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THE ARTIFICIAL WOMB

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Abstract

Since around the 80's of the last century, with the clinical advent of in vitro fertilization leading to the so-called “test-tube babies”, bioethicists have been concerned to issue ethical considerations regarding artificial womb technology. There are, in general, two main uses of this technology: first, ecogestation, that form of enhanced neonatal care in which only part of the gestation period takes place in an artificial womb, and second, ectogenesis, in which the entire gestation period takes place in an artificial womb. The fact that ecogestation could significantly reduce neonatal and maternal morbidity and mortality is a strong argument for supporting its development. As for ectogenesis, it may bring several challenges ranging from the potential pathologisation of pregnancy and childbirth to the further commercialization of babies.

Keywords: artificial womb; extreme prematurity; ectopic pregnancy

Introduction

A person who was born alive and whose birth was declared in accordance with the procedures prescribed by law has a legal existence. The rule *infans conceptus pro natur habetur quoties de commodo ejus agitur*⁶ applies only to a child born alive and viable, i.e. with a gestational age of at least 26 weeks after amenorrhea and weight of not less than 500 g. According to the World Health Organization, extreme prematurity, where the gestational age is between 26-30 weeks (850-1250 g), affects 0.4% of newborns globally and remains the leading cause of infant morbidity and mortality even in developed countries (Chawanpaiboon et al., 2019). These births are referred to maternity wards with neonatal intensive care, where early intervention will correct any deficits in adaptation to extrauterine life. The life prognosis of premature newborns is proportional to their birth weight and gestation length. The worst prognosis is given for preterm newborns who are also small for the date (they have a lower weight than anticipated for the calculated gestation period). Continued advances in neonatal intensive care such as minimally invasive ventilation, exogenous surfactant, prenatal corticosteroids, etc. have significantly influenced neonatal survival. The price is that of chronic morbidity due to structural immaturity of functional organs as well as iatrogenic injury. At the gestational age of 22-24 weeks pulmonary immaturity prevents adequate gas exchange at birth, resulting in life-threatening respiratory failure independent of placental support. Another sequela is bronchopulmonary dysplasia secondary to pulmonary ventilation (Bancalari & Jain, 2019).

In this regard, the artificial womb technique (AWT) allowing the product of conception to be held in a physiologic foetal state fundamentally changes the approach to the medical management of extreme prematurity (De Bie et al., 2022). This would be similar to

⁶ The child's conception is taken for granted whenever the child's interest is discussed.

other life-saving measures of the preterm neonate in the early stages of life including neonatal intensive care units (NICU) (Fraga, 2019).

Artificial Womb Technologies

The development of artificial womb technologies entails not only benefits but also risks, many of which are as yet unknown, which should prompt bioethicists to re-evaluate bioethical issues relating to reproduction.

There are generally two main uses of artificial womb technology. First, ectogestation, which is a form of enhanced neonatal care in which only part of the gestation period takes place in an artificial womb, and second, ectogenesis, in which all gestational life takes place in an artificial womb (Rodger & Blackshaw, 2024).

Ectogestation involves the gestation of a foetus in an ex utero environment. The availability of this technology raises a significant question for the bioethical debate on abortion. It is about a woman's right to decide over her body by interrupting the course of a pregnancy. In order to avoid the death of the foetus, science has made the ectogestation technique available, arguing that even if the foetus is not considered by some to be a person, its death must be avoided, i.e. after being removed from the womb of the natural mother, it is transferred and gestated in an artificial womb.

Although most bioethicists appreciate the value of the new technology especially for rescuing frozen embryos that are the result of in vitro fertilisation, there are still concerns about the "*potential for abuse*" and "*misuse*" that would lead to the industrialisation of human gestation (Reiber, 2010). Recent estimates show that in the US alone there are over 400,000 frozen embryos, many of them abandoned by their biological parents. An unjust situation awaiting a solution (Hoffman et al., 2003). In order to discuss the circumstances in which the use of the artificial womb is morally permissible, it is necessary to distinguish between complete ectogenesis and partial ectogenesis. While complete ectogenesis refers to the generation and development of a human being outside the womb from the beginning of embryonic existence up to 40 weeks gestation, partial ectogenesis refers to the development of a human being for only part of the gestation period. What differentiates them is the role that in vitro fertilisation plays in this process. In partial ectogenesis the product of conception is created through the conjugal act and the self-giving of the spouses, their love and fidelity. In contrast, in vitro fertilisation replaces mutual self-giving by moving procreation out of wedlock into a laboratory, thus turning children into commodities as a result of a production process. Such fertilisation entrusts the life and identity of the embryo to the power of doctors and biologists, establishing the domination of technology over the origin and destiny of the human person.

