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PARTICULAR CASES IN OBSTETRICS AND GYNECOLOGY

OBSTETRICS

Pregnancy-associated intracranial hypertension syndrome – diagnostic and therapeutic management

page 6

A retrospective study in a special case context: *vasa praevia* due to a velamentous umbilical cord insertion

page 20

GYNECOLOGY

Large tubo-ovarian abscess following retention of a Copper-T intrauterine device inserted ten years prior in an obese psychiatric patient

page 36

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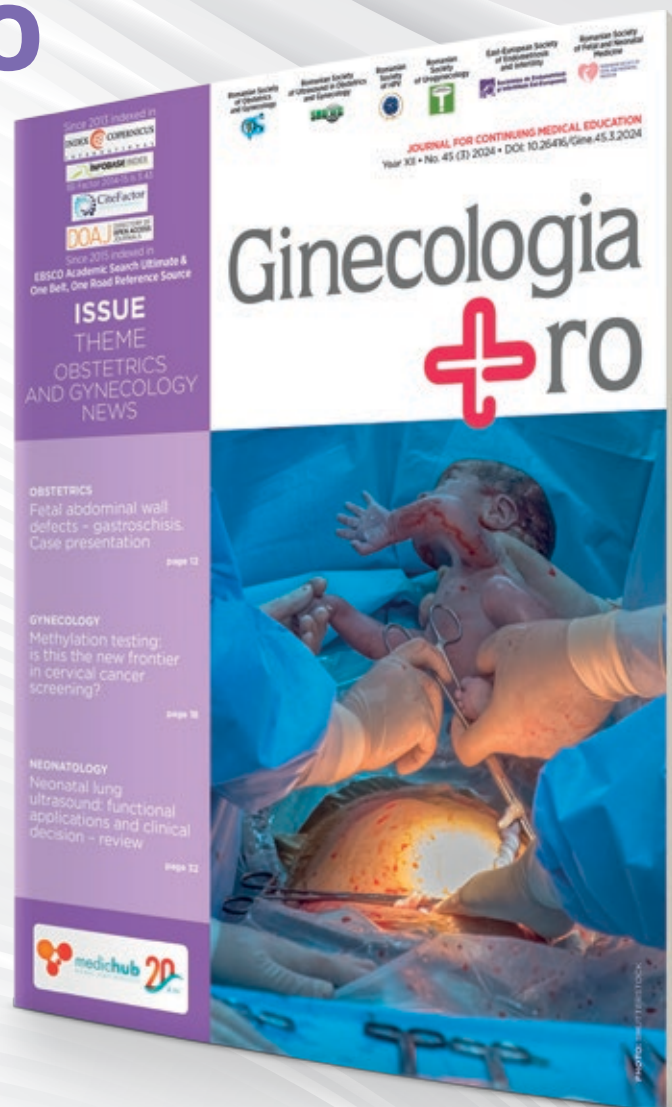
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Particular cases in obstetrics and gynecology

This edition of our journal emphasizes maternal and fetal aspects, beginning with the first paper that brings to the front the pregnancy-associated intracranial hypertension syndrome, that can result from various neurological and non-neurological conditions, presenting the case of a 38-year-old woman with an ongoing pregnancy at 27-28 weeks of gestation, who showed up to the emergency department with severe headache, vomiting and epileptic seizures.

The next paper presents a spectacular finding during emergency caesarean section in a patient with long-term infertility – a term pregnancy after 15 years of unprotected sexual contact with the same partner.

Cordia® platform is a digital health solution designed to provide continuous monitoring and personalized care for pregnant women in underserved areas. The following paper focuses on how Cordia® helps with early identification of potential complications, adherence to care plans, and promotes healthy lifestyle choices among participants.

Further, it is brought under attention a retrospective study conducted at the County Emergency Clinical Hospital Constanța, Romania, over a period of five years (2019-2023), that included a total of 14,166 births, among which seven cases were associated with velamentous insertion of the umbilical cord. In this retrospective study, it was included a case study to explore in detail the clinical manifestations and management of a specific case of velamentous insertion of the umbilical cord associated with *vasa praevia*.

The following article emphasizes the importance of regular screening and preventive measures to reduce the incidence of staphylococcal infections, especially methicillin-resistant *Staphylococcus*

aureus (MRSA), among hospitalized patients, presenting the results of a study carried at the “Prof. Dr. Panait Sirbu” Clinical Hospital of Obstetrics and Gynecology, Bucharest, from January 1 to October 31, 2024, revealing a 4.69% prevalence of staphylococcal infections, with 0.64% caused by MRSA.

The gynecology section reviews the advancements in laparoscopic techniques, such as sacrocolpopexy and Burch colposuspension, and discusses their application in reconstructive pelvic surgery and continence operations, pelvic organ prolapse and stress urinary incontinence being prevalent conditions among women, significantly impacting the quality of life.

Moving on, pelvic inflammatory disease (PID), often resulting from infections by pathogens like *Neisseria gonorrhoeae* and *Chlamydia trachomatis*, involves inflammation in the female reproductive tract. The case report of a 40-year-old woman, with a ten-year copper IUD, referred for left adnexal mass detection, highlights the challenges of managing PID in long-term IUD users, especially with large tubo-ovarian abscesses, that may not fully respond to antibiotics.

Type 2 diabetes mellitus (T2DM) is an expanding global health problem, being considered a chronic metabolic disease. The findings of the study presented in this paper can be used to reduce the HbA1C levels and help the T2DM patients to adjust their dietary patterns and change their personal life, thus increasing the women’s quality of life.

Last but not least, the editorial team would like to wish all the readers happy holidays, Merry Christmas and a Happy New Year!



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COMPANY ADDRESS:
MEDICHUB MEDIA SRL
Green Gate Office Building, 22 Tudor Vladimirescu Blvd.,
11th Floor, District 5, 050883, Bucharest, Romania
Phone: (031) 425.40.40, Fax: (031) 425.40.41
E-mail: redactia@medichub.ro
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OBSTETRICS

- 6** Pregnancy-associated intracranial hypertension syndrome –
diagnostic and therapeutic management
Elena-Evelina Stoica, Delia-Maria Grădinaru-Fometescu, Cristina Tiu,
Adina Crăciunoiu, Octavian Munteanu, Andreea Marinescu, Adriana Dan,
Sorin Vasilescu, Delia Iordache, Monica-Mihaela Cîrstoiu
- 10** Spectacular finding during emergency caesarean section
in a patient with long-term infertility – case report
Cristina-Diana Popescu, Romina-Marina Sima, Liana Pleș,
Ileana-Maria Conea
- 13** Evaluating the impact of the Cordia® digital health platform
on maternal care in underserved areas: a pilot study
Smit Bharat Solanki, Mandakini Pradhan, Neeta Singh, Khushboo Verma
- 20** A retrospective study in a special case context: *vasa praevia* due to
a velamentous umbilical cord insertion
Lucian Șerbănescu, Vadym Rotar, Paris Ionescu, Sebastian Mirea,
Dragoș Brezeanu
- 26** Detection and prevention of hospital-acquired staphylococcal
infections in pregnant women and postpartum mothers –
experience of “Prof. Dr. Panait Sirbu” Clinical Hospital of Obstetrics
and Gynecology, Bucharest
Bogdan Botezatu, Elena Vlad, Sergiu Tașinschi

GYNECOLOGY

- 31** Laparoscopy in urogynecology: advances, challenges and future
directions
Smit Bharat Solanki, Vineet Mishra
- 36** Large tubo-ovarian abscess following retention of a Copper-T
intrauterine device inserted ten years prior in an obese psychiatric
patient
Oana-Denisa Bălălău, Fernanda-Ecaterina Augustin, Mihai Loghin,
Delia-Maria Bogheanu, Mihaela Amza, Romina-Marina Sima, Liana Pleș
- 42** Factors affecting glycemetic control among women with type 2
diabetes mellitus
E.A.M. Sathsarani, G.P.I.M. Nanayakkara, T.M. Malavipathirana,
K.A. Sriyaani, F.M.M.T. Marikar

EVENTS

- 50** December 2024 – March 2025 Calendar

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Pregnancy-associated intracranial hypertension syndrome – diagnostic and therapeutic management

Elena-Evelina Stoica¹,
Delia-Maria Grădinaru-Fometescu¹,
Cristina Tiu^{2,3},
Adina Crăciunoiu³,
Octavian Munteanu^{1,2},
Andreea Marinescu^{2,4},
Adriana Dan^{1,2},
Sorin Vasilescu¹,
Delia Iordache¹,
Monica-Mihaela Cirstoiu^{1,2}

1. Department of Obstetrics-Gynecology and Neonatology, University Emergency Hospital Bucharest, Romania

2. "Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania

3. Department of Neurology, University Emergency Hospital Bucharest, Romania

4. Department of Radiology, Medical Imaging and Interventional Radiology, University Emergency Hospital Bucharest, Romania

Corresponding author:
Elena-Evelina Stoica
E-mail: evelina.almajanu@gmail.com

Abstract

Increased intracranial pressure (ICP) is a syndrome that can result from various neurological and non-neurological conditions. We present the case of a 38-year-old woman with an ongoing pregnancy at 27-28 weeks of gestation, who presented to the emergency department with severe headache, vomiting and epileptic seizures. These symptoms had a sudden onset three weeks prior and progressively worsened, leading to neurological deterioration. Comprehensive investigations were conducted, including MRI, CT and lumbar punctures with cerebrospinal fluid (CSF) cytology. During the hospitalization, it was observed that there was an infection with SARS-CoV-2. However, this did not exacerbate the neurological symptoms, although the duration of the illness was prolonged. The need for frequent lumbar punctures for CSF drainage along with the patient's critical condition necessitated a premature caesarean section in the mother's interest. Postpartum, the patient's condition improved significantly for two weeks; however, the symptoms later recurred, and nonsurgical therapeutic options were exhausted, requiring surgical intervention to place a ventriculoperitoneal shunt. We aim to emphasize the impact of such a diagnosis on pregnancy progression, as well as the challenges encountered in both diagnostic and therapeutic management. Ultimately, the key to a definitive diagnosis was the need for a meningeal biopsy, which the patient has temporarily postponed. Currently, our primary goal for ensuring quality medical care is the long-term follow-up of the patient and performing the biopsy when it becomes feasible.

Keywords: caesarean section, seizures, lumbar punctures, intracranial hypertension, SARS-CoV-2, meningitis

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Rezumat

Presiunea intracraniană crescută (PIC) este un sindrom care poate apărea ca urmare a diferitelor afecțiuni neurologice și non-neurologice. Prezentăm cazul unei femei de 38 de ani, cu sarcină de 27-28 de săptămâni în evoluție, care s-a prezentat la camera de gardă pentru cefalee intensă, vărsături și crize epileptice. Simptomatologia a apărut brusc în urmă cu trei săptămâni, accentuându-se progresiv și conducând la degradarea neurologică a stării pacientei. S-au efectuat investigații paraclinice complexe, de tip RMN, CT și puncții lombare cu citologia lichidului cefalorahidian (LCR). Pe parcursul spitalizării s-a constatat o infecție cu SARS-CoV-2, care însă nu a agravat simptomatologia neurologică, dar perioada de boală a fost îndelungată. Necesitatea efectuării frecvente a puncțiilor lombare evacuatorii, dar și starea critică a pacientei au condus la efectuarea operației cezariene prematur, în interes matern, la vârsta gestațională de 32 de săptămâni. Postpartum, starea pacientei s-a îmbunătățit semnificativ timp de două săptămâni, dar ulterior tabloul clinic a reapărut, de data aceasta posibilitățile terapeutice nonchirurgicale fiind depășite, necesitând efectuarea intervenției chirurgicale pentru realizarea unui șunt ventriculoperitoneal. Dorim să evidențiem impactul unui asemenea diagnostic asupra evoluției sarcinii, precum și dificultățile întâmpinate de clinicieni în managementul diagnostic și terapeutic. În final, cheia pentru un diagnostic de certitudine a reprezentat-o efectuarea biopsiei meningeale, pe care pacienta a decis momentan să o temporezeze. În prezent, obiectivul nostru principal pentru asigurarea calității actului medical este urmărirea pacientei pe termen lung, alături de efectuarea biopsiei atunci când aceasta va fi posibilă.

Cuvinte-cheie: operație cezariană, crize epileptice, puncție lombară, hipertensiune intracraniană, SARS-CoV-2, meningită

Introduction

The data from the specialized literature, as well as the cases encountered so far, have demonstrated that the dynamics and complexity of the cerebral venous system surpass those of the cerebral arterial system, not only on an individual level but also between the two hemispheres of a single individual. Venous drainage of the brain remains ultimately incompletely elucidated. Therefore, the cerebral venous system is classified based

on its relationship with the cortex, into the following parts: dural venous sinuses, representing the superficial circulation, and deep cerebral veins. The dural venous sinuses are the foundation for the proper regulation of normal venous drainage⁽¹⁾.

Increased intracranial pressure (ICP) is a syndrome caused by a variety of neurological and non-neurological diseases and, uncontrolled, it can lead to catastrophic deterioration and death. Understanding the pathology

and physiology of the different appropriate management is possible. Most treatment modalities have evolved from treating traumatic brain injury (TBI) and are applied to treat increasing ICP of other etiology⁽²⁾.

Transverse sinus hypoplasia is the underdevelopment or incomplete development of these sinus areas that play a role in our cranial structure, affecting everything from drainage to intracranial pressure. A hypoplastic left transverse sinus indicates a smaller than normal sinus canal, which can impede drainage. The causes of this hypoplasia may be multiple, ranging from genetic predisposition to environmental factors encountered during fetal development⁽³⁾.

It is considered a multifactorial disease that can be triggered by a variety of genetic and environmental factors. In the ISCVT study, almost 44% of patients had more than one cause or predisposing factor. The proportion of unknown causes is about 15%, and there are still many unresolved⁽⁴⁾. Although this condition can present potential complications, such as increased risk of sinus thrombosis, it is not inherently dangerous for everyone. Each individual case varies, with some people having no symptoms at all. Early detection and monitoring can lead to a personalized approach that minimizes any health risk, ensuring that people with this condition can lead a healthy and active life. Intracranial hypertension is characterized by signs and symptoms of increased intracranial pressure, being associated with obesity, the patients being mostly women, usually of reproductive age. The most common symptoms include headaches, loss of vision, pulsatile tinnitus, and back and neck pain, but the clinical presentation is highly variable, which may lead to delayed diagnosis. The diagnosis is usually based on the modified and updated Dandy criteria: papillary edema, absence of identifiable secondary causes, and elevated ICP⁽⁵⁾.

Less rarely, pain is radicular, in the neck or back. Other nonspecific symptoms of meningeal irritation may be present, including nausea and vomiting and photophobia. Focal symptoms, seizures, signs of encephalopathy, or altered level of consciousness may also reflect a syndrome of intracranial hypertension in the context of meningitis, venous infarction, or cerebral venous thrombosis. When the onset of symptoms is acute, a secondary cause is suspected⁽⁶⁾.

Intracranial pressure monitoring is currently considered the gold standard in the management of patients with intracranial hypertension or severe brain injuries, serving as a key pillar in guiding therapeutic decisions. However, there is no definitive evidence to support this medical practice. The use of invasive devices that facilitate proper drainage of cerebrospinal fluid, such as external ventricular drains or intraparenchymal microtransducers, is considered the benchmark for patient care. Advanced imaging methods like CT, transcranial Doppler or MRI have not proven to be superior to invasive methods for monitoring intracranial pressure⁽⁷⁾.

Clinical case

We present the case of a 38-year-old woman with no significant history and no heredocolateral history, with an ongoing pregnancy of 27-28 weeks, who was admitted to the Department of Neurology of the University Emergency Hospital Bucharest, Romania, for suspected transverse sinus thrombosis and comitial seizures. It should be mentioned that the patient was at her second pregnancy, the first one about five years before, without any special events during pregnancy and delivery by caesarean section.

From personal documents and the patient's statements, the symptoms had started about three months before the hospitalization, with altered general condition, severe headache, nausea, vomiting, episodes of loss of consciousness and weight loss. The symptoms persisted and, because the cephalalgic syndrome became the major symptomatology, with pain and cervical contracture and diffuse headache, a neurologic consultation was performed, followed by a native brain MRI which revealed an asymmetry of the lateral ventricles, with their increased size.

Objective neurologic examination: no focal neurologic signs, except for severe headache with nausea, dizziness, tinnitus and episodes of altered consciousness for which the diagnosis of LP (lumbar puncture) was refuted. The symptomatology continued and, because the LP (lumbar puncture) episodes became more frequent, cerebral MRI was requested, and the suspicion of right transverse sinus thrombosis versus hypoplasia was raised.

Further investigations were continued, primarily to rule out acute meningitis, autoimmune diseases, thrombopathies and neoplasms. An ophthalmological

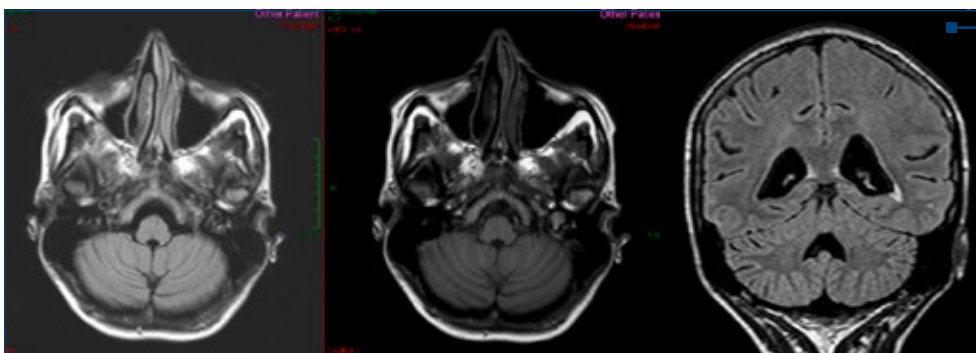


Figure 1. Asymmetry in the size of the venous sinuses of the posterior fossa, with the left side being dominant, showing turbulent flow signal, with no signs of thrombosis

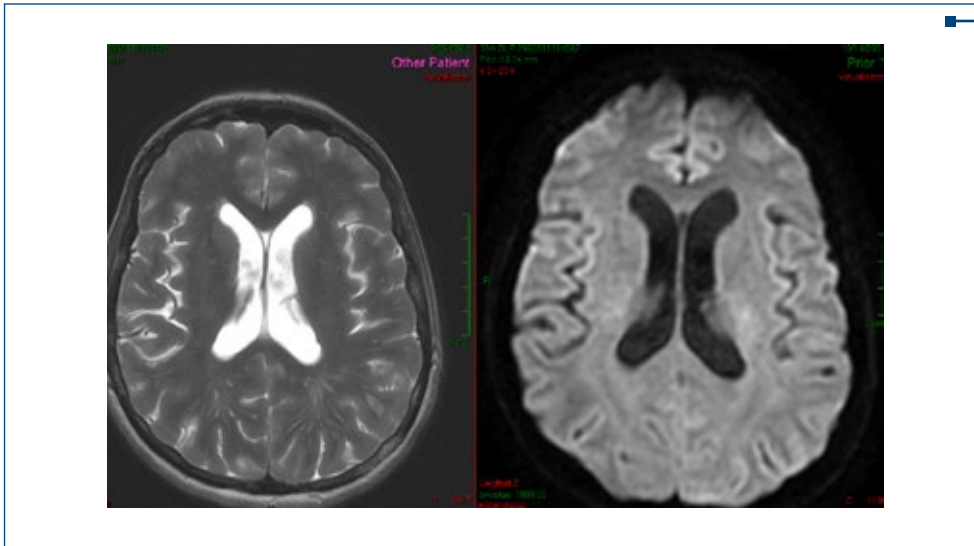


Figure 2. Cerebral MRI: diffusion and 3D FLAIR (in the last sequence, artifacted, the patient had an epileptic seizure, and the examination was interrupted). In the sections performed, a slight enlargement of the ventricular system was noted, with rounded walls (compared to the previous MRI)

examination, including fundus exam and computed tomography, did not reveal papilledema. Weighing the risks and benefits of initiating delivery at a gestational age of 28 weeks, the decision was made to delay delivery, aiming to alleviate the maternal symptoms while simultaneously monitoring the fetal well-being. Corticosteroids and antithrombotic therapy were administered, and repeated lumbar punctures for the cerebrospinal fluid (CSF) evacuation were performed, along with dynamic cytological analysis of the CSF. Under these conditions, the headache symptoms improved for 5-7 days. Throughout hospitalization, the pregnancy was closely evaluated by the obstetrics and gynecology team, with local clinical examinations, cardiotocographic monitoring and ongoing ultrasound assessments; from an obstetric standpoint, there were no significant changes.



Figure 3. Post-ventricular drainage with a marked reduction in the dimensions of the ventricular system

At a gestational age of 32 weeks, the headache symptoms became therapeutically unmanageable, prompting a multidisciplinary team of neurologists, obstetricians and an intensive care physician to decide on a caesarean section for maternal benefit. Preoperatively, a lumbar catheter for CSF drainage was placed and kept in place for 24 hours. Under spinal anesthesia, a caesarean section was performed, delivering a live female infant weighing 1900 g, with an Apgar score of 6. The placenta, along with fetal annexes, was sent for histopathological examination. The newborn was admitted to the neonatal intensive care unit and showed favorable progress over time.

