is characterised by VB before the 20th week of pregnancy, with a closed cervix on examination in the context of an otherwise healthy pregnancy [4]. More than 50 % of women who experience TM in the first trimester of

Abbreviations: TM, Threatened Miscarriage; DHIR, Directorate for Health Information and Research; A&E, Accident and Emergency; VB, Vaginal Bleeding; CPU, Clinical Performance Unit; APH, Antepartum Haemorrhage; IUGR, Intrauterine Growth Restriction; WHO, World Health Organisation; LBW, Low Birth Weight.

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pregnancy experience pregnancy loss, while women who carry the pregnancy to term are at greater risk of experiencing maternal and fetal complications, such as preeclampsia, intrauterine growth restriction (IUGR), premature rupture of membranes (PROM), pregnancy induced hypertension (PIH) and preterm labour [5,6]. These risk factors should be considered during antenatal surveillance and pregnancy management in order to mitigate adverse pregnancy outcomes.

The exact aetiology of TM and early pregnancy loss is not fully understood, particularly after excluding chromosomal abnormalities, which are found in about 60 % of miscarried tissue [7]. Nonetheless, demographic, clinical, and environmental factors, along with lifestyle choices, are significant contributors, with maternal age being one of the most prominent risk factors [8]. Understanding the prevalence and epidemiology of TM is crucial for several reasons: it can help in healthcare planning, resource allocation and the development of policies to support high-risk pregnancies. Additionally, identifying trends in miscarriage rates after TM can address public health concerns and promote health education on risk factors and prevention [9].

The only data available in Malta concerning pregnancy outcome are limited to outcomes beyond 22 weeks. They are published annually by the Directorate for Health Information and Research (DHIR), with no publicly accessible data on pregnancies before this gestational age.

This study aims to investigate pregnancy outcomes following first trimester VB at a local state hospital over a 12-month period. The objectives are to estimate the prevalence of TM in Malta and to determine factors associated with TM, which may lead to enhanced early intervention strategies and improved maternal and fetal outcomes.

Methodology

Study design

This study utilised a retrospective cohort design to investigate the association between first trimester VB and pregnancy outcomes among women treated at a local state hospital over a 12-month period. The independent variable, first-trimester bleeding, was defined as any VB occurring before 12 weeks of gestation. The dependent variables included continued pregnancy, pregnancy loss, ectopic and molar pregnancies. For women with continued pregnancy, outcomes of interest included fetal gender and any recorded abnormality, as well as pregnancy complications which included gestational hypertension, preeclampsia, IUGR, antepartum haemorrhage (APH), placenta praevia, placental abruption and eclampsia. Maternal age was also documented for comparison with outcome.

A retrospective design was chosen primarily for time efficiency. Such research design was also inexpensive and ethically sound as it allowed leverage of medical records without the need for patient participation [10]. A cohort design was best suited for this study as it ascertained a clear temporal relationship between the exposure and the outcome, thereby reducing bias [11].

Eligibility criteria

The inclusion criteria encompassed all females who registered at Accident & Emergency (A&E) between 1st January and 31st December 2019 reporting VB during the first trimester of pregnancy. Patients having incomplete medical records, especially those directly concerned with pregnancy follow-up were excluded from the study. Females within the first trimester of pregnancy who attended A&E complaining of symptoms unrelated to VB, as well as all second and third trimester patients, were also excluded from the study. The year 2019 was selected because it predates the COVID-19 pandemic, ensuring that patient numbers were not influenced by pandemic-related impacts on the healthcare system.

Sampling method and size

Consecutive sampling approach was adopted, meaning that all eligible patients during the defined time frame were included in the study. This approach also ensured minimisation selection bias, making it more representative of the entire population [12]. The study aimed to achieve a margin of error (MOE) of under 5 % such that a strong inference of any conclusion of the study may be reflected onto the general population [13]. The MOE is estimated by Eq. (1) for large populations (> 10,000). Consequently, a sample size greater than 400 was considered essential for this study and the possibility of extending the study to patients beyond December 2019 being left open, had this not been reached.