Given the many health difficulties associated with preterm birth, including death, partial ectogenesis in artificial wombs may qualify as a licit procedure provided that the risk to the embryo is not disproportionate to the potential benefit. An example of the therapeutic use of ectogestation would be pre-eclampsia as a complication of pregnancy, which can have serious consequences for the health of both mother and foetus. Between 50,000 and 100,000 such deaths are reported annually globally. In most cases, the treatment is birth induction, which is usually premature, in which ectogestation can be life-saving (Oyston et al., 2015). Ectogestation has already been used experimentally for up to four weeks in lamb foetuses with favourable results. The artificial womb prototype which was used was named "the biobag" (Partridge et al., 2017). Researchers hope that this technology will have the potential to overcome the current limitations of intensive neonatal therapy and improve the prognosis of extreme maturity. While ectogestation could be tested on humans within the next decade, ectogenesis, which is much more speculative, is likely to take several decades before it can be technologically realized.

Legislative Dilemmas in Using the Artificial Womb

According to the law, legal personality and all the rights resulting from it are conferred at birth. The advances in foetal surgery and artificial wombs, however, introduce the possibility of ex utero gestation and/or temporal existence ex utero, and consequently the existence of some human beings outside the law. It is hoped that the above mentioned “biobag” experiment will have the capacity of overcoming the current limitations of neonatal intensive therapy, and of improving morbidity patterns and the prognosis of extreme prematurity. Secondly, the “biobag” changes the physiological approach of intensive therapy for human beings, treating the unborn subject removed from the uterus, transferring it in an environment closely imitating intrauterine conditions in order to effectively extend gestation. Thirdly, it should be remembered that the product of conception is a developing human being, ontologically identical to a foetus in utero, but without the support of a gestating human being. This developing human being is neither in utero nor does it exist independently ex utero. This is a reason why the born/unborn dichotomy should be legally reconsidered (Romanis, 2018).

Innovative foetal surgical interventions are giving rise, like the artificial womb, to questions about the attribution of legal personality. Take the case of the “twice-born child”. During pregnancy, a woman discovered that her unborn foetus had an aggressive, life-threatening tumour. An innovative surgical team was able to remove the pre-viable foetus almost entirely from the womb, leaving only the placenta in situ. After the removal of the tumour, the foetus was placed back into the womb for continued gestation. A healthy baby was born at the end of the normal gestation period (Scutti, 2016). The question that bioethicists ask concerns the terminology that should be used to describe the subject of such foetal surgery ex utero. The use of a distinct term for this entity can bring clarity to the discussion while avoiding misleading moral connotations. We can consider that the subject undergoing foetal surgery, as an entity independent of the pregnant woman, becomes a second “patient” of the surgeons. However, the status of “patient” naturally implies access to the rights which the law grants to all patients. In the present case, however, there is no guarantee of such protection. Therefore, the human being in the course of this surgery was referred to when it was removed from the womb as a “*foetal operatee*.” (Romanis, 2019). Jurists argue, however, that conferring legal status on foetuses may put pregnant women in direct conflict with those of their foetuses. The lack of foetal personality also prevents criminal charges brought against pregnant women for harm caused in utero. In conclusion, the recognition of foetal personality in both civil and criminal law could be a significant restriction of the freedom of pregnant women, and could even be a reason for vulnerable women to evade health and social care by endangering both themselves and the foetus (Romanis, 2017). In view of the need to provide a pragmatic response to the beginning of legal life, for the time being, childbirth has been the decisive moment for triggering legal protection. The possibility of an ex utero gestation for various reasons is proof that the focus on “birth” has today become an outdated approach to the granting of legal personality. The classical language of childbirth seems inadequate, however, when the product of conception is removed from the uterine environment to be placed in an artificial womb. Both rapidly advancing foetal surgery and the artificial womb are entirely new legal issues. Both raise concerns for bioethicists because it is not clear to what legal protection human beings subjected to these processes would be entitled.

Extrauterine Pregnancy

Extrauterine pregnancy or ectopic pregnancy is characterised by the implantation of the embryo outside the endometrium. Such a pregnancy will not be able to be completed, and life-threatening complications can arise during the course of the pregnancy. In an extrauterine

pregnancy, an egg is fertilized by sperm in the female genital tract. In more than 90% of the cases, the implantation site of the zygote is in the fallopian tubes. Other sites may be: abdominal cavity, pelvic cavity, ovaries, uterine interstitium, cervix. Termination of extrauterine pregnancy is not possible. This may lead to invasion of neighbouring tissues, with the onset of specific symptoms of pelvic pain and vaginal bleeding. In some cases, it may involute.

The treatment options available for ectopic pregnancy are surgical (salpingectomy, salpingostomy) or medication (methotrexate). Salpingectomy involves removal of the entire fallopian tube containing the ectopic pregnancy, and salpingostomy involves an incision on the tube and removal of the embryo and its trophoblast-derived structures. Rigorous comparisons of salpingectomy and salpingostomy have shown no difference in the rate of subsequent intrauterine pregnancy or recurrent ectopic pregnancy (“ACOG Practice Bulletin No. 193 Summary,” 2018).

