doi:10.1093/hropen/hox029

human reproduction open

ORIGINAL ARTICLE

Gestational surrogacy. Medical, psychological and legal aspects: 9 years of experience in Mexico

R. Cabra * *, A. Alduncin, J.R. Cabra, L.H. Ek, M. Briceño, and P.B. Mendoza

Centro de Cirugía Reproductiva y Ginecología Reprogyn, Prolongación Usumacinta 2085, Interior 840, Villahermosa, Tabasco, C.P. 86035, Mexico

*Correspondence address. Centro de Cirugía Reproductiva y Ginecología Reprogyn. Prolongación Usumacinta 2085, Interior 840, Villahermosa, Tabasco, C.P. 86035, Mexico. Tel: +55-993-310-0433. E-mail: rcabra@reprogyn.com.mx © orcid.org/0000-0003-2096-1995

Submitted on June 7, 2017; resubmitted on December 7, 2017; editorial decision on December 22, 2017; accepted on January 8, 2018

STUDY QUESTION: What are the medical, psychological and legal aspects involved in running a gestational surrogacy (GS) program in Mexico?

SUMMARY ANSWER: The correct and complete implementation of a medical protocol, adherence to legality and psychological screening are key elements for the success of a GS program.

WHAT IS KNOWN ALREADY: To our knowledge, this is the first reported GS case series in Mexico.

STUDY DESIGN, SIZE, DURATION: This was a retrospective, descriptive study of 135 cycles performed between 2007 and 2016 at a fertility center in Villahermosa, Tabasco, Mexico.

PARTICIPANTS/MATERIALS, SETTING, METHOD: We analyzed data from 135 GS cycles, 57 intended parents (IP) and 63 gestational carriers (GC).

MAIN RESULTS AND THE ROLE OF CHANCE: GS in Mexico is only allowed in its altruistic mode. The legal requirements for the GCs are age 25–35 years and a complete medical examination that certifies no pregnancy during the last 365 days before embryo transfer and excludes infectious and chronic diseases. The IPs must be aged 25–40 years of age, have Mexican citizenship, and provide life insurance and medical expenses for the GCs. The GC recruitment was carried out by word of mouth. Of the 150+ women that requested information, 89 were identified as possible candidates. In total, 77 underwent the psychological evaluation protocol and nine were rejected owing to behavior and emotional alterations, giving 68 who began the medical selection protocol. Five women were not accepted as they were positive for human papilloma virus, or had experienced endometrial polyposis or recurrent pregnancy loss. Finally, 63 women entered the IVF protocol as GCs. The indications for GS were: hysterectomy 32%, implantation failure 21%, single fathers 14%, maternal medical condition 14%, recurrent pregnancy loss 11%, previous pregnancy complication 5% and uterine pathologies 3%. The mean age of intended mothers was 38.8 years. The average number of embryos transferred per cycle was 1.9, with 22.2% of cycles resulting in pregnancies. The live-birth rate per IP was 33.3%, 18.5% of cycles resulted in live births, with 24% of live births being twins.

LIMITATIONS, REASONS FOR CAUTION: Owing to the retrospective nature of this study conclusions must be drawn accordingly.

WIDER IMPLICATIONS OF THE FINDINGS: As the first article addressing GS in Latin America, it may serve as a reference for future practice and publications. The results demonstrate the importance of having an assisted reproduction program in the form of GS.

STUDY FUNDING/COMPETING INTERESTS: There was no external funding used and there are no conflicts to report.

Key words: gestational surrogacy / ART / IVF / ICSI / gestational surrogacy laws

2 Cabra et al.

WHAT DOES THIS MEAN FOR PATIENTS?

This study looks at the medical, psychological and legal aspects of the experience of surrogacy at a fertility clinic in Mexico.

Surrogacy is relatively new in Mexico, and is still quite controversial. This study looked at 135 cycles of surrogacy at one clinic over a period of 9 years since 2007. The cases were all of gestational surrogacy, where the surrogate uses an egg from the Intended Mother or a donor rather than her own egg, so she is not genetically related to the embryo.

The researchers concluded that surrogacy can offer help to couples who would not otherwise be able to have a child, but that it is vital that thorough preparation is carried out before treatment starts. Surrogates must have medical and psychological screening and there should be proper legal counseling with a formal surrogacy agreement to ensure that surrogacy is safe for the intended parents, surrogates and children.

