

Evaluation of the Predictive Value of a Newer Scoring System (SHUDE Score) for Chronic Endometritis in Women with Previous Reproductive Failure Undergoing IVF Treatment: A Research Protocol

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ABSTRACT

Introduction: Chronic Endometritis (CE) is a persistent inflammation of the endometrial lining, frequently asymptomatic but associated with Recurrent Implantation Failure (RIF) and Recurrent Pregnancy Loss (RPL) in women undergoing In-Vitro Fertilisation (IVF).

Need of the study: Preliminary evidence indicates CE prevalence varies with diagnostic methods, underscoring the need for standardised tools. The SHUDE score could close this gap by offering a structured, accessible approach to CE diagnosis. If validated it may enhance early detection and management of CE, improve IVF outcomes, and serve as a cost-effective option in resource-limited environments.

Aim: To evaluate the predictive value of the newer scoring system for diagnosing CE in women with previous reproductive failure undergoing IVF treatment in comparison to the gold standard, i.e., CD138.

Materials and Methods: A cross-sectional study will be conducted at the Department of Obstetrics and Gynaecology, Jawaharlal Nehru Medical College (DMIHER), Wardha, Maharashtra, India, from January 2024 to December 2025. It will involve 121 IVF patients with a history of implantation failure or pregnancy loss. Each participant will undergo hysteroscopy and CD138 IHC testing. SHUDE score will be calculated incorporating the various clinical parameters, hysteroscopic findings and tuberculous molecular testing. The diagnostic accuracy of the SHUDE score in comparison to CD138 will be studied using Statistical Package for Social Sciences (SPSS) version 22.0, and the R package(s) will be used for the Receiver Operating Characteristic (ROC). Diagnostic accuracy, including sensitivity, specificity, predictive values and likelihood ratios, will be assessed. Youden's Index will be calculated. A p-value <0.05 will be considered statistically significant.

Keywords: Hysteroscopy, Immunohistochemistry, Infertility, In-vitro fertilisation, Plasma cells, Recurrent pregnancy loss

INTRODUCTION

The role of endometrial factors in RPL and RIF following IVF is an area of ongoing investigation. Approximately 45.5% of patients with RIF or RPL undergoing IVF may eventually receive microbiological confirmation of CE, particularly among those with unexplained infertility [1]. Although most patients are asymptomatic, they may exhibit prolonged vaginal discharge, dyspareunia, irregular uterine bleeding, or chronic pelvic pain [2]. Histologic identification of plasma cells in the endometrial stroma is the gold standard for diagnosing CE. A more precise diagnosis can be obtained by using Immunohistochemistry (IHC) stains for syndecan-1 (CD138), a proteoglycan present on the cell surface of keratinocytes and plasma cells [3]. Kitaya K and Yasuo T noted that while novice pathologists struggled to identify plasma cells effectively, they found it easy to recognise them through CD138/CD38 Immunohistochemical (IHC) staining [4]; however, there is an issue of interobserver variability. CD138-based IHC remains the reference test, but access and turnaround can be limiting in many Indian settings. Hysteroscopy is an effective technique for observing and assessing the uterine cavity. In fact, hysteroscopy combined with biopsy has a Positive Predictive Value (PPV) for identifying intrauterine inflammation and is regarded as the most reliable method for diagnosing intrauterine issues [5]. Tsonis O et al., concluded that diagnostic hysteroscopy can reliably diagnose cases of CE [6]. Higher diagnostic accuracy will more likely be attained in subgroups of infertile women with previous reproductive loss. A major limitation of hysteroscopy is