$$MOE(\%) \approx 1.96\sqrt{\frac{0.25}{n}} \times 100 \quad (1)$$

Information sources, search strategy and data extraction

Following the necessary ethical approvals, the study was conducted at the local state hospital between January and June 2024. Women were retrospectively identified from the hospital Clinical Performance Unit (CPU) through an intermediary person. This list was cross-referenced with records from the obstetrics and gynaecology admission room and Central Delivery Suite by a second intermediary person, to ensure completeness. The revised list was used to verify, through the National Obstetrics Information System, which patients had a live birth or intrauterine death beyond 22 weeks of gestation. The DHIR linked this information with CPU data to create a comprehensive database of first trimester VB cases. Pregnancies earlier than 22 weeks of gestation were cross-checked with hospital records to determine if patients had miscarriages, ectopic pregnancies, molar pregnancies or unknown outcomes. These data were pseudonymised and sent to the researcher, who filtered out patients who did not satisfy the inclusion criteria. The dataset included patient demographics, clinical details, pregnancy complications and birth outcomes, providing a comprehensive overview of TM cases in Malta.

Results

A total of 711 women met the study criteria and were included as summarised by Fig. 1. The MOE was computed to be 3.7 % for the study. Of the 241 (33.9 %) women who experienced TM during the first trimester of pregnancy and delivered their baby beyond 22 weeks' gestation, 28 (11.6 %) patients were diagnosed with gestational hypertension, two of whom had preeclampsia. There were 15 (6.2 %) reported cases of preterm labour, 10 (4.2 %) cases of IUGR and 8 cases (3.3 %) of APH. There were 121 (50.2 %) male and 120 (49.8 %) female babies born, of which 11 (4.6 %) males and 7 (2.9 %) females were diagnosed with abnormalities at birth (Table 1). Of all 18 births with documented abnormalities, 7 had experienced complications during pregnancy, the most common of which were gestational hypertension and IUGR. Three mothers, two of them having also experienced pregnancy complications, had early neonatal deaths (2 male and 1 female babies), due to hypoplastic lungs.

Association between maternal age and pregnancy outcome

Maternal age is one of the most predisposing risk factors for early pregnancy failure [8]. From the data available, the average maternal age was found to be 31 years, having a standard deviation of 5.85 years. The youngest mother was 14 years old and the oldest was 46 years old. Ectopic and molar pregnancies were not considered for this analysis, since they were not considered to be viable IUPs. Mothers suffering miscarriage had an average age of 31.66 years and standard deviation of 6.11 years, whilst those that progressed with the pregnancy were found

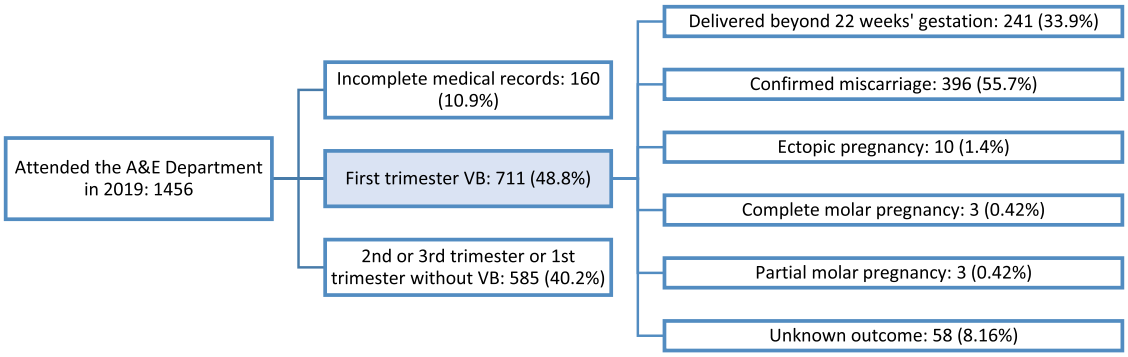

Fig. 1. Summary of results.

Table 1
Births diagnosed with malformations.

