2017-2018 – ISAR’s year of Education, Ethics, Empathy

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<tr>
<th>State</th>
<th>Chairperson</th>
<th>Secretary</th>
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<td>Bihar</td>
<td>Dr. Shanti Roy</td>
<td>Dr. Pragya Mishra</td>
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<td>Chhattisgarh</td>
<td>Dr. A. Suresh Kumar</td>
<td>Dr. Tripti Nagaria</td>
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<td>Mr. Virendra Shah</td>
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<td>Dr. Nandita Palshetkar</td>
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<td>Dr. Vijay Nahata</td>
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<td>Dr. Sanjay Makwana</td>
<td>Dr. Renu Makwana</td>
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<td>Tamilnadu &amp; Pondicherry</td>
<td>Dr. Kamala Selvaraj</td>
<td>Dr. Sanjeeva N Reddy</td>
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<td>Dr. Mamata Deendayal</td>
<td>Dr. Shantha Kumari</td>
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<td>Dr. Sadhna Gupta</td>
<td>Dr. Rajul Tyagi</td>
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<td>West Bengal</td>
<td>Dr. Gita Ganguly</td>
<td>Dr. Gautam Khastgir</td>
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President’s Message

Dear Friends

Six months of my Presidential year are already over! Days, weeks and months have flown by with a lot of work done by our team at ISAR from the word “Go”.

Keeping in mind the theme of the year “Education, Ethics & Empathy”, we have launched four new educational programs targeted to all groups – for our postgraduates in Obgyn we have the ISAR-Breach Candy Hospital Series of Webinars on the subject – “Infertility Management” through an interactive sessions, for Practicing Clinicians interested in infertility management, we have the ISAR Travelling Seminars on “Stimulating Ovaries Stimulating Minds”. The “ISAR Certificate Course in ART” for 5 days, for clinicians aspiring to increase their depth of knowledge in advanced management of female and male infertility and finally the “Fertility Enhancing Endoscopic Surgery” focusing on endoscopy related to infertility. Our Convenors for all the programs are doing a brilliant job and their reports are enclosed in this issue.

Our ‘National Quiz’ is trying to identify infertility experts between 30-40 years and Embryologists below 35 years, who will be the final winners at the National ISAR-Quiz which will be held during our Annual Conference in Kolkata in April 2018! The final winner from the “Clinician group” will receive a complimentary free Registration by the American Societies of Reproductive Medicine (ASRM) at the annual conference, to be held between the 6th-10th October, 2018 in Denver, USA. The final winner of the Embryologist group will receive a complimentary free Registration by the European Society of Human Reproductive & Embryology (ESHRE) at the annual conference to be held between the 1st-4th July 2018 in Barcelona, Spain. ISAR will offer travel and local stay to both these winners!

The “Clinicians Quiz” has already been held is some States and State winners who have been selected will be eligible to appear at the National Quiz in Kolkata. Those appearing for the Quiz at the Yuva Conference in December 2017 in Ahmedabad will also be included for the National Quiz.

The Embryologist Quiz will be held in February 2018 in Bhopal during the 3rd ISAR Embryology Annual Conference and the top 8 winners will be eligible for the National Quiz in Kolkata. Of course, all those who reach the National Quiz level will be expected to become ISAR members before they can appear for the final Quiz! So, please pass the word around and encourage all our young clinicians and embryologists to participate in this activity. 3 winners to be sent for the National Quiz.

There have been many firsts, we have added this year the ISAR flag, the National ISAR Quiz, four new educational programs, a totally new look to the ISAR Journal – Journal of Human Reproductive Sciences (JHRS) and the First Midterm Full Day ISAR Governing Council Meeting which was held at the J.W. Marriott Hotel in Mumbai to review the functioning and programs of the Society. During the next 6 months of my tenure, the courses will continue and we will work on upgrading them based on suggestions received.

The next arm of our program consists of “Ethics in ART”. The Ethics Committee will work on creating Guidelines for ISAR members on Ethical issues related to assisted reproduction which will be helpful to our members. The Committee is in the process of being formed and soon we will have a working group preparing the guidelines.

A Master class of Male Infertility is being organized on February 10th & 11th, 2018 which will be conducted by Dr. Ranjith Ramasamy (USA) and Dr. Rupin Shah (India), registration will soon be opened for the same. Various Conferences, especially the Yuva ISAR, Embryology ISAR and the Annual Conference of ISAR have already been announced and we will be adding some more CME’s and Webinars. I request you all to take advantage of all what’s on at ISAR and we look forward to meeting you at some forum, somewhere in the country!

We need to Empathize with our patients both physically and financially, we need to make it easier for them, to avail of services related to Assisted Reproduction. Our plan this year is to educate our patients through short videos which could be relayed on “ISAR’s You Tube Channel! My endeavor is also to include infertility related services under Insurance cover. I am truly trying my best, I hope I can manage it sometime, if not in my Presidential Year!

My sincere thanks to all my team especially the Convenors of the various programs who have truly made ISAR take huge strides towards a Stronger Society. My personal thanks to “Dr. Ameet Patki, our Secretary General and Dr. Krishnakumar our Treasurer who have truly been great Colleagues. We also appreciate the unconditional support of Abbott India Limited and GlaxoSmithKline Pharmaceuticals Ltd. towards this Newsletter!

Wishing you all a Happy Diwali and a Wonderful New Year!!

With Warm regards

Duru Shah
Activities of ISAR – May 2017 onwards

"Infertility Management Simplified" – A Digital Series of 6 Webinars

Supported through an unrestricted educational grant from Torrent Pharmaceuticals.