that assessment of the uterine cavity relies on visual interpretation, which is inherently subjective and can vary depending on the clinician's expertise. To address this issue of interobserver variability, Liu H et al., developed a hysteroscopic scoring system based on characteristic visual patterns, demonstrating high sensitivity and specificity for diagnosing CE through ROC analysis [7]. If a CE prediction scoring system is developed by gathering clinical data and looking at the potential impact of different parameters on CE based on earlier research [8], it will assist us in creating a scoring system that can be used to forecast results for women undergoing IVF treatment who have experienced reproductive failure in the past. In contrast to previous hysteroscopic scores that mainly depend on visual findings, SHUDE creates a single quantitative risk score for CE by combining three commonly available domains: (1) clinical history and examination; (2) standardised hysteroscopic signs; and (3) an India-relevant TB screen {Cartridge-Based Nucleic Acid Amplification Test (CBNAAT)}. In low-resource settings where quick IHC is not always possible, this expanded input set seeks to: (a) increase applicability; (b) decrease misclassification when hysteroscopic symptoms are mild or operator-dependent; and (c) offer a graded risk to guide biopsy, empiric therapy, and IVF timing. SHUDE score addresses these gaps by integrating clinical, endoscopic, and CBNAAT features into a single, validated score suitable for triage in low-resource contexts. In addition, the score will undergo internal validation. The name SHUDE has been derived from the names of the authors SHUCHI and DEEPTI.

Objectives

1. To develop and validate the SHUDE scoring system
2. To develop and assess the diagnostic accuracy of the SHUDE scoring system compared to CD138 on Immunohistochemistry (IHC).

Null hypothesis: The newer scoring system (SHUDE score) does not have better predictive value in diagnosing CE in women undergoing IVF treatment for previous reproductive failure compared to the gold standard.

Alternate hypothesis: The newer scoring system (SHUDE score) has better predictive value in diagnosing CE in women undergoing IVF treatment for previous reproductive failure compared to the gold standard.

REVIEW OF LITERATURE

The diagnostic accuracy of hysteroscopy for CE varies across studies due to differences in diagnostic criteria, reference standards, and study populations. Nevertheless, it remains valuable for identifying suspicious endometrial features and guiding targeted biopsy, particularly because CE may be focal and missed by blind sampling [9]. Characteristic hysteroscopic findings include micropolyps, stromal oedema, and focal or diffuse hyperaemia. Cicinelli E et al., reported that micropolyps had a sensitivity of approximately 54% and specificity of 93% for histological CE [10], while the presence of combined findings improves predictive value, especially in women with RIF or RPL.

Despite these advantages, hysteroscopic interpretation is partly subjective, and its overall diagnostic accuracy has been reported to be around 67%. Hysteroscopy's sensitivity, specificity, and positive and Negative Predictive Values (NPV) for detecting CE were 86.36%, 87.30%, 70.37%, and 94.82%, respectively, according to a study by Zargar M et al., [11]. He concluded that hysteroscopy is a trustworthy diagnostic method that may accurately identify CE in individuals with RIF following IVF and RPL.

Meta-analysis data further support the diagnostic value of hysteroscopy. Riemma G et al., reported pooled sensitivity and specificity of 84% and 89%, respectively, with an area under the receiver operating characteristic curve of 0.93, indicating high diagnostic accuracy [12].

According to a comprehensive systematic review by Gkrozou F et al., the heterogeneity of the included studies presents a high-risk of bias as assessed according to Cochrane Collaboration criteria. Hysteroscopy is not suitable as a first-line diagnostic tool in cases of chronic or subclinical endometritis. They recommended that randomised controlled trials are required to determine the function of hysteroscopy as a first-line diagnostic procedure in patients with chronic or subclinical endometritis [13].

Hysteroscopy-guided biopsy is more effective than blind techniques such as curettage or Pipelle sampling for detecting endometrial pathology, as it allows for more accurate and representative tissue sampling. In contrast, blind methods evaluate only a limited portion of the endometrium, whereas hysteroscopy facilitates direct visualisation and identification of focal or minimally distributed lesions [14]. It is hoped that a new scientific method would suggest hysteroscopic indicators that can reliably identify CE instances without additional histologic verification.

Liu H et al., developed a hysteroscopic scoring system and assigned weighted scores: diffuse endometrial hyperaemia (4), haemorrhagic spots (2), focal hyperaemia (2), dilated endometrial vessels (2), micropolyps (1), polyps (1), and a history of repeated artificial insemination failure (2). The total score ranged from 0 to 14. Based on the ROC curve and the optimal Youden Index, a cut-off value greater than 2 (excluding 2) [7] will be established, with scores above this threshold indicating a strong likelihood of CE and a lower likelihood of alternative diagnoses. Such scoring systems are particularly useful, but due to interobserver variability, there is a lack of universal standardisation. Thus, further studies are required to

establish their reliability across diverse populations. Thus, this study aims to investigate the predictive value of a new scoring system (SHUDE score) for diagnosing CE in women experiencing previous reproductive failures while undergoing IVF treatment.