Gender	Gestational age at birth/ weeks	Maternal Age/ years	Birthweight/g	Pregnancy complications	Fetal abnormality	Early neonatal death
M	38	26	2310	IUGR	Sacrococcygeal dimple	No
M	40	31	3780	None documented	Positional talipes	No
M	38	28	3720	None documented	Bilateral positional talipes	No
M	38	26	3970	None documented	Mild left hydronephrosis	No
M	39	27	3240	None documented	Sacral dimple	No
M	34	30	2380	Threatened labour	Left parietotemporal naeivus	No
M	40	37	3270	Gestational hypertension	Sacral tuft of hair	No
M	39	33	3040	None documented	Hypospadias	No
M	40	20	2500	Gestational hypertension	Distinct facial features, hypoplastic lungs	Yes
M	39	31	3210	Gestational hypertension	Bilateral hydronephrosis	No
M	37	36	2200	None documented	Severe abnormalities, hypoplastic lungs	Yes
F	40	20	3500	None documented	Hypospadias	No
F	39	28	2990	None documented	Down syndrome	No
F	27	31	750	IUGR, threatened labour, APH	Hypoplastic lungs	Yes
F	39	34	Undocumented	None documented	Structural talipes	No
F	38	20	2780	None documented	Skintag on neck	No
F	37	32	2230	APH, IUGR	Anal atresia with vestibular fistula	No
F	37	29	3320	None documented	Bilateral hydronephrosis	No

to have an average age of 30 years and standard deviation of 5.29 years (Table 2). This is more clearly illustrated in the box-plot of Fig. 2. Fig. 3 displays the distribution of maternal age in relation to pregnancy outcomes within the collected data, within the collected data, using 5-year age intervals.

To evaluate if maternal age impacts pregnancy outcomes in TM cases, three age groups were analysed: 14–19 years, 20–34 years, and 35–46 years. This categorisation is based on the higher risk of adverse pregnancy outcomes for women younger than 19 and older than 35 [14]. Fig. 4 shows the distribution of TM cases across these age groups, while a contingency table (Table 2) details the frequencies of births and miscarriages within each group. The data reveal that mothers over 35 with TM have a significantly higher probability (73.7 %) of experiencing miscarriage as opposed to a successful birth. In the youngest age group (14–19 years), the likelihood of miscarriage is also high (69 %) compared to successful births. For the 20–34 age group, the risk of miscarriage in TM cases is marginally higher, but this difference alone does not confirm a significant association between maternal age and pregnancy outcome. The Pearson chi-square (χ^2) test of hypothesis was

Table 2
Statistics for maternal age for miscarriage and continues birth cases.

	μ	σ	♯ of samples
Miscarriage	31.6	6.11	396
Birth	30	5.29	241
Combined	31	5.85	637

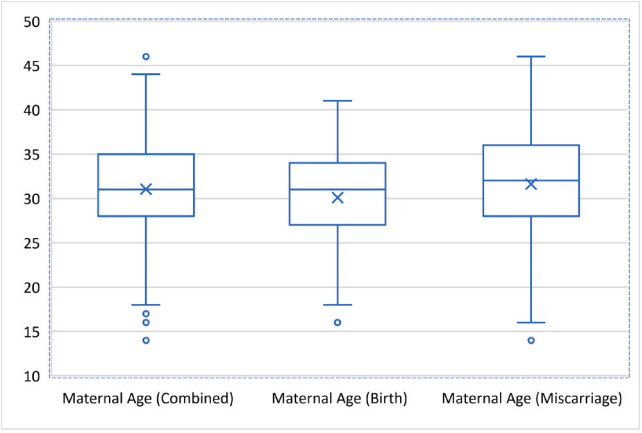

Fig. 2. Box-plot of maternal age. Central mark is the median, cross is the mean, the edges of the box represent the 25th and 75th percentiles and the whiskers extend to the most extreme data points (excluding outliers which are shown separately).

consequently conducted to determine whether an association indeed existed. A p-value of 0.001 for the χ^2 test was obtained ($\chi^2 = 16.499$, $p < 0.001$), which revealed that the probability of a successful pregnancy outcome following first trimester TM, varies significantly across

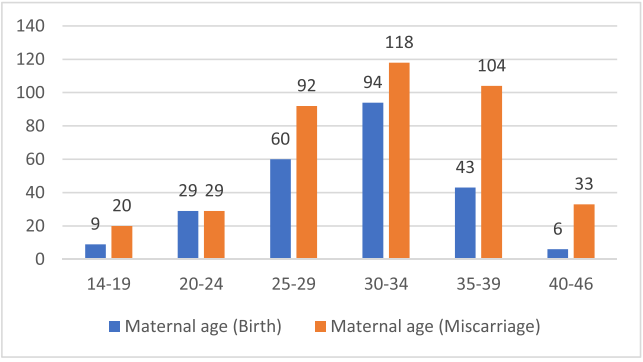

Fig. 3. Histogram of maternal age for miscarriage and continued pregnancy cases.

