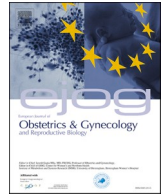




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Full length article

Proof-of-concept study: Remote capillary blood collection for hCG analysis in early pregnancy

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ABSTRACT

Introduction: Capillary blood collection, a technique traditionally used in diabetes care, shows promise for many applications including pregnancy monitoring. Serial measurement of serum human Chorionic Gonadotrophin (hCG) is frequently necessary for managing early pregnancy, including molar pregnancy, requiring multiple visits to a maternity hospital for blood collection by venepuncture. This proof-of-concept study aimed to assess the clinical performance and user acceptability of capillary blood samples collected remotely, as an alternative to venous blood for hCG measurement.

Methods: Women attending the early pregnancy unit who required serum hCG measurement, were invited to participate. Following informed written consent, participants were shown how to collect capillary blood samples using the Mini-Collect® collection device. Matched venous and capillary blood samples were collected in clinic for hCG comparison purposes. Participants were also supplied with a home collection kit in a prepaid return envelope. They were asked to perform a finger-prick blood collection at home using the instructions provided and to return the capillary blood sample by post within 24 h of collection, along with a completed user-satisfaction questionnaire. Statistical analysis was performed using Analyse-it® software.

Results: The study enrolled 71 participants and over a third of these women collected a capillary blood sample at home. The median age of participants was 33 years (range 29–36). Passing-Bablok linear regression ($y = -0.037 + 1.04x$) and Spearman correlation ($r = 0.999$, $p < 0.0001$), demonstrated good agreement and strong correlation between venous and capillary samples, over a broad range of hCG values (1.2 to 224,000 IU/L). The majority of capillary samples collected remotely (39%, 27/69) had sufficient blood volume for analysis (74%, 20/27). Respondents (77%, 18/25) found the collection device easy to use and expressed willingness to use a future service if available (80%, 20/25)

Conclusion: The study demonstrated excellent agreement between the hCG results obtained from both collection methods, suggesting that capillary blood can serve as a reliable alternative for venous hCG measurement, particularly in clinical settings requiring frequent hCG monitoring. Feedback from the study questionnaire indicates a preference for this type of follow-up among women, indicating potential improvements in compliance for blood based diagnostic tests.

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Introduction

During early pregnancy, serial hCG measurement is frequently required for the clinical management of a pregnancy of unknown location (PUL), resulting in a significant volume of hCG tests conducted in Early Pregnancy Units (EPU). These tests are crucial for triaging women and identifying those at high risk of complications, such as ectopic and molar pregnancies. However, visits to maternity hospital for phlebotomy following pregnancy loss can be distressing. Women with molar pregnancies, the most common form of Gestational Trophoblastic Disease (GTD), have reported that this adds to their distress during the hCG surveillance period, which can extend up to 6 months. Multiple factors such as arranging childcare and transport costs can impact a woman's ability to attend her nearest maternity hospital for phlebotomy to facilitate serial hCG monitoring [1]. Furthermore, general practitioners (GPs) are often uncomfortable monitoring blood tests for patients under tertiary care management [2].

The search for alternative phlebotomy options for women experiencing pregnancy loss, including molar pregnancy, coupled with the need to centralise hCG testing for GTD management in Ireland, has necessitated a departure from standard laboratory testing [3]. Remote capillary blood collection (CBC) has emerged as a potential solution capable of addressing both challenges.

During the SARS-CoV-2 pandemic, remote CBC was employed to monitor glycosylated haemoglobin (HbA1c) levels as a measure of glycaemic control in patients with diabetes [4]. Capillary blood comprises a mixture of arterial and venous blood and interstitial fluid, and provides a viable alternative to venepuncture for diagnostic purposes, although some analyte concentrations may differ between sample types [5]. Recently, there has been a surge in consumer demand for at-home self-diagnostic testing with the market witnessing a proliferation of direct-to-consumer tests [6,7].

To meet the demand for centralised hCG testing, the option of home blood collection offers a practical solution to address the logistical challenges associated with establishing a central hCG testing laboratory. Centralised hCG testing for GTD ensures the use of an oncology-specific hCG assay and maintains consistency throughout treatment, aligning with National Clinical Practice Guidelines [3]. This approach streamlines access to hCG results for specialist GTD nurses who play a pivotal role in monitoring hCG levels and providing support to women enrolled in the national GTD registry.

