Human Reproduction, Vol.30, No.2 pp. 345–352, 2015
Advanced Access publication on December 17, 2014 doi:10.1093/humrep/deu333

human reproduction

ORIGINAL ARTICLE *Infertility*

Assisted reproduction involving gestational surrogacy: an analysis of the medical, psychosocial and legal issues: experience from a large surrogacy program

Shir Dar[1,2], Tal Lazer[1,2], Sonja Swanson[1], Jan Silverman[1], Cindy Wasser[4], Sergey I. Moskovtsev[1,2], Agata Sojecki[1], and Clifford L. Librach[1,2,3,*]

[1]CReATe Fertility Center, University of Toronto, 790 Bay Street, Suite 1100, Toronto, ON, Canada M5G 1N8 [2]Department of Obstetrics and Gynecology, University of Toronto, Toronto, ON, Canada [3]Department of Obstetrics and Gynecology, Women's College Hospital, Toronto, ON, Canada [4]Law Society of Upper Canada, 130 Queen St W Toronto, ON, Canada M5H 2N6

*Correspondence address. Tel: +1-416-323-7727; Fax: +1-416-323-7334; E-mail: dr.shirdar@gmail.com or drlibrach@createivf.com

Submitted on June 7, 2014; resubmitted on November 5, 2014; accepted on November 25, 2014

STUDY QUESTION: What are the medical, psychosocial and legal aspects of gestational surrogacy (GS), including pregnancy outcomes and complications, in a large series?

SUMMARY ANSWER: Meticulous multidisciplinary teamwork, involving medical, legal and psychosocial input for both the intended parent(s) (IP) and the gestational carrier (GC), is critical to achieve a successful GS program.

WHAT IS KNOWN ALREADY: Small case series have described pregnancy rates of 17–50% for GS. There are no large case series and the medical, legal and psychological aspects of GS have not been addressed in most of these studies. To our knowledge, this is the largest reported GS case series.

STUDY DESIGN, SIZE AND DURATION: A retrospective cohort study was performed. Data were collected from 333 consecutive GC cycles between 1998 and 2012.

PARTICIPANTS/MATERIALS, SETTING, METHODS: There were 178 pregnancies achieved out of 333 stimulation cycles, including fresh and frozen transfers. The indications for a GC were divided into two groups. Those who have 'failed to carry', included women with recurrent implantation failure (RIF), recurrent pregnancy loss (RPL) and previous poor pregnancy outcome ($n = 96$; 132 cycles, pregnancy rate 50.0%). The second group consisted of those who 'cannot carry' including those with severe Asherman's syndrome, uterine malformations/uterine agenesis and maternal medical diseases ($n = 108$, 139 cycles, pregnancy rate 54.0%). A third group, of same-sex male couples and single men, were analyzed separately ($n = 52$, 62 cycles, pregnancy rate 59.7%). In 49.2% of cycles, autologous oocytes were used and 50.8% of cycles involved donor oocytes.

MAIN RESULTS AND THE ROLE OF CHANCE: The 'failed to carry' group consisted of 96 patients who underwent 132 cycles at a mean age of 40.3 years. There were 66 pregnancies (50.0%) with 17 miscarriages (25.8%) and 46 confirmed births (34.8%). The 'cannot carry pregnancy' group consisted of 108 patients who underwent 139 cycles at a mean age of 35.9 years. There were 75 pregnancies (54.0%) with 15 miscarriages (20.0%) and 56 confirmed births (40.3%). The pregnancy, miscarriage and live birth rates between the two groups were not significantly different ($P = 0.54$; 0.43; 0.38, respectively). Of the 178 pregnancies, 142 pregnancies were ongoing (surpassed 20 weeks) or had ended with a live birth and the other 36 pregnancies resulted in miscarriage (25.4%). Maternal (GS) complication rates were low, occurring in only 9.8% of pregnancies. Fetal anomalies occurred in only 1.8% of the babies born.

LIMITATIONS, REASONS FOR CAUTION: Although it is a large series, the data are retrospective and conclusions must be drawn accordingly while considering bias, confounding and power. Due to the retrospective nature of this study, follow-up data on 6.3% of birth outcomes were incomplete. In addition, long-term follow-up data on GCs and IPs were not available to us at the time of publication.

WIDER IMPLICATIONS OF THE FINDINGS: To our knowledge, this is the largest GS series published. We have included many details regarding not only the medical protocol but also the counseling and legal considerations, which are an inseparable part of the process. Data from this study can be included in discussions with future intended parents and gestational carriers regarding success rates and complications of GS.

STUDY FUNDING/COMPETING INTEREST(S): There was no external funding used and there are no conflicts to report.