MATERIALS AND METHODS

A cross-sectional study will be conducted at the Department of Obstetrics and Gynaecology, conducted at Jawaharlal Nehru Medical College, Sawangi (M), Wardha, Maharashtra, India, from January 2024 to December 2025. The study has been approved by the Institutional Ethics Committee of Datta Meghe Institute of Medical Sciences, Sawangi, Wardha (Re-Regd. number: DMIMS (DU)/IEC/2022/844). The study will be explained to all participants, and an informed consent form will be obtained.

Inclusion criteria: It is based on American Society for Reproductive Medicine (ASRM) diagnostic criteria [15]. All women with infertility who have had previous reproductive failure (RPL and RIF) and fulfil the inclusion criteria will be included in the study.

The ASRM defines RPL as the spontaneous loss of two or more pregnancies, excluding confirmed molar or ectopic pregnancies - before 22 weeks of gestation [15], while RIF should be defined as the failed implantation of the estimated number of good-quality blastocysts to achieve a 95% cumulative chance of a positive pregnancy test [16].

Exclusion criteria:

- Unexplained uterine bleeding;
- History of antibiotic treatment in the month preceding the biopsy;
- Uterine malformation;
- Cavity-deforming submucosal myoma or a polyp >5 mm;
- Smokers or alcohol consumers;
- Participants who do not wish to continue with this study.

Sample size calculation: The sample size will be calculated using the single population proportion formula:

$$n = Z^2 \times p \times q / d^2$$

Where:

Z= 1.96 (standard normal deviate at 95% confidence level)

p= anticipated prevalence of CE=30.3%=0.303

q= 1-p=0.697

d= absolute precision=8.2%=0.082

The reported prevalence of CE 30.3% among women with RIF undergoing IVF [17].

Substituting the values:

$$n = (1.96)^2 \times 0.303 \times 0.697 / (0.082)^2$$

$$n = 120.6$$

Therefore, the minimum required sample size will be approximately 121 participants.

Study Procedure

Women enrolled in the study will have data collected regarding sociodemographic factors, previous obstetric history, and history of reproductive failure, and interventions will be taken. A detailed history of symptoms and thorough physical examination of women with reproductive failure will be done and noted.

Each participant will undergo hysteroscopy three to five days following their period. The hysteroscopy medium will be a 0.9% saline solution (Karl Storz), using an A 40211 A hysteroscope with a viewing angle of 30° and an outer sheath diameter of 3.5 mm. The endometrium, uterus, and cervical canal will be assessed. All hysteroscopy examinations will be conducted by skilled medical professionals (MS Obstetrics and Gynaecology trained in hysteroscopy with a minimum of 10 years of experience). Haemorrhagic patches,

localised hyperaemia, diffuse endometrial hyperaemia, dilated endometrial arteries, endometrial polyps or micropolyps are among the morphologic characteristics that doctors will look for.

The CE scoring system (SHUDE): The SHUDE scoring system will be developed following an extensive review of published literature and consultation with clinicians experienced in reproductive medicine, infertility, hysteroscopy, and gynaecology. Clinical variables consistently reported to be associated with CE will be identified and incorporated into the preliminary scoring system [Table/Fig-1]. Appropriate weights will be assigned to individual variables based on available literature and expert consensus before finalisation of the preliminary scoring system.

Domain	Components
Demographic characteristics	Age
Reproductive history	Duration of married life, previous implantation/pregnancy loss
Clinical history	Chronic pelvic pain, treatment of acute/chronic PID, vaginal discharge, abnormal uterine bleeding, history of tubo-ovarian mass/pelvic surgery
Clinical examination	Suprapubic tenderness, unhealthy vaginal discharge, cervical congestion, restricted mobility of uterus, tenderness, fullness of fornix
Hysteroscopic findings	Diffuse hyperaemia, focal hyperaemia, haemorrhagic spots, dilated endometrial vessels, micropolyps, polyps
Laboratory finding	Evidence of endometrial tuberculosis

[Table/Fig-1]: The preliminary SHUDE scoring system consisted of the following domains.