Indian Society for Assisted Reproduction (ISAR) has initiated Series of 6 Webinars on "Infertility Management Simplified" through a multi-disciplinary approach to infertility through case discussions. This course is conducted at Breach Candy Hospital Auditorium and webcasted live in different cities of the country. It is aimed at educating young Gynecologists and Post Graduates on infertility management.

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<tr>
<th>Topics</th>
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<tbody>
<tr>
<td>Ovulation Induction</td>
<td>September 13th, 2017</td>
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<tr>
<td>Fertility Management in PCOS patients</td>
<td>October 11th, 2017</td>
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<td>Imaging in infertility</td>
<td>November 8th, 2017</td>
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<td>Minimally Invasive Surgery</td>
<td>December 13th, 2017</td>
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<td>Male infertility and sexual dysfunction</td>
<td>January 10th, 2018</td>
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<td>Procedures in Assisted Reproduction</td>
<td>February 14th, 2018</td>
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**Time:** 7.30-10.30 pm

**Venue:** Breach Candy Hospital, Auditorium

**Launch of the Series – 13th September, 2017**

This was followed by an engaging round of Questions & Answers involving all the webcast locations. A total of around 1320 delegates participated in the Webinar including online presence. The entire program has been video graphed, edited and archived on the ISAR website.
Taking further our endeavor at ISAR to educate, we have introduced the "Fertility Enhancing Surgeries – What to do and what not to do" a program organized by ISAR in collaboration with Johnson & Johnson Institute. It is a two day course on Fertility enhancing endoscopic surgeries. This course is aimed at training especially our budding post-graduates. Endoscopic surgeries are being done extensively countrywide and they have a huge role in fertility treatment. We are enrolling only 16 candidates per batch at both Mumbai and Chennai centers every month for the next 12 months. I am sure our post graduates will enjoy the course as it includes hands on training on pigs and simulators and it is free! Endoscopic surgeons and infertility experts will deliver lectures to the students followed by supervised training and video demonstrations on common fertility enhancing surgeries.

I would like to express my gratitude to Dr. Krishna Kumar and Dr. Parul Kotdawala the Course Coordinators for this program (and their teams of faculties both at Mumbai & Chennai). I would also like to thank Dr. Vivek Iyer and Dr. Vivek Raul and the entire team at Johnson & Johnson for supporting this program. For further details on the course please log on to our ISAR website http://www.isarindia.net/

This free Course includes didactic and hands-on training on Infertility related Endoscopic Surgeries. (Please refer to page 15 further details). The topics are as follows:

**SATURDAY**
- Welcome & Introduction
- Instrumentation – Hysteroscopy Laparoscopy
- Video Lectures – Laparoscopy
- Video Lectures – Hysteroscopy

**SUNDAY**
- Diagnostic & operative Hysteroscopy on Simulators
- Hands on Training in Animal Lab (live tissue)

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### MUMBAI

**July 15/16, 2017**
- **Faculty**
  - Dr. S. Krishnakumar
  - Dr. Santek Pisat
  - Dr. Nikita L. Patel
  - Dr. Falahunisa Shaikh
  - Dr. Shital Sonone
  - Dr. Zarna Pegu
- **Delegates**
  - Dr. Sonali Tawde
  - Dr. Amruta Anish Raut
  - Dr. Ketan Shah
  - Dr. Aditi Parikh
  - Dr. Renu Raut
  - Dr. Aditi Tandon

**Aug. 26/27, 2017**
- **Faculty**
  - Dr. Kedar Ganla
  - Dr. Santek Pisat
  - Dr. Anurag Bhaete
  - Dr. Shivanand Sakhare
  - Dr. Amriti Agrawal
  - Dr. Charumati Pekhale
  - Dr. Maulik Joshi
  - Dr. Sonali Hiwale
  - Dr. Shiwani Katarka Agarwal
- **Delegates**
  - Dr. Ridhi Desai
  - Dr. Deepa Talreja
  - Dr. Jeetika Thakkar
  - Dr. Vikram Shah

**Sept. 23/24, 2017**
- **Faculty**
  - Dr. Duru Shah
  - Dr. Prakash Trivedi
  - Dr. S Krishnakumar
  - Dr. Parul Kotdawala
  - Dr. Mala Raj
  - Dr. Vinayak Chandra
  - Dr. Pratibha Makhija
  - Dr. Yogesh Singhal
  - Dr. Shilpa Shah Gohil
  - Dr. Rucha Teje
  - Dr. Ridhi Garg
  - Dr. Sarika Tendulkar
- **Delegates**
  - Dr. Sonali Kanthed
  - Dr. Rohan Krishna Kumar
  - Dr. Jili Basumtary
  - Dr. Richa Sharma
  - Dr. Mansi Shukla

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### CHENNAI

**July 29/30, 2017**
- **Faculty**
  - Dr. Archana K
  - Dr. Rohan Krishna Kumar
  - Dr. Manu Lakshmi
  - Dr. Divya
  - Dr. Shanthy
  - Dr. Swathy S
  - Dr. Gayathri
- **Delegates**
  - Dr. Priyasakthi
  - Dr. Archana
  - Dr. Mahalakshmi A
  - Dr. Manu Lakshmi
  - Dr. Divya
  - Dr. Vasanthakumary
  - Dr. Irshad Nasreen
  - Dr. Jayalakshmi

**Aug. 12/13, 2017**
- **Faculty**
  - Dr. Geetha D
  - Dr. Deepa Vadhana
  - Dr. Jayanthi Leelavathy G
  - Dr. Priya Pragasam
  - Dr. Nidhi Sharma
- **Delegates**
  - Dr. Charumathy
  - Dr. Jayanthi Leelavathy G
  - Dr. Nandha Rjalakshmi

