Pregnancy following intracytoplasmic sperm injection treatment with dead husband’s spermatozoa: ethical and policy considerations

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This paper describes the first pregnancy in a childless widow after intracytoplasmic sperm injection (ICSI) treatment with her deceased husband’s spermatozoa which had been stored for nearly 3 years before use. Before his death the husband had received treatment for testicular cancer and he had given the appropriate written consent for the future use of his spermatozoa. Of the 10 eggs injected, six resulted in normal embryos. Three embryos were transferred and the remaining three embryos are currently stored for possible future use. The treatment resulted in a continuing singleton pregnancy. The case demonstrated the suitability of ICSI in those difficult cases where the sperm quality is extremely poor. This success is also compared with a widely debated case of another widow who was refused permission to use her deceased husband’s spermatozoa. It is concluded that in the case of posthumous use of frozen spermatozoa, the current laws are conveniently applicable in a chronic illness but not so in an acute illness leading to death. In the light of the wide public debate on the issues raised by this legal case, the UK Government has also decided to conduct a review of consent procedures involving the storage and use of genetic material.

Key words: consent/ethics/ICSI/posthumous use of gametes/testicular cancer

Introduction

The posthumous use of frozen spermatozoa to attempt to achieve a pregnancy has been available for cancer patients since the commencement of sperm cryopreservation, but only recently has assisted reproduction technology offered a realistic chance of success for those in need (Steele et al., 1995). The UK law permits this only when there is evidence that the deceased husband was given a suitable opportunity to receive proper counselling at the time of depositing semen and had given his written consent. Informed consent as a device to protect the patient’s autonomy and the welfare of the child are the two basic principles enshrined in the Human Fertilisation and Embryology Act of 1990.

The concept of posthumous assisted reproduction is by no means universally acceptable as this procedure arouses strong ethical feelings. The majority of UK licensed in-vitro fertilization (IVF) centres support the posthumous storage and use of spermatozoa and embryos, though some are concerned about the problems surrounding the regulations governing this aspect of assisted conception treatment (Corrigan et al., 1996). We describe here what we believe is the first case of pregnancy following ICSI (intracytoplasmic sperm injection) and embryo transfer in a widow using her deceased husband’s spermatozoa. A brief discussion of the ethical and legislative considerations is also pertinent in view of a similar, highly publicized case which was recently disallowed, and which has prompted a debate concerning the ambiguities of the current guidelines.

Clinical details

A 36 year old childless widow was referred to us for infertility treatment using her deceased husband’s spermatozoa. Before her husband’s unsuccessful chemotherapy treatment for testicular cancer, he requested and was able to store his semen in a cryobank. He left appropriate written instructions that he wished his specimen to be stored for the maximum period allowed (i.e. 10 years) and be used to establish a pregnancy which was recently disallowed, and which has prompted a debate concerning the ambiguities of the current guidelines.

During the following 18 months the widow attended our fertility clinic for assessment and counselling. She was menstruating normally [follicle stimulating hormone (FSH) 4 IU/l] and her tubes were patent. The continued support of her family and her general practitioner was also evident during this period. She was initially offered intrauterine insemination (IUI) treatment, nearly 2 years after the death of her husband.

Her ovaries were stimulated with clomiphene citrate and the follicular response was monitored by serial ultrasound scans. When the larger of the two follicles was >18 mm in diameter she was induced to ovulate with 10 000 IU of human chorionic gonadotrophin (HCG) (Pregnyl, Organon Laboratories Ltd., Cambridge, UK). Thirty-six hours later she was inseminated with washed and prepared spermatozoa using a vial of her husband’s stored semen. The specimen was found to be of suboptimal quality, although sufficient numbers (10×10⁶/ml; 45% motility) of motile spermatozoa were obtained for the procedure. Unfortunately, the treatment was unsuccessful on two consecutive attempts. When only a single vial of frozen spermatozoa remained it was clear that the next attempt would be the last.

At this stage after further discussions and counselling it became evident that she wished her last vial of semen to be
used for ICSI treatment, as she was convinced that this would give her the best chance to achieve a pregnancy with suboptimal spermatozoa. She was again supported by her family, her general practitioner and an independent counsellor. The woman’s ability to support herself and the welfare of any future child was never in doubt. Her request for ICSI treatment was also supported by the Cromwell Ethics Committee, nearly 3 years after the death of her husband. Her desire for the treatment was consistent with the guidelines of the Human Fertilisation and Embryology Authority (HFEA).