PID: Pelvic inflammatory disease

The preliminary tool will independently be evaluated by six subject experts comprising reproductive medicine specialists, obstetricians and gynaecologists, and hysteroscopy specialists. Each expert assessed the relevance, clarity, and clinical applicability of each domain using a four-point Likert scale (1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, and 4 = highly relevant). Suggestions provided by the experts will be incorporated to improve the clarity and applicability of the scoring system before finalisation.

Content validity will be assessed using the Item Content Validity Index (I-CVI) for individual domains and the Scale CVI (S-CVI/Ave) for the overall scoring system.

Following expert validation, the finalised SHUDE scoring system will be pilot-tested among 30 women fulfilling the study eligibility criteria. Internal consistency reliability of the scoring system will be assessed using Cronbach's alpha coefficient.

The full sample will include 121 consecutive eligible participants. All candidate variables listed will enter a multivariable logistic regression with CD138-positive CE {>5 plasma cells/10 High-power Field (HPF)} [18] as the reference outcome. Continuous variables (e.g., age, infertility duration) will be checked for linearity and modelled using restricted cubic splines or clinically sensible cut-points. Collinearity will be assessed {Variance Inflation Factor (VIF)>5 triggers review}. β -determined coefficients will be scaled and rounded to create the points-based SHUDE score (nomogram in supplement). Missing data will be handled by multiple imputation (m=10) under missing at random assumptions.

The parameters [Table/Fig-2] will be included in the scoring system based on their reported association with implantation biology and suspicion of CE. Age ≥ 18 years [14], duration of infertility [19], and history of previous pregnancy loss may serve as relevant clinical correlates of impaired implantation and CE. Clinical symptoms may indicate chronic endometrial inflammation [20], while specific examination findings may increase suspicion of subclinical pelvic or endometrial inflammation. Hysteroscopic features will select based on available consensus/Delphi criteria and previous studies, with higher scores assigned to findings considered to have greater specificity for CE. CBNAAT positivity will assign a higher weight (+4) because genital tuberculosis is a regionally relevant and treatable

cause of endometrial inflammation, with direct implications for clinical management [21].

Variables	0	1	2	3	4
Age					
<35 years	√				
36 to 39 years		√			
>40 years			√		
Married life years					
<3	√				
>3		√			
History of prior implantation or pregnancy loss					
History of one Prior Implantation/Pregnancy loss		√			
History of >1 Prior implantation/ Pregnancy loss			√		
History					
Chronic pelvic pain		√			
Treatment of acute or chronic PID		√			
Vaginal discharge		√			
Abnormal uterine bleeding		√			
H/O Tubo-ovarian mass/pelvic surgery		√			
Clinical examination					
P/A-tenderness in suprapubic area		√			
P/S- Unhealthy vaginal discharge		√			
Cervical congestion		√			
P/V-Restricted mobility of uterus		√			
Tenderness		√			
Fullness of fornix		√			
Hysteroscopy findings					
Endometrial diffuse hyperaemia			√		
Haemorrhagic spots			√		
Focal hyperaemia			√		
Dilated endometrial vessels			√		
Micropolyps		√			
Polyps			√		
Evidence of endometrial tuberculosis				√	

[Table/Fig-2]: SHUDE score for Chronic Endometritis (CE).

P/A: Per abdomen; P/S: Per speculum; P/V: Per vaginum

The score will be determined with the help of an ROC curve. The maximum possible score represents a greater likelihood or severity of endometrial inflammation/CE, whereas a lower score indicates fewer associated risk factors or findings and a more favourable clinical profile.

The Delphi poll reached agreement on the following diagnostic criteria [22]:

- Strawberry aspect: large areas of hyperaemic endometrium flushed with white central points;
- Focal hyperaemia: small areas of hyperemic endometrium;
- Haemorrhagic spots: focal red areas with sharp and irregular borders, possibly in continuity with capillary;
- Micropolyps: small intrauterine new growths <1 mm in size with a distinct connective tissue vascular axis, distributed on focal areas or on the entire endometrial surface;
- Thick and pale appearance of the endometrium in the follicular phase owing to stromal oedema (a normal finding during the secretory phase).