**Sept. 9/10, 2017**
- **Faculty**
  - Dr. Krishnakumar
  - Dr. Vanitha
  - Dr. Manjula Anangani
  - Dr. Priya
  - Dr. Prasansham
  - Dr. Priya
  - Dr. Priya
- **Delegates**
  - Priya Kannappa
  - Divya R
  - S M Nivethiya
  - Jyothi Susan
  - Prashitha Panneerselvam

**Oct. 28/29, 2017**
- **Faculty**
  - Dr. Anith
  - Dr. Aruna
  - Dr. Siri Vummaneni
  - Dr. Geovin Ranji
  - Dr. Shantha Rani
- **Delegates**
  - Dr. Priya
  - Dr. Maya Menon
  - Dr. Sirisha
  - Dr. Padma

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**ISAR-J&J Course on Fertility Enhancing Surgery**

**Course Director, Mumbai**
- Dr. S. Krishnakumar

**Course Coordinator, Mumbai**
- Dr. Santek Pisat

**Course Director, Chennai**
- Dr. Parul Kotdawala

**Course Coordinator, Chennai**
- Dr. Mala Raj
ISAR-ART Course

1st course held on 4th-8th Oct 2017 in Mumbai. To enlighten and further motivate the budding and junior gynaecologists who have taken up the challenges to take a step further in the field of infertility and have decided to proceed with their own IVF laboratories. The need to amalgamate the gynaec related work pattern along with embryology related issues was to induce a sense of confidence and self-sufficiency so that they can foray into this field with minimum of stress and maximum of confidence!

Topics

DAY 1
- Registration and Introduction
- When to move from simple treatments to IVF?
- Pre-IVF assessment
- Pre-IVF Counselling
- Case discussions 1
- Ovarian reserve testing – when and how?
- Individualized Controlled Ovarian Stimulation in IVF
- Role of adjuvants in IVF
- Case discussion 2
- Male factor assessment: SA and Beyond
- Sperm preparations
- Lab tour and Demonstration of sperm preparation techniques

DAY 2
- Monitoring IVF cycles
- Prevention and management of OHSS
- Luteal phase management in IVF (standard and intense)
- Case Discussion 3
- Management of male factor subfertility
- Azospermia – assessment of azospermic Male
- Sperm Donation: ethical, medical and legal aspects
- Case discussion 4
- Oocyte retrieval: Preparation, anesthesia, procedure
- Hands on OPU / ICSI demonstration
- OPU in difficult scenario
- Complications of OPU

DAY 3
- Endometrial factors in implantation
- Effect of COS on oocytes and embryo
- Role of natural / minimal stimulation in IVF?
- Case Discussion 5
- Fine-tuning the embryo transfer
- Do’s and Don’ts of ET
- Dealing with Difficult embryo transfers
- Case Discussion 6
- Setting an ART Lab
- Culture media
- Choosing the right embryos for ET
- Poor IVF Outcome – What to look in Lab
- Cryopreservation – Principles
- Demonstration of cryopreservation of embryos

DAY 4
- Oocyte Donation: ethical, medical and legal aspects
- Surrogacy: ethical, medical and legal aspects
- Status of third party reproduction in India
- Group Interaction
- Hands on Training for OR and ET
- Group Interaction
- Hands on Training for OR and ET
- Video clips
- Endometrial preparation for a recipient
- Registration of IVF Clinic
- L 34 PCPNT and Assisted Reproduction
- Group Interaction
- Laboratory aspects
- Certificate distribution
- Conclusion

DAY 5
- Endometrial preparation for a recipient
- Registration of IVF Clinic
- PCPNT and Assisted Reproduction
- Group Interaction
- Laboratory aspects
- Certificate distribution
- Conclusion

Faculty
- Dr. Madhuri Patil
- Dr. Duru Shah
- Dr. Padma Rekha Jirge
- Dr. Ameet Patki
- Dr. Kedar Ganla
- Dr. Shreyas Padgaonkar
- Dr. Padma Rekha Jirge
- Dr. Vijay Mangoli

Delegates
- Dr. Ashirwad Thatte
- Dr. A Rajeshwari
- Dr. Rana Chaudhari
- Dr. Shrirewati Sadahsivam
- Dr. Quresha Qureshi
- Dr. G Somayajulu
Luteal support in ART – Current Evidence

Assisted reproduction – In vitro fertilization (IVF) and embryo transfer (ET), is the current standard of care for unresolved subfertility in women with functional responsive ovaries and endometrium. The integral steps in an IVF cycle are Controlled Ovarian Hyperstimulation (COHS), final oocyte maturation trigger, oocyte pick up (OPU) and embryo transfer (ET). It is now accepted that luteal phase physiology is disrupted in in vitro fertilization (IVF) cycles, and that supplementation of the luteal phase with progestogens is necessary to optimize IVF cycle outcomes. Luteal insufficiency is caused by the defective functioning of the granulosa lutein cells in the pharmacologically stimulated ovaries and worsened by the loss of granulosa cells during follicular aspiration for oocyte retrieval. The use of Gonadotropin releasing hormone analogue (GnRHa) or GnRH antagonist to control the ovarian stimulation and the use of human chorionic gonadotropin (hCG) or GnRH agonist to induce final oocyte maturation also contribute to luteal phase defect in IVF cycles. Thus, direct progestogen support, or administration of compounds that improve endogenous progesterone production is advocated to support the luteal phase. This allows favorable endometrial preparation for implantation improving the ART cycle outcomes.

**Luteal phase support**

The two protocols commonly used for luteal phase support in IVF cycle include either natural micronized progesterone and/or human chorionic gonadotropin (hCG). These protocols are often combined with estrogens and adjuvants like aspirin/heparin or human chorionic gonadotropin (hCG). These protocols are often combined with estrogens and adjuvants like aspirin/heparin or黄瓜酸。It is also usual practice to use multiple routes of micronized progesterone together hoping it will help clear the hurdle of implantation-the bottleneck of ART success.