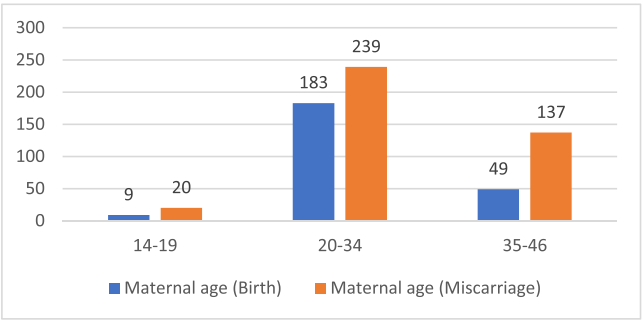

Fig. 4. Histogram of maternal age for miscarriage and continued pregnancy cases, grouped into three main risk groups.

the three defined age groups (Table 3). The success rate is notably lower for the youngest and oldest age groups.

In order to confirm with certainty which age group faces the highest risk of miscarriage, the z-test was performed, comparing the difference in proportions between pairwise age groups. As shown in Table 4, the z-test reveals that the percentage of miscarriages for mothers aged 35–46 years is significantly higher than the corresponding percentages for the two other younger age groups. The z-test also reveals that there is no significant difference in the chances of miscarriage for mothers with TM across the age groups of 14–19 years and 20–34 years.

Comparison of birthweights

In the case of successful births, birthweights were plotted on World Health Organisation (WHO) published growth charts [15] according to sex of the neonate, to understand whether birthweights corresponded to estimated fetal weights (EFWs) as established by the WHO. Two birth weights remained unrecorded in the data provided by the DHIR and were therefore removed from the data set for the purpose of this comparison. Fig. 5 shows the distribution of birth weights for the 239 cases, 118 being male and 121 female.

Among female babies, 5.8 % of babies were classified as overweight, exceeding the WHO's 95th percentile confidence limit, while 8.26 % were categorised as underweight, falling below the WHO's 5th percentile confidence limit. For male babies, 2.54 % were classified as overweight, surpassing the WHO's 95 % confidence limit, while 17.8 % were categorised as underweight falling below the WHO's 5 % confidence limit. This is a strong indicator of low birth weight (LBW), likely brought about by TM complications.

Table 3
Contingency table and results from the Chi-square test showing a significant difference between pregnancy outcome across the different age groups defined.

			Outcome		Total
			Birth	Miscarriage	
Age group	< 19 years	Count	9	20	29
		Percentage	31.0 %	69.0 %	100.0 %
	20–34 years	Count	183	239	422
		Percentage	43.4 %	56.6 %	100.0 %
	> 35 years	Count	49	137	186
		Percentage	26.3 %	**73.7 %**	100.0 %
Total		Count	241	396	637
		Percentage	37.8 %	62.2 %	100.0 %

Table 4
Descriptive statistics for maternal age against pregnancy outcome.

Age Group	Percentage Group 1	Percentage Group 2	Percentage Diff	Z-Score	P-value
20–34 years vs 14–19 years	43.4 %	31.0 %	12.4 %	1.299	0.194
20–34 years vs 35–46 years	43.4 %	26.3 %	17.1 %	3.981	< 0.001
14–19 years vs 35–46 years	31.0 %	26.3 %	4.7 %	0.529	0.596

Discussion

Main findings

This study found that in 2019, 54.8 % of pregnant women who attended the A&E Department in Malta were women in their first trimester of pregnancy, complaining of VB. Of these, 33.9 % were confirmed TM cases and delivered their baby beyond 22 weeks' gestation. First trimester VB in mothers aged above 35 years was significantly associated with higher risk of miscarriage. Male babies born from women who experienced first trimester VB and had ongoing pregnancies beyond 22 weeks' gestation had a 50 % higher likelihood of LBW compared to female babies, when matched to WHO growth charts.