The patient’s ovaries were down-regulated using a long buserelin (Suprefact; Hoechst UK Ltd., Hounslow, Middlesex, UK) protocol and follicular stimulation was achieved by daily i.m. injections of 225 IU of human menopausal gonadotrophin (Humegon; Organon Laboratories). The follicular and uterine responses were monitored by serial ultrasound scans as described earlier (Ahuja et al., 1996; Ahuja and Simons, 1996; Sharp et al., 1996).

When the dominant ovarian follicle reached 20 mm in diameter and the Doppler measurements of the uterine arterial blood flow confirmed maximal endometrial score, she was given 10 000 IU of HCG to induce ovulation. After 36 h 16 eggs were collected under local anaesthesia, using a transvaginal ultrasound-guided technique.

Ten eggs were found to be suitable for ICSI, as judged by the presence of the first polar body. The last vial of semen contained an oligozoospermic specimen (0.5 ml, 10×10⁶ spermatozoa/ml, 30% motility) which was used for ICSI after preparation. All the suitable eggs (n = 10) were injected using a biological micromanipulator (Research Instruments,Cornwell, UK) with prepared spermatozoa from her hus-

band’s semen.

Six eggs showed the presence of two pronuclei 24 h after ICSI. These early embryos were cultured for another day, when three normally-dividing embryos were replaced into the patient’s uterus using a plastic embryo transfer catheter (Frydman, France). In view of the unusual circumstances, the remaining three embryos, though suboptimal, were frozen and stored using propanediol in a slow cooling method. The luteal phase was supported by progesterone pessaries (Cyclogest, Hoechst, UK Ltd.) 400 mg twice daily. A β-HCG pregnancy test carried out 2 weeks later was found to be consistent with the presence of a pregnancy. At 6 weeks an ultrasound scan of her pregnancy revealed the presence of two gestation sacs, each with ultrasound fetal heart movements. At 12 weeks only one gestation sac with a normal heart beat was seen. The pregnancy is continuing satisfactorily.

Discussion

During the last five years, ICSI has rapidly become a treatment of choice for alleviating male infertility including severe oligoasthenoteratozoospermia, obstructed vasa deferentia and repeated failure of fertilization at IVF. Spermatozoa retrieved from sites which were previously considered ‘unphysiological’ for fertilization have been shown to produce significant success with ICSI, sometimes even better than routine IVF using ejaculated spermatozoa. Epididymal or testicular spermatozoa and even undifferentiated spermatids have apparently been successful in generating viable embryos and pregnancies (Fishe1 et al., 1996; Oates et al., 1996; Tournaye et al., 1996).

Sperm motility, the main yardstick of sperm performance for normal fertilization, is apparently not a requirement for ICSI as immotile spermatozoa are also successful. Children born following ICSI treatment have been studied and no disconcerting neonatal evidence has emerged thus far (Bonduelle et al., 1996).

The case reported here demonstrates the suitability of ICSI for achieving pregnancies in women who have lost their husbands/partners due to testicular or other forms of cancer, but who fulfil medical and legal requirements for assisted conception using pre-treatment semen stored by their husbands/ partners, as defined by the Human Fertilisation and Embryology Act of 1990. The technique could have particular relevance in those cases, presumably a majority, where only a limited volume of semen is available in cryostorage. In patients with testicular tumours or Hodgkin’s disease who have an impaired sperm production and sperm quality, the spermatozoa suffer from cryopreservation (Sanger et al., 1980; Khalifa et al., 1992; Thrachil et al., 1994). In these cases ICSI is likely to produce significantly better results than IUI or even IVF and, if available, it should be the treatment of choice in these circumstances.

We welcome the ICSI success reported here and the technology which has made it possible. However, we also acknowledge that posthumous assisted reproduction success like this raises a number of ethical and legal concerns (Aziza-Shuster, 1994; Bahadur, 1996). The Human Fertilisation and Embryology Act of 1990 places great stress on informed consent when creating or destroying an embryo.

Two recent legal cases which captured the imagination of the British public and the media illustrate the point. The first was the case of a 35 year old woman who used a court injunction to stop the thawing of her 5 year old embryo but subsequently lost her case in the High Court. This was because her estranged husband whose spermatozoa were used for the original IVF treatment would not agree to an extension of the storage period (Edwards and Beard, 1997).

