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Executive Committee
Dr. Duru Shah, Founder President
duru@shah.com
Dr. Shashank Joshi, Vice President
shashank.joshi@shah.com
Dr. Rekha Sheth, Vice President
rekha@sheth.com
Dr. Piya Thakkar, Honorary Secretary
piyathakkar@hotmail.com
Dr. Sangeeta Agarwal, Joint Honorary Secretary
sangeetaagrawal@yahoo.com
Dr. Uday Thanawala, Honorary Treasurer
udaythan@thanawala.com
Dr. Madhuri Patil, Scientific Coordinator
madhuripatil59@gmail.com

Constitution Committee
Krishnendu Gupta, Chair
krishnendugupta@gmail.com
Shashank Joshi, Chair
shashank@shashank.com

Newsletter Committee
Anita Soni, Chair
anita.soni8@hotmail.com
Toral Shinde, Co-Chair
toral.tosh@gmail.com

Research Committee
Padma Rekha Jirge, Chair
rekha@jirge.com
Ganpat Sawant, Co-Chair
ganpat.sawant@gmail.com

CME Committee
Sujata Kar, Chair
sujata@kar.com
Kanthi Bansal, Co-Chair
kanthibansal@gmail.com

Website Committee
Nandini Rambabu, Chair
nandini@rambabu.com
Sharda Maroju, Co-Chair
shardamaroju@gmail.com

Gautam Kastigir, Co-Chair
birthindia@gmail.com

Membership Committee
Ritu Joshi, Chair
ritu@jo@sh.com

International Committee
Shanti Shrinivasan, Member
shanthi@shrivasan.com

Social Media Committee
Bina Vasan, Chair
bina@vasan.com
Altamash Shaikh, Co-Chair
altamash@shaikh.com

Our New Patrons

Our New Life Members

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Dr. A. M. Uma
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Dr. Anagha Kamath
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Dr. R. Poongothai
Dr. R. Shanthi
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Our New Initiatives

The Second Annual Conference of the PCOS Society of India in collaboration with the Androgen Excess and PCOS Society organized by Dr. Madhuri Patil in Bengaluru, between 16th-18th June 2017, was a huge success! All credit to Madhuri for such an excellent meeting which was attended by over 800 delegates! Please read the full report on pages 4th, 5th 6th. I welcome you all to our next meeting to be held in Gurgaon between June 22nd-24th, 2018. Do come, I will look forward to seeing you all there!

During the Inaugural function of the Conference in Bengaluru, we launched the first Module of our "PCOS Tutorials" the Online Certificate Program, which will be published as 6 Modules, by an Online Test in order to receive a beautiful Certificate on Completing the Course.

I encourage all of you to go through the Modules which have excellent information on the subject of PCOS, supported through an educational grant by USV.

We also released a Book entitled "World Clinics of Gynecology on PCOS", with Dr. Madhuri Patil and myself being Guest Editors for this Volume, the Editor in Chief being Dr. Mala Arora who has created many such volumes on various topics through her Series which she publishes through Jaypee Brothers. Do have a look at the Book. I truly think if you want to be well read on this subject, please get a copy for yourself, you will treasure it!

The PCOS Society of India has partnered with the National Institute for Research in Reproductive Health (NIRRH), Tata Institute of Social Sciences (TISS) and Kasturba Health Society – Medical Research Centre, to create "Abhiyaan PCOS" which is to initiate and encourage an integrative and inclusive endeavor to enable women with PCOS to attain a better quality of life. As a collective team, our objective is to create an impact on the morbidity in PCOS women.

To create awareness on PCOS amongst lay people, we have collaborated with Metropolis Healthcare to create the "Conquer PCOS" program. All of you are welcome to join in and help us in taking the program forward. Log on to www.conquerpcos.in and help us in taking the program forward.

The PCOS Society of India has made connections internationally besides hosting programs nationally. We recently held programs in Dubai (with support from Alkem) and Sri Lanka and are now part of a Federation, "FISGE" – the Federation of International Societies of Gynecological Endocrinology.

FISGE will host its conference in March 7th-10th, 2018 in Florence where the PCOS Society of India has a Session. Dr. Sangeeta Agrawal is coordinating the trip to Florence along with a pre-conference & post-conference holiday with all of those going to Florence for the conference. Do check out the scientific program on http://isge2018.isgesociety.com/ and get in touch with Dr. Sangeeta Agarwal on drsdagrawal@gmail.com for further details about the tour.