Remote blood collection also addresses many of the challenges related to patient access to phlebotomy services following virtual consultations [4]. It eliminates the need for women to visit maternity hospitals for phlebotomy following pregnancy loss and molar pregnancy, as previously mentioned [1]. This approach also ensures clinicians have access to contemporaneous hCG results, allowing more effective consultations and facilitating shared decision-making, ultimately leading to improved patient satisfaction [8]. From the hospital's perspective, this solution saves on phlebotomy services and outpatient clinics.

This study sought to develop a prototype home testing solution by adapting capillary blood sampling for remote application and optimising the associated steps in this process. This proof-of-concept study had two primary objectives, (1) to assess the clinical utility and efficacy of capillary blood for hCG measurement in early pregnancy compared with standard venepuncture and (2) to evaluate the user acceptance of remote capillary blood sampling.

Materials and methods

Study design

This cross-sectional study enrolled pregnant women consecutively from the EPU at Cork University Maternity Hospital (CUMH), a tertiary maternity facility, over a 6-month period (January–June 2023). Women attending the EPU requiring hCG testing for scheduled care were invited

to participate. Following informed written consent, participants received instructions on the CBC technique (Supplemental file 1), viewed an online video tutorial on the MiniCollect® device, and received hands-on training during their clinic visit [9]. Participants were also provided with a home CBC kit, a questionnaire (Supplemental file 2) and a pre-paid addressed envelope. They were instructed to collect approximately 250 µl of capillary blood and to return it with the completed questionnaire within 24 h of collection. The study was approved by the hospital research ethics committee (ECM4 (b) 01/11/2022 & ECM5 (8) 05/10/2022 & ECM3 (ss) 28/03/23).

The study objectives are twofold: (A) to prospectively compare hCG results from matched venous and capillary blood samples collected in the EPU, and (B) to evaluate the user acceptability of remote CBC (Fig. 1).

Questionnaire

A 14-question Likert scale questionnaire (Supplemental file 2) was designed to assess user acceptability of remote CBC. Six questions focused on experiences with the MiniCollect® device and home-based CBC, while eight addressed participant preferences for the service compared to venepuncture and their willingness to pay for it.

Capillary blood collection in EPU

Prior to blood collection, participants washed their hands and pre-warmed them for 10 min using a rechargeable hot water bottle (DeVieille Ltd UK), while gently massaging their fingers downward to enhance blood flow. The side of the middle or ring finger was chosen for fingerprick due to its adequate tissue depth, cleaned with disinfectant wipes (Clinel 2% Chlorhexidine in 70% Alcohol, GAMA healthcare Ltd UK) and allowed to air-dry [10]. The finger was swiftly punctured using Unistik® 3 sterile purple lancets (Owen Mumford Ltd, UK, reference AT1042), with safety Comfort Zone Technology™ and 28-gauge needle [11]. Blood was collected into a Mini-Collect® device (Greiner Bio-One, Austria, reference 450548) featuring an integrated scoop for easy blood droplet collection. Mini-collect tubes lacked anticoagulant but contained a separating gel and were preassembled with carrier tubes to aid centrifugation.

Capillary blood collection at home

Home collection kits were pre-assembled into SpeciSafe® Multivial Biological Specimen UN3373 compliant mailing packs (Alpha laboratories ltd, reference SHO400). The Mini-Collect® tube could be held upright in the transport container during blood collection. Participants collected approximately 250 µl blood (halfway to the first graduation mark) and applied a sterile gauze pad to the puncture site to facilitate haemostasis.

hCG immunoassay

Analysis of paired venous and capillary blood samples in duplicate was performed at Cork University Hospital's central laboratory using the Abbott Architect analyser (Abbott Diagnostics, Illinois, USA), according to manufacturer's instructions [12]. The Architect total beta-hCG (β-hCG) assay is accredited to ISO15189 (2012) international standards and the laboratory participates in external quality assessment (EQA) with UKNEQAS. The immunoassay is linear from 1.2 to 15,000 IU/L and requires 75 µl blood for the initial hCG measurement and 25 µl extra for duplicate analysis [12].