The second case was that of a 30 year old widow whose husband’s spermatozoa was obtained at her request in an emergency operation whilst he lay in a coma from bacterial meningitis. It is an obligation under the general law that people may be examined or treated without first obtaining their consent only in exceptional circumstances. The doctors interpreted the circumstances as exceptional—the patient was in a coma and unlikely to regain consciousness—so they complied with his wife’s request to obtain a sperm sample from him. However, storage of gametes without written consent and without evidence of prior counselling is forbidden (Section 5.9b, HFEA Code of Practice) even if it is impractical or impossible to use the spermatozoa immediately. The HFEA ruled that verbal or implied consent even within the context of a marriage is no substitute for written consent despite the woman’s suitability and other extenuating circumstances (Deech, 1996).
overseas (e.g. Belgium, where verbal evidence of prior consent is acceptable). The HFEA decision was upheld in the High Court, but the woman has appealed against this ruling to the Court of Appeal (Brahams, 1996; Dyer, 1996).

Whilst the outcome of the case was awaited, public awareness of this form of treatment and support for this young woman developed nationwide. The case also revealed the limitations of the current laws regulating assisted conception within a marriage; the current regulations do not appear to address satisfactorily certain extreme but apparently justifiable conditions, such as sudden death of the husband. The woman did not appear self-centred or irresponsible. Bearing a child with her late husband’s spermatozoa appeared to be consistent with their earlier desire to have a family, even though she knew that in law her late husband would not be considered as the father of the child. It was not merely a part of the grieving process. Had she so desired, the young widow, after appropriate counselling, could have undergone treatment with a (consenting) donor’s spermatozoa quite legally, just like lesbians or single women (Englert, 1994; Golombok and Tasker, 1994). The doctrine of explicit consent, a fundamental requirement to medical care, somehow did not appear to be germane to the case of this unfortunate widow (Ahuja et al., 1997). To many in the media and in the profession, the HFEA seemed inflexible (Lancet, 1996; The Independent, 1996; The Sunday Telegraph, 1996). However, the Act did not allow the HFEA any discretion.

The pregnancy reported here demonstrates clearly that the HFEA is not opposed to posthumous assisted reproduction. It could also be argued that a more flexible view of consent in sudden illness leading to death would not have any serious policy implications (Bahadur, 1996). Assuming there are never more than 50 potential cases in the UK (Bahadur, 1996), posthumous assisted conception would have been applicable to rather less than 0.001% of treatments. Unlike the success reported here, the younger widow’s desire for treatment was frustrated. Her husband did not regain consciousness so written consent after possible counselling could not occur. In circumstances like these legal provision should be made for the appointment of an assessor by the regulatory body who could then take appropriate action in individual cases.

Addendum

After this paper was submitted for publication, on 6 February 1997 the Court of Appeal gave judgment in relation to the case of the younger widow discussed in this paper. She may not lawfully be treated with the spermatozoa of her late husband in this country as no effective consent was available. The posthumous storage or use of spermatozoa or eggs without consent remains unlawful in this country. The exception to the need for written consent to the use of gametes for ‘treatment together’ only applies where the spermatozoa are used immediately and where no storage has occurred. It is not possible to regard a person who is dead as being treated together with anyone else. The HFEA has no discretion to authorize treatment in the UK without written consent.

The HFEA was asked to reconsider the widow’s request to export her late husband’s spermatozoa to Belgium where the prior written consent of the donor is not mandatory (Brahams, 1997). This is primarily because this unique case would set no undesirable precedent. Furthermore, under European Union Law a UK citizen has the right to unimpeded access to medical treatment in other member states.

In the light of the wide public debate on the issues raised by this legal case on 6 February 1997, the Government also decided to conduct a review of consent procedures involving the storage and use of genetic material. The review will be conducted by Professor Sheila McLean, Professor of Law and Ethics in Medicine, University of Glasgow and will have the following terms of reference: (i) to review whether—and in which circumstances—explicit consent under the common law to the removal of gametes might be waived; (ii) to consider in the light of (i) whether changes are required to the Human Fertilisation and Embryology Act 1990 whereby effective consent to storage and use of gametes must always be given in writing; (iii) to consider the implications of any changes to the present consent regime in the Human Fertilisation and Embryology Act 1990 for the remainder of that Act, including the operation of the HFEA; and (iv) to consider the implications for (i), (ii) and (iii) above of the judgement given by the Court of Appeal in this case.

Note added in proof

On February 27, 1997, the HFEA allowed the widow to export her late husband’s sperm to a Belgian clinic providing that the specimen is used for her own treatment, and an account has been taken of the welfare of the child that might be born, including the child’s need for a father.

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References


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