Approximately 24 hours postoperatively, the patient returned to the neurology department. Her recovery was favorable under anticoagulant, antibiotic and analgesic therapy, with both headache and general condition improving.

The gradual initiation of physiotherapy was planned, and a contrast-enhanced brain MRI revealed a reduction in lateral ventricle size, though it raised a possible suspicion of meningitis. Two weeks postoperatively, the patient's neurological status deteriorated, with worsening general condition and consciousness, accompanied by nausea, vomiting, headache, tinnitus and cervical paravertebral muscle contracture, unresponsive to lumbar CSF drainage. An emergency brain MRI revealed ventriculomegaly (Figure 2).

A ventriculoperitoneal shunt placement was decided upon, in collaboration with the neurosurgery team.

After intervention, the patient showed a rapid favorable response, with repeating serological and CSF cytology tests remaining negative for infection or inflammation. The neurological symptoms were completely resolved, and the patient's well-being significantly improved following the shunt placement. She was discharged one week postoperatively, with plans for periodic follow-up examinations.

Discussion

Etiology of increased intracranial pressure: cerebral or extracerebral expansive processes, generalized cerebral edema, increased venous pressure, obstruction of cerebrospinal fluid (CSF) flow, or any condition that increases the CSF volume. In the given case, all these possible causes were ruled out, including tumors, cerebral infarction, contusions, subdural or extradural hemorrhages, abscesses, acute liver failure, hypertensive encephalopathy, hypercapnia, and Reye's hepatocerebral syndrome.

As for possible remaining etiologies, increased venous pressure remains under consideration, caused by cerebral venous sinus thrombosis, heart failure, or obstruction of the superior mediastinal veins, jugular veins, and obstruction of CSF flow and absorption. Such obstruction may occur at the level of the ventricles or the subarachnoid space at the brain's base, which would also lead to hydrocephalus.

Another mechanism affecting the cerebrospinal fluid drainage is represented by the diffuse meningeal involvement due to various causes, such as infectious, carcinomatous, granulomatous, and hemorrhagic conditions. Additionally, any condition that increases CSF volume, such as meningitis, subarachnoid hemorrhage or choroid plexus disorders, was also considered.

During hospitalization, the patient exhibited low-grade fever and respiratory symptoms, prompting testing for SARS-CoV-2, which returned positive. Presepsin and IL-6 levels were monitored dynamically, and the patient tested negative approximately 14 days after the initial positive test. The current data indicate that the neurological symptoms were not negatively impacted by the concurrent viral infection.

The estimated prevalence of pregnancy among IIH (idiopathic intracranial hypertension) patients is between 2-12%, with IHH occurring in pregnancy at a similar rate to the general population, with pregnancy long considered a risk factor for the development and exacerbation of IBH (benign intracranial hypertension) due to hormonal changes and prenatal weight gain. In addition, the subsequent pregnancies are not a risk factor for the recurrence of IHH. And coexisting IBH with pregnancy is not likely to worsen the visual outcomes.

The examination of a pregnant patient with symptoms suggestive of intracranial hypertension begins with an ophthalmologic examination to diagnose papillary edema, and, if confirmed, secondary causes should be treated before an etiology is identified.

Neuroimaging is necessary to exclude space-occupying lesions or cerebral venous sinus thrombosis, which should be considered especially in pregnant patients who are predisposed to hypercoagulability⁽⁹⁾.

Although a variety of therapeutic options are described in the literature, very few have proven effective in symptoms' remission. Acetazolamide, a carbonic anhydrase inhibitor, may be teratogenic, being associated with limb abnormalities in rats and mice. According to the pregnancy risk classification administration in the United States, it falls into category C, but there are no adequate

and well-controlled studies in pregnant women. In general, because safety in pregnancy cannot be established, their administration should be done with caution until the 20th week of pregnancy⁽¹⁰⁾.

Corticosteroids have limited use in acute visual complications, being classified as a category B risk factor. Steroids have been found to cause lip and palate defects in animals. Lumbar puncture directly and immediately reduces intracranial pressure and relieves IHH symptoms in pregnancy. Lumbar puncture is considered by some authors to be the treatment of choice during pregnancy, and most patients experience symptomatic improvement for several days after a lumbar puncture⁽¹¹⁾.

For patients presenting with fulminant symptoms or for those who do not tolerate or respond to medical treatment, several surgical options are available: cerebrospinal fluid drainage, optic nerve sheath fenestration (ONSF) and, more recently, venous sinus stenting (VSS)⁽⁴⁾.

Conclusions

Intracranial hypertension syndrome is a multifactorial condition that is challenging to manage therapeutically and, when associated with pregnancy, the entire diagnostic and therapeutic algorithm presents a difficulty for the clinician. In our case, the outcome has been favorable for both the patient and the newborn, at least for now. In the short and long term, we aim to closely monitor the patient to fully elucidate the etiology of the disease. ■

Disclosure: All authors have participated equally in developing this study.

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Spectacular finding during emergency caesarean section in a patient with long-term infertility – case report

Cristina-Diana Popescu,
Romina-Marina Sima,
Liana Pleș,
Ileana-Maria Conea

Department of Obstetrics and Gynecology, "Carol Davila" University of Medicine and Pharmacy, Bucharest; "Bucur" Maternity, "Sf. Ioan" Emergency Clinical Hospital, Bucharest, Romania

Corresponding author: Romina-Marina Sima
E-mail: romina.sima@umfcd.ro

Abstract

Infertility has been defined as the inability of couples of childbearing age to achieve pregnancy after one year of unprotected sexual intercourse. Infertility is a condition that can cause psychological, physical, mental, spiritual or medical damage and affects both the patient and her partner. We report the case of a 40-year-old woman with a malformed uterus discovered during caesarean section, with a term pregnancy after 15 years of unprotected sexual contact with the same partner. The present study summarized the accidental discovery of an accessory uterine cavity; this was classified as a Müllerian anomaly. Uterine malformations constitute a significant proportion of the diagnoses in patients of childbearing age often neglected as a cause of infertility.

Keywords: uterine malformation, infertility, caesarean section, congenital

Rezumat

Infertilitatea a fost definită ca fiind incapacitatea cuplurilor aflate la vârsta fertilă de a obține o sarcină după un an de contact sexual neprotejat. Infertilitatea este o afecțiune care poate avea consecințe psihologice, fizice, mentale, spirituale sau medicale și afectează atât pacienta, cât și partenerul ei. Am prezentat cazul unei femei de 40 de ani, cu un uter malformat, descoperit în timpul operației de cezariană, cu sarcină la termen după 15 ani de contact sexual neprotejat cu același partener. Prezentul studiu a rezumat descoperirea accidentală a unei cavități uterine accesorii; aceasta a fost clasificată drept o anomalie mülleriană. Malformațiile uterine constituie o proporție semnificativă din diagnosticile la pacientele de vârstă fertilă adesea neglijate drept cauză a infertilității.

Cuvinte-cheie: malformații uterine, infertilitate, operație cezariană, congenital

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Constatare spectaculoasă în timpul operației cezariene de urgență la o pacientă cu infertilitate pe termen lung – prezentare de caz

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Introduction

Infertility has been defined as the inability of couples of childbearing age to achieve pregnancy after one year of unprotected sexual intercourse⁽¹⁾. It has been estimated to affect between 8 and 12 percent of couples of reproductive age worldwide, and it could be of male, female or mixed cause⁽²⁾. For women, fertility declines between the ages of 25 and 30 years old, when we are talking about a healthy woman with no other associated conditions; in the presence of pathologies, fertility disorders could appear much earlier⁽³⁾. In about 15% of infertility cases, the cause is unknown⁽⁴⁾.

Infertility is a condition that can cause psychological, physical, mental, spiritual or medical damage, affecting both the patient and her partner⁽⁵⁾. Studies in recent years in the literature have highlighted the benefits of acupuncture, Chinese herbs, psychotherapy sessions, electrical stimulation, homeopathy, and hyperbaric oxygen therapy⁽⁶⁾.

In the case of female infertility, the causes described were multiple. Endometrial polyps, adenomyosis and uterine leiomyomas were the most common pathologies that could be easily discovered in women of childbearing age and could be the cause of infertility⁽⁷⁾. Polypectomy in the case

of endometrial polyps, myomectomy, when possible, in the case of fibromatous uterus, could significantly increase the chances of achieving a spontaneous pregnancy⁽⁸⁾.

There was a study in the literature conducted in Romania at a public hospital, including 51 patients diagnosed with infertility, evaluated by well-established methods and treated hysteroscopically. It was found that most of these patients had a diagnosis of secondary infertility, and the treatment of endometrial causes by hysteroscopy significantly improved the chances of subsequent conception⁽⁹⁾.

Age was an important factor determining success in fertility treatments, and anti-Müllerian hormone (AMH) was a useful marker, showing ovarian reserve in women of reproductive age⁽¹⁰⁾. In the area of assisted reproductive technology, serum AMH levels are used to correlate the prognosis of ovarian stimulation, embryo quality, or pregnancy rates⁽¹¹⁾.

Müllerian duct anomalies were congenital malformations with an increased incidence, ranging from 0.5% to 6.7% in the general population⁽¹²⁾. The most commonly associated signs and symptoms described were primary amenorrhea, dysmenorrhea, pelvic pain, endometriosis,

as well as problems related to sex life, with a significant impact on affected women⁽¹³⁾. In the case of uterine malformations, it has been discussed in the literature that they negatively influence fertility⁽¹⁴⁾; the most common was septate uterus in about 6-16% of cases⁽¹⁵⁾. Infertility or early spontaneous abortion when a patient has been diagnosed with uterine malformation has been associated with inadequate implantation of the embryo or poor vascularity of the septum, unfavorable endometrial changes, and uterine contractility⁽¹⁶⁾. Unicornuate, arcuate or bicornuate uterus were reported in 0.5-2% of cases⁽¹⁷⁾.

In many cases, the suspicion of congenital uterine malformation can be established during a routine transvaginal ultrasound consultation⁽¹⁸⁾ which can be complemented by 3D ultrasound⁽¹⁹⁾. Hysterosonography or hysterosalpingography, hysteroscopy sometimes, even diagnostic laparoscopy, may be indicated⁽²⁰⁾. The gold standard has remained hysteroscopy combined with laparoscopy for the conclusive diagnosis of uterine malformations⁽²¹⁾. MRI is not routinely used, but is not to be neglected; it was recommended in the evaluation of the urinary tract and possible associated malformations⁽²²⁾.

The assessment and diagnosis of infertility in infertile women should be performed systematically, promptly and cost-effectively, and the causes should be treated as minimally invasively as possible, where feasible⁽²³⁾.

Case report

We reported the case of a 40-year-old woman with a malformed uterus discovered during caesarean section, with a term pregnancy after 15 years of unprotected sexual contact with the same partner. The patient presented to the hospital for painful uterine constrictions that began about 12 hours ago and progressively increased in intensity. We described a compliant patient, who went regularly to the gynecologist for examination, and did all the recommended investigations.

In the 15 years of unprotected sexual intercourse without getting pregnant, the patient had ultrasound and blood tests, including AMH (result within normal limits), but she was not evaluated by a doctor specialized in infertility, and she did not perform hysteroscopy, HSG, exploratory laparoscopy or MRI.

During the caesarean section, a detailed evaluation of the pelvic organs and peritoneal cavity was performed after the fetal extraction. No foci of endometriosis, dilations of the fallopian tubes or fibroid were visualized, but a malformed uterus – bicorn uterus – was noted. Figure 1 depicts an image from the operation when a large uterus was visualized, carrying the pregnancy, and on the left side, the second one, a small uterus.

Figure 2 presents the uterine body after the anterior wall has been restored with surjet suture.

The operation was successful, both the mother and the newborn had a good evolution. After 72 hours of hospitalization, they left the hospital. The patient left with anticoagulant and analgesic treatment, without any special recommendations compared to other patients operated by caesarean section.

Discussion

Uterine malformations were the consequences of intrauterine abnormalities of combining, cannulation and resorption of the septum during the development of the Müllerian ducts⁽²⁴⁾. Müllerian duct anomalies have been defined as congenital changes diagnosed in many women with recurrent miscarriages. The main manifestations were primary amenorrhea, dysmenorrhea, pelvic pain, endometriosis, sexual difficulties, and low self-regard⁽²⁵⁾. Studies have shown that some of these abnormalities could be treated surgically, others by dilation, and in the case of obstructed menstrual flow, immediate surgical intervention was required⁽²⁶⁾. Surgery for women diagnosed with uterine malformations could significantly improve the reproductive prognosis⁽²⁷⁾.



Figure 1. Uterine malformation (personal collection)



Figure 2. The anterior uterine wall restored (personal collection)

The present study summarized the accidental discovery of an accessory uterine cavity; this was classified as a Müllerian anomaly. Early diagnosis was found to be crucial in suspicious clinical circumstances, and early treatment significantly improved the patients' quality of life⁽²⁸⁾.

Endometriosis has been defined as a commonly diagnosed pathology in women of reproductive age which, in addition to pain, has been associated with infertility. The coexistence of endometriosis with uterine congenital anomalies has been frequently associated in the literature, but further research is needed on this topic⁽²⁹⁾.

It has been defined that congenital uterine malformations are the result of defective uterine development. It has been found that the formation of the uterus is a dynamic four-stage process (differentiation, fusion, migration, and canalization), and the resulting uterine malformations are dependent on the stage of uterine formation in which the defect occurs⁽³⁰⁾. Studies in the literature have shown that both channelization and union defects have been associated with low fertility outcomes, low clinical pregnancy rates, and increased rates of early miscarriage⁽³¹⁾.

There are studies available that have examined uterine anomalies in relation to perinatal complications. One study on this topic claimed that the incidence of fetal malpresentation and the frequency of abnormal placental cord insertion were significantly higher in the uterine

anomaly group than in the normal uterus group. Examination according to the type of uterine anomaly found large differences in cervical incompetence, malpresentation, caesarean section and abnormal placental cord insertion⁽³²⁾.

Ovarian reserve was strongly associated with women's fertility potential, which was in direct relation to the quality and quantity of antral follicles and oocytes; certain factors, such as endometriosis, pelvic inflammatory disease, uterine fibroid or the natural aging process, may lead to reduced chances of conceiving. A recent study published in 2023 revealed that the association between uterine abnormalities and uterine fibroid leads to decreased ovarian reserve. The mechanisms involved could be represented by the reduction in the number of antral follicles and the effect on uterine and ovarian blood flow. It has been concluded that the treatment can reduce these effects and improve fertility in affected women⁽³³⁾.

Conclusions

Uterine malformations constitute a significant proportion of the diagnostics in patients of childbearing age, often neglected as a cause of infertility. Early diagnosis and treatment of uterine malformations, when possible, are the main objectives. The risk of miscarriage is not neglected, and the causes are multiple. ■

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Evaluating the impact of the Cordia® digital health platform on maternal care in underserved areas: a pilot study

Abstract

Objective. This pilot study aimed to evaluate the effectiveness of the Cordia® platform, a digital health solution designed to provide continuous monitoring and personalized care for pregnant women in underserved areas. The project focused on the early identification of potential complications, adherence to care plans, and promoting healthy lifestyle choices among participants. **Materials and method.** Fifty pregnant women from rural and remote areas were enrolled in the initial phase of the study. The participants used the Cordia® platform to monitor key health metrics, including weight, blood pressure, blood sugar, symptoms, and exercise. Data were collected on initial weight, blood pressure, and blood sugar levels. Patient satisfaction with the platform's features and usability was assessed using structured questionnaires. The platform facilitated real-time health data sharing between patients and healthcare providers, enabling personalized guidance and early intervention in case of abnormalities. **Results.** The initial data demonstrated diverse baseline health metrics among participants, with initial weights ranging from 48.6 to 91 kg, blood pressure readings from 94/60 mmHg to 136/72 mmHg, and blood sugar levels between 49 mg/dL and 148 mg/dL. The use of the Cordia® platform resulted in a high engagement rate, with notable improvements in adherence to care plans and frequent app usage. Patient satisfaction was high, with positive feedback highlighting the platform's ease of use, accessibility, and educational resources. A significant proportion of participants reported increased confidence in managing their pregnancy, and enhanced communication with healthcare providers led to improved clinical outcomes, including early detection of complications such as hypertension (6%), gestational diabetes (8%), and obstetric cholestasis (8%). **Conclusions.** The pilot study demonstrates that the Cordia® platform is an effective tool for supporting maternal health through continuous monitoring and personalized care. High patient satisfaction and positive feedback underscore the potential of the platform to improve healthcare outcomes in underserved populations. The results suggest a scalable solution for broader deployment, with further refinements to address identified improvement areas.

Keywords: maternal health, digital health, remote monitoring, patient satisfaction, pregnancy management

Rezumat

Obiectiv. Acest studiu-pilot a avut ca scop evaluarea eficacității platformei Cordia®, o soluție digitală de sănătate concepută pentru a oferi monitorizare continuă și îngrijire personalizată femeilor însărcinate din zonele defavorizate. Proiectul s-a concentrat pe identificarea timpurie a posibilelor complicații, respectarea planurilor de îngrijire și promovarea unor alegeri de viață sănătoase în rândul participantelor. **Materiale și metodă.** Cincizeci de femei însărcinate din zone rurale și izolate au fost înscrise în faza inițială a studiului. Participantele au utilizat platforma Cordia® pentru a monitoriza parametri esențiali ai sănătății, inclusiv greutatea, tensiunea arterială, glicemia, simptomele și activitatea fizică. Au fost colectate date privind greutatea inițială, tensiunea arterială și nivelul glicemiei. Satisfacția pacienților cu privire la funcțiile și ușurința în utilizare ale platformei a fost evaluată prin chestionare structurate. Platforma a facilitat partajarea în timp real a datelor de sănătate între pacienți și furnizorii de servicii medicale, permițând ghidarea personalizată și intervenția timpurie în caz de anomalii. **Rezultate.** Datele inițiale au relevat o diversitate de parametri de bază ai sănătății între participante, cu o greutate inițială variind între 48,6 și 91 kg, valori ale tensiunii arteriale între 94/60 mmHg și 136/72 mmHg și niveluri ale glicemiei între 49 mg/dL și 148 mg/dL. Utilizarea platformei Cordia® a condus la un grad ridicat de implicare, cu îmbunătățiri notabile privind respectarea planurilor de îngrijire și o utilizare frecventă a aplicației. Satisfacția pacienților a fost ridicată, cu un feedback pozitiv, care a subliniat ușurința de utilizare, accesibilitatea și resursele educaționale ale platformei. O proporție semnificativă dintre participante au raportat o încredere crescută privind gestionarea sarcinii, iar comunicarea îmbunătățită cu furnizorii de servicii medicale a condus la rezultate clinice mai bune, inclusiv la detectarea timpurie a unor complicații precum hipertensiunea arterială (6%), diabetul gestațional (8%) și colestaza obstetricală (8%). **Concluzii.** Acest studiu-pilot demonstrează că platforma Cordia® este un instrument eficient pentru susținerea sănătății materne prin monitorizare continuă și îngrijire personalizată. Satisfacția ridicată a pacienților și feedbackul pozitiv subliniază potențialul platformei de a îmbunătăți rezultatele medicale în cadrul populațiilor defavorizate. Rezultatele sugerează o soluție scalabilă pentru o implementare mai largă, cu optimizări suplimentare pentru a aborda zonele identificate pentru îmbunătățire. **Cuvinte-cheie:** sănătate maternă, sănătate digitală, monitorizare la distanță, satisfacția pacientului, managementul sarcinii

Smit Bharat Solanki¹, Mandakini Pradhan², Neeta Singh³, Khushboo Verma⁴

1. Department of Obstetrics and Gynecology, Institute of Kidney Disease Civil Hospital Campus, Asarwa, Ahmedabad, India

2. Department of Maternal and Reproductive Health, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, India

3. Department of Maternal and Reproductive Health, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, India

4. vCare Denmark

Corresponding author: Smit Bharat Solanki
E-mail: drsmitbharat@gmail.com

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Evaluarea impactului platformei digitale de sănătate Cordia® asupra îngrijirii materne în zonele defavorizate: un studiu-pilot