Remote CBC samples received by post were visually inspected for volume adequacy using tube graduations and processed immediately. After sample centrifugation (4,000g for 10 mins at 4 °C), serum was transferred into a micro-sample cup (Abbott Diagnostics, reference 5106). Assay accuracy (mean) and precision (coefficient of variation,

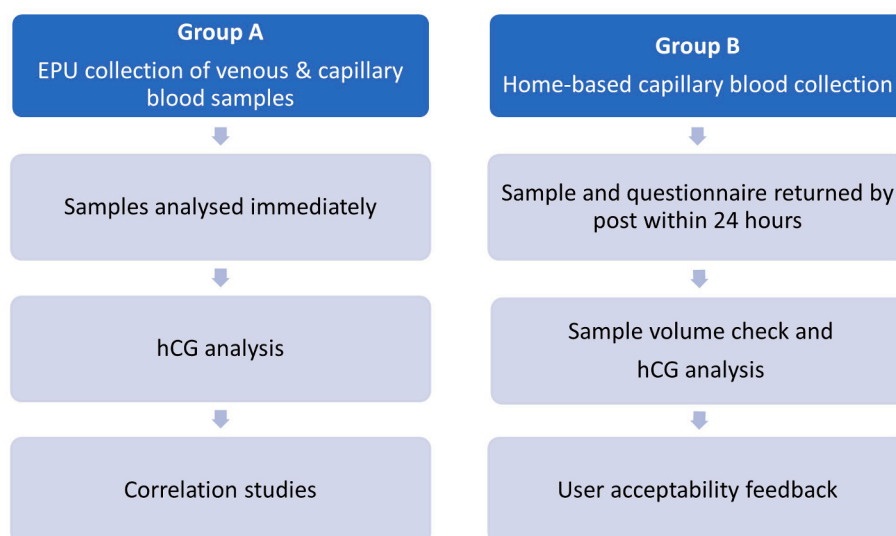


Fig. 1. Study Design.

CV) was monitored by four levels of quality control (Technopath Multichem IA Plus).

Statistical analysis

Statistical analysis was performed using Analyse-IT® software. Normality was assessed using the Shapiro-Wilk test, with descriptive statistics applied to baseline study characteristics. Continuous parametric data was represented as mean and standard deviation (SD) and non-Gaussian data as median and interquartile range (IQR). Spearman's rank coefficient assessed venous and capillary blood hCG correlation at statistical significance of $p < 0.05$. Passing-Bablok linear regression and Bland-Altman difference plots were used to assess agreement and bias, following the Clinical Laboratory Standards Institute (CLSI) EP09-A3 guideline [13].

Results

Study characteristics

Seventy-four women initially consented to participate in the study, but three were excluded due to insufficient blood volume or lack of a matched venous sample giving a final study population of 71 women. Participant median age was 33 years (IQR, 30–36) and mean gestational age was 7 weeks (SD, 2.4). Clinical indications for hCG measurement included ectopic pregnancy, PUL, molar pregnancy and miscarriage (Table 1).

Statistical analysis

Paired samples from EPU (Group A)

Venous blood hCG results were used as the reference comparator. The hCG assay demonstrated accuracy and precision, with mean hCG concentrations of 2.8, 21.7, 518, 15,185 IU/L and CVs of 13%, 5%, 3% and 2.8%, respectively, reported for quality controls. The assay also achieved satisfactory EQA performance during the study period. The Shapiro-Wilk test showed normally distributed data ($W = 0.61$, $p < 0.001$). Spearman's correlation coefficient revealed a significant correlation between venous and capillary samples hCG results ($r = 0.99$, $p < 0.0001$). For robust statistical analysis, two approaches were employed: analysis of all hCG results ($n = 71$) and analysis of a subset of hCG results within the linear range of the assay ($n = 67$). This strategy was used to mitigate potential errors from dilution of samples with hCG

Table 1

Clinical indications for hCG at time of measurement.

Clinical Indication	Number of Women
Intrauterine pregnancy/pregnancy of uncertain viability	13
Pregnancy of unknown location	7
Ectopic pregnancy	11
Miscarriage	32
Complete Hydatidiform Mole	3
Partial Hydatidiform Mole	2
Atypical Placental Site Nodule	1
Retained products of conception	2
Total	71

concentrations exceeding the linear range of the assay, by 10 to 30 orders of magnitudes (Table 9.1). However, both approaches yielded almost identical results, indicating agreement between the collection methods across all hCG concentrations.

Passing-Bablok regression analysis ($n = 67$) showed excellent agreement between venous and capillary blood samples with a slope of 1.03 (95% CI: 1.006 to 1.064), a minimal intercept of 0.084 (95% CI: –1.008 to 0.858) and a proportional bias of approximately 3% (Fig. 2A). A Bland-Altman difference plot revealed a minimum mean difference of 26.6 IU/L, showing the consistency of results by both collection methods (Fig. 2B).

