



Atlantic Assisted Reproductive Therapies
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INFORMED CONSENT FOR INTRACYTOPLASMIC SPERM INJECTION (ICSI)

INTRACYTOPLASMIC SPERM INJECTION (ICSI)

Intracytoplasmic sperm injection (ICSI) is a procedure that can be used to increase the chance of fertilization for a couple undergoing in vitro fertilization and embryo transfer (IVF - ET) who may have a reduced chance of fertilization through standard egg insemination procedures. Clinical situations in which the techniques of assisted fertilization may be useful include cases of male infertility, cases where one or more variables on analysis of a semen sample is/are abnormal, immunological infertility, or when there has been failure of fertilization or low rate of fertilization in previous IVF treatment sessions. Furthermore, where sperm has to be retrieved surgically such as by sperm aspiration, then IVF and ICSI may be the best approach to care. The method of microinsemination used at AART is intracytoplasmic sperm injection or ICSI.

Eggs and sperm are obtained by using standard methods during an in vitro fertilization treatment cycle. Sperm are then prepared in a manner to select and retain only the most active sperm in a small volume of culture medium. Substances known to increase the motility of sperm may be added to the nutrient liquid used to prepare sperm in cases where the movement of the sperm is reduced. After exposing the mature eggs to an enzyme that removes the cumulus cells which surround the egg, each egg is placed under a microscope and held in a place by gentle vacuum with a small glass tube called a micropipette. A single sperm is then drawn up into an extremely sharp, hollow glass needle along with a very small amount of the nutrient liquid medium. The needle is then quickly passed through the zone pellucida (the gel-like substance surrounding each egg) and the cell membrane to inject the sperm into the center of the egg by using a special microscope assembly. Approximately 16 - 18 hours after ICSI, the eggs are examined under the microscope for any sign of damage and to assess for the presence of two distinct pronuclei which indicates normal fertilization. Subsequent maintenance of embryos and the performance of the embryo transfer is the same as standard IVF.

Microinsemination is a relatively new procedure. The first pregnancy resulting from the injection of sperm into the subzonal space of human eggs was reported by Ng and colleagues in Singapore in 1988. Subsequently, pregnancies and births resulting from microinsemination of human eggs have been reported by clinical groups in North America, Europe, Japan, and Australia. Fertilization rates with ICSI are higher than with other micromanipulation techniques utilized to achieve fertilization, such as partial zone dissection (PZD) or subzonal insemination (SZI).

RISKS OF INTRACYTOPLASMIC SPERM INJECTION (ICSI)

Injection of sperm into the egg is a new procedure with thousands of on-going pregnancies or babies being born worldwide since the introduction of ICSI. Therefore, this procedure may involve risks and discomforts to the fetus and/or mother that are presently not identified. Perforation of the zona may decrease the protective effect of the zona on the egg and early embryo. The procedures of microinsemination may result in degeneration of the egg or result in formation of abnormal embryos. Unforeseen technical problems may arise which preclude successful fertilization via microinsemination. Success cannot be guaranteed.

BENEFITS OF INTRACYTOPLASMIC SPERM INJECTION (ICSI)

Microinsemination may increase the chances of pregnancy in couples whose chance of successful fertilization through standard IVF techniques is reduced. While microinsemination may increase the chances of becoming pregnant, there are no assurances, either stated or implied, that microinsemination may result in pregnancy. Both in vitro fertilization and embryo transfer together with microinsemination are new technologies and are still considered experimental; therefore, predictions about the likelihood of success of such treatments are less certain than is usually the case with other medical procedures.

The chance of any woman giving birth to a child with congenital birth defects in the Canadian population is approximately 3 - 4 % no matter how pregnancy is achieved. While available data does not indicate any reason to expect that microinsemination will result in increased incidence of chromosomal abnormalities in human infants, the relatively few births resulting from microinsemination of human eggs does not allow a reliable analysis of congenital abnormalities in infants born of eggs that have been microinseminated. The Brussels, Belgium fertility treatment center which pioneered the ICSI technique has reported that 7 of 289 babies born through this procedure had major congenital malformations (2.4%) which falls within the expected range of malformations in the general population where pregnancy was achieved spontaneously through intercourse. However, in the absence of more information and on clinical grounds, we may offer chromosome screening to male partners of women undergoing IVF. Once results are available, we can offer further reassurance to women before undergoing IVF with microinsemination.

RESCUE ICSI - WHAT IS IT AND MIGHT I NEED IT?

Sometimes after IVF there are either very few or even no eggs fertilized, i.e. "Poor fertilization". In some IVF clinics a procedure called "Rescue ICSI" is offered whereby the IVF eggs that were not fertilized by the morning after the egg retrieval are "reinseminated" using ICSI. However, Rescue ICSI is really only successful in cases where the poor/failed fertilization was due to unidentified sperm problems. At AART those situations are very rare - only 1 or 2 percent of IVF cases - because of the

great care we take with the investigation of the man's sperm before recommending IVF (the "Sperm Functional Analysis"), allowing our doctors to identify many of the possible causes of poor sperm fertilizing ability and direct those men to have ICSI in the first place. In addition, our IVF culture system is extremely good when measured in terms of the rate of fertilization of mature eggs. Therefore, at AART almost all of the poor or failed fertilization cases are due to problems with the eggs, and Rescue ICSI would not be expected to achieve fertilization in such cases since it only helps sperm-based problems.

Should you experience poor or failed fertilization in your IVF cycle, we will discuss the likely causes of the problem so that you can make a properly informed decision as to whether or not to spend the extra money on having Rescue ICSI. Experience with the systems we are now using at AART tells us that the chance of getting any embryos for transfer from the Rescue ICSI cases we might see is much less than 10%. Of course, the final decision is yours, and you can request Rescue ICSI even though it might not be considered appropriate or is considered to have a very poor expected outcome.

If you do chose to have Rescue ICSI, then both you and your partner will need to sign an extra consent form before the scientists can do the ICSI procedure, just as you would in a normal ICSI cycle. You will also need to pay the fee for ICSI. Unfortunately, Rescue ICSI cannot be performed without a properly signed consent form and payment of the fee.

ALTERNATIVES TO MICROINSEMINATION

The alternatives to microinsemination include increasing the sperm numbers that surround the egg while it is incubating in the laboratory or, in cases of male factor infertility, the use of donor sperm. Increasing the sperm concentration may increase the chance of fertilization but may have an adverse effect on the laboratory environment of the egg.

MICROINSEMINATION RELEASE & CONSENT

We, the undersigned, have read the above information and recognize the described potential benefits and risks of in vitro fertilization by microinsemination and uterine transfer of resultant embryos. We voluntarily request, authorize, and direct the personnel of AART to perform any and all procedures necessary for in vitro fertilization, microinsemination, and embryo transfer, as well as, any such additional procedures that any of the staff may deem necessary. We acknowledge that we have previously executed the In Vitro Fertilization - Embryo Transfer Consent and that this Consent to Microinsemination is in addition to, and supplements, such other Consent. Furthermore, we understand that the contents and terms of all AART consent forms that we have signed apply to this Consent and are incorporated herein by reference.

I understand that there is a fee for intracytoplasmic sperm injection which is additional to the fee for IVF treatment. I have been informed by a member of the AART staff of what that fee is.

I understand that there is no guarantee that my eggs (oocytes) will fertilize as a result of ICSI.

I understand that there is some risk of trauma/damage to oocytes whilst undergoing ICSI.

_____ Date: _____
(Patient Signature)

_____ Date: _____
(Spouse's Signature)

_____ Date: _____
(Witness' Signature)