Introduction

A new obstetric paradigm has emerged as the result of infertile couples seeking a genetic offspring. Modern surrogacy involving IVF was first reported by Utian et al. (1985)

Gestational surrogacy (GS) usually involves both the intended parents (IP) gametes, but it also can involve oocyte or sperm donation if necessary, and the embryos obtained are transferred to the previously prepared endometrium of a gestational carrier (GC). This differs from 'traditional surrogacy', where artificial insemination with the intended father's sperm is performed on the GC (ASRM Ethics Committee Medicine, 2013), and the GC is therefore is genetically related to the embryo. Both types of surrogacy are controversial in Mexico because it is a relatively new method of ART that is not fully understood by the society and is therefore considered an objectification of women and their dignity.

Surrogacy may be commercial or altruistic. In commercial surrogacy, the surrogate is usually recruited through an agency, reimbursed for her medical costs and paid for her gestational services. With altruistic surrogacy, the surrogate is found through friends, acquaintances or an advertisement. She may be reimbursed for medical costs directly related to the pregnancy and for loss of income owing to the pregnancy (FIGO, Committee for Ethical Aspects of Human Reproduction and Women's Health, 2008; Dempsey, 2013).

Findings revealed that the psychological suitability of surrogate mother candidates appears to be a composite of being both toughminded and sensitive, sufficiently resilient to manage the role of surrogacy, and aware of the importance of emotional boundary-setting related to pre-natal attachment (Pizitz et al., 2013).

There are numerous medical indications where this reproductive treatment is an option, and in other cases it is the only treatment available. The most important categories in which this procedure should be performed include uterine absence (congenital or surgical) or severe Mullerian abnormalities; recurrent pregnancy loss or recurrent implantation failure; previous medical conditions where pregnancy would mean a health risk for the intended mother, such as systemic lupus or nephropathy; oncological treatments with increased teratogenic risk; and same-sex male couples or single fathers (Anchan et al., 2013). However, GS is not restricted to these indications.

GS is a reproductive procedure with multiple requirements that make it a complex process; it involves various medical, psychological and legal aspects, such as the psychological screening, the surrogacy agreement, and the IVF protocol selection (Goldfard et al., 2000). In

addition, it is assumed that the relationship between the two parties is based on respect and empathy (MacCallum et al., 2003; Goldfarb, 2010).

In Mexico, there is no national regulation of surrogacy and it has only been legislated in 2 of the 31 Mexican states. Since 1997, gestational and traditional subrogation was included within the civil code of Tabasco, only in its altruistic mode.

The objective of our study was to review and share our experiences of 9 years of IVF cycles from the CS program at the Centro de Cirugía Reproductiva y Ginecología REPROGYN[®], representing the widest Surrogacy program in Mexico.

Materials and Methods

This is a retrospective, descriptive study of 135 IVF cycles performed during our Surrogacy program from 2007 to 2016 at the Centro de Cirugía Reproductiva y Ginecología REPROGYN $^{\tiny (8)}$ in Villahermosa, Tabasco, Mexico.

Psychological aspects

The methodology used for the selection of GCs has undergone changes year by year; these modifications have been made in response to the needs that have arisen in practice such as the need for a more objective evaluation and to obtain a broader profile of the GCs.

The Department of Psychology is the first contact for the GCs. At the first session, it is explained what GS is, what the psychological and medical protocols consist of, possible treatment risks, and the legal requirements. If they agree and wish to continue in the program, the GC candidate will then undergo the psychology evaluation protocol, which is composed of questionnaires, clinical scales and psychometric tools measured by Cronbach's alpha (listed in Table I).

The evaluation is carried out in at least 15 sessions over a period of 4–5 months, in which we seek exclusion criteria such as suicide risk, depression, reality distortion, paranoia, substance abuse, anti-social or aggressive behavior, and domestic violence. When the psychological profile is complete, the IPs are evaluated in a face-to-face interview using the Scale of Dysfunctional Attitudes by Weissman and Beck (1978) which measures how a person values the processes of social interaction, and determines whether or not they are vulnerable to failure, frustration or depression.

The results of these tests can only be seen by staff at the center and the person being evaluated. Psychological profiles are a valuable tool for an accurate selection of the GC for each IP to create a bond between them that allows emotional stability during the process and favors the optimum psychological development of the child.

Test	Objectives	Bernbach alpha	Reference
Beck's hopelessness scale	Measures feelings about the future, loss of motivation and expectations	0.83	González (2009)
Violence scale	Measures the level of domestic violence	0.99	Valdez et al. (2006)
MINI International Psychiatric	Detects psychiatric disorders	0.76-0.93	Sheehan et al. (1998
Alcohol, Smoking and Substance Involuntary Screening Test (ASSIST)	Identifies consumption of toxic substances	0.78	Pérez et al. (2012)
Minnesota Multiphasic Personality Inventory 2 Restructured Form (MMPI-2-RF®)	Detects exaggeration or minimization of symptoms, allows a more efficient evaluation	0.81	Ayearst (2011)
Autobiography	To know aspects of their family, personal, sexual and work history	Not measurable by Bernbach alpha	Sabogal (2004)
Machover´s human figure test	Yields data of the emotional experience and emotional maturity, as well as the environment that surrounds the patient	Not measurable by Bernbach alpha	Sabogal (2004)

The psychology department accompanies the GCs and IPs throughout the process to detect possible changes in the emotional state, the family environment or perception of the treatment.