Remote capillary blood collection (Group B)

In total, 74 women consented to participate in home collection, 3 were excluded due to insufficient or unmatched blood samples and 2 left the home collection kit behind in clinic, leaving 69 participants. Among participants, 39% (27/69) returned a remote CBC, and most of these, 74% (20/27) had sufficient blood for hCG analysis. The volume of serum obtained from CBC ranged from a minimum of 20 μ l to a maximum of 250 μ l.

Questionnaire responses (Group B)

Of the 27 home testing kits returned, 25 included completed questionnaires. Most participants (72%, 18/25) found the Mini Collect® device easy to use with 28% (7/25) reporting soreness in the lanced finger post the fingerprick procedure. Despite this discomfort, 80% (20/25) expressed a willingness to take another capillary blood sample in the future. A significant proportion, 72% (18/25) preferred home CBC over the traditional method of visiting a hospital or GP for phlebotomy (Fig. 3). Additionally, 52% (13/25) believed they had insufficient blood collected whereas only 26% (7/27) of samples were insufficient. All

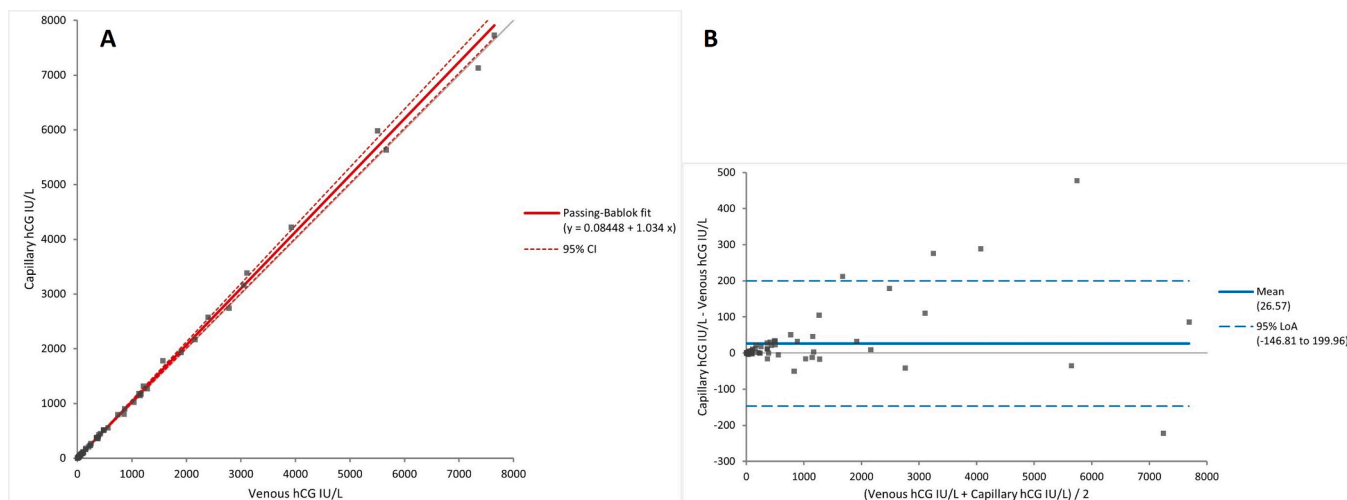


Fig. 2. (A) Passing-Bablok linear regression and (B) Bland-Altman difference plot (n=67) CI, confidence interval; LOA, limits of agreement.

participants indicated their willingness to obtain a future home testing pack from a local pharmacy and were willing to pay greater or less than €10, suggesting that cost may not be a major concern.

Discussion

This proof-of-concept study demonstrated the equivalence of hCG results between venous and capillary blood sampling, establishing capillary blood hCG testing as a viable alternative for serial hCG monitoring in women with early pregnancy complications or GTD. There was also positive feedback on the convenience of CBC, with women expressing a preference for CBC over traditional venepuncture.

The study findings are consistent with other studies, showing near-perfect agreement for certain analytes in capillary and venous blood [14]. A UK study reported good correlation for HbA_{1c} and a positive bias for some lipid and liver function analytes. This study piloted a remote CBC kit to support virtual outpatient clinics and 87% of participants found CBC easy to use [15]. An Irish study reported similar agreement for HbA_{1c} [4]. Another UK study showed good agreement for specific tests in a chronic disease management outpatient clinic, enabling shared decision-making [2]. A pilot study evaluating remote CBC for tumour marker surveillance in colorectal cancer reported a preference for finger-prick testing, particularly among younger participants (<65 years) [16].

