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Intracervical Lakes as A Sonographic Marker of Placenta Accreta Spectrum (PAS) in Patients with Previa and Low-Lying Placenta; A Prospective Observational Study

A Thesis

Submitted for Partial Fulfillment of MD Degree in
Obstetrics and Gynecology

By

Nader Mohamed Ibrahim Mohamed

M.B.B.CH., (2013), M.Sc. (2018)

Faculty of Medicine, Ain Shams University

Under Supervision of

Prof. Dr. Karam Mohamed Bayomy

Professor of Obstetrics & Gynecology

Faculty of Medicine - Ain Shams University

Dr. Mohamed Mahmoud Abd El Aleem

Assistant Professor of Obstetrics & Gynecology

Faculty of Medicine - Ain Shams University

Dr. Mohamed Mahmoud Salman

Lecturer of Obstetrics & Gynecology

Faculty of Medicine - Ain Shams University

**Faculty of Medicine
Ain Shams University**

2022

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List of Abbreviations

Abb.	Full term
2D	<i>Two dimensional</i>
3D	<i>Three-dimensional</i>
AFI	<i>Amniotic fluid index</i>
ART	<i>Assisted reproductive technology</i>
CD	<i>Cesarean delivery</i>
CI	<i>Confidence interval</i>
CS	<i>Cesarean section</i>
Cx.....	<i>Cervix</i>
DA.....	<i>Diagnostic accuracy</i>
DIC	<i>Disseminated intravascular coagulation</i>
DOR.....	<i>Diagnostic odds ratio</i>
EVT	<i>Extravillous trophoblast</i>
GS	<i>Gestational sac</i>
ICL	<i>Intracervical lakes</i>
JZ	<i>Junctional zone</i>
LR-.....	<i>Negative likelihood ratio</i>
LR+.....	<i>Positive likelihood ratio</i>
MAP	<i>Morbid adherent placenta</i>
MNGC	<i>Multinucleated trophoblast giant cells</i>
MOMS	<i>Multiples of the median</i>
MSAFP	<i>Maternal serum alpha-fetoprotein</i>
NPSA	<i>National Patient Safety Agency (UK)</i>
NPV	<i>Negative Predictive value</i>
PAS	<i>Placenta accreta spectrum</i>
PPV.....	<i>Positive Predictive value</i>
YI	<i>Youden's index</i>



Protocol of a Thesis for Partial Fulfillment of MD Degree in Obstetrics and Gynecology

Title of the Protocol: Intracervical Lakes as A Sonographic Marker of Placenta Accreta Spectrum (PAS) in Patients with Previa and Low-Lying Placenta; A Prospective Observational Study

Postgraduate Student: Nader Mohamed Ibrahim Mohamed

Degree: M.B.BCH.2013, M.Sc.2018.

Academic Position: Assistant lecturer

Department: Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University

DIRECTOR: Prof. Dr. Karam Mohamed Bayomy

Academic Position: Professor

Department: Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University

CO-DIRECTOR: Dr. Mohamed Mahmoud Abd El Aleem

Academic Position: Assistant Professor

Department: Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University

CO-DIRECTOR: Dr. Mohamed Mahmoud Salman

Academic Position: Lecturer

Department: Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University

**Faculty of Medicine
Ain Shams University
2020**



What is already known on this subject? AND What does this study add?

The incidence of placenta accreta should rise steadily over the next century as the frequency of cesarean sections and advanced maternal age, both independent risk factors, increases. The diagnosis of placenta previa accreta is possible by using gray-scale sonography, conventional color Doppler imaging and MRI through studying the relation of placenta to the uterine wall and nearby pelvic structures.

The introduction of new imaging signs is crucial in identifying women affected by this condition. The aim of our study is to evaluate the diagnostic accuracy of a new ultrasound sign, which it has been named “intracervical lakes”, in predicting presence and outcome of PAS disorders.

Introduction:

Placenta previa refers to the presence of placental tissue that extends over the internal cervical OS (*ACOG, 2002*).

Placenta previa and placenta accreta are associated with high maternal and neonatal morbidity and mortality (*Silver, 2015*).

The rates of placenta previa and accreta have increased and will continue to do so as a result of rising rates of caesarean deliveries, increased maternal age and use of assisted reproductive technology (ART) (*Bowman et al., 2014*).

The estimated incidence of placenta previa at term is 1 in 200 pregnancies (*Silver, 2015*).

