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AOGD BULLETIN



Women's Health to New Horizons

Theme: Fibroids- Exploring Newer Avenues

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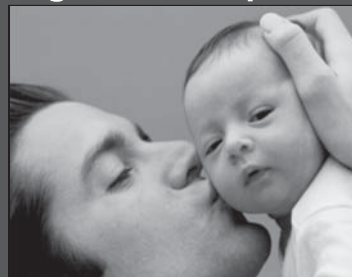
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Message from the President



Greetings to all!

With March comes the month of joy, colour and of course the time to celebrate the achievements of women of past and present throughout the world.

It is always proud being a woman and International Women's Day is a day to celebrate being a woman. The international Women's day, observed on March 8 is to rejoice the accomplishments of women in various fields like economic, political and social aspects. It is the need of the day, as progress made by women needs due recognition, more empowerment and equality in everything. It's the day to recognise the contribution made by women in various facets of life. This day is more important in our country where women were not given the same platform as that of men. A great progress has been made in the field of education for women and they are participating in all fields like sports, science, IT, politics and many more. But still there are many issues that need to be tackled such dowry, sexual harassment, crime against women, rape, child marriage, domestic violence, eve teasing and sex related abortions. We need to travel a long way to ensure that women are empowered, educated, safe, healthy and free to be fully participating members of equal societies.

The month march also embarks as the season of spring and festival of colours. Holi, the festival of love and compassion is marked at the onset of spring to rejoice new life and triumph of good over evil. We at AOGD pledge that we shall unite together and create awareness for both women and men about their responsibilities to promote and practice gender-equality.

Wish you all a very bright and colourful holi!

Dr Sudha Prasad

President

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From the Secretary's Desk



Dear Members,

Namaskar !

We welcome you all to this season of colors in festival (Holi) & flowers (Spring).

In this month, AOGD is celebrating International Women's Day on 8th March and also congratulates Dr Surbhi Singh for her commendable social work for adolescents. She has been awarded by the Govt of Delhi on this occasion.

We have planned an academic interactive programme on 18th March to discuss various issues pertaining to 'PCPNDT Act' and a video endoscopy CME on 19th March to learn various skills at Hotel Lalit.

Nominations for President, Vice-President and Chairperson of various subcommittees of AOGD are being invited. All details are available on the website as well as in the bulletin of January and February, 2017.

We will be handing over the AOGD secretariat to Dr Shalini Rajaram and her team on 31st March at UCMS & GTB Hospital at the monthly clinical meeting.

We do hope that all members will continue to actively participate in these events.

Dr Ashok Kumar

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From the Editor's Pen



Dear friends

Greeting from the editorial team!

The month of March brings with itself one of the most awaited festivals of the year, the festival of colors, Holi. May this splendid festival spread colorful joy, wealth, celebration and remove sorrows and ignorance in your life.

This issue of the Bulletin is dedicated to one of the most common benign conditions encountered in gynaecological practice, fibroids. Fibroids being the most common benign tumors of female genital tract, almost 20-30% of women have fibroids in their reproductive age group, majority of which are asymptomatic. When and how to treat them continues to be a dilemma in a large number of patients. Traditionally the management options used to be hysterectomy and myomectomy in women with symptomatic fibroids. The newer modalities include uterine artery embolization, a minimally invasive technique which can be used alone or in conjugation with myomectomy; and MRgFUS which is a non invasive technique utilizing the thermogenic effect of ultrasound. Both of these modalities require special expertise and are not approved for women desiring fertility. Management of fibroids in infertile women and women with recurrent pregnancy loss continues to be enigmatic. The medical management of fibroids still remains a mystery to be unraveled. The newer drugs on horizon seem to be promising. All these topics have been dealt very skillfully by experts in the field. We hope that you all enjoy reading this issue and benefit from it in your daily practice.

"The greater our knowledge increases, the more our ignorance unfolds." John F Kennedy

Dr Sangeeta Gupta

Editor

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Monthly Clinical Meeting

Monthly Clinical Meeting will be held at UCMS & GTB Hospital, Delhi
on **31st March, 2017** at 4:00pm.

Fibroid Growth and Medical Options for Therapy

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Introduction

Uterine leiomyomata or fibroids are the most common benign tumour in women, with a lifetime prevalence of about 30% and are apparent in reproductive age patients. Fibroids are one of the leading indication for hysterectomy. Majority of the patients with fibroid uterus are asymptomatic. The prevalence of fibroid on clinical evaluation is 33%, ultrasonography is 50%, and histopathological examination of hysterectomy specimen is 77%.¹ The associated symptoms depend on the location and size of the leiomyoma. Symptoms include heavy menstrual bleeding (HMB), dysmenorrhoea, and urinary or defecation problems. The patients may present with compromised reproductive functions, like subfertility, early pregnancy loss, and later pregnancy complications. Fibroids usually do not present before menarche and tend to regress in size after menopause.^{2,3} They are cause of concern in women of reproductive age because of heavy, irregular menstrual bleeding and pain, which can have a negative impact on a woman's quality of life and warrants intervention. The treatment options available to the woman include medical therapy, Uterine artery embolisation (UAE), Magnetic resonance imaging guided focussed ultrasound (MRgFUS), Minimally invasive surgery which includes hysteroscopic myomectomy, laparoscopic myomectomy and hysterectomy, open surgery like abdominal myomectomy and hysterectomy and non descent vaginal hysterectomy. The choice of therapy has to be tailored for each woman according to their wishes, the location and type of the fibroid, the associated symptoms and availability of skills.

Majority of fibroids are monoclonal oestrogen-dependent uterine neoformations.⁴ A lot of conflicting data about the pathogenesis of leiomyomas coexist in the literature. The development of uterine myomas can be linked to predisposing risk factors, genetic mechanisms, initiation, promoters, and effectors. Various pathogenetic factors such as genetics, microRNA, steroids, growth factors, chemokines, cytokines, and extracellular matrix components have been implicated in the development and growth of leiomyoma.

Pathogenesis of Uterine Leiomyoma

1. **Risk factors:** Many epidemiologic studies have linked uterine fibroids to the effects of estrogens

and progesterone levels and their metabolism; other mechanisms may be involved in fibroids pathogenesis. Wei et al.⁵ found ethnic differences in expression of the dysregulated proteins in uterine fibroids. The size of the tumour has been related to variation in molecular markers⁵⁻⁸, and it has been assumed that the molecular differences reflect differences in tumor growth rates. Moreover, molecular markers also may differ between tumors from blacks and whites^{7,8}. The incidence of fibroids is more in blacks than in Caucasian and Hispanic populations. Furthermore the cause of the higher prevalence among black women is unclear; though differences in circulating estrogen levels have been found⁹.

An inverse correlation between serum 25-(OH) Vit D levels and fibroid prevalence in black subjects which is statistically significant has been reported by some authors^{10,11}. The pathogenesis of myoma may involve a positive feedback loop between extracellular matrix production and cell proliferation, and vitamin D might act to block the positive feedback.¹²

The family history may represent a strong predisposing factor; the first-degree relatives of affected women have a more than twice the risk of developing fibroids^{13,14}. Several studies showed rapid increase of fibroid incidence after the age of 30^{13,14}. The risk of uterine leiomyomata is increased with increasing body mass index (BMI)¹⁵. The peripheral conversion of androgens into estrogen takes place in adipose tissue. Furthermore obesity results in reduced sex hormone binding globulin. This results in rise of biologically available estrogen which results in fibroid growth.

2. **Genetic Mechanisms:** The Chromosomal alteration is seen in 40% of Uterine fibroids.¹⁶ The most common chromosomal abnormality is HMG2 (translocation 12:14) is seen in 20% of cytogenetically abnormal lesion. This gene is expressed by tissues with proliferative phenotype. Heritable cancer syndromes such as hereditary leiomyomatosis and renal cell cancer (HLRCC) is characterised by benign leiomyoma and early onset renal cell carcinoma. The gene responsible is Fumarate hydratase which converts fumarate to malate in Krebs cycle.¹⁸ The defect in COL4A5 and

COL4A6 genes results in Alport syndrome which is X-linked progressive nephropathy and fibroids.¹⁹

Chromosome 10q24.33 has shown to have best association with fibroids, the region was mapped to the 5' region of the SLK gene encoding STE20-loke kinase which has a role in myogenic differentiation and, after activation by epithelial disruption, it is expressed in proliferating myoblasts.²⁰ The transcriptional regulator complex subunit 12 (MED12) mutation is seen in 70% of fibroids. In comparison with normal myometrium, there is over expression of $\beta 3$ subunit of TGF- $\beta 3$ in fibroids.²²

3. **MicroRNA:** Studies have shown that fibroids can occur due to epigenetic changes. The epigenetic changes seen were abnormally hypomethylated ER- α .²³ Many dysregulated microRNAs like let7, miR-21, miR-93, miR-106b & miR200 are seen in fibroids.²⁴
4. **Estrogens:** The growth of fibroids is directly related to estrogens and their receptors. The estrogens may promote the growth stimulatory affects on fibroids intermediated by growth factors, apoptosis factors and cytokines. Also Progesterone receptors are maintained by estrogen due to which progesterone can also cause the proliferation of fibroid.^{25,26} The upregulation of platelet derived growth factor and downregulate activin and myostatin is caused by estrogen.
5. **Progesterone:** The progesterone receptors PR-A and PR-B, under the influence of progesterone has important role in myometrial and fibroid biologies. The fibroid has higher concentration of progesterone receptor and mRNA levels than the normal myometrium.²⁷⁻³⁰ Progesterone upregulates EGF (mitogenic) and transforming growth factor (TGF) $\beta 3$ and downregulates IGF-I expression through PRB. L-type amino acid transporter 2 (LAT2) has been recently described as a novel Progesterone receptor gene.³¹ Progesterone receptor antagonist mifepristone blocks progesterone induced LAT2 and mRNA levels.
6. **Growth factors:** Growth factors like EGF, heparin binding endothelial growth factor (HB-EGF), VEGF, IGF, TGF- α , TGF- β , acidic fibroblast growth factor (aFGF) and basic Fibroblast growth factor (bFGF) have shown to induce the proliferation of fibroid.
7. **Cytokines and Chemokines:** Some cytokines like tumor necrosis factor-, erythropoietin, interleukin-(IL)-1 [116], and IL-6 [117], have been implicated in development of fibroids. Even chemokines and their receptors (MIP-1 α , MIP-1 β , RANTES, eotaxin, eotaxin-2, IL-8, CCR1, CCR3, CCR5, CXCR1, and CXCR2 mRNA) have been shown to be mediators.

Medical Options for Therapy

Medical options are used to treat problems associated with fibroids. Medical treatment is commonly offered in perimenopausal women whose symptoms are likely to resolve with the onset of the menopause, in women who are unfit for surgery and in some women receiving fertility treatment, preoperatively to reduce the size of the fibroid and to reduce menstrual bleeding to improve haemoglobin levels before surgery.

Non Hormonal Treatment for Heavy Menstrual Bleeding due to Fibroid

Tranexamic acid is an antifibrinolytic agent which is most frequently used to treat menorrhagia and it reduces the menstrual loss.

Hormonal Treatments

Fibroids have estrogen and progesterone receptors and both estrogen and progesterone may promote their growth. Published data for the outcome of treatment with the combined pill or progesterone-only pill in women with a fibroid uterus are inconclusive.³²

Levonorgestrel Intrauterine System

The levonorgestrel intrauterine system (LNG-IUS) is successful in treating heavy menstrual bleeding. The LNG-IUS use in women with fibroids is effective in reducing menstrual blood loss by inducing endometrial atrophy. It helps by increasing haemoglobin and relieving symptoms. LNG-IUS may not be used in fibroids distorting the uterine cavity.

Gonadotropin - Releasing hormone analogues

Gonadotropin-releasing hormone can be used preoperatively to shrink the size of fibroids and reduce the blood loss during the surgery. GnRH analogue treatment induces a pseudo-menopausal state with low estrogen levels. There are intolerable side effects and loss of bone mineral density. The hypoestrogenic side effects could be minimised by adding low dose estrogen and progestin or tibolone after initial phase of downregulation. GnRH analogue treatment is therefore limited to a maximum of 6 months. After discontinuation of therapy menstruation returned in 4–8 weeks and fibroid size returned to pretreatment levels within 4–6 months. There have been concerns about difficulties during myomectomy in obtaining an appropriate plane for dissection between the fibroid

capsule and myometrium and that small fibroids were often poorly defined and therefore were missed in women pretreated with GnRH analogues.

Progesterone - Mediated medical treatment

Selective progesterone-receptor modulators (SPRMs) are effective in treatment of fibroids. SPRMs, including mifepristone, telapristone, asoprisnil and UA, have been used in clinical trials for the treatment of uterine fibroids.³³⁻³⁶

Selective Progesterone - Receptor Modulators (SPRM)

Mifepristone

Mifepristone, a synthetic steroid, acts as progesterone receptor antagonist and has been used to reduce the symptoms of fibroids. The reduction in menstrual loss and symptomatic improvement with mifepristone appears to be a consistent finding. However, there is no consensus about the effect of mifepristone on fibroid volume and the endometrium. Its use in treatment of fibroids is currently restricted to research settings.