Interpretation

These findings indicate that first trimester bleeding is significantly associated with increased risk of early pregnancy loss, aligning with previous studies [16–18]. While these studies were also retrospective and conducted over a single calendar year, they were all case control studies with a smaller number of participants compared to our study. Study [16] considered a group of 120 women who experienced bleeding prior to 20 weeks' gestation, with an incidence of confirmed miscarriage of 52.8 %, being similar to the incidence of 55.7 % obtained in our study. Although the incidence of confirmed miscarriage cases in study [17] (13.7 %) and [18] (16.9 %) is considerably lower, they were still significantly higher when compared to the confirmed miscarriage rate in their control groups (3.4 % and 2.2 % respectively), which included only non-bleeding patients. While our study included all pregnant women with symptoms of first trimester bleeding and [16] only excluded patients with multiple pregnancies, chronic hypertension and cervical pathology, [17] employed a comprehensive list of exclusion criteria, that addressed various medical and pregnancy complications, which may explain the lower confirmed miscarriage rate. Study [18] did not provide details on the exclusion criteria used in their study. The ages of participants in all three studies spanned from the early 20 s to early-to-mid 40 s. In contrast, prospective study [19] found that in 1204 bleeding participants, 527 (42.9 %) miscarriages were observed. Most participants (85.4 %) in this study were women under 35 years of age which may account for the discrepancy in miscarriage rate compared to our study and aforementioned studies.

Additionally, advanced maternal age may also play a role in the increased prevalence observed. Our study found a significant association between first trimester bleeding and miscarriage among women aged