**Drugs used for LPS**

- Micronized Progesterone – different doses and routes
- Human Chorionic Gonadotropin (hCG)
- Estrogen + Progesterone
- GnRH agonist + Progesterone (Triptorelin 0.1 mg day 6 of IVF / ICSI)
- Dydrogesterone (10mg TID)

**Routes of micronized progesterone LPS**

- Vaginal pessaries (200-600 mg daily)
- IM injections (50-100mg IM daily)
- SC injection (25-50mg daily)
- Vaginal gel (90 mg daily)
- Oral capsules (200-600 mg daily)

**Modified Luteal Phase support after GnRHa trigger**

- Estrogen + Progesterone +/- hCG.
- But are these protocols beneficial? Are we just blindly giving whatever is available hoping to achieve better pregnancy rates?
- The answers to these questions lie in exploring the vast data base of research and evidence and the recommendations and guidelines formed based on it.

Initially hCG based LPS with or without progesterone was the norm. As wealth of evidence started pointing towards the efficacy and safety of progesterone alone, a change in the LPS protocols came underway. A review by Ludwig M and Diedrich K in 2001 concluded that vaginal progesterone should be the standard choice for luteal phase support. They found that progesterone is as effective as hCG for luteal phase support but provides a higher safety with regard to ovarian hyper stimulation syndromes, and vaginal progesterone is as effective as intramuscular progesterone. An evidence based debate on LPS published in 2008 in Middle East Fertility Society Journal concluded that Progesterone intramuscularly (IM) seems to yield a better pregnancy rate; however the side effects of IM progesterone make local vaginal progesterone cream/pessaries more accepted and used by patients. hCG, though is a good LPS, was associated with a higher incidence of OHSS. Adding estrogens to LPS was not found useful in 2008, Kassab et al. noted that micronized progesterone pessaries were the most frequently used LPS in the United Kingdom.

**Nice Guidelines 2013-Luteal phase support after IVF**

- Women to be offered progesterone for luteal phase support after IVF treatment. (new 2013)
- Do not routinely offer women human chorionic gonadotropin (hCG) for luteal phase support after IVF treatment because of the increased likelihood of ovarian hyper stimulation syndrome (OHSS) (2013)
- Inform women undergoing IVF treatment that the evidence does not support continuing any form of treatment for luteal phase support beyond 8 weeks’ gestation (new 2013)

**The Cochrane evidence – Luteal phase support for assisted reproduction (ART) (2015)**

Of the strata of evidence available, evidence based systematic reviews and meta-analysis of randomized controlled trials (RCT) is the most dependable. Thus, the RCT based Cochrane data base provides invaluable evidence based recommendations. The 2015 Cochrane analysis on luteal phase support for assisted reproduction (ART) by van der Linden M et al, reviewed the many different interventions, dosages and administration routes of luteal phase support. Ninety-four RCTs (26,198 women) were included. They concluded that though the evidence available was of low quality due to poor quality reporting and imprecision

- hCG or progesterone given during the luteal phase may be associated with higher rates of live birth or ongoing pregnancy than placebo or no treatment.
- But hCG may increase the risk of OHSS compared to placebo/progesterone luteal support.
- No particular route for progesterone LPS was found superior to the other in term of outcomes.
- Addition of estrogen to progesterone LPS showed no benefit.
- The addition of GnRHa to progesterone appears to improve ART outcomes.

This evidence helps the clinician shift more into providing Progesterone only LPS and avoiding hCG and Estrogen LPS, which in turn reduces the OHSS risk and morbidity. Also the addition of a single dose of GnRHa to progesterone 6 days following IVF/ICSI is very promising in improving Live birth rates.

**Current Evidence – Dydrogesterone**

All this said, the horizons of research to improve implantation in ART cycles is ever widening and the use of Dydrogesterone based luteal phase support is gaining evidence based recommendations. Domitz et al in 1999 conducted a retrospective study on 518 patients and found that Dydrogesterone was as effective and more convenient as Intramuscular micronized progesterone LPS but more expensive. Indian pioneer, Dr. B. N. Chakravarty and his team, compared outcomes and patient satisfaction of vaginal micronized progesterone versus dydrogesterone LPS in an RCT including 430 women. They found dydrogesterone was as good as micronized progesterone for LPS in terms of pregnancy rates. Orally administered dydrogesterone was better tolerated than vaginal progesterone that caused vaginal irritation in around 10% of patients. The patient satisfaction with dydrogesterone LPS was significantly more compared to vaginal micronized progesterone.

Continued on page 9
Are Environmental Toxicants Affecting Human Reproductive Health and Outcomes?

Environmental Contributors to Reproductive and Developmental Health

A growing body of scientific evidence suggests that human reproductive health and ultimately reproductive capacity are under strain. Across the globe, indicators of reproductive adversity include increased rates of compromised birth outcomes (preterm birth, small for gestational age), developmental disorders and chronic childhood diseases (e.g., autism, asthma, diabetes), certain cancers, obesity, earlier onset of puberty, altered sex ratios, longer time to pregnancy, and decreased sperm counts. These changes have occurred in a relatively short timeframe, suggesting they are unlikely to be explained solely by genetic mutations, and thus warrant consideration of other causes, including the environment – social, built, nutritional, and chemical agents.