This study highlights a demand for and acceptance of remote CBC

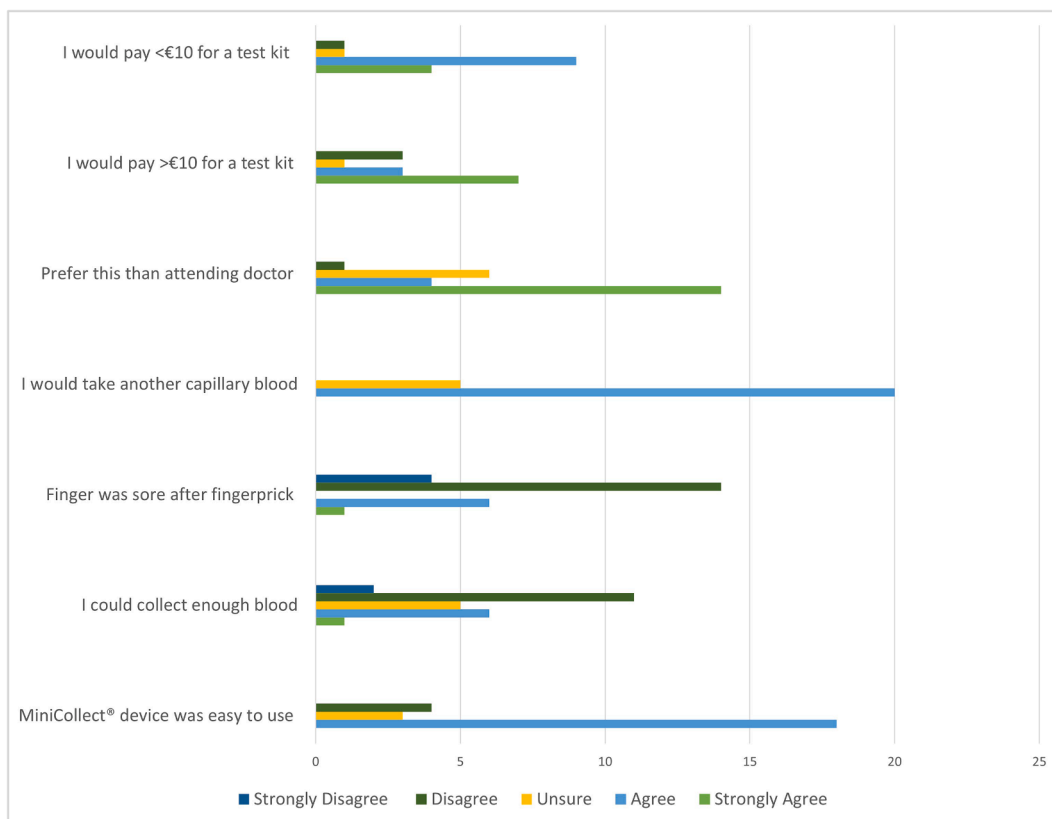


Fig. 3. Responses to Questionnaire.

among pregnant women, suggesting a shift to a hybrid approach, combining home and clinic-based blood collection. The biomarker hCG plays a pivotal role in investigating and managing GTD, suspected miscarriage, ectopic pregnancy, and PUL [18,19]. Remote CBC holds promise for various applications beyond pregnancy monitoring. It could significantly contribute to infectious disease surveillance and facilitate the expansion of screening tests, as evidenced by recent Hepatitis C awareness campaigns [20]. Remote CBC could support chronic disease management by reducing hospital clinic visits and supporting telemedicine and video consultations [2]. It could simplify regular therapeutic drug monitoring for transplant recipients, offering a convenient alternative to hospitals for immune-compromised patients [15,21]. Furthermore, it may benefit people with disabilities who face challenges attending regular physician appointments or commuting long distances to access healthcare.

Innovative blood collection systems, such as the Tasso-SST self-contained device for capillary blood samples and the Touch Activated Phlebotomy (TAP) II® device, using HALO™ technology have shown promise for the measurement of multiple analytes [25–28]. Additionally, Mitra microsampling devices using Volumetric Absorptive Microsampling (VAMs) technology absorb a fixed amount of capillary blood (10 µl), which has been used for therapeutic monitoring of Prograf® in transplant patients [29]. A Dutch study using a novel topper technology has successfully facilitated self-collection of blood for PSA testing in prostate cancer patients with favourable user feedback [30].