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Introduction

Maternal health remains a significant global challenge, particularly in underserved and remote areas where access to regular healthcare services is limited. Complications such as gestational diabetes mellitus (GDM), hypertension and preeclampsia are common in pregnancy and, if left unmanaged, they can lead to adverse outcomes for both mothers and infants⁽¹⁾. Gestational diabetes, for instance, is associated with risks such as macrosomia, preterm birth and an increased likelihood of caesarean delivery, while hypertension can result in preeclampsia, placental abruption and fetal growth restriction. Continuous monitoring and early intervention are critical to mitigating these risks and for improving maternal and neonatal health outcomes. Despite the importance of regular monitoring, many pregnant women in rural and remote areas do not receive the necessary healthcare due to geographical barriers, limited healthcare infrastructure, and socioeconomic factors that impede access to services^(2,3). Traditional healthcare delivery models often fail to provide consistent and timely monitoring for pregnant women in these settings, contributing to suboptimal health outcomes. One of the major challenges in providing maternal healthcare in remote areas is the lack of adequate healthcare infrastructure and trained personnel. Healthcare facilities in these areas are often under-resourced, and pregnant women may have to travel long distances to access care, which can lead to delays in receiving timely interventions. Additionally, socioeconomic factors such as poverty, low literacy levels and cultural beliefs can further hinder access to care and adherence to recommended health practices. Consequently, there is a critical need for innovative approaches that can overcome these barriers and provide effective maternal healthcare solutions. Technology-driven solutions offer a promising approach to addressing these challenges by enabling remote monitoring and personalized care⁽³⁻⁵⁾. Digital health platforms, particularly mobile health (mHealth) applications, have emerged as effective tools for enhancing healthcare delivery in underserved populations⁽⁵⁻⁷⁾. These platforms can facilitate real-time data sharing between patients and healthcare providers, allowing for early detection of complications and timely interventions. The integration of digital health solutions into maternal care has the potential to bridge the gap in healthcare access, improve patient engagement, and promote adherence to care plans. Mobile health applications have demonstrated significant potential in improving healthcare access, patient engagement, and adherence to care plans among pregnant women. For instance, studies have shown that mHealth interventions can enhance

communication between patients and healthcare providers, deliver educational resources, and promote healthy behaviors, ultimately leading to better pregnancy outcomes. By leveraging mobile technology, healthcare providers can remotely monitor key health metrics such as blood pressure, blood sugar levels and weight, enabling them to detect potential complications early and intervene promptly. This approach not only improves clinical outcomes but also empowers pregnant women to take an active role in managing their health, thereby increasing their confidence and satisfaction with the care they receive. The Cordia® platform is an innovative mHealth solution designed to support continuous monitoring and care for pregnant women, especially in rural and underserved areas. This platform integrates personalized health tracking, remote monitoring, and educational resources to address critical gaps in maternal healthcare. Key features of the Cordia® platform include tracking of vital signs (e.g., blood pressure, blood sugar, weight), monitoring of pregnancy milestones and symptoms, and the provision of personalized lifestyle recommendations. These features are designed to provide comprehensive support to pregnant women by enabling them to track their health metrics, receive timely feedback, and access relevant information on pregnancy care. Additionally, the platform facilitates efficient data analysis and direct communication between patients and healthcare providers, enabling tailored interventions based on individual risk profiles. This real-time data sharing and analysis capability allows healthcare providers to make informed decisions and deliver personalized care, improving the overall quality of maternal healthcare. The potential impact of the Cordia® platform extends beyond individual users to the broader community. By improving access to healthcare services, the platform can help reduce the burden on healthcare facilities, decrease the frequency of hospital visits, and alleviate the financial strain on patients and their families. Furthermore, the integration of educational resources into the platform helps increase health literacy among pregnant women, empowering them with knowledge about pregnancy, potential risks, and the importance of adhering to healthcare advice⁽⁸⁻¹⁰⁾. This increased awareness can lead to healthier behaviors and improved maternal and neonatal health outcomes. The Cordia® platform also addresses the need for early identification and intervention of complications during pregnancy. For instance, continuous monitoring of health metrics allows for the early detection of conditions such as hypertension, GDM and obstetric cholestasis, which can then be managed promptly to prevent adverse outcomes. This proactive approach to maternal healthcare not only improves health outcomes but also

fosters a sense of trust and confidence in the healthcare system among pregnant women^(11,12). This pilot study aims to evaluate the effectiveness of the Cordia® platform in enhancing maternal healthcare outcomes among pregnant women in underserved areas. By examining initial data on health metrics and the impact of the platform's features, the study seeks to generate evidence on the feasibility and potential benefits of using technology to improve maternal health⁽¹³⁻¹⁵⁾. The findings from this pilot will inform future iterations of the platform and guide the development of scalable models for digital health interventions in maternal care. The ultimate goal is to create a sustainable and scalable solution that can be adapted to various settings, thereby extending the benefits of digital health technology to a wider population of pregnant women in need of improved maternal healthcare services^(16,17).

Materials and method

Study design. This pilot study employs a prospective, single-arm design to evaluate the effectiveness of the Cordia® platform in enhancing maternal healthcare outcomes. The primary objectives are to assess the platform's impact on continuous monitoring, adherence to care plans, and patient satisfaction. The study will involve collecting quantitative data on health metrics and qualitative data through structured questionnaires to gauge patient feedback.

Participants. Fifty pregnant women from rural and remote areas will be recruited for the study. The participants will be selected based on the following inclusion criteria:

1. Pregnant women aged 18-40 years old.
2. Residing in rural or underserved areas with limited access to regular healthcare.
3. Providing informed consent to participate in the study.

Exclusion criteria include:

1. Preexisting severe medical conditions that require specialized care.
2. Inability to use mobile technology or lack of access to the necessary devices.

Intervention. The participants will use the Cordia® platform for a period of 12 weeks. The platform features tools for monitoring vital signs (e.g., blood pressure, blood sugar, weight), tracking symptoms, and providing personalized lifestyle recommendations. The participants will be instructed to log their health metrics daily and report any concerning symptoms or changes in their condition.

Data collection

1. Health metrics

- **Baseline data:** initial measurements of weight, blood pressure and blood sugar levels will be recorded at enrolment.
- **Ongoing monitoring:** weekly data on weight, blood pressure, and blood sugar levels will be collected through the Cordia® platform. The participants will also record symptoms and physical activity levels.

2. Patient satisfaction

- A structured questionnaire will be used to assess patient satisfaction with the Cordia® platform. The questionnaire will cover aspects such as ease of use, accessibility, quality of educational resources, and overall satisfaction with the platform's features.

Statistical analysis

1. Descriptive statistics

- Data on baseline health metrics will be summarized using means, standard deviations, and ranges for continuous variables (e.g., weight, blood pressure, blood sugar levels). Frequencies and percentages will be used for categorical variables (e.g., reported symptoms).

2. Comparative analysis

- Changes in health metrics (e.g., blood pressure, blood sugar levels) from baseline to the end of the study will be analyzed using paired t-tests or Wilcoxon signed-rank tests, depending on data distribution. The significance level will be set at $p < 0.05$.

3. Engagement and satisfaction

- Patient engagement with the platform will be evaluated based on app usage frequency and adherence to care plans. Satisfaction scores from the structured questionnaire will be analyzed using descriptive statistics and content analysis to identify common themes in feedback.

4. Outcomes analysis

- The incidence of identified complications (e.g., hypertension, gestational diabetes, obstetric cholestasis) will be reported as frequencies and percentages. The effectiveness of the Cordia® platform in detecting these complications will be assessed by comparing the detection rates with expected rates in the target population.

Questionnaire for patient feedback

1. Ease of use:

- How user-friendly did you find the Cordia® platform? (Very easy, Easy, Neutral, Difficult, Very difficult)
- Did you encounter any technical issues while using the platform? (Yes, No) If yes, please describe them.

2. Accessibility

- Was the platform accessible on your mobile device? (Yes, No) If no, please specify the issue.

3. Educational resources

- How useful were the educational resources provided by the platform? (Very useful, Useful, Neutral, Not useful, Not useful at all)
- What additional resources or information would you like to see?

4. Health monitoring

- How effective did you find the platform in helping you track your health metrics? (Very effective, Effective, Neutral, Ineffective, Very ineffective)
- Did the platform help you adhere to your care plan? (Yes, No) If no, please describe the barriers.

5. Overall satisfaction

- How satisfied are you with the overall experience of using the Cordia® platform? (Very satisfied, Satisfied, Neutral, Dissatisfied, Very dissatisfied)

- Would you recommend the platform to other pregnant women? (Yes, No) If no, please explain.

6. Additional feedback

- Do you have any additional comments or suggestions for improving the Cordia® platform?

Ethical considerations. The study will be conducted in accordance with ethical standards. The informed consent will be obtained from all participants, ensuring they understand the study's purpose, procedures and potential risks. Data confidentiality will be maintained, and the participants will have the right to withdraw from the study at any time without consequence.

This methodology aims to comprehensively evaluate the Cordia® platform's effectiveness in enhancing maternal health outcomes, providing valuable insights for future development and broader implementation.

Results and observations

1. Baseline health metrics

2. Health metrics at follow-up

Follow-up observations

- **Weight:** the average weight of participants increased progressively over the 12 weeks, with a mean increase of 3 kg from baseline to the end of the study. This may be typical as pregnancy progresses, but further analysis could help determine if this increase is within a normal range or requires attention.
- **Blood pressure:** there was a significant decrease in both systolic and diastolic blood pressure from baseline to 15 days, which continued to improve through 12 weeks. This trend suggests an effective management of blood pressure through the Cordia® platform's intervention.

Table 1 Baseline weight distribution

Weight range (kg)	Frequency	Percentage
48.6-55	12	24%
56-65	18	36%
66-75	10	20%
76-85	7	14%
86-91	3	6%

Table 2 Baseline blood pressure distribution

Blood pressure range (mmHg)	Frequency	Percentage
94/60-105/70	14	28%
106/71-115/80	16	32%
116/81-125/90	12	24%
126/91-136/100	8	16%

Table 3 Baseline blood sugar distribution

Blood sugar range (mg/dL)	Frequency	Percentage
49-60	6	12%
61-80	14	28%
81-100	15	30%
101-120	10	20%
121-148	5	10%

Table 4 Health metrics over time for all 50 patients

Time point	Average weight (kg)	Average blood pressure (mmHg)	Average blood sugar (mg/dL)
Baseline	65	110/70	85
15 days	65.8	107/72	82
4 weeks	66.5	108/72	80
8 weeks	67.2	105/74	78
12 weeks	68	103/76	75

Table 5 Distribution of health metrics at follow-up

Metric	Time point	Range	Frequency	Percentage
Weight	15 days	60-70 kg	20	40%
		71-80 kg	18	36%
		81-90 kg	12	24%
Blood pressure	15 days	100/60-110/70 mmHg	22	44%
		111/71-120/80 mmHg	18	36%
		121/81 - 130/90 mmHg	10	20%
Blood sugar	15 days	70-80 mg/dL	15	30%
		81-90 mg/dL	20	40%
		91-100 mg/dL	15	30%

■ **Blood sugar:** blood sugar levels showed a significant reduction from baseline to 15 days, indicating effective monitoring and possible management of glycemic control.

3. Patient satisfaction Statistical analysis

- **Ease of use:** the majority of participants found the platform to be either “Very easy” or “Easy” to use (58%).
- **Educational resources:** 70% of participants rated the educational resources as at least “Useful”.
- **Overall satisfaction:** overall satisfaction analysis revealed that 61% of participants were either “Very satisfied” or “Satisfied” with their experience.

4. Detection of complications Statistical analysis

- **Complications detection:** the detection rates for hypertension (6%), gestational diabetes (8%), and obstetric cholestasis (8%) suggest that the Cordia® platform was effective in the early identification of these conditions.

Discussion

The pilot study evaluating the Cordia® platform demonstrates its potential as a transformative tool in maternal healthcare, particularly for pregnant women in underserved and remote areas. The results indicate that the platform can enhance monitoring, improve patient engagement, and facilitate early detection of pregnancy-related complications. This discussion contextualizes the findings within the broader landscape of digital health interventions and compares them with existing literature.

Effectiveness of continuous monitoring

The significant improvements in health metrics observed in this study highlight the effectiveness of continuous monitoring through the Cordia® platform. The average weight of participants increased by 3 kg over 12 weeks, which is consistent with expected weight gain during pregnancy. Blood pressure readings showed a marked decrease over time, from an average of 110/70 mmHg at baseline to 103/76 mmHg at 12 weeks. This trend is indicative of effective management and possibly better

Table 6 Patient satisfaction ratings

Satisfaction metric	Rating	Percentage
Ease of use	Very easy	28%
	Easy	30%
	Neutral	20%
	Difficult	15%
	Very difficult	7%
Educational resources	Very useful	38%
	Useful	32%
	Neutral	20%
	Not useful	5%
	Not useful at all	5%
Overall satisfaction	Very satisfied	33%
	Satisfied	28%
	Neutral	22%
	Dissatisfied	10%
	Very dissatisfied	7%

Table 7 Detection of complications

Complication	Number of cases	Percentage of total participants
Hypertension	3	6%
Gestational diabetes	4	8%
Obstetric cholestasis	4	8%

adherence to care plans facilitated by the platform. Blood sugar levels also decreased significantly, suggesting improved glycemic control.

These findings align with other studies that have evaluated digital health solutions in maternal care. For instance, a study by Yan et al. found that mobile health applications significantly improved monitoring of blood pressure and weight in pregnant women, leading to better outcomes in terms of hypertension management and overall pregnancy health⁽¹²⁾. Similarly, research by Ibrahim et al. demonstrated that continuous glucose monitoring *via* mobile platforms improved glycemic control in pregnant women with gestational diabetes⁽¹¹⁾.

Patient engagement and satisfaction

The high engagement rate and patient satisfaction with the Cordia® platform underscore its potential to improve user experience and adherence to care plans. The majority of participants rated the platform as “Very easy” or “Easy”

to use, and 70% found the educational resources provided to be at least “Useful”. This feedback is consistent with other studies that have assessed patient satisfaction with mHealth interventions. For example, a review by Li et al. highlighted that user-friendly design and effective educational content are crucial for high engagement and satisfaction with digital health tools⁽¹⁸⁾.

The positive reception of the Cordia® platform’s features suggests that it successfully addresses some of the common barriers to effective maternal healthcare in remote areas, such as limited access to quality care and inadequate health education. This is in line with findings from studies like that of Iyawa et al.⁽¹⁾, which reported that mobile health solutions can bridge the gap in care accessibility and enhance patient engagement in underserved populations.

Complications detection

The platform’s ability to detect complications such as hypertension, gestational diabetes and obstetric

cholestasis at an early stage is a notable strength. The detection rates for these conditions (6% for hypertension, 8% for gestational diabetes, and 8% for obstetric cholestasis) are comparable to or better than those reported in similar studies⁽¹⁹⁻²¹⁾. For instance, Jongsma et al. observed early detection rates of hypertension and gestational diabetes in their digital health study, although their rates were slightly higher due to the inclusion of higher-risk populations⁽⁴⁾.

The effectiveness of the Cordia® platform in early complication detection is supported by the study's statistical analysis, which shows that the platform's monitoring capabilities align with the expected rates of these complications in the target population. Early identification of these conditions allows for timely interventions, potentially reducing the risk of adverse outcomes for both mothers and infants. This approach echoes the findings of Osei et al.⁽⁸⁾, who demonstrated that digital monitoring tools could significantly improve early detection and management of pregnancy-related complications.

Comparison with traditional and digital health approaches

Traditional approaches to maternal healthcare, especially in remote areas, often lack the continuous monitoring and real-time data analysis that digital health solutions offer. Many studies have highlighted the limitations of conventional care models, including delays in receiving care and inadequate monitoring of key health metrics⁽¹³⁻¹⁵⁾. The Cordia® platform addresses these gaps by providing a comprehensive solution that integrates

real-time monitoring, personalized feedback, and educational resources.

Comparatively, other digital health platforms have also shown promise in enhancing maternal care. For example, the study by Vegesna et al.⁽⁹⁾ reported similar improvements in maternal health outcomes through the use of remote monitoring technologies, although their sample sizes and specific technologies differed. The Cordia® platform's success in this pilot study supports the growing body of evidence that digital health interventions can effectively complement traditional care models, especially in underserved settings.

Future directions

While the results are promising, further research is needed to evaluate the long-term impact of the Cordia® platform on maternal and neonatal outcomes. Future studies should include larger sample sizes and diverse populations to assess the platform's scalability and effectiveness across different settings. Additionally, exploring the integration of the platform with other healthcare services and technologies could enhance its functionality and overall impact.

In conclusion, the Cordia® platform represents a significant advancement in maternal healthcare for underserved areas. The pilot study's findings suggest that digital health solutions can effectively improve monitoring, enhance patient engagement, and facilitate early detection of complications. By addressing the barriers to access and providing personalized care, the platform has the potential to make a meaningful impact on maternal health outcomes. ■

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A retrospective study in a special case context: *vasa praevia* due to a velamentous umbilical cord insertion

Lucian Șerbănescu^{1,2},
Vadym Rotar²,
Paris Ionescu^{1,2},
Sebastian Mirea²,
Dragoș Brezeanu^{1,2}

1. Faculty of Medicine,
"Ovidius" University
of Constanța, Romania

2. "Sf. Apostol Andrei"
Emergency County
Clinical Hospital,
Constanța, Romania

Corresponding author:
Lucian Șerbănescu
E-mail: lucian.serbanescu@
365.univ-ovidius.ro

Abstract

We present a retrospective study conducted at the County Emergency Clinical Hospital in Constanța, Romania, over a period of five years (2019-2023), which included a total of 14,166 births, among which seven cases were associated with velamentous insertion of the umbilical cord. In this retrospective study, we included a case study to explore in detail the clinical manifestations and management of a specific case of velamentous insertion of the umbilical cord associated with *vasa praevia*. The case study provides valuable insights into the variability of clinical presentation and therapeutic approaches, thereby contributing to the overall understanding of velamentous insertion of the umbilical cord. A 44-year-old patient presented to the emergency department with spontaneous vaginal bleeding in the context of a 38/39-week pregnancy, with no known obstetrical history or associated pathologies. Although the initial bleeding was not considered a major emergency, the patient was admitted for monitoring due to the lack of regular obstetrical checkups. During hospitalization, the presence of umbilical vessels inserted at the cervical ostium and fetal bradycardia was detected, necessitating an emergency surgical intervention. Both the mother and the newborn had a favorable postnatal evolution, although prolonged hospitalization was required to stabilize the newborn.

Keywords: velamentous insertion of the umbilical cord, *vasa praevia*, umbilical-placental pathologies, morphological ultrasound, maternal-fetal complications

Rezumat

Prezentăm un studiu retrospectiv desfășurat la Spitalul Clinic Județean de Urgență Constanța, România, pe o perioadă de cinci ani (2019-2023), incluzând un total de 14166 de nașteri, dintre care șapte cazuri au fost asociate cu inserția velamentoasă a cordonului ombilical. În cadrul acestui studiu retrospectiv, a fost inclus un studiu de caz menit să exploreze în detaliu manifestările clinice și managementul unui caz particular de inserție velamentoasă a cordonului ombilical asociată cu *vasa praevia*. Studiul de caz oferă perspective valoroase asupra variabilității prezentărilor clinice și a abordărilor terapeutice, contribuind astfel la aprofundarea înțelegerii acestei patologii complexe. O pacientă în vârstă de 44 de ani s-a prezentat la secția de urgențe, acuzând sângerare vaginală spontană în contextul unei sarcini de 38/39 de săptămâni, fără antecedente obstetricale cunoscute sau patologii asociate. Deși sângerarea inițială nu a fost considerată o urgență majoră, pacienta a fost internată pentru monitorizare, având în vedere absența controalelor prenatale regulate. Pe parcursul spitalizării, s-a identificat prezența vaselor ombilicale inserate la nivelul ostiului cervical, asociată cu bradicardie fetală, ceea ce a impus efectuarea unei intervenții chirurgicale de urgență. Evoluția postnatală a fost favorabilă atât pentru mamă, cât și pentru nou-născut, deși a fost necesară o spitalizare prelungită pentru stabilizarea acestuia din urmă.

Cuvinte-cheie: inserție velamentoasă, *vasa praevia*, patologii ombilico-placentare, ecografie morfologică, complicații materno-fetale

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Un studiu retrospectiv într-un context de caz special: *vasa praevia* cauzată de o inserție velamentoasă a cordonului ombilical

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Introduction

Velamentous cord insertion was first described in the medical literature by Friedrich Wilhelm Lell in 1907, being known and described as a condition in which the umbilical cord inserts into the amniotic membrane near the placental margin, rather than attaching directly to the placenta. This insertion can lead to the formation

of fragile blood vessels that extend from the cord to the placenta, covered only by the amnion. The situation becomes more serious when these vessels tend to insert near or over the internal cervical os, thus associating velamentous insertion with *vasa praevia*^(1,2).

The etiology of this pathology is complex and not fully understood, primarily because it is a relatively rare

condition. The main risk factors listed by authors include twin gestation, pregnancies conceived through assisted reproductive technology, while bleeding during pregnancy, advanced maternal age, multiparity, female fetus, and previous pregnancy with abnormal cord insertion were other risk factors⁽³⁻⁵⁾.

Additional risk factors predisposing to this umbilical cord anomaly, as documented in medical literature and studies conducted on different cohorts of pregnant women worldwide, include the following:

- **Genetic factors.** Certain genetic anomalies can influence how the umbilical cord develops and attaches to the placenta and uterus. For example, genetic mutations can affect placental vascular formation or predispose to umbilical cord anomalies^(6,7).
- **Placental factors.** Placental anomalies, such as malposition or abnormal placental shape, can play a role in the occurrence of velamentous cord insertion. These anomalies can affect how the umbilical cord attaches to the placenta or disrupt the development of placental vascularization^(8,9).
- **Environmental factors.** Exposure to certain harmful environmental factors during pregnancy, such as smoking, alcohol consumption, or exposure to toxins, can increase the risk of umbilical cord anomalies, including velamentous insertion. These substances can affect placental development and umbilical cord formation.
- **Factors related to fetal development.** Anomalies in fetal development, such as disorders in the formation of blood vessels around the umbilical cord, can contribute to velamentous insertion. Factors such as deficiencies in angiogenesis or vascular development can influence how the umbilical cord forms and attaches^(10,11).
- **Complex interactions between the above factors.** In many cases, velamentous cord insertion results from the interaction of multiple genetic, placental, environmental, and fetal development factors.