Ulipristal Acetate

Ulipristal Acetate is a new Selective Progesterone Receptor Modulator that is considered effective in the treatment of uterine fibroids. It induces apoptosis in uterine fibroid cells and inhibits proliferation of cells.³⁷ The first trial (PEARL I), 27.5 mg and 10 mg UA doses were compared with placebo for 13 weeks. Both doses of UA were effective in reducing menstrual blood loss in over 90% of patients after 13 weeks of treatment.²⁷ Amenorrhoea was noted within 10 days in three-quarters of patients receiving UA. The median change in uterine fibroid volume was 41% compared with 18% ($P = 0.0100$) and this reduction was maintained for at least 6 months after discontinuation of treatment.³⁷

The PEARL II trial was a noninferiority, double-blind 13 weeks comparison of UA with a GnRH analogue (monthly injection of leuprolide acetate). There was no difference in the control of menstrual bleeding between UA and leuprolide. However, UA was tolerated better and controlled bleeding more rapidly than leuprolide. Uterine volume change was greater with leuprolide than UA, but ultrasound assessment showed no difference in fibroid volume change.³⁸ UA use was associated with benign endometrial changes

termed progesterone-receptor modulator-associated endometrial changes. These changes were noted in up to two-thirds of women during treatment and resolved within 6 months of discontinuation of treatment.

The PEARL III and extension trials were performed to investigate long-term use of UA with repeated treatment cycles. In PEARL III, 209 patients used 10 mg of UA for 12 weeks and results were similar to those of PEARL I and II. In the PEARL III extension, a subsample of 107 women received four courses of UA as well as norethisterone acetate between courses.³⁹ The use of norethisterone acetate between courses of UA had no effect on progesterone-receptor-modulator associated endometrial changes.

Progesterone plays an important role in normal physiological function of reproductive organs, mammary glands, and bone, brain and endothelial cells in vessels and the central nervous system. Studies are needed to evaluate the effects of SPRMs on other body systems, especially after prolonged use.

Selective estrogen - receptor modulators and Aromatase inhibitors have limited evidence for the use in fibroid management and should be restricted to research settings until further evidence is available.

Conclusion

Fibroids have multifactorial etiology including genetic predisposition. Medical therapy successfully treats the symptoms. SPRMs has potential to reduce the rates for surgical treatment for fibroids. Other non invasive method to treat fibroid is MRI-guided focused ultrasonography and Uterine artery embolisation. Surgical treatment for fibroids should be offered to select patients with pressure symptoms and patients not responding to medical line of therapy.

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Improving Surgical Skills in Myomectomy

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Fibroid (leiomyoma) is one of the most common benign uterine tumour in females. They are a major cause of morbidity and at times even mortality in reproductive age group and sometimes even after menopause. The overall incidence is 20% to 40% in women during their reproductive years.^{1,2} They are monoclonal tumours of uterine smooth muscle cell origin. They are classified by their location relative to the layers of the uterus as subserous, intramural or submucous and can be single or multiple.

Uterine fibroids are mostly asymptomatic but can cause multitude of symptoms e.g. abnormal uterine bleeding, pressure symptoms, urinary incontinence & retention, pain & reproductive problems like miscarriage and infertility.

The approach to management has a wide spectrum, comprising of medical management & surgical management according to the patient profile. Recent advance in the management of fibroid is the advent of minimally invasive techniques in the form of minimal invasive surgery (MIS) or minimal access surgery (MAS). MIS are credentials for patients with a desire for future pregnancy or in those where fibroid is the cause of infertility. Even women with completed families do not wish to lose their uterus for various reasons and opt for other options instead of hysterectomy. Though hysterectomy is the definitive solution but these minimally invasive options have various advantages. It not only preserves the uterus and hence the fertility but also reduces morbidity and recovery time in comparison to hysterectomy.

The standard treatment for symptomatic uterine fibroid has been surgical and in patients who wish to preserve their fertility, a more conservative option of myomectomy. Myomectomy can be carried out via hysteroscopy, laparoscopy or by abdominal approach. Fibroid being one of the most common indications for gynaecological surgery in life time of the patient. The treatment has to be individualized based on symptom, size and location of fibroids, age, need and most importantly the desire of the patient to preserve fertility or the uterus, the availability and the experience of the surgeon. Myomectomy is among those operations in which surgeons experience plays a very prime role whether it is laparoscopic or abdominal. Since 1977, laparoscopic myomectomy has gained considerable importance among clinicians worldwide. Till date, there are number of publications including randomized controlled trials comparing laparoscopic

myomectomy with open myomectomy stating the feasibility and safety of laparoscopic myomectomy.^{3,4} Although laparoscopic and laparotomy surgeries appear to have similar success rate but laparoscopic myomectomy associated with reduced blood loss, lower haemoglobin drop, most importantly less postoperative pain, shorter hospital stay and recovery period, less risk of complications and reduced cost of medical care.^{5,6} Thus, it can be concluded that laparoscopic myomectomy is a better choice than open myomectomy in appropriately selected patients. Patient selection is the most important criteria for deciding the approach. One limitation always persists in laparoscopic approach of missing small fibroids as there is lack of tactile sensation.

The Preparation of women for myomectomy starts with the consent and counselling. It plays a very prime role for these patients as any myomectomy can end up in hysterectomy. Hence, consent should always be taken for both myomectomy as well as hysterectomy. Laproscopic myomectomy is associated with reduced blood loss, lower haemoglobin drop, less postoperative pain, shorter hospital stay and recovery period, and lower risk of complications in comparison to open myomectomy.

There are various strategies and criterias for improving the surgical skills as well as the outcome of surgeries as follows:

Pre-operative mapping of fibroid: Preoperatively mapping of number, size and location of fibroids must be carefully done either by ultrasound (both abdominal and vaginally) with Doppler or if feasible by MRI. This step is very crucial in decision making especially in the laparoscopic approach as there is no possibility of palpating the uterus intraoperatively. Mapping is important not only to decide the approach but also in guiding the type of uterine incision to be given. And most importantly reduces the risk of residual fibroids.

Decision for approach of procedure: Decision of the approach of procedure is important as it depend upon the expertise of surgeon, availability of laparoscope or hysteroscope, size and site of fibroid. Experienced surgeon in open or laparoscopic surgery is most important factor.³ The approach for the management of symptomatic intracavitary fibroid is hysteroscopic myomectomy.⁴ Hystroscopic morcellation is also a simple, safe, minimal invasive, easy to use and efficient treatment option for polyps and intrauterine

submucosal myomas. Less than 12 cm intramural fibroid can be removed laparoscopically but more than 12 cm fibroid is difficult to be removed because of its bulk and lack of space to work comfortably with laparoscopic instruments in lower abdominal cavity⁵. But these restrictions can be overcome by various strategies like appropriate patient selection, preoperative medical management to reduce the size of the fibroid, intraoperative optimization of port placement, use of vasoconstrictive agents, and most importantly good surgical technique to enucleate the fibroid and repair the myometrial defect. The number and size of fibroid that can be removed laparoscopically does not depend on the criteria given but on the surgeons experience and expertise.

Pre-operative intervention: General built up of the patient should be done prior to surgery and most importantly anaemia to be corrected.

Pre-operative drug therapy: Selective progesterone receptor modulators, danazol, aromatase inhibitors, mifepristone and gonadotropin releasing hormone (GnRH) analogues are very effective in correcting anaemia when used preoperatively. It is seen that about 40-50% reduction in myoma size is seen after 3 doses of GnRH analogues. On the other hand GnRH therapy is expensive and associated with menopause like side effects. It is unknown whether dissection planes become more difficult or not.

Methods to reduce blood loss: Various methods are used to reduce blood loss at myomectomy like use of vasopressin, bupivacaine, epinephrine, pericervical tourniquet, gelatine thrombin matrix & bonney's myomectomy clamp. Care should be taken during vasopressin injection to give it in correct subserosal plane to avoid intravascular injection & anaesthetist to be informed prior to injection. Also the syntocinon drip or misoprost during the procedure also helps in enucleation.

Deciding incision on uterus: The incision to be given on myoma bulge. The length of incision over the intramural fibroid should be equal to or more than diameter of fibroid, no matter if the incision is straight, elliptical, oval or circular. For subserosal fibroid the incision should be circular and at a distance from the base so that retracting edges of the scar will approximate after myomectomy. In case of multiple fibroid tunnelling technique to remove adjacent fibroids or incision should be planned for en-bloc myomectomy on anterior and posterior wall of uterus separately, thus avoiding entry in cavity or damaging the cornual ends of fallopian tube. Excessive blood loss and time spent can be prevented when the incision simultaneously excises the myo-hyperplastic uterine wall.

Port placement: In case of laparoscopic myomectomy port placement should be planned to create enough space

between laproscope and the uterus. All the ports should be placed according to the location of the fibroids, type of incision and the suturing technique of the surgeon.

Myometrial dissection and suturing: Minimum use of cautery should be done to avoid myometrial damage. Cutting during dissection to be done on the side of fibroid then uterine side. It will prevent dissection of myometrial fibres. The uterine suturing to be done in such a way that it will make a strong scar with minimum risk of hematoma, also it will avoid various complication like postoperative bleeding, infection and uterine rupture in next pregnancy. So depending upon the depth a one or two layer deep mattress suture required. In laparoscopy Quill bi-directional barbed suture is considered best for the myomectomy suturing. Suturing should not be very tight as it leads to necrosis.

Myoma removal: Morcellation is important step in laparoscopy myomectomy. Care to be taken during morcellation by keeping the rotating blades in the view at all the times, be on the surface of myoma and holding it steady. After removal smaller fibroids to be placed in pouch of Douglas and larger fibroids in upper abdomen.

The use of intraoperative cell salvage can also be considered to reduce the requirement of heterologous blood products.

Preventing adhesion formation: Intercede graft and goretex graft can be applied over the uterus after the completion of myomectomy. It reduces the risk of intraperitoneal adhesions which remains a major complication of myomectomy surgeries.

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The Fibroid Morcellation Controversy

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The Laparoscopic fibroid morcellation came into scrutiny after the case of a Boston-based anesthesiologist Amy Reed, who was subjected to routine laparoscopic hysterectomy followed by power morcellation for symptomatic fibroid in October 2013, in Brigham and Women's Hospital. There was no suspicion for malignancy on preoperative workup. Unfortunately, the pathological examination showed a leiomyosarcoma. The article about Dr Reed's case in The Wall Street Journal in December 2013 ignited the fibroid morcellation controversy. On 17th April 2014, the FDA discouraged the use of morcellation for uterine fibroid, but did not ban its use outrightly. The FDA encouraged the physicians to look for alternatives of power morcellation.¹

The benefits of minimally invasive gynecologic surgery include small incision, rapid recovery, reduced pain in postoperative period, lower risk of wound infection and faster return to activity.² The morcellation enables surgeon to offer minimally invasive approach for hysterectomies and myomectomies in women with large fibroid. On the other hand the morbidities associated with abdominal hysterectomy and myomectomy are high like infections, bleeding, deep vein thrombosis, and genitourinary and gastrointestinal tract injury.

The major disadvantage of open power morcellation is spreading of small pieces of tissue in the peritoneal cavity and surgical ports. Tissue disruption also makes tissue diagnosis more difficult.³ The most dreaded problem after morcellation, though rare, is the risk of occult malignancy in the specimen. It is well established that the minimally invasive surgery spare most women from the morbidity and mortality associated with open surgery. But, with morcellation going into controversy, it is important to weight the risk and benefits of the procedure.

Risk associated with morcellation of benign disease

The uterine fibroid are due to somatic mutation in a precursor cells. The tumors with this mutation have increased growth potential because the mechanism that limits cell growth have been suppressed at the level of cell DNA. The karyotype of these fibroids show exchange of genetic material between chromosome

12 and 14 (t(12;14)(q13-15,q23-24)).⁴ These mutations are associated with an increased expression of HMGIC, a gene that stimulates cell growth.⁵ The bits of fibroid containing these genetic mutations have more chance to disseminate postoperatively in the abdominal cavity & surgical ports.⁶ These disseminated nodules of fibroid tumors are called *morcellomas*.⁷

Moreover, the AAGL (Advancing Minimally Invasive Gynecology Worldwide) practice guidelines for laparoscopic subtotal hysterectomy emphasizes that morcellation of uterine fibroid rarely results in leiomyomatosis.⁸ The retrospective study report the incidence of parasitic leiomyomata from 0.1% to 1% following laparoscopic morcellations.⁶ The tissue dispersion is estimated to occur in 0.9% of patients undergoing laparoscopic morcellation in cases of endometriosis, adenomyosis and leiomyomatosis.⁶

Risk associated with morcellation of occult uterine leiomyosarcomas

Leiomyosarcoma are highly malignant tumors, with poor prognosis even without morcellation. Nearly 0.08% to 0.13% of uterine masses thought to be due to fibroid are proven by postoperative histology to be a uterine leiomyosarcoma on histopathology.⁹ Most leiomyosarcoma are early stage.¹⁰ Morcellation of occult leiomyosarcoma leads to upstaging of the tumor due to dispersion of its bits into the peritoneal cavity.¹¹ In a retrospective study of women with leiomyosarcoma, five years survival was 73% if the tumor was removed without morcellation and 46% if the tumor was morcellation.¹¹ If histopathology of morcellated fibroid reveals leiomyosarcoma, surgical re-exploration is needed to detect any spread of cancer, and chemotherapy is required if spread is detected.¹²

Current Scenario

The present scenario is a state of dilemma. There are certain unanswered questions.