A Pipelle will take a biopsy following hysteroscopy. Once more, a vaginal speculum will be positioned, and the Pipelle will be visually guided into the uterus without making contact with the vaginal walls to reduce the possibility of sample contamination. Formalin solution will be used to fix the biopsy sample before it is delivered to the lab for IHC staining evaluation using anti-syndecan-1 (CD138)

monoclonal antibodies. The same pathologist, who specialises in endometrial pathology and is not aware of hysteroscopic results, will analyse all specimens when they are sent to the same lab.

To accomplish IHC staining, mouse monoclonal antibodies diluted 1:100 against syndecan-1, a particular marker of plasma cells, will be incubated for one hour at room temperature.

Each patient's hysteroscopic and IHC staining results will be documented on unique forms.

The gold standard will be IHC staining results showing more than five plasma cells per 10 HPFs [17].

The pathologist performing CD138 IHC will be blinded to SHUDE and hysteroscopy.

CBNAAT technicians will be blinded to both clinical and IHC data.

Hysteroscopists and clinicians assigning SHUDE components will be blinded to CD138 report of the same woman.

Outcomes

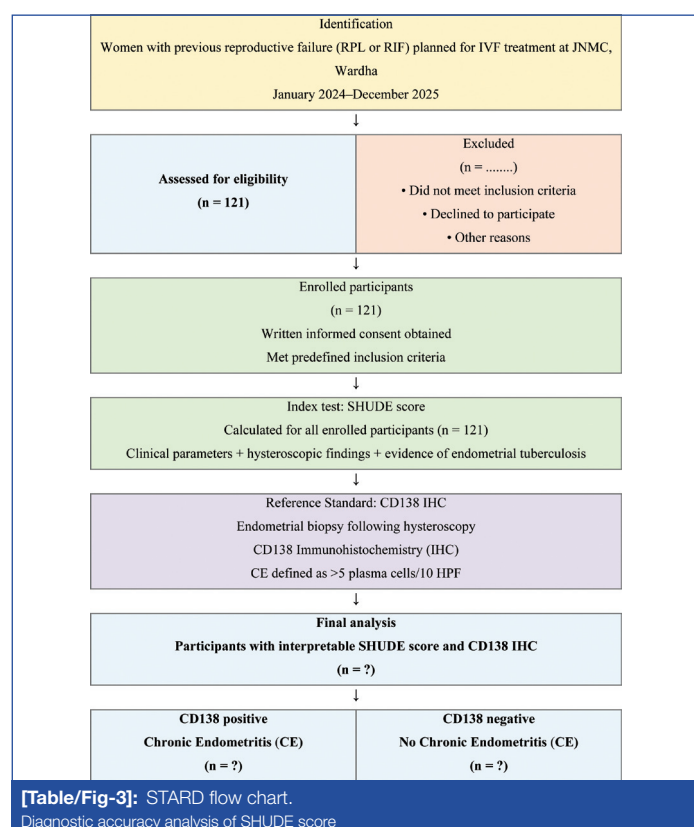
Primary outcomes: Diagnostic accuracy (sensitivity, specificity) of SHUDE score for CE.

Secondary outcomes: Secondary outcomes like AUC, PPV, NPV, likelihood ratios and Youden Index will be calculated.

STATISTICAL ANALYSIS

Data analysis will be done using IBM SPSS Statistics v22.0, IBM Corp., Armonk, NY, and the R package(s) will be used for ROC. Discrimination: Area Under the ROC Curve (AUC) with 95% CI. Optimal cut-off via Youden's J; sensitivity, specificity, PPV, NPV, and likelihood ratios will be reported at the prespecified cut-off and across clinically relevant thresholds. Decision-curve analysis will quantify net benefit across thresholds. A p-value <0.05 will be considered statistically significant.

The guidelines that are followed in this study are the Standards for Reporting of Diagnostic Accuracy (STARD) Guidelines [Table/Fig-3].



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