

Can We Assure Patients Safety And
Autonomy Away From Home And
The “Pregnancy”?

The Kiran Infertility Centre
Experience





INTRODUCTION

- * Surrogacy and Third Party Parenting has become an effective method for overcoming both biological and social infertility; and is a dynamic and rapidly evolving area in Fertility Treatments, Law and Psychology. (K Svitnev: Legal Control of Surrogacy – International Perspectives)
- * No survey is able to exactly gauge the number of patients travelling abroad for Infertility treatment. But It is estimated that 1% to 3% of the Infertile Population will travel to other countries for Surrogacy and other ART related Treatments.
- * European Society for Human Reproduction and Embryology (ESHRE) and the American Society for Reproductive Medicine (ASRM) have held seminars over the past few years focusing mainly on the psychological needs of recipients and consumers, including cross-cultural counselling.
- * Guidelines have been drafted for counselling of all individuals participating in third-party reproduction in practically every country where patients seek such kind of fertility care.



Safety & Autonomy of Patients

- * **Safety & Autonomy(Decision making) is a vital part of Reproductive Tourism. Patients coming from various parts of the globe are mostly concerned about safety and autonomy of the process involved.**
- * **Facilities associated with Reproductive Tourism have to gain the trust of international patients by continuously addressing their concerns both Medically & logistically and simultaneously improving with the introduction of the latest technology.**
- * **Safety & Autonomy is a combination of various factors. These factors can broadly be classified into two.**
 - * **Medical Factors**
 - * **Non-Medical Factors**



Medical Factors

- * **Repute & Experience of the Medical Facility and Doctors.**
- * **Diagnosis, Monitoring, Reporting and maintenance of Medical Records.**
- * **Quality control of the IVF Laboratory and Procedures.**
- * **Using latest Evidence based guidelines for medication.**
- * **Having a Result Oriented Program**
- * **Maintaining Confidentiality**



Non Medical Factors

- * **Demography & Geographical Location of the facility**
- * **Costs involved**
- * **Secure Environment**
- * **Ease of Access**
- * **Communication & Transparency**
- * **Travel & Accommodation**
- * **Legal Process & Complications**
- * **Food & Hygiene**
- * **Foreign Exchange**
- * **Tourism**



Medical Factors >>



How to Ensure Safety in Cross Border Reproductive Care?

Safety Precautions are taken for the following individuals:

- 1. Genetic Mother**
- 2. Genetic Father**
- 3. Oocyte & Sperm Donor**
- 4. Gestational Carrier**
- 5. Foetus and Newborn**



Safety Profile for Genetic Mother, Ovum Donor & Gestational Carrier

- **Antibodies for HIV I & II**
- **V.D.R.L.**
- **HBsAg**
- **Hepatitis -C**
- **Hb %**
- **Blood grouping and Rh typing**
- **BT CT**
- **TSH**
- **RBS**
- **Blood Urea**
- **ESR**
- **CUE**
- **Hormonal test if applicable**
- **X-Ray Chest**
- **ECG**
- **Chromosomal Disorders**
- **Screening for Cystic Fibrosis**
- **Screening for Fragile-X Chromosome**
- **Rubella & Varicella Titre**
- **Special Tests if the Donor or IP's country of residence is known for prevalent diseases.**



Flow of Activities: Screening (Day -14 to Day 0)

- Written informed consent
- Demography (DOB, Age, height, weight, BMI, gender, race, previous menstrual cycles)
- Vital signs (pulse rate, blood pressure-sys & dia, temperature in degree Centigrade)
- Medical history, procedure and surgical history
- Medication history (at least one month prior to screening)
- Physical examination
- Pelvic examination
- Trans-vaginal USG
- Laboratory sample collections- Blood [complete hemogram- (Hb, TLC, DLC, platelet),
- LFT (SGOT, SGPT, Serum Bilirubin, ALP).
- (Blood urea, serum creatinine), thyroid function tests (T₃, T₄, TSH levels), serology (HIV, HbsAg and HCV)] and Urine [urine pregnancy test, urine routine and microscopy]
- Adverse event and concomitant medication



Flow of Activities- Inclusion/Exclusion

Day 1(day 2 of menstrual cycle)

- Vital signs
- Oestradiol levels
- FSH administration

Day 2

- Vital signs
- FSH administration

Day 3

- Vital signs
- FSH administration

Day 4:

- Vital signs
- FSH administration

Day 5

- Vital signs
- Trans-vaginal USG
- FSH administration
- GnRH antagonist administration

