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THEME : IMPLEMENTATION OF EVIDENCE BASED CLINICAL CARE

MOTTO : SWEAT, SMILE & REPEAT

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TEAM AOGS MESSAGE

Dr. Jignesh Deliwala
President

Dr. Munjal Pandya
Hon. Secretary

Respected Members,

We are gradually emerging from one more spike of COVID infection; we hope that all the members and their families are doing great. Wishing all the health and happiness!

Republic Day marks the adoption of the constitution of India and the transition of the country to a republic on January 26, 1950. From this year onwards, R-Day celebrations would start on January 23 — birth anniversary of Netaji Subhash Chandra Bose (125th year this time). It would end on January 30, the day Mahatma Gandhi was assassinated, celebrated as "Martyrs' Day".

Uttarayan/ Makarsankranti is widely celebrated shifting of Sun towards North side; with its associated significance and religious beliefs. The same day has numerous festivals in various parts of our country.

We are in planning of few more academic events, will keep all the members updated as and when finalized. Please download AOGS App, which is available on Google Play Store as well as now, on iStore.

Wishing everyone best of the times ahead!

Dr. Jignesh Deliwala
President

Dr. Munjal Pandya
Hon. Secretary

Congratulations!

Congratulations and Pride of AOGS for being conferred Fellowship of ICOG (FICOG)

Dr. Janki Pandya

Dr. Munjal Pandya

Dr. Kirtan Vyas

Dr. Kunur Shah

Dr. Shashwat Jani

Dr. Sumesh Chaudhary

Assisted Reproductive Technologies (regulation) act 2021

Dr. Arati Gupte
MD, MICOG

The ART and surrogacy regulation acts were passed on 25th December 2021, and came into effect on 25th January 2022. A lot of practitioners have welcomed the act, as a way to legally regularize the practice and process of Assisted Reproductive Technology.

These are a few salient features mentioned in the Act, that differ from the regulations followed thus far.

Authorities:

Within 90 days of the commencement of this act, the central government must establish the following :

- National ART and Surrogacy board- chaired by the National Health Minister
- State ART and Surrogacy board
- National ART and Surrogacy Registry
- The appropriate ART and surrogacy authorities

All clinics and banks are to be registered with the Registry within 60 days of its establishment. The authorities will register, reject, or give an explanation for not processing the application. The authorities will then inform the state and national board about the application. The board will inspect the premises, after which registration will be granted.

Registration will be valid for a period of 5 years. It should be displayed prominently in the clinic.

Sourcing of gametes:

The act establishes the ART bank as an independent entity. It states that all ART clinics must procure gametes from registered ART banks only. The screening of donors, their selection, collection and storage of gametes are all to be done by the banks. (A small discrepancy- the act is unclear whether the banks will provide oocyte donors, or will actually provide stored oocytes, as both of these are mentioned in 2 different areas. Further clarification on this is needed).

Sperm donors: 21 to 55 years of age

Oocyte donors: 23 to 35 years

A woman can only be an egg donor once in her lifetime. Not more than 7 eggs can be retrieved, and these can be given to one recipient only. If the recipient chooses not to use them, the embryos will be allowed to perish or can be given for research. Each donor will be Aadhar linked, which will prevent her from donating more than once. Health insurance of the egg donor must be procured for a period of 1 year by the commissioning couple.

There is no mention of compensation to donors.

The donors are to be screened for diseases prescribed by the registry and board.

Confidentiality of donors and commissioning couples are to be maintained.

Gametes can be stored upto a period of 10 years, after which they can be destroyed or given for research as per prior consent from the commissioning couple.

ART services:

Treatment can only be offered to a married couple or to a single woman.

To avail treatment, the age of the woman must be between 21-50 years and that of the man between 21 to 55 years only.

Not more than 3 oocytes/embryos can be transferred at a time.

Every clinic must provide counseling to the patients, about procedure, success rates, advantages and disadvantages, possible side effects or complications, costs etc.

Every clinic and bank must have a grievance cell.

The clinics must explain to the patients, the rights of the child born through ART procedures.

There are no provisions for GBTQ+ or single men.