Vasa praevia is a rare pathology of the fetal appendages, characterized by the umbilical-placental vessels passing through the chorioamniotic membranes near or over the internal cervical os, without being protected by the Wharton's jelly. This condition is detected in approximately 1 in 1200 to 1 in 2500 births, with 15-30% of cases being discovered in the second trimester of pregnancy, and its incidence is on the rise⁽¹²⁾.

Depending on the insertion of the vessels, there are two types of *vasa praevia*:

- Type 1 (25-62%) represents the passage of placental vessels over the internal os to reach the placental margin (velamentous insertion).
- Type 2 (33-75%) results from the presence of an accessory lobe of the placenta, such as bilobate placenta, where unprotected vessels cross over the internal os⁽¹²⁾.

Some articles have discussed the necessity of introducing a third type of *vasa praevia*, which is more commonly associated with the insertion of umbilical-placental veins that form anastomoses with different parts of the placenta and are inserted low^(13,14).

Approximately 2% of velamentous insertions are associated with *vasa praevia*⁽¹⁵⁾.

Dr. William Hunter first described *vasa praevia* in 1774, but the ultrasound description was only performed in 1987 by Gianopoulos. In 1990, Nelson described *vasa praevia* using transvaginal examination with Doppler effect, having a sensitivity and specificity of 100% and 99%, respectively⁽¹⁾. Thanks to this diagnostic tool, the risk of accidentally detecting vascular pathology during labor is reduced, which is extremely important, because *vasa praevia* has severe consequences for both the mother and the fetus^(16,17).

In some articles, three theories are identified that might explain the occurrence of umbilical anomalies such as *vasa praevia* and velamentous cord insertion:

- The "polarity theory", which may arise when the embryo does not face the implantation base, and the umbilical vessels extend between the umbilical cord insertion and the placenta at the implantation base.
- The "trophotropism theory", which explains these pathologies as low-placenta pathologies. This situation occurs when an early placenta migrates with advancing gestational age to ensure better blood supply and proper development, resulting in either marginal or membranous insertion⁽¹⁸⁾.
- The "abnormal placental development theory due to decreased chorionic vessel branching", which suggests that off-center insertion results from abnormal vasculogenesis in the placenta.

The role of multiple pregnancies as a risk factor for these pathologies remains unclear, as some studies include it as a risk factor while others do not. Nevertheless, the frequency of *vasa praevia* is highly dependent on whether the placentation in multiple pregnancies is monochorionic or dichorionic, with the former having a higher incidence of *vasa praevia*.

We present a retrospective study conducted at the County Emergency Clinical Hospital in Constanța, Romania, over a period of five years (2019-2023), which included a total of 14,166 births, among which seven cases were associated with velamentous insertion of the umbilical cord. In this retrospective study, we calculated the incidence of the velamentous cord insertion (it was 0.05%), and we included a case study to explore in detail the clinical manifestations and management of a specific case of velamentous insertion of the umbilical cord associated with *vasa praevia*.

Case presentation

We present the case of a 44-year-old patient who presented to the gynecology emergency department with spontaneous vaginal bleeding. The decision was made to admit the patient with the diagnosis of IIIG IIP pregnancy at 38/39 weeks, live single fetus, vertex presentation, painful uterine contractions.

The patient had no known associated pathologies. Her first delivery was at term, without obstetric complications during pregnancy or postnatally. At the time of presentation, the bleeding was reduced and did not present as a major obstetric emergency. The baby had a



Figure 1. Ultrasound aspect of our case of vasa praevia (personal archive of Dr. L. Șerbănescu)

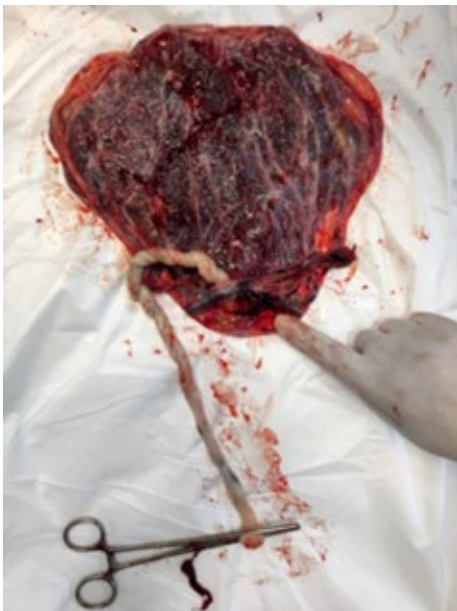
good biophysical profile, with normal uterine tone and no uterine contractions. Therefore, the decision was made to admit the patient to the maternity ward for appropriate monitoring and investigation, as the patient did not have regular obstetric checkups, either through a family doctor or otherwise, due to her low socioeconomic status and rural background. Despite this, the uterine bleeding led the patient to a high-level medical center.

During the day of admission, the patient’s condition was stable, with brownish discharge without other clinical signs. In the next 12 hours, after a shift change, the patient exhibited moderate spontaneous bleeding with clots, but no other clinical signs. A reevaluation by ultrasound revealed the presence of several fetal vessels inserting at the internal cervical os, originating from the lower placental pole (Figure 1). Given that vaginal bleeding and fetal bradycardia began to develop, an emergency surgical intervention was decided.

After fetal extraction, it was found that the placenta, inserted on the posterior uterine wall, had velamentous insertion of the umbilical cord with early placental abruption (Figures 2 and 3). Both fetal and maternal postnatal progress was favorable, although a prolonged hospitalization was needed for fetal stabilization. The obstetrical outcome was successful, and we are proud to have saved two lives, given that in such clinical-obstetrical situations, success is not always achieved, because of the severe pathological effects associated with placental abruption or vasa praevia, especially when these pathologies are present together.

Discussion

This umbilical-placental pathology is quite rare. According to *Williams Obstetrics*, the incidence is around 1%, though some sources report an incidence of up to 2.5%. However, in some studies conducted on large population samples, such incidence has been observed⁽¹⁹⁾. For example, in a study conducted by Räsänen et al. (2012) in Finland, between 2000 and 2011, on a cohort



Figures 2 and 3. Macroscopic aspects of the placenta in our case of vasa praevia (personal archive of Dr. L. Șerbănescu)

of 26,849 singleton pregnancies, the incidence of velamentous cord insertion was found to be 2.4%, with 633 cases out of 26,849⁽²⁰⁾.

In another study, on a smaller population group, a similar incidence was observed, but it was noted that assisted reproductive techniques predispose to a higher incidence. In a study conducted in Japan, in 2021, on a cohort of 906 births, where pregnancies were achieved through assisted reproductive technology, the authors, Furuya, Kubonoya and Yamaguchi (2021), reported that 55 out of 906 cases had velamentous cord insertion, resulting in an incidence of 6.1%⁽²¹⁻²³⁾.

Another study, conducted in South Korea, in 2021, Lee et al. (2021), on a cohort of 941 twin pregnancies, found that velamentous cord insertion was more common in dichorionic twin pregnancies (7.8%) compared to monochorionic placentation (5.8%)⁽²⁴⁻²⁷⁾.

Interestingly, the incidence of *vasa praevia* associated with velamentous cord insertion increases in cases where low placental development occurs. These data are evident in a 2010 article analyzing ultrasound examinations in *vasa praevia*, where 90% of *vasa praevia* cases were associated with velamentous insertion, compared to 1.6% in the control group⁽²⁸⁾.

It is essential to understand that, despite medical research advancements, the exact cause of velamentous cord insertion often remains unknown, and this pathology may be discovered during pregnancy monitoring or childbirth⁽²⁹⁻³¹⁾.

As an example, in an Australian study conducted in 2017 by Sullivan et al., 63 cases of *vasa praevia* were identified, of which 58 cases were detected during pregnancy. Out of these, 55 out of 58 *vasa praevia* cases were associated with velamentous cord insertion. In four out of five patients where these pathologies were not detected prenatally, emergency surgery was performed because of life-threatening situations, resulting in a 40% fetal prenatal mortality rate, with one vaginal birth due to antenatal fetal death. Additionally, 68% of births were premature, and 29% were associated with low birth weight⁽³²⁾.

Similarly, reviewing a meta-analysis conducted by Siargkas et al. in 2022, on 11 patients, of which four cases of velamentous insertion were discovered during pregnancy and seven postnatally, the authors found that the prevalence of velamentous insertion was 1.4% in singleton pregnancies. Compared to the control group with central and paracentral insertion, the presence of velamentous cord insertion was associated with a higher incidence of pathologies such as low birth weight, hypertension, preeclampsia, placental abruption, intrauterine fetal death, preterm birth, emergency surgical intervention, low Apgar scores, and admission to neonatal intensive care⁽³³⁾.

In a retrospective analysis conducted in 2020 by Yang et al., on 501 cases of velamentous cord insertion out of 59,976 births, over the period 2004-2014, the prevalence was found to be 0.84%. The colleagues observed that risk factors and various pathological aspects were linked to

fetal deaths, preterm birth, low birth weight, and low Apgar scores⁽³⁴⁾.

All these articles demonstrate that, although these umbilical-placental pathologies have a low population incidence, they have devastating maternal-fetal consequences. Therefore, it is crucial for every pregnant woman to undergo routine pregnancy ultrasound and, especially, fetal morphology scans, which are crucial moments for the timely detection of possible umbilical anomalies or pathological placental insertion. Otherwise, spontaneous detection of these anomalies during an emergency situation is associated with a very high rate of fetal death, significant neurological conditions for the fetus due to major fetal hemorrhages, and both fetal and maternal deaths, with lifelong repercussions⁽³⁵⁻³⁷⁾.

The anatomical-pathological aspect of placentas and of the placental vessels is extremely important to analyze in these cases, when the placental vascular appearance can be modified compared to normal⁽³⁸⁾.

A cohort study conducted in 2023 by Zhang et al. reported that, out of 2,278,561 pregnancies, there were 1320 pregnancies with *vasa praevia*. The weighted incidence of *vasa praevia* was 0.79 (95% CI; 0.59 to 1.01) per 1000 examined pregnancies, which corresponded to an incidence of one case of *vasa praevia* in 1271 pregnancies (95% CI; 990 to 1692)⁽³⁹⁾.

The guidelines of the Society for Maternal-Fetal Medicine (SMFM) published in 2015 state that "there are no standardized criteria for how close the vessels connecting the umbilicus to the placental disc must be to the internal os to constitute *vasa praevia*"⁽⁴⁾. Some authors consider it to be *vasa praevia* when the vessels are within 2 cm of the internal os; however, it is difficult to define this clinical situation as a standard because, regardless of the distance of the vessels from the internal os, the dilation of the cervical canal that occurs during labor can lead to the rupture of pathologically inserted vessels, which is associated with catastrophic bleeding, especially for the fetus, given that the fetal circulatory blood volume is approximately 300 ml.

A large international multicenter cohort study of 155 cases found that, when *vasa praevia* was not diagnosed prenatally, there was a perinatal mortality rate of 56%⁽⁴⁰⁾.

The risks of perinatal death and hypoxic morbidity were 25 times and 50 times higher, respectively, in those not diagnosed prenatally compared to those diagnosed prenatally⁽⁴¹⁾.

Similarly, maternal risks are primarily associated with continuous hospitalizations due to recurring uterine bleeding throughout pregnancy, especially when *vasa praevia* is associated with abnormal placentation, leading to maternal anxiety and socioeconomic consequences.

The most common of these include preterm birth, with its consequences on the fetal organism, chronic and acute fetal distress, having prenatal and postnatal effects, and in the most difficult situations, being associated with a high rate of fetal death⁽⁴²⁻⁴⁴⁾.

Maternal hemorrhages lead to the weakening of the body, predisposing it to chronic anemia, which in turn increases susceptibility to infections. In severe

situations, maternal shock with tubular renal necrosis, disseminated intravascular coagulation, and prolonged hospitalizations, with their psychological consequences, may occur^(42,45).

The symptomatology in these cases can be complex. Sometimes it can be represented by pain in the uterus or in one of the flanks, manifestations that can be included as a differential diagnosis with cases of ovarian tumors (tubo-ovarian cysts or abscesses)⁽⁴⁶⁾ or with placental abruption, especially when vaginal bleeding is present⁽⁴⁷⁾.

It is extremely important to understand that many pathological consequences due to the presence of this anomaly in fetal appendages can be prevented if umbilical-placental pathologies are detected early during periodic ultrasound examinations, with a significant emphasis on performing fetal morphology scans and the attentiveness of the operator conducting these ultrasound examinations^(42,48).

We must alert readers that, due to the presence of paternal Rh incompatibility, it is crucial to prevent potential immune sensitization by applying the SOGR protocol, including both prophylactic and therapeutic anti-Rh vaccinations. The presence or absence of anti-D antibodies is of great importance here. Additionally, maternal-fetal bleeding can predispose to chronic fetal anemia⁽⁴⁹⁾.

A useful tool in this context can be the maximum velocity on the middle cerebral artery; if it exceeds 1.5

MoM, and if the clinical situation warrants, cordocentesis can be performed to determine fetal hemoglobin and hematocrit levels.

As risk factors for developing umbilical and placental vascular anomalies, some authors describe assisted reproductive technologies. For example, a study by Matsuzaki et al. (2022) found that the prevalence of *vasa praevia* appears to be higher (approximately 0.3-0.5%) in women who have undergone assisted reproductive technologies⁽⁵⁰⁾.

Conclusions

Imaging examinations, especially the second-trimester morphological ultrasound, should be routinely performed on all pregnant women. In the case of unmonitored patients who have not benefited from a second-trimester pregnancy ultrasound and have not been monitored by ultrasound during pregnancy, a careful ultrasound examination of the placental surface and the insertion of the umbilical cord is necessary, even during labor.

Vaginal bleeding in a pregnant patient should also raise the suspicion of an umbilical cord insertion anomaly. ■

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Detection and prevention of hospital-acquired staphylococcal infections in pregnant women and postpartum mothers – experience of “Prof. Dr. Panait Sîrbu” Clinical Hospital of Obstetrics and Gynecology, Bucharest

**Bogdan Botezatu,
Elena Vlad,
Sergiu Taşinschi**

“Prof. Dr. Panait Sîrbu”
Clinical Hospital
of Obstetrics and Gynecology,
Bucharest, Romania

Corresponding author:
Bogdan Botezatu
E-mail: bogdan_zone@yahoo.com

Abstract

The article discusses the detection and prevention of hospital-acquired staphylococcal infections in pregnant women and postpartum mothers at the “Prof. Dr. Panait Sîrbu” Clinical Hospital of Obstetrics and Gynecology, in Bucharest, Romania, with a particular focus on infections caused by *Staphylococcus aureus* and its antibiotic resistance (MRSA). Screening methods involve bacterial cultures from various body sites (nose, axilla, skin) to detect the presence of staphylococcus. At the “Prof. Dr. Panait Sîrbu” Clinical Hospital, tests are performed on all hospitalized patients, and those who test positive undergo decolonization treatment. In cases of obvious infection, patients are isolated to prevent further transmission. Study results from January 1 to October 31, 2024 show a 4.69% prevalence of staphylococcal infections, with 0.64% caused by MRSA. In the neonatology departments, the contamination rate is lower (0.45%). The article emphasizes the importance of regular screening and preventive measures to reduce the incidence of staphylococcal infections, especially MRSA, among hospitalized patients.

Keywords: *Staphylococcus aureus*, infection, abscess, contamination, prevention, decolonization, treatment

Rezumat

Acest articol discută despre depistarea și prevenția infecțiilor stafilococice intraspitalicești la gravide și lehuze în cadrul Spitalului Clinic de Obstetrică și Ginecologie „Prof. Dr. Panait Sîrbu” din București, cu un focus special pe infecțiile cauzate de *Staphylococcus aureus* și rezistența acestuia la antibiotice (MRSA). Metodele de depistare includ culturi bacteriologice din diverse zone ale corpului (nas, axile, piele) pentru a detecta prezența stafilococului. La Spitalul Clinic „Prof. Dr. Panait Sîrbu”, testele sunt efectuate pentru toate paciențele spitalizate, iar cele cu rezultate pozitive urmează un tratament de decolonizare. În cazul infecțiilor evidente, paciențele sunt izolate pentru a preveni răspândirea. Rezultatele studiului din perioada 1.01.2024-31.10.2024 arată un procentaj de 4,69% cazuri de infecții stafilococice, dintre care 0,64% sunt cauzate de MRSA. În departamentele de neonatologie, rata de contaminare este mai mică (0,45%). Articolul subliniază importanța screeningului regulat și a măsurilor de prevenire pentru a reduce incidența infecțiilor stafilococice, în special MRSA, în rândul paciențelor spitalizate.

Cuvinte-cheie: *Staphylococcus aureus*, infecție, absces, contaminare, prevenție, decolonizare, tratament

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Introduction

Staphylococci are Gram-positive aerobic organisms. *Staphylococcus aureus* is the most pathogenic; it typically causes skin infections and sometimes pneumonia, endocarditis and osteomyelitis. It usually leads to the formation of abscesses. Some strains produce toxins that cause gastroenteritis, scalded skin syndrome and even toxic shock syndrome. The diagnosis is made through Gram staining and culture.

Staphylococcus aureus has the ability to cause the formation of vascular thrombi through coagulase (coagulase-positive staphylococci), and these are among the most virulent and dangerous pathogens that also have the capacity to develop resistance to antibiotics⁽¹⁾.

Coagulase-positive staphylococci are found on the skin of approximately 30-40% of the healthy population⁽²⁾.

Risk factors for staphylococcal infections

Individuals who are predisposed to infections include⁽³⁾:

- newborns and breastfeeding mothers
- patients with surgical incisions, open wounds or burns
- patients with influenza, chronic bronchopulmonary disorders (e.g., cystic fibrosis, emphysema), leukemia, tumors, chronic skin disorders or diabetes mellitus
- patients with transplants, prostheses or intravascular catheters
- patients receiving treatment with adrenal steroids, irradiation, immunosuppressants, or antitumor chemotherapy
- injecting drug users
- patients suffering from chronic kidney disease and undergoing dialysis.

Methicillin is a semi-synthetic derivative of penicillin, developed in the late 1950s, by modifying penicillin's structure to provide resistance to penicillinase⁽⁴⁾.

The emergence of methicillin-resistant *Staphylococcus aureus* (MRSA) strains in the 1960s in the UK made the

drug clinically ineffective. Methicillin resistance arises due to the acquisition of the *mecA* or *mecC* gene by previously susceptible staphylococcal strains⁽⁵⁾.

Predisposed patients can be infected with antibiotic-resistant staphylococci from other patients, medical staff, or contaminated objects in hospitals or medical institutions. Transmission through medical staff hands is the most common mode of spread, but airborne transmission can also occur.

Complications and diseases caused by staphylococci

■ Staphylococcal skin infections

Skin infections are the most common form of staphylococcal disease:

1. Superficial infections can be diffuse, with pustules and vesicular crusts (impetigo – Figure 1)⁽¹⁾. Common sites of infection include the face (e.g., around the nose and mouth), the flexures, hands, and lower limbs⁽⁶⁾.
2. Cellulitis or focal infections with nodular abscesses (boils and carbuncles). Furunculosis is an inflammatory, draining, painful nodule that involves the hair follicle, typically following an episode of folliculitis (Figure 2)⁽¹⁾. A carbuncle is a series of interconnected boils in the subcutaneous tissue⁽⁷⁾.
3. Deeper skin abscesses are common. Severe necrotizing skin infections and postoperative wound superinfections can also occur (Figure 3).
4. Neonatal staphylococcal infections

Neonatal infections usually occur within four weeks after birth, including skin lesions with or without exfoliation, bacteremia, meningitis, pneumonia, endocarditis, osteomyelitis, staphylococcal joint infections, and toxic shock syndrome (Figure 4)⁽⁸⁾.

Screening for staphylococcal infection

At the “Prof. Dr. Panait Sirbu” Clinical Hospital of Obstetrics and Gynecology, Bucharest, all hospitalized patients, including pregnant women, undergo screening for staphylococcal colonization or infection, by



Figure 1. Impetigo⁽¹⁾



Figure 2. Furunculosis⁽¹⁾



Figure 3. Postoperative wound infection (personal collection image)



Figure 4. A case of a newborn with severe junctional epidermolysis bullosa (A), with staphylococcal skin infection of the left foot (B) and the left hand (C)⁽⁸⁾

collecting nasal and axillary cultures, detecting over 80% of cases⁽⁹⁾. Patients who test positive and are not medical or surgical emergencies undergo general antibacterial cleaning (antiseptic soap, betadine) and local treatment with fusidic acid, followed by retesting. If hospitalization is required, cleaning is performed in the hospital, and patients with obvious infectious clinical signs are isolated.

In the neonatology departments, a second screening is performed to detect staphylococcal colonization and infection in newborns.

If inflammation or erythema is observed on the skin and postoperative wounds, bacterial cultures are taken, including tests for staphylococcus and decolonization, and the infection prevention procedures are continued⁽¹⁰⁾.

Materials and method

Patients were recruited for the study from those hospitalized in the Obstetrics-Gynecology 1st Ward during the first ten months of 2024, as well as from newborns from the Neonatology Departments (1st and 2nd).

All patients underwent tests (bacterial cultures from the nose and skin in adult patients, and from the nose, ear and skin in newborns).

The isolation of *Staphylococcus aureus* from wounds, purulent collections, and lochia meets the criteria for postoperative wound infection⁽¹¹⁾.