The increasing consumer demand for home-based blood collection solutions empowers patients to actively participate in their healthcare [8]. Home-based CBC holds promise in centralising tumour marker testing for patients with rare tumours, such as hCG testing in trophoblastic disease. Previous studies have piloted tumour marker testing for CEA and PSA, for colorectal and prostate cancer, respectively [16,30]. This approach effectively addresses logistical challenges associated with intra-laboratory dispatch and analytical variation in commercial immunoassays for tumour markers.

Despite its relatively small size, this proof-of-concept study met the CLSI requirements for method comparison and bias estimation [13]. Moreover, the range of hCG concentrations tested encompassed the clinical decision thresholds (1,500, 3,000 and 5,000 IU/L) used to manage ectopic pregnancy and miscarriage [17]. The availability of matched venous blood for CBC samples in clinic, provided a control for analytical variation between matrices [5]. However, a limitation in the study design was the absence of a control arm to match remote CBC samples for immediate analysis, thereby hindering the performance of stability studies. Additionally, the use of a MiniCollect® device with graduation fill lines (0.5/0.8 ml) that did not align with the required blood volumes (0.1 ml), may have deterred some participants. The availability of patient information leaflets in English only may also have discouraged non-English speaker participation. We were unable to investigate further why some women did not participate in the home CBC sampling, as participation was entirely voluntary, and women were allowed to withdraw from the study at any time without providing a reason. Some women may have faced challenges returning home CBC samples, due to difficulties using the MiniCollect® device or collecting sufficient blood volume. While an online video was provided for guidance, a telephone helpline may have been more effective in supporting participants encountering difficulties using the CBC, possibly affecting return rates. Nevertheless, active patient involvement in this study was a notable strength, with questionnaire feedback providing insights into the efficacy and acceptability of remote CBC.

Future studies should include preanalytical validation to address concerns about the standardisation of capillary blood sampling procedures, which may compromise the quality and accuracy of test results [14,22]. Additionally, the selection of collection tube, lancet and needle gauge may influence the blood volume collected and the discomfort experienced by users [23,10,24]. Integrating a QR code into the CBC kit could also streamline the collection process by alerting the clinician and

laboratory upon test dispatch. Further research is required to determine the health economic benefit of remote capillary blood collection in facilitating outpatient clinics and telemedicine.

Conclusion

Capillary blood sampling, a minimally invasive technique traditionally used in diabetes, shows promise for numerous healthcare applications, including in pregnancy. This proof-of-concept study successfully demonstrated the equivalence of capillary blood testing for hCG compared to standard venous blood sampling, achieving full clinical concordance. Validation of these findings by further larger prospective studies is necessary and should include a comprehensive cost-benefit analysis, before recommending the integration of capillary blood sampling into routine diagnostic practice.

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CRediT authorship contribution statement

Caroline M. Joyce: Writing – review & editing, Writing – original draft, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Paula M. O'Shea:** Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization. **Rebecca Lynch:** Writing – review & editing, Data curation. **Sean J. Costelloe:** Writing – review & editing. **Tommie V. McCarthy:** Writing – review & editing. **John Coulter:** Writing – review & editing. **Deirdre Hayes-Ryan:** Writing – review & editing, Writing – original draft, Conceptualization. **Keelin O'Donoghue:** Writing – review & editing, Writing – original draft, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: [Caroline M Joyce reports financial support was provided by Irish Research Council.].

Data availability statement

In accordance with the journal's guidelines, we will provide our data for independent analysis by a selected team or by the Editorial Team for the purposes of additional data analysis or for the reproducibility of this study in other centres if such is requested.

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Author Contributions

Study design: CMJ, PMOS, DHR and KOD; Study data collection: CMJ and RL; Statistics: CMJ and PMOS; Drafting manuscript: CMJ, PMOS, DHR and KOD. Approval of final version of manuscript: CMJ, POS, DHR, SC, JC, TMcC and KOD. KOD is the guarantor.

Ethics approval

Written informed consent was obtained from all patients participating in this study in accordance with ethical approval from the Clinical Research Ethics Committee of the Cork Teaching Hospitals (ECM4 (b) 01/11/2022 & ECM5 (8) 05/10/2022 & ECM3 (ss) 28/03/23).

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejogrb.2024.07.040>.

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