Question 1- Is it logical to abandon minimally invasive approaches for all women with uterine fibroid due to the risk of occult malignancy?

Question 2- Myomectomy, itself involves tissue disruption, should all myomectomy be abandoned?

Question 3- What will be the take on the noninvasive

options like uterine artery embolization; MRI-guided focused ultrasound and radiofrequency ablation, where the presumed fibroid is left inside the body?

On May 9th 2014, ACOG released a special report titled *"Power Morcellation and Occult Malignancy in gynecologic surgery* advises practitioners to quote patients a rate of 1/500 for undiagnosed sarcoma and also recommend extensive patient counselling as well as offering alternatives method to laparoscopic power morcellation".¹³

Preoperative Diagnosis & Evaluation

It is of utmost importance to evaluate the patients carefully before deciding on the route of operation, with appropriate measures to diagnose malignancy before surgery. The demographic factors which increase the suspicion of malignancy are increasing age and rapid tumor growth. However, both these factors are not very reliable. Leiomyosarcoma are also reported in young patients in their twenties. The important considerations before morcellation are as follows-

Increasing Age- Broadly speaking, the chance of leiomyosarcoma increases with age, the incidence is lowest before the age of 35. The highest incidence of sarcoma is after the age of 65 years.

Menopausal status- Postmenopausal women with fibroid are at an increased risk of having occult malignancy.

Rapid uterine growth- Rapidly growing leiomyomas increase the concern of sarcoma

Certain treatment & hereditary conditions- Women who have undergone treatment with tamoxifen or pelvic radiations or have hereditary conditions like Lynch syndrome, hereditary leiomyomatosis and renal cell cancer are at high risk of uterine malignancy. Morcellation should not be done in these cases. Currently there are no established imaging studies that can reliably detect a uterine sarcoma preoperatively.¹⁴ The recommended standardized preoperative evaluation in all patients of fibroid undergoing open power morcellation include¹⁵

1. MRI/ sonography
2. Endometrial sampling in cases with abnormal uterine bleeding
3. Cervical cytology

All these preoperative evaluation can detect an occult cervical or endometrial cancer, but they are unlikely to detect an occult leiomyosarcoma. Screening

techniques like magnetic resonance imaging (MRI), particularly diffusion-weighted, and serum samples of lactate dehydrogenase (LDH) are potential screening methods.¹⁶

Patient Counseling and Informed Consent

If a minimally invasive surgery is being considered for the women with leiomyoma, the discussion with patient should include the risk, benefits and alternative procedure available. Patient should be encouraged to make an informed consent. During the consent, the patient must be informed of the risk of occult leiomyomasarcoma, increased chance of intraperitoneal dissemination as a consequence of power morcellation in these cases. Patient must be warned about worsening of prognosis and difficulty in accurate staging of underlying malignancy. Need of additional surgery and chemotherapy in case there is occult malignancy. If an intraperitoneal bag is to be used with power morcellation, the concern regarding insufficient bag size, disruption of bag and reduced visualization as a result of bag should be briefed upon. The alternative procedures like abdominal hysterectomy, vaginal hysterectomy, or a procedure involving removal of the uterine tissue through a mini-laparotomy or colpotomy incision, needs to be discussed with the patients.

Morcellation in a bag and in bag removal of specimen through an abdominal or vaginal incision

In this approach, the uterine tumor is placed in the bag, then hand /power morcellated within the bag to reduce the intraperitoneal spill and remove the bag with the specimen through an abdominal incision or a colpotomy. However, power morcellation within the bag is still not time tested and has limitations like size, disruption of bag by the morcellator and poor visualization.

Future Technology

Contained laparoscopic morcellation involves inflation of endobag with carbon dioxide with fitted camera and morcellator placed within the inflated bag, allowing for contained morcellation under direct visualization.¹⁷ Completely automatic specimen extraction devices are also being developed, which enables automatic morcellation in a closed environment without the need for a rotating blade and inflated bag.¹⁸

Another potential area of research include a reliable diagnostic tool to differentiate between leiomyoma and leiomyosarcoma, making it easy to decide on morcellation and pass on the benefits of minimally invasive surgery to most of the patients.

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Dr Surbhi Singh receives Government of Delhi - International Women's Day Awards 2017 on 3rd March, 2017, for Social Work

Embolisation of Uterine Fibroids: Current concepts

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Introduction

Uterine fibroids are the most common form of benign uterine tumors.¹ Nearly half of women with fibroids have significant symptoms such as heavy menstrual bleeding, menorrhagia, or intolerable pelvic pain.² Although, the current management strategies involve mainly surgical interventions, the choice of treatment is influenced by the age of patient, desire for future fertility, number, size and location of fibroids or a desire to avoid surgical intervention.³

Uterine artery embolisation (UAE) has now been accepted as one of a viable alternative to surgical treatment in the management of symptomatic fibroids. This technique was first described in the management of fibroids by Ravina et al in 1995.⁴ UAE is a minimally invasive procedure in which an interventional radiologist uses a catheter to deliver small particles that induces ischemic necrosis of the fibroids thus shrinks the fibroids, while the myometrium revascularizes. There are several advantages of UAE over other treatments including its less invasive nature, established favourable cost profile, and associated rapid recovery with most women being back to work within 2 weeks.⁵

Indications of UAE

As recommended by National Institute of Clinical Excellence (NICE), the main indication for UAE is symptomatic fibroids i.e causing menorrhagia, dysmenorrhoea, pressure effects, pelvic pain and dyspareunia.⁶ Earlier, the role of UAE in adenomyosis was controversial but a recent systematic review confirms that it is an effective therapy for the condition.⁷

Contraindications

There are only a few clear contraindications for UAE i.e Pregnancy, active uterine or adnexal infection or suspected reproductive tract malignancy. The other relative contraindications are presence of coagulopathy, renal impairment (renal effects of contrast), contrast allergy, pedunculated submucous fibroid and the desire for future fertility due to associated risk of pregnancy complications.⁸ The presence of pedunculated subserosal fibroid, uterine size >20-24 weeks or prior pelvic radiation have been removed from the list in the revised recommendations.⁵

Pretreatment Assessment

A woman should have a thorough evaluation by her gynaecologist prior to UAE. Appropriate selection of patients is important and decision should be made in conjunction with an interventional radiologist. Complete blood count, serum creatinine levels, prothrombin time, and partial thromboplastin time should also be obtained. Candidates for UAE should be adequately counselled about the increased risk (25%-35% within 5 years after UAE) of subsequent re-intervention, i.e, re-embolization, myomectomy, or most likely, hysterectomy and consent should be taken prior to the procedure.⁹

Procedure

UAE is performed under conscious sedation in an interventional radiology suite with fluoroscopic guidance. The embolic agent is generally either polyvinyl alcohol (PVA) microspheres or gelatine coated trisacryl spheres. The right femoral artery is usually selected, catheterised, and a narrow calibre catheter (4 or 5 Fr or microcatheter) with guidewire passed retrograde up the right external iliac and common iliac arteries, then over the bifurcation and down the left common and internal iliac arteries to the uterine vessel. There, the embolic agent is injected until there is no uterine blood flow. Then, the catheter is withdrawn back into the right common iliac artery and opposite uterine artery is embolised in a similar fashion. The total treatment time ranges from 30-90 minutes.¹⁰

Complications

Immediate (peri-procedural): upto 24 hours

- Hospitalisation >48 hours for prolonged pain
- Local: groin hematoma, arterial thrombosis
- Allergic contrast reactions
- Non target embolisation -most likely to affect the ovaries due to extensive collateral vascular network between the ovarian and uterine arteries.¹¹

Subacute (from 24 hours to 1 week) and chronic (> 1 week post procedure)¹¹

- Post-embolisation syndrome (~50 % of patients)- usually a self limiting condition that consist of pain, nausea, fever and malaise and subsides within 10-

14 days. Management includes analgesics and anti-inflammatory drugs.¹²

- Urinary tract complications
- Vaginal discharge -a common (16% at 12 months) symptom but usually self limiting.¹³
- Fibroid expulsion and impaction: more frequent in sub-mucosal fibroids. Management is usually expectant with need for hysteroscopic removal if necessary.
- Infection-Endometritis is sometimes associated with fibroid expulsion most commonly due to anaerobic infection and it usually responds well to antibiotics.
- Impact on ovarian reserve – more likely in women over the age of 45 years.¹⁴

Evidence Review

UAE has been recognised as a safe and effective procedure by the American College of Obstetricians and Gynecologists guidelines 2008.⁸ NICE has also updated its guidance in November 2010 and stated that this procedure is efficacious for symptom relief in short and medium term for a substantial proportion of patients.⁶

UAE versus Hysterectomy or Myomectomy

In a recent review by the Cochrane collaboration in 2012, outcomes of UAE were compared with hysterectomy or myomectomy.¹⁵ It included two large randomised studies [the EMMY Trial from the Netherlands (n=177) and the REST Trial from the United Kingdom (n=157)], and a large UK retrospective study (HOPEFUL with n=1108) published in 2007 that compared outcomes of UAE vs. hysterectomy.^{9,16,17} UAE has been shown to result in quality of life (QoL) similar to that achieved after surgery, but with a shorter hospital stay and earlier resumption of normal activities.^{15,18} The major RCTs included in the Cochrane study that compared outcomes of UAE vs myomectomy were FUME trial (n=147) in 2012 and a study by Mara (n=121) in 2007.^{19,20} Patient satisfaction with outcome was reported by most of the studies and no difference in satisfaction was noted between surgery and UAE at 12 to 24 months and at 5 years, regardless of whether the surgical procedure was hysterectomy or myomectomy.¹⁰ The latest 10-year outcomes from the randomized EMMY trial comparing UAE versus hysterectomy in the treatment of symptomatic uterine fibroids found that the majority of patients declared being (very) satisfied about the received treatment (78% of the UAE group vs 87% in the hysterectomy group) and hysterectomy could be avoided in about two thirds of UAE treated patients.²¹

Although UAE is highly effective for treating symptoms (reduction in bleeding and fibroid size), but it was found in some studies that the risk of re-intervention needs to be considered too (15–20% after successful embolization and up to 50% in cases of incomplete infarction).¹⁰ Several trials comparing UAE and myomectomy and UAE with focused ultrasound are currently ongoing, whose outcomes are awaited.²²

UAE and Fertility

There have been controversies on the use of UAE in young women desiring pregnancies as a number of complications have been identified in women during pregnancy subsequent to UAE like increased risk of miscarriage, postpartum hemorrhage, and caesarean delivery, fetal growth restriction and abnormal placentation.²³ The risk of infertility or subfertility following UAE is unknown.²⁴

The recent studies have shown that women can become pregnant after UAE and pregnancy rates are comparable to myomectomy (60% to 70%) but the data are limited as there are only a few studies²⁰. The only randomized controlled trial that compared the reproductive outcomes in infertile women trying for conception after myomectomy or UAE have reported a higher pregnancy and delivery rate and a markedly lower abortion rate in surgically treated women. Post UAE, an alarming high rate of first trimester abortion (64%) was found.²⁰

A recently revised guideline on UAE has suggested that there should be an individualised counselling of women interested in future pregnancy opting for UAE.⁵ Myomectomy should be offered as the first option for most women with fibroids who have not had any prior uterine surgery. However, for women who have had a prior myomectomy, who have large or difficult to resect fibroids, or who are poor candidates for surgery, UAE is an acceptable choice.¹⁰

Conclusion

UAE is a well established, minimally invasive, and safe treatment option for the management of symptomatic fibroids. Due to its effectiveness in treating symptoms, UAE should be considered in patients with higher surgical risk and in those who are poor candidates for surgery. Although reproductive outcomes favour surgery in patients desiring pregnancy, UAE should be discussed as an option and only carefully selected and appropriately counselled patients should be considered for UAE.²⁴

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Forthcoming Events

1. Update on - PCPNDT Act: Medico-legal Implications for Practitioners, on 18th March, 2017.
2. CME on Endoscopic Video Session in association with DGES to develop learning skills on 19th March, 2017.
3. CME on "Breast Cancer: Gynaecologist Perspective" on 23rd March, 2017 at 2pm preceded by lunch in old L.T. (Behind OPD), Safdarjung Hospital under aegis of AOGD.
4. Department of Obstetrics and Gynecology, UCMS & GTB Hospital is organizing a CME & Hands on Workshop on IUI on the 26th March, 2017 at Conference Hall, Library Block. Registration fee Rs.500/. Contact Dr Gita Radhakrishnan (9868399736), Dr A. G. Radhika (9868399726).
5. AOGD monthly clinical meeting at LT- 4, University College of Medical Sciences & Guru Teg Bahadur Hospital, Dilshad Garden, Delhi (entry from gate number 2 GTB Hospital) on 31st March, 2017 at 4.00pm.
6. AOGD & Department of Obstetrics and Gynecology, UCMS & GTBH plan to hold skill workshop series in the year April 2017 to March 2018. The first workshop is planned for 5th May, 2017 on Maternal Resuscitation. Contact Dr A. G. Radhika (9868399726).
7. 20th Post Graduate Practical Course and CME is scheduled to be held on 22nd to 24th September, 2017 in MAMC auditorium, New Delhi. Please contact Dr Pushpa Mishra (09873617596, 09811507470).