Ethical-legal aspects

Our center is mostly responsible for GC recruitment. The IPs may source their own candidate and their participation or exclusion is determined according to the Ethical criteria of the center and the State's Civil Code decree 205 (1997) in which it is first stated that a third person can be involved as a GC when the IP has a physical limitation or medical contraindication. The changes made to the State's Civil Code on January 2016 (Decree 233, art. 380) added multiple requirements to GCs such as all GCs must be between 25 and 35 years of age; all GCs must have had at least one previous uncomplicated pregnancy and no pregnancy during the last 365 days prior to embryo transfer; and all GCs must have normal psychological and medical examinations with a signed informed consent form, certifying the following: negative infectious and chronic diseases, and a normal psychological profile excluding emotional and behavioral alterations.

Requirements were also added for the IPs such as all IPs must be between 25 and 40 years of age; all IPs must have Mexican citizenship and provide medical expenses and life insurance for the GC; the right of the child to acquire a name, identity, nationality; and there is no statement declaring the right of the child to know the GC identity.

The reform also stated the policy of prohibiting the transfer of more than two embryos per cycle.

The Surrogacy Agreement is a legally binding document that ensures the right of the child to acquire a name, identity, nationality and the parenthood of the IPs; it is signed in the presence of a public notary and it becomes enforceable once the pregnancy is confirmed.

Medical aspects

All GCs and IPs undergo a series of clinical examinations such as determination of titers for HIV I-2 and HPV, Hepatitis B-C, VDRL, Rubella, Chlamydia T, Mycoplasma H and Ureaplasma U, a metabolic profile, blood typing, and hysterosalpingography and sonohysterography.

We defined a cycle as a fresh or thawed embryo transfer to a GC, and live birth as the successful outcome.

None of our GC had more than one live birth.

We used a standardized ART treatment using a flexible GnRH-antagonist protocol with recombinant FSH (rFSH) (Folitropin alpha) (Gonal- F^{\otimes} , Merck Serono, shipped from Mexico City) stimulation, with a

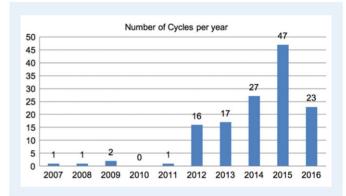


Figure 1 The number of surrogacy cycles performed per year from 2007 to 2016.

fixed rFSH dose of 150 IU-450 IU according to female age, BMI, antral follicle count, anti-Mullerian hormone and response to previous stimulations on Day 2 or 3, with the option of adjusting the dose according to the response to stimulation. Daily administration of Cetrorelix 0.25 mg (Cetrotide®, Merck Serono, shipped from Mexico City) was initiated when a follicle >14 mm diameter was present. For the hCG trigger we used 250 μg of hCG (Ovidrel®, Merck Serono, shipped from Mexico City) when two or more follicle reached >18 mm. Luteal phase support was provided, using vaginal progesterone 200 mg three times daily (Utrogestan®, Corne, shipped from Mexico City), and initiated the day after of oocyte retrieval.

Thawed embryo transfers were performed on substituted estradiol and progesterone cycles with oral estradiol 2 mg three times daily (Primogyn®, Bayer, shipped from Mexico City) to achieve an endometrium 8 mm thick, and vaginal progesterone as luteal phase support, 200 mg three times daily (Utrogestan®, Corne, shipped from Mexico City).

Embryo transfer was performed on Days 3 and 5, and blood HCG levels were measured 2 weeks later.

Results

We reviewed 135 cycles performed in the period from 2007 to 2016. There was a gradual annual increase in the number of cycles, and a maximum of cycles in 2015, with 47 cycles (Fig. 1).