Day 6

- FSH administration
- GnRH antagonist administration

Day 7

- Vital signs
- Trans-vaginal USG .
- Oestradiol levels
- FSH administration
- GnRH antagonist administration



Ovulation Induction: Points to be noted

- **Precise Calculation of Gonadotropin Dosage**
- **Avoidance of OHSS**
- **Preference of Antagonist Cycle over Agonist Cycle (Shorter Duration of Stay away from Home, Patient Friendly, Lower Incidence of OHSS, comparable Pregnancy Rates to other Protocols).**
- **About 90% of cycles were Antagonist Cycle and 10% Agonist Cycle.**

Monitoring

- **Trans-vaginal USG and Follicular Study are the main stay.**
- **Start the Antagonist on Day 5 or if follicle size is more than 10 mm. Continue till the day of HCG.**
- **Trigger with Recombinant HCG if 3 Follicles more than 17mm in Size.**
- **OPU after Pre-Anesthetic check-up & Surgical Profile under GA.**
- **OPU is done under Ultra Sound Guidance using a 17 G Single Lumen Needle.**
- **Stay in India for 2-3 Days for post operative Monitoring and Intervention if needed.**



OHSS (Ovarian Hyper Stimulation Syndrome)

Incidence:

- Mild to Moderate OHSS- 10%
- Severe OHSS- 1%

Strategy to avoid OHSS, if number of mature follicles are more than 18:

- Triptorelin Acetate is used instead of HCG to trigger Ovulation
- Cabergoline was administered for 8 Days post OPU.
- Daily Monitoring by Urinary Output, Hb%, PCV, USG
- Administration of Antagonist applicable to Oocyte Donors not undergoing Embryo transfer
- Other Ancillary Measures



Preparation for the Receptient

- **After Screening and recruitment: Down Regulation with Triptorelin Acetate is given on day 21st of her cycle.**
- **Oral Contraceptive Pills are given if indicated**
- **Day 2 of Menstrual Cycle: Estradiol Valerate 2mg T.I.D. is started and continued till the Endometrial Thickness reaches 9-10mm. Average duration of Estradiol Valerate is 7 to 15 days**
- **Injection Progesterone (50 -100 mg) is started on Day of OPU of Genetic Mother/ Donor.**
- **On Third day after OPU: Embryo Transfer is carried out & maximum of 3 Embryo's are implanted as per guidelines of ICMR (Indian Council of Medical Research)**
- **Injection Progesterone is continued till day 12 of Embryo Transfer when Beta HCG Test is done.**



Pregnancy Care and Monitoring in Gestational Carrier/ Mother

- **Beta –HCG level on day 12 of Embryo Transfer. If positive, repeat on Day 15**
- **USG for Presence of Gestational Sac on Day 21 after Embryo Transfer.**
- **All due care and precautions taken to rule out the possibility of Ectopic Pregnancy.**



Follow-up of Pregnancy

- **6 weeks of Pregnancy: Scan to detect the Heart Beat and other Routine Tests if needed.**
- **Every 15 Days: Ultrasound Scan of the Fetus till 12th Week**
- **Ultra Sonography and Color Doppler Study every Month till Birth.**
- **11 Weeks of Pregnancy: Nuchal Translucency, Double Test (PAPP-A, B-HCG).**
- **18 weeks: Triple Test (Alpha Feoto Protien, Unconjugated Estriol, Beta Human Chronic Gonodotropin Hormone) to rule out Trisomy 13, 18 & 21**
- **24 weeks: TIFFA (Targeted Image Fetal Anomaly Scan).**
- **30 weeks: Color Doppler Study (Umbilical Artery Blood Flow)**



Safety Measures for Genetic Father and Procedures

Surgical Procedures: TESA, MESA, PESA were undertaken for 2% of the patients after Surgical Profile and Pre-anesthetic Checkup by a Urologist. Chromosomal & Genetic Testing carried out if indicated.

- Sperm Retrieval Rate was around 93%
- Antibiotics and Other Measures



Chromosomal & Genetic Safety

PGD

- If History of repeated Pregnancy Loss or Chromosomal Anomaly in Parents
- Genetic Mother more than 40 Years of Age
- Genetic Father more than 50 Years Old
- Known Genetic Defects



Areas of Special Care

Twin Pregnancy: Incidence about 20%, Special Care and measures to avoid complications like Anemia, Pregnancy induced Hypertension, Diabetes, IUGR, Premature Labor.