Events Held

- AOGD celebrated month of February as "Heart Disease Awareness" & "Cancer Screening & Awareness" month. Various activities held at Lok Nayak Hospital, Hindu Rao Hospital, Lady Hardinge Medical College, Safdarjung Hospital & GTB Hospital.
1. AOGD monthly clinical meeting at Lady Hardinge Medical College on 3rd February, 2017. Interesting cases were discussed.
 2. CME by DGF North under aegis of Reproductive Endocrinology subcommittee AOGD on 7th February, 2017 at Apollo Spectra, Karol Bagh.
 3. Conference on " Low cost IVF: Can we make it a reality" by Miracles Fertility & IVF, Gurgaon, under the aegis of Indian Fertility Society and Infertility subcommittee AOGD on 11th -12th February, 2017 at Hotel Ibis, Aerocity, Delhi.
 4. CME on 'Consensus Statement on Antenatal Care' by Indian Medical Association and Knowledge Partner: Association of Obstetricians & Gynaecologists in Delhi on 15th February, 2017 at Hotel Lalit.
 5. CME on Heart Disease by NARCHI and Safe Motherhood subcommittee of AOGD on 17th February, 2017 at Lady Hardinge Medical College.
 6. A 'Cancer Screening Camp' for breast and cervical cancer was organized by AOGD at MCW centre Kanchan Puri, Daryaganj, Delhi on 17th February, 2017
 7. Second MAMC-Maternal -Fetal Medicine Workshop on Fetal Growth Restriction by Maulana Azad Medical College on 18th February, 2017.
 8. "International Gynae Cancer Congress 2017" by Dharamshila Hospital & Research Centre under the aegis of the Association of Obstetricians and Gynaecologists of Delhi (AOGD) on 18th and 19th February, 2017 at India Habitat Centre.
 9. Nukkad Natak was organized at Lok Nayak Hospital by AOGD on 22nd February, 2017 to increase awareness about public health.
 10. CME under aegis of Reproductive Endocrinology subcommittee AOGD and DGF North on 23rd February, 2017 at Fortis Hospital, Shalimar Bagh.
 11. CME by the Fetal Medicine and Genetics Subcommittee AOGD in association with the Society of Fetal Medicine (SFM) on 26th February, 2017 at Apollo Hospital, Delhi.



AOGD monthly clinical meeting at Lady Hardinge Medical College on 3rd February, 2017



CME by DGF North under aegis of Reproductive Endocrinology subcommittee AOGD on 7th February, 2017 at Apollo Spectra, Karol Bagh.



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'Nukkad natak' organised at Lok Nayak Hospital by nursing students on infertility awareness on 15th February, 2017

CME on 'Consensus Statement on Antenatal Care' by Indian Medical Association and Knowledge Partner: Association of Obstetricians & Gynaecologists in Delhi on 15th February, 2017 at Hotel Lalit



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AOGD celebrated month of February as "Heart Disease Awareness" & "Cancer Screening & Awareness" month at Hindu Rao Hospital, Delhi



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Magnetic Resonance - Guided Focused Ultrasound Treatment of Uterine Leiomyomas: Insights and Challenges

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Preface

The **impetus** to research into and develop treatment modalities for various diseases and conditions is provided by specific needs of individual patients. Even what has been considered as the “standard” treatment for a particular condition, continues to **evolve** and **metamorphose**. Constant endeavors remain ongoing to search for “the best, the safest and the most suited and durable” therapeutic option.

Leiomyomas, being one of the commonest benign gynaecological afflictions, have been the focus of further refinements in classification and management, which we keep updating ourselves with. This write-up is meant to serve as a ready-reckoner pertaining to a relatively newer, non-surgical modality of management of leiomyomas, namely MRgFUS, for practicing obstetricians and gynecologists, and, specially, postgraduate students and trainees.

Women are often well aware of existing treatment options. It is required that we are forearmed with the information pertaining to magnetic resonance-guided focused ultrasound for treatment of leiomyomas and are in a position to judge the suitability of offering this modality to a particular patient, even though the final decision be taken in joint consultation of the radiologist, the gynaecologist and the patient.

Introduction

Uterine leiomyomas, or fibroids, are benign tumors derived from the smooth muscle of the uterus and occur in 70-80% of women during their lifetime, making them one of the most frequently encountered gynecologic conditions¹. Approximately 30% of women with leiomyomas request treatment on account of heavy menstrual bleeding, abdominal pain, bulk-related symptoms, and/or infertility, understandably resulting in a profound impact on their quality of life (QOL)^{2,3,4}. Earlier on, estrogen was held as the dominant hormone responsible for the growth of myomas, but currently, progesterone is considered the main “player” in this regard⁴. Progesterone is implicated in the regulation of genes linked with proliferation and apoptosis⁴.

Leiomyomas are the leading indication for hysterectomy.⁵ The United States Food and Drug Administration (U.S. FDA)–approved *alternatives to hysterectomy* include, short-term treatment with GnRH agonists, myomectomy, uterine artery embolization (UAE) and magnetic resonance imaging-guided focused ultrasound (MRgFUS)⁶, also expanded as magnetic resonance guided focused ultrasound surgery. Another term, MR-HIFU, refers to the same procedure and stands for magnetic resonance-guided high intensity focused ultrasound.

Few additional treatments for leiomyomas, which have come to the fore, include medical therapies such as selective steroid receptor modulators, radiofrequency cryoablation, and vascular clamping techniques⁷⁻¹⁰. The FDA's warning about the risk of inadvertently morcellating undiagnosed uterine leiomyosarcomas during myomectomy (or hysterectomy), has resulted in changes and curtailment of some of these operative procedures⁴. However, conservative procedures such as UAE, MRgFUS and others, or for that matter, pharmacotherapy, notwithstanding their advantages, do not provide tissue for histopathological examination, thereby not being entirely foolproof in themselves.

MRgFUS is a technique of thermal ablation, approved by the U.S. FDA in 2004. Only some symptomatic women with leiomyomas would be suitable candidates for treatment with MRgFUS. Initially, MRgFUS was contraindicated by the FDA for treatment of premenopausal women with symptomatic fibroids and desiring future fertility, however, in 2009, the FDA modified it to a relative contraindication, following the results of various studies showing that women conceived and carried pregnancies to term following the procedure^{11,12}. The method utilizes MRI to acquire details of the anatomy and define the target leiomyoma(s). It also allows for monitoring and control of the parameters of ablation including the thermal effect. The ultrasonic energy is directed to a focal point within the leiomyoma and results in coagulative necrosis with minimal damage to the surrounding tissue^{13,14}.

Ultrasound-guided HIFU is also available. It proves less expensive but has the disadvantages of there being no

method to monitor the temperature, distinguishing bowel loops from other soft tissue with accuracy and also, possesses poor bone resolution¹¹.

History of development of MRgFUS: History enables us to understand how the present came to be and helps us learn from past mistakes and errors. It thereby enables improvements, be they in clinical management, technology or elsewhere.

MRgFUS evolved through many developmental milestones¹⁵. In the 1920s, Wood and Loomis, known as the “fathers of ultrasonics”, were the first to describe that ultrasound has a biologic effect on living tissues¹⁶. Lynn et al, in the year 1942, suggested the utilization of *focused ultrasound* (FUS) to bring about thermal or mechanical effects at a focal location in living tissue¹⁷. Following events included the designing of a clinical FUS device by the Fry brothers, to treat hyperkinetic states such as Parkinson’s disease in the 1950s^{18,19}. Further, FUS was introduced as a treatment modality for glaucoma in the 1980s²⁰. In the 1990s, Hynynen et al and others, introduced MRgFUS²¹⁻²³. In the 2000s, designs were improved to enable treatment of larger volumes of tissue and make possible the delivery of *sonications* (application of sound energy to bring about effect on tissue), in different areas by *steering* the ultrasound beam. At the same time, MRI-based *thermal dosimetry* was developed so as to confirm and assess thermal delivery²⁴⁻²⁸. The ExAblate 2000 system (InSightec), received FDA clearance in 2004. (Figure 1)



MRgFUS Platforms

- At present, there are two US FDA-approved platforms for MRgFUS: the ExAblate 2000 and the ExAblate 2100 (InSightec). This device uses a *point-by-point ablation technique*. Advanced features of the 2nd generation ExAblate 2100 include the elevation of the transducer close to the skin, thereby reducing energy in the near and far field, decreased average focal distance and an increase in maximum energy to allow for greater spot sizes and thereby, quicker treatment, automatic disabling of some transducer elements, in case structures/organs at risk fall in the path of the beam, and an automatic detection of patient movement and treatment correction²⁹. (Figure 1)
- Sonalleve MR-HIFU (Philips Healthcare, Andover,

MA, USA), is another system for MRgFUS with approval in Europe¹⁵. Regulatory approvals for the Philips Sonalleve MRgHIFU system for treatment of uterine fibroids were obtained in India in 2009²⁹. This equipment utilizes a *volumetric-based ablation strategy*, which may be more energy efficient than the point-by point ablation method²⁹. (Figure 2)



Fundamentals of Physics Pertaining to MRgFUS: On the part of the medical fraternity, acquisition of knowledge of basic physics, where relevant, has profound benefits. The effort is always rewarded.

Principles of Ultrasound: With MRgFUS, an attempt is made to deliver a *focused high-energy ultrasound wave* into tissue. Minimally mobile, as leiomyomas generally are, prove an ideal target¹¹. The resultant effect is a conversion of *mechanical energy into heat*. Ultrasound also works by causing *cavitation*. *Thermal coagulation* of the target tissue occurs thus. The basic principles of this therapy are much like focusing the sun’s rays with a magnifying glass to burn a hole in a paper³⁰. A piezoelectric (derived from the Greek word, ‘piezein’ which means to squeeze or press) plate inside the ultrasound transducer generates the ultrasound wave. Focusing of the wave is performed by lenses, reflectors or by a self-focusing transducer³⁰. Electrical focusing can be performed using phased arrays (lots of radiating elements, each with a phase shifter, used in forming beams), as in the ExAblate machine. *The ultrasound waves are focused into a beam and multiple beams can be focused on the target*. The sound waves pass through the skin and non-target tissues and focus on, and deliver energy to the target³¹.

In addition to the phased array system, the MRgFUS equipment includes a computer-controlled positioning system, radiofrequency amplifier system and a user interface. These are integrated with an MR imaging system, the standard being 1.5 Tesla, but the system can also be used with a 3 Tesla machine²⁹.

The high-intensity focused ultrasound causes an increase in temperature in the focal area. Tissue necrosis occurs if the temperature is 50 degree C for 10 seconds, 56 degrees C for 1 second, or, 60 degree C for 0.1 second³⁰. The effect is an increase in the *non-perfused volume* (NPV, discussed below), resulting in shrinkage of the fibroid. The tissue in the path is warmed, but not to dangerous levels.

Principles of MRI Temperature Measurement: MRI is a very useful modality for monitoring the focused ultrasound procedure, due to the former's excellent soft-tissue contrast and the ability to provide fast and quantitative temperature imaging in a variety of tissues. *MRI is able to assess the temperature* by a variety of techniques: apparent constant diffusion of water, the spin-lattice relaxation time and the water proton resonance frequency shift (PRF). The PRF of water changes in response to the changes in the temperature^{31,32}. *Real time thermal mapping* can be done on the basis of this shift.