4 Cabra et al.

The IP indications for GS were grouped into seven categories: hysterectomy 18 cases, implantation failure 12 cases, single fathers 8 cases, maternal medical condition 8 cases (systemic lupus erythematosus one

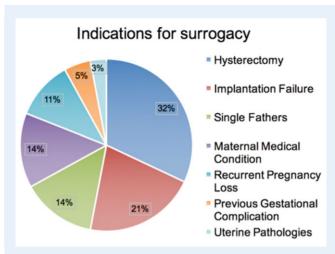


Figure 2 Graphical representation of indication categories for gestational surrogacy.

case, nephropathy two cases, Malignant Chronic Absorption Syndrome two cases, leukemia one case, colon cancer one case, severe endometriosis one case) recurrent pregnancy loss six cases, previous gestational complication three cases (placental abruption one case, eclampsia one case and HELLP (hemolysis, elevated liver enzymes and low platelet count)) syndrome one case; uterine pathologies two cases (Asherman syndrome one case and Rokitansky syndrome one case) (Fig. 2).

In 78 cycles (58%) IPs used donor oocytes and in 57 cycles (42%) patients used their own oocytes. The indications for oocyte donation were poor oocyte quality (45%), single fathers (21%), poor ovarian reserve (21%), oophorectomy (8%) and premature ovarian failure (6%).

In total, 63 GCs were included and the selection process and reasons for rejection are listed in Fig. 3. The difference between the number of IPs and GCs is because some IPs performed more than one cycle and/or were linked to more than one GC, and likewise, some GCs were linked to different IPs when a previous cycle failed. We performed 2.14 cycles per GC on average.

The mean age of intended mothers was 38.8 years (range: 29–56), with the highest number of cases in the 36–39 years age group. The mean age of GCs was 27.5 years (range: 18–38), with a mean BMI of $26.18 \, \text{kg/m}^2$, average monthly income of \$289.85 USD, and with 1.9 children on average with a mean age of 7 years.

>150 requests for information by telephone calls, appointments or emails.

89 females were identified as possible GC Candidates.

77 females were seen for a first psychological consultation and initiated the Psychological evaluation protocol.

68 females completed the psychological protocol and initiated Medical examination.

63 females were seen for a complete legal counselling.

63 females entered the IVF protocol as GCs.

>40 did not completed a follow-up consultation.

9 Dropped Out

9 were not accepted

 5 due to behavioral alterations (irresponsibility, aggressiveness or drug addiction)

 4 due to emotional alterations (depression, suicide risk or emotional dependency)

5 were not accepted

- –2 due to Endometrial Polyposis
- –2 due to HPV+
- 1 due to Recurrent pregnancy loss

Figure 3 Gestational carrier selection process and reasons for rejection. GC, gestational surrogacy; HPV+, positive for human papilloma virus.

Table II Data from 9 years of cycles in the Mexican
gestational surrogacy program.

135
22.2 (n = 30)
18.5 (n = 25)
33.3%
14.2%
1.9
24

The average number of embryos transferred per cycle was 1.9 in nine cycles. Three embryos were transferred, owing to poor embryo quality (this was performed prior to the 2016 reform) and two of these cycles resulted in twin pregnancies. The implantation rate was 14.23%, with 22.22% of the cycles resulting in pregnancy and 18.52% of cycles resulting in live births, of which 24.0% were twins (Table II).

No adverse obstetric or perinatal complications were observed in the pregnancies achieved.

Discussion

This is the first article published about GS in Mexico. A total of 135 cycles were analyzed over a 9-year period, and we observed that the number of cycles increased gradually each year, probably caused by greater acceptance of this mode of treatment. In 2016, there was a decrease in the number of cycles, and we believe the cause was the civil code reform, which added restrictions to GCs and IPs, such as the age limit for participation, Mexican nationality and compulsory life insurance for the GCs.

GS is the only treatment available for many women, especially those with no uterus, which is the most frequent indication for GS in our study and in international reports (Raziel, 2005; Dermout et al., 2010), as well as being a suitable option for patients with a history of recurrent pregnancy loss, autoimmune diseases and oncological problems, and for same-sex couples and single fathers.

As for the age of admission to the surrogacy program, it is predominantly at the end of the fourth decade of life, as reported by Dar et al. (2015), with the mean age being 38.2 years, which is consistent with the average age of intended mothers of our population (38.8 years). In the Mexican context this means that there is a very short time window for a woman to seek help with this method of reproduction, and because of the age limit imposed in the reform of 2016 (40 years), this point must be re-valued and legislated according to these observations.

As in the various reports to date, the indications for ovodonation remain the same as in any modality of IVF. Specifically referring to surrogacy, single parents are added as an indication, and these account for approximately one quarter of our patients for ovodonation.

Our surrogacy program results are comparable to those published by Goldfard et al. (2000), who performed 180 cycles, a number similar to ours, with a pregnancy rate of 19% and a live-birth rate of 15.8%. They are also similar to those published by Raziel (2005), who obtained a pregnancy rate of 17% and a percentage of live births of

15%, however our results differ from those of Dar et al. (2015) who reported a pregnancy rate of 53% and a live-birth rate of 39.93% in 333 cycles.