In developed and developing countries, air pollution, stress, nutrition, and chemicals in personal care and household cleaning products, in industrial waste and pesticides, and nearly ubiquitous plastics are of concern. Since 1950, chemical production has increased 23.5-fold between 1947 and 2007, and in 2012 in the U.S. alone, 9.5 trillion pounds of industrial chemicals (e.g., pesticides, plastics, chemicals in drugs and personal care products) were domestically manufactured or imported, yielding about 30,000 pounds/person/year (www2.epa.gov). Most chemicals in commerce have little regulatory oversight for their introduction, use and re-use, disposal or effects on chronic toxicities or reproductive harm, other than teratogenicity in animal models. Toxicity testing varies from country to country, and while in Europe, the REACH regulation has been the most progressive approach, the majority of chemicals in commerce known to have health impacts have been tested after a health problem is recognized or potentially associated. This is in marked contrast with pharmaceuticals that undergo extensive pre-clinical in vitro and in vivo testing before widespread use is permitted.

Randomized controlled trials for specific chemicals or mixtures of chemicals in humans is, of course, ethically impermissible, and so information about possible harm is gathered from laboratory animal experiments, wildlife observations, and human epidemiologic data. Recently, Woodruff et al, developed the Navigation Guide Systematic Review methodology (http://content.healthaffairs.org/content/30/5/931. full.pdf + html?ijkey= z58 MCEPW2 x49.&keytype=ref&siteid=healthaff), building on best practices in research synthesis in evidence-based medicine and environmental health, providing a rigorous and transparent approach to translate environmental health science into better outcomes.

These are important to studies in environmental health and equally to reproductive environmental health.

Environmental Chemical Exposures in the Pre/Periconception/Prenatal Periods

Pre-conceptual, peri-conceptual, and prenatal exposure to environmental chemicals and their effects on fecundity, pregnancy and developmental outcomes and long-term health of exposed individuals (parents and fetus/neonate) and trans-generationally comprise a growing area of inquiry. Toxic chemicals are currently widely distributed in homes, workplaces and communities, and contaminate food, water, air and consumer products. Human gametogenesis, the developing fetus, neonate and adolescent periods are particularly vulnerable developmental "windows" to biological perturbations caused by ambient levels of environmental contaminants. This is because cellular processes (meiosis, imprinting, mitosis, cell migration, proliferation, and differentiation) are occurring uniquely or more rapidly in these periods. Mechanisms underlying toxic chemical alterations of cellular functions include mimicking or blocking natural hormones’ actions and their signaling pathways or by modifying epigenetic marks that regulate gene expression and ultimately, protein synthesis and cell behavior. Also, most exposures are to multiple chemicals simultaneously at different levels, which can have different mechanisms of actions together as each one alone.

Endocrine Disrupting Chemicals (EDCs)

Of importance to reproductive capacity is exposure to “endocrine disrupting chemicals” (EDCs), which are compounds that “interfere with the synthesis, secretion, transport, binding, action, or elimination of natural hormones in the body that are responsible for the maintenance of cellular/organismal homeostasis, reproduction, development, and/or behavior”. Examples of EDCs commonly found in food, water, air, house dust, and/or personal care products include phthalates, bisphenol A (BPA), polybrominated diphenylethers (PBDEs), perchlorate and some pesticides. Because hormone action is critical to human reproduction, chemicals that perturb the system can cause permanent effects. The most well-known EDC to physicians is diethylstilbestrol (DES) and its delayed effects of benign and malignant reproductive tract abnormalities and increased risk of female breast cancer. DES remains one of the most scientifically robust illustrations of the link between developmental exposure to a hormonally active exogenous chemical and adult disease. However, increasing evidence supports EDCs and their roles in disruption of the male and female reproductive tracts during development in utero and the increased risk of polycystic ovarian syndrome, endometriosis, uterine fibroids, early puberty, and decreased sperm counts and infertility. In fact, disruption of ovarian and testicular steroidogenesis and gamete development have been reported with in utero and/or adult exposures to specific EDCs at every step in these processes, in mice, rats, hamsters, lamb, sheep, and humans.

Virtually all pregnant women in the U.S. have at least 43 toxic exogenous chemicals in their bodies – many at levels associated with adverse health outcomes, including harm to human reproduction and/or development. These include lead, mercury, toluene, perchlorate, BPA, and some phthalates, pesticides, perfluorochemicals (PFCs), poly-chlorinated biphenyls (PCBs) and polybrominated diphenylethers (PBDEs). Many of these chemicals are found in consumer products and in the home. In some cases, such as mercury, fetal exposures to environmental contaminants may be higher than maternal exposures. Postnatally, maternal exposure to environmental contaminants can continue to expose a newborn through breast-feeding, although this is not a reason to discontinue breast-feeding per se.

Implications of the New Science for Reproductive Health Professionals

Our understanding of the nature and extent of the relationship between reproductive health and environmental chemicals is rapidly evolving. The
Dydrogesterone is also an immunomodulator molecule known to promote favorable immunomodulator effect supporting pregnancy. Among physicians, OB/GYNs and reproductive health professionals are uniquely poised to intervene in critical stages of human development (i.e., pre/peri-conception and during pregnancy) to prevent harm. In 2009, the Endocrine Society reviewed the evidence of health impacts from EDCs and concluded that “the evidence for adverse reproductive outcomes (infertility, cancers, malformations) from exposure to endocrine disrupting chemicals is strong, and there is mounting evidence for effects on other endocrine systems, including thyroid, neuro-endocrine, obesity and metabolism, and insulin and glucose homeostasis” and advised that “Until such time as conclusive scientific evidence exists to either prove or disprove harmful effects of substances, a precautionary approach should be taken in the formulation of EDC policy.” The recent report from the World Health Organization and the United Nations on Endocrine Disrupting Chemicals came to virtually the same conclusions.