Key words: gestational surrogacy / assistant reproductive technology / medical indications / counseling / legal issues

Introduction

Modern gestational surrogacy (GS) involving *in vitro* assisted reproductive technology (ART) was first reported by Utian *et al.* (1985). GS usually involves gametes derived from both a male and female intended parent, but may also involve male and/or female gamete(s) donated from a third party. In GS, the GC is not genetically related to the embryo. This is in contrast to the 'traditional' surrogate who is artificially inseminated with sperm from a commissioning couple. In this case, the surrogate is genetically related to the embryo.

There are a myriad of underlying medical indications where GS is a potential option for family building, and in many cases, the only option available. The major categories which would indicate the need for a GC include: (i) no uterus (congenital or post-hysterectomy) or a severe Müllerian anomaly; (ii) unexplained, or failed treatment for, recurrent pregnancy losses (RPL; 2 or more unexplained pregnancy losses) or repeated implantation failure (RIF; 3 or more failed IVF embryo transfers); (iii) maternal medical conditions where pregnancy could pose a significant health risk; (iv) maternal medications used to treat a disease, which are, or could potentially be, teratogenic; (v) prior poor obstetrical history; and (vi) same-sex male couples or single men. However, GS is not restricted to only these indications.

The medical aspects of IVF and GC coordination are standard and relatively straightforward. However, there are many important and controversial medical, psychosocial and legal aspects to GS that afford complexity to the process from beginning to end. Overall, this includes aspects surrounding: (i) medical and psychosocial screening of GCs; (ii) counseling (medical, legal and psychological) for both the IPs and the GC; (iii) the legal contract between IPs and the GC; (iv) cycle coordination of the GC and IPs; (v) antenatal care and the birth process; (vi) post-birth psychosocial and legal issues; and (vii) breast feeding issues. All of this requires a multidisciplinary approach that involves unique and tight collaboration between fertility physician(s), fertility clinic support staff, agency facilitators, psychosocial counselors, lawyers, the GC, the IPs, an obstetrician/midwife and the hospital where the delivery takes place. All of these factors will be addressed in this article.

The purpose of our study was to review and share our experience over the last 15 years with 333 GC cycles that were carried out in a Canadian university-affiliated fertility centre, the Create Fertility Centre (CFC). This represents, to our knowledge, the largest GS program in Canada.

Materials and Methods

Subjects

A retrospective cohort study was carried out. Research ethics board (REB) approval was obtained for this study from the Sunnybrook Health Sciences Centre REB, Toronto, Canada (approval #144-2011). Anonymized data were collected regarding 333 consecutive GC cycles (1998–2012) directly from patient charts and from the Create IVF database (a custom-designed Microsoft SQL server database).

Gestational carrier and intended parent coordination

The IPs are responsible for GC recruitment. In some cases (25%), the GC was already known to the IP (e.g. sister, cousin, niece, friend) and most others were found with the assistance of a consulting agency. According to the CFC ethics board established criteria, all GCs must be between the age of 21 and 45 and have had one or more uncomplicated term pregnancies resulting in the birth of at least one child. All GCs undergo a detailed history and physical examination. The GC and IPs are screened for the presence of, and/or immunity to, the following transmissible diseases: HIV (1 and 2), HTLV (1 and 2), HBV, HCV, CMV, Rubella, Varicella, Parvovirus B19, Gonorrhea, Chlamydia and Syphilis. A pelvic ultrasound and sonohysterogram are also performed. Detailed medical counseling is carried out with the GC, and her partner (if applicable), in private without the presence of the IPs. During this discussion, the GC (and her partner) are informed about all aspects of being a GC. Special emphasis is given to: undesired outcomes (failed cycles, miscarriages, ectopic pregnancies and the potential for fetal anomalies), the number of embryos to transfer with related risk of multiple pregnancy, maternal complications of pregnancy, potential for bed rest and antepartum hospitalization, delivery mode issues, nutrition issues and lifestyle issues during the pregnancy. After obtaining permission from the GC to disclose this information to the IPs, a group discussion of pertinent issues is conducted and all participants are all informed about potential issues that could impact the GC's health and the health of the fetus(es). The IPs are also given the opportunity to discuss any issues with the physician privately. If the GC has a partner, confirmation of their supportive is essential.

Cycle coordination is initially achieved by using birth control pills for both the GC and the IP (or an oocyte donor) in order to synchronize cycles. GC receptivity preparation is carried out using oral estradiol to build up the endometrial lining, followed by progesterone (administered i.m. or by vaginal suppository). No GnRH analogs are used for the GC's protocol. Embryo transfer is carried out 3–5 days after oocyte retrieval. In 17 (5.1%) of the cases, embryo(s) were also transferred concurrently to the IP's uterus. Each of these cases involved an IP diagnosis of RPL or RIF.

IVF for the IP oocyte provider or the oocyte donor involves either a long (GnRH agonist) or short (GnRH antagonist) protocol for ovarian stimulation. The choice of cycle protocol is based on physician preference, the ovarian reserve characteristics and/or prior cycle performance of the oocyte provider. The protocol is not influenced by the involvement of GS. Oocyte retrieval is performed under intravenous conscious sedation.