Despite the cultural, ethical and legal controversies that it has generated, this modality of ART has had from its beginnings the objective of helping patients for whom the only available fertility treatment is GS. In this way, GS adds one more option to the range of possibilities and fertility treatments that are offered to all couples, single parents or mothers who want to start a family.

In conclusion, the importance of having an ART program that includes GS has favored couples who are at reproductive disadvantage and offers hope to couples seeking to have their own genetic offspring or form a family. According to our experience, adequate legal counseling regarding the surrogacy agreement, patient care and preparation, and medical and psychological screening are key to the success of the GS program and help to ensure that it is safe for the IP, GCs and children in medical, psychological and legal terms.

Authors' roles

All authors participated in the study design and interpretation of the data. J.R.C. and L.H.E. collected the data and drafted the article, it was finalized by all co-authors. The final version of the article was approved by all authors.

Funding

No external funding was used.

Conflict of interest

None declared.

References

Anchan RM, Missmer S, Correia KF, Ginsburg ES. Gestational carriers: a viable alternative for women with medical contraindications to pregnancy. *Open J Obstet Gynecol* 2013;**3**:24–31.

Ayearst LE. The Creation and Construct Validity of MMPI-2-RF Based Personality Disorders Scales. York University, 2011.

Dar S, Lazer T, Swanson S, Silverman J, Wasser C, Moskovtsev SI, Sojecki A, Librach CL. Assisted reproduction involving gestational surrogacy: an analysis of the medical, psychosocial and legal issues: experience from a large surrogacy program. *Hum Reprod* 2015;**30**:345–352.

Dermout S, van de Wiel H, Heintz P, Jansen K, Ankum W. Non-commercial surrogacy: an account of patient management in the first Dutch Centre for IVF Surrogacy, from 1997 to 2004. *Hum Reprod* 2010; **25**:443–449.

Ethics Committee of the American Society for Reproductive Medicine. Consideration of the gestational carrier: a committee opinion. *Fertil Steril* 2013;**99**:1838–1841.

FIGO. Committee for Ethical Aspects of Human Reproduction and Women's Health, 2008; Dempsey, 2013.

Goldfarb J. Gestational carrier outcomes in the USA: The SART experience. *Annual Meeting of ESHRE*, Rome Italy. June 2010.

6 Cabra et al.

Goldfard JM, Austin C, Peskin B, Lisbona H, Desai N, Loret de Mola R. Fifteen years experience with an in vitro fertilization surrogate gestational pregnancy programme. *Hum Reprod* 2000; **15**:1075–1078.

- González C. Propiedades psicométricas de la escala de desesperanza de Beck en una muestra bogotana. *Psychol Av Discip* 2009;**3**:17–30.
- MacCallum F, Lycett E, Murray C, Jadva V, Golombok S. Surrogacy: the experience of commissioning couples. *Hum Reprod* 2003;18: 1334–1342.
- Pérez P, Calzada N, Rovira J, Torrico E. Estructura factorial del test ASSIST: aplicación del análisis factorial exploratorio y confirmatorio. *Trastor Adict* 2012;**14**:44–49.
- Pizitz TD, McCullaugh J, Rabin A. Do women who choose to become surrogate mothers have different psychological profiles compared to a normative female sample? Women Birth 2013;26:e15–e20.
- Raziel A. Eight years' experience with an IVF surrogate gestational pregnancy programme. Reprod Biomed Online 2005; 11:254–258.

- Sabogal L. Pruebas proyectivas: acerca de su validez y confiabilidad. Duazary 2004;1:134–138.
- Sheehan DV, Lecrubier Y, Sheehan KH, Amorim P, Janavs J, Weiller E, Hergueta T, Baker R, Dunbar GC. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J Clin Psychiatry* 1998; **59**:22–33;quiz 34-57.
- Utian WH, Sheean L, Goldfarb JM, Kiwi R. Successful pregnancy after in vitro fertilization and embryo transfer from a infertile woman to a surrogate. *N Engl J Med* 1985;**313**:1351–1352.
- Valdez R, Híjar MC, Salgado S, Rivera L, Avila L, Rojas R. Escala de violencia e índice de severidad: una propuesta metodológica para medir la violencia de pareja en mujeres mexicanas. Salud Pública Méx 2006;**48**:221–231.
- Weissman A, Beck AT. Development and validation of the Dysfunctional Attitude Scale: A preliminary Investigation. *Paper presented at the Education Research Association*, Toronto, Ontario, Canada, 1978.