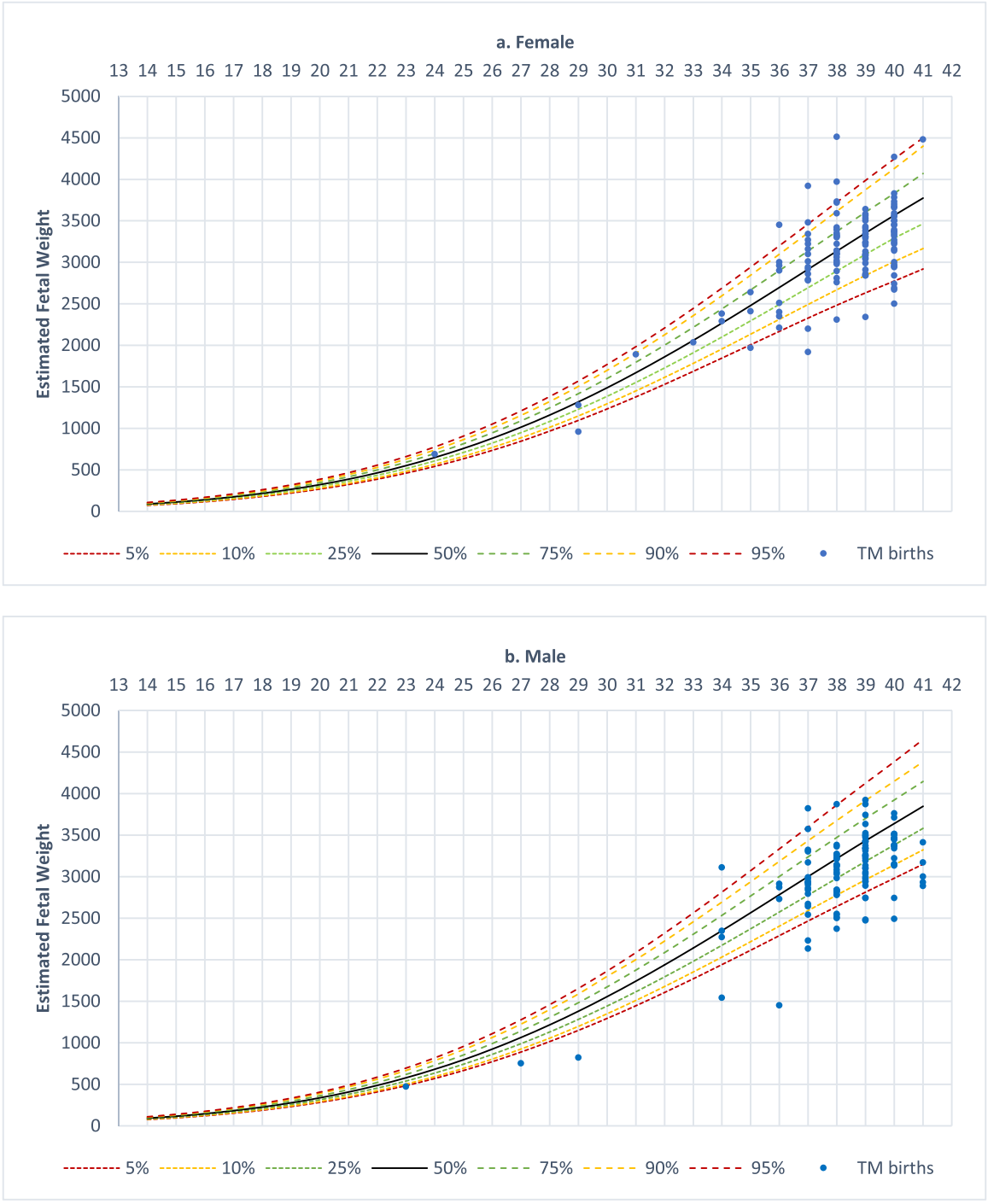

Fig. 5. WHO published growth chart with birthweights from collected TM cases superimposed. a) Female, b) Male.

35–46. Similarly, prospective cohort study [20] found that women aged 35 and older who experienced first trimester VB had a significantly lower live birth rate and a higher miscarriage rate compared to women in the 15–34 age group. Women in the advanced age group accounted for 18.5 % of the total study population. Women who were haemodynamically unstable and/or experienced very heavy bleeding were excluded from the study. This exclusion may have influenced the results obtained as [19] concluded that heavy bleeding in the first trimester, especially when accompanied with pain, is associated with a higher risk of miscarriage.

Our findings of low birthweight (LBW) associated with first trimester VB are consistent with several other studies. Systematic reviews and meta-analyses [21–23] concluded that LBW is more frequently observed in women who have experienced first trimester VB. Similarly [24] demonstrated a statistically significant association between LBW, preterm birth and first trimester VB in their systematic review on maternal and perinatal outcome in women with TM in the first trimester. To our knowledge, no studies have compared male vs female birth weights following first trimester VB, which prevented us from drawing comparisons in our findings.

Strengths and limitations

The strength of the study lies in the fact that a large population-based

cohort was used, which allowed for a thorough investigation of pregnancy outcomes following first trimester VB.

Having been conducted at the only local state hospital in Malta and women who deliver their babies in this hospital or any of the private hospitals are captured by the DHIR, our study encompasses a comprehensive and representative sample of the population. This minimises the risk of selection bias and findings may therefore be generalisable to the population.

A limitation of the study is the dependence on retrospective data, which may not have captured all relevant variables that could influence pregnancy outcomes, such as lifestyle factors, preexisting medical conditions, use of medication and smoking. However, when retrospective research is carefully designed and interpreted, it provides valuable insights into the relationship between exposure and outcome in a relatively low-cost and efficient manner [25]. Additionally, it enables relatively quicker assessment of long-term outcomes, such as full-term pregnancies [26].

Conclusion

In this study, first trimester bleeding was seen to have significant association with early pregnancy loss, especially in the 35 + age group, as well as LBW for ongoing pregnancies beyond the first trimester. Understanding complications and associated pregnancy outcomes following first trimester VB may facilitate pregnancy management and possibly improve maternal and neonatal outcome.

CRediT authorship contribution statement

Lara Sammut: Writing – review & editing, Writing – original draft, Visualization, Methodology, Data curation, Conceptualization. **Paul Bezzina:** Writing – review & editing, Supervision, Methodology. **Vivien Gibbs:** Writing – review & editing, Supervision, Methodology. **Yves Muscat Baron:** Writing – review & editing, Data curation. **Jean Calleja Agius:** Writing – review & editing, Supervision, Methodology.

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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