Placenta accreta occurs when placental trophoblasts invade the endometrium beyond the Nitabuch's layer of decidua basalis, placenta increta occurs when placental trophoblasts invade the myometrium, and placenta percreta occurs when placental trophoblasts invade the serosa (*Abuhamad et al., 2014*).

Morbid adherent placenta (MAP) is generally associated with excess blood loss, bladder injuries and hysterectomies. The incidence of MAP has increased significantly over the last 50 years (*Wortman et al., 2013*).

The three forms of morbidly adherent placenta (MAP): placenta accreta, increta and percreta, represent a significant obstetric challenge, at times resulting in life-threatening bleeding and/or peripartum hysterectomy. The increasing rate of cesarean section (CS) deliveries correlates with the rising incidence of MAP (*Daskalakis et al., 2007*).

The risk increases with women with previous placenta previa and in those with a previous CS. In addition to previous CS, a maternal age over 35 years, multiparity, previous curettage are risk factors associated with MAP



(Mazouni et al., 2007).

This condition is often diagnosed during CS, upon placental removal, with unfavorable maternal outcome: attempts to remove the placenta can cause severe uterine bleeding. An accurate prenatal diagnosis is required to reduce the risk of maternal/fetal morbidity and mortality **(Tikkanen et al., 2011).**

Aim/objectives:

The aim of our study is to evaluate the diagnostic accuracy of a new ultrasound sign, which it has been named “intracervical lakes”, in predicting presence and outcome of PAS disorders.

Methodology:

- **Type of Study:** A prospective observational study.
- **Study Setting:** Ain Shams University Maternity Hospital.
- **Study Period:** 12 month.
- **Study Population:** Women with with previa and low-lying placenta.

Inclusion Criteria:

- Age group (20 –35 years old).
- BMI between (20 –35 kg/m²)..
- Single, viable, pregnancy ≥ 36 weeks gestation.
- Previous one or more c.s

Exclusion Criteria:

- Patients with bleeding disorders or on anticoagulant therapy.
- Mental illness.
- Abruptio placenta.
- Over distended uterus eg: multiple gestation, polyhydramnios, fetal macrosomia (>4.5kg).
- Rupture of membranes, intra-ammonitic infection and fever during admission (>38°C).

Elimination of bias:

- All procedures were done by obstetricians having the same level of surgical skills.
- Laboratory samples were done in the same laboratory preoperative and postoperative.
- Preoperative ultrasound was performed by the same sonographer.

Ethical Considerations:

The nature and scope of the clinical study were explained in an understandable way to the patients and an informed consent form, in Arabic language, including all the study procedures, advantages and possible risks and specifying who informed the patient, were provided and the patient signed on it



before participation. The study protocol and patient informed consent were reviewed and approved by the Ethics Committee of the Obstetrics and Gynecology Department, Ain Shams University.

Sample Size:

Using PASS 11 program for sample size calculation and assuming rate of placenta accreta spectrum =13%, sensitivity and specificity of intracervical lakes =95 %, sample size of 110 women can detect this measures with power 92% for sensitivity and 100% for specificity with α –error 0.05

Study Procedures:

All women who met the inclusion criteria underwent full assessment.

This assessment was included:

Detailed History:

Personal (age, duration of marriage), *Present* (any current medical or surgical diseases and any current medication), *Past history* (history of any medical disorders), *Obstetric history* (including Parity, Gestational age, obstetric complications), *Contraception history* and *Menstrual history*.

Clinical examination:

General examination:

- 1) Assessment of the patients general condition (chronic fatigue e.g: in anemic patients)
- 2) Body Mass index (BMI) measured in kg/m².
- 3) Color of complexion e.g.: pallor in anemic patients.
- 4) Vital data (pulse, blood pressure, temperature).

- **Abdominal examination:** assessment of fundal level, fetal lie, presentation, liquor volume and previous scar were done.

- **Vaginal examination:** not done.

Ultrasound examination:

1. Using Samsung H 60 machine, 2D ultrasound was carried out trans-abdominally to assess fetal viability and number, placental location, determined gestational age and fetal anomalies and calculated exact amniotic fluid index (AFI).
2. TVUS and placental bed Doppler were done to confirm exact placental site and to assess whether the placenta is morbidly adherent according to RCOG criteria or not which were as follows (**RCOG, 2019**).