Imaging Features of Leiomyomas: Ultrasound assessment of leiomyomas usually shows them as solid, hypoechoic masses arising from the myometrium. They reveal varying degrees of echogenicity depending on their fibrous, calcified and degenerating components¹¹. Their encroachment on endometrium/serosa, can be assessed, and we have found the integration of the FIGO system of classification of myomas³³, quite useful in patient management. MR imaging offers superior soft-tissue contrast, tissue characterization of each leiomyoma, multiplanar imaging and details of perfusion. *These features help triage patients into therapeutic option of choice.* MRI also helps in diagnosing concomitant adenomyosis.

Based on MR imaging and the patterns of enhancement, individual leiomyomas can be classified as *classical*, *hypercellular* or *degenerating*¹¹. Classical leiomyomas appear hypointense on T2-weighted sequences and enhance on gadolinium-enhanced T1-weighted sequences. Hypercellular leiomyomas are T2-hyperintense and enhance profoundly on gadolinium-enhanced T1-weighted sequences. Degenerating fibroids have variable T1 and T2 signal and do not show contrast-enhancement¹¹. *These details can help decide which treatment modality would be suitable, as classical fibroids respond better to high intensity focused ultrasound (HIFU) than do hypercellular fibroids. Degenerating fibroids respond poorly to both HIFU and UAE*³⁴.

Guidance on MRgFUS

US FDA: Over a period of time, the FDA relaxed the technical restrictions, especially with respect to the fibroid volume that could be treated. The FDA originally permitted the ablation of only 33% of the fibroid, to a maximum of 100 ml for a single fibroid, restricted the maximum procedure time to 120 minutes, and did not allow a second or further procedure. After April 2004, the FDA permitted second or staged procedures, increased the maximum procedure time to 180 minutes, and increased the ablation extent to 50% and 150 ml of the fibroid volume. In April 2009, the FDA

liberalized the allowance and lifted these restrictions allowing for 100% ablation of the target. The FDA, in 2009 also revised the contraindication on childbearing and opined that women "*should be family complete*" rather than "*must be family complete*"³⁵⁻³⁷. At present, the FDA restricts no minimum distance of sonication from the endometrium but prohibits ablation within 10mm of the uterine serosa. Restrictions on maximum fibroid size have also been lifted³⁷.

NICE: The National Institute for Health and Care Excellence (NICE) updated their guidance in 2011. This guidance mentions that the current evidence on the efficacy of MRI-guided transcutaneous focused ultrasound for uterine fibroids in the short term is adequate. Further treatment maybe required, and the effect on pregnancy is uncertain³⁸.

Indications for MRgFUS^{11, 13, 37, 39}: Evaluation prior to the procedure must include a thorough history and physical examination, a recent gynecologic examination and a Pap smear. An endometrial biopsy should be performed in women with abnormal uterine bleeding. Imaging should be carried out to confirm the presence of, and to map the location of fibroids. In many institutions, and what would be considered good practice in all instances, suitable candidates complete the symptom-severity score (SSS) of the Uterine Fibroid Symptoms and Quality of Life (UFS-QOL) questionnaire, which is a validated instrument for assessment of symptoms specific for quality of life due to uterine fibroids. The score is higher in women with symptom-causing fibroids. This score is useful in *pre-procedure evaluation as well as post-procedure monitoring*¹⁵.

The indications and suitability for MRgFUS include:

- Symptomatic leiomyomas causing heavy menstrual bleeding, pressure-related symptoms such as pelvic fullness, urinary urgency or frequency and/or dyspareunia
- Women desiring uterine preservation and/or wanting to avoid surgical intervention
- Less than a 20-week pregnancy uterine size
- A less than 12 cm targeted fibroid
- Centre of fibroid to skin surface depth of less than 12cm
- Intramural myomas are more suited for MRgFUS. Subserosal lesions are acceptable as long as at least 30% of the circumference of the myoma is within the uterine wall. Myomas less contained in the uterine wall suffer the risk of post-treatment torsion and detachment into the abdominal cavity.
- The patient's family should be complete
- Fibroids that are homogeneously dark on T2 weighted images respond well to MRgFUS

Contraindications to MRgFUS^{11,3,15,39}: Women should be judged suitable for the treatment after a joint consultation between the radiologist and gynaecologist. Contraindications include:

Pregnancy, obesity exceeding table capacity (upper limit of weight is up to 115 kg), intolerance to a prolonged stationary position, inability to comprehend instructions or communicate sensations during the procedure (safe treatment depends upon prompt feedback of sensations such as leg, buttock, skin or back pain to the treating team), abdominal wall scarring in the planned ultrasonic beam's path to target fibroids, women harboring other pelvic diseases such as extensive adenomyosis or endometriosis, which may be responsible for the symptoms (concomitant mild adenomyosis is not a contraindication), active pelvic infection, fibroid which is too posterior (> 12 cm from center of fibroid to abdominal wall) or less than 4 cm from sacrum, size of fibroid exceeding 10 cm (as accepted till recently), 3 or more myomas greater than 5cm, very small, multiple fibroids, pedunculated, subserosal or submucosal fibroids, fibroid tissue that is bright on T2-weighted MRI sequences responds less well to standard sonication, presence of calcified or degenerated fibroids, ovarian dermoids, surgical clips or intrauterine devices, postmenopausal status, ovarian, endometrial, uterine or cervical cancer, lesions suspicious for sarcoma, claustrophobia, women with cardiac pacemakers, unstable cardiac status, cerebrovascular disease, hemolytic anemia, anticoagulation therapy, underlying bleeding disorders, and a history of liposuction.

Equipment^{36,39}

- MRI
 - o T2-weighted non-enhanced imaging
 - o T1-weighted spin-echo, contrast-enhanced for post-treatment
- MRgFUS System
 - o Built into the modified MRI table and docks with a compatible 1.5T or 3T MR scanner
 - o Ultrasound transducer located in the water tank within the MRgFUS equipment and covered by a thin plastic membrane, allowing the ultrasound beam to propagate to the patient from the table.

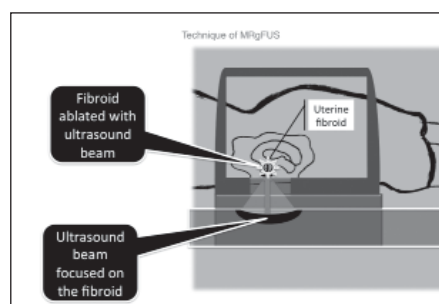
Positioning and Assessment^{37,39,40}

The procedural requirements include:

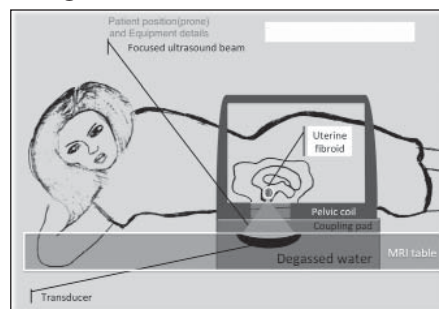
- 6 hours pre-procedure fasting
- Serum beta-hCG test performed in the morning to exclude pregnancy
- Hair in the lower abdominal wall shaved up to level

of symphysis pubis

- The skin of the anterior abdominal wall should be free of oil or cream, as these agents may obstruct the passage of the ultrasound beam and cause it to become unfocused
- Foleys catheter placed
- Intravenous line sited
- Monitoring leads attached (oxygen saturation and heart rate)
- Clear audio communication of the operator with the patient in the bore of the magnet established
- Conscious sedation
- The patient is placed in the *prone* position. The skin of the anterior abdominal wall lies over the *degassed water and gel pad* (used to enhance acoustic coupling), which is coupled to the transducer. There should be no intervening air between the coupling membrane and the thin water layer on top of it, including the patient's skin (Figure 3)



Technique^{11,29,37,39,40}: The ExAblate system has a transducer power ranging from 0 to 3000 W/cm² and an ultrasound frequency of 1.0-1.3 MHz. Over a 20 second period, the deposition of energy can vary between 2000 to 4000 Joules into the target site per each sonication. The target site is in the shape of an ellipse of 8-40 mm size, parallel to the sonication beam and 1-10 mm perpendicular to the beam at the 17 cm focal distance from the therapeutic transducer (up to 13 cm deep to the skin within the pelvis of the patient)¹¹. Up to 120 sonications may be required to ablate a given volume in the 3-hour period, which is allowed¹¹. (Figure 4)



Technique

- Outpatient procedure
- The transducer is moved along three axes in order to allow correct localization of the focal spot within the target. T2-weighted, non-enhanced MR images in three orthogonal dimensions are acquired
- Images are reviewed. Planning software is used to target parts of the fibroid to be ablated
- The transducer can also be *pitched* to allow *angled sonication*
- Any interposed tissues in the beam path are looked for, as they may come to harm
- The plan of each sonication is prepared manually to ensure safety by altering the beam path, intensity and preventing injury to adjacent structures
- The physician can control cranio-caudal and medio-lateral tilting of the transducer (*pitch and roll*), frequency, power and site of focal spot
- The procedure can be *stopped* at any time by the patient by activating a stop button if pain is felt, or by the treating doctor, the nurse, or the device's over-ride safety programming
- Software *alerts* the doctor to any sonication which may result in non-target injury
- Targeted volume earlier allowed were no more than 50% of the volume each fibroid ablated, presently recommendations permit greater volumes
- No sonication should be closer than 15 mm to the serosal surface of the uterus
- *Low-dose geometric verification sonication* is performed and monitored by an MR thermal map (50-100 W test sonication)
- Corrections and changes made if necessary
- *Therapeutic dose* is delivered to the same spot (high power bursts, 20 sec in duration), the energy increased slowly and checked if appropriate temperature reached for tissue destruction (usually 60°C). Traditionally, a *cooling-off time of 90 seconds* has been advised between sonications. There are modifications (the FDA approved 'interleaved mode', detailed below) to decrease the total time
- *Multiple sonications* performed to create a single larger area of ablated tissue within the previously defined target volume
- *Temperature is monitored* by obtaining temperature-sensitive MR images in coronal, axial and sagittal planes
- *Safety of surrounding areas checked via thermal images*
- Images are evaluated to look for any patient movement

- The entire procedure takes approximately 3 hours
- The procedure can be repeated another day to treat more fibroid volume
- With the patient in the same position, post-treatment T1-weighted spin-echo contrast-enhanced MR is conducted to confirm treatment success by checking the non perfused volume (NPV)
- The abdominal wall is inspected for skin burns

Post-procedure Follow-up and Care⁴⁰

- The patient is observed for 1-2 hours before discharge
- She is explained that mild menstrual-type cramping or nausea may be experienced
- Non-steroidal anti-inflammatory drug may be required
- The patient leaves for home with an escort and is followed up on phone 24 hours later
- Clinical and imaging follow-up is advised

Assessment of Therapeutic Effect: Technical Success and Treatment Effectiveness

Pelvic pressure and pain resolve the fastest³⁰, at times immediately after treatment, and improvement in menstrual bleeding takes about 3 menstrual cycles⁴⁰. In some women, pressure symptoms may be relieved gradually after 3-12 months⁴¹. Fibroid shrinkage as assessed by measurement also takes about 3-4 months³⁰.

The non-perfused volume (NPV) assessed at the end of the procedure by T1-weighted gadolinium contrast MRI is a predictor of the success of treatment by MRgFUS^{29,42,43}. The non-enhancing regions correspond to an absence of blood perfusion in the regions. The NPV is a ratio defined as the volume of myoma no longer perfused by gadolinium after the procedure divided by the total myoma volume⁴⁴. Any retreatment need can be predicted by the NPV. Lower the NPV, greater the chances of retreatment. The optimal NPV for MRgFUS has been defined variably. Park et al observed that an NPV of 80% was a practical and possible goal of HIFU therapy, whereas others have cited an NPV of 60% as a measure of technical success, with re-intervention rates of less than 15% at 24 months^{45,46}.

The technical success was generally higher in the near-complete ablation group, ranging from 93% to 100%, compared to 89% to 95% in the restricted ablation group²⁹.

Treatment effectiveness of MRgFUS is assessed on the basis of the degree of fibroid reduction, symptom resolution, rate of re-intervention for persistent symptoms and the impact on health-related quality of life²⁹.

Overall symptom improvement rating reported for the 3-month, 6-month, and 12-month follow-up was 86%, 93%, and 88% respectively in a study by Gorny et al, in 2011, in the complete or near-complete MRgFUS protocol⁴⁷.

Reported Adverse Events

Even though MRgFUS is widely considered safe, it can have a few unwanted side effects. Skin burns may occur from air being trapped between the patient's skin and the transducer. Images should therefore, be evaluated carefully for any evidence of trapped air bubbles. Although these burns are usually small and superficial, they are likely to be more serious when there is an abdominal scar from a previous surgery. Full thickness skin burns may require excision and closure, or skin grafting³⁰.