Psychological counseling

Separate counseling is mandatory for every set of IPs and GC. The IPs and the GC are first seen separately to assure confidentiality and to establish trust when discussing areas of potential stress and concern. When possible, this is followed up with a joint session between all parties to provide an opportunity to share goals, expectations and strategies and to assure that everyone on

the 'team' is well informed and in agreement. Issues that could develop before, during and after the pregnancy are explored during the counseling session. The suitability of the GC is assessed by means of a psycho-educational evaluation. Her background, her coping strategies, potential attachment to a developing fetus with whom she has no genetic connection, her personal motivation, her expectations as a carrier and her support networks are all discussed. Attitudes toward multiple pregnancy and views on selective reduction and termination for fetal anomalies are explored. Pregnancy issues of control, trust, envy, detachment or over-attachment are considered. End of pregnancy issues regarding the birth plan and plans around relinquishing the baby as well as the future relationship between the GC, the IPs and the potential offspring are reviewed. Throughout the counseling session, themes of mutual respect and the development of fluid communication strategies are stressed. All of this is coupled with the availability of ongoing support, should it be required.

Legal counseling and contracts

In Canada, GC arrangements are regulated under the Assisted Human Reproduction Act of Canada (AHRAC). The AHRAC prohibits direct payments to gestational carriers, but allows reasonable reimbursements for pregnancy-related expenses. A contract or legal agreement signed by all parties after obtaining independent legal advice (ILA) is mandatory in our program. For each case, the contract clarified the nature of the relationship, the full intention of all parties and specifies that all monies provided to the GC are for reasonable expenses related to the procedure and pregnancy. Depending on the province in which the baby was born, the IPs may have required either a court order or appropriate legal documentation in order to be registered as the child's only parents.

GS contracts have not been litigated in Canada and therefore the clauses within them have not been judicially considered. As a result, lawyers prefer to refer to them as 'agreements' rather than 'contracts'. They are therefore regarded as a written statement of intention that will provide evidence, if necessary, of the parties' understanding. ILA for the contract is mandatory in our clinic. Usually, the IPs retain a fertility lawyer to draft the agreement and reimburse the GC for her legal expenses incurred to obtain ILA. The GC must have an independent lawyer to review the agreement with her and negotiate any changes to be made. The clinic does not require a copy of the agreement itself, but once it is complete, the IPs' lawyer must provide the clinic with a letter confirming the execution of an agreement that complies with relevant provincial and federal Canadian laws, and stating that ILA was obtained by all parties.

The agreement itself is drafted in a chronological order including clauses referring to the background history of the parties, definitions, pre-IVF issues, pregnancy and post-partum issues. Often a schedule for reimbursement is attached at the end. One repetitive concept that permeates the agreement is that legal, social and physical custody of the child will be given to the IPs immediately upon birth. Another clause that is repeated several times provides that all parties acknowledge that they are aware of all medical issues and risks involved as well as the medical tests to be completed prior to the procedure and during the pregnancy.

The GC stipulates that she will provide the treating and attending physicians with all pertinent information required to keep the IPs informed and will waive relevant medical privilege she holds with respect to the procedure and the pregnancy.

All parties agree to sign a letter of introduction to the hospital which includes information about the arrangement (and may even include some phrases from the contract itself); asks for identification bracelets for the IPs; acknowledges that the GC is the patient and makes decisions for her own care; and provides that the parties agree that the IPs will make decisions for the baby only after the umbilical cord is cut. Some letters also request that the IPs be present for the birth unless a Caesarean section takes place. The letter also provides that the GC will arrange for her health-care power of attorney or a substitute decision maker should she be rendered incapacitated. The IPs must also have appointed a guardian to take custody of the child should they become incapacitated. At some point during the third trimester, the parties meet with the hospital social workers to review the situation and deliver the letter. Any further issues that needed to be addressed to alleviate hospital concerns are dealt with well in advance of delivery. In addition, the legal agreement provides appropriate consideration to the GC for her recovery time and after care during the post-partum period.

Statistical analysis

Differences in pregnancy outcomes were compared using χ^2 analyses with a *P*-value of ≤ 0.05 considered as significant. Age and other continuous data were analyzed using a two-tailed Student's *t*-test.

Results

We reviewed 333 cycles which involved 256 IPs and 247 GCs. A cycle was defined as one stimulation cycle with fresh transfer and any subsequent frozen embryo transfers from the same cycle. The difference between the number of IPs and GCs was due to the fact that some IPs had more than one cycle and/or worked with more than one GC to achieve a pregnancy, and likewise, some GCs worked with more than one IP. We saw a gradual increase in the number of cycles per year (Fig. 1). The mean age of the IPs was 38.2 and the mean age of the GCs was 31.8 (range 21–44). The diagnostic indications for GS were divided into seven groups (Fig. 2, Table I). In 25% of cases, the GC was a family member (e.g. sister, cousin, aunt) or friend of the IPs and 75% of cases were coordinated through an agency or independently. Of these 333 cycles, 155 did not achieve a pregnancy, 36 resulted in a miscarriage and 142 were ongoing pregnancies or had resulted in a live birth.