Methotrexate is an injectable antimetabolite, which can be administered in single or multiple doses, depending on the clinical scenario. No adverse effects on fertility have been reported to date. Methotrexate appears similar or slightly superior to salpingectomy in terms of future fertility outcomes (Baggio et al., 2020).

Bioethics textbooks do not yet have a special section on ectopic pregnancy. According to professional obligation, the autonomy of the woman is preferred over embryonic or foetal benefit (American College Of Obstetricians And Gynecologists, 2004). In this context, the embryo is labelled “non-viable”, but it seems that the term is used equivocally. Occasionally, it is used to signal death, and at other times to suggest that it is incapable of survival. Obstetricians explain this by describing “unviable gestation” as “an early miscarriage or ectopic pregnancy”, which equates to a dead or dying embryo. However, “inevitable to die” is not the same as “not alive now” and a moral discussion about ectopic embryos should not be dismissed simply because science is incapable of resolving the issue.

An analogy is being attempted today between ectopic pregnancy and a cancerous pregnant uterus. Just as a cancerous uterus can be removed to treat the cancer, even if the death of the foetus is anticipated and inevitable, so in the case of ectopic pregnancy, the fallopian tube can be removed to treat the lesions that threaten rupture. This respects the principle of the double effect and all that remains is to look for a procedure that operates on the tube and leads to the indirect death of the foetus, as in the case of a cancerous uterus. However, things are quite different, since the fundamental problem in ectopic pregnancy is the ectopic location of the trophoblast (not the tube), whereas in a pregnant cancerous uterus, there is a life-threatening peripheral pathology (cancer) present in the organ containing a functional pregnancy. The current goal of all treatments for ectopic pregnancy is to eliminate the pregnancy because there is currently a lack of any procedure that could support an embryo without a trophoblast. Ethically, this sounds like abortion or homicide (Buskmiller, 2024). That is why transplantation of an ectopic embryo would be the best solution to solve the problem. This procedure, being at an experimental stage, is still far from being evidence-based and cannot be seriously supported from the perspective of a practicing physician. The ectopic transfer procedure proposed in an animal model study by Camillieri, Buskmiller and Sammut (2021) requires a uterine incision that would predispose a mother to uterine rupture in future pregnancies. This procedure, which requires lifelong caesarean sections, is an extraordinary means of therapy (Camillieri et al., 2020).

Perhaps the famous “Maltese twins” make a better analogy for the double-effect reasoning. Fully invested with human dignity, even though they may lack its full expression (e.g. one of them does not have a fully formed brain), they are joined by vital tissue and one twin’s life may be endangered by the other. In this situation the death of a twin who cannot survive the separation is not intentional, but unfortunately tolerated.

Ectopic pregnancy, unlike cases of vital maternal foetal conflicts involving a normal pregnancy and incidental uterine pathology (e.g. gravid uterus cancer) more resemble cases of severe placental pathology requiring prior delivery such as for example, preventable rupture of membranes with chorioamnionitis. In ectopic pregnancy, the healthy trophoblast is the source of the pathology because of its abnormal localization. This tissue is vital for the embryo, which has human dignity and the right to bodily integrity. This is why current treatment options such as salpingectomy, salpingostomy and methotrexate should be reconsidered.

Conclusions

Traditionally, legal personality is granted to human beings at birth. The development of new and emerging reproductive technologies requires that the two elements of the personality law, birth and the live-born, undergo further clarification and nuancing. Granting legal personhood to developing human beings would have broad implications for the treatment of fetuses and embryos the existence of ex utero human beings without legal personality creates vulnerabilities for both the operated foetus and the pregnant woman.

As the artificial womb technique becomes a reality, bioethicists must make judgements about how the technology can be used in a lawful way. If partial ectogenesis is a form of early surgical intervention akin to NICU incubators aimed at alleviating suffering and prolonging the lives of extremely premature newborns, full ectogenesis should be evaluated differently even when the artificial womb is used to rescue frozen embryos that are abandoned and stuck in a cryogenic stat. Benefits such as the possible elimination of surrogacy are outweighed by the likely increase in the use of invitro fertilization resulting in more cryopreserved embryos as well as a new avenue for the potential commercialization of children. Ectogenesis also raises concerns of a dystopian future in which human beings become artificially gestated and women and men are no longer needed for reproduction. Although, for the time being, it seems unlikely that traditional pregnancy and childbirth will be eliminated, the artificial womb technique remains a possibility, and bioethicists should be well informed to be effectively involved in regulating the use of these techniques that once unleashed become difficult to implement and regulate.

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