Sciatic nerve damage may occur resulting from heating of the bone close to the nerves. It usually involves a long period of recovery. Self-remitting edema of tissues of the anterior abdominal wall, experienced as a painful lump, can occur as well which usually disappears in 7-10 days. Deep venous thrombosis in the lower extremity has been reported. A burn of the bowel may rarely occur and would require laparotomy and resection of bowel. It is extremely important to keep checking the space between the anterior abdominal wall and uterus to exclude the presence of bowel, especially in a lady who tends to fidget³⁰. Other adverse events, as per *case reports*, include generalized constitutional symptoms, spontaneous vaginal discharge of fibroid material, infection, detection of an unsuspected leiomyosarcoma after MRgFUS, bladder perforation, failure of the console stop-sonication mechanism or other system malfunction leading to incorrect display of the frequency and power of the ultrasonic beam, ileal or rectal perforation and even cardiac arrest²⁹.

Safety Review Sources

Many sources of information are available on safety of MRgFUS, along with case report details of adverse events. These include the FDA's Manufacturer and User Facility Device Experience Database (MAUDE) in the U.S. and Health Canada's Medical device Problem Reports. The Society of Interventional Radiology (SIR) Standards of Practice Classification Outcomes has defined complications to be addressed as major or minor²⁹.

Requirement of Additional/ Retreatment

This is an important endpoint for assessing the effectiveness of MRgFUS treatment. The most common *retreatments* in the restricted ablation group were hysterectomy (52.7%), myomectomy (18.2%) or UAE (14.5%), and in the near-complete ablation group,

hysterectomy (46.1%) and myomectomy (25.6%).

Re-intervention rates for restricted ablation groups at 12-month follow-up ranged from 4.9-33%, compared to 3.8-13.7% in the near-complete ablation protocols²⁹.

Reproductive Outcomes

When MRgHIFU was initially evaluated as an alternative treatment to hysterectomy, a major restriction was that 'women *must* have had completed their childbearing' because of the uncertainty of the impact of HIFU on reproductive outcomes. However, many young women successfully underwent the procedure and, because their uterus was preserved, further pregnancies were possible. In 2006, the FDA relaxed the contraindication related to childbearing and stated that 'women *should* have completed their families' to be eligible for the procedure²⁹.

The FIRSTT study (Fibroid Interventions: Reducing Symptoms Today and Tomorrow), an RCT currently underway comparing MRgHIFU with UAE, is the only study so far in which reproductive potential is a stated study objective⁴⁸.

Optimizing Outcome of MRgFUS ^{6,40,49-55}

- Currently, women with more than 6 leiomyomas ≥ 900 cm³ volume are not suitable for MRgFUS
- Pretreatment of large fibroids (> 10 cm) with a *GnRH agonist (GnRHa)* for 3 months prior to the procedure will shrink the fibroid and may make it more accessible. Also it has been found, that *after GnRHa treatment, there is a 50% larger area of targeted ablation per unit of energy applied.* GnRHa *potentiate* the effect of MRgFUS and may have a role in treating fibroids which would otherwise have been found to respond poorly, such as hypercellular lesions
- The goal of achieving as much ablation of the fibroid as possible, within prescribed limits, has led to changes in the strategy from the initial point-by-point technique to create 5 mm ablation by the ExAblate 2000. The FDA has approved the 'interleaved mode' for the ExAblate 2000, which permits the system to target different parts of the fibroid, allowing the recently ablated area to cool off while the beam shifts to another area. This *reduces the cooling-time required.* This mode also allows a *greater number of sonications to be delivered during the same treatment session*
- Along similar principles, the Philips system has started a method of *volumetric ablation*, which involves creation of *multiple outward-moving concentric circles.* This method is thought to be more *energy-efficient*, as it uses the heat already deposited in the inner part of the trajectory to *preheat* the outer parts

- Heat accumulation in the near-field can be utilized and would be useful in the treatment of large fibroids. This is called the “one-layer strategy”
- There is some research into *targeted vessel ablation* in which procedure, the MRgFUS is aimed at the blood vessel supplying the fibroid, with greater NPVs achieved
- Overcoming anatomical restrictions: device inaccessible myomas, fibroids shielded by bowel or bone, obesity and previous abdominal scars are challenges in this modality of treatment. Simple measures like *massage or filling the rectum with ultrasonic gel and/or bladder with saline*, often manage to clear the acoustic window. Behera et al, and few others, did not exclude patients with Pfannenstiel or laparoscopic abdominal scars. They felt that the scarred areas are usually visible on MRI and can be avoided during the procedure⁶.
- At the present time, the FDA does not permit the use of gadolinium *during* the procedure. There is a concern that the gadolinium salt may be affected by the FUS with the release of free gadolinium, which is toxic. If this was not the case, and gadolinium could have been given during the procedure, one could find out which areas are still perfused and focus the energy there. Gadolinium, however, is being given in MRgFUS breast cancer studies in Japan with no untoward effects reported so far³⁰.

Conclusions

MRgFUS is a safe and effective treatment for selected women with symptomatic uterine fibroids, especially if they are looking for alternatives to hysterectomy. The procedure is performed on an outpatient basis and the recovery is usually quite rapid. The effectiveness and durability of the treatment depends upon the delivery of appropriate energy to the target fibroid, which is dependent upon patient selection and technical limitations. There are other limitations to the procedure that include the availability of the equipment, the length of time required to carry out MRgFUS and the cost. The procedure has not so far been carried out to preserve fertility. However, spontaneous pregnancies and uneventful deliveries of healthy infants have been reported after the procedure. This would imply that MRgFUS may have a role in fertility preservation and also that women who do not wish to conceive, should use some form of contraception after the procedure. There is, to date, lack of comparative evidence between MRgFUS and other uterine preserving treatments for symptomatic fibroids including UAE and myomectomy. The average recovery time following the procedures is

1-2 days, 2 weeks and 6 weeks following MRgFUS, UAE and myomectomy or hysterectomy respectively.

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Calendar of Monthly Clinical Meetings 2016-17

Months	Name of the Institute
March, 2017	UCMS & GTB Hospital
April, 2017	Apollo Hospital

Case Summaries for AOGD Bulletin may be sent by email to the editor/CD may be handed over on the day of the meeting.
-Dr Sangeeta Gupta

Journal Scan

Deepti Goswami

Director-Professor, Department of Obstetrics & Gynaecology, Maulana Azad Medical College & Lok Nayak Hospital, New Delhi

Abstract of the research articles are available free at the journal websites and on PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>). A summary of the articles has been provided so as to put the findings of the articles into perspective for current clinical practice.

Outcomes of uterine sarcoma found incidentally after uterus-preserving surgery for presumed benign disease

Lee JY, Kim HS, Nam EJ, Kim SW, Kim S, Kim YT

Citation: Lee JY, Kim HS, Nam EJ, Kim SW, Kim S, Kim YT. Outcomes of uterine sarcoma found incidentally after uterus-preserving surgery for presumed benign disease. *BMC Cancer*. 2016 Aug 23;16(1):675.

Study Question: Does initial uterus-preserving surgery, such as myomectomy or subtotal hysterectomy impact the recurrence rates of uterine sarcoma found incidentally on histopathological examination?

What is the role of surgical re-exploration in this disease subset?

Methods

- This was a retrospective chart review for patients who had previously undergone either total hysterectomy or subtotal hysterectomy or myomectomy at the time of initial surgery for presumed benign uterine leiomyoma and were found to have uterine sarcoma on final pathology.
- Survival analysis was performed comparing patients according to the type of initial surgery.

Results

- Between 2006 and 2014, 45 patients with uterine sarcoma were identified. Myomectomy or subtotal hysterectomy was performed in 15 patients, and 30 patients underwent total hysterectomy as the initial surgery.
- Of the patients who underwent myomectomy or subtotal hysterectomy as the initial surgery (n=15), 14 were re-explored to complete staging.
- Of the patients who underwent re-exploration (n=14), five (35.8 %) had remnant sarcoma on the remaining uterus and no patients had disseminated disease.
- A Kaplan-Meier curve and log-rank test showed no difference in progression-free survival (P=0.941) between the two groups.

Conclusion

Initial uterus-preserving surgery does not appear to be associated with an adverse impact on survival outcomes for unexpected uterine sarcoma when surgical re-exploration was performed immediately. Surgical re-exploration may be useful for removing any remnant sarcoma.

Perspective

Finding of uterine sarcoma in histopathological report after myomectomy or hysterectomy done for presumed fibroid is a cause of concern and challenging to manage. FDA has reported that one in 352 women have unsuspected uterine sarcoma while undergoing surgery for presumed benign disease. This study found no difference in survival between uterus-preserving surgery and total hysterectomy, in cases with unexpected sarcoma. Authors recommend that patients who undergo myomectomy or subtotal hysterectomy where uterine sarcoma is detected should undergo immediate surgical reexploration for removing remnant sarcoma in the remaining myometrium. Value of lymphadenectomy or omentectomy for identifying occult metastasis in early-stage uterine sarcoma appears to be low.

Long-term medical management of uterine fibroids with ulipristal acetate

Donnez J, Donnez O, Matule D, Ahrendt HJ, Hudecek R, Zatik J, Kasilovskiene Z, Dumitrascu MC, Fernandez H, Barlow DH, Bouchard P, Fauser BC, Bestel E, Loumaye E

Citation: Donnez J, Donnez O, Matule D, Ahrendt HJ, Hudecek R, Zatik J, Kasilovskiene Z, Dumitrascu MC, Fernandez H, Barlow DH, Bouchard P, Fauser BC, Bestel E, Loumaye E. Long-term medical management of uterine fibroids with ulipristal acetate. *Fertil Steril*. 2016 Jan;105(1):165-173.e4.

Study Question: Are repeated 12-week courses of 5 or 10 mg daily ulipristal acetate for intermittent treatment of symptomatic uterine fibroids safe and efficacious?

Methods

- Double-blind, randomized administration of four 12-week courses of ulipristal acetate.
- Four hundred fifty-one subjects with symptomatic uterine fibroid(s) and heavy menstrual were included.
- Four repeated 12-week treatment courses of daily 5 or 10 mg ulipristal acetate were given.

- Main outcome measure(s) were endometrial safety and general safety, laboratory parameters, amenorrhea, controlled bleeding, fibroid volume, quality of life (QoL), and pain.

Results

- Efficacy results, such as bleeding control and fibroid volume reduction, were in line with previously published data. Pain and QoL showed marked improvements from screening, even during the off-treatment intervals.
- The safety profile of ulipristal acetate was confirmed, and repeated treatment courses did not increase the occurrence of adverse reactions.
- There were no significant changes in laboratory parameters during the study.
- The percentage of subjects with endometrial thickness ≥ 16 mm was 7.4% (all subjects) after the first treatment course and returned to below screening levels (4.9%) in subsequent treatment courses.
- As in previous studies, ulipristal acetate did not increase the occurrence of endometrial features of concern. The frequency of nonphysiological changes did not increase with repeated treatment. They were observed in 17.8% and 13.3% of biopsies after treatment courses 2 and 4, respectively, and were reversible after treatment cessation.
- No postoperative complications were encountered using this approach.

Conclusion

The results of this study demonstrate the efficacy and further support the safety profile of repeated intermittent treatment of symptomatic fibroids with ulipristal acetate.

Perspective

Ulipristal acetate is a selective progesterone receptor modulator- a new class of synthetic steroids which can exert agonist, antagonist or mixed effects on various progesterone target tissues. Short term treatment using 5 or 10mg of ulipristal acetate were studied in the series of four PEARL studies (NEJM. 2012: 366:409-420 & 421-432; Fertil Steril. 2014;101(6):1565-73.e1-18; Fertil Steril. 2015;103(2):519-27.e3.). This study shows the efficacy and safety of repeated intermittent courses of treatment with ulipristal acetate in women with symptomatic fibroids.

Evaluation of the effects of cabergoline (Dostinex) on women with symptomatic myomatous uterus: a randomized trial

Vahdat M, Kashanian M, Ghaziani N, Sheikhsari N

Citation: Vahdat M, Kashanian M, Ghaziani N,

Sheikhsari N. Evaluation of the effects of cabergoline (Dostinex) on women with symptomatic myomatous uterus: a randomized trial. Eur J Obstet Gynecol Reprod Biol. 2016 Nov;206:74-78.

Study Question: Does cabergoline has an effect on the size of myoma and the amount of bleeding in the women with myoma of the uterus?

Methods

- The study was performed as a single blind randomized clinical trial on the women with symptomatic myoma.
- The women were randomly assigned in 2 groups. In the case group, 0.5mg cabergoline was prescribed weekly for three months, and in the control group, nothing was prescribed and the women only had close observation for symptoms.
- The reduction in symptoms including pelvic pain and duration and amount of uterine bleeding, and the size of myoma, were compared between the 2 groups.