All data were recorded and transmitted to the Bucharest Public Health Directorate.

The identification of bacterial cultures was performed in our laboratory. Screening samples for *Staphylococcus aureus* were analyzed locally on chromogenic culture

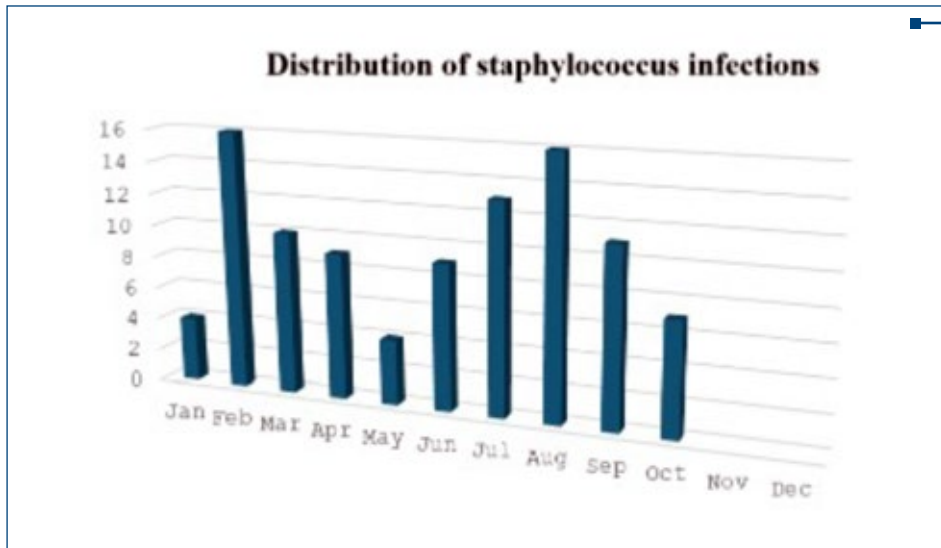


Figure 5. Distribution of *Staphylococcus aureus* infections

media, using standardized methods. The presence of *Staphylococcus aureus* was determined based on phenotypic criteria (pink or purple colonies). This culture medium has a sensitivity of 95.5% and a specificity of 99.4% for detecting *Staphylococcus aureus*⁽¹²⁾.

Missing information

We could not quantify the patients with *Staphylococcus aureus* positive results detected in the outpatient setting, decolonized, or treated at home who then tested negative on retesting. Therefore, the data we provide do not have the sensitivity to describe the level of contamination in the general population, but offer a “snapshot” of the contamination level among obstetrical patients hospitalized at the “Prof. Dr. Panait Sirbu” Clinical Hospital of Obstetrics and Gynecology, Bucharest.

Results

The number of hospitalized patients from 1.01.2024 to 31.10.2024 in the Obstetrics-Gynecology 1st Ward, including pregnant women, parturients and postpartum women, was 2193.

The number of newborns hospitalized from 1.01.2024 to 31.10.2024 in the Neonatology Departments (1st and 2nd) was 1894 (Figure 5).

Staphylococcus aureus was detected in 103 cases, with the following monthly distribution: 4.69% total prevalence of staphylococcal infection; 0.64% prevalence of MRSA.

There were detected 14 MRSA-positive patients of the cases above, with the following sites of detection: 11 from nasal secretions, two from skin, and one from lochia cultures, which is about 14% of the cases. The

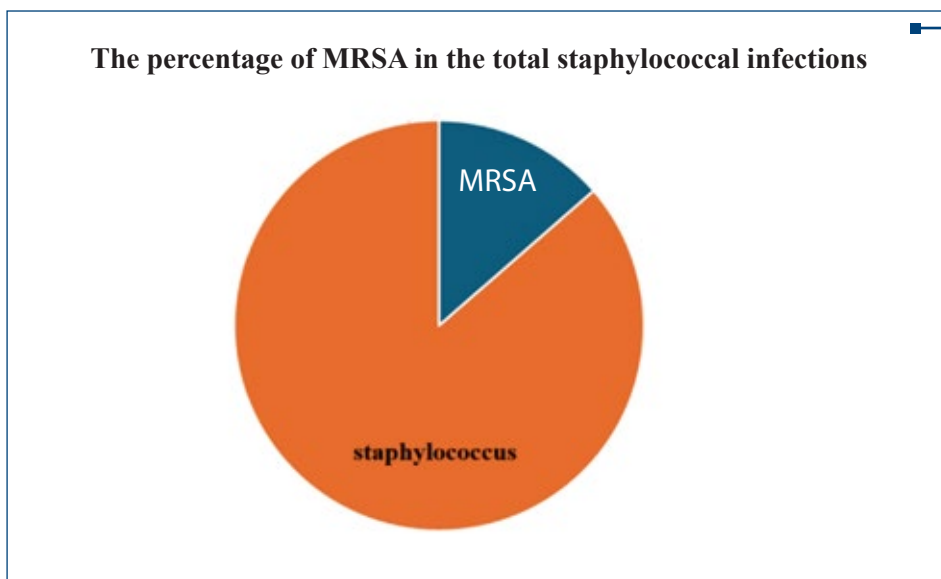


Figure 6. Percentage of MRSA-positive cases in the First Department of Obstetrics and Gynecology

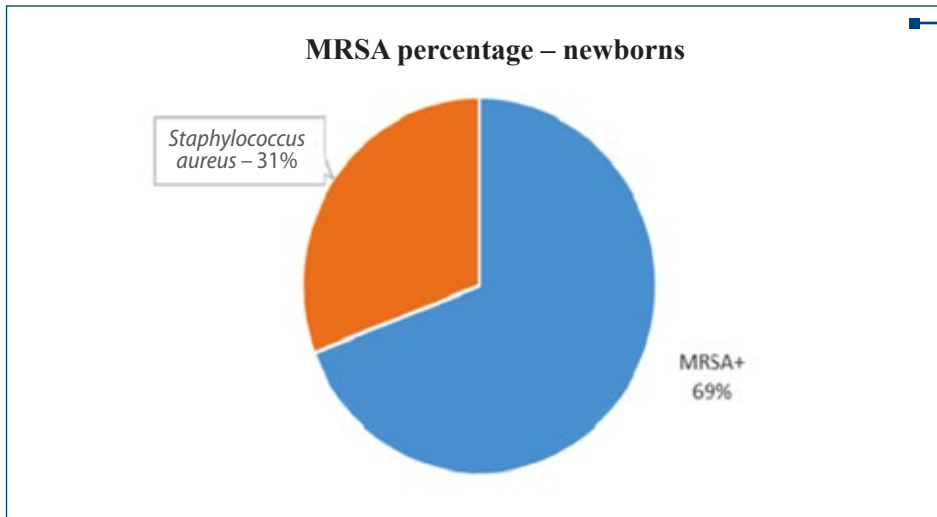


Figure 7. MRSA-positive percentage in the neonatology departments

weighted average in the general European population is 17.4%⁽¹³⁾.

In the neonatology departments, the screening results were very good, with 13 cases of *Staphylococcus aureus* contamination detected, of which nine cases were MRSA positive.

The prevalence of MRSA-positive cases in the general neonatal population is estimated at 1.5%⁽¹⁴⁾, while in our case the prevalence in the neonatology departments was 0.45%.

Conclusions

1. The colonization rate with positive MRSA in pregnant women is, on average, 4.3%, according to international literature⁽¹⁵⁾. In our hospital, the contamination rate with MRSA was 0.64%.

2. MRSA-positive colonization in neonatology departments ranges from 0.65% to 8.45% according to international literature⁽¹⁶⁾. In our hospital, it was 0.45%.

3. The data obtained confirm the effectiveness of staphylococcal infection screening through the small number of contaminations in hospitalized obstetrical patients, further validated by the small number of MRSA contaminations in newborns.

Measures to increase the effectiveness of preventing staphylococcal infection:

- a) Screening, individual isolation, cohort isolation of patients, and the use of gloves, gowns and face masks.
- b) Hand hygiene, including the use of antiseptics with water or alcohol-based hand gel, in the absence of water.
- c) Hygiene of the living environment, including cleaning, disinfection and sterilization procedures. ■

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Laparoscopy in urogynecology: advances, challenges and future directions

Abstract

Pelvic organ prolapse and stress urinary incontinence are prevalent conditions among women, significantly impacting the quality of life. Laparoscopic surgery has emerged as a preferred approach for managing these conditions due to its advantages over traditional open surgery, including smaller incisions, reduced blood loss, and quicker recovery times. This article reviews the advancements in laparoscopic techniques, such as sacrocolpopexy and Burch colposuspension, and discusses their application in reconstructive pelvic surgery and continence operations. While laparoscopic approaches offer superior intraoperative visibility and less postoperative discomfort, they are associated with a steep learning curve and require specialized training. Challenges such as high costs, limited access to technology, and mesh-related complications can hinder broader adoption. Nonetheless, the benefits in terms of patients' outcomes and quality of life are compelling, with high success rates and patients' satisfaction reported across multiple studies. Future directions include the integration of robotic assistance, single-incision techniques, and AI-driven surgical planning, which promise to further enhance the precision and accessibility of laparoscopic surgery. Emphasizing comprehensive training programs will be essential to expand the expertise in these minimally invasive techniques and improve patient care. Ongoing research and innovations are expected to solidify the role of laparoscopic surgery in urogynecology, providing effective and patient-centered solutions for pelvic organ prolapse and stress urinary incontinence.

Keywords: laparoscopic surgery, pelvic organ prolapse, stress urinary incontinence, urogynecology

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Rezumat

Prolapsul organelor pelviene și incontinența urinară de efort sunt afecțiuni prevalente în rândul femeilor, cu un impact semnificativ asupra calității vieții. Chirurgia laparoscopică a devenit o metodă preferată pentru gestionarea acestor afecțiuni datorită avantajelor sale față de chirurgia deschisă tradițională, implicând incizii mai mici, pierderi de sânge reduse și timpi de recuperare mai scurți. Acest articol trece în revistă progresele privind tehnicile laparoscopice, precum sacrocolpopexia și colposuspensia Burch, și discută aplicarea lor în chirurgia reconstructivă pelviană și operațiile pentru continență. Deși abordările laparoscopice oferă o vizibilitate intraoperatorie superioară și un disconfort postoperatoriu redus, acestea sunt asociate cu o curbă de învățare abruptă și necesită pregătire specializată. Provocări precum costurile ridicate, accesul limitat la tehnologie și complicațiile asociate meșelor pot limita adoptarea pe scară largă a acestor tehnici. Totuși, beneficiile în ceea ce privește rezultatele și calitatea vieții pacienților sunt remarcabile, cu rate ridicate de succes și satisfacție raportate în mai multe studii. Direcțiile viitoare includ integrarea asistenței robotice, a tehnicilor cu incizie unică și a planificării chirurgicale asistate de inteligența artificială, care promit să îmbunătățească precizia și accesibilitatea chirurgiei laparoscopice. Punerea accentului pe programe de instruire cuprinzătoare va fi esențială pentru extinderea expertizei în aceste tehnici minim invazive și pentru îmbunătățirea îngrijirii pacienților. Se preconizează că cercetările și inovațiile continue vor consolida rolul chirurgiei laparoscopice în uroginecologie, oferind soluții eficiente și centrate pe pacient pentru prolapsul organelor pelviene și incontinența urinară de efort.

Cuvinte-cheie: chirurgie laparoscopică, prolapsul organelor pelviene, incontinență urinară de efort, uroginecologie

Smit Bharat Solanki¹,
Vineet Mishra²

1. Department of Obstetrics and Gynecology, Institute of Kidney Disease and Research Centre, Ahmedabad, India

2. Advanced Gynecology and Fertility Apollo Hospital, Ahmedabad, India

Corresponding author:
Smit Bharat Solanki
E-mail: drsmitbharat@gmail.com

Introduction

Pelvic organ prolapse (POP) is a prevalent condition that significantly impacts the quality of life of women, particularly those above 50 years of age. The prevalence of POP increases with age, with estimates suggesting that up to 50% of women over 50 years old are affected by some degree of prolapse⁽¹⁾. Furthermore, the lifetime risk of requiring surgical intervention for prolapse is estimated at 11%, a figure that is expected to rise as life expectancy increases and as lifestyle changes influence health outcomes⁽²⁾. The primary objective of prolapse

surgery is to restore normal pelvic anatomy and support, thus returning pelvic organs to their normal function. Traditionally, pelvic floor reconstruction surgeries have been performed through abdominal or vaginal routes; however, the advent of laparoscopic techniques has revolutionized the surgical management of POP⁽³⁾.

Laparoscopic surgery, which operates on the same principles as related open procedures, has been successfully applied to several urogynecological surgeries. The advantages of laparoscopy include superior intraoperative visibility of pelvic anatomy and the retroperitoneal

area, reduced blood loss, decreased postoperative pain, and shorter hospital stays, leading to faster recovery times⁽⁴⁾. Despite these benefits, laparoscopic surgery requires a high level of skill, particularly in suturing and retroperitoneal dissection, which can pose a steep learning curve. Additionally, insufficient training opportunities during residency and fellowship programs have limited the widespread adoption of laparoscopic techniques for prolapse and urinary incontinence surgeries⁽⁵⁾.

This paper explores the various laparoscopic surgical methods currently available for continence procedures and reconstructive pelvic surgery, with a focus on their efficacy, safety and role in modern urogynecology.

Laparoscopic sacrocolpopexy for vaginal vault prolapse

Vaginal vault prolapse is a condition that can occur in up to 43% of women following a hysterectomy⁽⁶⁾. Abdominal sacrocolpopexy is widely regarded as the gold standard treatment for vaginal vault prolapse due to its high success rate, ranging from 78% to 100%, and lower recurrence, postoperative dyspareunia, and re-surgery rates compared to other vaginal procedures such as sacrospinous fixation and high uterosacral suspension⁽⁷⁾. Laparoscopic sacrocolpopexy has evolved from the traditional abdominal approach, offering similar efficacy without the need for a large abdominal incision, packing, or extensive bowel manipulation, which can result in less postoperative pain, reduced immobility, and a lower risk of ileus⁽⁸⁾. The laparoscopic approach allows surgeons to apply mesh lower over the posterior vaginal wall, extending down to the pelvic floor (*levator ani* muscle) and perineal body, which has been shown to enhance the efficacy of the procedure⁽⁹⁾. Visualization through laparoscopy magnifies anatomical structures, facilitating precise mesh placement and minimizing the risk of complications, as shown in Figure 1. A 2-0 polyglactin suture is commonly used to reapproximate

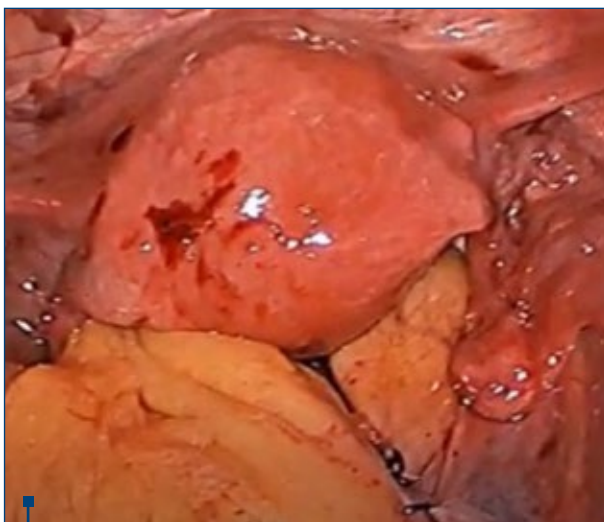


Figure 1. Operative field after sacrocolpopexy

the peritoneum after mesh placement and hemostasis inspection in the presacral cavity⁽¹⁰⁾. Laparoscopic sacrocolpopexy demonstrates a high success rate of 90-96%, with mesh erosion rates reported between 1% and 8%⁽¹¹⁾.

One of the key benefits of laparoscopic sacrocolpopexy is the enhanced intraoperative visibility, which allows for meticulous dissection and suturing, leading to improved surgical outcomes. However, a significant drawback is the technical difficulty associated with retroperitoneal dissection and suturing, necessitating advanced laparoscopic skills that may not be readily acquired during standard surgical training⁽¹²⁾.

Laparoscopic uterine preservation surgeries for uterine prolapse

The concept of uterine preservation in uterovaginal prolapse repair has gained traction, particularly among women who wish to maintain their fertility. The notion that the uterus plays only a passive role in uterovaginal prolapse dates back to Bonney in 1900, and since then, numerous procedures utilizing vaginal and abdominal techniques have been proposed for prolapse repair with uterine preservation⁽¹³⁾. Laparoscopic approaches for uterine prolapse repair include ventrosuspension and sacrohysteropexy. Ventrosuspension involves suspending the uterus to the round ligaments, uterosacral ligaments, and sacral promontory, while sacrohysteropexy suspends the uterus from the sacral promontory using a polypropylene mesh placed medially to the uterine arteries⁽¹⁴⁾.

Sacrohysteropexy is currently considered the preferred method among laparoscopic uterine-preserving surgeries due to its ability to provide robust support while preserving the uterus. However, evidence supporting the long-term effectiveness and safety of these procedures is still limited, with a lack of extensive longitudinal studies assessing the impact on subsequent conception and childbirth⁽¹⁵⁾. Although uterine preservation offers advantages such as reduced adhesion formation and faster recovery, more research is needed to validate these benefits and establish standardized protocols⁽¹⁶⁾.

Laparoscopic and minimally invasive techniques for stress urinary incontinence

Stress urinary incontinence (SUI) is another common condition addressed through minimally invasive surgical techniques. Historically, open Burch colposuspension was regarded as the gold standard for SUI treatment, providing long-term continence results⁽¹⁷⁾. Laparoscopic Burch colposuspension, first described in the early 1990s, offers several advantages over the open approach, including better visualization of pelvic anatomy, reduced blood loss, less postoperative pain, shorter hospital stays, and quicker recovery times⁽¹⁸⁾.

The laparoscopic Burch colposuspension involves placing four permanent helix sutures at the levels of the bladder neck and midurethra, with two sutures

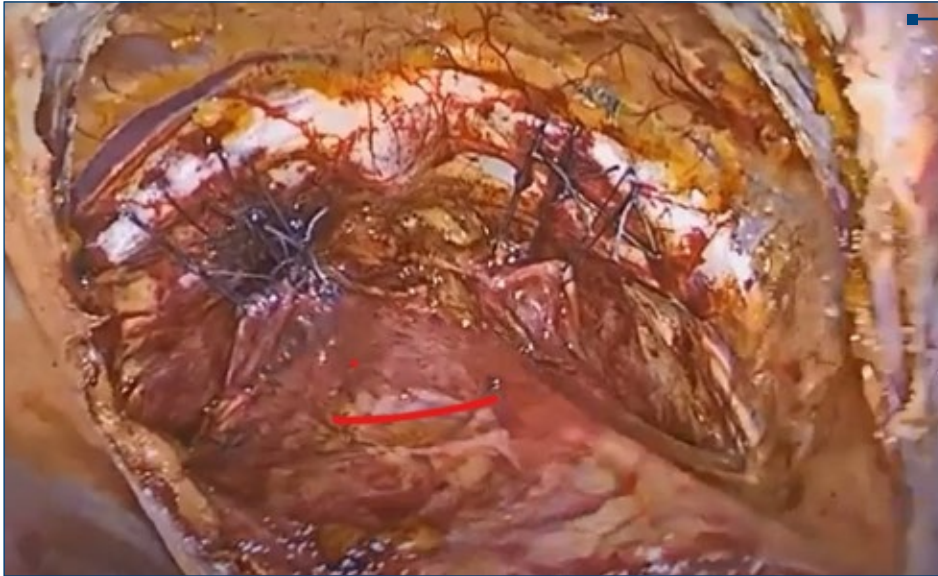


Figure 2. Helical sutures in Burch colposuspension

placed at each level and passed through the Cooper's ligament⁽¹⁹⁾, as shown in Figure 2. Studies have revealed that using four sutures rather than two results in higher cure rates⁽²⁰⁾. A recent Cochrane review that included nine studies on laparoscopic versus open Burch colposuspension found that the laparoscopic approach was consistently associated with less blood loss, decreased postoperative discomfort, shorter catheterization time, and reduced hospital stays⁽²¹⁾.

Despite the advantages of laparoscopic Burch colposuspension, the procedure requires advanced laparoscopic skills, particularly in suturing and tissue manipulation, which can be a barrier to its widespread adoption. The learning curve for this procedure is steep, and adequate training and experience are crucial for achieving outcomes comparable to the open technique⁽²²⁾.

Laparoscopic anterior wall prolapse repair

Anterior vaginal wall prolapses, or cystocele, is the most common type of vaginal prolapse, often exacerbated by vaginal childbirth⁽²³⁾. The traditional treatment for cystocele is anterior colporrhaphy, a vaginal repair technique with success rates ranging widely from 36% to 100%, depending on various factors such as patient characteristics and surgical technique⁽²⁴⁾. Laparoscopic approaches for anterior wall prolapse repair include paravaginal repair, which addresses lateral defects by reattaching the lateral side of the anterior vaginal wall to its original attachment site at the *arcus tendineus fascia pelvis* (ATFP)⁽²⁵⁾.

The laparoscopic paravaginal repair involves reapproximating the vaginal wall and fascia overlying the obturator internus muscle to the ATFP, thereby restoring the normal anatomical position of the bladder and urethra⁽²⁶⁾. The success rates for paravaginal repair, whether performed using a vaginal or an abdominal approach, have been reported to range from 76% to 100%⁽²⁷⁾.