In 169 cycles, IPs used donor oocytes (mean donor age 26.2) and in 164 cycles, patients used their own (autologous) oocytes (mean IP age 36.1) (Table II). The mean age of female IPs who used donor oocytes

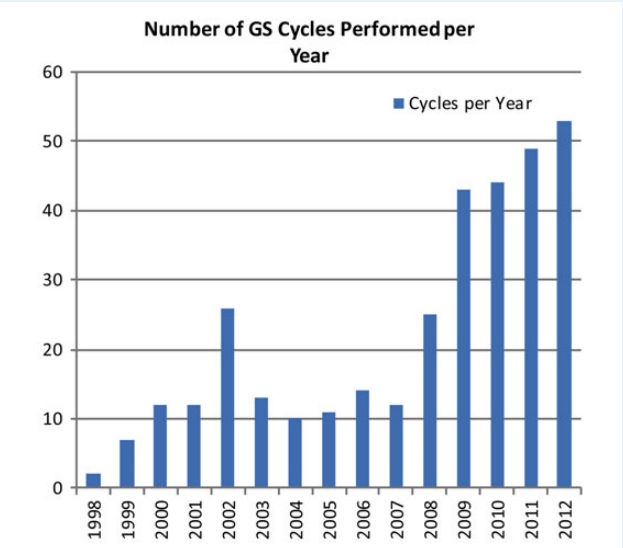

Figure 1 The number of gestational carrier cycles performed per year from 1998 to 2012 at the CReATe Fertility Centre (CFC).

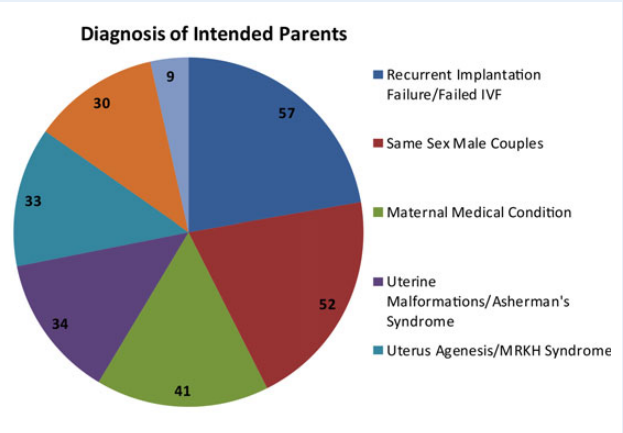

Figure 2 Graphical representation of indication categories for the use of GS.

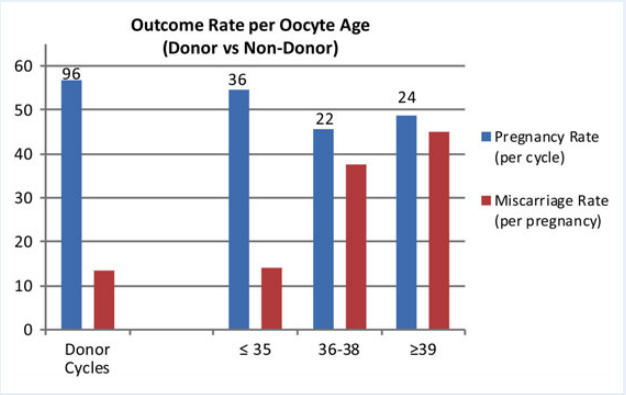

Figure 3 The outcomes of autologous-oocyte surrogacy cycles stratified by oocyte age. Note: Values above pregnancy rate bars are total pregnancies in that subgroup.

Table I Indication categories for the use of GS.

Intended parents diagnosis	*n*	%
Recurrent implantation failure (RIF)	57	22.3
Same-sex male couples	52	20.3
Maternal medical condition	41	16.0
Uterine malformations/Asherman's syndrome	34	13.3
Uterine agenesis/MRKH syndrome	33	12.9
Recurrent pregnancy loss (RPL)	30	11.7
Previous poor pregnancy outcome	9	3.5
Total	256	

Table II Comparison of pregnancy, miscarriage and live birth rates in donor oocyte versus autologous oocyte cycles.