Our Society has also initiated the "PCOS Travelling Seminar" on "Understanding PCOS" in 65 cities all over the country with the support of an educational grant from USV. Please do participate when the Travelling Seminar visits your City!

That’s a lot of news to share over a period of 4 months from May to August!

Wish you all the best for the festivities this year. Till then, surf on the PCOS Society Website to get to know the Society better and join us in the 2 year old Society!

With warm regards,

Dr. Duru Shah
Founder President
The PCOS Society, India
The Second International Conference of the PCOS Society (India) entitled “Unraveling the Enigma” was held at at The Lalit Ashok, Bengaluru between 16th- 18th June, 2017.

It was jointly organized by the PCOS Society (India) and the Androgen Excess and PCOS Society (AE-PCOS Society).

A galaxy of international faculties, which included Professor Helena Teede, President of the AE-PCOS Society, Professor Enrico Carmina - Executive Director and CEO of AE-PCOS Society, Professor Anuja Dokras - Immediate Past President of the AE-PCOS Society along with Professor Richard Legro- Penn State, USA and Professor Joop Laven – Erasmus University, Rotterdam attended the conference.

Topics right from the genetic origin of PCOS to its effects during Adolescence, Reproductive Age and in the Peri and Post Menopause were covered by a multidisciplinary faculty of Endocrinologists, Gynecologists, Fertility Specialists, Dermatologists, Sonologists, Obesity Surgeons, and Nutriotinists.

Two workshops on “Ultrasound in PCOS” and “Ovulation Induction in PCOS” were held. The ultrasound workshop, which focused on newer diagnostic criteria that have been encompassed in the ultrasound both for diagnosis as well as management, was followed by a live demonstration. The Workshop on Ovulation Induction was a Case-Based discussion on safe and efficient protocols for ovulation induction, which gave a new insight to infertility management especially to gynecologists. There was a lot of audience participation for both workshops with questions being answered by the audience using the voting pads and live interaction between the delegates and the faculty after every session. Both the workshops were well attended by 548 delegates.

The inaugural lectures by international faculty, Helena Teede and Enrico Carmina included the International Guidelines and Obesity, which has become an epidemic in the world. Smita Mahale from the NIRRH gave an overview on the various research projects on PCOS being carried out in India.

The sessions over 3 days covered all topics related to PCOS, right from diagnosis and complications, to management of PCOS. The other important sessions were on associated disorders in PCOS, which included obesity, skin and respiratory problems and the long-term consequences of PCOS.

There were five round tables, which discussed “Vitamin D deficiency and PCOS”, “Use of Oral Contraceptives in PCOS”, “Increased lipids”, “Gestational Diabetes Mellitus” and “Ovulation induction in PCOS”. All these tables were lead by international and national faculty with 10-15 experts to form the algorithms which are displayed on the “PCOS Society” website.

All lectures slides, which have consent of the authors are available free of cost to all Members of the PCOS Society as Continuing Medical Education on the PCOS Society website.

35 abstracts showcasing research in the field of PCOS were received for free paper presentation of which six were chosen for oral presentation and rest were displayed as posters, which were judged by esteemed international and national faculty.

3 posters were from Bangladesh, one of which won the consolation prize.

The 3 day conference including the workshop was well attended by 837 delegates and 60 faculties. There were 8 delegates from Bangladesh who actively participated in this congress with 3 posters to display their work on PCOS. All delegates at this international congress actively participated in the discussions after each session.

‘All work and no play makes Jack a dull boy’. After attending exhaustive lectures on PCOS, our participants had some music to their ears by “Subra Mania” - Bindu and Ambi Subramaniam and Fusion Music by “Udupa Foundation”, both of which were highly appreciated and enjoyed.
Round Tables with development of Algorithms

PCOS and Assisted Reproduction

Surgical options in PCOS

Valedictory
Multicenter Randomized Clinical Trials in Reproduction in India: A Five Step Footmap

Richard S. Legro
M.D.
Professor of Obstetrics and Gynecology, Penn State College of Medicine, Hershey, PA

Introduction
In the beginning was the word and that word is a hypothesis. The science of medicine begins with a testable hypothesis. The most difficult step in the science of medicine is to develop a testable hypothesis and this includes writing a detailed study protocol to test the hypothesis. Most testable hypotheses will require a large sample size which exceeds the scope of a single site. Doctors must come together as a group. Bringing doctors together to agree on the primary hypothesis, the details of the study protocol, the conduct of the study, the authorship of the paper is like herding cats. Additionally, funding is required to complete such studies, which is always difficult to obtain especially in resource-challenged settings. The word on the street is that you can’t do these types of studies in India—there are too many hurdles. E.g. There is too much discord among doctors and clinics; there is a lack of research infrastructure and funding, and no track record of such studies.