However, there is limited evidence from randomized controlled trials to definitively establish the superiority of laparoscopic paravaginal repair over traditional methods⁽²⁸⁾.

Laparoscopic posterior wall prolapse repair

Posterior compartment prolapses, including rectocele and enterocele, are typically managed through vaginal repair, which is favored for its simplicity, accessibility, and generally high success rates⁽²⁹⁾. However, for women undergoing surgery for uterine or vault prolapse, concurrent laparoscopic repair of posterior compartment defects can prevent the need for subsequent vaginal procedures⁽³⁰⁾. Laparoscopic posterior compartment repair during sacrocolpopexy involves extending the mesh placement across the posterior vaginal wall to the level of the *levator ani* muscle and perineal body, which has been shown to provide good anatomic and functional outcomes for prolapse⁽³¹⁾.

The laparoscopic approach to posterior compartment repair offers the advantage of superior visualization and access to the deep pelvic structures, allowing for precise dissection and mesh placement. However, the procedure's efficacy and safety require further evaluation through well-designed studies to compare it with traditional vaginal repair techniques⁽³²⁾.

Discussion

The advent of laparoscopic techniques has revolutionized the field of urogynecology, offering numerous benefits over traditional open surgery. Laparoscopic surgery, characterized by smaller incisions, reduced blood loss and shorter hospital stays, has become increasingly favored in the management of pelvic organ prolapse and stress urinary incontinence. Despite these advantages, the transition to minimally invasive surgery in urogynecology is not without challenges. This

discussion expands on the advancements, challenges and potential future directions of laparoscopic surgery in urogynecology.

Advancements in laparoscopic techniques

Laparoscopy has evolved significantly with the integration of advanced technologies such as high-definition imaging, robotic assistance, and enhanced suturing devices, which have improved surgical precision and outcomes. The introduction of 3D visualization and robotics has provided surgeons with enhanced depth perception and dexterity, which are crucial in the confined spaces of the pelvic anatomy. Robotic-assisted laparoscopic sacrocolpopexy, for instance, has shown promising results in terms of durability and lower recurrence rates of prolapse, making it a preferred option for many surgeons⁽³³⁾.

Moreover, the application of energy-based devices, such as bipolar and ultrasonic energy systems, has reduced intraoperative bleeding and minimized tissue trauma, contributing to faster recovery and less postoperative pain. Laparoscopic procedures, including colposuspension, sacrocolpopexy and midurethral sling placements, have become standard practices in many institutions, offering effective alternatives to open and vaginal surgeries for POP and SUI⁽³⁴⁾.

Challenges and limitations

Despite the clear advantages, the widespread adoption of laparoscopic surgery in urogynecology faces several barriers. A significant challenge is the steep learning curve associated with advanced laparoscopic techniques. Mastering the required skills demands extensive training, which is often time-consuming and resource-intensive. Many residency and fellowship programs may not provide sufficient hands-on experience with complex laparoscopic procedures, resulting in a slower adoption rate among newly trained urogynecologists⁽³⁵⁾.

Another challenge is the cost associated with laparoscopic and robotic surgeries. Robotic systems, while offering enhanced precision and reduced surgeon fatigue, are expensive and may not be readily available in all healthcare settings, particularly in low-resource environments. This financial barrier can limit access to the most advanced surgical care for patients, perpetuating disparities in treatment options based on geographic and socioeconomic factors⁽³⁶⁾.

In addition, the potential for complications such as organ injury, mesh erosion, and chronic pain remains a concern. Mesh-related complications, in particular, have garnered significant attention and have led to increased scrutiny and regulation of mesh use in prolapse surgeries. Although the incidence of these complications is relatively low, the severity and impact on quality of life can be substantial, necessitating careful patient selection and thorough preoperative counseling⁽³⁵⁾.

Patients' outcomes and quality of life

The primary goal of laparoscopic surgery in urogynecology is to improve patients' outcomes, including symptom relief, anatomical correction, and enhancement of

quality of life. Studies have demonstrated that laparoscopic procedures can achieve these outcomes with high success rates and patient satisfaction. For example, laparoscopic sacrocolpopexy has shown favorable long-term results in terms of prolapse recurrence and maintenance of vaginal length, which is critical for sexual function and overall pelvic floor health⁽³⁰⁾.

Quality of life metrics, such as reduced postoperative pain, faster return to normal activities and improved sexual function, are consistently reported advantages of laparoscopic over open surgery. These benefits are particularly relevant for younger, sexually active women who may prioritize these aspects when choosing a surgical option. However, it is essential to balance these benefits with a thorough discussion of the risks and potential for complications, ensuring that patients are fully informed and involved in the decision-making process⁽³⁴⁾.

Future directions

The future of laparoscopic surgery in urogynecology is likely to be shaped by ongoing technological innovations, including the development of even less invasive techniques such as single-incision laparoscopy and natural orifice transluminal endoscopic surgery (NOTES). These approaches aim to further reduce the invasiveness of surgical interventions, minimize scarring, and enhance recovery times. Additionally, advancements in simulation training and virtual reality are expected to play a pivotal role in overcoming the learning curve associated with these procedures, allowing for safer and more efficient training of new surgeons⁽³⁷⁾.

Research into the long-term outcomes and cost-effectiveness of laparoscopic and robotic-assisted surgeries will also be critical. Large-scale, multicenter randomized controlled trials are needed to establish standardized protocols and guidelines, which can help streamline practices and ensure consistent, high-quality care across different healthcare settings. Furthermore, patient-reported outcome measures (PROMs) should be incorporated into clinical trials and routine practice to capture the full impact of surgical interventions on patients' lives, beyond just anatomical success⁽³⁵⁾.

Another promising area is the use of artificial intelligence (AI) and machine learning to enhance surgical planning and intraoperative decision-making. AI algorithms can analyze large datasets from past surgeries to predict outcomes and assist surgeons in identifying optimal approaches tailored to individual patient characteristics. This precision medicine approach has the potential to further refine laparoscopic techniques, reduce complication rates, and improve overall patient satisfaction⁽¹⁸⁾.

Training and education

To address the skills gap in laparoscopic surgery, there is a growing need for comprehensive training programs and workshops specifically tailored to urogynecological procedures. Simulation-based training, using virtual reality platforms and robotic simulators, offers a safe and effective way for surgeons to practice and refine

their skills before operating on patients. These training modalities can help reduce the initial learning curve, improve surgical confidence, and ultimately lead to better patient outcomes⁽³⁶⁾.

Additionally, the integration of laparoscopic skills training into residency and fellowship programs is essential. This includes not only technical skills but also a thorough understanding of the indications, contraindications, and patient selection criteria for various laparoscopic procedures. Enhanced training efforts will be crucial in expanding the pool of skilled laparoscopic surgeons and promoting the broader adoption of minimally invasive techniques in urogynecology⁽³⁶⁾.

Conclusions

Laparoscopic surgery has established itself as a cornerstone of modern urogynecology, offering a minimally invasive alternative with substantial benefits for patients undergoing treatment for pelvic organ prolapse and stress urinary incontinence. Despite the challenges associated with its adoption, continued advancements in technology, training and research are poised to enhance the role of laparoscopy in urogynecology. By addressing the current limitations and embracing innovative approaches, the field can move towards a future where laparoscopic surgery is accessible, effective, and tailored to meet the needs of every patient. ■

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Large tubo-ovarian abscess following retention of a Copper-T intrauterine device inserted ten years prior in an obese psychiatric patient

Oana-Denisa Bălălaşu^{1,2},
Fernanda Ecaterina Augustin^{1,2},
Mihai Loghin^{1,2},
Delia-Maria Bogheanu²,
Mihaela Amza^{1,2},
Romina-Marina Sima^{1,2},
Liana Pleş^{1,2}

1. Department of Obstetrics and Gynecology, "Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania

2. "Bucur" Maternity, "Sf. Ioan" Emergency Clinical Hospital, Bucharest, Romania

Corresponding author:
Romina-Marina Sima
E-mail: romina.sima@umfcd.ro

Abstract

Introduction. Pelvic inflammatory disease (PID), often resulting from infections by pathogens like *Neisseria gonorrhoeae* and *Chlamydia trachomatis*, involves inflammation in the female reproductive tract. The risk factors include younger age, other sexual transmitted infections (STIs), lack of contraceptive barriers, substance abuse, and long-term intrauterine device (IUD) use. The clinical presentations range from silent to acute forms, with complications like tubo-ovarian abscesses (TOA). For severe cases, the treatment involves antibiotics, but drainage or surgery may be necessary for large or unresponsive abscesses. **Case report.** A 40-year-old woman, with a ten-year copper IUD, was referred for left adnexal mass detection. She was initially admitted for recurrent depression, but she was found to have an 8.9-cm left TOA on ultrasound and computed tomography (CT). Despite empirical triple antibiotic therapy (doxycycline, cefuroxime, metronidazole), her inflammatory markers, C-reactive protein (CRP), and leukocytes remained elevated, and the IUD was subsequently removed. The imaging confirmed a persistent TOA with left ureteral compression and second-grade hydronephrosis. With CRP levels and inflammatory markers only partially responsive to treatment, surgical intervention was pursued. During exploratory laparotomy, a left tubo-ovarian mass was observed, adherent to the small intestine, rectum, and uterine border. A left adnexectomy, lavage and pelvic drainage were performed, with purulent material collected for bacteriologic examination. The pathology confirmed a tubal abscess with extensive inflammatory infiltration, but no specific infectious agents. Postoperatively, the patient showed gradual normalization in inflammatory markers and WBC levels. She was discharged, and at follow-up reached full recovery with no subsequent complications. **Conclusions.** This case highlights the challenges of managing PID in long-term IUD users, especially with large TOAs that may not fully respond to antibiotics. The prolonged IUD use and minimal symptoms contributed to the delayed diagnosis and significant abscess formation. The surgical management, after initial antibiotic therapy, was crucial for resolution. This case underscores the importance of early management in high-risk patients to prevent severe outcomes and the potential complexities when common pathogens are not identified.

Keywords: tubo-ovarian abscess, intrauterine device, pelvic inflammatory disease

Rezumat

Introducere. Boala inflamatorie pelviană (BIP), cauzată adesea de infecții cu agenți patogeni precum *Neisseria gonorrhoeae* și *Chlamydia trachomatis*, implică inflamația tractului reproductiv feminin. Factorii de risc includ vârsta tânără, alte infecții cu transmitere sexuală (ITS), lipsa metodelor de contracepție de tip barieră, abuzul de substanțe și utilizarea prelungită a dispozitivelor intrauterine (DIU). Manifestările clinice variază de la forme asimptomatice la forme acute, cu complicații precum abcesul tubo-ovarian (ATO). În cazurile severe, tratamentul include antibiotice, dar pentru abcesele mari sau neresponsive poate fi necesar drenajul sau intervenția chirurgicală. **Prezentare de caz.** O femeie de 40 de ani, cu DIU din cupru de zece ani, a fost trimisă la noi după depistarea unei mase anexiale stângi. Inițial a fost internată în alt spital pentru depresie recurentă, dar la ecografie și tomografie computerizată (CT) s-a descoperit un ATO stâng de 8,9 cm. În ciuda terapiei empirice triple cu antibiotice (doxiciclină, cefuroximă, metronidazol), markerii inflamatori, proteina C reactivă (PCR) și leucocitele (WBC) au rămas crescute, iar DIU-ul a fost ulterior îndepărtat. Imagistica a confirmat persistența TOA cu compresia ureterului stâng și hidronefroză ipsilaterală de gradul doi. Având în vedere răspunsul parțial la tratament al PCR și al altor markeri inflamatori, s-a recurs la intervenția chirurgicală. În timpul laparotomiei exploratorii, s-a observat o masă tubo-ovariană stângă aderentă la intestinul subțire, rect și cantul uterin stâng. S-au practicat aneختomie stângă, lavaj și drenaj pelvian, cu recoltarea de material purulent pentru examenul bacteriologic. Examenul histopatologic a confirmat prezența unui abces tubar cu infiltrare inflamatorie extinsă, dar fără decelarea vreunui agent infecțios. Postoperatoriu, pacienta a prezentat o normalizare treptată a markerilor inflamatori și a valorilor WBC. A fost externată, iar la urmărirea postoperatorie a avut o recuperare completă, fără complicații ulterioare. **Concluzii.** Acest caz evidențiază provocările de gestionare a BIP la utilizatorii de DIU pe termen lung, mai ales în cazul ATO mari care nu răspund complet la antibiotice. Utilizarea prelungită a DIU și simptomele minime au contribuit la diagnosticul tardiv și la formarea unui abces semnificativ. Gestionarea chirurgicală, după terapia inițială cu antibiotice, a fost crucială pentru rezoluție. Cazul subliniază importanța managementului precoce la pacientele cu risc ridicat pentru a preveni complicațiile severe și complexitatea potențială în absența identificării agenților patogeni comuni.

Cuvinte-cheie: abces tubo-ovarian, dispozitiv intrauterin, boală inflamatorie pelviană

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Abces tubo-ovarian mare la zece ani de la montarea unui dispozitiv intrauterin Copper-T la o pacientă psihiatrică obeză

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Introduction

Pelvic inflammatory disease (PID), also known as upper genital tract infection, including salpingitis and tubo-ovarian abscess, is associated with the infection caused by multiple pathogens, such as *Neisseria gonorrhoeae*, *Chlamydia trachomatis* and *Trichomonas vaginalis*. These microorganisms alter the normal immunological response, predisposing individuals to an inflammatory response due to potential pathogens such as *Escherichia coli*, *Bacteroides* spp. and *Enterococcus faecalis*. The risk factors for PID include positive cervical cultures for *N. gonorrhoeae* or *C. trachomatis*, younger age, lower socioeconomic status, substance abuse, other sexually transmitted infections, sexual partners with urethritis of gonorrhea, and the absence of mechanical and/or chemical contraceptive barriers. Previous diagnoses of PID also increase risk. Clinical forms of PID include silent, acute, chronic PID and tubo-ovarian abscess (TOA). Silent PID is an exclusion diagnosis, suspected in cases of tubal-factor infertility without a history of upper tract infection; adhesions and hydrosalpinx may be present, but most commonly, the fallopian tubes appear macroscopically normal. The clinical presentation of acute pelvic inflammatory disease includes uterine, adnexal or cervical tenderness, most commonly after menstruation. Other diagnostic indicators include fever, mucopurulent cervical discharge, cervical secretion rich in leukocytes, elevated inflammatory probes, and positive cervical cultures for *N. gonorrhoeae* and/or *C. trachomatis*. In acute salpingitis, sonographic findings may reveal a distended tube with anechoic or echogenic fluid inside, thickened fallopian walls, images of incomplete internal septa and a “cogwheel” appearance in cross section, often with positive color Doppler. Chronic PID is usually diagnosed histologically; hydrosalpinx and chronic pelvic pain may be present. A tubo-ovarian abscess occurs when the suppurated fallopian tube adheres to the ovary, typically presenting unilaterally, with potential involvement of the bladder, bowel and contralateral adnexa. Progression of the suppuration can cause abscess rupture and consecutive peritonitis⁽¹⁾.

Pelvic inflammatory disease guidelines from 2024 recommend as treatment for PID ceftriaxone i.v. or i.m. at 1 g as a single daily dose, combined with doxycycline i.v. at 100 mg twice daily (or orally if tolerated), followed by doxycycline orally at 100 mg, twice daily, plus metronidazole orally at 500 mg, twice daily, for a total of 14 days, or clindamycin intravaginally at 100 mg, once daily, for six days. An alternative parenteral regimen includes clindamycin i.v. at 900 mg, three times daily, plus gentamicin i.m. or i.v. at 3-6 mg/kg, once daily (with renal function monitoring), followed by clindamycin

orally at 450 mg, four times daily, or doxycycline orally at 100 mg, twice daily, plus metronidazole orally at 500 mg, twice daily, for 14 days, or clindamycin intravaginally at 100 mg, once daily, for six days⁽²⁾.

Drainage of a tubo-ovarian abscess is indicated in cases with no improvement within 2-3 days of treatment after modifying the antimicrobial regimen, as well as in larger abscesses (more than 8 cm in diameter) as a first-line treatment, concurrently with antibiotics. Drainage can be performed with CT or sonographic guidance via transabdominal, transvaginal, transgluteal, or transrectal routes. Exploratory laparoscopy or laparotomy is not usually recommended in the initial management of TOA, although surgical treatment can be performed after achieving the “cold abscess” state⁽¹⁾.

Case report

This case report describes a 40-year-old woman, non-smoker, with a copper T intrauterine device (IUD) inserted ten years prior. She was referred to our hospital for hospitalization and management after being diagnosed in the outpatient setting with a left adnexal tumoral mass. Previously, she was admitted to a psychiatry hospital for a recurrent depressive episode. Her medical history includes bronchial asthma and class I obesity, with a Body Mass Index of 34 kg/m². She had one birth by caesarean section and four elective abortions.

The speculum examination revealed normal external genital organs and a cervix with intact epithelium, without macroscopic lesions; the IUD wire could not be identified, and there was no vaginal bleeding. Bimanual palpation indicated a normal-sized, mobile, and non-tender uterus, with supple adnexal zones; in the posterior cul-de-sac, a spherical tender tumoral mass measuring about 8 cm with reduced mobility and soft consistency could be palpated. Transvaginal ultrasound showed the uterus in anteversion flexion (AVF), measuring 72/68/42 mm, with a homogeneous myometrium and an 8-mm endometrium. In the Douglas pouch, an acoustically heterogeneous formation measuring 8.9/7.5 cm was noted, suggestive of a left tubo-ovarian abscess (Figure 1). The right adnexa appeared normal on ultrasound, with no anechoic fluid behind the uterus.

Blood tests showed leukocytosis (WBC) with neutrophilia (18,530/mm³ with 16,180/mm³), moderate normochromic normocytic anemia (hemoglobin 9.5 g/dL, secondary to the inflammatory process), normal platelet count (343,000/mm³), altered coagulation, and significantly elevated inflammatory markers (fibrinogen 1086 mg/dL, C-reactive protein 463 mg/L, procalcitonin 0.47 ng/mL). CA-125 was slightly elevated (37.6 compared to 35). The cervical cultures tested negative for

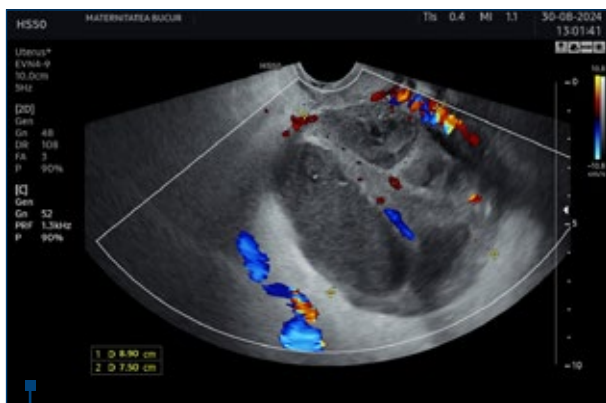


Figure 1. Left adnexal mass measuring 89/75 mm, with heterogeneous content, thick, coarse septa, and grade 1-2 color Doppler signal

Enterobacteriaceae, *Staphylococcus aureus*, *Streptococcus* spp., *Enterococcus* spp., and *Pseudomonas* spp. The patient was transferred to our hospital with the diagnosis of left adnexal tumoral mass and retained IUD.

During hospitalization, she received triple antibiotic therapy (doxycycline, cefuroxime, metronidazole) and anti-inflammatory treatment. On the sixth day, the IUD was removed under sedation. The dynamic of the laboratory test under medical treatment is presented in Table 1.

Abdomen and pelvis computed tomography with contrast revealed a left parauterine lesion measuring 86/71 mm, with fluid densities, a vascularized wall, a few septa, and fine densifications of the adjacent adipose tissue (possible left tubo-ovarian abscess), causing a compressive effect on the left ureter (resulting in second-grade ureterohydronephrosis and post-obstructive perfusion

disorders of the left kidney). Scanned sections noted bilateral pleurisy (maximum 12 mm on the left side) and small lymph nodes bilaterally at the pulmonary hila, as well as infracarinal. On the eighth day of treatment, following IUD removal, the inflammatory markers showed little improvement (fibrinogen 799 mg/dL, CRP 212 mg/L), along with a rise in hemoglobin (9.7 g/dL), but with thrombocytosis ($548,000/\text{mm}^3$) and a stationary leukocyte formula. The patient was discharged with recommendations to continue the antibiotic treatment for three more weeks at home and to return for reevaluation.

After almost one month of antibiotic therapy and IUD removal, the patient was readmitted to our hospital for surgical excision. Blood tests showed a normal leukocyte formula (WBC $8220/\text{mm}^3$, neutrophils $5670/\text{mm}^3$), mild normochromic normocytic anemia (Hb 11 g/dL), and normal platelet count ($404,000/\text{mm}^3$). C-reactive protein levels were normal (4.62 mg/L), fibrinogen slightly above the upper limit (467 mg/dL), and ESR remained high at 113 mm/hour. The examination of vaginal secretions indicated frequent yeast cells, rare leukocytes, relatively frequent lactobacilli, and the absence of *Neisseria gonorrhoeae* and *Trichomonas vaginalis*. On transvaginal ultrasound, the uterus was in an intermediate position, measuring 82/44/53 mm, with a homogeneous myometrium and a 5-mm endometrium. In the projection zone of the left adnexa, there was an acoustically heterogeneous formation measuring 7/6.2 cm, suggestive of a left tubo-ovarian abscess. The right adnexa appeared normal on ultrasound, with no anechoic fluid behind the uterus (Figure 2).