	Oocyte donor cycles (*n* = 169)	Non-oocyte donor cycles (*n* = 164)	*P*-value
Mean age of oocyte provider	26.2 ± 3.3	36.1 ± 4.4	<0.001
Pregnancies (%)	96 (56.8%)	82 (50.0%)	0.273
Miscarriages (%)	14 (14.6%)	22 (26.8%)	0.060
Live birth (%)	76 (45.0%)	57 (34.8%)	0.060

(*n* = 107; excluding male-only recipients) was 41.3 years. Therefore, the indication for oocyte donation in the majority of these was advanced maternal age. We found a higher overall pregnancy rate (PR) in the oocyte donor cycles, although the difference in pregnancy rate was not found to be statistically significant (56.8 versus 50.0% respectively, $P = 0.273$). However, as expected by the age difference between the groups, we did see a difference in the miscarriage rate (MR) between donor-oocyte cycles and non-donor cycles (14.6 versus 26.8% respectively, $P = 0.060$), but this did not achieve significance. This translated into a higher ongoing pregnancy rate (>20 weeks) in those patients who used donor oocytes (48.5 versus. 36.6% $P = 0.035$) which was statistically significant. The difference in live birth rate did not reach significance with confirmed live birth resulting from 76 (45.0%) cycles with donor oocytes and 57 (34.8%) cycles with autologous oocytes ($P = 0.06$), although some pregnancies were lost to follow up. The pregnancy and MRs by oocyte age in non-donor cycles are represented in Fig. 3.

We then created two groups: Group 1, 'failed to carry', included the diagnoses of recurrent implantation failure (RIF), RPL and previous poor pregnancy outcome. This group consisted of 96 patients who completed 132 cycles with a mean age of 40.3 years. There were 66 pregnancies (50.0%), which included 17 miscarriages (25.8%), and 46 live births (34.8%). Group 2, 'cannot carry pregnancy', comprised: uterine malformations/Asherman's syndrome, Müllerian agenesis (Mayer–Rokitansky–Kuster–Hauser, MRKH syndrome) and maternal medical conditions precluding pregnancy. This group had 108 patients and 139 cycles, and a mean age was 35.9 years. There were 75 pregnancies (54.0%), which included 15 miscarriages (20.0%), and 56 live births (40.3%). The pregnancy, miscarriage and live birth rates between the two groups were not significantly different ($P = 0.54$; 0.43 and 0.38, respectively). The maternal medical conditions and previous poor obstetrical outcome cases are detailed in Tables III and IV, respectively.

Male couples/single men were excluded from the 'cannot carry' group, since they are a separate population with unique circumstances. There were 52 GC patients in this group, with a mean age of 38.5 years. They completed 62 cycles resulting in 37 pregnancies (59.7%) and 4 miscarriages (10.8%). There was gradual increase in the number of cycles per year for male couples and single men over time from 2 in 2005 to 17 in 2012 (Fig. 4).

We reviewed data from the 178 pregnancies which were achieved. Of these, 142 pregnancies were ongoing (surpassed 20 weeks) and the other 36 pregnancies resulted in a miscarriage (20.2%). We have available data from 133 pregnancies that resulted in a live birth; the other 9 patients (6.3%) with ongoing pregnancies were lost to follow up. From these 133 confirmed live births, 175 total children were born. We had a vaginal delivery rate of 76.7% (*n* = 102) and a Caesarean section rate

Table III Summary of specific medical condition indications for GS.

Diagnosis	n
Ankylosing spondylitis with renal failure	1
Autoimmune hepatitis and factor 8 deficiency	1
Breast cancer	1
Congenital bladder defect with ileal conduit	1
Crohn's disease after extensive surgery	3
Dilated cardiomyopathy with defibrillator	1
Endometrial cancer	1
Heart transplantation	1
Hemihyperplasia/lipomata syndrome	1
Hereditary hemorrhagic telangiectasia	1
History of severe hyperemesis gravidarum	1
Insulinoma	1
Lupus after kidney transplant	3
Methotrexate treatment for autoimmune diseases	2
Ovarian cancer	3
Portal vein thrombosis (prothrombin mutation)	1
Reflex sympathetic dystrophy	1
Renal disease	1
Scleroderma	1
Severe endometriosis with multiple surgeries	1
Severe hypertension	1
Severe thrombotic thrombocytopenic purpura	1
Severe urticaria/angioedema	1
Spinal cord injury	1
Thoracic aortic aneurysm	1
Turner's syndrome	1
Type 1 diabetes	4
Ulcerative colitis	2
Ventral hernia	1
Wilm's renal tumor	1

Table IV Summary of previous poor obstetrical history of intended parents as indications for GS.

Diagnosis	n
Stillbirth (one or more)	3
Neonatal death	2
Severe PET severe prematurity/child with CP	3
Previous uterine rupture/neonatal death	1

of ($n = 31$; 23.3%). In our series, 93 (69.9%) live births were singletons, 38 (28.6%) were twin births and 2 (0.02%) were triplets. As with the worldwide trend, and the trend in Canada in the last 4–5 years, the elective single-embryo transfer (eSET) rate in our program has increased significantly (all cases of eSET in our series took place in the last 4 years). As a result, the mean number of embryos transferred decreased from 3.3 to 2.2, when comparing the years from 1998 to 2001 to the interval from 2002 to 2012.