I think the word on the street is wrong and I heard similar things about conducting such trials in reproductive medicine in China. We have proven the critics wrong with two such trials designed, conducted and completed in China which have been published in high impact journals and, in my opinion, will change clinical practice. My personalizable hypothesis is: High impact multi-center trials in reproduction are possible in India. You are the world’s most populous country; no country has a greater interest in healthy reproduction than yours. You are an intensely competitive country, not only with China, but with other leading countries of the world.

Let’s test this hypothesis together and further let me throw down the gauntlet: It is time to step up to China, but with other leading countries of the world. Let’s test this hypothesis together and further let me throw down the gauntlet: It is time to step up to China, but with other leading countries of the world.

Step 1: Establish a System of Governance for the Study
The first step is to form a system of governance. That will involve selecting a leader who will serve as the overall Chair and creating a Steering Committee (SC) that will consist of the other co-investigators, usually those who will lead the study at individual sites. This person who will chair the committee is often a senior leader who is respected and listened to, but also someone who can bring in the money and resources to conduct the trial, i.e. a rainmaker. The committee must establish a means for making decisions. This usually includes debate and discussion of the issue followed by a motion to resolve the issue, followed by a vote to decide it. Such a system requires mutual respect and tolerance and willingness to compromise. Adopting Robert’s Rules of Orders, capturing written minutes from the meeting, and even developing a written constitution for study governance are all possible options. Frequent face to face meetings (several a year) and phone conferences and email chains are necessary to move the work forward.

Step 2: Develop a Testable Hypothesis
The second step is to develop a testable hypothesis. While the SC is an important sounding board for determining the issue to be studied, the development of the hypothesis is best done in a smaller group led by the Key or Lead investigator of the protocol with this sub-committee serving as the initial feedback group. Trimming the size narrows the focus and expedites the process. One person must take on the responsibility of developing the hypothesis, in conjunction with a trained and experienced biostatistician. This will require an extensive review of the literature, including utilization of existing meta-analyses and if none are recent, completing one (and publishing it) as part of the study development. There must be suggestive or supportive preliminary data supporting an intervention to proceed with a multi-center trial to test it. Such effort cannot be wasted on ‘pie in the sky’ hypotheses. The choice of a comparator to the study intervention is often not obvious and is part of the difficulty in choosing the primary hypothesis. The hypothesis, if tested adequately, will only answer one question. This answer will be found in the Primary Outcome. It is difficult for a trial of human reproduction to include a primary outcome that does not involve live birth or healthy live birth. All other outcomes that are tracked are relegated to a lesser role as secondary and tertiary outcomes and thus can only serve as additional evidence to bolster the primary outcome (for example conception rates as a secondary outcome and live birth as the primary outcome) or as an outcome that the study was not designed to answer (for example in such a fertility study, favorable changes in glycated hemoglobin levels with one treatment over another). An error is often made in which the eye of the investigator is larger than the stomach and standing before the smorgasbord of outcomes to be tested, heads liberally to this outcome plate till it is overflowing. Do not give in to this temptation, make the primary outcome the one which is clinically most relevant and one which if the hypothesis is upheld (and sometimes if it is rejected) will change medical practice. Relegate all other outcomes to another smaller plate.

Do not underestimate the amount of work that goes into the development and writing of such a protocol. They usually top over 100 pages!! The U.S. Food and Drug Administration has developed a template to guide protocol development which has been approved by the U.S. National Institutes of Health (https://osp.od.nih.gov/clinical-research/clinical-trials/). This is both helpful and at first glance overwhelming, but with each trial sections are easily adapted to the current context. Thus the first protocol is the most difficult. The steering committee

![Diagram](https://osp.od.nih.gov/clinical-research/clinical-trials/)

<table>
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<th>Problem or question</th>
<th>leads to</th>
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can then review and revise the protocol before approving it. In my experience this is a rapid process with few substantive changes as the major issues have been worked out within the protocol sub-committee.