After obtaining the patient's informed consent, she was prepared for the surgical intervention. Under general anesthesia, exploratory laparotomy was performed. At the examination of the peritoneal cavity, the

Table 1

Laboratory tests evolution in the first hospital admission under triple empirical antibiotic therapy and intrauterine device removal in the sixth day

Day	WBC (/mm ³)	N (/mm ³)	Hb (g/dl)	PLT (x 10 ³ /mm ³)	FBG (mg/dl)	CRP (mg/l)	PC (ng/ml)	ESR (mm/h)
I	18,530	16,180	9.5	343	1086	463	0.47	
II								
III	15,260	12,810	8.6	361	1006	345	0.25	
IV								
V	15,980	13,520	8.4	423	962	265		114
VI	IUD removal							
VII								
VIII	15,920	13,240	9.7	548	799	212		120

WBC – white blood cells; N – neutrophils; Hb – hemoglobin; PLT – platelet count; FBG – fibrinogen; CRP – C-reactive protein; PC – procalcitonin; ESR – erythrocyte sedimentation rate



Figure 2. The ultrasonography aspect after almost one month of antibiotic treatment and IUD removal showed no important change in the lesion size or appearance

following were noted: the right adnexa appeared normal macroscopically, while the left adnexa was enlarged, approximately 8/6 cm, intensely adherent to the left uterine border, small intestine, rectum and visceral peritoneum, with the appearance of false membranes – meticulous viscerolysis was performed. Upon mobilizing the left adnexa, gray purulent fluid was spontaneously evacuated and collected for bacteriological examination (negative for *Enterobacteriaceae*, *Staphylococcus aureus*, *Streptococcus* spp., *Enterococcus* spp., *Pseudomonas* spp. and anaerobes). Left adnexectomy was performed following meticulous digital debridement up to the Douglas pouch, where the abscess had been extended (Figure 3). Lavage in abundance with betadine solution and pelvic drainage were conducted. The extracted specimens were sent for histopathological examination. The postoperative evolution was favorable under anticoagulant, antibiotic (ceftriaxone), anti-inflammatory and hydroelectrolytic rebalancing therapy. The dynamic

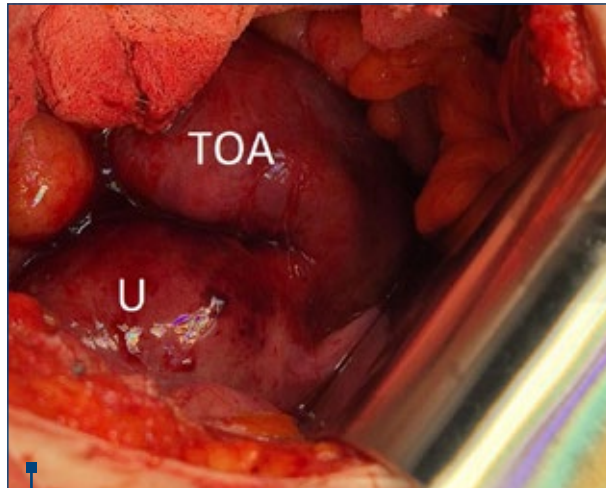


Figure 3. After three weeks of continuous outpatient antibiotic therapy, exploratory laparotomy was decided. The left tubo-ovarian abscess was intensely adherent to the nearby organs, including the uterine border, small intestines and rectum. The abscess was extended in the Douglas pouch (U – uterus, TOA – tubo-ovarian abscess)

of the laboratory test after surgical excision is presented in Table 2. The patient was discharged surgically cured on the fifth day.

The patient's follow-up revealed a favorable evolution with a fully recovery, without complications or recurrence.

The histopathological examination of the surgical specimen revealed a salpingeal wall with marked diffuse polymorphous inflammatory infiltration, edema, and focal transwall hyperemia with areas of substance loss in the wall; fibrino-leukocytic deposits on the tubal serosa. The histopathological findings are compatible with the clinical diagnosis of a tubal abscess.

Table 2

Laboratory tests evolution in the second hospital admission with exploratory laparotomy, left adnexectomy, lavage and pelvic drainage in the second day

Day	WBC (/mm ³)	N (/mm ³)	Hb (g/dl)	PLT (x 10 ³ /mm ³)	FBG (mg/dl)	CRP (mg/l)	ESR (mm/h)
I	8220	5670	11	404	467	4.62	113
II	Surgery						
III	15,550	11,440	10.1	336	419		
IV							
V	7740	5350	9.5	347		40	67
VI							
VII							

WBC – white blood cells; N – neutrophils; Hb – hemoglobin; PLT – platelet count; FBG – fibrinogen; CRP – C-reactive protein; ESR – erythrocyte sedimentation rate

Discussion

The factors associated with the failure of antibiotic therapy in patients with tubo-ovarian abscesses include advanced age, larger abscess size, history of intrauterine device use, postmenopausal status, underlying medical conditions such as diabetes mellitus or pelvic inflammatory disease, the presence of fever, elevated white blood cell count, and increased levels of erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP)⁽³⁾.

In a 2020 report analyzing 146 patients diagnosed with TOA, divided into two groups – those successfully treated with antibiotics alone and those requiring surgical treatment after antibiotic therapy failure –, the predictive risk factors for antibiotic treatment failure were examined. According to the study, the antibiotic treatment is likely to be ineffective in women over 41 years and 6 months of age, with a BMI over 26.72 kg/m², a CRP level above 143.5 mg/L at admission, and an abscess diameter greater than 6.25 cm⁽⁴⁾. In our case, three out of four criteria were above the cutoff level (BMI 34 kg/m², CRP 463 mg/L, abscess diameter 8.9 cm), thus predicting the failure of antibiotic treatment alone.

A 2022 retrospective study tracking the evolution of inflammatory markers and leukocyte formula after the surgical management of TOA highlighted the following findings. All inflammatory markers increased within the first 48 hours postoperatively and subsequently decreased over time. On average, WBC levels were the first to normalize postoperatively (2.5 days; 95% CI; 1-4.3), followed by the neutrophil-to-lymphocyte ratio (7.1 days; 95% CI; 4.7-10.8), and CRP (after more than 14 days). The study concluded that the CRP levels are not useful for assessing the postoperative success, as this inflammatory marker normalizes later, while WBC levels and the neutrophil-to-lymphocyte ratio are valuable in evaluating the operated TOA patient⁽⁵⁾. In our case, in the first day postoperatively the WBC count was 15,550/mm³ and the neutrophil-to-lymphocyte ratio was 11,440/2980 (3.83). In the third day, the WBC count was 7740/mm³, the neutrophil-to-lymphocyte ratio was 5350/1850 (2.89) and the CRP remained high at 40 mg/L.

A retrospective study from 2020 included 50 patients diagnosed with TOA between 2013 and 2017, divided into two groups: initial medical treatment (further subdivided into a successful medical group and late surgical treatment) and early surgical treatment. The medical treatment included triple antibiotic therapy (ceftriaxone 2 g/day, azithromycin 500 mg/day, and metronidazole 1000 mg/day). The surgical treatment was preferably performed *via* laparoscopic drainage, with other methods, including ultrasound-guided drainage, CT-guided drainage and laparotomy. The study showed that patients initially treated medically required late surgical intervention more frequently when the abscesses were larger (73.9 mm versus 53.5 mm in the successful medical group; p=0.19) and when the WBC and CRP values were higher (WBC 15,900/mm³ versus 13,500/mm³ in the successful medical group; p=1.00, and CRP 263.5

mg/L versus 171 mg/L in the successful medical group; p=0.43). Despite the promising results, these findings are not statistically significant (p>0.05). The duration of hospitalization was also analyzed between the two groups, being significantly shorter in the successful medical group compared to the late surgical group (p=0.01), but without statistically significant differences from the early surgical group⁽⁶⁾.

A prospective study conducted between 2015 and 2017 in Israel, which included 94 patients diagnosed with TOA, evaluated the utility of daily CRP measurement in predicting the need for early surgical intervention. In the requiring surgery group, the CRP values followed an upward trend from the day of admission to the second day and from the second day to the third day (128.26 mg/L, 173.75 mg/L and 214.66 mg/L, respectively; p<0.05 for both). In the group that did not require surgery, the same values were analyzed, showing a downward trend from the second, third and fourth days, while a plateau was observed between the day of admission and the second day (110 mg/L, 120.49 mg/L, 97.52 mg/L and 78.45 mg/L, respectively)⁽⁷⁾. In our case, the C-reactive protein was not measured daily, but every other day. Thus, the CRP levels decreased from the day of the first admission compared to day 3, day 3 compared to day 5, and day 5 compared to day 8 (463 mg/L versus 345 mg/L versus 265 mg/L versus 212 mg/L). Still, it should be added that, beside the triple antibiotic therapy that was initialized on the first day, the IUD was removed on the sixth day.

A case study from September 2024 followed a 61-year-old patient with an IUD and pseudoactinomycotic radiate granules (PAMRAGs) diagnosed on endometrial biopsy using Periodic acid-Schiff-diastase, Gram stain, and modified acid-fast bacilli stains, all of which were negative. PAMRAGs are nonpathogenic microorganisms, presenting a diagnostic challenge due to their resemblance to actinomycotic granules (AMGs)⁽⁸⁾. Actinomyces are Gram-positive, filamentous, anaerobic bacteria commonly found in the oral cavity, reproductive tract and gastrointestinal tract. *Actinomyces* spp. are associated with PID and TOA in patients with IUDs (the foreign body acting as a risk factor for microbial aggregation)⁽⁹⁾. This case report is valuable as it highlights an alternative pathogenesis in the TOA development. In our case, no etiological agent was found, but the tested bacteria did not include this microorganism.

A 2020 study from Türkiye included 124 patients diagnosed with TOA with a present IUD, all initially receiving medical treatment and later divided into a successful group (29.8%) if surgery was not required, and a failed group (70.2%) if surgery was necessary. The IUD was removed just before discharge in the medically treated group and during surgery in the other group. The study showed that the duration of IUD presence was significantly longer in the surgically treated group compared to the medically treated group (7.61±3.34 years versus 4.41±1.95 years; p<0.001). Other factors were also evaluated, among which statistically significant ones included:

patients' age (36.03 ± 9.04 in the successful group versus 39.46 ± 7.49 in the failed group; $p=0.03$), parity (1.92 ± 0.89 in the successful group versus 2.47 ± 1.12 in the failed group; $p=0.01$), maximum TOA size in cm (3.73 ± 1.33 in the successful group versus 6.51 ± 2.19 in the failed group; $p<0.001$), and WBC count/ mm^3 (11.150 ± 4300 in the successful group versus 14.430 ± 6720 in the failed group; $p=0.007$). The best calculated cutoff value for TOA size predictive of medical treatment success was 4.5 cm (sensitivity of 85.1% and specificity of 78.4%), and for IUD duration, it was 5.5 years (sensitivity of 67.8% and specificity of 78.4%)⁽¹⁰⁾. In our case, the large abscess size (8.9 cm) and the longer presence of the IUD (10 years) indicated the failure of the medical treatment alone and the requirement of later surgical intervention. Also, in our case, the patient presented multiple risk

factors for failure of medical treatment alone, such as age (40 years old), maximum TOA size (8.9 cm) and WBC count ($18,530/\text{mm}^3$).

Conclusions

The peculiarities of the case presented above include the inability to identify a causative agent despite the final histopathological diagnosis of a tubal abscess, the success of the combined treatment – initially medical with triple empirical antibiotic therapy followed by “cold” excision of the abscess after infection source eradication. Another notable aspect is the patient's medical history, which likely contributed to a delayed diagnosis, allowing the abscess to reach a large size with minimal symptoms, as well as the presence of an intrauterine device for approximately ten years. ■

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Factors affecting glycemic control among women with type 2 diabetes mellitus

E.A.M. Sathsarani¹,
G.P.I.M. Nanayakkara¹,
T.M. Malavipathirana¹,
K.A. Sriyaani¹,
F.M.M.T. Marikar²

1. Department of Nursing,
Faculty of Health Sciences,
The Open University Sri Lanka,
Nawala, Sri Lanka

2. Staff Development Centre,
General Sir John Kotelawala
Defence University,
Ratmalana, Sri Lanka

Corresponding author:
F.M.M.T. Marikar
E-mail: faiz@kdu.ac.lk

Abstract

Background. Type 2 diabetes mellitus (T2DM) is an expanding global health problem, being considered a chronic metabolic disease. It is a rapidly growing noncommunicable disease. According to World Health Organization (WHO), about 422 million people have diabetes worldwide. A total of 1.5 million deaths are reported each year due to diabetes. Glycemic control is very important to decrease the mortality and complications from diabetes. Social, psychological and dietary factors influence the control of blood glucose level. We studied the factors affecting glycemic control among women with type 2 diabetes mellitus. We tried to identify dietary factors and psychological factors among women with T2DM in our study objectives. **Methodology.** We used a quantitative approach, with a descriptive design. Data were collected from a random sample of 300 participants using self-administrated questionnaire. **Results.** The majority of T2DM patients fell within the 60-65 years old age category (26%), making it the most affected group compared to others. Among the participants, Tamil (8%), Muslim (14%), and Burger (2%) individuals were reported to suffer from T2DM. All retired women in the study were found to have T2DM. Additionally, participants who consumed starch-rich foods daily (2%) or 3-4 times per week (8%), as well as those who used to eat fast food 3-4 times per week (1%) or twice a week (4%) were identified as T2DM patients. The mean value of psychological factors was close to 1.01 on a Likert scale, where a value of 1 represents a minor problem level. None of the participants highlighted significant psychological reasons as being directly related to T2DM. **Conclusions.** The study indicated common causes related to glycemic control among women with type 2 diabetes mellitus. Our findings can be used to reduce the HbA1C levels and help the T2DM patients to adjust their dietary patterns and change their personal life, thus increasing the women's quality of life.

Keywords: type 2 diabetes mellitus, HbA1C level, glycemia, Sri Lanka

Rezumat

Context. Diabetul zaharat de tip 2 (DZ2) reprezintă o problemă globală de sănătate, tot mai des întâlnită, fiind considerat o boală metabolică cronică, netransmisibilă, cu o creștere rapidă. Potrivit Organizației Mondiale a Sănătății (OMS), aproximativ 422 de milioane de persoane suferă de diabet la nivel mondial, fiind raportat un total de 1,5 milioane de decese anuale din cauza diabetului. Controlul glicemic este foarte important pentru a reduce mortalitatea și complicațiile asociate diabetului. Factorii sociali, psihologici și alimentari influențează controlul nivelului de glucoză din sânge. În cadrul acestui studiu, am investigat factorii care afectează controlul glicemic la femeile cu diabet zaharat de tip 2, obiectivul nostru fiind identificarea factorilor alimentari și psihologici. **Metodologie.** Am utilizat o abordare cantitativă, cu un design descriptiv. Datele au fost colectate de la un eșantion aleatoriu de 300 de participante, folosind un chestionar autoadministrat. **Rezultate.** Majoritatea pacienților cu DZ2 s-au încadrat în grupa de vârstă 60-65 de ani (26%), aceasta fiind cea mai afectată. Dintre participante, s-a raportat că persoanele de etnie Tamil (8%), cele musulmane (14%) și cele Burger (2%) suferă de DZ2. Toate femeile pensionare din studiu au fost diagnosticate cu DZ2. În plus, pacientele care consumau alimente bogate în amidon zilnic (2%) sau de 3-4 ori pe săptămână (8%), precum și cele care obișnuiau să consume fast-food de 3-4 ori pe săptămână (1%) ori de două ori pe săptămână (4%) au fost diagnosticate cu diabet zaharat de tip 2. Valoarea medie a factorilor psihologici a fost apropiată de 1,01 pe o scală Likert, unde valoarea 1 reprezintă un nivel problematic minor. Nicio participantă la studiu nu a subliniat motive psihologice semnificative legate direct de DZ2. **Concluzii.** Acest studiu a descris cauzele comune asociate controlului glicemic la femeile cu diabet zaharat de tip 2. Constatările noastre pot fi utilizate pentru a reduce nivelurile de HbA1C și pentru a ajuta pacientele cu DZ2 să-și ajusteze modelele alimentare ori să-și modifice stilul de viață, crescând astfel calitatea vieții femeilor. **Cuvinte-cheie:** diabet zaharat de tip 2, nivelul HbA1C, glicemie, Sri Lanka

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Factorii care afectează controlul glicemic la femeile cu diabet zaharat de tip 2

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Introduction

Type 2 diabetic mellitus (T2DM) is world known metabolic disorder, and its prevalence has been increasing rapidly⁽¹⁾. T2DM is characterized by hyperglycemia and late presentations of vascular and neuropathic complications. This disease has an important

association with a hormonal deficiency known as insulin deficiency⁽²⁾. This is also called insulin resistance, T2DM being associated with irreversible risk factors such as age, genetic, race and ethnicity, and also with reversible factors like diet, physical activity and smoking⁽³⁾.

Dietary patterns are defined by the variety, quantity, or combination of different foods and drinks included in a diet, as well as the frequency with which these are consumed as part of habitual behavior. These patterns are influenced by various factors, including ethnicity, race, economic status, gender, educational level, and many other aspects. The dietary pattern of the individual influences many diseases, not only the type 2 diabetes mellitus^(4,5). Sociodemographic factors, such as age, gender, race and ethnicity, cultural barriers, marital status, religion, social support, economic status and educational level, have a great involvement in T2DM⁽⁶⁾.

As an endocrine disorder, type 2 diabetes mellitus has also a psychological involvement. Stress, anxiety disorder, and depressive symptoms are playing a major role⁽⁷⁾. Local studies emphasize that there is an upward trend in the prevalence of T2DM. The earliest study reveals a prevalence of 2.5% in 1990. The largest study on the diabetes prevalence in 2005 revealed a prevalence of 14.2% among males and 13.5% among females⁽⁸⁾. Women diagnosed with T2DM show higher self-control than males. However, it depends on the support from spouse, race and ethnicity, along with many other factors⁽⁹⁾.

The authors of a study performed in Southern Sri Lanka⁽¹⁰⁾ mentioned: "Even though the majority had adequate knowledge on diabetes, there is still some room for improvement as one fourth of study participants had poor knowledge on variance aspect of diabetics". In Sri Lanka, T2DM prevalence has rapidly increased all over the years, due to a combination of genetic and environmental factors, like a sedentary life style, physical inactivity, stress and obesity⁽¹¹⁾. Our study focused on describing factors affecting the glycemic control among women with type 2 diabetes mellitus. Therefore, this study will assess the factors affecting glycemic control among women with T2DM attending the diabetic clinic of the Teaching Hospital Karapitiya (THK), Sri Lanka.

Methodology

Research approach and design

In this study, we used self-administered questionnaire as a data collecting tool to generate numerical data and statistical analysis for organizing data. Therefore, the quantitative approach is the most suitable method for this study. The benefits of quantitative research are represented by the fact that we can gather empirical evidence that is rooted in objective reality, and we can obtain a significant accuracy through measuring psychological phenomena.

Research setting

The study setting was the diabetic clinic at Teaching Hospital Karapitiya in Sri Lanka. Teaching Hospital Karapitiya is the largest government hospital in Galle district, located in Karapitiya. It is a teaching-oriented hospital that maintains a bed strength of 2500 and around 4500 staff involved in patient care. It provides treatment for about 250,000 in ward patients and 800,000 outpatients per year. It covers most of the tertiary specialties and is properly equipped to treat the patients and provide the

best training for students. It provides outpatient care in various clinical settings. The diabetes clinic of the THK is the research setting according to feasibility of the study team. There are about 10,500 patients registered here, and the clinic is conducted from 8.00 a.m. to 4.00 p.m. every weekday except Sunday. There are six medical officers working under specialists. Other than that, four nursing officers, nutritionists and healthcare assistants are also allocated to this unit.

Population and sample

The study sample consisted of female patients who have registered in the diabetes clinic of the Teaching Hospital Karapitiya. Patients were selected for the study using simple random sampling technique. Researchers got the list of female clinic attendees with T2DM from the clinic's register. A total of 300 participants were selected, by one in every three patients, according to clinic's register. Simple random sampling method was used.

Lawanga & Lame show equation (1991):

$$N = \frac{z^2 P(1-P)}{d^2}$$

N = required minimal sample size

Z = 1.96; critical value of specified confidence, at 95% confidence interval

P = probable estimate of proportion of given characteristic

d = degree of accuracy desired set as 0.06.

Since no previous prevalence study on factors affecting glycemic control among women had been carried out in Sri Lanka, the anticipated population proportion was taken at 50% (*N*=294). Sample size (*N*) was rounded to 300 participants.

Inclusive and exclusive criteria

Female patients who have registered in the diabetes clinic of THK with diagnosed T2DM more than two years before, with ages between 30 and 65 years old. Critically ill patients and cognitive impaired patients were not included.