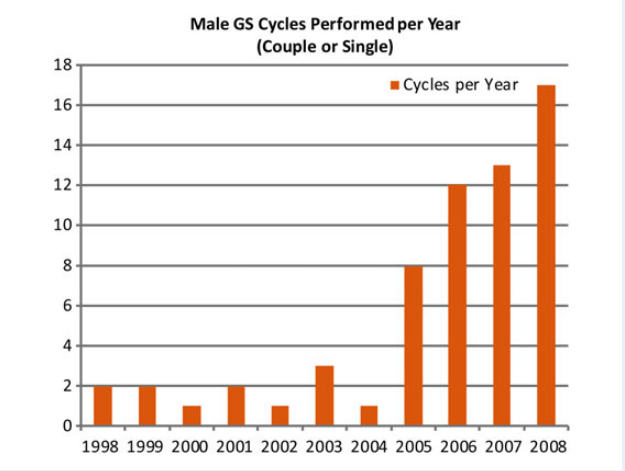

Figure 4 The number of gestational carrier cycles performed for same-sex male couples or single men per year from 2002–2012 at the CReATe Fertility Centre (CFC).

Maternal (GC) complications were reported in 13 cases (9.8%) (Table V). Of these, 12 were relatively minor and only one was major. This was a Caesarean hysterectomy after birth of a twin pregnancy due to uterine atony, which resulted in a severe post-partum hemorrhage (PPH). There were no maternal deaths. The overall Caesarean section rate was 23.3%.

We have birthweight data on 169 of the 175 total babies born. The number of singletons classified as low birthweight (<2500 g) was 11 (11.8%) and 43 (52.4%) of multiple birth babies had a low birthweight. The incidence of pre-term birth (<37 weeks) was 22.6% for singletons and 68.3% for multiple births. Since pre-term birth is associated with low birthweight, our subanalysis showed that 45.5% of preterm singletons and 58.6% of preterm multiples were born under 2500 g. With respect to fetal complications, there were two instances of stillbirth: one from a twin pregnancy that had twin to twin transfusion syndrome and the other was a singleton after a placental abruption. As well, there was one singleton neonatal death (<1 h) born prematurely at 21 weeks gestation, secondary to placental abruption, and there was another neonatal death from a twin pregnancy at 30 weeks. There were three congenital anomalies reported. One baby of a twin pregnancy had one non-functioning kidney and two children (one twin and one singleton), each with an atrial septal defect that resolved spontaneously. The overall rate of fetal anomalies was 1.8% of babies born (Table V).

In our study group, there were 17 cycles in which embryos were transferred to both the IP and GC concurrently. Of these, 10 achieved a pregnancy, with 9 of the pregnancies established in the GC and only one in the IP. Three of these 10 pregnancies resulted in a miscarriage, two GC pregnancies and the only IP pregnancy. There were no cases in which both the IP and GC conceived simultaneously. In all of these cases, the IP had either unexplained recurrent failed implantations or RPL and requested that one or two embryos be transferred to themselves as well as the GC, hoping that they would still be able to carry their own pregnancy despite losses in previous attempts.

Table V Gestational carrier and fetal complications.

Complication	*n* (%)	Singleton pregnancy	Twin pregnancy	Triplet pregnancy
Gestational surrogate complications				
PIH	3 (2.3%)	2	1	
Placenta previa	1 (0.8%)	0	1	
Placental abruption	1 (0.8%)	1	0	
Gestational diabetes	4 (3.0%)	3	1	
Pre-eclampsia	1 (0.8%)	1	0	
Pre- or Post-partum Bleeding	2 (1.5%)	2	0	
Caesarean hysterectomy	1 (0.8%)	0	1	
Total	13/133 (9.8%)			
Fetal complications				
Low birthweight (<2500 g)	54 (32.0)	11	37	6
Prematurity (<37 weeks)	46 (27.2)	6	34	6
Prematurity and low birthweight	30 (17.8)	4	20	6
IUGR	1 (0.1%)	0	1	
Stillbirth	2 (1.2%)	1	1	
Neonatal death	2 (1.2%)	1	1	
Congenital defects (one renal, two cardiac)	3 (1.8)	1	2	
Total (with 1 or more complications)		11/93 (11.8%)	51/76 (67.1)	6/6 (100%)

Complication rate for twins and triplets is per newborn.