Results

- 51 women finished the study (26 women in the case group and 25 women in the control group).
- There was no significant difference between the 2 groups according to age, gravidity, parity, history of abortion, having living children, pretreatment hemoglobin, pain and amount of uterine bleeding, uterine size, and the size of myoma.
- After treatment, hemoglobin levels had dropped in the control group but not in the case group ($p=0.004$).
- Pain had also decreased significantly in the case group in comparison with the control group ($p=0.001$).
- The amount of menstrual bleeding ($p=0.004$), uterine size ($p=0.001$) and the size of the largest myoma ($p=0.013$) showed significant reduction in the case group.

Conclusion

Cabergoline can decrease the amount of bleeding and pain in the cases of myomatous uterus and can be used for the symptomatic women who want to preserve uterus for a certain period of time.

Perspective

Cabergoline has estrogen lowering action probably by inhibiting GnRH secretion and by affecting prolactin receptors in myometrium. Thus it could inhibit growth of fibroid. This drug was proposed as a possible medical treatment for fibroid for the first time in a preliminary study in 2007. The side effects of the drug are few making it acceptable to the patients. However optimal dose and duration of treatment needs to be explored in a larger number of patients.

The Mystery of Uterine Stones

Swati Rai¹, Nilanchali Singh²

¹Senior Resident, ESI Hospital, ²Assistant Professor, Department of Obstetrics and Gynaecology, Maulana Azad Medical College, New Delhi

The Mystery of Womb

The Greeks believed that the womb is the origin of all diseases in women. The supporting myth is about the first woman Pandora. In ancient Greece, gynecology originated in the myth of the first woman Pandora, whose beautiful appearance was seen to cover her dangerous insides. Pandora represented to male humanity as beautiful, marriageable lady, who threatens the work of the healer because her outside is deceptive, concealing the fact that her body contains a voracious womb-Jar and the mind of a bitch. Pandora's dangerous insides were considered to be her womb. This belief can be correlated to the writings found in Hippocratic corpus, where the wandering womb was responsible for all illnesses. Hysteria was the name given to a number of female illnesses.



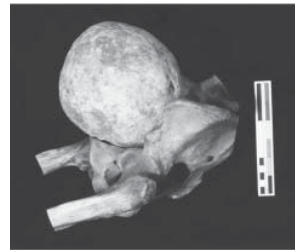
The Hippocratic thought that the womb moved upward in the woman's body whenever it became hot and dry from overwork, or lack of irrigation from male seed, searching for cool and moist places. As the womb tried to force its way toward the crowded places

at the center of a woman's trunk, it wreaked havoc with her physical and mental well being, causing her to faint or become speechless. Foul odors at the nose and sweet smells at the vagina were prescribed, to lure the uterus back to its seat!!

Discovery of Fibroids and its Nomenclature

Fibroids were known as "uterine stones" in the period of Hippocrates (460-375 B.C). Galen coined the term "scleromas" for these lesions during the second century of the Christian Era. The term fibroid was coined by Rokitansky in 1860 and later, used by Klob in 1863. In 1854, a German pathologist named Virchow demonstrated that these neoplasms (fibroids) were composed from smooth muscle cells. It was Virchow who introduced the word "myoma".

Although fibroids are the commonest tumours to afflict the pelvic organs of women and have been recognized and named since ancient times they were not amenable to treatment until the first laparotomy was performed just over 200 years ago.



Archaeologists carrying out excavations at a cemetery in southeast England discovered an unusual object resting in the pelvis of an old skeleton, which they first believed to be a skull that had rolled into that position. Analysis soon revealed that the object was actually a solid, 7-pound (3kg) calcified uterus, likely to be a fibroid, the largest of its kind in the archaeological record.

First Surgery for Fibroid on President's Cousin

The first laparotomy for a fibroid was done in 1809, on Mrs. Jane Todd Crawford, who was the cousin of President Abraham Lincoln, at the age of 56 years. A surgeon named Ephraim McDowell performed laparotomy to remove the ovarian cyst containing complex content. When it was evaluated, it turned out to be a pediculate leiomyoma.



The first laparotomy for a fibroid was done in 1809, Danville, USA. Mrs. Jane Todd Crawford, who was the cousin of President Abraham Lincoln, was operated for

fibroid at the age of 56 years. Her complaints were abdominal distention and she and her friends and relatives had a doubt that she was pregnant with twins. Initial therapies like laxatives, enemas and phytotherapy were tried once her pregnancy was ruled out. They were done to relieve the distention of the abdomen.

Earliest Vaginal Myomectomy

The first successful myomectomy, for a fibroid, was performed in 1840 by Jean Zuléma Amussat of Paris. In 1842, Amussat reported two submucous fibromyoma cases in which vaginal myomectomies were performed.

First Abdominal Myomectomy: An Incidental Surgery

Dr. Washington Atlee from Pennsylvania along with his brother John Atlee, is reported to be the first surgeon

who performed a successful abdominal myomectomy operation that appeared in the American Journal of Medical Science in 1845. The laparotomy was not done for a fibroid and it was an incidental surgery.

Washington, the older brother, eventually published his experience with 14 abdominal myomectomies, winning the annual essay award of the American Medical Association despite the death of 5 of the patients.

First Deliberate Myomectomy

In 1853 Gilman Kimball of Massachusetts conducted the first deliberate myomectomy after diagnosing his patient with uterine fibroids. He is also the first doctor to successfully perform a hysterectomy for the purpose of removing uterine fibroids.

Downfall of Myomectomy

Myomectomy was slow to gain widespread use. In 1875, W.H. Byford gave the Chairman's address to the American Medical Association Section on Obstetrics and Gynecology and said abdominal myomectomy was "so dangerous and difficult" as not to be thought of except in desperate conditions.

Bonney's Contribution

At the turn of the 20th century, abdominal myomectomy was associated with a mortality rate of 40%, compared with 6-7% for abdominal hysterectomy. Victor Bonney is credited for advocating and popularizing the procedure in the 1920s.



Myomectomy was abandoned until 1922 when British surgeon Victor Bonney, invented the Clamp for myomectomy in an attempt to

decrease intra-operative bleeding. By 1930, Victor reported 403 myomectomy cases with minimal fatalities. As medical knowledge evolved so did the treatment methods for uterine fibroids, which is no more a history.

Suggested Reading

Nilo Bozini; Edmund C Baracat, *Division of Gynecology - Medical School of University of São Paulo. The history of Myomectomy at the Medical School of University of São Paulo. São Paulo Clinics* 2007; 62(3)

Hysterectomy: A historical perspective (1997) Bailliere's *Clinical Obstetrics and Gynaecology*; 11 (1):1-22.

Association of Obstetricians & Gynecologists of Delhi (AOGD)

Elections

Nominations are invited from eligible AOGD members for the posts of

President and Vice President of AOGD for the year 2019-2020.

The nomination should be Proposed by one AOGD life member and seconded by two AOGD life members. The last date of filing the nominations is **30th May 2017.**

Eligibility criteria

1. President AOGD has to be a faculty of medical colleges / leading, multidisciplinary clinic hospital with Para-clinic and clinical departments (oncology, radiology, pathology etc).
2. Experience of having been chairperson of committee of AOGD/FOGSI or experience as Vice President/ Secretary/Treasurer/Editor of AOGD.
3. Life member AOGD having above 10 years of experience in specialty after post –graduation and holding post of professor/senior consultant for more than 7 years.
4. Experience of conducting conferences, seminars or workshops etc.
5. In case of a tie after election, the senior most person out of the contestants will be nominated.

The application should be sent to the AOGD Secretariat, GTB Hospital, Delhi – 110092 by **30th May 2017.**

Proceedings of Monthly AOGD Clinical Meeting ESIC Model Hospital and PGIMSR, Basai Darapur New Delhi, 3rd March, 2017

Case 1

An Unusual Case Report of Leiomyoma and Condyloma Accuminata of Clitoris in Young Female

Deepika, Taru Gupta, Sangeeta Gupta

A 22 Year old unmarried girl presented to gynae outpatient department with complaints of a spontaneous swelling in the clitoral region of 11 months duration. The swelling was painless gradually increased in size, not associated with trauma. She sometimes had difficulty in urination. On examination, her secondary sexual characters were normal. Clitoral mass was 6 x 3 cm, pink in colour with firm consistency, grape like vesicles on apex of growth, none tender, irreducible, non compressible. There was no ulceration and degenerative changes. No inguinal lymph nodes were palpable. Karyotyping and her hormonal levels were normal. Pap smear and HPV DNA-negative. MRI pelvis: well defined soft tissue mass lesion seen in vulvar region with non visualisation of clitoris separately likely clitoral mass with involvement of anterior urethral wall and rest normal study. BIOPSY of mass- acanthotic squamous epithelial lining with fibro epithelial tissue. Patient underwent excision of the mass under spinal anaesthesia. Histopathological examination report of the excised specimen diagnosed as 'Leiomyoma with Condyloma accuminata of the clitoris'.

Clitoromegaly refers to the Enlargement of Clitoris, when size of clitoris is greater than 35 mm², which is almost twice the size for an average sized clitoris. It can be congenital or acquired. Clitoral leiomyoma is a rare benign tumor. The clitoral leiomyomas are usually asymptomatic, painless, and can present with urinary symptoms. MRI is very useful not only in diagnosis but also in differentiation of benign from malignant tumor. Diagnosis is confirmed with biopsy. Anogenital warts are also benign proliferative epithelial growths caused by infection with human papillomavirus (HPV). Diagnosis by biopsy and viral typing is not routinely done. Surgery in the form of simple excision is usually sufficient.

Case 2

Cervical Dysgenesis with Transverse Vaginal Septum with Imperforate Hymen

Pratiksha Gupta, Sanjana N Wadhwa

This case highlights the importance of careful evaluation of girls presenting with imperforate hymen as this is accompanied by other female reproductive tract anomalies. It is of utmost importance that a correct timely diagnosis is made so that the right treatment can be chosen with the perspective of future fertility. Cervical dysgenesis associated with vaginal septum and imperforate hymen has not been reported in literature so far. Present case highlights the simple mode of management with a successful outcome.

Case 3

Fibroid Arising from Uterine Remnant in A Case of MRKH

Smita Gupta, Leena Wadhwa, Sangeeta Gupta, Lata Singh Deepika

Mullerian agenesis or Mayer Rokitansky- Kuster-Hauser syndrome is defined by congenital absence of both the uterus and vagina. It affects 1 in 4000-5000 females. Leiomyoma arising from the uterine remnant in case of MRKH is very rare. Very few cases have been reported in literature. The exact etiopathogenesis of leiomyoma from the rudimentary uterus in MRKH syndrome is not known. We are reporting a rare case of 35 year old married, nulliparous female who presented with primary amenorrhea and lump in lower abdomen since 1 year. On physical examination, a mass of 18 week size of uterus, firm in consistency, irregular, nontender, mobile from side to side, occupying right iliac and hypogastric region was detected. Provisional diagnosis of multiple leiomyoma with mullerian anomaly was made on USG and MRI for which laparotomy was performed. Per-operatively, there was a mass of approx. 15 x 8 x 8 cm consisting of multiple fibroids present, uterus not visualized separately. Right ovary and tube absent. Left fallopian tube and ovary were normal arising from left rudimentary horn with no endometrial tissue. Cervix was absent with partial agenesis of vagina. Patient underwent removal of fibroid with hysterectomy in view of nonfunctioning

horn. Histopathology report confirmed the same. It was diagnosed as a case of MRKH with multiple leiomyoma. Post-operative period was uneventful. Rudimentary uterine horns, irrespective of whether they exist in association with a patent uterovaginal tract or in isolation, should be removed. Patient presenting with

primary amenorrhoea/ known mullerian anomaly with lump abdomen should be suspected for leiomyoma. The assisted reproductive techniques and maternal surrogacy enable a woman without a uterus to have her own genetic children. Uterine transplantation can be thought of in near future.

AOGD: Calendar of Skill Workshops (April 2017 – March 2018)

AOGD & The Department of Obstetrics and Gynecology, UCMS & GTBH, Delhi plan to hold skill workshop series in the year April, 2017 to March, 2018

Proposed Workshops

1. Maternal Resuscitation - 5th May, 2017 (other dates will announced soon)
2. Resuscitation of the neonate
3. Techniques for control of PPH (including Bakri Balloon demonstration & internal iliac artery ligation)
4. Guidelines for workup of sexual assault victim
5. Interpreting the CTG: practical aspects
6. Basic techniques in Laparoscopy & Hysteroscopy
7. Medico-legal aspects in Obstetrics, Gynecology & Family Planning
8. Basics of Evidence Based Health Care

Contact

Skill workshops Chairperson:

Dr A.G.Radhika (9868399726)

Skill Workshops Co-Chairperson:

Dr Richa Sharma (9868399747)

Applications are also invited from interested individuals/ Institutions to conduct skill workshops on any of the above-mentioned subjects and/or Ultrasonography, Uro-Gynaecology, Colposcopy and any other skill the practicing gynecologist should acquire.