Embryos or gametes cannot be moved within the country or be transferred to another country for the use of the commissioning couple, without permission of the Board. Export or import of donor gametes is prohibited.

Medical records:

All medical records must be updated within one month to the national registry. The format will be clarified subsequently. All medical records must be maintained by the clinic for a period of 10 years, after which they will be transferred to the National Registry. Records should be available for inspection at all times.

Pre- implantation genetics:

The Pre-implantation Genetic testing shall be used to screen the human embryo for known, pre-existing, heritable or genetic diseases only

The screening must be done in approved labs. The National Board may specify the prerequisites for pre-implantation testing.

Contraventions:

The punishment for contravention of the regulations of the act are as follows:

1st time: Rs 5-10 lakh fine. Then, Rs 10-20 lakh fine with 3-8 years imprisonment. The offence is considered cognizable and bailable.

The act hold true the concept of vicarious responsibility- i.e. the executive head of the clinic or bank will be held liable for punishment unless proved otherwise in court.

Surrogacy (Regulation) Act 2021

Many of the points mentioned are similar to those of the ART act above. The differences are as follows:

Definitions:

This act defines “embryologist” as person who possesses any post-graduate medical qualification or doctoral degree in the field of embryology or clinical embryology from a recognized university with not less than two years of clinical experience.

Authorities and registration:

Registration of the surrogacy clinic must be done within 60 days of establishment of the National Registry. The registration will be given within 90 days of application and will be valid for 3 years.

The law makers have allowed a grace period of 10 months from the commencement of the Act (i.e upto 25th November 2022), to finish all existing cycles as per the old rules.

Types of surrogacy:

According to this Act, India will only allow altruistic surrogacy. The surrogate can be a relative or could be any woman between the ages of 25-35 years. She must be married and have at least 1 child of her own. The commissioning couple must pay for all medical expenses, any other expenses incurred, as well as for health insurance of the surrogate. Compensation in any form is prohibited.

Commercial surrogacy is banned in India.

Criteria for surrogacy:

For a couple to avail of surrogacy services, the couple should be married, the wife must be between 23- 50 years of age, and husband between 26-55 years. They should have a valid medical indication for surrogacy, and should have no living child. The only time an exception can be made to this rule is if the surviving child is certified by the Board and authorities as being disabled or suffering from a fatal illness.

The intending couple must possess:

- Essentiality certificate
- Order of parentage and custody (this will serve as a birth certificate once the child is born)
- Insurance policy- the couple/woman must have an insurance policy for 36 months in favour of the surrogate.

Frozen embryos cannot be used for transfer into surrogate. Only embryos from a fresh cycle are to be transferred. All remaining embryos are to be destroyed or given for research purposes.

Pregnancy with Fibroid

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Fibroids (leiomyomas) are benign smooth muscle cell tumors of the uterus. Although they are extremely common, with an overall incidence of 40% to 60% by age 35 and 70% to 80% by age 50, the precise etiology of uterine fibroids remains unclear.[1]

The exact prevalence of uterine fibroids is not accurately determined. This is partly due to the asymptomatic nature of the vast majority of the fibroids, and partly due to the difficult diagnosis. However, the prevalence of uterine fibroids during pregnancy reported in some studies ranges from 1.6 to 10.7%, and the prevalence varies from one trimester to another.[2]

The prevalence of uterine fibroids during pregnancy is therefore likely underestimated. Reflecting the growing trend of delayed childbearing, the incidence of fibroids in older women undergoing treatment for infertility is reportedly 12% to 25%. Despite their growing prevalence, the relationship between uterine fibroids and adverse pregnancy outcome is not clearly understood.[3] A study observed a lower incidence of uterine leiomyomata with later age at menarche, longer menstrual cycles, parity, later age at first and last birth, shorter time since last birth, and breastfeeding.[4]

The diagnosis of fibroids in pregnancy is neither simple nor straight forward. The ability of ultrasound to detect fibroids in pregnancy is even more limited (1.4%-2.7%) primarily due to the difficulty of differentiating fibroids from physiologic thickening of the myometrium and due to fetal parts altering diagnosis in posterior wall fibroids.[5]

CHANGE IN SIZE DURING PREGNANCY AND POST-PARTUM:

The majority of fibroids (60%-78%) do not demonstrate any significant change in volume during pregnancy. Fibroids that did increase in volume, the growth was limited almost exclusively to the first trimester, especially the first 10 weeks of gestation, with very little if any growth in the second and third trimesters. Some studies have shown that small fibroids are just as likely to grow as large fibroids[6], whereas other studies have suggested that small and large fibroids (≥ 6 cm) have different growth patterns in the second trimester (small fibroids grow whereas large fibroids remain unchanged or decrease in size), but all decrease in size in the third trimester.[7,8] Multiple myomas are less likely to disappear than solitary myomas. The majority of fibroids show no change during the puerperium, although 7.8% will decrease in volume by up to 10%.[6,7]

EFFECT OF FIBROID ON PREGNANCY

Most fibroids are asymptomatic. In some cases, various MILD TO SEVERE complications have been reported. Approximately 10% to 30% of women with uterine fibroids develop complications during pregnancy.[9] Although decreased uterine distensibility or mechanical obstruction may explain some adverse outcomes, the precise mechanism by which uterine fibroids induce obstetric complications is not clear.[10]

Location of fibroid also matters. Fibroids located in the lower uterine segment are accompanied by a higher frequency of caesarean section and retained placenta. Fibroids located in the uterine corpus are more frequently associated with early abortions. Multiple fibroids are accompanied by a higher frequency of malpresentation and premature contractions compared with cases with one or two fibroids.[8]

MATERNAL COMPLICATIONS:

1. During antepartum period:-

- Spontaneous abortion - Spontaneous miscarriage rates are greatly increased in pregnant women with fibroids. The size of the fibroid does not affect the rate of miscarriage, but multiple fibroids may increase the miscarriage rate compared with the presence of a single fibroid only (23.6% vs 8.0%).[11]
- Abdominal pain - Severe localized abdominal pain can occur if a fibroid undergoes "red degeneration," torsion (seen most commonly with a pedunculated subserosal fibroid), or impaction. Pain is the most common complication of fibroids in pregnancy, and is seen most often in women with large fibroids (>5 cm) during the second and third trimesters of pregnancy.5Analgesics, rest and tocolytics if needed to relieve the pain.
- Preterm labour and birth - Multiple fibroids and fibroids contacting the placenta appear to be independent risk factors for preterm labor.[8]
- Premature rupture of membrane (PROM)- Preterm labour pain and malpresentation can lead to PPROM.
- Malpresentation- Fibroid specifically in lower uterine segments and multiple fibroids can lead to fetal malpresentation.
- Placenta previa and abruption- Submucosal fibroids, retroplacental fibroids, and fibroid volumes > 200 cm^3 are independent risk factors for placental abruption.[12] One possible mechanism of placental abruption may be diminished blood flow to the fibroid and the adjacent tissues which results in partial ischemia and decidual necrosis in the placental tissues overlaying the leiomyoma.[5] The presence of fibroids is associated with a 2-fold increased risk of placenta previa even after adjusting for prior surgeries such as caesarean section or myomectomy.[3,10,13]

2. During intrapartum period:-

- Dysfunctional labour and increased rate of caesarean section.
- Uterine rupture after past myomectomy –Possibility of rupture of uterus during future pregnancy is present in patients having past history of myomectomy.
- Malpresentation
- Cesarean myomectomy – possibility of myomectomy in cesarean section due to large fibroid in lower uterine segment or large fibroid on suturing site or multiple uterine fibroids in whole uterus.
- PPH (Postpartum Hemorhhage) – Inadequate uterine contraction due to fibroid can lead to PPH. Surgically; myomectomy

during cesarean can also lead to PPH.

- Obstetric hysterectomy – Rarely, PPH or cesarean myomectomy can lead to obstetric hysterectomy.
- Retained placenta – due to lower segment large fibroid.