Summary and Conclusions

It is increasingly of concern that environmental chemicals are affecting human health, including reproductive health. We are at a unique time in history, as reproductive health professionals and scientists, to assure that the state of the science and quality of the evidence are critically evaluated and that sound scientific principles are followed to guide us in minimizing environmental chemical exposures in our patients, the population at large, and generations to come. We must educate ourselves, our trainees, our patients, and our communities about potential harms and ways to mitigate them, including policy changes for widespread effects. This is a global challenge best approached by global collaboration to minimize harm and maximize health and well being for all citizens of the world.

References


Luteal support in ART – Current Evidence

Continued from page 7

An Indian RCT including 1373 women undergoing ART, published in Fertility and Sterility 2011, concluded that dydrogesterone, micronized progesterone, vaginal gel and pessary LPS were comparable in terms of pregnancy and miscarriage rates.

The results of Lotus I, an international Phase III randomized controlled trial including 1031 women, has been published in Human Reproduction in 2017. It compared oral dydrogesterone 10 mg TID with Micronized vaginal Progesterone (MVP) three times daily and clinical pregnancy rates at 12 weeks of gestation were assessed. The study demonstrated non-inferiority of oral dydrogesterone, with pregnancy rates at 12 weeks of gestation of 37.6% and 33.1% in the oral dydrogesterone, with pregnancy rates at 12 weeks of gestation of 37.6% and 33.1% in the oral dydrogesterone and MVP treatment groups, respectively. Dydrogesterone was also well tolerated and had a safety profile similar to MVP.

Dydrogesterone is also an immunomodulator molecule known to promote favorable T Helper cell immune response during implantation and pregnancy.

Conclusion

Luteal phase support is advocated in all gonadotropin stimulated ART cycles where same cycle embryo transfer is planned. Natural micronized progesterone especially micronized vaginal progesterone 600-800 mg daily is a safe and effective luteal support. Addition of GnRhA to progesterone LPS is associated with higher live birth rates. Dydrogesterone LPS is a promising and safe oral LPS which has added benefit of favorable immunomodulator effect supporting pregnancy.
ISAR Travelling Seminars on "Stimulating Ovaries Stimulating Minds"

ISAR Travelling Seminars on "Stimulating Ovaries Stimulating Minds" is one of the most tricky, but satisfying area in the management of women seeking fertility care. It is important to understand the basic physiology of ovulation and the luteal phase, so as to be very clear on how to move forward in the management of individual women. Treatment has to be customized and should not be a standard protocol for every patient. This "Travelling Seminar" was conceptualized to bring to you the tips for effective ovulation induction and luteal support through case presentations and a lot of interaction. Experts from the ISAR Team have been delivering the lectures in their own style, though the modules are standardized to deliver a similar message all across the country.

Topics

OPTION 1

1. Impact Of Ovarian Stimulation On Luteal Phase Dynamics
2. Evidence Based Luteal Phase Support in management of infertility
3. Ovulation Induction in hyper responders
4. Ovulation Induction in normal responders
5. Ovarian Reserve Tests & Prediction of Ovarian Response
6. Ovulation Induction in poor responders

OPTION 2

1. Gonadotropins in Ovulation Induction- A stepwise approach
2. Complications in Ovulation Induction:
3. Evaluation in infertile couple
4. Role of Ultrasonography & Folliculodynamics in Ovulation Induction
5. Clomiphene citrate in non-responders: What's next?
6. Luteal phase support- In ovulation induction, IUI, ART (IVF / ICSI) & R

UTTAR PRADESH

July 22nd, 2017

Dr. Jagdish Gada
Dr. Kaustub Kulkarni
Dr. Rakhi Singh
Dr. Meera Agnihotri
Dr. Pratibha Rohtagi
Dr. Madhu Loomba
Dr. Kiran Pandey
Dr. Kalpana Dixit

JAIPUR

August 20th, 2017

Dr. Kedar Ganla
Dr Sanjay Makwana
Dr. Nooren Mirza
Dr. Urmila Sharma
Dr. Vinita Agarwal
Dr. Nishant Dixit

HARYANA

August 20th, 2017

Dr. Rohit Gupta
Dr. Rakhi Singh
Dr. Maninder Ahuja
Dr. Jyoti Malik
Dr. Jyoti Gupta
Dr. Rakhi Singh
Hypothyroidism in Infertility

Difficulty to conceive or subfertility is a major psychological burden on a couple wishing to conceive. Endocrine and immunological factors play a significant role in conception failure. Assisted reproductive technology has tremendously lead to change in perspective of infertility but endocrine factors have to be taken care of first. Thyroid disorders affect adversely and thus have an important role in management of infertility. The prevalence of hypothyroidism in the reproductive age group is 2-4%. Thyroid dysfunction is more common in females than in males. Both hypothyroidism and hyperthyroidism and thyroid autoimmunity have a profound effect on fertility.

Hypothyroidism is a spectrum of clinical symptoms and signs related to thyroid hormone deficiency or autoimmunity. Mild degree has a little role in reproduction but moderate to severe degrees have a detrimental effect on both female and male fertility. Primary hypothyroidism occurs due to thyroid gland failure and secondary hypothyroidism is due to abnormal hypothalamic-pituitary axis resulting in inadequate production of bioactive Thyroid Stimulating Hormone (TSH).

TSH
Causes of hypothyroidism are agenesis, defects in synthesis, infective, post radiotherapy, post surgery, autoimmune and atrophic. Manifestations such as menstrual irregularities, spontaneous miscarriage, premature birth, unexplained stillbirths and infertility are common. Screening is made by TSH sensitive assay and free T4 estimation. After diagnosing hypothyroidism, anti-microsomal and anti-thyroglobulin antibodies should be tested.

Hypothyroidism can be divided into clinical and subclinical categories for deciding the plan of management. Recent studies have shown that by prescribing thyroxin supplement in infertile women with hypothyroidism and anovulation, pregnancy rates have risen up to 64% following treatment.