**Step 3: Start Up the Trial**

The third step is to implement the trial. This will require establishing a series of checks and balances to ensure the integrity of the trial. A Data Safety and Monitoring Committee should be established which will consist of outside expertise not involved with the trial and who lack conflicts of interest. They will approve the protocol (often again with amendments), oversee the trial to ensure the proper risk-benefit of the study, react to emerging data about safety and efficacy, and ensure the feasibility of the study by monitoring recruitment and compliance. They should first review the protocol and it should be amended to reflect their concerns. An independent Data Coordinating Center should be established led by a biostatistician who is personally not invested in the hypothesis and whose primary concern is to ensure the integrity of the trial. This group will develop standardized case report forms to ensure proper enrollment and consenting of subjects as well as the proper capture of key data. They will write a detailed Manual of Operations and Procedures (MOP) to ensure uniform conduct of the study at each study site. They will create a central database and monitor data quality and completeness, making queries for missing data and outliers. Finally they will make site visits to the individual study sites to review source materials and the conduct of the study and ensure compliance with the protocol. Written reports will be provided to the Sites and if necessary the SC and DSMB. Protocol exceptions and violations will be identified and tabulated for report to the site investigator, SC and DSMB. These aberrant practices will be stamped out at the site level as well as at the SC and DSMB. These aberrant practices will be stamped out or the site will be dropped from the trial.

If Humans are involved there will be errors, both unintentional and intentional. Both must be identified, but it is this intentional error that must be rooted out as one bad apple can taint the whole barrel. There are investigators who will cut corners, make exceptions to the inclusion/exclusion criteria, not follow the protocol for treatment as their primary concern is to ensure the integrity of the trial. This group will develop standardized case report forms to ensure proper enrollment and consenting of subjects as well as the proper capture of key data. They will write a detailed Manual of Operations and Procedures (MOP) to ensure uniform conduct of the study at each study site. They will create a central database and monitor data quality and completeness, making queries for missing data and outliers. Finally they will make site visits to the individual study sites to review source materials and the conduct of the study and ensure compliance with the protocol. Written reports will be provided to the Sites and if necessary the SC and DSMB. Protocol exceptions and violations will be identified and tabulated for report to the site investigator, SC and DSMB. These aberrant practices will be stamped out or the site will be dropped from the trial.

**Step 4: Conduct and Complete the Trial**

The fourth step is to conduct and complete the study. The conduct of the study must be overseen by the SC which is meeting regularly. Enrollment, drop-out, compliance, adverse events and serious adverse events should be regularly reviewed with input from the DSMB and local IRBs as needed. Because protocols begin as thought experiments, many of the details prove unwieldy once the study starts up. Protocols can be revised and amended by the SC and usually are. A democratic process underlies the revision of the protocol by the SC. All changes must be tracked by date and content and will be reported to the registration site and become part of the eventual source documents required by high impact journals as part of the manuscript review (and available online as a supplement).

**Step 5: Close out and publish**

After enrollment is complete, study subjects are completing the protocol and the study is winding down, close out can commence. Close out is a detailed process which involves entering all missing data and correcting data that appears aberrant. Before final analyses can be conducted the database must be cleansed and locked. The International Committee of Medical Journal Editors (ICJME) including the editors of high impact journals will soon require not only the protocol, but the study database with de-identified data as part of the submission process. These data will be available online as supplemental data where study results can be replicated by all. The burden of proper data reporting will increase both for individual study sites but also the DCC under this new reporting obligation. The data will be analyzed according to the written analysis plan which exists in the protocol. This can often lead to surprising findings and additional analyses to clarify the issue, however such analyses if reported in the manuscript must be identified as post hoc analyses addressing post hoc hypotheses. The results of the primary and secondary outcomes as well as the safety data will be reported to the DSMB and the SC.

Writing the paper is usually done by the Lead Investigator who essentially follows the protocol for rationale, materials and methods, statistical plan, results and discussion. The lead biostatistician and team will proof and verify all data. The SC will review the draft manuscript and make comments. Key authorship and authorship order has been determined as part of the protocol. It is important to establish authorship early in the protocol process so there are no lingering misconceptions about authorship or authorship order which can only become more deeply rooted with time. Ultimately there is only one first author and one senior author. However the SC may assign additional authorship to individuals who have performed extraordinary service during the trial. The abstract of the manuscript can also serve as an abstract for a major meeting. In my experience such abstracts are uniformly plenary presentations. Prompt submission to a high impact journal should follow and the SC should monitor progress and ensure rapid turnaround of the manuscript.