Data collection method

Data collection is a systematic process of gathering, measuring and analyzing information to address research objectives and answer specific questions. It involves selecting appropriate tools and techniques, such as surveys, interviews, observations or experiments, based on the nature of the study and the type of data required (qualitative or quantitative). A well-designed data collection method ensures accuracy, reliability and validity while minimizing biases. The process typically includes defining the research population, developing instruments, piloting tools and implementing the method while adhering to ethical standards to protect participants' confidentiality and integrity. In this study, we used simple random sampling technique.

Data collection instrument and tool

The data were collected using both self-administered questionnaire and biochemical laboratory reports. Questionnaire consisted of three sections to be filled

by patients. Sociodemographic data were included into part A. Part B included the questions referring to dietary factors, using food frequency questionnaire. Part C consisted of questions referring to psychological factors to assess depression, anxiety and diabetes-related distress. Last HbA1c levels were filled by researchers.

Validity and reliability

The questionnaire was prepared by researchers. Reliability was assessed with 10 participants, using test-retest method. For assessing reliability and consistency of the questionnaire, Cronbach's alpha test was used.

Data collection

Prior to conducting the main research, the scholars obtained approval from the Faculty of Medicine, University of Ruhuna. All the research studies, data collections and data presentations were done purely with the university's knowledge and administration. After personal discussions with each and every patient who wanted to be participate in the research, 300 patients were given the questionnaire to collect the data, and 297 responses were received.

Ethical consideration

For this study, ethical approval for the study was obtained from the Ethical Review Committee of the Faculty of Medicine, University of Ruhuna, and an information

sheet was distributed among the subjects, containing the purpose, objectives, risks and benefits of the study. A serial number was allocated to each questionnaire distributed among each participant to assure the anonymity. The participants who wished to participate in the study were permitted to withdraw from the study at any time. Data were stored under password protected file with restricted access only to the principal investigator and other members. The data were used for research purpose only. The hard copies of data will be retained under lock and key for five years.

Data analysis

Data were introduced, managed and analyzed using MS Excel and Statistical Package of the Social Sciences Software (SPSS) version 21. Data from complete questionnaires were entered into MS Excel and SPSS. The reliability of the questionnaire was checked using the Cronbach's alpha test. Data analysis was conducted both descriptive and inferential statistics to present the results of the study. Demographic characteristics were analyzed with the use of descriptive statistics such as mean, median, mode, standard deviation and frequencies. The results were summarized and presented by tables and charts. SPSS software and Microsoft Excel were used as tools for statistical and the graphical analysis.

Table 1 Sociodemographic factors of participants

		Number	Percentage
HbA1C	Normal	17	5.7%
	Prediabetes	34	11.4%
	Diabetes	246	82.8%
Age	30-39	35	11.8%
	40-49	93	31.3%
	50-59	106	35.7%
	>60	63	21.2%
Ethnicity	Sinhala	236	79.5%
	Tamil	20	6.7%
	Muslim	35	11.8%
	Burger	6	2%
	Other	0	0%
Marital status	Single	39	13.1%
	Married	213	71.7%
	Divorced	23	7.7%
	Widow	22	7.4%

Table 1 Sociodemographic factors of participants (cont.)

		Number	Percentage
Occupation	Government sector	46	15.5%
	Private sector	82	27.6%
	Housewife	117	39.4%
	Self-employed	32	10.8%
	Retired	20	6.7%
Educational status	Illiterate	15	5.1%
	Primary	21	7.1%
	Ordinary Level	120	40.4%
	Advanced Level	116	39.1%
	Higher education	25	8.4%
Monthly income	<10,000	11	3.7%
	10,000-30,000	50	16.8%
	30,000-50,000	152	51.2%
	50,000-100,000	71	23.9%
	>100,000	13	4.4%
Durations of diabetes	Less than 5 years	142	47.8%
	5-10 years	125	42.1%
	10-15 years	30	10.1%
	15-25 years	0	0%
	More than 25 years	0	0%
Types of diabetes treatment	Medical nutrition therapy	5	1.7%
	Only oral drugs	208	70%
	Only insulin combination of oral drugs and insulin	65	21.9%
	Medical nutrition therapy	19	6.4%
Self-monitoring of blood glucose level	Yes	86	29%
	No	211	71%

Results

Data collection was done by self-administered questionnaire, with 300 participants selected from the clinic's register of the diabetes clinic in the Teaching Hospital Karapitiya, Sri Lanka. A total of 297 participants gave their responses. All were female attendees with T2DM.

Table 1 indicates the HbA1C level of the participants. Most of the participants were suffering from diabetes (82.8%), and 11.4% of the participants were suffering from prediabetes. This shows that the larger part of our study participants were included in the age category 50-59 years old (35.7% of the total respondents). Those between 30 and 39 years old represented 11.8%.

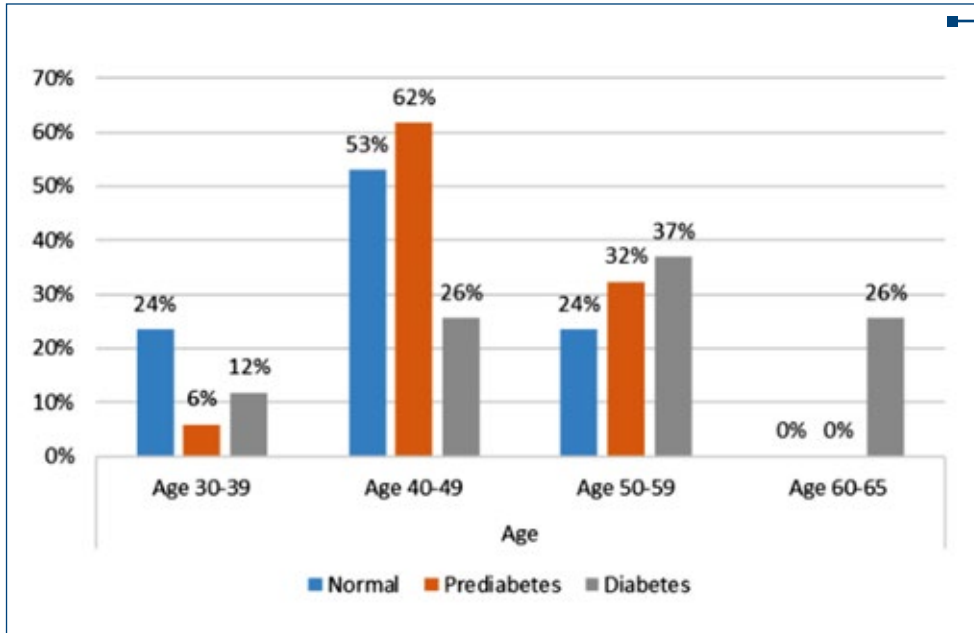


Figure 1. The association between the HbA1C level and age

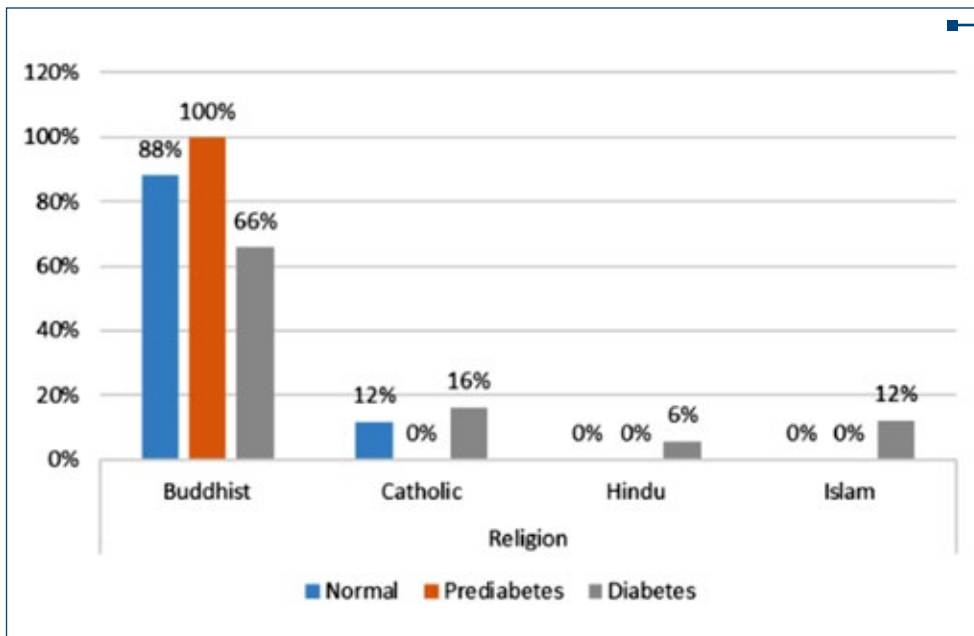


Figure 2. The association between the HbA1C level and religion

Figure 1 presents the association between the HbA1C level and the age of the participants. All those aged 60-65 years old were suffering from diabetes (26%), while 37% of those aged 50-59 years old were suffering from diabetes.

Table 1 further reveals that, regarding religion, most of the participant were Sinhala (79.5%) followed by Muslims (11.8%). Figure 2 shows that all the Hindu and Islam participants were suffering from diabetes (6% and 12%, respectively).

Regarding the marital status of the participants, all the widowed participants were suffering from

prediabetes or diabetes (18% and 7%, respectively), and 24% of the single participants had normal HbA1C levels.

As seen in Figure 3, regarding the association between the HbA1C level and the monthly income status of the participants, all those with a monthly income below 10,000 were suffering from diabetes (4%).

Figure 4 presents the association between the HbA1C levels and the participants' diabetes treatment. It was found that all participants who adhered to medical nutrition therapy were suffering from diabetes (2%), while 24% of those using only insulin were affected.

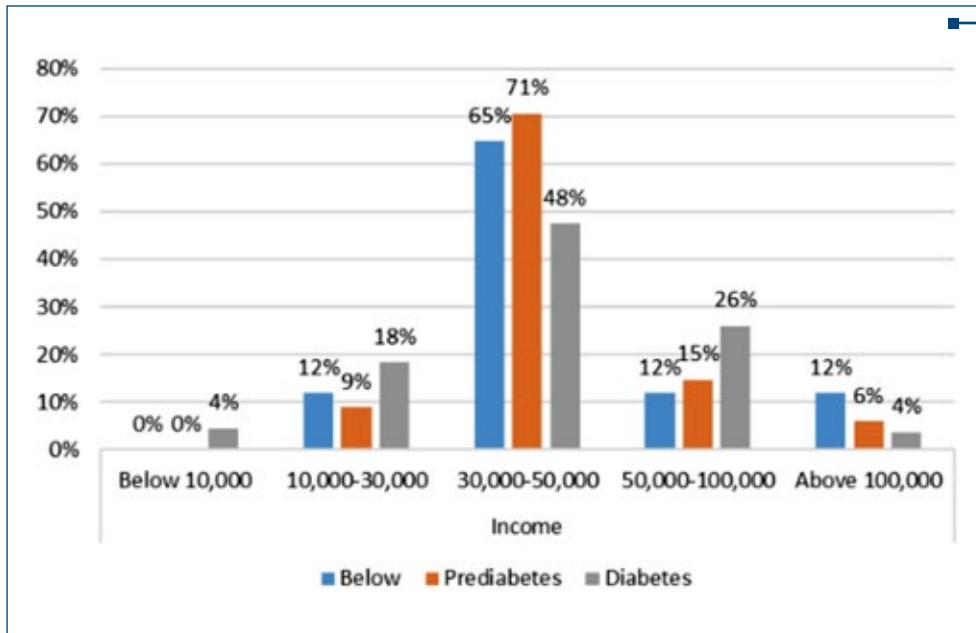


Figure 3. The association between the HbA1C level and the education status

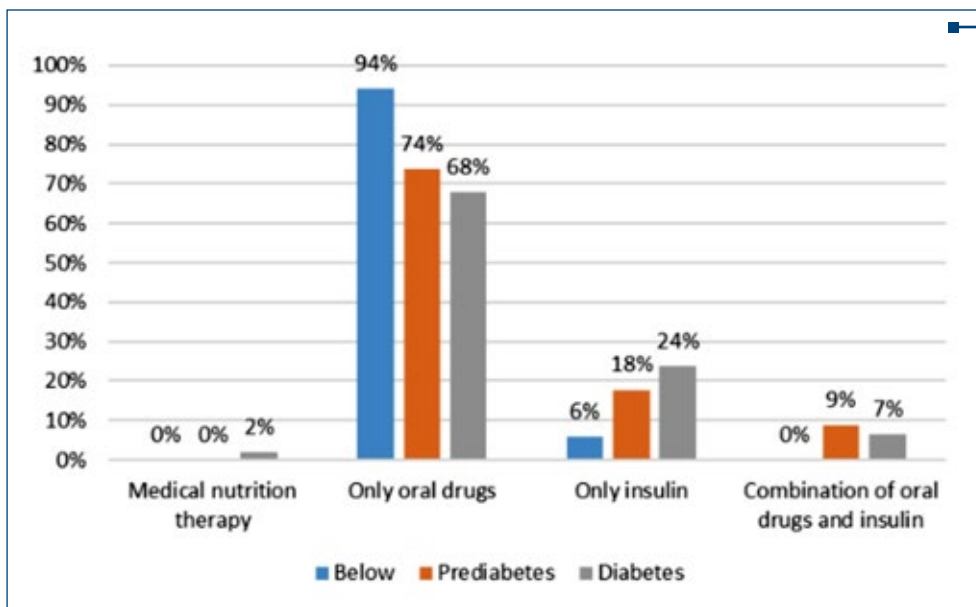


Figure 4. The association between the HbA1C level and the duration of diabetes

Discussion

More than 37 million Americans have diabetes (about one in ten people), and approximately 90-95% of them have type 2 diabetes. Type 2 diabetes most often develops in people over the age of 45, but more and more children, teenagers and young adults are also developing it⁽¹²⁾.

Factors such as age, gender, marital status, experience of working and present residence affect their HbA1C level. However, there is limited research regarding type 2 diabetes mellitus (T2DM) in Sri Lanka, including the developing countries. So, this is a descriptive hospital-based study on T2DM and related factors. In this study, we used 300 patients. Our questionnaire included three

parts, regarding sociodemographic data, dietary factors, and psychological factors.

Based on our findings, 26% of participants aged 60-65 were affected by T2DM, the highest among all age groups. Among ethnic groups, Tamil participants (8%), Muslim participants (14%), and Burgher participants (2%) were affected by T2DM. Hindu (6%) and Islam (12%) participants were also affected. Widowed participants had the highest rates of prediabetes (18%) and diabetes (7%), while most single participants (24%) had normal HbA1C levels.

It was revealed in this study that retired individuals represented the most common group affected by type 2

diabetes mellitus (T2DM), with 8% of this demographic group suffering from the condition. Retired individuals are considered the most stressed group, as the transition from employment to a normal lifestyle requires significant adaptation to new routines, dietary habits, and a different level of freedom. The study also highlighted the role of education level as a major factor in the prevalence of noncommunicable diseases. Among the surveyed participants, 6% of illiterate individuals and 9% of those with only primary education were found to have T2DM. Furthermore, monthly income emerged as another significant determinant, as dietary patterns often depend on financial capacity. According to the survey, 4% of participants with a monthly income below 10,000 reported having T2DM.

Conclusions

Significant evidence was observed regarding HbA1C levels and related factors among women with T2DM. The presence of more dependents was associated with variations in HbA1C levels and dietary factors. According to the respondents, HbA1C levels were categorized as normal in 5.7% of cases, prediabetic in 11.4%, and

diabetic in 82.8% of cases. T2DM is a chronic medical condition that affects millions of people worldwide. Unmanaged diabetes may lead to blindness, kidney failure, heart disease, and other serious conditions.

Implication for patients

These findings can be used to reduce the HbA1C levels among women with T2DM, to identify the causes of T2DM, and to prevent unhealthy behaviors among patients. This research study findings are especially useful in further educational opportunities of patients, nurses and students. This study experience helped us to conducting further research studies.

Recommendations

This study can serve as a baseline for further studies to recognize the factors related to type 2 diabetes mellitus and reduce the HbA1C levels.

Limitation

The test group, along with the purposes and outcomes of the test, is difficult to define, and the participants are hard to identify. ■

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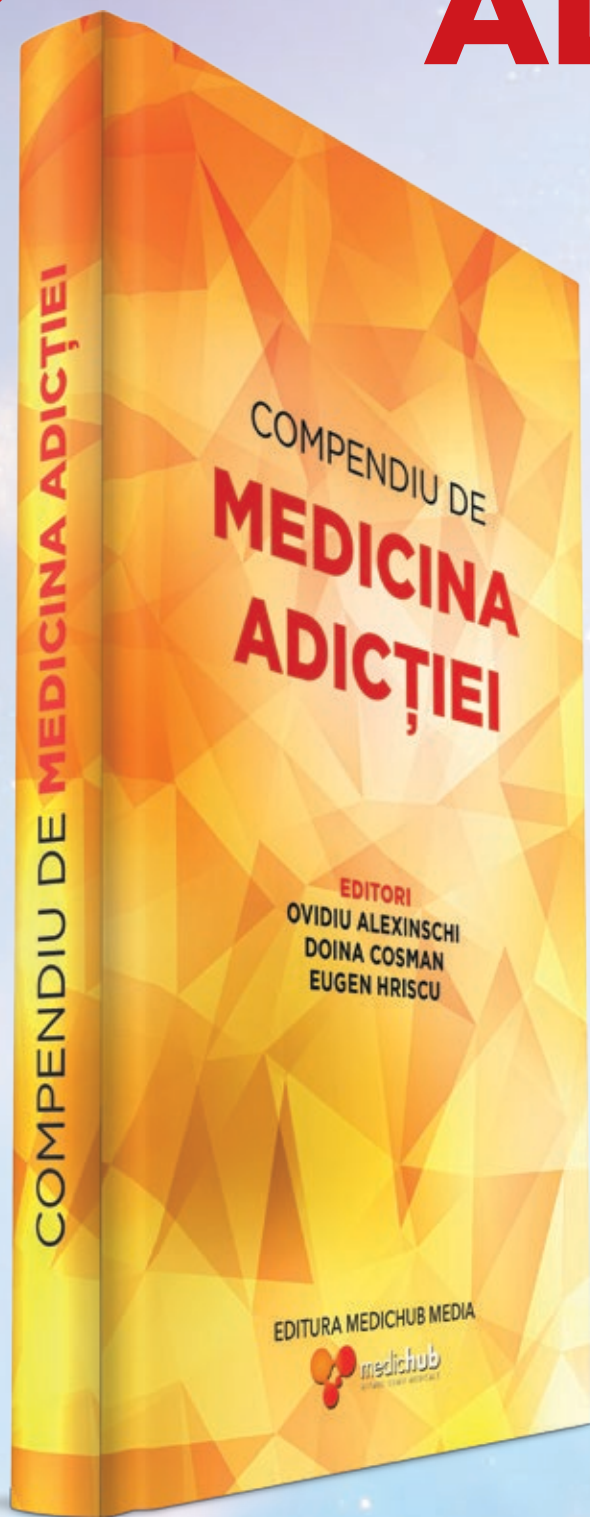
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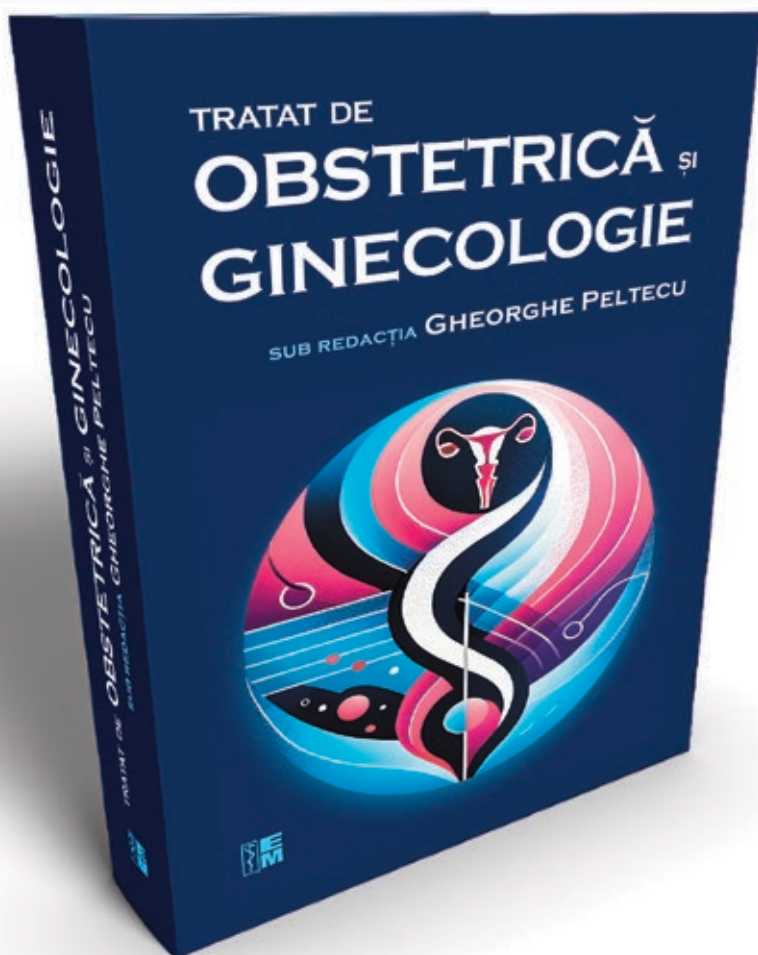
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