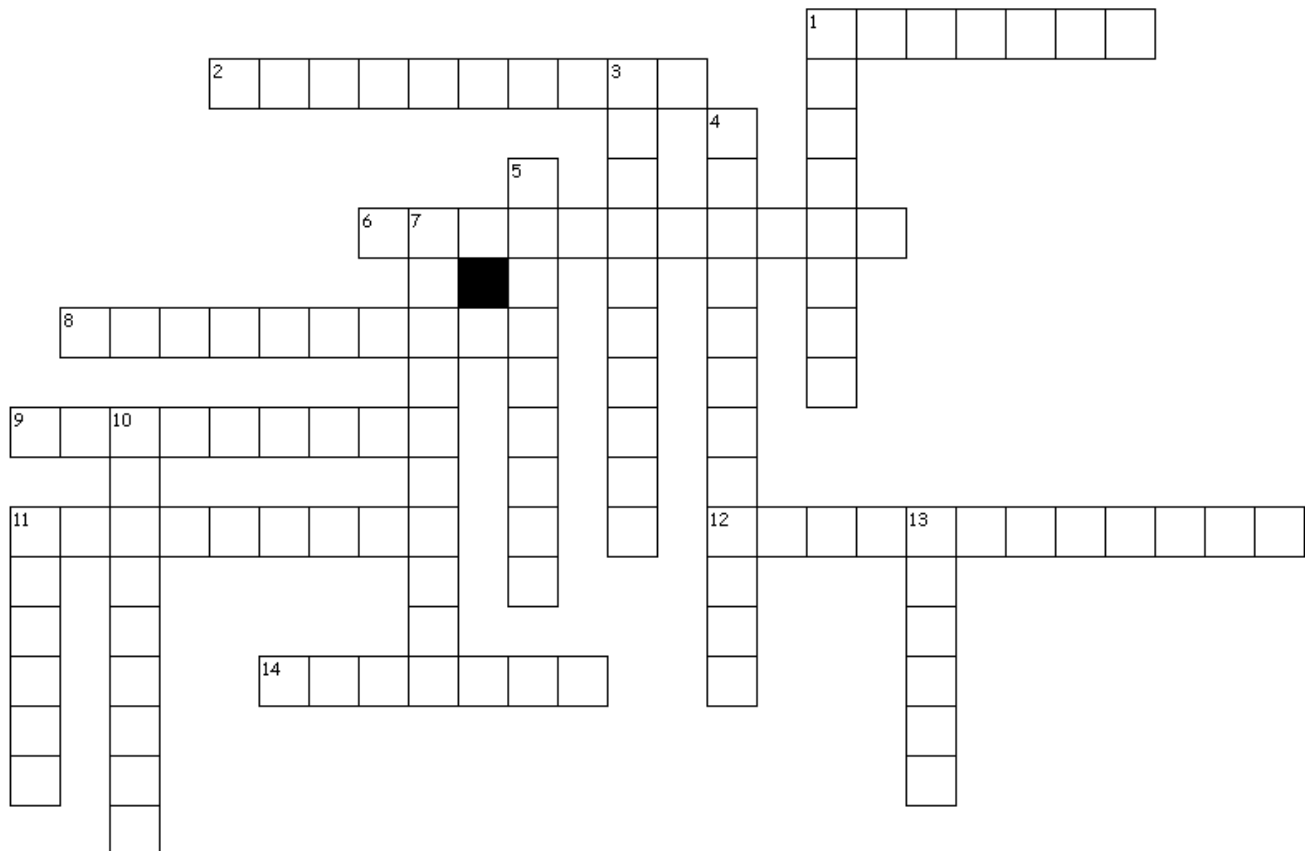
Maternal Resuscitation - 5th May, 2017

- Programme duration : 11am - 5pm
- Venue: 7th floor Seminar Room, O & G, MCH Block, GTB Hospital, Delhi
- Workshop content
 - CPR guidelines 2015
 - Implications of physiological changes in pregnancy on maternal resuscitation
 - Hands on practice on Mannequin

Crossword: Fibroid uterus

Compiled by Anubhuti Rana¹, Sangeeta Gupta²

¹Senior Resident, ²Professor, Department of Obstetrics & Gynecology, Maulana Azad Medical College, New Delhi



Across

1. Lantern on Dome of St.Paul's appearance is seen in which type of cervical fibroid?
2. Rarest change in fibroid is _____
6. The drug used for local injection to minimize bleeding during myomectomy
8. A synthetic derivative of ethinyl-nortestosterone with antiestrogen and antiprogesterone properties seen to induce regression of leiomyoma is _____
9. Adhesions are more likely to form when the myomectomy site is located on _____ wall of the uterus.
11. Most common fibroid complicated by infection
12. Name the technique which uses cryotechnology to freeze myometrial stroma of fibroids and result in shrinkage of volume?

14. Which is the most common degeneration in fibroid uterus?

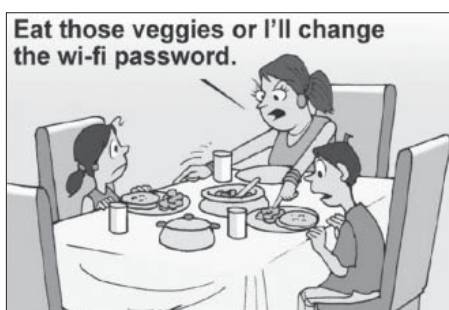
Down

1. Retention of urine is caused by which type of fibroid?
3. A GnRH antagonist used in medical management of fibroids?
4. Best investigation for submucous fibroid is _____
5. A GnRH agonist used to reduction in size of fibroids and intraoperative blood loss?
7. The selective progesterone receptor modulator which can be used in the medical management of fibroid
10. This fibroid associated with pseudomeigs syndrome
11. Red degeneration in fibroid is most common in which trimester?
13. The noninvasive procedure which destroys myoma tissue using ultrasonic energy

Tickle the Funny Bones

Compiled by Dr Sangeeta Gupta

Professor, Obstetrics & Gynecology, Maulana Azad Medical College, New Delhi, India



Childbirth at 65

(Too good not to pass on, Enjoy!)

With all the new technology regarding fertility recently, a 65-year-old friend of mine was able to give birth. When she was discharged from the hospital and went home, I went to visit.

'May I see the new baby?' I asked

'Not yet,' She said 'I'll make coffee and we can chat for a while first..'

Thirty minutes had passed, and I asked, 'May I see the new baby now?'

'No, not yet,' She said.

After another few minutes had elapsed,

I asked again, 'May I see the baby now?'

'No, not yet,' replied my friend.

Growing very impatient, I asked, 'Well, when can I see the baby?'

'WHEN HE CRIES!' she told me.

'WHEN HE CRIES?' I demanded. 'Why do I have to wait until he CRIES?'

'BECAUSE I FORGOT WHERE I PUT HIM, O.K.?'

Answers: Crossword - Fibroid uterus

Across

- | | | |
|----------------|---------------|------------------|
| 1. Central | 8. Gestrinone | 12. cryomyolysis |
| 2. Malignancy | 9. Posterior | 14. Hyaline |
| 6. Vasopressin | 11. submucous | |

Down

- | | | |
|-----------------|---------------|------------|
| 1. Cervical | 5. Goserelin | 11. Second |
| 3. Cetrorelix | 7. Asoprisnil | 13. MRgFUS |
| 4. Hysteroscopy | 10. Subserous | |



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Overview

This revision course is aimed at candidates preparing for the next Part 2 MRCOG exam. It focuses on polishing your exam techniques to improve your chances of passing the written papers. Developed and taught by experienced MRCOG Examiners, this course reflects the new format and standards of the Part 2 MRCOG written exam from September 2016. You will hear about the exam question formats and will have ample opportunity to practice Single Best Answer Questions (SBAs) and Extended Matching Questions (EMQs). This course will map the RCOG core curriculum and the examination syllabus, and you will also have lectures from experts about current developments and hot topics in key curriculum areas.

We recommend you book early to avoid disappointment. There are a maximum of **25** places.

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- Candidate sitting the September 2017 Part 2 MRCOG exam

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- Understand the standard of the required knowledge
- Understand core O & G topics in relation to UK practice
- Understand training within the NHS

Course Fee: Rs 30,000

Venue: RCOG North Zone Academic Centre
B-235, C R Park, New Delhi-110019, India

UK Conveners of International Part 2 Revision Course -Ms Rhona Hughes

UK Course Organizer & Convener -Dr Sanjeev Sharma

India Conveners and Contacts for details -Dr Saritha Shamsunder - (shamsundersaritha@gmail.com/9313826748)
-Dr Sweta Gupta (swetagupta06@yahoo.com/8130140007)
-Dr Mamta Sahu (mamta2sahu@yahoo.co.in/ 9810106470)

Certificate of attendance for this course will be provided by the RCOG UK

Registration Guidelines (Online registration available on website)

- Registration form to be downloaded from website www.aicccognzindia.com.
- Bank Transfer or Demand Draft must be made in favour of "RCOG NZ 2012 Plus" payable at New Delhi. (cheques not accepted).
- There will be no refunds on cancellation.
- Registration request along with Demand Draft to be posted to the Secretariat mailing address as given below:-

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- The clinic is closed on Saturday & Sunday.
- Ovulation studies are done between 8.00 a.m. & 8.15 a.m.
- Telephone calls for appointments are attended to by the receptionists. This is from 8.30 a.m. to 6.00 p.m. only, from Monday to Saturday.
- No reports will be delivered after 6.30 p.m. and on Sundays.



Newborn Screening - A public health revolution akin to the preventive program of immunization

Newborn Screening is a preventive health measure to detect disorders not clinically visible at birth but can cause significant morbidity and mortality. The process is simple and involves a few drops of blood collected by a small lancet on a piece of filter paper. Up to 40 disorders can be tested on this sample. The test has to be performed anytime after 24 hours of birth and ideally less than 7 days after birth. A template disorder, which is the most important preventable cause of mental retardation, is Congenital Hypothyroidism.

Congenital Hypothyroidism (CH)

Congenital hypothyroidism occurs when the thyroid gland fails to develop or function. The common causes are agenesis of the thyroid gland, ectopic location of the gland and dyshormonogenesis (failure of any of the hormones to be synthesized). Mothers with hypothyroidism, when euthyroid do not cause any of the above mentioned conditions. Left undetected, it leads to intellectual disability and abnormal growth. Treatment must be started within the first 2 weeks of life of infants to prevent development of mental retardation, learning disabilities, and/or growth delays.

CH India Perspective

Globally, the incidence of CH is about 1:3000 or 1:4000. In India, preliminary research indicates that it is much higher at 1:1130.¹

Disorder Screened	Prevalence	Effect if not screened	Effect if Screened & Managed	Management
Congenital Hypothyroidism (CH)	1:1130	Severe mental retardation, intellectual disability and abnormal growth.	Normal, if treatment begins in the first month after birth.	Daily oral dose of thyroid hormone (thyroxine)

References:

1. ICMR Multicentric Study (2007-2012)

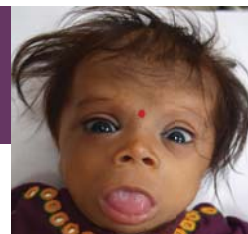
Why it is important – A Case Study

A simple blood test would have changed his life - encourage newborn screening. There is nothing more encouraging for an obstetrician to see a healthy fetus grow into an active productive child what can be better than a preventive measure right when the newborn is still under your care.

This baby Laxman now nine months old does not even hold neck and has global developmental delay. The mother is tired of his constipation. She reports that he was born healthy with good APGAR scores. The obstetrician had congratulated her on the birth of a healthy child. Somewhere something went wrong.

Her neighbour who has just been blessed with a baby daughter has undergone a heel prick test.

Baby Laxman was not screened after birth and later it was found that he is suffering from Congenital Hypothyroidism (CH). If Newborn Screening was done in time, the situation would have been in favor of this little child.



Rinki was blessed with a baby girl at the same time when Laxman was born, but she knew about Newborn Screening. After getting her baby screened, it was found that her baby is also suffering from CH. Today after 9 months, her little angel is healthy and leading a normal life.

CH prevention with Newborn Screening

This baby has congenital hypothyroidism. Imagine that a very low cost intervention in the form of supplementation of L Thyroxine could have ensured normal growth and development of this child. Let us all give our promise to encourage newborn screening.

1
Safe

2
Mild

3
Effective



The
JOHNSON'S®
Triple Baby
Protection™
promise.

Johnson's®
so much more

BABY SKIN NEEDS
SAFE, MILD
and
EFFECTIVE
care

JOHNSON'S® baby products in India
carry the international seal of
JOHNSON'S® commitment.

SAFE

We only use ingredients that are proven to be
appropriate for babies and have passed through
rigorous safety checks

MILD

Our formulas are rigorously developed and
tested to avoid irritation of baby skin

EFFECTIVE

Our products are designed to respect the skin
barrier, and the delicate scalp, to support good
hair condition and healthy skin development



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