Completion of the primary outcome manuscript can be accompanied by the simultaneous preparation of secondary manuscripts. Often with careful protocol preparation, secondary data can be prospectively collected to improve the quality of these manuscripts or if a specimen repository has been established additional assays can be run to address a hypothesis. This is an area where Co-Investigators can take a lead role, become primary authors of important manuscripts and, at least temporarily, smooth any ruffled feathers from the authorship position in the primary outcome manuscript.

**Summary**

To conduct a meaningful, high impact multi-center trial in India will require a substantial dedication of time, effort and resources. In my experience, this is a minimum of a 5 year process. Establishing a mode of governance, a commitment to excellence in developing testable hypotheses and protocols, a system of checks and balances, and finding the resources to conduct the trial will challenge even the greatest mother of invention. Egos will have to be checked at the door to the SC and all investigators dedicated to a common goal, that no one person could ever achieve alone. The voyage is long and daunting and the investigators must stay the course. Great endeavors require great courage, the ability to deal with failure and setbacks, yes even shipwrecks. The final prize, if achieved, however is well worth the effort and a small share in a large treasure (recognized as such by all) ultimately is more satisfying than a complete ownership of a small treasure (recognized as such by few or none).
Vitamin D Levels and Reproductive Outcome in PCOS Patients

A retrospective study was carried out in a cohort of PCOS patients to assess the relationship of Vit D status with ovulation induction (OI) outcomes. Serum 25OHD was measured in the stored sera of PCOS patients. Live birth (LB), ovulation and pregnancy loss after OI were assessed.

It was found that the likelihood for LB was reduced by 44% for women if the 25OHD level was < 30 ng/mL.

Vit D status was found to be an independent predictor of LB and ovulation after OI in women with PCOS.

Conclusion
In women with PCOS, serum 25OHD was an independent predictor of reproductive success after OI.

Reference

Vitamin D in Adolescent PCOS Females

A retrospective analysis was done to compare 25OHD levels in adolescent females with and without PCOS. 107 participants were included in the study. Of the included participants, 37 were PCOS females and 70 were non-PCOS, with a mean age of 15.2 years. 97.2% were obese in the PCOS group and vitamin D deficiency was noted in 62.2% females. The mean serum 25(OH)D level was 18.4 and 21.6 ng/mL in PCOS and control groups, respectively. The difference in mean 25(OH)D levels between the two groups, however, was not statistically significant.

Conclusion
In this study, there was no statistically significant difference in mean 25(OH)D levels between PCOS and control groups. Further studies in adolescent females with PCOS and normal body mass index are needed to establish a role of vitamin D deficiency in the pathogenesis of PCOS.

Reference

Vitamin D Supplementation and PCOS

A systematic review and meta-analysis of 9 identified studies involving to study the effect of vitamin D supplementation with placebo or metformin in 502 PCOS patients.

Vitamin D supplementation had significantly improved follicular development with a higher number of dominant follicles (OR, 2.34; 95% CI, 1.39 to 3.92). There was better regularization of menstrual cycles when metformin plus vitamin D was compared with metformin alone (OR, 1.85; 95% CI, 1.01 to 3.39).

Conclusion
Vitamin D supplementation may be beneficial for follicular development and menstrual cycle regulation in patients with PCOS.

Reference

Body Mass Index (BMI) and Vitamin D Receptor Gene Expression and Vitamin D Levels in Follicular Fluid in Overweight Patients With PCOS

A comparative study of 80 women with PCOS undergoing IVF carried out to examine the effect of BMI on vitamin D levels in follicular fluid and vitamin D receptor (VDR) expression in granulosa cells. Vitamin D levels in follicular fluid were found lower in women with PCOS compared to controls. Vitamin D levels in the overweight women were lower as compared to normal-weight women. Follicular fluid-Vitamin D levels were highly correlated with BMI. VDR gene expression was significantly lower in PCOS/overweight women compared to non-PCOS/normal-weight women, thus establishing a strong negative correlation between VDR expression and BMI.

Conclusion
The study concluded significant differences in VDR expression in granulosa cells and vitamin D of follicular fluid in PCOS/overweight patients.