Effects of Hypothyroidism in Females
1. There is decreased rate of pharmacokinetics resulting in decreased metabolic clearance of estrone and androstenedione and increased peripheral aromatization of androgens.
2. Unbound fractions of steroid hormones are increased due to decreased plasma binding activity of sex hormone binding globulin.
3. Hypothalamic Thyroid Releasing Hormone (TRH) is increased causing both Thyroid Stimulating Hormone (TSH) and prolactin secretion to increase. This can cause galactorrhea.
4. Hemostatic coagulation pathway is affected. There may be decrease in levels of factor VII, VIII, IX and XI, which may contribute to menstrual irregularities such as polymenorrhea and menorrhagia.

Infertility due to Hypothyroidism
1. There is altered peripheral estrogen metabolism.
2. Defects in hemostasis, affecting implantation and pregnancy.
3. Hyperprolactinemia
4. Disturbed hypothalamic-pituitary axis.

Clinical Hypothyroidism
The prevalence of clinical hypothyroidism is less as compared to subclinical hypothyroidism. It is 3.2% in the infertile population. Measurement of TSH and FT4 are of utmost importance in making a diagnosis of thyroid disorders. Antibodies like anti thyroid peroxidase and anti thyroid globulin form a part of investigations while concluding the etiology of both clinical hypothyroidism and sub clinical hypothyroidism. The mainstay of diagnosis of thyroid auto immuno disease (TAI) is presence of anti thyroid peroxidase antibodies in serum.

Levothyroxine (LT4) replacement is the standard treatment for clinical hypothyroidism to achieve a normal serum TSH level of 0.3-2.5 mU/L.

It should be administered orally once daily early in the morning on empty stomach with a gap of at least one hour with any other food or medication. This is to avoid interference of any protein binding or cross metabolism effect of other medications. There should be at least a 4 hour separation between thyroid hormone supplement and supplements such as calcium carbonate and ferrous sulphate.

Levothyroxine has a long half life of 18-21 hours, making a single daily dose sufficient. Whenever steroids such as estrogens and androgens have to be supplemented, reassessment of TSH and FT4 levels is a must.

Levothyroxine replacement is decided based on the patient's body weight, lean body mass, body mass index, TSH levels, etiology and compliance. It is started at 1.6-1.8 micrograms per kilogram body weight. Monitoring is done for any unusual symptoms like tremors, headache and palpitations. Repeat TSH and FT4 levels should be checked after minimum 3-4 weeks as this much time is required for body homeostasis to occur. Initially there should be partial replacement with levothyroxine medication and gradually titrated upwards using optimal serum thyrotropin levels as target.

Current studies support the fact that in presence of raised prolactin levels, hypothyroidism should be ruled out first and treated before evaluation for increased prolactin levels.

Subclinical Hypothyroidism (SCH)
Many medical societies have defined SCH as follows:
1. AMERICAN THYROID ASSOCIATION (ATA) has defined sub clinical hypothyroidism as a TSH level greater than the upper limit of normal range (4.5-5.0 mU/L) with normal FT4 levels.
2. EUROPEAN THYROID ASSOCIATION (ETA) defines it as mild and severe SCH; mild being TSH values between 4-10 and severe being >10 with normal FT4 levels. According to this definition, the incidence of sub clinical hypothyroidism is 4-10%, with 90% being of the mild severity. Women opting for pre-conceptional management should be treated for subclinical hypothyroidism also.

Hence in a medical scenario, sub clinical hypothyroidism should be defined as TSH value of >2.5mU/L with normal FT4 values. Evidence shows that TSH > 4 mU/L is associated with recurrent pregnancy losses.

Recommendations of AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE (ASRM) for management of SCH in infertile female population are as follows:
1. If TSH concentrations are over the non-pregnant lab reference range (typically > 4 mU/L), patients should be treated with levothyroxine to maintain levels below 2.5 mU/L. It is a grade B recommendation.
2. Given the limited data, if TSH levels prior to pregnancy are between 2.5 and 4 mU/L, management options include either monitoring the levels or treating with levothyroxine to maintain TSH <2.5mU/L. It is a grade C recommendation.
3. During the first trimester of pregnancy, it is advisable to treat when the TSHs > 2.5 mU/L. While thyroid antibody testing is not routinely recommended, one might consider testing anti-thyroid peroxidase (TPO) antibodies for repeated TSH values >2.5mU/L. If there is no other risk factors for thyroid disease are present. It is a grade C recommendation.
4. If Anti-TPO antibodies are detected, TSH levels should be checked and treatment should be considered if the TSH level is over 2.5 mU/L. It is a grade B recommendation.

According to EUROPEAN THYROID ASSOCIATION (ETA) 2014 guidelines, and ENDOCRINE SOCIETY (ES) 2012 guidelines, subclinical hypothyroidism should be treated whether or not it is associated with thyroid auto immuno disease.

According to AMERICAN THYROID ASSOCIATION (ATA) 2011 guidelines, subclinical hypothyroidism associated with thyroid auto immuno disease should be treated. No treatment is required for thyroid auto immuno disease without hypothyroidism.

Thyroid Autoimmunity (TAI)
Prevalence of thyroid autoimmunity is 5 to 10 times more in women than men because of genetic factors, other auto immune diseases and estrogen related effects. It is the most common auto immune disorder in women and affects 5-20% of women of reproductive age group. Thyroid auto immunity has an indirect relationship with endometriosis, Poly Cystic Ovarian Syndrome and premature ovarian failure, vitiligo and myasthenia gravis.

Analysis of Investigations Before Starting Controlled Ovarian Stimulation for a Patient (according to research of Clinical Endocrinology and Metabolism Society)
1. If TSH is >2.5 mU/L Start LT4 before starting controlled ovarian stimulation (COS) or any other assisted reproductive technology procedure.
if serum TSH levels are within normal range. Women with thyroid autoimmunity are more affected and the effect is permanent leading to subclinical hypothyroidism. Hence it is very important to monitor TSH levels during pre-conceptional period. 