Discussion

Medical issues

ART with a GC is the only option for many couples. In our study, 108 of the 256 couples (42.2%) were unable to carry a pregnancy (due to uterine damage, absent uterus and severe chronic conditions that contraindicate pregnancy). We chose not to include male couples/single men in the 'cannot carry' category since they are distinct from women who are unable to carry a pregnancy; there are 52 same-sex/single men cases in our series (20.3%). In keeping with our previous report (Grover *et al.*, 2013), we observed a significant increase in same-sex male couples and single males utilizing GS over time (Fig. 4). The other 86 couples (33.6%) had tried and failed to achieve a pregnancy and chose to pursue GS. The most common indications for patients in our series were RIF (22.3%), same-sex male couples or single men (20.3%), maternal medical conditions (16.4%) and uterine malformations or Asherman's syndrome (13.3%). Direct comparison of pregnancy outcome between our series and others reported in the literature has limited value due to the significant differences between reported study populations. Brinsden *et al.* reported on one British fertility center experience with creating a GS program. They reported 87 cycles from 1989 to 1998 with a live birth/ongoing pregnancy rate of 21% per transfer with 37% of IPs ultimately having a child (Brinsden *et al.*, 2000). Goldfarb *et al.* (2000) reported on 112 GC cases. A majority of their patients had a prior hysterectomy or MRKH syndrome and no cases involved oocyte donors. Their clinical pregnancy rate was 19%. Raziel *et al.* (2005) analyzed 60 cycles and their pregnancy rate per transfer was 17% (10/60), and their live birth rate was 15% (9/60). Similar to our study, Raziel also compared uterine-related indications with non-uterine indications and found no significant difference in pregnancy rate. In our study, there was not a statistically significant difference between these groups with respect to pregnancy rate (54.0 versus 50.0%, $P = 0.54$). The patients in the 'cannot carry' group were younger (35.9 versus 40.3, $P < 0.001$) and also had a lower use of oocyte donors (35.9 versus 42.4%, $P = 0.32$), although not significantly so. Also, we presume that in some cases of RPL and RIF, there may be an 'oocyte factor' that is not present in the 'uterine' cases. Of the 169 (50.8%) cycles involving oocytes from an oocyte donor (including male recipient cycles), the pregnancy rate was 56.2%, which is comparable to the pregnancy rate in our donor program. We had a pregnancy rate in the non-donor cycles of 50.0%, similar to another study (Soderstrom-Anttila *et al.*, 2002). However, in this group that used their own (IPs) oocytes, there was a large variety of indications for a GC and each indication subgroup also differed significantly in age, so pregnancy rate comparisons between subgroups would not be meaningful.

Duffy *et al.* (2005) reported the outcome of nine GC pregnancies. In two cases, Caesarean hysterectomy was performed (uterine rupture and placenta accreta in a triplet pregnancy). Our overall maternal complication rate was only 9.8% (13/133). Of these, 12 were relatively minor and one was major and there were no maternal deaths (Table V). This relatively low rate of maternal complications is consistent with the fact that all GCs were multiparas and could not serve as a GC if they had any significant complications in prior pregnancies. There was also a relatively low overall rate of fetal anomalies (1.8% of babies born) and this may also be related to the generally good obstetrical history of all GCs based on prior screening and the relatively high number of oocyte donor cases in this series. Our overall mean gestational age (GA) at birth was 37.9 weeks. The mean GA was 38.9 for singletons and 35.8 weeks for multiple births. This is comparable to an early study on GS (Parkinson *et al.*, 1998) in which the mean gestational age

was 38.7 weeks for singletons and 36.2 weeks for twins and also a more recent study (Gibbon *et al.*, 2011) where the mean gestational age for GS singleton pregnancies was 37.2 weeks. We also noted a trend in our series toward more eSETs in recent years, which is consistent with the overall trend in Canada (Gunby, 2011). When considering optimal safety for the GC and the IP's offspring, this is certainly a welcome trend.

Reilly (2007), in his guidelines to Canadian prenatal healthcare providers, recommended separate medical and social counseling for both parties, which is our practice. He also recommended separate physicians for the GC and the IPs. While it is important to maintain confidentiality of medical information, it is essential to obtain permission to share pertinent medical information between the GC and IPs in this unique medical situation. The IPs must know whether the GC has any medical conditions that could put their potential offspring at risk before deciding on entering into a GS arrangement with her. The GC should be made aware of any medical issues that could be life-threatening or otherwise impair the IPs ability to take custody of the baby(s) after birth. In addition, medical information related to the cycle coordination must be shared for timing purposes. Therefore, we view care for the IPs and the GC as part of one coordinated process. Therefore, in our clinic, our policy is that one physician cares for both, keeping in mind the unique needs of each party. In addition, both the IPs and the GC are well informed that decision-making regarding the GC's medical care, especially in an emergency situation, is made solely by the GC, or a designated independent family member or friend in the case of incapacity. Furthermore, if a conflict between parties were to arise, or upon request, there is an option available to assign separate physicians for the IPs and GC as a contingency plan.

Counseling

Although thousands of GC cycles are performed around the world annually, GS has often been criticized for its potential exploitative nature (Wilkinson, 2003), sometimes referred to as being a 'womb for rent'. Some even compare it with organ transplant from a live donor (Ber, 2000). For this reason, in addition to a legal contract (discussed below), a thorough psychosocial assessment and counseling regarding these types of issues is essential and is mandatory in our program. Pre-GS counseling will explore the varying concept of 'family' based on genetic link, social link and gestational link, and redefines what it means to be a family following ART procedures. The IPs often view GS as either an opportunity or a last resort, depending on the indication. For same-sex male couples or single men, it offers an option once thought to be unattainable; the ability to be genetically linked to a child. For some women, it can lead to a final confrontation of her infertility as she copes with the challenges associated with not being able to carry a child. For those without a uterus, it is often a tremendous opportunity that many thought would never be available to them.