Complicated Pregnancies: Important to look out for conditions encountered:

- Anemia- 23%
- Hypertension- 2%
- Gestational Diabetes- 2%
- Ante Partum Hemorrhage- 3%
- Medical conditions like Fever, GI Upset, Urinary Tract Infection

Management of these conditions is carried out as per accepted protocols in accordance with evidence based practice.



Pregnancy

Early Pregnancy Loss before 12 Weeks: 17%

- Bio Chemical Pregnancies- 6%
- Anembryonic Pregnancies- 4%
- Early Fetal Demise- 7%

Ectopic Pregnancy- 3%

Pregnancy Loss between 12- 25 Weeks of gestation:

- 2 Twin pregnancies were lost between 20-22 weeks due to Pre Term Labor
- Singleton Fetal Demise before 25 Weeks- 3 Cases
- Incidents of Birth Defects- Single Case of Diaphragmatic Hernia diagnosed by TIFFA Scan at 20 Weeks as a single anomaly defect, pregnancy continued uneventfully and was terminated at 38 Weeks by an elective Caesarean Section. Baby underwent surgery after one week of birth and is doing well.



Baby with Diaphragmatic Hernia





Care during Delivery and Post Partum Care

- * **Incidence of Normal Delivery- 46%**
- * **Incidence of Caesarean Section- 54%**
- * **Routine Tests conducted before Delivery.**
- * **LSCS and Delivery conducted in Level III Hospitals with all Ultra Modern Facilities like well Equipped Delivery Room and Theatres and World Class Neo Natal Care and Intensive Care New Born Unit**



Non- Medical Factors >>



Various Stages of Communication

The association of Intended Parents with Medical Facility in the process of Reproductive Tourism can broadly be classified into 3 Stages:

- * Enquiry and Screening**
- * Enrolment**
- * Post Enrolment**



Enquiry and Screening

In this stage, the Ease, Time and Quality of communication plays a major role.

An effective communication:

- **Should Specify the existing terms, regulations & laws applicable**
- **Should be Transparent**
- **Should Address precisely the queries of the Patient**
- **Should specify the costs involved**
- **Should be logical**
- **Should also provide a resolution to all Medical and Non-Medical Needs of the Patient.**



Enquiry and Screening: the KIC Process Flow

Receive an Enquiry



Designated Case Manager to ascertain Details of the Case



Questionnaire sent to ascertain the requirements of the case and know the case details



Case put up before Ethics Committee to study the Legal Implications of the case and it's decided whether to enroll a Case or not



If the Case is accepted: the KIC Process Flow (Enrolment)

Send relevant information which include Medical and Non Medical Services offered & excluded, mentioning all associated costs and exclusions.

Along with this, our legal team also sends the applicable Legal Process for patients opting for Surrogacy, depending upon their Nationality.

Prescribe the applicable Medical tests.

Consents are obtained. Selection of Donor .

Arrange Travel and Accommodation for patients



Post Enrolment- KIC Way

Counsel & Screen Donor/ Surrogate Mother



Provide Medical Protocol for the Patient and Surrogate Mother/ Donor



The patient arrives and provides the Genetic Material.



Medical Procedure is carried out.



Post-enrolment- KIC Way

In case the Surrogate Mother is Pregnant, Scans & Reports are sent as per designed protocol to Intended Parent. Else communicate to Intended Parent about the negative result and preparation for the next transfer



Monitor Pregnancy and then inform the parent about the Estimated Date of delivery at-least a month in advance. Arrange for Travel & Accommodation.



Birth takes place, the New born is kept in the NICU for at least 24 hours for necessary screening/ observation; and then handed over to the Parents.



Post birth process is initiated to get passports and Immigration formalities done for the new born.



Conclusion

If carried out with all the above factors in mind, Gestational Surrogacy is a very good option for commissioning parents who are not able to achieve pregnancy on their own because of several reasons. Treatment of a gestational surrogate is straight forward and follows routine IVF And ICSI procedures. The results of treatment are good as expected because a Surrogate Mother is a fit, young and fertile woman.



About Kiran Infertility Centre (KIC)

- * KIC was started in 1970 under the able leadership of Dr Kiran D. Sekhar and Dr Naresh Kumar Sekhar.
- * The clinic has its presence in fields of Infertility Treatment, Medical Research, Clinical Trials and Training of Doctors.
- * KIC ventured into Reproductive Tourism in late 2007 and since then has been one of the preferred Centre's in India providing Infertility Treatments such as IVF, ICSI, Egg Donation and Surrogacy.



Thank You!