3. During post-partum period:-Retained placenta, post-partum haemorrhage (PPH), sepsis.

Fetal complications:-

- Intrauterine growth restriction (IUGR) & Low birth weight (LBW)
- Intra-uterine death (IUD)
- Fetal deformity- Large uterine fibroid may chronically compress some of the fetal part may lead to fetal deformity.[14]

Rare complications:

- Humoral Hypercalcemia or hypercalcemic crisis: Some cases have been reported of this condition, features shared with malignant neoplasms. Obstetricians should be aware of the existence of humoral hypercalcemia related to leiomyomas and the potential effects on pregnancy.[15,16]
- A rare condition of women with erythrocytosis and a concurrent myomatous uterus has been classified as "myomatous erythrocytosis syndrome". Substantial myoma size has been noted as a common denominator in this condition in which recent evidence have confirmed erythropoietin (Epo) production by myoma tissues themselves. Apart from its primary endocrine role in controlling erythropoiesis, Epo has been demonstrated to mediate several cellular processes such as angiogenesis, mitogenesis, and inhibition of apoptosis by autocrine and paracrine mechanisms.[17]

Management of fibroid during pregnancy:

Management of leiomyomas in pregnancy is conservative and limited, when it is necessary, to medical therapy. The main conditions that induce inevitably the surgical procedure are the torsion of pedunculated fibroid or rare cases of necrosis, pyomyomas and resultant inflammatory peritoneal reaction. Laparoscopy technique has several advantages in comparison to previous techniques such as best postoperative course with reduction of pain, fast recovery, less hospitalization and, absence of large and unaesthetic scars. The importance of maternal and fetal welfare thus requires a careful evaluation of several factors that, varying from case to case, lead the surgeon to choose the most appropriate management.

Management of pain: Prostaglandin synthase inhibitors (eg, nonsteroidal anti-inflammatory drugs) should be used with caution, especially prolonged use (> 48 hours) in the third trimester where it has been associated with both fetal and neonatal adverse effects, including premature closure of the fetal ductus arteriosus, pulmonary hypertension, necrotizing enterocolitis, intracranial hemorrhage, or oligohydramnios.[18] Rarely, severe pain may necessitate additional pain medication (narcotic analgesia), epidural analgesia, or surgical management (myomectomy).[19,20]

Myomectomy: myomectomy can increase the rate of pregnancy in women with infertility, attempting to restore a normal anatomy and reduce uterine contractility and local inflammation associated with the presence of fibroids, improving the blood supply[21] andalso in recurrent pregnancy loss[22,23,] although whether such surgical interventions actually improve fertility rates and perinatal outcome remains unclear.

It is rare for fibroids to be treated surgically in the first half of pregnancy. If necessary, however, several studies have reported that antepartum myomectomy can be safely performed in the first and second trimester of pregnancy.[12,24-30] Current evidence does not suggest routine myomectomy during pregnancy or at the cesarean birth, as fibroids-related complications are rare and may be overcome by the risks of surgery. However, in selected cases, myomectomy is a feasible and safe technique and associated to a good outcome.[21] Acceptable indications include intractable pain from a degenerating fibroid especially if it is subserosal or pedunculated, a large or rapidly growing fibroid, or any large fibroid (> 5 cm) located in the lower uterine segment. Obstetric and neonatal outcomes in women undergoing myomectomy in pregnancy are comparable with that in conservatively managed women[12,28,] although women who had a myomectomy during pregnancy were far more likely to be delivered by cesarean due to concerns about uterine rupture[12,24,26-30]

Myomectomy at the time of cesarean delivery should only be performed if unavoidable to facilitate safe delivery of the fetus or closure of the hysterotomy. Pedunculated subserosal fibroids can also be safely removed at the time of cesarean delivery without increasing the risk of hemorrhage.[31]

Uterine artery embolization. Bilateral uterine artery embolization (UAE) has long been performed by interventional radiologists to control postpartum hemorrhage. More recently, UAE has been used as an alternative procedure for treating large symptomatic fibroids in women who are not pregnant and, most importantly, do not desire future fertility.[3] A recent prospective study reported that UAE performed immediately after cesarean delivery in women with uterine fibroids may be effective in decreasing postpartum blood loss and minimizing the risk of myomectomy or hysterectomy by inducing shrinkage of the fibroids.[32] Although not recommended, there are several reports of successful and uneventful pregnancies after UAE for uterine fibroids.[32-35]

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