**Hypothyroidism in Male Infertility**

Hypothyroidism is less common in men and has less effect on their reproductive function. Thyroid problems generally seen in men are hypothyroidism, Hashimoto’s thyroiditis (autoimmune hypothyroidism), Graves’ disease (autoimmune hyperthyroidism) and thyroid cancers. 

Hypothyroidism is related with decreased libido and erectile dysfunction. Prospective controlled studies have concluded that it has an adverse effect on gametogenesis, with sperm morphology significantly affected. There is decrease in sex hormone binding globulin, estrogen and androgen metabolites and total and free testosterone. There is elevation of prolactin concentration with longstanding cases of hypothyroidism. Measurement of FT3, FT4, TSH and thyroid autoantibodies such as thyroid peroxidase and anti thyroid globulin antibodies is done to confirm the diagnosis. Pathoautoantibodies and ashenzoautoantibodies are related with thyroid peroxidase (TPO) antibodies.

In today’s world of ever expanding horizons of science and technology, infertility treatment has taken a quantum leap, making available a great many treatment options that will help eliminate some of the barriers to conception. Newer information regarding diagnosis of thyroid dysfunction and its treatment is becoming available all the time. For women and men desirous of getting pregnant normal thyroid functioning is one of the first critical steps to a successful outcome.

**References**

9. Anderson S, Pederson XM, Bruun NN. Narrow individual variations in serum T4 and T3 in normal subjects; a clue to the understanding of subclinical thyroid disease. J Clin Endocrinol Metab. 2002;87:1669-72.

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**Expert Opinions...**

<table>
<thead>
<tr>
<th>Q1. What percentage of ART cycles at your center are Frozen-thaw transfers (FET)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-40%</td>
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<tr>
<td>40%</td>
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<tr>
<th>Q2. How do you prepare the endometrium for FET cycles?</th>
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<tbody>
<tr>
<td>Down regulated HT, HT, Natural and Stimulated, with oral Ovulogens.</td>
</tr>
<tr>
<td>Lupride down regulation with Progynova for endometrial growth.</td>
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<tr>
<td>Estradiol valerate and Progesterone sequentially.</td>
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<tr>
<th>Q3. Do you prefer Natural Cycle-FET or Artificial Cycle-FET (AC-FET)?</th>
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<tbody>
<tr>
<td>Natural Cycle FET.</td>
</tr>
<tr>
<td>I usually prefer the Artificial cycle.</td>
</tr>
<tr>
<td>AC-FET.</td>
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<tr>
<th>Q4. What drugs do you prefer for endometrial preparation in the AC-FET?</th>
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<tbody>
<tr>
<td>Estradiol valerate (Progynova) &amp; Estradiol hemihydrate (Estrabet).</td>
</tr>
<tr>
<td>Estradiolvalerate.</td>
</tr>
<tr>
<td>Estradiol valerate and 17 beta estradiol.</td>
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<tr>
<th>Q5. Your experience with endometrial preparation by Estradiol Valerate (EV) and/or 17b-Estradiol (17b-E).</th>
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<tbody>
<tr>
<td>In 20% of patients the oral form does not give the desired result.</td>
</tr>
<tr>
<td>All experience with EV, not yet convinced with 17b. Used sparingly.</td>
</tr>
<tr>
<td>Majority with EV but nearly 30 percent on EV has endometrium less than 7 mm in spite of 15-20 days treatment and doses up to 8-10 mg.</td>
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<tr>
<th>Q6. What is better in terms of patient tolerability- EV or 17b-E?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both similar.</td>
</tr>
<tr>
<td>No experience yet.</td>
</tr>
<tr>
<td>EV.</td>
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<table>
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<tr>
<th>Q7. How are EV and 17b-E different?</th>
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<tbody>
<tr>
<td>They act similarly. However, the hemihydrate salt (Trade name: Estrabex) is absorbed more easily through the oral route hence more effective.</td>
</tr>
<tr>
<td>-------</td>
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<tr>
<td>17 beta E useful in thin endometrium with EV.</td>
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<tr>
<th>Q8. How do you tackle the enigma of thin endometrium?</th>
</tr>
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<tbody>
<tr>
<td>By giving non oral Estradiol valerate, increasing the blood flow with LMWH.</td>
</tr>
<tr>
<td>Increase the dose of EV, aspirin, Sildenafil, G-CSF, hysteroscopic adhesiolyis if indicated.</td>
</tr>
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<tr>
<th>Q9. Do adjuvants have a role to play in the endometrial growth? If yes, which ones do you use in your clinical practice?</th>
</tr>
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<tbody>
<tr>
<td>Baby aspirin, steroids and LMWH in most cases and sometimes GCS.</td>
</tr>
<tr>
<td>Aspirin, Sildenafil, G-CSF.</td>
</tr>
<tr>
<td>No role for Low dose aspirin or sildenafil.</td>
</tr>
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<tr>
<th>Q10. What is the role of Gonadotropins in endometrial preparation for an FET cycle?</th>
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<tbody>
<tr>
<td>It is effective but expensive. Only used when all measures fail.</td>
</tr>
<tr>
<td>Is a good alternative if all above strategies are failing.</td>
</tr>
<tr>
<td>Havent used it.</td>
</tr>
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Prof. Dr. Duru Shah (president@isarindia.com), Dr. Kanthi Bansal (kanthi.bansal@gmail.com)
Dr. Fessy Louis (fessylouis@gmail.com), Dr. Maninder Ahuja (ahujam@isarindia.com)

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