***2D greyscale signs:**

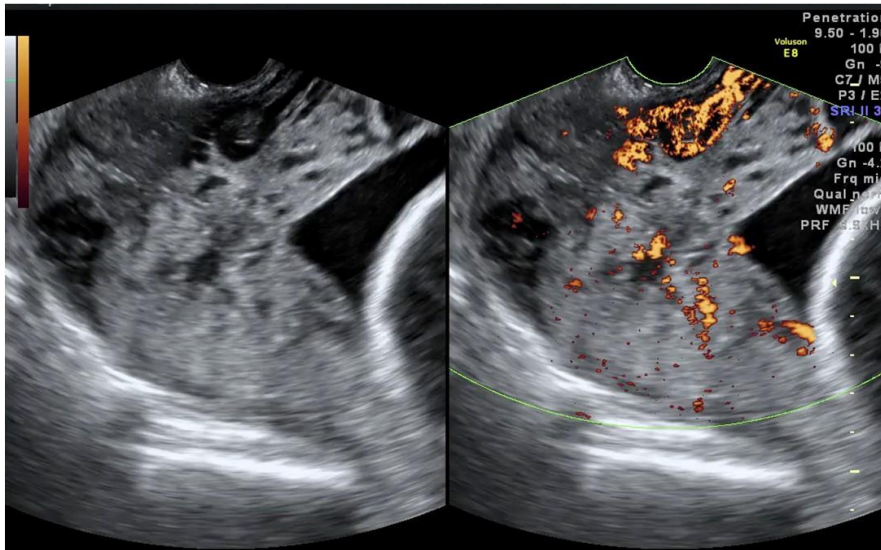
- Loss of the ‘clear zone’
- Abnormal placental lacunae.
- Bladder wall interruption
- Myometrial thinning.

- Placental bulge.
- Focal exophytic mass.

***2D colour Doppler signs:**

- Utero-vesical hyper-vascularity.
- Subplacental hypervascularity.
- Bridging vessels.
- Placental lacunae.

All patients were evaluated by Ultrasonography examinations using Samsung H 60 machine. That were performed in Ain Shams University Maternity hospital ultrasound unit staff to confirm the gestational age, placental location, criteria for invasion and intracervical lakes sign which is defined as tortuous Anechoic spaces within the cervix which appear hypervascular at color Doppler.



All the patients in the study underwent caesarean section and final diagnosis of MAP was made intraoperative and specimen was sent for pathological examination

- **Baseline laboratory investigations:** venous blood sample was withdrawn from all participants to assess:
 - Hemoglobin level.
 - Hematocrit value.
 - Platelet count.
 - RH and blood group.
 - Preparation of 4 units of cross matched PRBCs and 4 units of FFP will be ensured.



- Viral markers (HBs Ag, HCV Ab).
- Coagulation profile (PT, PTT, and INR).

▪ **Pre anesthetic medication:**

- Antibiotic prophylaxis was given as a single dose of intravenous 1st generation cephalosporins (Cefazoline®) 2gm to be taken 30 to 60 minutes before skin incision and the dose was repeated if the operation lasted for more than 3 hours or blood loss was more than 1500 cc (*ACOG, 2005*).

▪ **Operative technique:**

- Patients were placed in dorsal lithotomy position followed by induction of general anaesthesia, urinary catheterization and skin anti-sepsis.
- Skin was incised through a transverse or midline sub umbilical incision followed by opening of anterior abdominal wall in layers then observation for invasion like placenta bulge or invasion of pelvic structures by placental tissue.
- Identification and selective ligation of uterovescical venous plexus were done.
- The bladder dissected downwards.
- A low transverse uterine incision was done in the lower uterine segment followed by delivery of the fetus.
- Bilateral uterine artery ligation while waiting for placental separation.
- If placenta is adherent we proceeded for caesarean hysterectomy.
- In case of partially separated placenta accreta with ensuring bleeding, further action depends on patient's fertility wishes, conservative surgery was done.
- Ensuring adequate hemostasis and counting of towels and gauzes.
- Closure of anterior abdominal wall in layers.
- Subcutaneous tissue closure followed by skin closure using non-absorbable prolene suture No.2/0.

▪ **Postoperative:**

- Post-operative venous blood samples of hemoglobin and hematocrit levels were withdrawn from patients after 24 hours to avoid wrong results due to hemodilution by intravenous fluids in the first 24 hours

Measured variables:

- Diagnostic accuracy of intracervical lakes in detecting the presence and the depth of PAS disorders.
- explore the accuracy of this sign in predicting the following clinical outcomes:
 - Total estimated blood loss
 - Antepartum bleeding; post-partum haemorrhage at the time of Caesarean Section
 - Need for Caesarean hysterectomy.