Reference
"The Digital Connect"– A Webinar on Optimizing Fertility in Obese PCOS

The PCOS Society of India and the Indian Society for Assisted Reproduction (ISAR) jointly conducted an International Webinar on "Optimising fertility in Obese PCOS" on 15th July, 2017, Grand Hyatt, Mumbai. 35 cities countrywide were connected live with the Mumbai hub. This Webinar was supported by an unconditional educational grant from Alkem Laboratories.

Prof. Fabio Facchinetti was connected live from Italy as the international faculty, and was joined by a panel of distinguished gynaecologists from India - Dr. Duru Shah, Dr. Ameet Patki, Dr. Nandita Palshetkar and Dr. Sujata Misra. The Webinar began with Dr Duru Shah delivering a welcome speech and setting the tone with an introduction on Obesity and PCOS, for an informative and engaging session.

This was followed by an interesting case presentation and discussion on Obese PCOS patient. After the case presentation, the national and international faculties engaged in a very interactive panel discussion on various aspects of diagnosis and management of Infertility in Obese PCOS, followed by an engaging round of Questions & Answers from all the webcast locations.

A total of 1800 delegates participated in the Webinar, including 1250 from 35 cities and 550 online viewers.

First International Middle East PCOS Update Meeting – Dubai

The PCOS Society, India, in collaboration with the AE-PCOS Society, held its First International Middle East Conference at an International City, Dubai on 5th May, 2017.

The one day conference was held at Indigo Optima, Dubai in a beautiful conference hall with approximately 150 delegates from the Middle East region and India. Distinguished speakers from around the world included Prof. Enrico Carmina, Prof. Anuja Dokras, Prof. Duru Shah, Prof. Roberto Vita, Prof. Pratap Kumar and Dr. Uday Thanawala. The one day conference focused on ‘Pathogenesis and Diagnosis of PCOS’, ‘AMH as a new marker in PCOS’, ‘Ultrasound in the diagnosis of PCOS’ and ‘Gestational Diabetes in PCOS’. The conference was very well appreciated by the delegates and the PCOS society received invitations to hold more such programs in the region.
The PCOS Society in collaboration with Metropolis Healthcare launched an awareness and support initiative, "Conquer PCOS" on the 25th of July 2017. This was formally announced at 'The International PCOS Conference – Unraveling the Enigma', held at Bangalore in June. The website is live and the url is www.conquerpcos.in. The website contains important information regarding PCOS, a risk tracker in ask me section and a robust support forum. It would be great if you could take a look and give your feedback and inputs. Going forward, we will be having patient workshops, college programs and a full fledged campaign to ensure conversations on PCOS and create a space where women with PCOS can interact with each other. This is a unique opportunity and campaign to strengthen our initiative for providing support to women suffering from PCOS, create awareness among general public, especially young girls and helping them. The core objectives with Conquer PCOS are the following:

- Spread awareness about the condition
- Get more women diagnosed
- Offer support for women with PCOS
- Create a support forum for these women

Pre-Congress workshop in West Zone Yuva FOGSI Conference

The PCOS Society organized a Pre-Congress Workshop on various aspects of PCOS on 2nd June, 2017 during the West Zone Yuva FOGSI Conference at CIDCO Convention Centre, Vashi, Navi Mumbai.

The workshop, organized by Dr. Uday Thanawala, was attended by approximately experts in the field of PCOS and over 100 delegates and was very well appreciated. Detailed discussions were held on 'Diagnosis of PCOS', 'Ovulation Induction in PCOS', 'Associated Conditions in PCOS' & 'Pathophysiology of PCOS' & Lean Vs. Obese PCOS'.

Travelling Seminar on Understanding PCOS

The Polycystic ovary syndrome (PCOS) is one of the most frequent cases encountered by Gynaecologists in contemporary clinical practice. The overall prevalence of PCOS is increasing alarmingly, not only in metros but also in rural areas of India.

On behalf of The PCOS Society of India, it is a great pleasure to invite you to attend and participate in one of its kind & exciting Travelling Seminar on “Understanding PCOS”

This Seminar will provide a unique forum where medical professionals have the opportunity to meet and exchange ideas and information about the management of PCOS.

The scientific programme of the Seminar aims to be a perfect balance between clinical education and the latest developments in this area.

For more details visit www.pcosindia.org
A Post Graduate Certificate Course in PCOS Management
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