In both psychosocial and medical counseling, we strongly encourage female IP partners to consider breastfeeding as a helpful way to enhance bonding. Therefore, all are given the opportunity for referral to a medical practitioner who specializes in lactation induction. In addition, all IPs and GCs are offered the opportunity for post-birth counseling to address any psychosocial issues that may arise in the post-natal period or beyond. Some important issues discussed with the GC during counseling would include: overall experience of the pregnancy, birth, potential depression and future contact with the IP(s) and the child(ren). Some important issues in post-natal IP counseling would include: the experience of the pregnancy, bonding, future contact with the GC and issues of future disclosure to the child(ren).

Legal issues

Dermount *et al.* (2010) described the medical and legal process of recruitment of gestational carriers in one Dutch fertility center from 1997 to 2004 following legalization of altruistic GS in 1994. In this program, 24 completed treatment and 13 successfully became parents. There were no cases in which custody was disputed after the birth. Similarly, in our series, all but one of the children had their legal parenthood successfully transferred to the IPs. In this one case, the child was taken by the provincial child care services due to the development of a maternal psychiatric illness that rendered the intended mother unable to care for the child and the child was eventually adopted by another couple.

Our experience in Canada suggests that most hospitals are 'GC friendly' and that the experience of GCs and IPs has been positive. Further education for hospitals that have not cared for a GC is certainly achievable. A strict program, a clear and transparent process and tight collaboration between the medical, legal and social professionals have guaranteed success in the vast majority of cases.

To date, we do not have long-term follow-up data concerning disclosure to children, the incidence of depression or regret, or any relationship that the GC may have with the IPs and their children following birth. These important issues will be the subject of future studies.

In conclusion, a meticulous multidisciplinary process involving legal input, counseling and medical care for both the IP and the GC, as described in this paper, is of critical importance and has enabled us to achieve a successful GS program.

Authors' roles

S.D., T.L. and S.S. were involved in data collection, statistical analysis and preparation of the manuscript. A.S. performed the data collection. J.S., C.W. and S.I.M. significantly contributed to the manuscript. C.L.L. was involved in the overall study design and preparation of the manuscript.

Funding

No external funding was used.

Conflict of interest

None declared.

References

Ber R. Ethical issues in gestational surrogacy. *Theor Med Bioeth* 2000; **21**:153–169.

Brinsden P, Appleton TC, Murray E, Hussein M, Akagbosu F, Marcus SF. Treatment by in vitro fertilsation with surrogacy: experience of one British centre. *BMJ* 2000;**320**:924–929.

Dermount 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.

Duffy DA, Nulsen JC, Maier DB, Engmann L, Schmidt D, Benadiva CA. Obstetrical complications in gestational carrier pregnancies. *Fertil Steril* 2005;**83**:749–754.

Gibbone WE, Cedars M, Ness R. Toward understanding obstetrical outcome in advanced assisted reproduction: varying sperm, oocyte and uterine source and diagnosis. *Fertil Steril* 2011;**95**:1645–1649.

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

Grover SA, Shmorgun Z, Moskovstev SI, Baratz A, Librach C. Assisted reproduction in a cohort of same-sex male couples and single men. *Reprod Biomed Online* 2013;**27**:217–221.

Gunby J. CARTR Annual Reports (2007–2011). 2011. www.cfas.ca.

Parkinson J, Tran C, Tan T, Nelson J, Batzofin J, Serafini P. Perinatal outcome after in-vitro fertilization-surrogacy. *Hum Reprod* 1998;**14**:671–676.

Raziel A, Schachter M, Strassburger D, Komarovsky D, Ron-El R, Friedler S. Eight years' experience with an IVF surrogate gestational pregnancy programme. *Reprod Biomed Online* 2005;**11**:254–258.

Reilly DR. Surrogate pregnancy: a guide for Canadian prenatal health care providers. *CMAJ* 2007;**176**:483–485.

Soderstrom-Anttila V, Blomqvist T, Foudila T, Hippelainen M, Kurunmaki H, Siegberg R, Tulppala M, Tuomi-Nikula M, Vilska S, Hovatta O. Experience of in vitro fertilization surrogacy in Finland. *Acta Obstet Gynecol Scand* 2002;**81**:747–752.

Utian WH, Sheean L, Goldfarb JM, Kiwi R. Successful pregnancy after in vitro fertilization and embryo transfer from an infertile woman to a surrogate. *N Engl J Med* 1985;**313**:1351–1352.

Wilkinson S. The exploitation argument against commercial surrogacy. *Bioethics* 2003;**17**:169–187.